

National Diabetes & Digestive & Kidney Diseases Advisory Council Orientation Handbook

JANUARY 2015



National Institute of
Diabetes and Digestive
and Kidney Diseases

Orientation for New Advisory Council Members

A MESSAGE FROM THE DIRECTOR, NIDDK

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) is one of 27 Institutes and Centers that make up the National Institutes of Health (NIH), part of the Public Health Service in the U.S. Department of Health and Human Services. The Institute conducts and supports basic and clinical research in some of the most serious, common, disabling, and costly conditions affecting the public's health. The diseases in NIDDK's research mission cut across the full spectrum of medicine and include:

- Diabetes and other endocrine diseases;
- Cystic fibrosis and other inherited diseases;
- Digestive diseases;
- Obesity;
- Nutrition;
- Diseases of the kidney, genitourinary tract, and blood.

Most arise from the complex interaction of genetic, autoimmune, neuroendocrine, metabolic, nutritional, and environmental factors. Some diseases such as diabetes, obesity, hepatitis, and kidney failure disproportionately affect minority populations. NIDDK funds research projects that relate directly to these diseases, but it also places a high priority on fundamental, untargeted research.

Training is critically important to continued progress in medical research. NIDDK supports research training and career development, with special emphasis on increasing the ranks of physician scientists and recruiting underrepresented minorities and women into biomedical research careers.

The National Diabetes and Digestive and Kidney Diseases Advisory Council's most important purpose is to make recommendations regarding the funding of grant applications, focusing primarily on the relevance to the programmatic missions and priorities of the Institute. The Council also has the responsibility to ensure the adequacy of the scientific review by the initial review groups. In addition, the Council offers advice on a wide variety of policies and programs within the Institute.

As you begin service on the National Diabetes and Digestive and Kidney Diseases Advisory Council, we hope this orientation material will help answer some of your questions and provide the information you will need in your role as a Council member. In addition, your comments on the usefulness of this material and suggestions for improvement will be appreciated.



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National Institute of Diabetes
and Digestive
and Kidney Diseases
National Institutes of Health

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NIH Gateway Center Map



Main Visitor Entrance: NIH Gateway Drive

Gateway Center - Building 66 (for pedestrians entering campus)

- Open Monday – Friday 6am – 10pm
- Closed on Weekends and Observed Holidays
- After 10pm weekdays, all day weekends and holidays, pedestrian visitors enter via Commercial Vehicle Inspection Facility (CVIF) – Building 67 (on Rockville Pike between North Drive and Wilson Drive)

Gateway Inspection Station - Building 66A (for vehicles entering campus)

- Monday-Friday: 5am – 10pm
Weekends and after 10 pm: Closed
After 10pm on weekdays, all day weekends, and holidays, visitors in vehicles should enter campus via the [CVIF](#)
- All vehicles and their contents will be inspected upon entering the campus.
- After inspection, vehicles enter campus at Center Drive
- Roadway at Center Drive is for entering campus only; visitors exiting campus may exit from other open locations.

Multi-Level Parking Garage 11 – MLP-11 (car inspection not required; visitor badges obtained at Gateway Visitor Center – Bldg 66) Hours: Monday - Friday: 6am – 9pm (entrance) 6am – 11pm (exit) Cost: \$2 per hour for the first three hours, \$12 maximum for entire day. Closed weekends.

Security Procedures for Entering the NIH Campus:

All visitors and patients – **please be aware:** Federal law prohibits the following items on Federal property: firearms, explosives, archery equipment, dangerous weapons, knives with blades over 2 ½ inches, alcoholic beverages and open containers of alcohol.

The NIH has implemented security measures to help ensure the safety of our patients, employees, guests and facilities. All visitors must enter through the **new** NIH Gateway Center and Visitor Center on Rockville Pike just south of the Metro station and previous visitor entrance at South Drive and Rockville Pike. **Except for persons parking in multi-level parking garage at the NIH Gateway Center (MLP-11)**, all vehicles entering the campus must submit to a vehicle inspection.

Whether arriving by Metro, hotel shuttle, or private or commercial vehicle, visitors over 15 years of age must show one (1) form of a government-issued photo ID—driver's license, passport, green card, etc. Visitors under 16 years of age must be accompanied by an adult.

Tobacco-Free Campus – Effective October 1, 2008, the use of all tobacco products (including cigarettes, cigars, pipes, smokeless tobacco, or other tobacco products) is prohibited at all times in all buildings; on all outside property or grounds, including parking areas; and in government vehicles.

Vehicle Inspections – Except for those parked in MLP-11, all vehicles and their contents will be inspected upon entering the campus. Additionally, all vehicles entering certain parking areas will be inspected, regardless of any prior inspection. Drivers will be required to present their driver's license and may be asked to open the trunk and hood. If you are physically unable to perform this function, please inform the inspector and they will assist you.

Vehicle inspection may consist of any combination of the following: Detection Dogs Teams (K-9), Electronic Detection Devices and Manual Inspection.

After inspection, you will be issued a vehicle inspection pass. It must be displayed on your vehicle's dashboard while you are on campus. The inspection pass is not a "parking permit." It only grants your vehicle access to enter the campus. You can only park in designated parking areas.

Personal Inspections – All visitors should be prepared to submit to a personal inspection prior to entering the campus. These inspections may be conducted with a handheld monitoring device, a metal detector and by visible inspection. Additionally, your personal belongings may be inspected and passed through an x-ray machine.

If driving onto campus, the personal inspection and issuance of a visitor badge will take place where your private or commercial vehicle (including a taxi) is inspected.

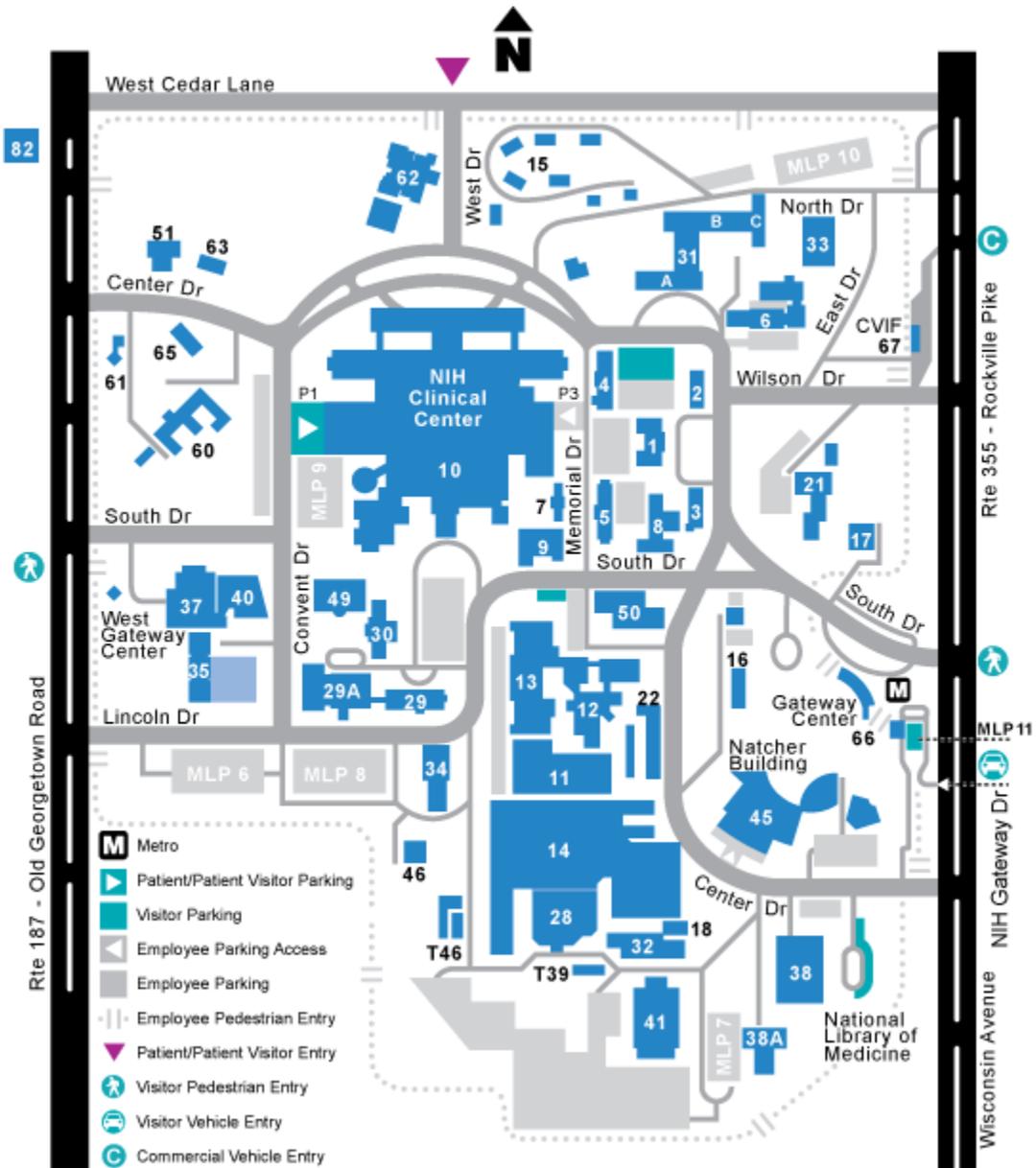
If you parked in the NIH Gateway Center multi-level garage (MPL-11), the personal inspection and issuance of a visitor badge will take place in the Visitor's Center. Outside the Visitor Center, campus shuttles will take you to Building 31 on campus. Any shuttle, except the Campus Perimeter Route, will stop at Building 31. To access the NIH campus shuttle schedules, see http://dtts.ors.od.nih.gov/NIHShuttle/scripts/shuttle_map_live.asp. Directional signs within Building 31 will guide you to the meeting room.

Visitor passes must be prominently displayed at all times while on the NIH campus.

To learn more about visitor and security issues at the NIH, visit: <http://www.nih.gov/about/visitor/index.htm>.

For questions about campus access, please contact the ORS Information Line at orsinfo@mail.nih.gov or 301-594-6677, TTY - 301-435-1908.

NIH Visitors Map of Campus



Street Address:
National Institutes of Health
9000 Rockville Pike
Bethesda, MD 20892

See Parking on Following Page

General Visitor Parking Information

Parking:

Visitors may park at the **Gateway Parking Garage (MLP-11)** (see Gateway Center Map) or in designated visitor parking lots (see Campus Map):

Monday – Friday, 6am – 9pm (entrance); 6am – 11pm (exit):
\$2.00 per hour for the first three hours
\$12.00 for the entire day

Metered parking lots:
Monday – Friday, 7am – 7pm
\$2 per hour

Arriving at NIH:

When traveling to the main NIH campus, use of the Metro is strongly encouraged. Visitor parking lots on the NIH campus fill up quickly.

The NIH Has implemented security measures to help ensure the safety of our patients, employees, guests, and facilities. All visitors must enter through the NIH Gateway Center at Metro or the West Gateway Visitor Center. You will be asked to submit to a vehicle and personal inspection.

Visitors over 15 years of age must provide a form of government-issued ID such as a driver's license or passport. Visitors under 16 years of age must be accompanied by an adult.

If traveling via Metro or hotel shuttle to Medical Center Metro stop: The Washington D.C. Metro-Rail system Red Line has a station right on the NIH campus, called "Medical Center." Once you're out of the station, it's a short walk to the NIH Visitor Center where you will go through the NIH security procedures and receive a visitor's badge. Outside the Visitor Center, campus shuttles will take you to Building 31 on campus. Any shuttle, except the Campus Perimeter Route, will stop at Building 31. To access the NIH campus shuttle schedules, see http://dtt.ors.od.nih.gov/NIHShuttle/scripts/shuttle_map_live.asp. Directional signs within Building 31 will guide you to the meeting room

If taking a taxi directly to the meeting site: Upon entering the campus please let the driver know that you wish to be dropped off in front of Building 31. **The taxi must first go through an NIH security inspection of the car, and you and the driver must go through the security procedures and receive visitor badges.** Directional signs within Building 31 will guide you to the meeting room.

If driving private vehicle to the meeting site: Unless you choose to park in the NIH Gateway Center parking garage, receive your security processing at the Visitor Center, and take a shuttle to Building 31, you and your car must first go through security procedures. Visitor parking is located directly across from Building 31 (see **circles** on map). Parking fees are \$12 per day and are fully reimbursable. Directional signs within Building 31 will guide you to the meeting room.

Vehicle and Visitor passes must be prominently displayed at all times while on the NIH campus.



wmata.com
 Customer Information Service: 202 637-7000
 TTY Phone: 202 638-3780
 Metro Transit Police: 202 962-2121

Legend

- RD** Red Line • Glenmont / Shady Grove
- OR** Orange Line • New Carrollton / Vienna
- BL** Blue Line • Franconia-Springfield / Largo Town Center
- GR** Green Line • Branch Ave / Greenbelt
- YL** Yellow Line • Huntington / Fort Totten
- SV** Silver Line • Wiehle-Reston East / Largo Town Center

Station Features

- Bus to Airport
- Parking
- Hospital
- Airport

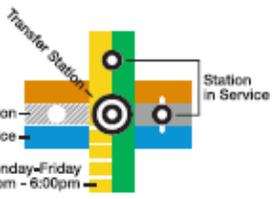
Connecting Rail Systems



Under Construction

Full-Time Service

Rush-Only Service: Monday-Friday
 6:30am - 9:00am 3:30pm - 6:00pm



Metro
 Operating Times
Mon-Thu
 5am-midnight
Fri
 5am-3am
Sat
 7am-3am
Sun
 7am-midnight
 Times are approximate

Metro is accessible.
 www.wmata.com/accessible

N
 Map is not to scale

- No Smoking
- No Eating or Drinking
- No Animals (except service animals)
- No Audio (without earphones)
- No Littering or Spitting
- No Dangerous or Harmful Items

Bethesda Area Map Showing NIH Campus and Off-Campus Facilities



Glossary of Terms

For extensive list of grant terms see <http://grants.nih.gov/grants/glossary.htm>

A

Accession Number – Related to electronic submission of applications, the Accession number is the Agency tracking number provided for the application after Agency validations.

Acquisition – Obtaining supplies or services by the Federal Government with appropriated funds through purchase or lease.

Active Grant – A grant meeting the following criteria: (1) Today's date is between the budget start and end dates; (2) The grant has an eRA System (IMPAC II) application status code of "Awarded. Non-fellowships only." or "Awarded. Fellowships only."

Activity Code – A three-digit code assigned by the National Institutes of Health (NIH) to identify funding mechanisms (e.g. F32, K12, P01, R01, T32, etc.). *See* Funding Mechanisms in NIDDK section of Background Information.

Administrative Expenses – Expenses incurred for the support of activities relevant to the award of grants, contracts, and cooperative agreements and expenses incurred for general administration of the scientific programs and activities of the National Institutes of Health.

Administrative I/C – The NIH Institute or Center to which the Center for Scientific Review (CSR) routes NIH grant applications for a funding decision. An I/C may request to change this assignment if the application is more suited to another I/C. Also referred to as primary assignment.

Administrative Supplement – Monies added to a grant without peer review to pay for items within the scope of an award but unforeseen when a grant application was submitted.

Amendment (amended or revised applications) – Resubmission of an unfunded application revised in response to a prior review.

Appeal - A procedure for contesting the peer review of a grant application. Synonymous with rebuttal.

Application – A request for financial support of a project or activity submitted to NIH on specified forms and in accordance with NIH instructions.

Application Identification Numbers – The application number identifies: type of application (1); activity code (R01); organization to which it is assigned (DK); serial number assigned by the Center for Scientific Review (CSR) (183723); suffix showing the support year for the grant (-01); other information identifying a supplement (S1), amendment (A1), or a fellowship's institutional allowance. For contracts, the suffix is replaced by a modification number. *See* Sample Application Number Graphical Overview of Grants Process.

Application Types – Type 1, New; Type 2, Competing continuation (a.k.a. renewal, re-competing); Type 3, Application for additional (supplemental) support; Type 4, Competing extension for an R37 award or first non-competing year of a Fast Track SBIR/STTR award; Type 5, Non-competing continuation; Type 7, Change of grantee institution; Type 9, Change of NIH awarding Institute or Division (competing continuation).

Appropriation – Law authorizing Federal Agencies to obligate funds and make payments from the U.S. Treasury for specified purposes. Appropriations are in annual acts and permanent law.

Approved Budget – The financial expenditure plan for the grant-supported project or activity, including revisions approved by NIH as well as permissible revisions made by the grantee. The approved budget consists of Federal (grant) funds and, if required by the terms and conditions of the award, non-Federal participation in the form of matching or cost sharing. The approved budget specified in the Notice of Grant Award may be shown in detailed budget categories or as total costs without a categorical breakout. Expenditures charged to an approved budget that consists of both Federal and non-Federal shares are deemed to be borne by the grantee in the same proportion as the percentage of Federal/non-Federal participation in the overall budget.

Award – The provision of funds by NIH, based on an approved application and budget or progress report, to an organizational entity or an individual to carry out a project or activity.

Awarding Office – The NIH I/C responsible for the award, administration, and monitoring of particular grants.

B

Bilateral Agreement – A general science agreement between the U.S. and a foreign country. Grant applications from institutions in these countries that have been recommended for approval by the scientific review group are given special funding consideration by Council.

Bridge Awards (R56) – Provides limited interim research support based on the merit of a pending R01 application while current researcher or new applicant gathers additional data to revise a new or competing renewal application. This grant will underwrite highly meritorious applications that if given the opportunity to revise their application could meet IC recommended standards and would be missed opportunities if not funded. Investigators do not apply for Bridge Awards but are selected from R01 grants at the pay-line margin. A Bridge Award is made as an R56 with 1 year of funding, which the PI can choose to spend over a 2-year period. This enables the PI to submit an amended R01 application for the next receipt date while receiving interim (bridge) funding under the R56 mechanism. Interim funding ends when the applicant succeeds in obtaining an R01 or other competing award built on the R56 grant. These awards are not renewable.

Budget Appropriation – The yearly amount given to a Government Agency by Congress.

Budget Period – The intervals of time (usually 12 months each) into which a project period is divided for budgetary and funding purposes.

C

Career Development Awards (CDA K Series) – Award supporting Ph.D.'s and clinicians who wish to develop a career in biomedical research.

Capital Expenditure – The cost of an asset (land, building, equipment), including the cost to put it in place. A capital expenditure for equipment includes the net invoice price and the cost of any modifications, attachments, accessories, or auxiliary apparatus to make it usable for the purpose for which it was acquired. Other charges, such as taxes, in-transit insurance, freight, and installation, may be included in capital expenditure costs in accordance with the recipient's regular accounting practices consistently applied regardless of the source of funds.

Clinical Research – Patient-oriented research, including epidemiologic and behavioral studies, outcomes research, and health services research. Patient-oriented research is research conducted with human subjects (or on material of human origin such as tissues, specimens, and cognitive phenomena) in which a researcher directly interacts with human subjects. It includes research on mechanisms of human disease, therapeutic interventions, clinical trials, and development of new technologies, but does not include in vitro studies using human tissues not linked to a living individual.

Clinical Trial – A biomedical or behavioral research study of human subjects designed to answer specific questions about biomedical or behavioral interventions (drugs, treatments, devices, or new ways of using known drugs, treatments, or devices). Clinical trials are used to determine whether new biomedical or behavioral interventions are safe, efficacious, and effective. Clinical trials of an experimental drug, treatment, device, or intervention may proceed through four phases: Phase I. Testing in a small group of people (e.g. 20-80) to determine efficacy and evaluate safety (e.g., determine a safe dosage range and identify side effects); Phase II. Study in a larger group of people (several hundred) to determine efficacy and further evaluate safety; Phase III. Study to determine efficacy in large groups of people (from several hundred to several thousand) by comparing the intervention to other standard or experimental interventions, to monitor adverse effects, and to collect information to allow safe use; Phase IV. Studies done after the intervention has been marketed. These studies are designed to monitor the effectiveness of the approved intervention in the general population and to collect information about any adverse effects associated with widespread use.

Close Out – Procedure to officially conclude a grant. Institute staff must ensure necessary scientific, administrative, and financial reports have been received, implemented and documented in compliance with Federal records management policy; includes the Final Financial Status Report (FSR), Final Invention Report, and Final Progress Report.

Co-Funding – Funding arrangement through which two or more Institutes or Centers pay for a grant.

Co-Investigator – An individual involved with the PI in the scientific development or execution of a project. The co-investigator (collaborator) may be employed by, or be affiliated with, the applicant/grantee organization or another organization participating in the project under a consortium agreement. A co-investigator typically devotes a specified percentage of time to the project and is considered “key personnel.” The designation of a co-investigator, if applicable, does not affect the PI’s roles and responsibilities as specified in the NIH Grants Policy Statement (NIH GPS). Note: NIH does not recognize the term “co-PI.”

Commitment Base – Funds used for non-competing (type 5 or ongoing awards), typically 70-80 percent of the dollars spent for research project grants.

Competing Applications – Either new or re-competing applications that must undergo initial peer review.

Competing Continuation – Application requiring competitive peer review and Institute/Center action to continue beyond the current competitive segment. (Also known as a Renewal or Type 2.)

Competitive Range – Contracting term denoting a group of proposals considered acceptable by the initial peer review group which are potential candidates for an award.

Concept – The earliest planning stage of an initiative [request for applications (RFA), request for proposals (RFP), or program announcement (PA)]. Concepts are brought before the Advisory Council for

concept clearance. Not all concepts cleared by Council are published as initiatives depending on the availability of funds.

Conflict of Interest – Regulations to ensure Government employees, scientific review group members, Council members, or others having the ability to influence funding decisions have no personal interest in the outcome.

Consortium Agreement – Formalized agreement whereby a research project is carried out by the grantee and one or more other organizations that are separate legal entities. Under the agreement, the grantee must perform a substantive role in the conduct of the planned research and not merely serve as a conduit of funds to another party or parties.

Constant Dollars – Dollar amounts adjusted for inflation, based on buying power in a selected base year. The BRDPI is used to determine constant dollars from current dollars.

Contract (R&D) – Award instrument establishing a binding legal procurement relationship between NIH and a recipient obligating the latter to furnish a product or service defined in detail by NIH and binding the Institute to pay for it.

Contracting Officer – Government employee authorized to execute contractual agreements on behalf of the Government.

Cooperative Agreement (U Series) – Support mechanism used when there will be substantial Federal scientific or programmatic involvement. Substantial involvement means that, after award, scientific or program staff will assist, guide, coordinate, or participate in project activities.

Council/Board, Advisory – National Advisory Council or Board, mandated by statute, providing the second level of review for grant applications for each Institute/Center awarding grants. The Councils/Boards are comprised of both scientific and lay representatives. Council/Board recommendations are based on scientific merit (as judged by the initial review groups) and the relevance of the proposed study to an institute's programs and priorities. With some exceptions, grants cannot be awarded without recommendations for approval by a Council/Board.

Council Round – At NIH, there are typically three council rounds each fiscal year: September, January/February, and May/June. Application receipt dates, initial review dates, and council review dates all fall within one of these council rounds. Incoming grant applications all are assigned to a council round.

Critique – An overall evaluation of a grant application prepared by a reviewer before an initial peer review meeting and presented to a Scientific Review Group at a meeting.

Current Dollars – Actual dollars awarded, without adjustment for inflation.

D

Direct Costs – Costs that can be specifically identified with a particular project or activity.

Direct Operations – Funds for salary and other administrative costs.

Dual Assignments – Applications simultaneously assigned to two Institutes, Centers, or Divisions. The primary Institute has complete responsibility for administering and funding the application; the secondary assumes this responsibility only if the primary is unable or unwilling to support it.

Dual Review System – Peer review process used by NIH. The first level of review provides a judgment of scientific merit. The second level of review (usually conducted by an ICD's advisory Council) assesses the quality of the first review, sets program priorities, and makes funding recommendations.

DUNS Number – The Data Universal Numbering System (DUNS) number is a unique nine-digit number assigned by Dun and Bradstreet Information Services. It is recognized as the universal standard for identifying and keeping track of more than 92 million businesses worldwide. Grants.gov requires a DUNS number for registration. For applicants, the DUNS number in the application must match the DUNS number in the Institutional Profile in Commons.

E

Early Stage Investigator (ESI) – A New Investigator (*see* definition under N) who is within 10 years of completing a terminal research degree or within 10 years of completing medical residency. Between 1980 and 2001, the duration of postdoctoral training increased and the average age at which an investigator first obtained R01 funding increased by more than 5 years. Under the ESI program (NOT-OD-08-121 released September 26, 2008), New Investigators identified as ESIs will have their career stage considered at the time of review and award of R01 applications. By providing this advantage to ESIs, NIH can directly encourage earlier application for NIH research grant support. In some cases there may have been one or more lapses in the period of research or research training after the terminal degree or completion of medical residency. [A new NIH Guide Notice](#) (NOT-OD-09-034, released December 31, 2008, by the Office of Intramural Research) describes the procedures for requesting an extension of the ESI period and the conditions under which such extensions can be considered.

Electronic Research Administration (eRA) – NIH's infrastructure for conducting interactive electronic transactions for the receipt, review, monitoring, and administration of NIH grant awards to biomedical and behavioral investigators worldwide. Registration is required.

Enrollment Data – Provides race and ethnicity data for the cumulative number of human subjects enrolled in an NIH-funded clinical research study since the protocol began. This data is provided in competing continuation applications and annual progress reports.

Equipment – An article of tangible nonexpendable personal property that has a useful life of more than 1 year and an acquisition cost per unit that equals or exceeds \$5,000 or the capitalization threshold established by the organization, whichever is less.

eRA Commons – A secure meeting place on the Web where research organizations and grantees electronically receive and transmit information about the administration of biomedical and behavioral research grants. Registration is required. At this site applicants access the status of their applications and grantees access the status of their awards, submit reports, and make requests electronically

Expiration Date – The date signifying the end of the current budget period, after which the grantee is not authorized to obligate grant funds regardless of the ending date of the project period or "completion date."

Extramural Research – Research supported by NIH to researchers and organizations outside the NIH through a grant, contract, or cooperative agreement.

F

Facilities and Administrative Costs (F&A) – Costs that are incurred by a grantee for common or joint objectives and cannot be identified specifically with a particular project or program. These costs are also known as "indirect costs."

Federal Acquisition Regulations (FAR) – Laws regulating government contracting.

Federal Advisory Committee Act (FACA) – A law regulating Federal advisory committees to ensure an appropriate balance of scientists and lay persons and minority, geographical, and racial representation.

Federal Register – An official, daily publication communicating proposed and final regulations and legal notices issued by Federal agencies, including announcements of the availability of funds for financial assistance.

Federal-Wide Assurance (FWA) – Online form every institution and collaborating institution conducting human subjects research must file with the Office for Human Research Protections—HHS to establish policies and procedures to protect human subjects as required by 45 CFR 46.

Fee – An amount (in addition to actual, allowable costs) paid to an organization providing goods or services consistent with normal commercial practice. This payment also is referred to as "profit."

Fellowship - An NIH training program award where the NIH specifies the individual receiving the award. Fellowships comprise the F activity codes.

Fiscal Year (FY) – The annual period established for Government accounting purposes. A Fiscal Year begins on October 1 and ends September 30 of the following year. Example: FY2009 – Started October 1, 2008 and ends September 30, 2009.

Full-Time Appointment – Number of days per week and/or months per year representing full-time effort at the applicant/grantee organization, as specified in organizational policy. The organization's policy must be applied consistently regardless of the source of support.

Funding Opportunity Announcement (FOA) – *See* Initiative.

G

Gender – Human subject term indicating a classification of research subjects into women and men.

Grant – Financial assistance mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity. A grant is used whenever the NIH IC anticipates no substantial programmatic involvement with the recipient during performance of the financially assisted activities.

Grant Appeals – A DHHS policy providing for an appeal by the grantee institution of post award administrative decisions made by awarding offices. The two levels of appeal are an informal NIH procedure and a formal DHHS procedure. The grantee must first exhaust the informal procedures before appealing to the DHHS Appeals Board.

Grant Project Period – Total period a project has been recommended for support, which may include more than one competitive segment. For example, a project period for a grant begun in 2008 can be divided into competitive segments 2008 to 2012, 2012 to 2016, etc.

Grant Start Date – Official date a grant award begins; same as the first day of the first budget period.

Grantee – Organization or individual awarded a grant or cooperative agreement by NIH that is responsible and accountable for the use of the funds provided and for the performance of the grant-supported project or activities. The grantee is the entire legal entity even if a particular component is designated in the award document. The grantee is legally responsible and accountable to NIH for the performance and financial aspects of the grant-supported project or activity.

Grants Management Officer (GMO) – An NIH official responsible for the business management aspects of grants and cooperative agreements, including review, negotiation, award, and administration, and for the interpretation of grants administration policies and provisions. Only GMOs are authorized to obligate NIH to the expenditure of funds and permit changes to approved projects on behalf of NIH. Each NIH Institute and Center awarding grants has one or more GMOs with responsibility for particular programs or awards.

Grants Management Specialist (GMS) – An NIH staff member who oversees the business and other non-programmatic aspects of one or more grants and/or cooperative agreements. These activities include, but are not limited to, evaluating grant applications for administrative content and compliance with statutes, regulations, and guidelines; negotiating grants; providing consultation and technical assistance to grantees; and administering grants after award.

Grants.gov – An access point through which any person, business, or State, local, or Tribal government may electronically find and apply for more than 1,000 competitive grant opportunities from the 26 Federal grant-making Agencies. The Department of Health and Human Services (DHHS) is the managing partner for the Federal Grants.gov initiative, one of 24 initiatives of the overall E-Government program for improving access to Government services via the Internet. Registration is required to apply. Go to <http://www.grants.gov/>.

H

High Risk/High Impact (HR/HI) – A category of applications identified by a scientific review group as having a high degree of uncertainty in approach but also a high potential for impact. NIH tracks how many of these applications are identified and funded.

Human Subject – A living individual about whom an investigator (whether professional or student) conducting research obtains data through intervention or interaction with the individual or obtains identifiable private information. Regulations governing the use of human subjects in research extend to use of human organs, tissues, and body fluids from identifiable individuals as human subjects and to graphic, written, or recorded information derived from such individuals.

Human Subjects Assurance – A document filed by an institution conducting research on human subjects with the Office for Human Research Protections—HHS that formalizes its commitment to protect the human subjects prior to receiving any HHS grant funding.

I

Identifier – Information linking specimens or data to individually identifiable living people or their medical information. Examples include names, social security numbers, medical record numbers, and pathology accession numbers.

Indirect Costs – Costs that are incurred by a grantee for common or joint objectives and cannot be identified specifically with a particular project or program. These costs are also known as "Facility and Administrative Costs."

Information for Management, Planning, Analysis, and Coordination (IMPAC) – A computer database system developed and maintained by the Office of Extramural Research for information concerning PHS extramural programs.

Informed Consent – Person's voluntary agreement, based upon adequate knowledge and understanding, to participate in human subjects research or undergo a medical procedure. In giving informed consent, people may not waive legal rights or release or appear to release an investigator or sponsor from liability for negligence.

Initial Peer Review Criteria – Significance: Is the topic important? Will it advance Scientific Knowledge? **Approach:** Are the hypothesis, design, and methods well developed and appropriate? Are potential problems addressed? **Innovation:** Does the proposal involve new ideas or methods; does it challenge existing paradigms? **Investigator:** Does the investigator and collaborators have the training and experience to do the work? **Environment:** Will the scientific environment contribute to success? Is there institutional support for the project? Does the work take advantage of existing opportunities including collaborations? Note: criteria-based scoring commences in 2009.

Initiative – A request for applications (RFA), request for proposals (RFP), or program announcement (PA) stating the Institute or Center's interest in receiving research applications in a given area because of a programmatic need or scientific opportunity. RFAs and RFPs generally have monies set aside to fund the applications responding to them; program announcements generally do not. *See* Funding Opportunity Announcement (FOA)

Institutional Base Salary – The annual compensation paid by an applicant/grantee organization for an employee's appointment whether that individual's time is spent on research, teaching, patient care, or other activities. The base salary excludes any income that an individual is permitted to earn outside of duties for the applicant/grantee organization. Base salary may not be increased as a result of replacing organizational salary funds with NIH grant funds.

Institutional Review Board (IRB) – IRBs are set up by research institutions to ensure the protection of rights and welfare of human research subjects participating in research conducted under their auspices. IRBs make an independent determination to approve, require modifications in, or disapprove research protocols based on whether human subjects are adequately protected, as required by federal regulations and local institutional policy.

Interactive Research Project Grant (IRPG) – An award made to two or more investigators funded independently as R01 grantees but brought together as a collaborative group receiving additional support for collaborative work, shared resources, or the exchange of ideas.

Interagency Agreement – Formal agreement among Government agencies to collaborate on and fund research; Y series activity code.

Integrated Review Group (IRG) – A cluster of study sections responsible for the review of grant applications in scientifically related areas. These study sections share common intellectual and human resources.

Internet Assisted Review (IAR) - Allows reviewer to submit critiques and preliminary scores for applications they are reviewing. Allows Reviewers, SROs, and GTAs to view all critiques in preparation for a meeting. IAR creates a preliminary summary statement body containing submitted critiques for the SRO or GTA.

Intramural Research - Research conducted by, or in support of, employees of the NIH.

Investigational New Drug (IND) – Status given by the FDA to a new drug or biological product to be used in a clinical investigation.

Investigator-Initiated Research – Research funded as a result of an investigator, on his or her own, submitting a research application. Also known as unsolicited research. Unsolicited applications are reviewed by chartered CSR review committees. Its opposite is targeted research.

J

Just-In-Time – Within the Status module of the eRA Commons, users will find a feature to submit Just-In-Time information when requested by the NIH. NIH policy allows the submission of certain elements of a competing application to be deferred. Through this module, institutions can electronically submit the information that is requested after the review, but before award.

K

Key Personnel – The PI and other individuals who contribute to the scientific development or execution of a project in a substantive, measurable way, whether or not they receive salaries or compensation under the grant. Typically these individuals have doctoral or other professional degrees, although individuals at the masters or baccalaureate level may be considered key personnel if their involvement meets this definition. Consultants also may be considered key personnel if they meet this definition. “Zero percent” effort or “as needed” is not an acceptable level of involvement for key personnel.

M

Matching or Cost Sharing – The value of third party in-kind contributions and the portion of the costs of a federally assisted project of program not borne by the Federal Government. Matching or cost sharing may be required by law, regulation, or administrative decision of an NIH Institute or Center. Costs used to satisfy matching or cost sharing requirements are subject to the same policies governing allowability as other costs under the approved budget.

Mechanism – Another term for Activity Code.

MEDLINE - National Library of Medicine's database for scientific publications.

Minority Group – Human subject term indicating a subset of the U.S. population distinguished by racial, ethnic, or cultural heritage. Categories are: American Indian or Alaskan Native, Asian, black or African American, Hispanic or Latino, and Native Hawaiian and other Pacific Islander. Inclusion of a group should be determined by the scientific questions under examination and their relevance. Not every study will include all minority groups or subpopulations.

Model Organism – Animal, plant, or other organism used to study basic biologic processes to provide insight into other organisms.

Modular Application – A type of grant application in which support is requested in specified increments without the need for detailed supporting information related to separate budget categories. When modular procedures apply, they affect not only application preparation but also review, award, and administration of the application/award.

Monitoring – A process whereby the programmatic and business management performance aspects of a grant are reviewed by assessing information gathered from various required reports, audits, site visits, and other sources.

Multiple Principle Investigator – Individual research awards in which more than one Principal Investigator (PI) is identified by the applicant or institution.

N

New Application (award, grant) – Refers to an application not previously proposed, or one that has not received prior funding. Also known as a Type 1.

New Investigator – New investigator is an individual who has not previously competed successfully for an NIH-supported research project other than the following small or early stage research awards: Pathway to Independence Award-Research Phase (R00); Small Grant (R03); Academic Research Enhancement Award (R15); Exploratory/Developmental Grant (R21); Clinical Trial Planning Grant (R34); Dissertation Award (R36); Small Business Technology Transfer Grant-Phase I (R41); Small Business Innovation Research Grant-Phase I (R43); Shannon Award (R55); NIH High Priority, Short-Term Project Award (R56). Additionally, an individual is not excluded from consideration as a “New Investigator” if he/she has received an award from the following classes of awards: Training-Related and Mentored Career Awards; Fellowships (F05, F30, F31, F32, F34, F37, F38); Mentored-career awards (K01, K08, K22, K23, K25, K99-R00; Other mentored career awards (developmental K02 as used by NINDS and the developmental K07); Loan repayment contracts (L30, L32, L40, L50, L60). Note: Current or past recipients of non-mentored career awards that normally require independent research support (K02, K05, K24, and K26) are not considered new investigators. *See* Early Stage Investigator.

Non-Competing Continuation – A year of continued support for a funded grant. Progress reports for continued support do not undergo peer review but are administratively reviewed by the Institute/Center and receive an award based on prior award commitments. Also known as a Type 5.

Non-Competing Grant – An ongoing grant whose award is contingent on the completion of a progress report as the condition for the release of money for the following year.

Notice of Award (NoA) – The legally binding document notifying the grantee and others that an award has been made. The NoA contains or references all terms and conditions of the award documenting the obligation of Federal funds and may be in letter format and may be issued electronically. Previously known as Notice of Grant Award (NGA).

Not Recommended for Further Consideration (NRFC) – A judgment made by a scientific review group for applications when the merit of the proposed research is not significant and substantial enough to warrant a further review. The study section does not recommend funding; the application cannot be funded by an Institute.

O

Obligation – Data based on NIH funds that have been awarded by an NIH Institute/Center.

Office of Extramural Research (OER) – NIH office overseeing policies and guidelines for extramural research grants.

Office for Human Research Protections (OHRP) – HHS office overseeing human subject protection for HHS-supported research.

Office of Laboratory Animal Welfare (OLAW) – NIH office overseeing compliance with the PHS Policy on Humane Care and Use of Laboratory Animals.

Office of Management and Budget (OMB) – Executive Branch office assisting the U.S. president in preparing the Federal budget, evaluating agency programs and policies, and setting funding priorities. In setting policy, OMB issues Government-wide policy directives, called circulars that apply to grants.

On Time – Paper applications using “standard” submission dates are on time if postmarked on or before the submission date. Electronic applications are on time if successfully submitted to Grants.gov by 5 p.m. local time on the date indicated. Note: For both paper and electronic submissions, when these dates fall on a weekend or holiday, they are extended to the next business day.

Organization – A generic term used to refer to an educational institution or other entity, including an individual, which applies for or receives an NIH grant or cooperative agreement.

Organizational Code – A two-letter code in the grant number identifying the first major-level subdivision of the funding organization. NIDDK’s organizational code is DK.

Other Research Grants – Research grants not classified as research projects or research centers.

Other Support – Includes all financial resources, whether Federal, non-Federal, commercial or organizational, available in direct support of an individual’s research endeavors, including, but not limited to, research grants, cooperative agreements, contracts, or organizational awards. Other support does not include training awards, prizes, or gifts.

Overlap of Support – Other support duplicating research or budgetary items already funded by an NIH grant. Overlap also occurs when any project-supported personnel has time commitments exceeding 12 person months.

P

Program Announcement Reviewed in an Institute (PAR) – Program Announcement with special receipt, referral and/or review considerations.

Parent Announcement – NIH-wide funding opportunity announcement enabling applicants to submit an electronic investigator-initiated grant application for a single grant mechanism [e.g., Research Project Grant (Parent R01)].

Payback – Time and effort fellows and T32 trainees must repay the Government. During the first year, trainees owe one month of payback for every month of support; then they start paying back one month for every month worked.

Payline – A percentile-based funding cutoff point determined at the beginning of the fiscal year by balancing the projected number of applications coming to an NIH Institute with the amount of funds available.

Peer Review – A system for evaluating research applications using reviewers who are the professional equals of the applicant.

Percentile – Represents the relative position or rank of each priority score (along a 100.0 percentile band) among the scores assigned by a particular study section.

Person Months – Measurement of a person's effort in academic, summer, or calendar months a year. Used on NIH applications and other forms instead of percent effort.

Pre-application – A statement in summary form of the intent of the applicant to request funds. It is used to determine the applicant's eligibility and how well the project can compete with other applications and eliminate proposals for which there is little or no chance for funding.

President's Budget – The annual budget request submitted to Congress by the U.S. President. The process begins with a budget request from the IC, which, as part of the entire NIH budget request, is modified by the Office of Management and Budget.

Principal Investigator – An individual designated by the grantee to direct the project or activity being supported by the grant. He or she is responsible and accountable to the grantee and NIH for the proper conduct of the project or activity. Also known as Program Director or Project Director.

Prior Approval – Written approval from the designated Grants Management Officer (GMO) required for specified post award changes in the approved project or budget. Such approval must be obtained before undertaking the proposed activity or spending NIH funds.

Priority score – A numerical rating that reflects the scientific merit of the proposed research relative to stated evaluation criteria.

Privacy Act – A law protecting against needless collection or release of personal data. Records maintained by NIH with respect to grant applications, grant awards, and the administration of grants are subject to the provisions of the Privacy Act.

Program - A coherent assembly of plans, project activities, and supporting resources contained within an administrative framework, the purpose of which is to implement an organization's mission or some specific program-related aspect of that mission. For the NIHGPS, "program" refers to those NIH programs carrying out their missions through the award of grants or cooperative agreements to other organizations.

Program Announcement (PA) – An announcement by an NIH Institute or Center requesting applications in the stated scientific areas. Program Announcements (PA) are published in the NIH Guide for Grants and Contracts.

Program Balance – The need to balance an Institute's support of research in all its programmatic areas with its high-quality applications eligible for funding.

Program Classification Code (PCC) – An internal code unique for each I/C indicating the I/C's scientific interest and used to identify internal programs, branch classifications, the science or disease area, and sometimes program officials.

Program Official (PO) – The NIH official responsible for the programmatic, scientific, and/or technical aspects of a grant.

Programmatic Reduction – The dollar amount a grant award is reduced from the amount recommended by the study section (scientific review group). This is done so Institutes can maintain a sufficient number of grants in their portfolio and to combat inflation of grant costs.

Progress Number – Commonly referred to as the application number or grant number, depending upon its processing status. This unique identification number for the grant is composed of the type code, activity code, Institute code, serial number, support year, and/or suffix code.

Project Period – The total time for which support of a project has been programmatically approved. The total project period comprises the initial competitive segment, any subsequent competitive segment(s) resulting from a competing continuation award(s), and non-competing extensions.

Protocol – Formal description and design for a specific research project. A protocol involving human subject research must be reviewed and approved by an Institutional Review Board (IRB) if the research is not exempt, and by an IRB or other designated institutional process for exempt research.

Public Access Policy – The NIH Public Access Policy implements Division G, Title II, Section 218 of PL 110-161 (Consolidated Appropriations Act, 2008). The law states: *The Director of the National Institutes of Health shall require that all investigators funded by the NIH submit or have submitted for them to the National Library of Medicine’s PubMed Central an electronic version of their final, peer-reviewed manuscripts upon acceptance for publication, to be made publicly available no later than 12 months after the official date of publication: Provided, That the NIH shall implement the public access policy in a manner consistent with copyright law.*

PubMed – Provides access to citations from biomedical literature. It includes over 17 million citations from MEDLINE and other life science journals for biomedical articles back to the 1950s, along with links to full text articles and other scientific resources. These citations are indexed with a PMID, a series of numbers.

R

Rating Criteria – See Initial Peer Review Criteria.

Real Property – Land, including land improvements, structures, and appurtenances, but not movable machinery and equipment.

Rebuttal – Procedure for contesting the peer review of a grant application. Synonymous with appeal.

Receipt, Referral, and Assignment of Applications – Routing of applications arriving at NIH. The referral section of CSR is the central receipt point for competing applications. CSR referral officers assign each application to an Institute and refer it to a scientific review group, notifying applicants of these assignments by mail. Alternatively, NIH encourages applicants to self assign.

Recipient – Organizational entity or individual receiving a grant or cooperative agreement. See Grantee.

Recommended – Designation given by a study section advising funding of an application. The application gets a priority score and summary statement. Roughly the top half of applications being reviewed are recommended for funding.

Recommended Levels of Future Support – Funding level recommended for each future year approved by the scientific review group, subject to availability of funds and scientific progress.

Re-Competing – Grant whose term (e.g., 4 years) is over and for which the applicant is again seeking NIH support. Also known as type 2, competing continuation application, and renewal.

Request for Application (RFA) – The official statement inviting grant or cooperative agreement applications to accomplish a specific program purpose. RFAs indicate the amount of funds set aside for the competition and generally identify a single application receipt date.

Request for Proposals (RFP) – Announces that NIH would like to award a contract to meet a specific need, such as the development of an animal model. RFPs have a single application receipt date and are published in the NIH Guide for Grants and Contracts.

Research – A systematic, intensive study intended to increase knowledge or understanding of the subject studied, a systematic study specifically directed toward applying new knowledge to meet a recognized need, or a systematic application of knowledge to the production of useful materials, devices, and systems or methods, including design, development, and improvement of prototypes and new processes to meet specific requirements. Also termed “research and development.”

Research Grants – Extramural awards made for Other Research Grants, Research Centers, Research Projects, and SBIR/STTRs. Includes the following: R,P,M,S,K,U series (excluding UC6) DP1, DP2, D42, G12.

Research Misconduct – Fabrication, falsification, or plagiarism in proposing, performing, or reporting research, or in reporting research results. Fabrication is making up data or results and recording or reporting them. Falsification is manipulating research materials, equipment, or processes, or changing or omitting data or results such that research is not accurately represented in the research record. Plagiarism is the appropriation of another person's ideas, processes, results, or words without giving appropriate credit. The term does not include honest error or honest differences of opinion.

Research Portfolio – The cohort of grants supported by a given NIH organization.

Research Projects – Includes the following selected Research Grant and Cooperative Agreement activities: R01, R03, R15, R21, R22, R23, R29, R33, R34, R35, R36, R37, R55, R56, RC1, P01, P42, PN1, U01, U19, UC1, NIGMS P41.

Research Project Grant (RPG) – Supports discrete, specified, circumscribed projects to be performed by named investigators in areas representing their specific interest and competencies. *See* Research Projects.

Research Supplement – Monies adding funds to an existing grant to support and promote diversity, people with disabilities, and people returning to work from family responsibilities.

Restriction – Special term and condition in a Notice of Award or article in a contract that limits activities and expenditures for human subjects or animal research. It may be lifted or adjusted after the award if the requirements are met.

Resubmission – Grants.gov term for a grant application resubmitted to NIH after a PD/PI applicant who did not succeed in getting funded revises it based on feedback from the initial peer review. Previous NIH term was "revision." A resubmission has an entry in its application identification number (e.g., A1).

Review Cycle – Refers to the Center for Scientific Review's thrice yearly initial peer review cycle, from the receipt of applications to the date of the review.

Revision – Grants.gov term for money added to a grant to expand its scope or meet needs of a research protocol. Applicants must apply and undergo peer review. The NIH term has been "competing supplemental." NOTE: The former NIH term, "revision," is now "resubmission" in Grants.gov.

S

Salary Cap/Limitation – A legislatively mandated provision limiting the direct salary (also known as salary or institutional base salary, but excluding any fringe benefits and F&A costs) for individuals working on NIH grants, cooperative agreement awards, and extramural research and development contracts.

Scientific Overlap – Overlap of support occurs when substantially similar research is proposed in more than one concurrent PHS grant application.

Scientific Review Officer (SRO) – Federal scientist who presides over a scientific review group and is responsible for coordinating and reporting the review of each application assigned to it. The SRO serves as an intermediary between the applicant and reviewers and prepares summary statements for all applications reviewed.

Scientific Review Group (SRG) – The first level of a two-stage peer review system. These legislatively mandated panels of subject matter experts are established according to scientific discipline or medical specialty. Their primary function is the review and rating of research grant applications for scientific and technical merit. They make recommendations for the appropriate level of support and duration of award. Also known as Study Section.

Scored – In the peer review process, applications judged by a study section to be competitive (i.e., generally in the upper half of the applications reviewed). These applications are assigned a priority score and forwarded to the appropriate Institute/Center for the second level of review.

Selective Pay – The funding of a small number of programmatically important applications at the margin of the payline as recommended by Council.

Set-Aside – Money taken out of the budget for a specific purpose, for example, to fund a congressionally mandated program.

Signing Official (SO) – Person with has institutional authority to legally bind the institution in grants administration matters. The individual fulfilling this role may have any number of titles in the grantee organization. The SO can register the institution, and create and modify the institutional profile and user accounts. The SO also can view all grants within the institution, including status and award information. An SO can create additional SO accounts as well as accounts with any other role or combination of roles. For most institutions, the Signing Official (SO) is located in its Office of Sponsored Research or equivalent.

Small Business Concern – A business independently owned and operated and not dominant in its field of operation; has its principal place of business in the United States and is organized for profit; is at least 51 percent owned, or in the case of a publicly owned business, at least 51 percent of its voting stock is owned by U.S. citizens or lawfully admitted permanent resident aliens; has, including its affiliates, not more than 500 employees; and meets other regulatory requirements established by the Small Business Administration at 13 Code of Federal Regulations (CFR) Part 121.

Small Business Innovation Research (SBIR) – A program designed to support small business concerns conducting innovative research/research & development with potential for commercialization. For the computation of success rates, SBIR awards are not included in the count of RPGs.

Small Business Technology Transfer (STTR) – A program designed to support cooperative research/research & development with potential for commercialization, through a formal cooperative effort between a small business and a U.S. research institution. For the computation of success rates, STTR awards are not included in the count of RPGs.

Special Emphasis – The NIDDK’s policy to set aside funds that are used by the respective program divisions to fund meritorious grants whose competitive position places them beyond the established regular payline. It is the responsibility of the respective program divisions to identify such grants and through its established review procedures to determine which grants meet the Special Emphasis (SE) criteria and receive Subcouncil endorsement for funding. Each such application is then nominated for the Division Director’s concurrence and approval by the Institute Director.

Specific Aims – A component of an application’s Research Plan which describes concisely and realistically what the proposed research or activity intends to accomplish by the end of the grant. Includes broad, long-term goals; hypothesis or hypotheses to be tested; and specific time-phased research objectives (e.g., to test a stated hypothesis, create a novel design, solve a specific problem, challenge an existing paradigm or clinical practice, address a critical barrier to progress in the field, or develop a product or new technology).

Statement of Work (SOW) – In a contract proposal, the detailed description of the work to be performed under the contract.

Streamlined Non-Competing Award Process (SNAP) – Simplified process for the submission of information prior to the issuance of a non-competing award. Funds are automatically carried over and are available for expenditure during the entire project period. All NIH award notices identify whether the grant is subject to or excluded from SNAP.

Streamlined Review (formerly Triage) – In the CSR peer review process, applications judged by a study section to be in the lower half of the applications evaluated in a given review round. These applications are generally not discussed during the study section meeting, but returned to the applicant with the assigned reviewers’ written comments with no priority score. *See* Unscored.

Study Section – Panel of experts established according to scientific disciplines or current research areas for the primary purpose of evaluating the scientific and technical merit of grant applications. Also called scientific review group (SRG) or initial review group (IRG).

Subaward – Collaborative arrangement in support of a research project in which part of an activity is carried out through a formal agreement between a grantee and one or more other organizations. Also known as consortium agreement.

Success Rate – Indicates the percentage of reviewed RPG applications receiving funding computed on a fiscal year basis. It is determined by dividing the number of competing applications funded by the sum of the total number of competing applications reviewed and the number of funded carryovers. NOTE: Applications having one or more amendments in the same fiscal year are only counted once. Success rate computations exclude SBIR/STTRs.

Success Rate Base – The basis for computing the Research Project Grant (RPG) success rate. It includes the total number of competing applications reviewed (the number of applications subjected to a streamlined review process). Also known as Rate Base.

Summary Statement – A combination of the reviewers' written comments and the Scientific Review Administrator's (SRA's) summary of the members' discussion during the study section meeting. It includes the recommendations of the study section, a recommended budget, and administrative notes of special considerations.

Supplement – A request for additional funds either for the current operating year or for any future year recommended previously. Also known as a Type 3 application or award, a supplement can be either non-competing (administrative) or competing (subject to peer review).

T

Targeted Research – Research funded as a result of an Institute set-aside of dollars for a specific scientific area. Institutes solicit applications using research initiatives (RFAs for grants, RFPs for contracts). Targeted research applications are reviewed by chartered peer review committees within Institutes. The opposite is Investigator-Initiated Research.

Technology Transfer – Sharing of knowledge and facilities among Federal laboratories, industry, universities, Government, and others to make federally generated scientific and technological advances accessible to private industry and State and local governments.

Terms and Conditions of Award – All legal requirements imposed on a grant by NIH, whether based on statute, regulation, policy, or other document referenced in the grant award, or specified by the grant award document itself. The Notice of Award may include both standard and special conditions that are considered necessary to attain the grant's objectives, facilitate post award administration of the grant, conserve grant funds, or otherwise protect the Federal Government's interests.

Tethered Application/Grant – When applications are submitted for multiple PI's from multiple organizations, the application from the partnering Institutions are associated and reviewed as a single project. If an award is made, each of the involved institutions will receive a separate grant to fund the collaborative project. All applications are linked by a common project title and by cross-references within each application.

Total Project Costs – The total allowable costs (both direct costs and facilities and administrative costs) incurred by the grantee to carry out a grant-supported project or activity. Total project costs include costs charged to the NIH grant and costs borne by the grantee to satisfy a matching or cost-sharing requirement.

Training Awards – Awards designed to support the research training of scientists for careers in the biomedical and behavioral sciences, as well as help professional schools to establish, expand, or improve programs of continuing professional education. Training awards consist of institutional training grants (T) and individual fellowships (F).

Translational Research – Translational research includes two areas of translation. One is the process of applying discoveries generated during research in the laboratory, and in preclinical studies, to the development of trials and studies in humans. The second area of translation concerns research aimed at enhancing the adoption of best practices in the community. Cost-effectiveness of prevention and treatment strategies is also an important part of translational science.

Triage – *See* Streamlined Review

Type – *See* Application Types.

U

Underrepresented Group – Group underrepresented in biomedical research, such as people with disabilities, people from disadvantaged backgrounds, and racial and ethnic groups such as blacks or African Americans, Hispanics or Latinos, American Indians or Alaskan Natives, and Native Hawaiians and other Pacific Islanders. Used as an eligibility requirement for diversity supplements, fellowships (F31), and other NIH programs.

Unscored – In the Center for Scientific Review peer review process, applications judged by a study section to be noncompetitive are generally in the lower half of the applications to be reviewed. These applications are not given a priority score, although they are reviewed and applicants receive a summary statement. Between FY 1992 and FY 1995 the term "Not Recommended for Further Consideration" (NRFC) referred to noncompetitive applications.

V

Validation – The systematic check of applications against the NIH application guide and Funding Opportunity Announcement instructions. The process can generate errors or warnings.

W

Withholding of Support – A decision by NIH not to make a non-competing continuation award within the current competitive segment.

Book of NIH Abbreviations and Acronyms

Letter Codes Designating Funding for NIH Institutes, Centers in Grant Applications

Abbreviation	NIH Institutes, Centers	Letter Code Designating Funding Institute In Grant Applications
CC	Clinical Center*	
CIT	Center for Information Technology*	
CSR	Center for Scientific Review*	
FIC	John E. Fogarty International Center	TW
NCATS	National Center for Advancing Translational Sciences	TR
NCCAM	National Center for Complementary and Alternative Medicine	AT
NCI	National Cancer Institute	CA
NEI	National Eye Institute	EY
NHGRI	National Human Genome Research Institute	HG
NHLBI	National Heart, Lung, and Blood Institute	HL
NIA	National Institute on Aging	AG
NIAAA	National Institute on Alcohol Abuse and Alcoholism	AA
NIAID	National Institute of Allergy and Infectious Diseases	AI
NIAMS	National Institute of Arthritis and Musculoskeletal and Skin Diseases	AR
NIBIB	National Institute of Biomedical Imaging and Bioengineering	EB

* Does Not Make Extramural Awards

Abbreviation	NIH Institutes, Centers, Offices	Letter Code Designating Funding Institute In Grant Applications
NICHD	<i>Eunice Kennedy Shriver</i> National Institute of Child Health and Human Development	HD
NIDA	National Institute on Drug Abuse	DA
NIDCD	National Institute on Deafness and Other Communication Disorders	DC
NIDCR	National Institute of Dental and Craniofacial Research	DE
NIDDK	National Institute of Diabetes and Digestive and Kidney Diseases	DK
NIEHS	National Institute of Environmental Health Sciences	ES
NIGMS	National Institute of General Medical Sciences	GM
NIH	National Institutes of Health	
NIMH	National Institute of Mental Health	MH
NIMHD	National Institute on Minority Health and Health Disparities (formerly National Center on Minority Health and Health Disparities)	MD
NINDS	National Institute of Neurological Disorders and Stroke	NS
NINR	National Institute of Nursing Research	NR
NLM	National Library of Medicine	LM
OD	Office of the Director	OD

Acronym	Definition
A	
AAALAC	Association for Assessment and Accreditation of Laboratory Animal Care
AALAS	American Association for Laboratory Animal Science
AAMC	Association of American Medical Colleges
AAP	American Academy of Pediatrics
AAPHP	American Academy of Pediatrics
ABL	Applied BioScience Laboratories for Acquired Immunodeficiency Syndrome
ABRCMS	Annual Biomedical Research Conference for Minority Students
ABSL	American Bio-Safety Level
ACD	Advisory Committee to the Director
ACEP	American College of Emergency Physicians
ACF	Administration for Children and Families (DHHS)
ACGME	Accreditation Council for Graduate Medical Education
ACPM	American College of Preventive Medicine
ACR	American College of Radiology
ACS	American Cancer Society
ACS	American College of Surgeons
ACSI	American Customer Satisfaction Index
ACSR	AIDS and Cancer Specimen Resource, NCI
ACTG	AIDS Clinical Trials Group
ACTIS	AIDS Clinical Trials Information Service
ACTU	AIDS Clinical Trials Unit
ACUC	Animal Care and Use Committee
ADAMHA	Alcohol Drug Abuse and Mental Health Administration (now SAMSHA)

ADB	Automated Data Base System
ADB	Administrative Database System (NIH)
ADC	AIDS Dementia Complex
ADCR	Associate Director for Clinical Research
ADD	Attention Deficit Disorder
AdEERS	Adverse Event Expedited Reporting System
ADP	Automated Data Processing
ADR	Adverse Drug Reactions
ADR	Alternative Dispute Resolution
AE	Adverse Event
AER	Adverse Event Reporting
AFGE	American Federation of Government Employees
AFIP	Armed Forces Institute of Pathology
AFIP	Animal Facilities Improvement Program
AFL/CIO	American Federation of Labor/Congress of Industrial Organizations
AGEMAP	Atlas of Gene Expressions in Mouse Aging Project
AGRICOLA	AGRICultural OnLine Access
AHCPR	Agency for Health Care Policy and Research
AHRQ	Agency for Healthcare Research and Quality
AI	Amelogenesis Imperfecta
AI/ANO	American Indian/Alaskan Native Organization
AID	U.S. Agency for International Development
AIDS	Acquired Immunodeficiency Syndrome
AIDSinfo	HHS AIDS information Web site
AIEDRP	Acute Infection and Early Disease Research Program

AIRO	Agency Intramural Research Integrity Officer
AIRO	American Indian Research Opportunities
AITRC	Allergy, Immunology, and Transplantation Research Committee
AITRP	AIDS International Training and Research Program, FIC
AJCC	American Joint Committee on Cancer
AL	Annual Leave
ALAT	Assistant Laboratory Animal Technician (Certified by AALAS)
ALERT system	HHS system for disseminating information to Public Health Service officials about organizations or people charged with or found to have engaged in scientific misconduct (PHS)
AMA	American Medical Association
AMB	AIDS Malignancy Bank
AMC	AIDS Malignancy Consortium
AMC	Acquisition Management Committee
AMD	Age-related Macular Degeneration
AMHPS	Association of Minority Health Professionals Schools
AMIA	American Medical Informatics Association
AMLCD	Active matrix liquid crystal display
AMSSC	Administrative Management Systems Steering Committee
AMWG	AIDS Malignancies Work Group
ANL	Argonne National Laboratory, Argonne, IL
ANPR	Advance Notice of Proposed Rulemaking
ANSI	American National Standards Institute
AO	Administrative Official/ Administrative Office/ Administrative Officer
AOA	Administration on Aging
AP	Acquisition Plan
APA	Administrative Program Assistant

APAC	Annual Payback Activities Certification
APAO	Asian and Pacific Islander American Organization
APC	NIH Purchase Card Program Agency Program Coordinator
APD	Animal Program Director
APHA	American Public Health Association
APHIS	USDA - Animal and Plant Health Inspection Service
API	Application Programming Interfaces
APN	Advanced Practice Nursing
ARA	Awaiting Receipt of Application
ARAC	Administrative Restructuring Advisory Committee/Work Group on Acquisition
ARAC	AIDS Research Advisory Committee (NIAID)
ARB	Architecture Review Board
ARC	Administrative Resource Center
AREA	NIH Academic Research Enhancement Award (R15)
ARL	U.S. Army Research Laboratory
ARND	Alcohol-related Neurodevelopmental Disorder
ARRA	American Recovery and Reinvestment Act of 2009
ARRR	AIDS-Related Research Review
ARS	Agriculture Research Service
ART	Antiretroviral Therapy
ARV	Antiretroviral
ASAP	As Soon As Possible
ASB	Administrative Services Branch
ASBTF	Assistant Secretary for Budget, Technology and Finance
ASDC	Administrative Skills Development Curriculum

ASH	Assistant Secretary for Health, PHS
ASI	Addiction Severity Index
ASP	Animal Study Proposal
ASPE	Office of the Assistant Secretary for Planning and Evaluation
ASPER	Assistant Secretary for Personnel Administration, DHHS
ASPH	Association of Schools of Public Health
ASTHO	Association of State and Territorial Health Officials
AT	Administrative Technician
ATCC	American Type Culture Collection, Manassas, VA
ATI	Analytic Treatment Interruption
ATIS	AIDS Treatment Information Service
ATPM	Association of Teachers and Preventive Medicine
ATSDR	Agency for Toxic Substances and Disease Registry
AVEG	AIDS Vaccine Evaluation Group
AVEU	AIDS Vaccine Evaluation Unit
AVRC	AIDS Vaccine Research Committee
AWA	Animal Welfare Act
AWOL	Absence Without Official Leave
AWS	AIDS-associated Wasting Syndrome
AZT	Zidovudine (generic name) or Azidothymidine

B

B&F	Buildings and Facilities
B&P	Bid and Proposal
B/Start	Behavioral Science Track Award for Rapid Transition

BAA	Broad Agency Announcement
BAFO	Best and Final Offer
BARC	Beltsville Agricultural Research Center
BBBP	Biobehavioral and Behavioral Processes
BC	Biomarker Consortium
BC/BS	Blue Cross/Blue Shield
BCP	Best Community Practice and Biophysical and Chemical Sciences
BCS	Biochemical Sciences
BDCN	Brain Disorders and Clinical Neuroscience
BDP	Biopharmaceutical Development Program
BDR	Budget Data Request
BEA	Bureau of Economic Analysis
BECON	Bioengineering Consortium (NIH OD)
BEMIS	Biomaterials and Medical Implant Science
BEP	Bureau of Engraving and Printing
BESA	Border Epidemiologic Study of Aging
BEST	Biomonitoring of Environmental Status and Trends
BFRL	Building and Fire Research Laboratory
BGCRG	Breast and Gynecologic Cancer Research Group
BHP	Bureau of Health Professions
BIA	Bureau of Indian Affairs
BIC	Business Information Center
BIG	Blacks in government
BIGR	Biomaterials and Information for Genomic Research™ (Ardais Corporation)
BIMAS	Bioinformatics Molecular Analysis Section

BIO	Biotechnology Industry Organization
BIRADS	Breast Imaging Reporting and Data System
BIRN	Biomedical Informatics Research Network
BIS	Bureau of Industry and Security
BISM	Blind Industries and Services of Maryland
BISTI	Biomedical Information Science and Technology Initiative
BISTIC	Bioinformatics Consortium (NIH OD)
BITS	Business Information Technology System
BJA	Bureau of Justice Assistance
BJS	Bureau of Justice Statistics
BL-3	Biosafety Level 3
BLA	Biologics License Application
BLIRC	Biomedical Library and Informatics Review Committee
BLM	Bureau of Land Management
BLS	Board on Life Sciences
BLS	Bureau of Labor Statistics
BMBL	Biosafety in Microbiological and Biomedical Laboratories
BMDO	Ballistic Missile Defense Organization
BML	Biological Material License
BMMR	Biological Models and Materials Research
BMO	Business Management Office
BNA	Bureau of National Affairs
BNL	Brookhaven National Laboratory, Upton, NY (Department of Energy Organization)
BOA	Basic Ordering Agreement
BOG	Board of Governors, NIH

BOP	Federal Bureau of Prisons
BOR	Board of Regents
BOR	Bureau of Reclamation
BoS	Board of Survey
BPA	Blanket Purchase Agreement
BPD	Bureau of Public Debt
BPH	Benign Prostatic Hyperplasia
BPHC	Bureau of Primary Health Care
BPSRG	Basic Prevention Science Research Group
BRB	Benefits Review Board
BRCA	Breast Cancer
BRD	Biological Resource Division,
BRDPI	Biomedical Research and Development Price Index, measures real annual changes in the prices of items and services required for research and development (R&D) activities
BRFSS	Behavioral Risk Factor Surveillance System
BRG	Biometry Research Group
BRIN	Biomedical Research Infrastructure Network
BRMP	Biological Response Modifiers Program
BSA	Board of Scientific Advisors
BSC	Board of Scientific Counselors
BSC	Business Service Centers
BSI	Brief Symptom Inventory
BSL	Bio-Safety Level
BSSC	Behavioral and Social Sciences Coordinating Committee
BTP	Biotechnology Training Program
BTR	Biomedical Technology Resource

BTS	Bureau of Transportation Statistics
BVA	Board of Veterans Appeals
C	
CAM	Complementary and Alternative Medicine
CBER	Center for Biologics Evaluation and Research
CBIAC	Chemical and Biological Defense Information Analysis Center
CBO	Congressional Budget Office
CBT	Computer-Based Training
CC	Warren Grant Magnuson Clinical Center, NIH
CCB	Configuration Control Board
CCB	Child Care Bureau
CCC	Commodity Credit Corporation
CCO	Chief Contracting Officer
CCR	Center for Career Resources (OD)
CCR	Center for Cooperative Resolution
CCR	Commission on Civil Rights
CCSS	Childhood Cancer Survivor Study
CCTAT	Cooperative Clinical Trials in Adult Kidney Transplantation
CCTPT	Cooperative Clinical Trials in Pediatric Kidney Transplantation
CDA	Confidential Disclosure Agreement
CDBG	Community Development Block Grants
CDC	Centers for Disease Control and Prevention, PHS (Public Health Service)
CDE	Common Data Element
CDER	Center for Drug Evaluation and Research

CDFI	Community Development Financial Institutions
CDHR	Center for Devices and Radiological Health
CDMC	Central Data Management Center
CDMRP	Congressionally Directed Medical Research Program
cDNA	Complementary DNA
CDs	Communication Directors
CES	Central E-mail Service
CDP	Career Development Plan
CDR	Clinical Drug Request
CDUS	Clinical Data Update System
CDW	Consultant Days Worked
CEA	Council of Economic Advisers
CEC	Contractor Establishment Code
CEDR	Comprehensive Epidemiologic Data Resource
CEGS	Centers of Excellence in Genomic Science
CEL	Commercial Evaluation License
CEN	Bureau of the Census
CEPPO	Chemical Emergency Preparedness and Prevention Office
CEPS	Center for Earth and Planetary Studies
CEQ	Council on Environmental Quality
CERCLIS	Comprehensive Environmental Response, Compensation, & Liability Information System
CETEC	Topographic Engineering Center
CF	Consent Form
CFAR	Centers for AIDS Research
CFC	Combined Federal Campaign

CFDA	Catalog of Federal Domestic Assistance, a database that helps the Federal Government track all programs it has domestically funded. Federal programs are assigned a number in the database called the “CFDA number.”
CFO	Chief Financial Office
CFOC	Chief Financial Officers Council
CFR	Code of Federal Regulations
CFS CRC	Chronic Fatigue Syndrome Cooperative Research Centers
CFSAN	National Center for Food Safety and Applied Nutrition
CGAP	Competitive Grant Application Process
CGH	Comparative genomic hybridization
CHAMPVA	Civilian Health and Medical Program of the Department of Veterans Affairs
CHB	Community Health Branch (DOHS)
CHID	Combined Health Information Database
ChiMP	NIH Chimpanzee Management Program
CHIMP	Chimpanzee Health, Improvement, Maintenance and Protection Act
CHTN	Cooperative Human Tissue Network
CIAO	Critical Infrastructure Assurance Office
CIC	Consumer Information Center
CID	Center of Infectious Diseases (CDC)
CIDI	Composite International Diagnostic Interview (Clinical Trials Standard)
CIO	Chief Information Officer
CIPRA	Comprehensive International Program for Research on AIDS
CIS	Cancer Information Service
CISET	Committee on International Sciences, Engineering, and Technology
CIT	Center for Information Technology
CJD	Creutzfeldt-Jakob Disease

CLC	Community Liaison Council
CLIA	Clinical Laboratories Improvement Act
CLM	Council of Logistics Management
CMAB	Complaints Management and Adjudication Branch (OEO)
CMAP	Cancer Molecular Analysis Project
CMB	Comparative Medicine Branch
CMBD	Collection Management & Delivery Branch (DLS)
CME	Continuing Medical Education
CMHS	Center for Mental Health Services
CML	Chronic Myeloid Leukemia
CMO	Committee Management Officer, IC person responsible for the oversight of all NIH Federal advisory committees under the auspices of the Federal Advisory Committee Act; responsible for developing committee charter, preparing nomination and appointment documents for membership to committees, providing technical assistance to committee members, providing initial review of conflict of interest disclosures, etc.
CMP	Contract Management Program
CMP/HMO	Comprehensive Medical Plans/Health Maintenance Organizations
CMPP	Center for Nutrition Policy and Promotion
CMS	Centers for Medicare and Medicaid Services
CMSP	Cooperative Medical Sciences Program
CMV	Center for Minority Veterans
CNCRIT	Collaborative Network for Clinical Research on Immune Tolerance
CNS	Central Nervous System
CO	Contracting Officer
COB	Close of Business
COBRE	Centers of Biomedical Research Excellence
CoC	Commission on Cancer

CoC	Council of Councils
COC	Certificate of Confidentiality
COG	Children's Oncology Group
COGA	Collaborative Study on the Genetics of Alcoholism
COI	Conflict of Interest
COLA	Cost of Living Allowance
CONSER	Cooperative Online Serials
COOG	Continuity of Operations Group
COOP	Continuity of Operations Plan
COP	Continuation of Pay
COP	Costal Ocean Program
COPR	Council of Public Representatives (serves NIH Director)
COPS	Office of Community Oriented Policing Services
COPTRG	Community Oncology and Prevention Trials
COR	Career Opportunities in Research Education and Training
COSEPUP	Committee on Science Engineering and Public Policy
COTA	Career Opportunities Training Agreement (HHS)
COTS	Commercial Off-The-Shelf Software Products
CPA	Cooperative Project Assurance
CPAF	Cost Plus Award Fee
CPDF	Central Personnel Data File
CPE	Continuing Professional Education
CPFP	Cancer Prevention Fellowship Program
CPI	Consumer Price Index
CPIF	Cost Plus Incentive Fee

CPMS	Defense Civilian Personnel Management Service
CPO	Corrections Program Office
CPS	Contractor Performance System
CPS	Center for Prevention Services (CDC)
CPSC	Consumer Product Safety Commission
CR	Continuing Resolution
CRA	Clinical Research Associate
CRADA	Cooperative Research and Development Agreement
CRC	Cooperative Research Center
CRC	Civil Rights Center
CRC	New Clinical Research Center
CRF	Case Report Form (Source Document for Clinical Studies)
CRIB	Central Institutional review Board
CRIC	Chronic Renal Insufficiency Cohort
CRIS	Clinical Research Information System
CRISP	Computer Retrieval of Information on Scientific Programs, A searchable biomedical database of federally supported proposed research conducted at universities, hospitals, institutions, etc.
CRL	Charles River Laboratories
CRM	Customer Relations Manager
CRO	Contract Research Organization
CRP	Conference Room Pilot
CRP	Conservation Reserve Program
CRS	Congressional Research Service
CRS	Clinical Research Scholar
CRS	Community Relations Service
CRTA	Cancer Research Training Award

C RTP	Clinical Research Training Program
CRVP	Clinical Research Volunteer Program
CS	Contract Specialist
CSAC	Central Services Advisory Committee
CSAP	Center for Substance Abuse Prevention
CSAT	Center for Substance Abuse Treatment
CSB	Customer Service Branch (DMAPS)
CSB	Chemical Safety and Hazard Investigation Board
CSD	Client Services Division
CSE	Office of Child Support Enforcement
CSI	Center for the Study of Intelligence
CSR	Center for Scientific Review
CSREES	Cooperative State Research, Education, and Extension Service
CT	Computed Tomography
CTA	Clinical Trial Agreement
CTAG	Clinical Translation Advisory Group
CTC	Common Toxicity Criteria
CTEP	Clinical Therapeutic Evaluation Program
CTEP	Cancer Therapy Evaluation Program
CTN	National Drug Abuse Treatment Clinical Trials Network
CTP	Community Treatment Program
CTSA	Clinical and Translational Science Awards
CTSU	Clinical Trials Support Unit
CU	Coordinating Unit
CUAP	College and University Affiliations Program

Cumulus SPMS	Cumulus Slide/Presentation Management System
CVS	Cardiovascular Sciences
CVS	Chorionic Villus Sampling
CWC	Chemical Weapons Convention
CWD	Chronic Wasting Disease
CY	Calendar Year

D

D&A	Design and Analysis Workgroup
D&B	Dun & Bradstreet Number
DAP	Division of Acquisition Programs, OLAO
DARPA	Defense Advanced Research Projects Agency
DASAM	Deputy Secretary for Administration and Management
DASPA	Division of Advanced Studies and Policy Analysis
DB	Design Branch (DMAPS)
DBASSE	Division of Behavioral and Social Sciences and Education
DBBD	Division of Biological Basis of Disease
DBDR	Division of Blood Diseases and Resources
DBPS	Division of Bioengineering and Physical Science
DBT	Division of Biomedical Technology
DCA	Division of Cost Allocation
DCAA	Defense Contract Audit Agency
DCCT	Diabetes Control and Complications Trial
DCIS	Department Contract Information System
DCLG	Director's Consumer Liaison Group

DCM	Division of Comparative Medicine
DCMC	Defense Contract Management Command
DCMS	Division of Mail and Courier Services (ORS)
DCPS	Division of Clinical and Population Based Studies
DCR	Division of Career Resources, OHRM, NIH
DCR	Division of Clinical Research
DCRT	Division of Computer Research and Technology (now CIT)
DDC	Defense Distribution Center
DDER	Deputy Director of Extramural Research, NIH
DDIR	Deputy Director for Intramural Research
DDKR	Drug Delivery & Kinetics Resource (DBPS)
DDM	Deputy Director for Management
DDN	Division of Digestive Diseases and Nutrition, NIDDK
DDP	Diamminedichloroplatinum
DEA	Division of Extramural Activities, NIDDK
DEC	Deputy Ethics Counselor
DeCA	Defense Commissary Agency
DEIS	Division of Extramural Information Systems
DELPRO	Delegated Procurement System
DEM	Division of Diabetes, Endocrinology, and Metabolic Diseases, NIDDK
DEMS	Division of Events Management Services (PES or P&ES)
DEPC	Division of Emergency Preparedness & Coordination
DEPS	Division of Epidemiology and Population Studies
DERT	Division of Extramural Research and Training
DES	Division of Engineering Services

DFAS	Defense Finance and Accounting Service (sends out DHHS/NIH W2s for honorariums, etc.)
DFM	Division of Financial Management
DHHS	Department of Health and Human Services
DHRS	Division of Human Resource Systems, OHRM, NIH
DHVD	Division of Heart and Vascular Diseases
DICOM	Digital Imaging and Communications in Medicine
DINFOS	Defense Information School
DIR	Division of Intramural Research, NIDDK
DITA	Division of Information Technology Acquisition, OLAO (also known as NITAAC)
DITR	Division of International Training and Research
DLD	Division of Lung Diseases
DLS	Division of Library Services
DLS	Division of Logistics Services, OLAO
DLT	Digital linear tape
DM	Data management
DMAPS	Division of Medical Arts and Printing Services
DMAS	Data Management and Analysis Subcommittee
DMCM	Division of Molecular and Cellular Mechanisms
DMCS	Division of Mail and Courier Services
DMDC	Defense Manpower Data Center
DMID	Division of Microbiology and Infectious Diseases
DMS	Division of Management Services
DNA	Deoxyribonucleic Acid
DOHS	Division of Occupational Health and Safety
DORRA	DLA Office of Operations Research and Resource Analysis

DPCPSI	Division of Program Coordination, Planning, and Strategic Initiatives
DPPS	Division of Personal Property Services, OLAO
DPS	Division of Physiological Systems
DPSM	Division of Physical Security Management
DRA	Division of Research Acquisition, OLAO
DRI	Division of Research Infrastructure
DRR	Division of Receipt and Referral
DRS	Division of Radiation Safety
DRSB	Diagnostic & Research Services Branch
DS	Division of Safety, Office of Research Services
DSEIS	Division of Scientific Equipment and Instrumentation Services (ORS)
DSFM	Division of Space and Facility Management
DSMB	Data and Safety Monitoring Board
DSM-IV	Diagnostic & Statistical Manual of Mental Disorders – 4 th Edition
DSO	Division of Security Operations
DSS	Division of Support Services
DSSA	Division of Station Support Acquisition, OLAO
DTIC	Defense Technical Information Center
DTM	Department of Transfusion Medicine (ORS)
DTP	Developmental Therapeutics Program
DTTS	Division of Travel and Transportation Services
DUNS	Data Universal Numbering System
DVR	Division of Veterinary Resources
DW	Data Warehouse
DWD	Division of Workforce Development

E

EA	Expanded Authorities
EA	Enterprise Architecture
EAC	External Advisory Committee
EACC	External Affairs Coordinating committee
EAP	Employee Assistance Program
EBSA	Employee Benefits Security Administration
EC	Executive Committee
EC	European Commission
ECA	Executive Committee for Acquisition
ECA	Bureau of Educational and Cultural Affairs
ECAB	Employees' Compensation Appeals Board
ECB	Electronic Council Book
ECFMG	Educational Commission for Foreign Medical School Graduates
ECIE	Executive council on Integrity and Efficiency
ECL	Executive Committee on Logistics
ECOSOC	Economic and Social Council
ECP	Emergency Conservation Program
ECR-LRP	Extramural Clinical Research Loan Repayment Program for Individuals from Disadvantaged Backgrounds
EDGAR	Electronic Data Gathering, Analysis, and Retrieval
EDI	Electronic Data Interchange
EDIC	Epidemiologic Cohort Study
Edison	Extramural Invention Information Management System
EDRG	Early Detection Research Group

EDRN	Early Detection Research Network
EEO	Equal Employment Opportunity
EEOC	Equal Employment Opportunity Commission
EES	Enterprise E-Mail System
EHP	Environmental Health Perspectives
EHRP	Enterprise Human resources and Payroll System
EIA	Energy Information Administration
EIN	Entity Identification Number
EIR	Employee Invention Report
EIS	Epidemic Intelligence Service
ELS	Earnings and Leave Statement
ELSI	Ethical, Legal and Societal Implications
EL-TRAINS	Electronic Logistics Training & Support Network
EM	Office of Environmental Management
EML	Environmental Measurement Laboratory
EMPSB	Events Management Program Support Branch (DEMS)
ENC	Eisenhower National Clearinghouse
ENR	Endocrinology and Reproductive Sciences
ENS	Early Notification System
EO	Executive Order
EOB	Editorial Operations Branch
EOC	Ethics Oversight Committee
EOD	Entrance on Duty
EOIR	Executive Office for Immigration Review
EOP	Executive Office of the President

EOUSA	Executive Office for United States Attorneys
EP	Extramural Programs
EPMC	Extramural Program Management Committee
EPN	Executive Plaza North (6130 Executive Blvd.; Rockville, MD 20852)
EPRU	Enteric Pathogens research Unit
EPS	Executive Plaza South (6120 Executive Blvd.; Rockville, MD, 20852)
EPSCoR	Experimental Program to Stimulate Competitive Research
EPSS	Electronic Performance Support Systems
eRA	Electronic Research Administration; responsible for IMPAC II
ERDA	Energy Research and Development Administration
EREN	Energy Efficiency and Renewable Energy Network
ERIC	Educational Resources Information Center
EROD	Educational Resource Organizations Directory
ERP	Extramural Research Program
ERS	Economic Research Service
ERSB	Equipment Rental & Sakes Branch (DSEIS)
ES	Executive Secretariat (NIH)
ESA	Extramural Scientist Administrator
ESA	Employment Standards Administration
ESA	Economics and Statistics Administration
ESDIM	Environmental Services Data and Information Management
ESG	Executive Staffing Group (REPS, PMB, NCI)
eSNAP	Electronic Streamlined Non-competing Award Process
ETA	Employment and Training Administration
ETSO	Employee Transportation Services Office

F

F & A	Facilities and Administrative Cost
F Awards	Fellowship Awards
FACA	Federal Advisory Committee Act
FAES	Foundation for Advanced Education in the Sciences
FAI	Fair Act Inventory
FAIR Act	Federal Activities Inventory Reform Act
FAQ	Frequently Asked Questions
FAR	Federal Acquisition Regulation
FARB	Funding Advisory Review Board
FASAB	Federal Accounting Standards Advisory Board
FASEB	Federation of American Societies for Experimental Biology
FCC	Federal Communications Commission
FCOI	Financial Conflict of Interest
FCRDC	Frederick Cancer Research and Development Center
FDA	Food and Drug Administration (PHS)
FDP	Federal Demonstration Partnership
FECA	Federal Employees' Compensation Act
FEGLI	Federal Employees' Group Life Insurance
FEHBP	Federal Employees' Health Benefit Program
FEMA	Federal Emergency Management Agency
FERC	Federal Energy Regulatory Commission
FERS	Federal Employees' Retirement System
FFLA	Family Friendly Leave Act
FIC	John E. Fogarty International Center

FICA	Federal Insurance Contributions Act (Social Security)
FIRST	First Independent Research Support and Transition Award
fMRI	Functional Magnetic Resonance Imaging
FMS	Financial Management Service
FNIH	Foundation for the National Institutes of Health
FOIA	Freedom of Information Act of 1966, amended 1986
FRB	Federal Reserve Board
FRS	Federal Reserve System
FTC	Federal Trade Commission
FTE	Full Time Equivalent
FTTP	Full-Time Training Position
FWA	Federal Wide Assurance
FY	Fiscal Year (October 1 – September 30)
FYI	For Your Information

G

GAO	General Accounting Office, Congress
GBV-C	Hepatitis G (GB Virus-C)
GCRC	General Clinical Research Center
GDB	Human Genome Database
GH	Growth Hormone
GM	Grants Management
GMB	Grants Management Branch Office
GME	Graduate Medical Education
GMO	Grants Management Officer

GMS	Grants Management Specialist
GPA	Grade Point Average
GPEA	Government Paperwork Elimination Act of 1998
GPO	Government Printing Office
GPRA	Government Performance Results Act of 1993
GPS	Global Positioning Satellite System
GRE	Graduate Record Examinations
GS	General Schedule
GSA	General Services Administration
GTA	Grants Technical Assistant
GWAC	Government-Wide Acquisition Contract
 H	
HAART	Highly Active Antiretroviral Therapy
HBCU	Historically Black Colleges and Universities
HBV	Hepatitis B Virus
HCV	Hepatitis C virus
HDR-LRP	Loan Repayment Program for Health Disparities Research
HEM	Hematology Study Section
hESC	Human Embryonic Stem Cells
HHMI	Howard Hughes Medical Institute
HHS	Health and Human Services (Department of)
HIPAA	Health Insurance Portability and Accountability Act of 1996
HIV	Human Immunodeficiency Virus
HMO	Health Maintenance Organization

HPV	Human Papillomavirus
HQ	Headquarters
HRSA	Health Resources and Services Administration, PHS
HRT	Hormone Replacement Therapy
HSA	Health Scientist Administrator
HSRAC	Human Subjects Research Advisory Committee
HSRB	Human Subjects Review Board
HSV	Herpes Simplex Virus
HTML	Hypertext Markup Language
I	
IACUC	Institutional Animal Care and Use Committee
IAG	Interagency Agreement
IAR	Internet Assisted Review
IBC	Institutional Biosafety Committee
IC	Institute and Center (NIH)
ICC	Interstate Commerce Commission
ICD	Institutes/Centers/Divisions
ICF	Informed Consent Form
ID	Identification
IDE	Investigational Device Exemption (FDA)
IDeA	Institutional Development Award Program (NCRR)
IDIQ	Indefinite Delivery Indefinite Quality Contract
IDM	Infectious Diseases and Microbiology
iEdison	NIH's Extramural Electronic Invention Reporting system

IFCN	Integrative, Functional and Cognitive Neuroscience
IG	Inspector General
IHS	Indian Health Service, PHS
IMA	Internal Monitoring Board
IMAGE	Integrated Molecular Analysis of Genomes and their Expression
IMF	International Monetary Fund
IMPAC	Integrated Management, Planning, Analysis and Coordination (Data System)
IMPAC II	Information for Management, Planning, Analysis, and Coordination (grants data system)
IMS/ADB	Information Management System/Administrative Data Base System (DELPRO)
IND	Investigational New Drug Application (FDA)
INS	Immigration and Naturalization Service (now the United States Citizenship and Immigration Services)
IO	Information Officer
IOM	Institute of Medicine, NAS
IP	Intellectual Property
IPC	Incidental Patient Contact
IPF	Institutional Profile File Number
IRA	Individual Retirement Account
IRACDA	Institutional Research and Academic Career Development Award
IRB	Institutional Review Board
IRG	Integrated Review Group, a cluster of study sections responsible for review of grant applications in scientifically related areas; sections share common intellectual and human resources.
IRM	Information Resources Management
IRP	NIH Intramural Research Program
IRPG	Interactive Research Project Grant
IRTA	Intramural Research Training Award or Agreement

ISO	International Organization for Standardization
ISSO	Information Systems Security Office
IT	Information Technology
ITAS	Integrated Time and Attendance System
ITB	Information Technology Branch
ITC	United States International Trade Commission

J

JAX	The Jackson Laboratory
JHU	Johns Hopkins University
JOFOC	Justification for Other than Full and Open Competition

Just-in-time	Grant application timeframe that requires applicants to send some information to NIH only if an award is likely. Also used for other support information, and other items, including: certification of IRB approval, Federal wide assurance, IACU certification, and letter stating key personnel have been trained in protecting human subjects
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K

K Awards	Mentored and Career Development Awards
KSA	Knowledge, Skills and Ability Form
KSASF	Knowledges, Skills, Abilities Supplemental Form (NIH-2252-3)
KUH	Division of Kidney, Urologic, and Hematologic Diseases, NIDDK

L

LABS	Laboratory Automated Bibliographic System
LAN	Local Area Network
LAO	Leave Approving Official

LAS	Laboratory Animal Sciences
LAT	Laboratory Animal Technician (AALAS Certified)
LATG	Laboratory Animal Technologist (AAALAS Certified)
LCM	Laser Capture Microdissection
LI	Lead Investigator
LOC	Library of Congress
LOCIS	Library of Congress Information System
LOE	Level of Effort
LOI	Letter of Intent
LRP	Loan Repayment Program (NIH)
LWOP	Leave Without Pay
 M	
MA	Master Agreement
MAC	Multiple Award Contract
MACs	Multiple Agency Contracts
MARC	Minority Access to Research Career Program
MBRS	Minority Biomedical Research Support
MC	Manual Chapter
MCDN	Molecular, Cellular and Developmental Neuroscience
MCP	NIH Management Cadre Program
MCR	Management Control Review
MCSB	Mail Customer Service Branch (DMCS)
MCRU	Metabolic Clinical Research Unit (in NIH Clinical Center)
MEDLINE/ PUBMED	National Library of Medicine's Database for Scientific Publications

MEO	Most Efficient Organization
MERIT	Method to Extend Research in Time Award
MeSH	Medical Subject Headings
MF	NIH Management Fund
MHC	Major Histocompatibility Complex
MHPF	Minority Health Professionals Foundation
MI	Minority Institutions
MIGA	Multilateral Investment Guarantee Agency
MIS	Medical Information System
ML	Military Leave
MM	Medical Monitor
MODY	Maturity Onset Diabetes of the Young
MORE	Minority Opportunities in Research
MOU	Memorandum of Understanding
MOU/MOA	Memorandum of Understanding/Memorandum of Agreement
MPA	Multiple Project Assurance
MPP	Merit Program Plan (NIH)
MPW	Medical Pathological Waste
MRA	Minimum Retirement Age
MRC	Medical Research Council (UK)
MRI	Magnetic Resonance Imaging
M-RISP	Minority-Research Infrastructure Support Program
mRNA	Messenger RNA
MRS	Magnetic Resonance Spectroscopy
MSDS	Material Safety Data Sheet

MSPB	Merit Systems Protection Board
MTA	Material Transfer Agreement
MTCT	Mother-to-Child Transmission
N	
N/A	Not Applicable/Not Available
NAFTA	North American Free Trade Agreement
NAHFE	National Association of Hispanic Federal Executives
NARA	National Archives and Records Administration
NARCH	Native American Research Centers for Health
NARFE	National Association of Retired Federal employees
NAS	National Academy of Sciences (U.S.)
NBAC	National Bioethics Advisory Commission
NBII	National Biological Information Infrastructure
NBN	National Biospecimen Network
NBRSS	NIH Business and Research Support System
NBS	New Business Systems/NIH Business System
NCATS	National Center for Advancing Translational Sciences
NCBI	National Center for Biotechnology Information
NCC	National Coordinating Center for Telecommunications
NCCAM	National Center for Complementary and Alternative Medicine (NIH)
NCCDPHP	National Center for Chronic Disease and Prevention Health Promotion (CDC)
NCCIC	National Child Care Information Center
NCCLS	National Committee for Clinical Laboratory Standards
NCD	National Council on Disability

NCEH	National Center for Environmental Health (CDC)
NCES	National Center for Education Statistics
NCHS	National Center for Health Statistics
NCI	National Cancer Institute (NIH)
NCICAS	National Cooperative Inner-City Asthma Study
NCIPC	National Center for Injury Prevention and Control (CDC)
NCRR	National Center for Research Resources (dissolved as of December 23, 2011)
NCSDR	National Center on Sleep Disorders Research
NCTR	National Center for Toxicological Research
NCUA	National Credit Union Administration
NCVHS	National Committee on Vital and Health Statistics
NDA	New Drug Application
NDDKDAC	National Diabetes and Digestive and Kidney Diseases Advisory Council
NDIC	National Drug Intelligence Center
NDRI	National Disease Research Interchange
NED	NIH Enterprise Directory
NEI	National Eye Institute (NIH)
NFT	Notification of Foreign Travel
NGA	Notice of Grant Award (also NoGA) [see NOGA p 36/59]
NGO	Non-Government Organization
NHGRI	National Human Genome Research Institute (NIH)
NHIC	National Health Information Center
NHLBI	National Heart, Lung, and Blood Institute (NIH)
NHP	Nonhuman Primate
NHRPAC	National Human Research Protection Advisory Committee

NHSC	National Health Sciences Scholarship
NIA	National Institute on Aging (NIH)
NIAAA	National Institute on Alcohol Abuse and Alcoholism (NIH)
NIAID	National Institute of Allergy and Infectious Disease (NIH)
NIAMS	National Institute of Arthritis and Musculoskeletal and Skin Disease (NIH)
NIBIB	National Institute of Biomedical Imaging and Bioengineering (NIH)
NICHD	<i>Eunice Kennedy Shriver</i> National Institute of Child Health and Human Development (NIH)
NIDA	National Institute on Drug Abuse (NIH)
NIDCD	National Institute on Deafness and Other Communication Disorders (NIH)
NIDCR	National Institute of Dental and Craniofacial Research (NIH)
NIDDK	National Institute of Diabetes and Digestive and Kidney Diseases (NIH)
NIDRR	National Institute on Disability and Rehabilitation Research
NIEHS	National Institute of Environmental Health Sciences (NIH)
NIGMS	National Institute of General Medical Sciences (NIH)
NIH	National Institutes of Health
NIH DW	NIH Data Warehouse
NIHAC	The National Institutes of Health Animal Center (Poolesville, MD)
NIHITS	NIH Integrated Training System
NIHTC	National Institutes of Health Training Center
NIMH	National Institute of Mental Health (NIH)
NIMHD	National Institute on Minority Health and Health Disparities (formerly National Center on Minority Health and Health Disparities)
NINDS	National Institute of Neurological Disorders and Stroke (NIH)
NINR	National Institute of Nursing Research (NIH)
NIOSH	National Institute for Occupational Safety and Health (CDC)
NIST	National Institute of Standards and Technology

NLAES	National Longitudinal Alcohol Epidemiologic Survey
NLM	National Library of Medicine (NIH)
NLT	Not Later Than
NMA	National Medical Association
NMR	Nuclear Magnetic Resonance
NMS	Nutritional and Metabolic Sciences
NOA	Nature of Action
NOGA	Notice of Grant Award [see NoGA prior page at NGA]
Non-FTE	Non Full-time Equivalent
NOTA	National Organ Transplant Act
NPEBC	National Programs of Excellence in Biomedical Computing
NPRC	National Primate Research Center
NREN	National Research and Education Network
NREVSS	National Respiratory and Enteric Virus Surveillance System
NRFC	Not Recommended for Further Consideration
NRL	Naval Research Laboratory
NRSA	National Research Service Award (e.g., T32, F32)
NS	No Score (lower 50% of grants in study section)
NSF	National Science Foundation
NSRG	Nutritional Science Research Group
NSTC	National Science and Technology Center
NSTL	National Space Technology Laboratories
NTE	Not To Exceed
NTIA	National Telecommunications and Information Administration
NTIS	National Technical Information Service

NTP	National Toxicology Program
O	
OA	Office of Administration
OACU	Office of Animal Care and Use
OAM	Office of Administrative Management (OD)
OAMP	Office of Acquisition Management and Policy, OA
OAPP	Office of Adolescent Pregnancy Programs (OASH)
OAR	Office of AIDS Research
OASDI	Old Age Survivor Disability Insurance
OASH	Office of the Assistant Secretary for Health, PHS
OASPA	Office of the Assistant Secretary for Public Affairs
OB	Office of Budget (NIH OD)
OBA	Office of Biotechnology Activities (NIH OD)
OBL	Office of Business Liaison
OBSF	Office of Business Systems & Finance (OD)
OBSSR	Office of Behavioral and Social Sciences Research (NIH OD)
OC	Office of Communications
OCAB	Office of the Assistant Secretary for Health, PHS
OCC	Operations Coordinating Committee
OCCC	Office of Clinical Center Communications
OCL	Office of Community Liaison (NIH OD)
OCPL	Office of Communications & Public Liaison
OD	Office of the Director, NIH
ODA	Official Duty Activities

ODEO	Office of the Director Executive Office (NIH OD)
ODEP	Office of Disability Employment Policy
ODP	Office of Disease Prevention (NIH OD)
ODS	Office of Dietary Supplements (NIH OD)
OE	Office of Education (NIH OD)
OEE0	Office of Equal Employment Opportunity (NIH OD)
OEO	Office of Equal Opportunity
OEODM	Office of Equality, Opportunity & Diversity Management
OEP	Office of Extramural Programs, OER, OD, NIH
OER	Office of Extramural Research, OD, NIH
OFACP	Office of Federal Advisory Committee Policy (NIH OD)
OFCCP	Office of Federal Contract Compliance Programs
OFM	Office of Financial Management
OFRM	Office of Financial Resources Management
OGC	Office of the General Counsel (NIH OD)
OGE	Office of Government Ethics
OHASIS	Office of Health and Safety Information System
OHER	Office of Health and Environmental Research
OHR	Office of Human Resources (NIH OD)
OHRM	Office of Human Resource Management (NIH OD)
OHRP	Office for Human Research Protections
OHS	Office of Healthy Start (HRSA)
OHSR	Office of Human Subjects Research
OIB	Office of Information Branch
OIG	Office of the Inspector General (USDA)

OIIA	Office of Intergovernmental and Interagency Affairs
OIR	Office of Intramural Research (NIH OD)
OIT	Office of Information Technology
OLAO	Office of Logistics and Acquisition Operations
OLAW	Office of Laboratory Animal Welfare, OER, OD, NIH
OLM	Office of Logistics Management
OLPA	Office of Legislative Policy and Analysis (NIH OD)
OLRS	Office of Loan Repayment and Scholarship (NIH OD)
OM	Office of Management (NIH OD)
OMA	Office of Management Assessment (NIH OD)
OMAR	Office of Medical Applications of Research (NIH OD)
OMB	Office of Management and Budget (White House)
OMBS	Office of Medical Board Services
OMH	Office of Minority Health (OASH)
OMS	Occupational Medical Services (DOHS)
ONC	Oncological Sciences
OPASI	Office of Portfolio Analysis and Strategic Initiatives (dissolved October 2008)
OPDIV	Operating Division (HHS)
OPEC	Office of Prevention, Education, and Control
OPERA	Office of Policy for Extramural Research Administration
OPF	Official Personnel File
OPHS	Office of Public Health and Science
OPL	Offices of Public Liaison (NIH OD)
OPM	Office of Personnel Management
OPRR	Office of Protection from Research Risks

ORA	Office of Reports and Analysis, OER, OD, NIH
ORD	Office of Rare Diseases (NIH OD)
ORI	Office of Research Integrity, HHS
ORIM	Office of Information Resources Management
ORS	Office of Research Services (NIH OD OM)
ORWH	Office of Research on Women's Health, OD, NIH
OS	Office of the Secretary
OSA	Office of Scientific Affairs, OER, OD, NIH
OSC	Office of Strategic Coordination, DPCPSI, OD, NIH
OSD	Office of the Scientific Director
OSE	Office of Science Education (NIH OD)
OSHA	Occupational Safety and Health Administration
OSHRC	Occupational Safety and Health Review Commission
OSMP	Office of Strategic Management and Planning (NIH OD)
OSP	Office of Science Policy (NIH OD)
OSPA	Office of Science Policy Analysis
OSPP	Office of Science Policy and Planning
OST	Office of Science and Technology
OSTI	Office of Scientific and Technical Information
OSTP	Office of Science and Technology Policy (White House)
OT	Overtime
OTA	Office of Technology Assessment
OTD	Office of Technology Development
OTS	Omega Travel Service (NIH Travel Agent)
OTT	Office of Technology Transfer

OUTPT	Outpatient
OWH	Office on Women's Health
P	
P/TRP	Promotion/Tenure Review Panel
PA	Program Announcement
PA	Purchasing Agent
PAM	Office of Acquisition and Property Management
PAR	Program Announcement with special receipt or review
PART	Program Assessment Rating Tool (OMB)
PAS	Program Announcement with Set-aside funds
PCA	Physicians Comparability Allowance
PCBE	President's Council on Bioethics
PD	Position Description
PDF	Portable Document Format
PET	Positron Emission Tomography
PETA	People for the Ethical Treatment of Animals
PhRMA	Pharmaceutical Research and Manufacturers of America
PHS	Public Health Service (U.S.)
PHS OWH	U.S. Public Health Service's Office on Women's Health
PHTN	Public Health Training Network
PI	Principal Investigator
PIA	Procurement Integrity Act
PIN	Personal Identification Number
PKU	Phenylketonuria

PLC	Program Leadership Committee
PMCID	PubMed Central Identification
PMI	Presidential Management Intern
PMIS	Property Management Information System
PMO	Property Management Officer
PO	Program Official
PO	Project Officer (For a Grant or Contract)
PO	Purchase Order
Post-Doc	Post-Doctoral Fellow
PP	Pay Period
PPE	Pay Period Ending
PPP	Public Private Partnerships
PPS	Pathophysiological Sciences
PR	Public Relations
PRB	Protocol Review Board
PRC	Processing Resource Centers
Pre-Doc	Pre-Doctoral Fellow
PRG	Progress Review Groups
PRIMR	Public Responsibility in Medicine and Research
PRMC	Protocol Review and Monitoring Committee
Project EXPORT	Centers of Excellence in Partnerships for Community Outreach, Research on Health Disparities and Training
PROTRACK	Clinical Center Protocol Tracking Database
PrP	Prion Protein
PRPL	Patient Recruitment and Public Liaison Office
PRRR	Program Review Report Record

PRS	Protocol Review Subcommittee
PSC	Program Support Center
PSC	Publications Subcommittee
PSO	Professional Service Order
PSP	Physician Special Pay (Title 38)
PTSD	Post-Traumatic Stress Disorder
PWS	Performance Work Statement

Q

Q&A	Questions and Answers
QA	Quality Assurance
QALY	Quality-Adjusted Life Years
QAP	Quality Assurance Program
QAS	Quality Assurance Subcommittee
QC	Quality Control
QRB	Quality Review Board
QSI	Quality Step Increase

R

R&D	Research & Development
R&W	Recreation and Welfare
R01	Standard NIH Research Project Grant
R34	Investigator-Initiated Clinical Trial Planning and Implementation Grants
R56	Grant allowing an interim award so principal investigator can continue while reapplying for an R01 grant. Also enables new investigators to gather preliminary data to improve their grant applications. (Bridge Award)

RA	Research Assistant
RAC	Recombinant-DNA Advisory Committee
RAID	Rapid Access to Intervention Development
RAL	Restored Annual Leave
RALAT	Registered Assistant Laboratory Animal Technician
RAO	Regulatory Affairs Officer
RCC	Research Coordination Council (Department-wide)
RCDA	Research Career Development Award (K-series awards)
RCDC	Research, Condition, and Disease Categorization
RCR	Responsible Conduct of Research
RCRII	RCMI Clinical Research Infrastructure Initiative
RCT	Randomized Controlled Trial
rDNA	Recombinant DNA
RePORT	NIH Research Portfolio Online Reporting Tools
RePORTER	RePort Expenditures and Results
RFA	Request for Application (request for grant applications for a research area)
RFC	Request For Contract
RFI	Request for Information
RFIP	Research Facilities Improvement Program
RFP	Request For Proposal (request for contract proposal for a project)
RFQ	Request for Quotation
RIF	Reduction In Force
RIMS	Robocom Inventory Management System
RISE	Research Initiative for Scientific Enhancement
RM	Roadmap

RMA	Risk Management Agency
RMS	Research Management Support
RNA	Ribonucleic Acid
RNAi	RNA interference
RPC	Review Policy Committee
RPG	Research Project Grant
RPHB	Risk, Prevention, and Health Behaviors
RPPR	Research Program Performance Report
RRTC	Regional Research and Training Center
RSA	Rehabilitation Services Administration
RSC	Radiation Safety Committee
RSO	Radiation Safety Officer
RSOB	Radiation Safety Operations Branch (DRS)
RSUM	Research Supplements for Underrepresented Minorities

S

SAC	Simplified Acquisition Committee
SAE	Serious Adverse Event
SAMHSA	Substance Abuse and Mental Health Services Administration, HHS
SB	Small Business
SBA	U.S. Small Business Administration
SBIR	Small Business Innovation Research
SBO	Small Business Office
SBRS	Senior Biomedical Research Service
SBS	Small Business Specialist

SBSA	Small Business Set-Aside
SC	Steering Committee
SCD	Service Computation Date
SCORE	Support of Continuous Research Excellence
SCR	Special Council Review
SD	Scientific Director
SDB	Small Disadvantaged Business
SEER	Surveillance, Epidemiology, and End Results
SE	Special Emphasis
SEP	Special Emphasis Panel (an SRG convened for a single meeting)
SES	Senior Executive Service
SF	Standard Form
SF	Staff Fellow
SIG	Shared Instrumentation Grant
SIMS	Scientific Initiative Management System
SIP	Summer Internship Program in Biomedical Research
SLA	Simple Letter of Agreement
SMSA	Small Business & Minority Business Set Aside
SNAP	Streamlined Noncompeting Award Process
SNEM	Social Science, Nursing, Epidemiology, and Methods
SNMA	Student National Medical Association
SNOMED	Systemized Nomenclature of Medicine
SNOMED CT	Systemized Nomenclature of Medicine – Clinical Terms
SNPs	Single Nucleotide Polymorphisms
SO	Signing Official

SOP	Standard Operating Procedure
SOW	Statement Of Work
SPA	Single Project Assurance
SPF	Specific-pathogen free
SPIN	Shared Pathology Informatics Network
SPORE	Specialized Program of Research Excellence
SRAs	Scientific Review Administrator (an NIH scientist administrator in charge of review and advisory groups; now called SROs)
SRB	Surgery, Radiology, and Bioengineering
SRB	Scientific Review Board
SREA	Scientific Review Evaluation Awards
SRFP	Summer Research Fellowship Program
SRG	Scientific Review Group (performs initial scientific merit review of grant application & contract proposals; also called Initial Review Group (IRG) when pertaining to grant applications)
SROs	Scientific Review Officer (manages the peer review process for grant applications and contract proposals; designated Federal official responsible for the peer review meeting; major focus is on scientific rather than administrative activities; former title was SRA)
SSB	Support Services Branch (DP)
SSEB	Source Selection Evaluation Board
SSF	Senior Staff Fellow
SSF	Service and Supply Fund
SSN	Social Security Number
SSS	Special Study Section
STD	Sexually Transmitted Disease
STDCRC	Sexually transmitted Disease Cooperative Research Centers
STDCTU	Sexually Transmitted Disease Clinical Trials Unit
STEP	Staff Training in Extramural Programs
STI	Scientific and Technical Information

STTR Small Business Technology Transfer

SV Student, or Special Volunteer

T

T&A Time and Attendance

TAIMS Time and Attendance Information Management System

TEHIP Toxicology and Environmental Health Program

TIA Time Off Incentive Award

TIG Time In Grade

TIN Payer Identification Number Tax

TK Timekeeper

TMA Tissue Microarray

TMJ Temporomandibular joint

TO Task Order

TOD Tour of Duty

TOXNET Toxicology Data Network

TQM Total Quality Management

TSC Training Subcommittee

TSP Thrift Savings Plan

TTB Technology Transfer Branch

TX Treatment

U

U.S.C. United States Code

UMLS Unified Medical Language System

URC	User Resource Center
USAID	United States Agency for International Development
USAMRIID	United States Army Medical Research Institute of Infectious Diseases
USDA	United States Department of Agriculture
USIA	United States Information Agency
USOPM	United States Office of Personnel Management
USUHS	Uniformed Services University of Health Sciences

V

VA	Veterans Administration
VA	Department of Veterans Affairs
VF	Visiting Fellow
VLTP	Voluntary Leave Transfer Program
VRC	Vaccine Research Center
VRP	Veterinary Resources Program
VS	Visiting Scientist
VSOF	Visual Status of Funds

W

WAG	Widely Attended Gathering
WFCL	Work and Family Life Center
WG	Wage Grade
WGI	Within-Grade Increase
WHI	Women's Health Initiative
WHO	World Health Organization, United Nations

WTO World Trade Organization

WWW World Wide Web

WYLBUR Interactive system providing simultaneous service to more than 825 terminals or microcomputers.

X

X-Train Trainee Activities System

Y

YTD Year To Date

Z

ZIP (Code) Zone Improvement Plan

National Institute of Diabetes and Digestive and Kidney Diseases Mission, Overview, and History

From 1950 until May 19, 1972, the Institute was known as the National Institute of Arthritis and Metabolic Diseases; until June 23, 1981, it was the National Institute of Arthritis, Metabolism, and Digestive Diseases; and until April 8, 1986, it was the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases.

Mission

The mission of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) is to conduct and support medical research and research training and to disseminate science-based information on diabetes and other endocrine and metabolic diseases; digestive diseases, nutritional disorders, and obesity; and kidney, urologic, and hematologic diseases, to improve people's health and quality of life.

OVERVIEW

The NIDDK supports a wide range of medical research through grants to universities and other medical research institutions across the country. The Institute also supports government scientists who conduct basic, translational, and clinical research across a broad spectrum of research topics and serious, chronic diseases and conditions related to the Institute's mission. In addition, the NIDDK supports research training for students and scientists at various stages of their careers and a range of education and outreach programs to bring science-based information to patients and their families, health care professionals, and the public.

External research funded by the NIDDK is organized into three scientific program divisions:

- Diabetes, Endocrinology, and Metabolic Diseases
- Digestive Diseases and Nutrition
- Kidney, Urologic, and Hematologic Diseases

The NIDDK's overarching principles in moving research forward include:

- maintaining a vigorous, investigator-initiated research portfolio that supports cross-cutting science that can be broadly applied to many disease-specific research areas
- supporting pivotal clinical studies and trials, with a focus on substantial participation of groups at highest risk.
- preserving a stable pool of talented new investigators
- fostering exceptional research training and mentoring opportunities
- ensuring that science-based health information reaches patients, their families, health care providers and the public through communications and outreach activities

Important Events in NIDDK History

August 15, 1950—President Harry S. Truman signed the Omnibus Medical Research Act into law, establishing the National Institute of Arthritis and Metabolic Diseases (NIAMD) in the U.S. Public Health Service. The new Institute incorporated the laboratories of the Experimental Biology and Medicine Institute, and expanded to include clinical investigation in rheumatic diseases, diabetes, and a number of metabolic, endocrine, and gastrointestinal diseases.

November 15, 1950—The National Advisory Arthritis and Metabolic Diseases Council held its first meeting and recommended approval of NIAMD's first grants.

1959—Dr. Arthur Kornberg, former chief of the Institute's enzyme and metabolism section, won the Nobel Prize for synthesizing nucleic acid.

1961—Laboratory-equipped mobile trailer units began an epidemiological study of arthritis among the Blackfeet and Pima Indians in Montana and Arizona, respectively.

October 16, 1968—The Nobel Prize was awarded to Dr. Marshall W. Nirenberg of the National Heart Institute, who reported his celebrated partial cracking of the genetic code while an NIAMD scientist.

November 1970—The Institute celebrated its 20th anniversary. U.S. Secretary of Defense Melvin R. Laird addressed leaders in the department, representatives from voluntary health agencies and professional biomedical associations, and past and present Institute National Advisory Council members.

May 19, 1972—The Institute's name was changed to the National Institute of Arthritis, Metabolism, and Digestive Diseases (NIAMDD).

October 1972—Dr. Christian B. Anfinsen, chief of the Institute's Laboratory of Chemical Biology, shared a Nobel Prize with two other American scientists for demonstrating one of the most important simplifying concepts of molecular biology: that the three-dimensional conformation of a native protein is determined by the chemistry of its amino acid sequence. A significant part of the research cited by the award was performed while Anfinsen was with the NIH.

September 1973—The creation of the first Diabetes-Endocrinology Research Centers marked the beginning of the Institute's Diabetes Centers Program.

November 1975—After nine months of investigation into the epidemiology and nature of diabetes mellitus and public hearings throughout the United States, the National Commission on Diabetes delivered its report, the *Long-Range Plan to Combat Diabetes*, to Congress. Recommendations included expanding and coordinating diabetes and related research programs; creating a diabetes research and training centers program; accelerating diabetes health care, education, and control programs; and establishing a National Diabetes Advisory Board.

April 1976—The National Commission on Arthritis and Related Musculoskeletal Diseases issued *The Arthritis Plan*. This report to Congress called for increased arthritis research and training programs, multipurpose arthritis centers, epidemiologic studies and data systems in arthritis, a National Arthritis Information Service, and a National Arthritis Advisory Board.

October 1976—Dr. Baruch Blumberg was awarded the Nobel Prize in Physiology or Medicine for research on the hepatitis B virus protein, the "Australia antigen," which he discovered in 1963 while at the Institute. This advance has proven to be a scientific and clinical landmark in detecting and controlling viral hepatitis and led to the development of preventive measures against hepatitis and liver cancer.

April 19, 1977—The NIH director established a trans-NIH program for diabetes, with the NIAMDD taking lead responsibility.

September 1977—Over \$5 million in grants was awarded to 5 institutions to establish Diabetes Research and Training Centers.

October 1977—In response to the recommendation of the National Commission on Diabetes, the National Diabetes Data Group was established within the Institute to collect, analyze, and disseminate diabetes data to scientific and public health policy and planning associations.

December 1977—Institute grantees Drs. Roger C.L. Guillemin and Andrew V. Shally shared the Nobel Prize in Physiology or Medicine with a third scientist. Guillemin's and Shally's prizes were for discoveries related to the brain's production of peptide hormones.

1978—The NIDDK created the National Diabetes Information Clearinghouse to increase knowledge and understanding about diabetes among people with these conditions and their families, health professionals, and the general public.

January 1979—The National Commission on Digestive Diseases issued the report, *The National Long-Range Plan to Combat Digestive Diseases*. Recommendations to Congress included establishing a National Digestive Diseases advisory board and information clearinghouse, and emphasizing digestive diseases educational programs more in medical schools.

June 1980—The NIDDK created the National Digestive Diseases Information Clearinghouse to increase knowledge and understanding about digestive diseases among people with these conditions and their families, health professionals, and the general public.

September 1980—Dr. Joseph E. Rall, director of NIAMDD intramural research, became the first person at the NIH to be named to the distinguished executive rank in the Senior Executive Service. President Jimmy Carter presented the award in ceremonies at the White House on September 9.

October 15, 1980—NIAMDD celebrated its 30th anniversary with a symposium, "DNA, the Cell Nucleus, and Genetic Disease." Dr. Donald W. Seldin, chairman of the department of internal medicine, University of Texas Southwestern Medical School, Dallas, was guest speaker.

1981—A report entitled *An Evaluation of Research Needs in Endocrinology and Metabolic Diseases* was prepared by an external group of scientific experts, and was submitted to the NIH and the Senate Committee on Appropriations.

June 23, 1981—The Institute was renamed the National Institute of Arthritis, Diabetes, and Digestive and Kidney Diseases (NIADDK).

April 1982—U.S. Department of Health and Human Services (HHS) Secretary Richard S. Schweiker elevated the NIADDK's programs to division status, creating five extramural divisions and the Division of Intramural Research.

November 1982—Dr. Elizabeth Neufeld, chief of the NIADDK's genetics and biochemistry branch, received a Lasker Foundation Award. She was cited, along with Dr. Roscoe E. Brady of the then-named National Institute of Neurological and Communicative Disorders and Stroke (NINCDS), for "significant and unique contributions to the fundamental understanding and diagnosis of a group of inherited diseases called mucopolysaccharide storage disorders (MPS)."

November 1984—Grants totaling more than \$4 million were awarded to six institutions to establish the Silvio O. Conte Digestive Diseases Research Centers. The research centers investigate the underlying causes, diagnoses, treatments, and prevention of digestive diseases.

April 8, 1986—The Institute's Division of Arthritis, Musculoskeletal and Skin Diseases became the core of the new National Institute of Arthritis and Musculoskeletal and Skin Diseases. The NIADDK was renamed the National Institute of Diabetes and Digestive and Kidney Diseases.

June 3, 1986—The National Kidney and Urologic Diseases Advisory Board was established to formulate the long-range plan to combat kidney and urologic diseases.

1987—The NIDDK created the National Kidney and Urologic Diseases Information Clearinghouse to increase knowledge and understanding about diseases of the kidneys and urologic system among people with these conditions and their families, health care professionals, and the general public.

August 1, 1987—Six institutions were funded to establish the George M. O'Brien Kidney and Urological Research Centers.

December, 1987—In response to congressional language on the fiscal year (FY) 1988 appropriation for the NIDDK, the Institute established a program of cystic fibrosis research centers.

March, 1990—The National Kidney and Urologic Diseases Advisory Board issued its "Long-Range Plan: Window on the 21st Century." The Plan presented recommendations for uniting the

public and private sectors in the quest to prevent these diseases; improve methods for early detection, treatment, and rehabilitation; and ultimately find cures.

September 16, 1990—The NIDDK celebrated its 40th anniversary. Dr. Daniel E. Koshland, Jr., editor of *Science*, was guest speaker.

June, 1991—The NIDDK Advisory Council established the National Task Force on the Prevention and Treatment of Obesity to synthesize current science on preventing and treating obesity and to develop statements about topics of clinical importance based on critical analyses of the scientific literature.

September 30, 1992—Three Obesity/Nutrition Research Centers were established, along with an extramural animal models core to breed genetically obese rats for obesity and diabetes research.

October 12, 1992—Drs. Edwin G. Krebs and Edmond H. Fischer were awarded the Nobel Prize in Physiology or Medicine for their work on "reversible protein phosphorylation." At the time of the award, the scientists had been receiving continuous NIDDK grant support since 1951 and 1956, respectively.

October 30, 1992—In response to congressional language on the Institute's FY 1993 appropriation, the NIDDK initiated a program to establish gene therapy research centers with emphasis on cystic fibrosis.

November 1, 1993—The functions of the NIH Division of Nutrition Research Coordination, including those of the NIH Nutrition Coordinating Committee, were transferred to the NIDDK.

October 10, 1994—Drs. Martin Rodbell and Alfred G. Gilman received the Nobel Prize in Physiology or Medicine for discovering G-proteins, a key component in the signaling system that regulates cellular activity. Dr. Rodbell discovered the signal transmission function of GTP while a researcher at the then-named NIAMD.

June 22, 1997—Led by the NIDDK, the NIH and the U.S. Centers for Disease Control and Prevention (CDC) announced the creation of the National Diabetes Education Program (NDEP) at the American Diabetes Association annual meeting in Boston. The NDEP's goals are to reduce the rising prevalence of diabetes, the morbidity and mortality of the disease, and its complications.

July 18, 2000—The NIDDK created the National Kidney Disease Education Program to raise awareness among the public of kidney disease and its risk factors, and make resources available to consumers and health care providers.

June 2000—To reduce the disproportionate burden of many diseases in minority populations, the NIDDK initiated an Office of Minority Health Research Coordination.

November 16, 2000—The NIDDK celebrated its 50th anniversary. Professional societies in eight U.S. locations and Canada sponsored scientific symposia and hosted an NIDDK exhibit. In addition, *A New Century of Science: A New Era of Hope* was published to highlight research supported and conducted by the NIDDK. The Institute concluded the year with a joint scientific symposium at the Society for Cell Biology's 40th anniversary meeting in December.

October 8, 2003—NIDDK grantee Dr. Peter Agre shared the Nobel Prize in Chemistry with another scientist for studies of channels in cell membranes. Agre discovered aquaporins, proteins that move water molecules through the cell membrane.

October 4, 2004—Dr. Richard Axel, once an intramural research fellow under Dr. Gary Felsenfeld at the NIDDK, shared the Nobel Prize in Physiology or Medicine with another scientist for discovering a large family of receptors selectively expressed in cells that detect specific odors.

October 6, 2004—Long-time grantees Drs. Irwin A. Rose and Avram Hershko shared the Nobel Prize in Chemistry with another scientist for discovering ubiquitin-mediated protein degradation inside the cell.

October 2007—Institute grantee Dr. Oliver Smithies shared the Nobel Prize in Physiology or Medicine with two other scientists for discovering principles for introducing specific gene modifications in mice by using embryonic stem cells.

2010—The NIDDK celebrated its 60th anniversary. Special events included the September 21 scientific symposium "Unlocking the Secrets of Science: Building the Foundation for Future Advances" and the publication of the commemorative report *NIDDK: 60 Years of Advancing Research to Improve Health*.

September 2010—NIDDK grantee Dr. Jeffrey Friedman and former grantee Dr. Douglas Coleman won the 2010 Albert Lasker Basic Medical Research Award for discovering the hormone leptin, which plays a key role in regulating energy intake and energy expenditure.

October 3, 2011—NIDDK grantee Dr. Bruce Beutler shared the 2011 Nobel Prize in Physiology or Medicine with NIH grantee Dr. Jules Hoffman for their discoveries concerning the activation of innate immunity. NIH grantee Dr. Ralph Steinman also shared the award posthumously for his discovery of the dendritic cell and its role in adaptive immunity.

December 2011—The journal *Science* named an HIV-prevention research study led by NIDDK grantee Dr. Myron Cohen the 2011 Breakthrough of the Year. The study found that people infected with HIV reduced the risk of transmitting the virus to their sexual partners by taking oral antiretroviral medicines when their immune systems were relatively healthy. Cohen, an NIH MERIT Award recipient, has received more than 20 years of continuous NIH funding, including NIDDK funding for basic science research earlier in his career.

April 29, 2012—The Treatment Options for type 2 Diabetes in Adolescents and Youth (TODAY) study, the results of which appeared in the *New England Journal of Medicine* on April

29, 2012, is the first major comparative effectiveness trial for the treatment of type 2 diabetes in young people. The NIDDK-funded study found that combined therapy with metformin and rosiglitazone was superior to metformin alone. The rate of treatment failure with metformin alone suggested that most youth with type 2 diabetes will require combination treatment or insulin within a few years after diagnosis.

September 21, 2012—Dr. Thomas E. Starzl, distinguished service professor of surgery at the University of Pittsburgh School of Medicine and a longtime NIDDK grantee, received the 2012 Lasker-DeBakey Clinical Medical Research Award – shared with Dr. Roy Calne, University of Cambridge emeritus — for his work developing liver transplantation, an intervention that has restored normal life to thousands of people with end-stage liver disease.

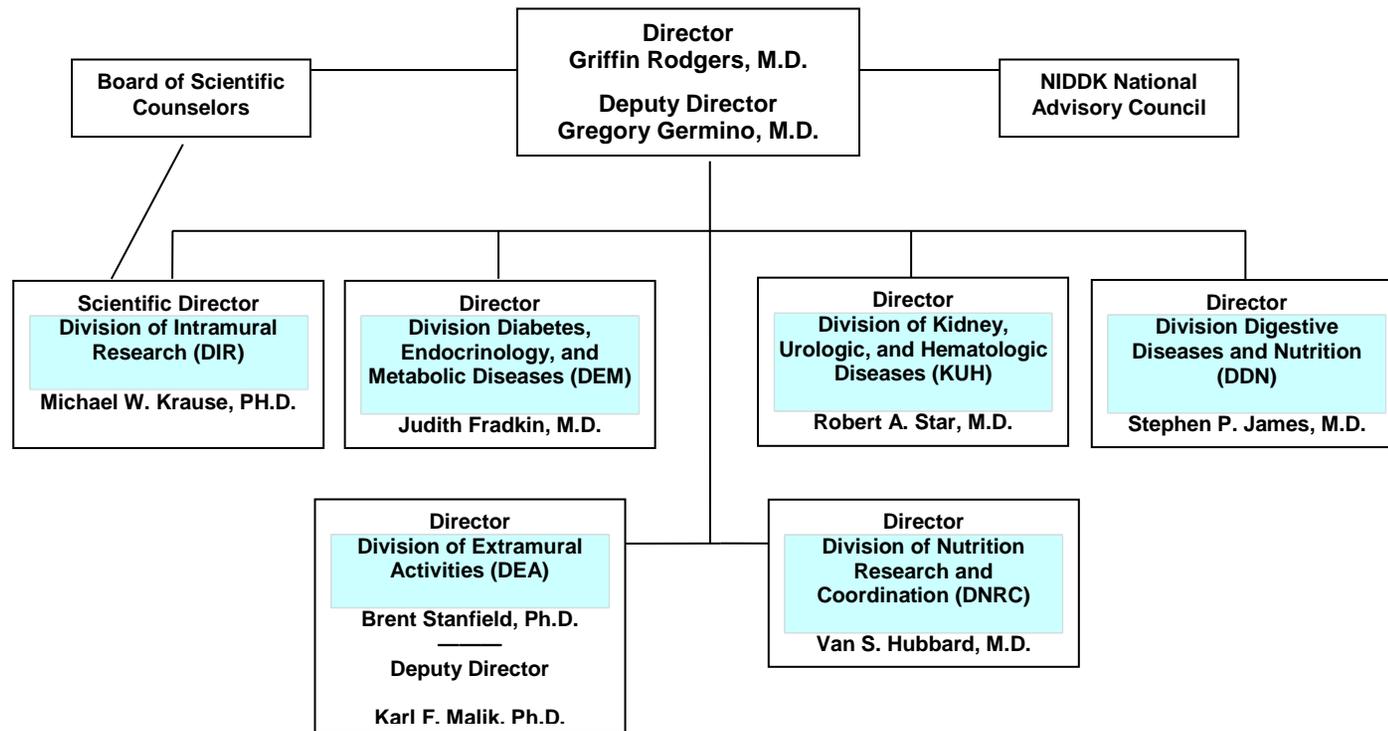
October 2012—Dr. Robert J. Lefkowitz, who trained at NIDDK from 1968-1970 as a clinical associate in the Clinical Endocrinology Branch, won the 2012 Nobel in chemistry for studies of protein receptors that let body cells sense and respond to outside signals.

October 2013—Dr. James Rothman, an NIDDK grantee, received the 2013 Nobel Prize in physiology or medicine [🔗](#), shared with fellow NIH grantees Drs. Randy W. Schekman and Thomas C. Südhof “for their discoveries of machinery regulating vesicle traffic, a major transport system in our cells,” according to the Nobel organization. The researchers’ work revealed how cells use small sacs, called vesicles, to import and export materials to and from cells. This transport system is a fundamental process in how cells work.

NIDDK Directors

Name	In Office from	To
William Henry Sebrell, Jr.	August 15, 1950	October 1, 1950
Russell M. Wilder	March 6, 1951	June 30, 1953
Floyd S. Daft	October 1, 1953	May 3, 1962
G. Donald Whedon	November 23, 1962	September 30, 1981
Lester B. Salans	June 17, 1982	June 30, 1984
Mortimer B. Lipsett	January 7, 1985	September 4, 1986
Phillip Gorden	September 5, 1986	November 14, 1999
Allen M. Spiegel	November 15, 1999	March 3, 2006
Griffin P. Rodgers	April 1, 2007	present

NIDDK Organizational Chart



Overview of the Office of the Director

In addition to the National Diabetes and Digestive and Kidney Diseases Advisory Council (NDDKAC), the Office of the Director includes the following offices:

- Executive Office, including administrative components:
 - Ethics Office
 - Office of Workforce Development and Planning (OWDP)
 - Office of Management and Policy Analysis (OMPA)
 - Office of Financial Management and Analysis (OFMA)
 - Extramural Administrative Management Branch (EAMB)
 - Intramural Administrative Management Branch (IAMB)
 - Computer Technology Branch (CTB)
 - Technology Transfer and Development Branch
- Office of Communications and Public Liaison (OCPL)
- Office of Scientific Program and Policy Analysis (OSPPA)

Also within the Office of the Director are the following two research coordination offices.

The NIDDK director created the *Office of Minority Health Research Coordination (OMHRC)* to address the burden of diseases and disorders that disproportionately impact the health of minority populations. The OMHRC will help implement the Institute's strategic plan for health disparities and build on the strong partnership with the National Center on Minority Health and Health Disparities at NIH.

The NIDDK *Office of Obesity Research (OBR)* is responsible for coordination of obesity-related research within NIDDK, and carries out its functions through the NIDDK Obesity Research Working Group. The Office is located organizationally under the auspices of the Office of the Director, NIDDK, and its co-directors represent the two divisions with primary responsibility for obesity-related extramural research, the Division of Digestive Diseases and Nutrition (DDN) and the Division of Diabetes, Endocrinology, and Metabolic Diseases (DEM). The Obesity Research Working Group consists of representatives of DDN, DEM, the Division of Kidney, Urologic, and Hematologic Diseases (KUH), the NIDDK Review Branch, the Office of Scientific Program and Policy Analysis (OSPPA), and the Division of Nutrition Research Coordination (DNRC). The responsibilities of the NIDDK Obesity Research Working Group are: (1) to provide a forum for sharing and coordination of trans-NIDDK and trans-NIH obesity research activities; (2) to assist the Director, NIDDK in identifying research opportunities, initiatives, and advances; (3) to identify and plan appropriate workshops and conferences; and (4) to assist in the preparation of obesity-related reports and inquiries.

Under the auspices of the NIDDK Advisory Council, the National Task Force on Prevention and Treatment of Obesity was established in June 1991. In June 2003, the name was changed to the *Clinical Obesity Research Panel (CORP)*. The mission of the CORP is to synthesize current scientifically based information on the prevention and treatment of obesity and to develop statements about topics of clinical importance that are based on critical analyses of the literature. It is composed of leading obesity researchers and clinicians who advise the institute on research needs and sponsor workshops on topics related to the prevention and treatment of obesity. The CORP serves in an advisory capacity to the Weight-control Information Network (WIN).

How To Contact Us

Office of the Director (NIDDK OD)

Position	Name	Location	Phone No./Email
Director	Dr. Griffin P. Rodgers	Building 31, 9A52	(301) 496-5741 griffinrodgers@mail.nih.gov
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Executive Office (NIDDK EO) (includes Ethics Office contacts)

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EEO Specialist	Alfreda Layne	2115 E. Jefferson St. Rm. BE64	(301) 435-6260 laynea@mail.nih.gov
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Office of Workforce Development and Planning (NIDDK OWDP)

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Workforce Resources Specialist	Camila Torrella	Building 31, 9A27	(301) 594-7772 torrellacm@mail.nih.gov
Workforce Resources Specialist	Andrea Brush	Building 31, 9A27	(301) 402-7122 brusha@mail.nih.gov

Office of Management and Policy Analysis (NIDDK OMPA)

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Management Analyst	Priscilla Logan	Building 31, 9A28	(301) 594-2192 prisl@mail.nih.gov
Management Analyst	Kelly Yager	Building 31, 9A28	301-594-3056 Kelly.yager@nih.gov

Office of Financial Management and Analysis (NIDDK OFMA)

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Budget Analyst	Ana Salcedo	Building 31, 9A34	(301) 594-2207 anas@mail.nih.gov

Grants Financial Analyst	Randy Copeland	Building 31, 9A34	(301) 435-2998 copelandr@mail.nih.gov
Grants Financial Analyst	Herman Utama	Building 31, 9A34	(301) 594-5230 Herman.utama@nih.gov

Extramural Administrative Management Branch (NIDDK EAMB)

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Administrative Officer	Kim Black	Democracy II, 901-A	(301) 594-9245 blackkm@mail.nih.gov
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Administrative Officer	Kimberly Lowery	Democracy II, 918	(301) 594-8888 loweryk@mail.nih.gov
Administrative Officer	Anthony Mcelroy	Building 31, 9A16	(301) 402-2648 tmcelroy@mail.nih.gov
Administrative Officer	Gwen Proctor	Building 31, 9A16	(301) 594-6615 proctogw@mail.nih.gov

Intramural Administrative Management Branch (NIDDK IAMB)

Position	Name	Location	Phone No./Email
Chief Administrative Officer	Randy Redmond	Building 10, 9N208	(301) 496-5100 redmonra@mail.nih.gov

Computer Technology Branch (NIDDK CTB)

Position	Name	Location	Phone No./Email
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Deputy Chief Information Officer	Max Niakani	2 Democracy Plaza, Rm. 940	(301) 594-7762 niakanim@mail.nih.gov

Office of Communications and Public Liaison (NIDDK OCPL)

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Office of Scientific Program and Policy Analysis (NIDDK OSPPA)

Position	Name	Location	Phone No./Email
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Deputy Director	Dr. Lisa Gansheroff	Building 31, 9A05	(301) 496-6623 gansheroffl@mail.nih.gov

Office of Minority Health Research Coordination (OMHRC)

Position	Name	Location	Phone No./Email
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Office of Obesity Research (OOR)

Position	Name	Location	Phone No./Email
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Co-Director	Dr. Sue Yanovski	2 Democracy Plaza, Rm. 665	(301) 594-8882 yanovskis@extra.niddk.nih.gov

Overview of the Division of Intramural Research

The [Division of Intramural Research](#) oversees research and training conducted within the NIDDK's laboratories and clinical facilities by government scientists in Bethesda, MD, and Phoenix, AZ. Several of NIDDK's intramural scientists have received national and international awards for scientific excellence.

The division includes 10 branches, nine laboratories, and four offices, which focus on issues of technology transfer, fellow recruitment and career development, and the overall management of the division's basic and clinical research efforts. In addition, nine core facilities provide centralized scientific support services to the laboratories and branches.

The intramural branches conduct basic, translational, and clinical biomedical research related to diabetes mellitus, endocrine, bone and metabolic diseases; digestive diseases, including liver diseases and nutritional disorders; kidney diseases; and hematologic diseases. The NIDDK's intramural labs are involved in fundamental research in biophysics; cell biology; chemical biology and medicinal chemistry; developmental biology; genetics, pathogenesis, and novel therapies of disease; molecular biology; signal transduction; and structural biology

Website: <http://www.niddk.nih.gov/research-funding/at-niddk/Pages/default.aspx>

How To Contact Us

Division of Intramural Research (DIR)

Position	Name	Location	Phone No./Email
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Director, Fellowship Office	Louis Simchowicz, M.D., MBA	Bldg. 12A, Rm. 3011	(301) 451-3640 ls347@nih.gov

Overview of the Division of Extramural Activities

The Division of Extramural Activities (DEA) provides leadership, oversight, tools, and guidance to manage the NIDDK's grants policies and operations, including efforts related to the scientific peer review process for assessing grant applications. The DEA also coordinates the NIDDK's committee management activities and [Advisory Council](#) meetings, and performs and coordinates programmatic analysis and evaluation activities.

The DEA is organized into three primary components:

- the Grants Management Branch, the focal point for all business-related activities associated with the negotiation, award, and administration of grants and cooperative agreements within the NIDDK
- the Scientific Review Branch, which coordinates the initial scientific peer review of applications submitted in response to Request for Applications (RFAs), training and career awards, program projects, multi-center clinical trials, and research contracts, including Loan Repayment Program applications. Most R01s, fellowship, and SBIR grant applications are reviewed in the Center for Scientific Review.
- the Office of Research Evaluation and Operations (OREO), within the DEA Office of the Director, oversees and coordinates disease coding/reporting for the NIDDK extramural program, manages the Early Notification System and NIH Guide publication process associated with publishing Funding Opportunity Announcements, and supports NIDDK Advisory Council activities. The office also facilitates harmonization of activities among NIDDK's four extramural divisions, and coordinates/performs special projects at the request of the NIDDK leadership.

Website: <http://www.nidk.nih.gov/about-nidk/advisory-coordinating-committees/Pages/default.aspx>

How To Contact Us

Division of Extramural Activities (DEA)

Building	U.S. Postal Address		UPS, Fedex, etc.
2 Democracy Plaza	6707 Democracy Blvd., Rm. 715, MSC 5452, Bethesda, MD 20892-5452		6707 Democracy Blvd., Rm. 715, Bethesda, MD 20817
Position	Name	Location	Phone No./Email
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Committee Management Office

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Grants Review Branch

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Grants Management Branch

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Position	Name	Location	Phone No./Email
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Overview of the Division of Diabetes, Endocrinology and Metabolic Diseases (DEM)

The Division of Diabetes, Endocrinology, and Metabolic Diseases (DEM) supports research, research training, and career development related to a vast and diverse range of diseases and conditions, including diabetes mellitus, obesity, osteoporosis, cystic fibrosis, thyroid and other endocrine disorders, and metabolic diseases. The division also leads the administration of trans-NIH diabetes research; coordinates federally supported, diabetes-related activities; promotes public awareness and education about diabetes and other diseases; and collects and disseminates data.

Diabetes Research Programs

The division encompasses 18 diabetes research programs, including the

- [Clinical Research in Type 1 Diabetes](#)
- [Clinical Research in Type 2 Diabetes](#)
- [Clinical, Behavioral, and Epidemiological Obesity Research](#)
- [Diabetes and Endocrine Disease Bioengineering, Biotechnology, and Imaging](#)
- [Diabetes and Metabolism HIV/AIDS](#)
- [Diabetes Centers](#)
- [Diabetes Genetics and Genomics](#)
- [Diabetes, Endocrine, and Metabolic Disease Translational Research](#)
- [Diabetes: Treatment, Prevention, and Complications](#)
- [Diabetic Kidney Disease](#)
- [Diabetic Urologic Disease](#)
- [Endocrine Pancreas](#)
- [Endocrinology and Hormone Signaling](#)
- [Genetic Metabolic Disease](#)
- [Kidney Genetics and Genomics](#)
- [Metabolic Pathways](#)
- [Obesity, Pregnancy, and the Intrauterine Environment](#)
- [Pathophysiology of Diabetes and Metabolic Disease](#)

Endocrine and Metabolic Diseases Research Programs

The division encompasses seven endocrinology research programs, including the

- [Chronic Kidney Disease](#)
- [Clinical, Behavioral, and Epidemiological Obesity Research](#)
- [Cystic Fibrosis Research and Translation Centers](#)
- [Cystic Fibrosis, CTFR](#)
- [Diabetes and Endocrine Disease Bioengineering, Biotechnology, and Imaging](#)
- [Diabetes and Metabolism HIV/AIDS](#)
- [Diabetes, Endocrine, and Metabolic Disease Translational Research](#)
- [Endocrine Pancreas](#)
- [Endocrine Tumors of the Pancreas](#)
- [Endocrinology and Hormone Signaling](#)
- [Genetic Metabolic Disease](#)
- [Metabolic Pathways](#)

- [Metabolism, Energy Balance, and Obesity](#)
- [Nutrient Metabolism, Status, and Assessment](#)
- [Obesity, Pregnancy, and the Intrauterine Environment](#)
- [Pathophysiology of Diabetes and Metabolic Disease](#)

Diabetes Mellitus Interagency Coordinating Committee

The Diabetes Mellitus Interagency Coordinating Committee (DMICC) coordinates diabetes research and activities across the NIH and other federal programs. The division director chairs the DMICC, which includes representatives from all federal departments and agencies whose programs involve health functions and responsibilities relevant to diabetes and its complications.

National Diabetes Data Group

The DEM's National Diabetes Data Group serves as the federal lead for collecting, analyzing, and sharing data on diabetes and its complications. The group draws on the expertise of the research, medical, and lay communities to support its data initiatives.

National Diabetes Education Program

See "Health Information and Education Services."

Website: <http://www.niddk.nih.gov/about-niddk/staff-directory/staff-by-office/division-diabetes-endocrine-metabolic-diseases/Pages/Division-of-Diabetes,-Endocrine-and-Metabolic-Diseases.aspx>

How To Contact Us

Division of Diabetes, Endocrinology, and Metabolic Diseases (DEM)

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Director, Metabolomics and Informatics Programs	Dr. Arthur L. Castle	2 Democracy Plaza, Rm. 791	(301) 594-7719 castlea@mail.nih.gov
Director, Diabetes Epidemiology Program	Dr. Catherine Cowie	2 Democracy Plaza, Rm. 691	(301) 594-8804 cowiec@mail.nih.gov
Director, Islet Transplantation Clinical Trials Program	Dr. Thomas L. Eggerman	2 Democracy Plaza, Rm. 697	(301) 594-8813 eggermant@mail.nih.gov

Position	Name	Location	Phone No./Email
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Type 1 Diabetes Trialnet Program Director	Dr. Ellen Leschek	2 Democracy Plaza, Rm. 603	(301) 402-8291 ellenl@mail.nih.gov
Senior Advisor for Childhood Diabetes Research	Dr. Barbara Linder	2 Democracy Plaza, Rm. 699	(301) 594-0021 linderb@mail.nih.gov
Senior Advisor for Endocrine Physiology	Dr. Saul Malozowski	2 Democracy Plaza, Rm. 607	(301) 451-4683 sm87j@mail.nih.gov
Senior Advisor, Molecular Endocrinology and Associate	Dr. Ronald Margolis	2 Democracy Plaza, Rm. 693	(301) 594-8819 margolisr@mail.nih.gov

Director for Grants Administration			
Director, Neurobiology of Obesity and Developmental Biology	Dr. Sheryl Sato	2 Democracy Plaza, Rm. 790	(301) 594-8811 smsato@mail.nih.gov
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Proteomic Program Director	Dr. Salvatore Sechi	2 Democracy Plaza, Rm. 611	(301) 594-8814 ss24q@mail.nih.gov
Director, Intracellular and Intrauterine Signaling Programs	Dr. Corinne Silva	2 Democracy Plaza, Rm. 794	(301) 451-7335 silvacm@niddk.nih.gov

Position	Name	Location	Phone No./Email
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Senior Advisor, Diabetes Research Translation	Dr. Myrlene Staten	2 Democracy Plaza, Rm. 6107	(301) 402-3151 statenm@mail.nih.gov
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Overview of the Division of Digestive Diseases and Nutrition

The Division of Digestive Diseases and Nutrition (DDN) supports research related to digestive diseases, including the alimentary tract, liver and pancreas, nutrition and obesity. The programs include basic, translational and clinical research. DDN also promotes public awareness and education about digestive diseases and related conditions, and oversees several national public awareness campaigns.

Digestive Diseases Research Programs

Alimentary tract programs

- [Digestive Diseases Clinical Research and Epidemiology](#)
- [Digestive Diseases Genetics and Genomics](#)
- [Digestive Diseases Research Core Centers](#)
- [Gastrointestinal Immunology, Inflammation, and Inflammatory Diseases](#)
- [Gastrointestinal Microbiology and Infectious Diseases](#)
- [Gastrointestinal Neuroendocrinology](#)
- [Gastrointestinal Physiology, Development, and Epithelial Biology](#)
- [Gastrointestinal, Nutrition, and Liver Research in HIV/AIDS](#)
- [Motility and Functional Gastrointestinal Disorders](#)
- [Nutrient Metabolism, Status, and Assessment](#)

Liver Disease Research Programs

- [Clinical, Behavioral, and Epidemiological Obesity Research](#)
- [Digestive Diseases Research Core Centers](#)
- [Gastrointestinal, Nutrition, and Liver Research in HIV/AIDS](#)
- [Genetic Metabolic Disease](#)
- [Iron and Heme Metabolism, Iron Chelation](#)
- [Liver Clinical Research and Epidemiology](#)
- [Liver Diseases Genetics and Genomics](#)
- [Nutrient Metabolism, Status, and Assessment](#)
- [Translational and Basic Liver Disease Research](#)

Pancreas Research Programs

- [Acute and Chronic Pancreatitis](#)
- [Endocrine Pancreas](#)
- [Endocrine Tumors of the Pancreas](#)
- [Hereditary and Pediatric Disorders of the Pancreas](#)
- [Pancreas Basic Research and Development](#)
- [Pancreas Clinical Research and Epidemiology](#)

Obesity Research Programs

- [Chronic Kidney Disease](#)
- [Clinical, Behavioral, and Epidemiological Obesity Research](#)
- [Endocrinology and Hormone Signaling](#)
- [Metabolic Pathways](#)
- [Metabolism, Energy Balance, and Obesity](#)
- [Neurobiology of Obesity](#)
- [Nutrient Metabolism, Status, and Assessment](#)
- [Nutrition and Obesity Genetics and Genomics](#)
- [Nutrition Obesity Research Centers](#)
- [Obesity Treatment and Prevention](#)
- [Obesity, Pregnancy, and the Intrauterine Environment](#)

Cross-cutting programs

- [Career Development](#)
- [Digestive Diseases Centers](#)
- [Loan Repayment](#)
- [Nutrition Obesity Research Centers](#)
- [Small Business](#)
- [T32 Training](#)

The division oversees the following health education and awareness campaigns:

- [Celiac Disease Awareness Campaign](#)
- [Ways to Enhance Children's Activity and Nutrition \(We Can!\)](#)
- [Weight-control Information Network](#)
- [Bowel Control Awareness Campaign](#)

For more information about these initiatives, see “Health Information and Education Services.”

Website: <http://www.niddk.nih.gov/health-information/Pages/default.aspx>

How To Contact Us

Division of Digestive Diseases and Nutrition (DDN)

Building	U.S. Postal Address	UPS, Fedex, etc.	
2 Democracy Plaza	6707 Democracy Blvd., Rm. 654, MSC 5450 Bethesda, MD 20892-5450 (301) 594-2323	6707 Democracy Blvd., Rm. 601, Bethesda, MD 20817	
NIH Building 31	31 Center Dr., Rm. 9A27, MSC 2560, Bethesda, MD 20892-2560	31 Center Dr. Rm. 9A27, Bethesda, MD 20892	
Position	Name	Location	Phone No./Email
Director	Dr. Stephen James	2 Democracy Plaza, Rm. 677	(301) 594-7680 Jamess@extra.niddk.nih.gov
Deputy Director	Dr. Jay Hoofnagle	Building 31, Rm. 9A27	(301) 496-1333 hoofnaglej@extra.niddk.nih.gov
Program Analyst	Ms. Lauren Meskill	2 Democracy Plaza, Rm. 677	(301) 402-7503 meskillL@extra.niddk.nih.gov

Epidemiology and Clinical Trials Branch

Position	Name	Location	Phone No./Email
Clinical Trials Specialist	Ms. Rebekah Van Raaphorst	2 Democracy Plaza, Rm. 648	(301) 594-0056 vanraaphr@niddk.nih.gov

Digestive Diseases Branch

Position	Name	Location	Phone No./Email
Branch Chief; Director; Gastrointestinal Motility Program Director; Gastrointestinal Mucosa and Immunology Program Director; AIDS Program	Dr. Frank Hamilton	2 Democracy Plaza, Rm. 669	(301) 594-8877 hamiltonf@extra.niddk.nih.gov
Director; Pancreas Program	Dr. Jose Serrano	2 Democracy Plaza, Rm. 657	(301) 594-8871 serranoj@extra.niddk.nih.gov
Director; Gastrointestinal Transport and Absorption Program	Dr. Michael J. Grey	2 Democracy Plaza, Rm. 665	(301) 640-8877 greym@mail.nih.gov
Director; Digestive Diseases Centers Program; Director; Training and Career Development Program	Dr. Judith Podskalny	2 Democracy Plaza, Rm. 667	(301) 594-8876 podskalnyj@extra.niddk.nih.gov

Director; Genetics and Genomics in Digestive Diseases and Obesity Programs	Dr. Robert Karp	2 Democracy Plaza, Rm. 671	(301) 451-8875 karpr@extra.niddk.nih.gov
Director; SBIR/STTR Training Program	Ms. Christine Densmore	2 Democracy Plaza, Rm. 649	(301) 402-8714 DensmoreC@extra.niddk.nih.gov
Director; Gastrointestinal Development and Epithelial Biology and Inflammation Program; Director; Basic Neuro-gastroenterology	Dr. Jill Carrington	2 Democracy Plaza, Rm. 788A	(301) 402-0671 carringj@mail.nih.gov
Director; Special Projects in Nutrition, Obesity, and Digestive Diseases	Dr. Mary Evans	2 Democracy Plaza, Rm. 681	(301) 594-4578 evansmary@mail.nih.gov
Program Director, Gastrointestinal transport and Absorption	Dr. Michael J. Grey	2 Democracy Plaza, Rm. 665	(301) 640-0121 greymj@mail.nih.gov

Nutritional Sciences Branch

Position	Name	Location	Phone No./Email
Branch Chief; Director, Obesity and Eating Disorders Program	Dr. Susan Yanovski	2 Democracy Plaza, Rm. 675	(301) 594-8882 yanovskis@extra.niddk.nih.gov
U.S.-Japan Nutrition and Metabolism Panel	Dr. Robert Kuczmariski	2 Democracy Plaza, Rm. 673	(301) 451-8354 kuczmariskir@extra.niddk.nih.gov
Director; Training and Career Development Program	Dr. Judith Podskalny	2 Democracy Plaza, Rm. 667	(301) 594-8876 podskalnyj@extra.niddk.nih.gov
Director; Obesity Special Projects Program; Director; Look AHEAD Program	Dr. Mary Evans	2 Democracy Plaza, Rm. 681	(301) 594-4578 evansmary@mail.nih.gov
Director; Obesity Prevention and Treatment Program	Dr. Robert Kuczmariski	2 Democracy Plaza, Rm. 673	(301) 451-8354 KuczmariskiR@extra.niddk.nih.gov
Director; SBIR/STTR Training Program	Ms. Christine Densmore	2 Democracy Plaza, Rm. 649	(301) 402-8714 DensmoreC@extra.niddk.nih.gov
Director; Pediatric Clinical Obesity Program	Dr. Mary Horlick	2 Democracy Plaza, Rm. 679	(301) 594-4726 horlickm@niddk.nih.gov

Director, Special Projects in Nutrition, Obesity, and Digestive Diseases	Dr. Mary Evans	2 Democracy Plaza, Rm. 681	(301) 594-4578 evansmary@mail.nih.gov
Director, Nutrition and Clinical Obesity Program	Dr. Padma Maruvada	2 Democracy Plaza, Rm. 663	(301) 594-8884 padma_maruvada@nih.gov

Liver Diseases Research Branch

Position	Name	Location	Phone No./Email
Deputy Director	Dr. Jay H. Hoofnagle	Bldg 31, Rm. 9A27	(301) 496-1333 Hoofnaglej@extra.niddk.nih.gov
Program Director; Liver and Biliary Diseases Program	Dr. Jose Serrano	2 Democracy Plaza, Rm. 657	(301) 594-8871 Serranoj@extra.niddk.nih.gov
Director; Liver Diseases Research Program	Dr. Edward Doo	2 Democracy Plaza, Rm. 651	(301) 451-4524 dooe@niddk.nih.gov
Director; SBIR/STTR Training Program	Ms. Christine Densmore	2 Democracy Plaza, Rm. 649	(301) 402-8714 DensmoreC@extra.niddk.nih.gov
Position	Name	Location	Phone No./Email
Director; Training and Career Development Program	Dr. Judith Podskalny	2 Democracy Plaza, Rm. 667	(301) 594-8876 podskalnyj@extra.niddk.nih.gov
Scientific Advisor, Viral Hepatitis and Liver Diseases	Dr. Averell H. Sherker	2 Democracy Plaza, Rm. 642F	(301) 451-6207 averell.sherkerj@nih.gov

Overview of the Division of Kidney, Urologic, and Hematologic Diseases

The Division of Kidney, Urologic, and Hematologic (KUH) Diseases provides research funding and support for basic, translational, and clinical research studies of the kidney, urinary tract, and disorders of the blood and blood-forming organs. The division also provides funding for training and career development of people committed to academic and clinical research in these areas.

Kidney Diseases Research Programs

The division encompasses research programs related to kidney research, including

- [Acute Kidney Injury](#)
- [Chronic Kidney Disease](#)
- [Diabetic Kidney Disease](#)
- [End-Stage Renal Disease](#)
- [Genetic Metabolic Disease](#)
- [Kidney Basic Research](#)
- [Kidney Bioengineering, Biotechnology, and Imaging](#)
- [Kidney Clinical Research and Epidemiology](#)
- [Kidney Developmental Biology and Aging](#)
- [Kidney Disease Centers](#)
- [Kidney Genetics and Genomics](#)
- [Kidney HIV/AIDS](#)
- [Kidney Inflammation and Inflammatory Diseases](#)
- [Pediatric Kidney Disease](#)
- [Polycystic Kidney Disease](#)

Urological Diseases Research Programs

The division encompasses research programs related to urology research, including

- [Diabetic Urologic Disease](#)
- [Genetic Metabolic Disease](#)
- [Pediatric Urology](#)
- [Urologic Disease Centers](#)
- [Urology Basic Research](#)
- [Urology Bioengineering, Biotechnology, and Imaging](#)
- [Urology Clinical Research and Epidemiology](#)
- [Urology Developmental Biology and Aging](#)
- [Urology Genetics and Genomics](#)
- [Urology HIV/AIDS](#)
- [Women's Urology](#)

Hematology Research Programs

The division encompasses research programs related to hematology research, including the

- [Erythropoiesis and Hemoglobin](#)
- [Genetic Metabolic Disease](#)
- [Hematology HIV/AIDS](#)
- [Hematopoiesis and Hematopoietic Stem Cell Biology](#)
- [Iron and Heme Metabolism, Iron Chelation](#)
- [Molecular Hematology Centers](#)

The division oversees the following health education and awareness campaigns:

- [Bladder Control for Women](#)
- [National Kidney Disease Education Program](#)

For more information about these initiatives, see “Health Information and Education Services.”

Website: <http://www.niddk.nih.gov/health-information/Pages/default.aspx>

How To Contact Us

Division of Kidney, Urologic, and Hematologic Diseases

Building	U.S. Postal Address		UPS, Fedex, etc.
2 Democracy Plaza	6707 Democracy Blvd., Rm. 654, MSC 5458, Bethesda, MD 20892-5458		6707 Democracy Blvd., Rm. 601, Bethesda, MD 20817
NIH Building 31	31 Center Dr., Rm. 9A-17, MSC 2510, Bethesda, MD 20892-2510		31 Center Dr., Rm. 9A-17, Bethesda, MD 20892
Position	Name	Location	Phone No./Email
Director, KUH	Dr. Robert Star	Bldg 31, Rm 9A-19 and 2 Democracy Plaza, Rm. 625	(301) 496-6325 starr@extra.niddk.nih.gov
Deputy Director, KUH Basic Science, Program Director, Kidney Basic Physiology	Dr. Chris J. Ketchum	2 Democracy Plaza, Rm. 647	(301) 594-7717 KetchumC@extra.niddk.nih.gov
Deputy Director, KUH Clinical Science, Program Director, Pediatric Nephrology and Urology; Kidney Centers; Kidney Small Business	Dr. Marva Moxey-Mims	2 Democracy Plaza, Rm. 639	(301) 594-7717 mm726k@nih.gov
Position	Name	Location	Phone No./Email
Director; Office of	Dr. Lawrence Agodoa	2 Democracy	(301) 594-7717

Minority Health Research Coordination		Plaza, Rm. 611 and Rm. 653	agodoal@mail.nih.gov
Program Director, Women's Urologic Health	Dr. Tamara Bavendam	2 Democracy Plaza, Rm. 615	(301) 594-7717 and (301) 594-4733 Tamara.bavendam@nih.gov
Program Director, Hematology Basic Research; Hematology Centers; Hematology Training and Careers	Dr. Terry Rogers Bishop	2 Democracy Plaza, Rm. 619	(301) 594-7717 bishopt@extra.niddk.nih.gov
Program Director, Clinical Chronic Kidney Disease; Inflammatory Kidney Disease; Clinical PKD; PKD Centers	Dr. Michael Flessner	2 Democracy Plaza, Rm. 641	(301) 594-7717 flessnermf@mail.nih.gov
Program Director, Kidney and Urogenital Development; Kidney and Urology Regeneration and Repair; Urology Centers	Dr. Deborah Hoshizaki	2 Democracy Plaza, Rm. 645	(301) 594-7712 hoshizakid@niddk.nih.gov
Program Director, Clinical Acute Kidney Injury; Kidney Translational Genetics; Kidney HIV/AIDS	Dr. Paul Kimmel	2 Democracy Plaza, Rm. 612	(301) 594-7717 KimmelP@extra.niddk.nih.gov
Program Director, Clinical and Translational Research in Urologic Diseases	Dr. Ziya Kirkali	2 Democracy Plaza, Rm. 627	(301) 594-7717 KirkaliZ@niddk.nih.gov
Program Director, Kidney and Urology Trials	Dr. John Kusek	2 Democracy Plaza, Rm. 617	(301) 594-7717 kusekj@extra.niddk.nih.gov
Position	Name	Location	Phone No./Email
Program Director, Urology Basic Cell Biology; Urology Small Business	Dr. Christopher Mullins	2 Democracy Plaza, Rm. 637	(301) 594-7717 mullinsc@extra.niddk.nih.gov
Director, National Kidney Disease Education Program;	Dr. Andrew Narva	2 Democracy Plaza, Rm. 645	(301) 594-8864 narvaa@extra.niddk.nih.gov

Program Director, Kidney Education and Translation			
Program Director, Kidney and Urology Training and Career Development; Diabetic Uropathy; Erectile Dysfunction; Urology Molecular Endocrinology; Urology HIV/AIDS	Dr. Tracy Rankin	2 Democracy Plaza, Rm. 623	(301) 594-7717 rankint@mail.nih.gov
Program Director, Genetics and Genomics; Basic PKD	Dr. Rebekah Rasooly	2 Democracy Plaza, Rm. 643	(301) 594-7717 Rasoolyr@extra.niddk.nih.gov
Program Director, Basic Acute Kidney Injury; Basic Chronic Kidney Disease	Dr. Krystyna Rys-Sikora	2 Democracy Plaza, Rm. 612	(301) 594-7717 ryssikok@mail.nih.gov
Clinical Trials Specialist	Yining Xie	2 Democracy Plaza, Rm.	(301) 594-7713 xieyi@mail.nih.gov

Overview of the Division of Nutrition Research Coordination

The Division of Nutrition Research Coordination (DNRC) advises the National Institutes of Health (NIH) Director and others on nutrition research issues and works with the NIH organizational components to coordinate nutrition research and research training initiatives. Since the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) is the lead institute for nutrition research at NIH, this NIH-wide division is located within NIDDK.

DNRC also represents NIH and provides liaison at DHHS and interagency level on various committees on nutrition research and policy issues such as the Interagency Committee on Human Nutrition Research and Nutrition Policy Board. Located within the DNRC is the NIH Nutrition Coordinating Committee (NCC) which operates as an NIH-wide forum to review, stimulate, and encourage the support of nutrition research and training to better define the role of nutrition in the promotion and maintenance of health and in the prevention and treatment of disease. The NCC also plays a key role in the development of nutrition research policy at the NIH. Further, the DNRC maintains the Human Nutrition Research Information Management (HNRIM) system. HNRIM is a searchable database of nutrition research and research training activities supported by the federal government. Data for the system is prepared and submitted by participating agencies, and is updated annually.

Website: <http://dnrc.nih.gov/>

How To Contact Us

Division of Nutrition Research Coordination (DNRC)

Building	U.S. Postal Address		UPS, Fedex, etc.
2 Democracy Plaza	6707 Democracy Blvd., Rm. 679, MSC 5461, Bethesda, MD 20892-5450		6707 Democracy Blvd., Rm. 679, Bethesda, MD 20817 (301) 594-8822
Position	Name	Location	Phone No./Email
Director	Dr. Van S. Hubbard	2 Democracy Plaza, Rm. 631 DNRC	(301) 594-8883 and 594-8827 Van_Hubbard@nih.gov
Deputy Director	Dr. Pamela Starke-Reed	2 Democracy Plaza, Rm. 633 DNRC	(301) 594-8805 Pamela_Stark-Reed@nih.gov
Program Analyst	Dannielle Brown	2 Democracy Plaza, Rm.624A DNRC	(301) 594- 8821 Dannielle.brown@nih.gov
Nutrition Program Analyst	Rachel Fisher	2 Democracy Plaza, Rm. 628 DNRC	(301) 594-7722 fisherrachel@mail.nih.gov

Senior Public Health and Science Policy Advisor	Sheila Fleischhacker	2 Democracy Plaza, Rm. 635 DNRC	(301) 594-7440 Sheila.fleischhacker@nih.gov
Position	Name	Location	Phone No./Email
Program Director	Jim Krebs-Smith	2 Democracy Plaza, Rm. 626 DNRC	(301) 594-8823 James_Krebs-Smith@nih.gov
Health Program Specialist	Crystal McDade-Ngutter	2 Democracy Plaza, Rm. 636 DNRC	(301) 451-2064 mcdade-ngutterc@mail.nih.gov
Nutrition Researcher	Margaret McDowell	2 Democracy Plaza, Rm. 629 DNRC	(301) 594-8824 mcdowellma@mail.nih.gov
Nutritionist	Karen S. Regan	2 Democracy Plaza, Rm. 640 DNRC	(301)-435-6199 Karen_Regan@nih.gov
Secretary	Sharon Frazier	2 Democracy Plaza, Rm. 624C DNRC	(301) 594-8822 fraziers@nidk.nih.gov

Funding Mechanisms (Activity Codes) Supported by NIDDK

Brief Overview

An Activity Code is a three-digit code assigned by the National Institutes of Health (NIH) to identify funding mechanisms (e.g. F32, K12, P01, R01, T32, etc.). General categories include:

- F – [fellowships](#)
- K – [career development awards](#)
- N – research contracts
- P – [program project and research center grants](#)
- R – [research project grants](#)
- S – [research-related programs](#)
- T – [training grants](#)
- U – [cooperative agreements](#)
- Y – interagency agreements

Extramural research activities are divided into three main mechanisms: grants, cooperative agreements, and contracts. A mechanism is the type of funding instrument used at the NIH. In general, with grants (all activity codes other than “N” or “U”), investigators are responsible for developing the concepts, methods, and approach for a research project. With contracts (“N” series), the DHHS awarding unit is responsible for establishing the detailed requirements. With cooperative agreements (“U” series), both the awarding unit and the recipient have substantial responsibility. Programs are areas within the funding mechanisms (for example, research, training, fellowships, and cooperative agreements). Activity codes identify categories applied to various mechanisms.

For NIH-wide activity codes and definitions beyond the NIDDK codes listed below, go to [Types of Grant Programs](#) page (http://grants.nih.gov/grants/funding/funding_program.htm) to search activity codes or to the [comprehensive list of extramural grant and cooperative agreement activity codes](#) for more information on selected grant programs.

Special NIH-Wide Programs

DP1 NIH Director’s Pioneer Award (NDPA) (Roadmap program)

To support individuals who have the potential to make extraordinary contributions to medical research. The NDPA is not renewable.

DP2 NIH Director’s New Innovator Awards (Roadmap program)

To support highly innovative research projects by new investigators in all areas of biomedical and behavioral research.

DP3 Type 1 Diabetes Targeted Research Award

To support research tackling major challenges in type 1 diabetes and promoting new approaches to these challenges by scientific teams.

Fellowship Programs**F 31 Predoctoral Individual National Research Service Award**

To provide predoctoral individuals with supervised research training in specified health and health-related areas leading toward the research degree (e.g., Ph.D.).

F 32 Postdoctoral Individual National Research Service Award

To provide postdoctoral research training to individuals to broaden their scientific background and extend their potential for research in specified health-related areas.

F 33 National Research Service Awards for Senior Fellows

To provide opportunities for experienced scientists to make major changes in the direction of research careers, to broaden scientific background, to acquire new research capabilities, to enlarge command of an allied research field, or to take time from regular professional responsibilities for the purpose of increasing capabilities to engage in health-related research.

Research Career Programs**K 01 Research Scientist Development Award - Research & Training**

For support of a scientist, committed to research, in need of both advanced research training and additional experience.

K 08 Clinical Investigator Award (CIA)

To provide the opportunity for promising medical scientists with demonstrated aptitude to develop into independent investigators, or for faculty members to pursue research aspects of categorical areas applicable to the awarding unit, and aid in filling the academic faculty gap in these shortage areas within health profession's institutions of the country.

K 12 Physician Scientist Award (Program) (PSA)

For support to a newly trained clinician appointed by an institution for development of independent research skills and experience in a fundamental science within the framework of an interdisciplinary research and development program.

K 18 The Career Enhancement Award

To provide either full-time or part-time support for experienced scientists who wish to broaden their scientific capabilities or to make changes in their research careers by acquiring new research skills or knowledge. Career enhancement experiences supported by this award should usually last no more than one year.

K 22 Career Transition Award

To provide support to outstanding newly trained basic or clinical investigators to develop their independent research skills through a two phase program; an initial period involving and intramural appointment at the NIH and a final period of support at an extramural institution. The award is intended to facilitate the establishment of a record of independent research by the investigator in order to sustain or promote a successful research career.

K 23 Mentored Patient-Oriented Research Career Development Award

To provide support for the career development of investigators who have made a commitment of focus their research endeavors on patient-oriented research. This mechanism provides support for a 3 year minimum up to 5 year period of supervised study and research for clinically trained professionals who have the potential to develop into productive, clinical investigators.

K 24 Midcareer Investigator Award in Patient-Oriented Research

To provide support for the clinicians to allow them protected time to devote to patient-oriented research and to act as mentors for beginning clinical investigators.

K 25 Mentored Quantitative Research Career Development Award

To engender and foster such activities by supporting the career development of investigators with quantitative scientific and engineering backgrounds outside of biology or medicine who have made a commitment to focus their research endeavors on behavioral and biomedical research (basic or clinical). This mechanism is aimed at research-oriented scientists with experience at the level of junior faculty (e.g., early to mid-levels of assistant professor or research assistant professor ranks). This award provides support for a period of mentored study and research for professionals with such backgrounds who have the potential to integrate their expertise with biomedicine and develop into productive investigators.

Examples of quantitative scientific and technical backgrounds outside of biology or medicine considered appropriate for this award include, but are not limited to: mathematics, statistics, computer science, informatics, physics, chemistry, and engineering.

K 30 Clinical Research Curriculum Award (CRCA)

The CRCA is an award to institutions and is intended to stimulate the inclusion of high-quality, multi-disciplinary didactic training as part of the career development of clinical investigators. This award is intended to support the development of new didactic programs in clinical research at institutions that do not currently offer such programs or, in institutions with existing didactic programs in clinical research to support or expand their programs or to improve the quality of instruction.

K 99 NIH Pathway to Independence Award (PI)

R 00 To provide an opportunity for promising postdoctoral scientists to receive both mentored and independent research support from the same award. The primary purpose of the Pathway to Independence Award (K99/R00) program is to increase and maintain a strong cohort of new and talented NIH-supported independent investigators. The initial phase (K99 Career Transition Award) provides 1-2 years of mentored support for highly motivated, advanced postdoctoral research scientists. The second phase (R00 Research Transition Award) provides 1-3 years of independent research support contingent on securing an independent research position. Award recipients will be expected to compete successfully for independent R01 support from the NIH during the R00 research transition award period.

KM1 Institutional Career Enhancement Awards - Multi-Yr Funding

Provides for part-time (minimum 25% effort) up to full-time support for medical, scientific, statistics and health care professionals with post-doctoral or equivalent experience selected by an institution, to broaden their research capabilities by acquiring new research skills or knowledge. Further it provides for curriculum development of new programs to support these same types of individuals. This is an institutional mentored career program, not an individual program. It is also a multi-year funded institutional mentored career development activity thus ICs need OER prior approval to use the KM1.

Extramural Loan Repayment Program

L 30 Loan Repayment Program for Clinical Researchers

To provide for the repayment of the educational loan debt of qualified health professionals involved in clinical research. Qualified health professionals who contractually agree to conduct qualified clinical research are eligible to apply for this program.

L 40 Loan Repayment Program for Pediatric Research

To provide for the repayment of the educational loan debt of qualified health professionals involved in research directly related to diseases, disorders, and other conditions in children.

Qualified health professionals who contractually agree to conduct qualified pediatric research are eligible to apply for this program.

Research and Development-Related Contracts

N 01 Research and Development Contracts

To develop and/or apply new knowledge or to test, screen, or evaluate a product, material, device, or component for use by the scientific community.

N 02 Resource and Support Contracts - Awarded in the ICD

To support intramural and extramural station support needs. This activity also includes the provision of resources to intramural research programs.

N 41 Small Business Technology Transfer (STTR) Contracts - Phase I

To support cooperative R&D projects between small business concerns and research institutions, limited in time and amount, to establish the technical merit and feasibility of ideas that have potential for commercialization. Awards are made to small business concerns only.

N 42 Small Business Technology Transfer (STTR) Contracts - Phase II

To support in-depth development of cooperative R&D projects between small business concerns and research institutions, limited in time and amount, whose feasibility has been established in Phase I and that have potential for commercialization. Awards are made to small business concerns only.

N 43 Small Business Innovation Research (SBIR) Contracts- Phase I

To support project, limited in time and amount, to establish the technical merit and feasibility of R&D ideas which may ultimately lead to a commercial product(s) or service(s). These contracts may be made only with small businesses.

N 44 Small Business Innovation Research (SBIR) Contracts - Phase II

To support in-depth development of R&D ideas whose feasibility has been established in Phase I and which are likely to result in commercial products or services. These contracts may be made only to small businesses.

Research Program Projects and Centers

P 01 Research Program Projects

For the support of a broadly based, multidisciplinary, often long-term research program which has a specific major objective or a basic theme. A program project generally involves the

organized efforts of relatively large groups, members of which are conducting research projects designed to elucidate the various aspects or components of this objective. Each research project is usually under the leadership of an established investigator. The grant can provide support for certain basic resources used by these groups in the program, including clinical components, the sharing of which facilitates the total research effort. A program project is directed toward a range of problems having a central research focus, in contrast to the usually narrower thrust of the traditional research project. Each project supported through this mechanism should contribute or be directly related to the common theme of the total research effort. These scientifically meritorious projects should demonstrate an essential element of unity and interdependence, i.e., a system of research activities and projects directed toward a well-defined research program goal.

P 20 Exploratory Grants

To support planning for new programs, expansion or modification of existing resources, and feasibility studies to explore various approaches to the development of interdisciplinary programs that offer potential solutions to problems of special significance to the mission of the NIH. These exploratory studies may lead to specialized or comprehensive centers.

P 30 Center Core Grants

To support shared resources and facilities for categorical research by a number of investigators from different disciplines who provide a multidisciplinary approach to a joint research effort or from the same discipline who focus on a common research problem. The core grant is integrated with the center's component projects or program projects, though funded independently from them. This support, by providing more accessible resources, is expected to assure a greater productivity than from the separate projects and program projects.

P 50 Specialized Center

To support any part of the full range of research and development from very basic to clinical; may involve ancillary supportive activities such as protracted patient care necessary to the primary research or R&D effort. The spectrum of activities comprises a multidisciplinary attack on a specific disease entity or biomedical problem area. These grants differ from program project grants in that they are usually developed in response to an announcement of the programmatic needs of an Institute or Division and subsequently receive continuous attention from its staff. Centers may also serve as regional or national resources for special research purposes.

P 60 Comprehensive Center

To support a multipurpose unit designed to bring together into a common focus divergent but related facilities within a given community. It may be based in a university or may involve other locally available resources, such as hospitals, computer facilities, regional centers, and primate colonies. It may include specialized centers, program projects and projects as integral components. Regardless of the facilities available to a program, it usually includes the following objectives: to foster biomedical research and development at both the fundamental and clinical levels; to initiate and expand community education, screening, and counseling programs; and to educate medical and allied health professionals concerning the problems of diagnosis and treatment of a specific disease.

Research Projects

R 01 **Research Project**

To support a discrete, specified, circumscribed project to be performed by the named investigator(s) in an area representing his specific interest and competencies.

R 03 **Small Research Grants**

To provide research support specifically limited in time and amount for studies in categorical program areas. Small grants provide flexibility for initiating studies which are generally for preliminary short-term projects and are non-renewable.

R 13 **Conference**

To support recipient sponsored and directed international, national or regional meetings, conferences and workshops.

R 15 **Academic Research Enhancement Awards (AREA)**

To support small scale research projects conducted by faculty in primarily baccalaureate degree-granting domestic institutions. Awards are for up to \$75,000 for direct costs (plus applicable indirect costs) for periods not to exceed 36 months.

R 18 **Research Demonstration and Dissemination Projects**

To provide support designed to develop, test, and evaluate health service activities, and to foster the application of existing knowledge for the control of categorical diseases.

R 21 **Exploratory/Developmental Grants**

To encourage the development of new research activities in categorical program areas. (Support generally is restricted in level of support and in time.)

R 24 **Resource-Related Research Projects**

To support research projects that will enhance the capability of resources to serve biomedical research.

R 25 **Education Projects**

For support to develop and/or implement a program as it relates to a category in one or more of the areas of education, information, training, technical assistance, coordination, or evaluation.

R 33 **Exploratory/Developmental Grants Phase II**

The R33 award is to provide a second phase for the support for innovative exploratory and development research activities initiated under the R21 mechanism. Although only R21 awardees are generally eligible to apply for R33 support, specific program initiatives may establish eligibility criteria under which applications could be accepted from applicants demonstrating progress equivalent to that expected under R33.

R 34 **Clinical Trial Planning Grant**

To provide support for the initial development of a clinical trial, including the establishment of the research team; the development of tools for data management and oversight of the research; the development of a trial design and other essential elements of the study, such as the protocol, recruitment strategies, and procedure manuals; and to collect feasibility data.

R 37 Method to Extend Research in Time (MERIT) Award

To provide long-term grant support to investigators whose research competence and productivity are distinctly superior and who are highly likely to continue to perform in an outstanding manner. Investigators may not apply for a MERIT award. Program staff and/or members of the cognizant National Advisory Council/Board will identify candidates for the MERIT award during the course of review of competing research grant applications prepared and submitted in accordance with regular PHS requirements.

R 41 Small Business Technology Transfer (STTR) Grants - Phase I

To support cooperative R&D projects between small business concerns and research institutions, limited in time and amount, to establish the technical merit and feasibility of ideas that have potential for commercialization. Awards are made to small business concerns only.

R 42 Small Business Technology Transfer (STTR) Grants - Phase II

To support in-depth development of cooperative R&D projects between small business concerns and research institutions, limited in time and amount, whose feasibility has been established in Phase I and that have potential for commercialization. Awards are made to small business concerns only.

R 43 Small Business Innovation Research (SBIR) Grants - Phase I

To support projects, limited in time and amount, to establish the technical merit and feasibility of R&D ideas which may ultimately lead to a commercial product(s) or service(s).

R 44 Small Business Innovation Research (SBIR) Grants - Phase II

To support in-depth development of R&D ideas whose feasibility has been established in Phase I and which are likely to result in commercial products or services. SBIR Phase II are considered "Fast-Track" and do not require National Council Review.

R 56 High Priority, Short Term Project Award

To provide limited interim research support based on the merit of a pending R01 application while applicant gathers additional data to revise a new or competing renewal application. This grant will underwrite highly meritorious applications that if given the opportunity to revise their application could meet IC recommended standards and would be missed opportunities if not funded. Interim funded ends when the applicant succeeds in obtaining an R01 or other competing award built on the R56 grant. These awards are not renewable.

RC1 NIH Challenge Grants and Partnerships Program

As part of the American Recovery and Reinvestment Act of 2009 (Recovery Act), NIH designated at least \$200 million in FYs 2009 - 2010 for this new initiative to fund 200 or more grants, contingent upon the submission of a sufficient number of scientifically meritorious applications. The new program will support research that addresses specific scientific and health research challenges in biomedical and behavioral research that will benefit from significant 2-year jumpstart funds. In addition, Recovery Act funds allocated to NIH specifically for comparative effectiveness research (CER) may be available to support additional grants.

RC2 High Impact Research and Research Infrastructure Programs

To support high impact ideas that may lay the foundation for new fields of investigation; accelerate breakthroughs; stimulate early and applied research on cutting-edge technologies; foster new approaches to improve the interactions among multi- and interdisciplinary research teams; or, advance the research enterprise in a way that could stimulate future growth and investments and advance public health and health care delivery. This activity code could

support either a specific research question or propose the creation of a unique infrastructure/resource designed to accelerate scientific progress in the future.

RC3 Biomedical Research, Development, and Growth to Spur the Acceleration of New Technologies (BRDG-SPAN) Program

To accelerate the transition of NIH-supported research innovations and technologies toward the development of products or services that will improve human health, through grants that may advance the mission of NIH and its Institutes and Centers (ICs), and create significant value and economic stimulus or, advance the research enterprise in a way that could stimulate future growth and investments and advance public health and health care delivery. This activity code is intended to support research and development (R&D) specifically targeted at activities that can help address the funding gap between promising R&D and transitioning to the market, often called the “Valley of Death” by contributing the critical funding needed by applicants to pursue the next appropriate milestone(s) toward ultimate commercialization; i.e., to carry out later stage research activities necessary to that end; to foster partnerships among a variety of research and development (R&D) collaborators working toward these aims. Awards are made only to U.S.-owned, for-profit enterprises doing a majority of its business in the United States. RC3 applications may be given funding priority if the applicant organization is associated with an enterprise that is of small size (e.g., 500 or fewer employees), and/or of limited resources, such as an early-stage company, and/or one positioned for receiving funding or in-kind support from a third-party investor and/or strategic partner. The RC3 SPAN program is not intended to support “upstream” R&D for doing feasibility testing of an innovative idea or to conduct early-stage R&D as an extension of such ideas. (Projects such as these should be submitted under the NIH SBIR/STTR programs.)

RC4 High Impact Research and Research Infrastructure Programs—Multi-Yr Funding

To support multi-year funded research with high impact ideas that may lay the foundation for new fields of investigation; accelerate breakthroughs; stimulate early and applied research on cutting-edge technologies; foster new approaches to improve the interactions among multi- and interdisciplinary research teams; or, advance the research enterprise in a way that could stimulate future growth and investments and advance public health and health care delivery. This activity code could support either a specific research question or propose the creation of a unique infrastructure/resource designed to accelerate scientific progress in the future. It is the multi-year funded companion activity code to the existing RC2; thus ICs need OER prior approval to use the RC4.

Research-Related Programs

S 06 Minority Biomedical Research Support - MBRS

To strengthen the biomedical research and research training capability of ethnic minority institutions, and thus establish a more favorable milieu for increasing the involvement of minority faculty and students in biomedical research.

SC 1 Research Enhancement Award

Individual investigator-initiated research projects aimed at developing researchers at minority-serving institutions (MSIs) to a stage where they can transition successfully to other s extramural support (R01 or equivalent).

SC 2 Pilot Research Project

Individual investigator-initiated pilot research projects for faculty at MSIs to generate preliminary data for a more ambitious research project.

SC 3 Research Continuance Award

Individual investigator-initiated research projects for faculty at MSIs to conduct research of limited scope in environments with limited research infrastructure/facilities.

Training Programs**T 32 Institutional National Research Service Award**

To enable institutions to make National Research Service Awards to individuals selected by them for predoctoral and postdoctoral research training in specified shortage areas.

T 35 NRSA Short-Term Research Training

To provide individuals with research training during off-quarters or summer periods to encourage research careers and/or research in areas of national need.

T90 Interdisciplinary Research Training Award

To support comprehensive interdisciplinary research training programs at the undergraduate, predoctoral and/or postdoctoral levels, by capitalizing on the infrastructure of existing multidisciplinary and interdisciplinary research programs.

Cooperative Agreements

Note: For all funding mechanisms within this section, substantial Federal programmatic staff involvement is intended to assist investigators during performance of the research activities, as defined in the terms and conditions of award.

U 01 Research Project--Cooperative Agreements

To support a discrete, specified, circumscribed project to be performed by the named investigator(s) in an area representing his specific interest and competencies.

U 10 Cooperative Clinical Research--Cooperative Agreements

To support clinical evaluation of various methods of therapy and/or prevention in specific disease areas. These represent cooperative programs between sponsoring institutions and participating principal investigators, and are usually conducted under established protocols.

U 13 Conference--Cooperative Agreements

To support international, national or regional meetings, conferences and workshops where substantial programmatic involvement is planned to assist the recipient.

U 19 Research Program--Cooperative Agreements

To support a research program of multiple projects directed toward a specific major objective, basic theme or program goal, requiring a broadly based, multidisciplinary and often long-term approach. This generally involves the organized efforts of large groups, members of which are conducting research projects designed to elucidate the various aspects of a specific objective. Each project supported through this mechanism should contribute to or be directly related to the common theme of the total research effort. The award can provide support for certain basic shared resources, including clinical components, which facilitate the total research effort. These scientifically meritorious projects should demonstrate an essential element of unity and interdependence.

U 24 Resource-Related Research Projects--Cooperative Agreements

To support research projects contributing to improvement of the capability of resources to serve biomedical research.

U-32 State-Based Diabetes Control Programs

Programs in cooperation with State health agencies: To reduce the effect of preventable problems in service delivery to diabetics (such as excess days of hospitalization, high amputation rates, and the effect of insurance policy on securing care), to define the preventable service delivery problems, and to demonstrate improved service delivery to diabetics.

U 34 Multi-Center Clinical Study Implementation Planning Grants

Clinical Planning Grant Cooperative Agreement—To provide support, substantial Federal programmatic involvement, and technical assistance for the initial development of a clinical trial. Also, it would include the establishment of the research team; the development of tools for data management and oversight of the research; the development of a trial design and other essential elements of the study, such as the protocol, recruitment strategies, and procedure manuals; and to collect feasibility data.

UC4 High-Impact Research and Research Infrastructure Cooperative Agreements

To support multi-year funded cooperative agreement research with high impact ideas that may lay the foundation for new fields of investigation; accelerate breakthroughs; stimulate early and applied research on cutting-edge technologies; foster new approaches to improve the interactions among multi- and interdisciplinary research teams; or, advance the research enterprise in a way that could stimulate future growth and investments and advance public health and health care delivery. This activity code could support either a specific research question or propose the creation of a unique infrastructure/resource designed to accelerate scientific progress in the future. It is the cooperative agreement companion to the RCA. It is also the multi-year funded companion to the existing UC2; thus ICs need OER prior approval to use the UC 4.

UH3 Exploratory/Developmental Cooperative Agreement Phase II

To provide a second phase for the support for innovative exploratory and development research activities initiated under the UH2 mechanism. Although only UH2 awardees are generally eligible to apply for UH3 support, specific program initiatives may establish eligibility criteria under which applications could be accepted from applicants demonstrating progress equivalent to that expected under UH2.

UM- Multi-Component Research Project Cooperative Agreements

To support large-scale cooperative agreements involving complex clinical trials with multiple components (e.g., clinical networks). The components represent a variety of supporting functions and are not independent of the research projects. Substantial Federal programmatic staff involvement is intended to assist investigators during performance of the research activities, as defined in the terms and conditions of award. The performance period may extend up to 7 years but only through the established deviation request process. ICs desiring to use this activity code for programs greater than 5 years must receive OPERA prior approval through the deviation request process.

X01 Resource Access Program

To invite eligible institutions to seek access to NIH research resources. This includes programs where institutions will request access to submit to the resource, e.g., high throughput screening assays. It also includes programs where access to a specific NIH research resource is needed to conduct certain research.

NIH Operates Under a Continuing Resolution

Notice Number:

NOT-OD-15-001

Key Dates

Release Date: October 1, 2014

Related Announcements

[NOT-OD-14-055](#)

Issued by

National Institutes of Health ([NIH](#))

Purpose

The Department of Health and Human Services (HHS), including NIH, operates under the Continuing Appropriations Act, 2015 ([H.J.Res. 124](#)) signed by President Obama on September 19, 2014. This Act (CR) continues government operations through December 11, 2014 at 99.9 percent of the FY 2014 enacted level.

Continuing the procedures identified under [NOT-OD-14-055](#) and consistent with NIH practices during the CRs of [FY 2006 – 2014](#), the NIH will issue non-competing research grant awards at a level below that indicated on the most recent Notice of Award (generally up to 90% of the previously committed level). Upward adjustments to awarded levels will be considered after FY 2015 appropriations are enacted, but NIH expects institutions to monitor their expenditures carefully during this period. All legislative mandates that were in effect in FY 2014 (see [NOT-OD-14-053](#) and [NOT-OD-14-046](#)) remain in effect under this CR including the salary limitation set at Executive Level II of the Federal Pay Scale as described in [NOT-OD-14-052](#).

Inquiries

Questions regarding adjustments applied to individual grant awards may be directed to the Grants Management Specialist identified on the Notice of Award.

NIH Fiscal Policy for Grant Awards – FY 2014 [example]

Notice Number: NOT-OD-14-055

Key Dates

Release Date: February 10, 2014

Related Announcements

[NOT-OD-15-001](#)

[NOT-OD-14-043](#)

Issued by

National Institutes of Health ([NIH](#))

Purpose

This Notice provides guidance about the NIH Fiscal Operations for FY 2014 and implements the [Consolidated Appropriations Act, 2014](#) (H.R. 3547/Public Law 113-76), signed by President Obama on January 17, 2014. The Act provides NIH with \$30.15 billion, an increase of \$1 billion (program level) over FY 2013. The NIH will continue to manage its portfolio in biomedical research investments in a manner that includes recognizing applications from and providing special incentives for new investigators.

The following NIH fiscal policies are instituted in FY 2014:

FY 2014 Funding Levels: Non-competing continuation awards that have already been made in FY 2014 were generally funded at levels below that indicated on the most recent Notice of Award (generally up to 90% of the previously committed level) as described in [NOT-OD-14-012](#), and in [NOT-OD-14-043](#). Such reductions may be fully or partially restored, depending on the Institute or Center. Non-competing continuation grants (research and non-research) including those that remain to be issued in FY 2014 likely will be made within the range between the commitment level indicated on the Notice of Award and 3 percent below that level. Out-year commitments for continuation awards in FY 2015 and beyond will remain unchanged. The number of competing awards will likely exceed the number of competing awards in FY 2013. The NIH awarding Institutes/Centers (IC) will develop and post their fiscal policies consistent with overall NIH goals and available FY 2014 funds.

Ruth L. Kirschstein National Research Service Awards (NRSA): Consistent with the [Consolidated Appropriations Act, 2014](#), and with the recommendations of the [Advisory Committee to the Director](#) regarding the [Biomedical Research Workforce](#), the NIH will increase undergraduate and graduate student stipends by

2 percent. Entry level postdoctoral stipends will be increased to \$42,000 with 4 percent increases between the individual levels of experience. The full range of stipend adjustments for FY 2014 is described at [NOT-OD-14-046](#).

New Investigators: NIH will continue to support new investigators on R01 equivalent awards at success rates comparable to that of established investigators submitting new (Type 1) R01 equivalent applications. Achievement of comparable success rates should permit the NIH to support new investigators in accordance with the policies established in FY 2009 and subsequent years as described at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-013.html> and at http://grants.nih.gov/grants/new_investigators/index.htm.

Salary Limits: Section 203 of the [Consolidated Appropriations Act 2014](#) prohibits payments for salaries under grants and other extramural mechanisms in excess of Executive Level II. It should be noted, that Executive Level II was increased by 1 percent from \$179,700 to \$181,500 by [Executive Order 13655](#) that became effective January 12, 2014. See [NOT-OD-14-052](#) for additional information.

Other Legislative Mandates: Other statutory requirements are described in [NOT-OD-14-053](#).

Additional Information: Additional details on Fiscal Operations, including specific funding strategies for ICs will be posted at <http://grants.nih.gov/grants/financial/index.htm>.

Inquiries

Questions about specific awards may be directed to the Grants Management Specialist identified in the Notice of Award.

2015 Award Funding Policy

The Department of Health and Human Services (HHS), including NIH is presently operating under a Continuing Resolution that continues government operations through December 11, 2014.

- Until FY 2015 appropriations are enacted, NIH will issue non-competing research grant awards at a level below that indicated on the most recent Notice of Award (generally up to 90% of the previously committed level). See [NOT-OD-15-001](#) for details.
- NIDDK will announce additional details regarding its interim FY 2015 funding policy, including details regarding funding of competing grant applications, once an NIH-wide policy has been announced.

2014 Award Funding Policy [example]

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) conducts and supports basic and clinical research on many of the most serious diseases affecting public health.

NIDDK extramural research is organized into 3 programmatic divisions:

1. Diabetes, Endocrinology, and Metabolic Diseases;
2. Digestive Diseases and Nutrition; and
3. Kidney, Urologic, and Hematologic Diseases.

The Institute supports basic and clinical research through investigator-initiated grants, program project and center grants, cooperative agreements, career development and training awards, and contracts.

Budget Data

Current Appropriation

NIH is operating at a program level of \$30.15 billion in FY 2014, an increase of \$1 billion (+3.46%) over fiscal year (FY) 2013.

NIDDK's discretionary appropriation for FY 2014 is \$1.744 billion. This is an increase of about 3.01% from NIDDK's appropriation in FY 2013. This figure does not include the FY 2014 Special Statutory Funding Program for Type 1 Diabetes Research appropriation of \$139.2 M (-2.21% from FY 2013) that NIDDK oversees on behalf of NIH.

Funding Strategy

NIDDK is committed to supporting as many meritorious competing research grant applications as possible. Consistent with NIH policy (see NIH Guide Notice [NOT-OD-14-055](#)), NIDDK will manage its portfolio in biomedical research investments in a manner that includes addressing the need for a highly productive pool of researchers by providing support for investigators who are at an early stage in their careers.

To maximize our available resources, all grant awards will continue to be subject to programmatic adjustments from the National Diabetes and Digestive and Kidney Diseases (NDDK) Advisory Council approved levels. These adjustments take into consideration the overall scientific and technical merit of the grant application, the cost of the proposed research, and other resources available for related research projects.

Funding Guidelines

Competing Awards

For FY 2014 NIDDK is establishing a nominal “payline” for new (Type 1) and renewal or competing continuation (Type 2) R01 applications of 13th percentile. Most R01 applications which have a primary assignment to NIDDK and which request less than \$500,000 direct cost per year and score at or better than the 13th percentile will receive an award (applications which have NIDDK as a secondary assignment do not benefit from this payline). R01 applications requesting \$500,000 or more in direct costs for any year will be held to a more stringent pay line – the 8th percentile for both Type 1 and 2 applications.

Please note the following regarding competing awards:

- NIDDK will exercise discretion and consider portfolio balance, programmatic importance and a number of other factors in determining precisely which applications are awarded.
- All grant awards will continue to be subject to programmatic adjustments from the NDDK Advisory Council approved levels.
- These funding levels are applicable for applications to be paid in FY 2014. Many applications submitted in FY 2014 (e.g., those submitted in January for September/October council consideration) will not be eligible for funding consideration until FY 2015. The funding levels for FY 2015 cannot now be reliably predicted.

Early Stage Investigators (ESIs)

Fostering the success of investigators establishing careers in biomedical research is a high priority of the NIDDK and NIH. In FY 2014 NIDDK will place special emphasis on supporting ESIs (investigators within 10-years of their terminal research degree or medical residency who have not yet been awarded a substantial, competing NIH research grant; [see ESI FAQs](#)) by establishing a nominal payline for R01 applications submitted by ESIs at the 18th percentile. In addition, when possible and appropriate the full period of support recommended will be awarded.

R01s applications submitted by New Investigators who are not also ESIs will be paid up to the 13th percentile (same as the general pay line).

Bridge Support

In cases where a competing renewal application falls near but beyond the nominal payline, NIDDK will continue to consider interim support on a case-by-case basis and provide limited support in selected cases. The goal is to preserve essential research resources pending the re-review of a

revised application. NIDDK can choose to award a one- or two-year R56 grant to an R01 application scored outside the payline. These awards provide support for investigators to collect preliminary data and use these data to revise and improve their R01 applications.

Duration of Grant Support

Competing awards are adjusted to achieve a 4-year average duration for research project grants. Nevertheless, applications from ESIs, MERIT extensions, program project grants, and clinical trial grants are generally awarded for the full length of their recommended project period.

Salaries

Section 203 of the [Consolidated Appropriations Act 2014](#)[External Link Disclaimer](#) prohibits payments for salaries under grants and other extramural mechanisms in excess of Executive Level II. It should be noted, that Executive Level II was increased by 1 percent from \$179,700 to \$181,500 by [Executive Order 13655](#)[External Link Disclaimer](#) that became effective January 12, 2014. See [NOT-OD-14-052](#) for additional information.

Non-competing (Continuation) Awards

Per the NIH Fiscal Policy for Grant Awards – 2014 (see [NOT-OD-14-055](#)) non-competing (Type 5) continuation grants (research and non-research) including those that remain to be issued in FY 2014 will likely be made at the commitment level indicated on the Notice of Award (including those that were initially issued at 90% of the commitment level in FY 2014). Out-year commitments for continuation awards in FY 2015 and beyond will remain unchanged.

Program Project (P01), Collaborative Interdisciplinary Team Science (R24), and Other Applications with Budgets Greater than \$500K

NIDDK has adopted a more stringent funding practice for awarding program project (P01) grants, Collaborative Interdisciplinary Team Science (R24) and other investigator-initiated grant applications with budgets of \$500,000 requested direct costs in any one year. Prior approval is required before submitting an application for review that requests \$500,000 or more in direct costs in any one year. The request to submit such applications should be received at least three months prior to the proposed submission date. Prior approval is required for renewal and revised applications as well as new applications. Please consult with the appropriate NIDDK program staff and visit the following site for information on research areas supported by NIDDK: <http://www.niddk.nih.gov/research-funding/research-programs/Pages/default.aspx>.

New (Type 1) program project (P01) applications may request a maximum of \$6.25 million in direct costs over five years, exclusive of the subcontract Facilities & Administrative (F&A) costs. Renewal (competing continuation [Type 2]) program project applications may request up to \$6.25 million in direct costs over five years, exclusive of Facilities and Administrative (F&A) costs associated with the subcontract(s). In addition to the caps on the amount requested, P01 awards are subject to administrative adjustment from the Advisory Council approved levels. Also, any P01 grant receiving a competing award in FY 2011 or later will be limited to one subsequent renewal.

Resources for New NIDDK Investigators

New investigators represent the future. They bring fresh ideas and technologies to research. NIDDK is dedicated to providing training and research funding for new investigators working on topics within its mission.

NIH Opportunities

NIH has [policies and resources](#) designed to assist [new investigators](#) in establishing their research programs and careers. New investigators should check the "New PI" box on the face page of their R01 applications so that they can be given special consideration. Peer reviewers are instructed to focus more on the proposed approach than on the track record, and to expect less preliminary data than would be provided by an established investigator. Institute staff pay special attention to applications from new investigators as well. In addition, NIH has piloted a [program for rapid turnaround](#) for new investigator applications allowing them to revise and resubmit more quickly.

NIDDK Opportunities

NIDDK has created a number of special new investigator opportunities and [Frequently Asked Questions](#) for new investigators. You are encouraged to discuss your ideas with NIDDK program staff as you are planning and preparing your grant application. Check NIDDK [scientific areas of interest](#) to find the right staff members and their contact information.

Differential payline – Each year, the NIDDK sets a percentile “payline” for R01 applications based on available funds and the volume of applications. The payline for new investigator grants is two percentile points more generous than the regular payline for established investigators. While NIDDK often makes administrative reductions in grant duration, applications from new investigators that fall within the payline are usually awarded the full requested duration.

Second-level review – The [NIDDK Advisory Council](#) meets to provide second-level review after the initial round of peer review by Scientific Review Groups (study sections). All new investigator R01 applications within ten percentile points of the payline receive individual consideration during the second-level review process. This could result in the award of an R01 with a reduced budget or a smaller award such as an R56.

NIH High Priority, Short-Term Project Award (R56) – Although you cannot apply for this grant mechanism, NIDDK can choose to award a one- or two-year R56 grant to an R01 application scored outside the payline. These provide support for an investigator to collect preliminary data in order to submit an improved revised R01 application. During second-level review, new investigators are given special consideration for R56 awards.

Career Development (K) awards – NIDDK has a vigorous [Career Award program](#).

Small grants (R03) awards – NIDDK has several relevant [funding opportunities for small grants](#).

Mentoring workshops – NIDDK regularly holds workshops for recently funded new investigators.

Role of NIDDK Advisory Council

Established by law and charter, the National Diabetes and Digestive and Kidney Diseases Advisory Council (NDDKAC) meets three times annually to advise the NIDDK about its research portfolio. The Council typically undertakes broad issues of science policy. An important role of the Council is to provide second-level peer review of grant applications that have been scored by scientific review groups. The Council members are an important liaison between the research communities they represent and NIDDK, which supports each community's research efforts.

Who are the Council members?

Members of the Advisory Council are drawn from the scientific and lay communities, are appointed for 4-year terms, and represent all areas within the Institute's research mission. The Council membership consists of 18 voting members, including 12 health or science experts and 6 public members.

Six nonvoting, *ex officio* members provide liaison with higher level agencies or organizations having missions consistent with that of NIDDK, including the Secretary, Department of Health and Human Services (DHHS), and representatives from the Department of Defense, Centers for Disease Control and Prevention, and Department of Veterans' Affairs.

Council's health or science experts contribute technical expertise and an understanding of the needs of the research communities of academia and industry. Council's public representatives impart a perspective of people affected by diseases in NIDDK's research mission.

Each Council member also belongs to one of the three Council subcommittees – Digestive Diseases and Nutrition; Diabetes, Endocrinology, and Metabolic Diseases; and, Kidney, Urologic and Hematologic Diseases, corresponding to NIDDK's extramural programmatic divisions.

A copy of the current Council roster is included in the next section on Advisory Council Logistical documents and online at <http://www.niddk.nih.gov/about-niddk/advisory-coordinating-committees/national-diabetes-digestive-kidney-disease-advisory-council/members/Pages/advisory-council-members.aspx>

What does the Council do? (For an abbreviated version see: “RESPONSIBILITIES OF NIDDK ADVISORY COUNCIL MEMBER” at the end of this book.)

As required by law, chartered advisory committees, including the councils, are part of every NIH institute. NIDDK's Council performs the following four key roles:

- Conducts second-level peer review of grant applications scored by scientific review groups
- Advises NIDDK on broad issues of science policy
- Reviews NIDDK programs
- Clears concepts for Program Announcements (PAs), Requests for Applications (RFAs), and Requests for Proposals (RFPs).

The subcommittees conduct most of the NIDDK Division-specific other business, including the closed-session discussion of grant applications.

What is second-level review?

Second-level review is the assessment of the quality of the initial review of grant applications. The Council has three options for recommendations: (1) concurrence with initial review; (2) modify the initial review action (e.g., an adjustment of the budget level and/or project period); or (3) defer an application for re-review. Applications that are brought to the Council subcommittees for closed-session discussion are then reported to the full Council in closed session. The remainder of the applications are considered through an en bloc vote.

Expedited Concurrence of En Bloc Actions. For grant and cooperative agreement applications that have no concerns noted that would represent an administrative bar to award (e.g., for human subjects, animal welfare, biohazards or inclusion of women, children and appropriate minority distribution), excluding those from foreign organizations, a process of expedited concurrence is available. The purpose is to provide NIDDK staff with the opportunity to make awards meeting specific circumstances in a more timely, responsive, and responsible manner. In this process, the power to review applications is delegated by the Chairman of the Advisory Council to specifically designated Council members acting on behalf of the Advisory Council as a whole. The concurrence committee consists of the Council Executive Secretary and six members of the NDDKAC. Two members are selected from each subcommittee of the NDDKAC. Electronic or written concurrence by a minimum of two members with no votes for nonconcurrence within 7 days of notification of posting is required for expedited concurrence approval.

For the first two Councils – January or February and May or June – expedited review enables NIDDK to fund grants a few weeks after the initial peer review meeting. Because September Council reviews applications for funding in the next fiscal year, applicants approved for funding through expedited review will get their awards after the Institute receives its next year's appropriation.

The NIDDK Director makes final funding decisions based on staff and Advisory Council/Board advice.

What happens at Council meetings?

Council meets in September, January or February, and May or June. Its activities are driven partly by the budget and appropriation cycle. For example, discussions in September reflect the beginning of the fiscal year.

In the morning, the full Council meets in open session to hear updates from the Director, NIDDK, and to discuss items that cut across NIDDK Divisional lines. This may include scientific and administrative topics for discussion, often presented by staff or outside speakers. ***Note: Open sessions are open to the public and members of the press may be present.***

In the early afternoon, the three subcommittees meet individually to review applications needing special consideration, discuss selective pay nominations, and recommend MERIT awards. Then, the Director, NIDDK, convenes the full Council for a short, closed meeting to discuss and formally approve subcommittee recommendations for funding grants.

Note: A sample agenda is included in the on Advisory Council Logistical documents. The next meeting's agenda is posted several weeks before each meeting and is available from the Council's home page (<http://www.niddk.nih.gov/about-niddk/advisory-coordinating-committees/national-diabetes-digestive-kidney-disease-advisory-council/Pages/advisory-council.aspx>). Minutes are also posted and available from the home page.

What is Council's role in concept clearance?

NIDDK seeks Council's advice for long-term planning at an early stage. However, the decision to go forward with an initiative is made by NIDDK, based on scientific and programmatic priorities and on the availability of funds.

Definitions of Special Issues Presented to Council

Program staff must prepare the following types of special issues to present to Council.

1. **Reinstatement of Research Aims.** Applications for which the division is requesting to reinstate [specific aims](#) or research not recommended for support by the study section.
2. **Non-Peer-Reviewed Applications.** Used in some circumstances. Council performs both [initial](#) peer review and second-level review functions. Renewal MERIT awards are the most common example.
3. **Deferred Applications.** All Council-deferred applications independent of review results.
4. **Unresolved Appeals.** Formerly called rebuttals. When program staff working with a [scientific review officer](#) have been unable to resolve the applicant's concerns, the DEA director reviews the appeal, and staff present it to Council.
5. **Foreign Applications.** Foreign applications a division proposes to award. (Foreign applicants may NOT receive R56-Bridge awards.)
6. **Council Member Applications.** Applications proposed for award where a Council member is PI. A subcommittee other than the one on which the Council member serves reviews these applications.
7. **Human Subjects.** Applications proposed for award with unresolved concerns about a lack of assurance of protection of human subjects.
8. **Biohazards.** Applications proposed for award with unresolved concerns about biohazards.
9. **Use of Animals in Research.** Applications proposed for award with unresolved concerns about a lack of assurance of protection of animals in research.
10. **Minority Recruitment Plans in Institutional Training Grant Applications.** Fundable, meritorious National Research Service Award applications with inadequate plans for minority recruitment. When the study section deems a plan inadequate, options are (1) no special action, pay by priority score; (2) defer payment pending submission and staff approval of a recruitment plan; or (3) defer for study section re-review pending receipt of an acceptable plan.
11. **Inclusion of Women and Minorities as Subjects in Clinical Research.** Applications a division plans to award with an unresolved inclusion issue ("U" code).
12. **Inclusion of Children as Subjects in Clinical Research.** Applications a division plans to award with an unresolved inclusion issue ("U" code).
13. **Special Council Review.** Review of research applications from Program Investigator with more than \$1,000,000 in direct costs in annual NIH support.

NATIONAL DIABETES AND DIGESTIVE AND KIDNEY DISEASES ADVISORY COUNCIL

AUTHORITY

42 U.S.C. 284a, sections 406 and [479] of the Public Health Service (PHS) Act, as amended, The National Diabetes and Digestive and Kidney Diseases Advisory Council (Council) is governed by the provisions of the Federal Advisory Committee Act, as amended (5 U.S.C. app.), which sets forth standards for the formation and use of advisory committees.

OBJECTIVES AND SCOPE OF ACTIVITIES

The Council will advise, assist, consult with, and make recommendations to the Secretary of Health and Human Services (Secretary) and the Director, National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK, also referred to as Institute) on matters related to the activities carried out by and through the Institute and the policies respecting these activities.

DESCRIPTION OF DUTIES

The Council may recommend to the Secretary, in accordance with section 231 of the PHS Act, as amended, acceptance of conditional gifts for study, investigation, or research on basic and clinical diabetes mellitus and endocrine and metabolic diseases, digestive diseases and nutrition, and kidney, urologic, and hematologic diseases, for the acquisition of grounds, or for the construction, equipping, or maintenance of facilities for the Institute.

The Council may review applications for grants and cooperative agreements for research and training and recommend approval of applications for projects which show promise of making valuable contributions to human knowledge; may review any grant, contract, or cooperative agreement proposed to be made or entered into by the Institute; may collect, by correspondence or by personal investigation, information as to studies which are being carried on in the United States or any other country and, with the approval of the Director of NIDDK, make available such information through appropriate publications for the benefit of public and private health entities, health professions personnel and scientists, and for the information of the general public.

The Council may prepare, for inclusion in the Biennial Report prepared by the Director, National Institutes of Health (NIH), under section 403 of the PHS Act, as amended (1) comments reflecting the activities of the Council in the fiscal years in which the report is prepared; (2) comments on the progress of the Institute in meeting its objectives; and (3) recommendations respecting the future directions and program and policy emphasis of the Institute.

AGENCY OR OFFICIAL TO WHOM TOHE COMMITTEE REPORTS

The Council will advise the Secretary; the Assistant Secretary for Health; the Director, NIH; and the Director, NIDDK.

SUPPORT

Management and support services will be provided by the Division of Extramural Activities,

ESTIMATED ANNUAL OPERATING COSTS AND STAFF YEARS

The estimated annual cost for operating the Council, including compensation and travel expenses for members, but excluding staff support, is \$93,758. The estimated annual person-years of staff support required is 0.3, at an estimated annual cost of \$49,807.

DESIGNATED FEDERAL OFFICER

The Director, NIDDK, will assign a full-time or permanent part-time NIDDK employee to serve as the Designated Federal Officer (DFO) of the Council. In the event that the DFO cannot fulfill the assigned duties of the Council, one or more full-time or permanent part-time NIDDK employees will be assigned these duties on a temporary basis.

The DFO will approve or call all of the Council's and subcommittees' meetings, prepare and approve all meeting agendas, attend all Council and subcommittee meetings, adjourn any meeting when it is determined to be in the public interest, and chair meetings when directed to do so by the Director, NIH, or Director, NIDDK.

ESTIMATED NUMBER AND FREQUENCY OF MEETINGS

Meetings of the full Council will be held not less than three times within a fiscal year. Meetings will be open to the public except as determined otherwise by the Secretary in accordance with subsection (c) of section 552b of Title 5 U.S.C. Notice of all meetings will be given to the public. In the event a portion of a meeting is closed to the public, as determined by the Secretary, in accordance with the Government in the Sunshine Act (5 U.S.C. 552b(c)) and the Federal Advisory Committee Act, a report will be prepared which will contain, as a minimum, a list of members and their business addresses, the Council's functions, dates and places of meetings, and a summary of the Council's activities and recommendations made during the fiscal year. A copy of the report will be provided to the Department Committee Management Officer.

DURATION

Continuing. This Council is mandated by statute with no specified end date.

TERMINATION

Unless renewed by appropriate action prior to its expiration, the Charter for the National Diabetes and Digestive and Kidney Diseases Advisory Council will expire two years from the date the charter is filed.

MEMBERSHIP AND DESIGNATION

The Council will consist of 18 members appointed by the Secretary and 6 nonvoting ex officio members: the Secretary; the Director, NIH; the Director, NIDDK; the Chief Medical Director of the Department of Veterans Affairs; the Assistant Secretary of Defense for Health Affairs; and the Assistant Secretary for Science and Education, United States Department of Agriculture (or their designees); and any additional officers or employees of the United States as the Secretary determines necessary for the Council to effectively carry out its functions. Of the 18 appointed members, 12 will be selected from among the leading representatives of the health and scientific disciplines (including not less than 2 individuals who are leaders in the fields of public health and the behavioral or social sciences) relevant to the activities of the NIDDK, particularly representatives of the health and scientific disciplines in the areas of diabetes mellitus, endocrinology, metabolism, digestive diseases, nutrition, nephrology, urology, hematology and public health. Six of the members will be appointed by the Secretary from the general public and will include leaders in the fields of public policy, law, health policy, economics, and management. All non-Federal members will serve as Special Government Employees. A member who has been appointed for a term of four years may not be reappointed to this Council before two years from the date of expiration of that member's term of office. A quorum for the conduct of business by the full Council will consist of a majority of currently appointed members.

Members will be invited to serve for overlapping four-year terms, except that any member appointed to fill a vacancy for an unexpired term will be appointed for the remainder of that term. A member may serve 180 days after the expiration of that member's term if a successor has not taken office.

The Chair of the Council will be selected by the Secretary from among the appointed members, except that the Secretary may select the Director, NIDDK, to be the Chair. The term of office of the Chair will be two years.

SUBCOMMITTEES

As necessary, subcommittees and ad hoc working groups may be established by the DFO within the Council's jurisdiction. The advice/recommendations of a subcommittee /working group must be deliberated by the parent advisory committee. A subcommittee may not report directly to a Federal official unless there is statutory authority to do so.

Subcommittee membership may be drawn in whole or in part from the parent advisory committee. All subcommittee members may vote on subcommittee actions and all subcommittee members count towards the quorum for a subcommittee meeting. A quorum for a subcommittee will be three members. Ad hoc consultants do not count towards the quorum and may not vote. The Department Committee Management Officer will be notified upon establishment of each standing subcommittee and will be provided information on its name, membership, function, and estimated frequency of meetings.

RECORDKEEPING

Meetings of the Council and its subcommittees will be conducted according to the Federal Advisory Committee Act, other applicable laws and Department policies. Council and subcommittee records will be handled in accordance with General Records Schedule 26, Item 2 or other approved agency records disposition schedule. These records will be available for public inspection and copying, subject to the Freedom of Information Act, 5 U.S.C. 552.

FILING DATE

October 31, 2012

APPROVED

9-15-12

Date



Director, NIH

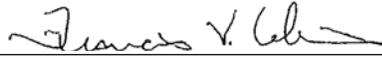
NOTICE OF RECHARTER

NATIONAL DIABETES AND DIGESTIVE AND KIDNEY DISEASES
ADVISORY COUNCIL

The Council was established by statute and has functions which are of a continuing nature so that its duration is not governed by section 14(a) of the Federal Advisory Committee Act but is otherwise provided for by law. The Council is hereby rechartered in accordance with section 14(b)(2) of that Act.

5-15-10

Date



Director, NIH

Reviewing Applications Prior to the Meeting: Using the NIH Electronic Council Book (ECB)

(For NIDDK Advisory Council Members Only)

What is the NIH Electronic Council Book

The NIH Electronic Council Book (ECB) provides access to NIH summary statements. Using World Wide Web and Internet capabilities for database search and retrieval, as an NIDDK Advisory Council member you may read, search, sort, and print any or all of the summary statements for a Council round that has either a DK primary or secondary assignment. NIH staff load data and summary statements into the ECB each night, so the ECB is always current.

The data in the ECB, and the codes you use for access to those data, are confidential and must be protected. Since the ECB contains confidential data, you should not leave it unattended. Use it and then disconnect. If for some reason you are inactive for approximately one hour, the system will automatically disconnect, and you will have to login again.

How do I get started?

You or your institution will supply your computer access to the NIH computer, via an Internet connection and a WEB browser (such as Firefox, Netscape Navigator, or Internet Explorer). An NIDDK staff member will give you the information necessary to identify yourself to the NIH computer where the ECB is located. That information includes two codes. The first is called your “USER NAME,” the second is your “PASSWORD.” Once you have this information, you are ready to start.

Assuming you are already connected to the internet, use your web browser to access the following page:
<https://ecb.nih.gov/council/login.cfm>

You will see a screen entitled “**NIH Electronic Council Book**” with two blank boxes for your USER NAME and your PASSWORD. Neither the USER NAME nor the PASSWORD are case sensitive. To login to the ECB:

- Enter your USER NAME, for example, ECB_JOHNST
- Press Tab or move the mouse cursor to the PASSWORD block
- Enter your PASSWORD
- Click on LOGON

Please note that the password issued to you by NIDDK staff is a temporary password and you must change it before you can login to the ECB. To change your password, go to the ECB login page (see below) and click on the link to the “Council Member Change Password Page.” Use the NIDDK-issued password as the “Old Password,” and follow the instructions on this page to change your password to a password of your choosing. If you have problems changing your password, please contact Teresa Lindquist (lindquit@niddk.nih.gov, 301-451-6418).

If you have entered an incorrect USER NAME, you can click on CLEAR, and enter the information again.

How Do I Use the System?

When you log on to the ECB, you will go directly to the Search For Projects tab. The Search Criteria appear in a list on the left of the screen; you can use this menu to move quickly through the sections of the search screen. Clicking on the name of any search item will provide you with help for that item.

PLEASE NOTE that when moving through the screens in the ECB it is best to use the small red arrows in the upper left hand corner of your screen rather than the “Back” button on your browser.

Note that in the Basic Search Options portion of the Search screen, there is an item entitled: **Output Option**. There are two choices: Standard Project List and Resumé Project List. A search using the Standard Project List format will return a list containing the following information:

- Project (or grant) number
- Principal Investigator (PI) name
- Project Title
- Request for Application (RFA) or Program Announcement (PA) number
- Percentile
- Priority score
- Study section name
- Institute or Center (IC) Program Class Code
- PI's institution.

The Resume Project List retrieves the “Summary of Review and Discussion” section of the summary statement in addition to the items in the Standard Project List. This version of the Project List provides a useful overview of the review of a single application or group of applications.

How do I initiate a search?

Commonly searched items are located near the top of the Search screen. Searching is very flexible. Please note that all searches default to applications on which NIDDK is the primary Institute. If you are looking for an application assigned to another NIH Institute or Center you will need to select either “Primary and Dual Projects” or “Dual Projects only” in the Review/Program Section of the Search screen.

Conduct a search by inserting the particular criteria (Principal Investigator's name; Application number; Study Section, etc.) (Examples are provided below.)

- **To search for a specific summary statement**, enter either the application number or the Principal Investigator's last name in the appropriate box. You do not need to enter the entire grant number or full PI name; the system will find all applications that meet your criteria.
- **To search for a group of summary statements that meet certain search criteria** (such as all the applications reviewed by a particular Scientific Review Group (SRG), projects in a range of priority scores or percentiles, or all applications reviewed in response to a particular RFA or any other combination of information), simply enter that information in the appropriate boxes.
- **To search for all applications on a specific scientific topic**, simply enter the appropriate term in the boxes labeled “Summary Text Contains.” This search criterion has two boxes and a drop-down menu between them that allows use of a Boolean logical operator (*AND*, *OR*, and *NOT*) to connect two character strings. Note: If one is searching for a topic such as “endocrine disruptors” consider the two words as a single character string and enter both words in the left box separated by a space rather than one in each box. You may use these fields to search the summary statement, the Project Title, or both of these items.

To initiate a new search, click on the **Clear Criteria** button. This will remove all prior search criteria except for the defaults in percentile and priority score. Clicking on the **Default Criteria** will reset all criteria to their default values.

SEARCH CRITERIA EXAMPLES

Principal Investigator (PI): In the PI/Institution section, enter the first several letters of the PI's last name in the box labeled "Principle Investigator Starts With." For example, searching for "**Ham**" will return matches for Hamilton, Hammerman, Hammes, Hampe, etc. The more complete the name, the more exact will be the search results.

Scientific Review Group (SRG): In the Review/Program section of the search screen, type the three- or four-character abbreviation of the SRG (e.g., MET, NTN, CVB) in the field labeled "Scientific Review Group Contains". If you are looking for an application that was reviewed in a Special Emphasis Panel, please enter information in the boxes labeled "Special Emphasis Panel." For example, if you enter "DK" in the first box for this search item, the search will return all applications reviewed in NIDDK Special Emphasis Panels (ZDK).

Program Code (PCC): It is important to enter the Program Class Codes correctly. All NIDDK Program Class Codes consist of 8 characters: three characters, a blank space, and then four characters. For example, to search for Obesity Special Projects (Program Class Code = **NBH OBSP**), place **NBH** in the first three boxes. Leave the next box blank and enter **OBSP** in the remaining 4 boxes.

Application/Grant Number: The identification number is commonly referred to as the application number or grant number, depending on its processing status. The identification number consists of several parts, each having a distinct meaning. The following example shows the parts of an ID number assigned to an amendment (A1) to a supplemental (Type 3) application for a traditional research project (R01) referred to the National Cancer Institute (CA). The number further identifies the application serially as the 65412st new proposal submitted to the National Cancer Institute and indicates that this is the first supplemental application (S1) to the fourth year (-04) of support to this project.

Explanation of Grant application/award identification NUMBERING system:

Application Type	Activity Code	Administering Organization	Serial Number	Suffixes	
				Grant Year	Other
3	R01	CA	65412	08	S1A1

- **Application Type Code:** A single-digit code identifying the type of application received and processed. The codes are as follows:

- 1 New
- 2 Competing Continuation
- 3 Supplement
- 4 Extension

- 5 Noncompeting Continuation
- 6 Change of Institute or Division
- 7 Change of Grantee or Training Institution
- 8 Change of Institute or Division (noncompeting continuation)
- 9 Change of Institute or Division (competing continuation)

- **Activity Code:** A three-digit code identifying a specific category of extramural activity (e.g., R01, R03, R33, T32, F33, R44, U01).
- **Administering Organization Code** (Also referred to as an IC Code or Admin PHS Org Code): A two-letter code identifying the primary NIH Institute or Center to which the application is assigned. In the above example, "CA" refers to the National Cancer Institute.
- **Serial Number:** A six-digit number generally assigned sequentially to a series within an NIH Institute or Center.
- **Suffixes:** A field composed of the following components:

Grant year. A two-digit number indicates the actual segment or budget period of a project. The grant year number (01, 02, etc.) is preceded by a dash to separate it from the serial number; (e.g., AI 12345-02 or CA 00900-04). The grant year number is increased by one for each succeeding renewal year. Thus, the 04 year suffix in the example above identifies a grant in its fourth year.

Supplement. The letter "S" and related number identify a particular supplemental record (e.g., S1, S2). Supplement designations follow the grant year or the amendment designation, as the case may be (e.g., AI 12345-01S1 and CA 00900-04A1S2).

Amendment. The letter "A" and related number identify each amended application (e.g., A1, A2, etc.). Amendment designations follow the grant year or the supplement designation, as the case may be (e.g., DE 34567-02A1 and HL 45678-01S1A2).

Text Search: A text word search retrieves applications containing one or two search terms. The search is performed against the summary statement narrative and the Project Title and may take slightly longer to return the results. Submitting a search with an entry in the first box will find all summary statements and/or Project Titles containing that single word anywhere in the text. To enter two text words, select the correct Boolean logical operator (*AND*, *OR*, *NOT*) from the drop-down menu between the two text boxes.

Priority Score/Percentile: The system sets a default priority score and percentile to focus on the applications being reviewed by the Advisory Councils. The default for the percentile is between 00 and 30 and for the priority score, between 100 and 300. These defaults can be deleted or changed. Score ranges can be cleared by clicking the "Clear Scores" button below the data entry boxes. If you wish to enter different ranges, highlight the contents of these boxes and enter different numbers.

ADVANCED SEARCH CRITERIA EXAMPLES

Summary Statements Released Since: A frequent user of the system will be able to retrieve summary statements released into the database since the last time the user logged into the system. For example, to retrieve all summary statements since January 15, 2008, the entry would be 01/15/2008 (mm/dd/yyyy). You can also select applications based on whether or not the summary statement has been released by selecting the appropriate option in the drop-down box.

RFA/PA Number: NIDDK will provide its Council members with valid RFA/PA numbers. **Please** use the format as provided on the search screen in the Application ID section. **Please note** that if you are interested in Roadmap applications, there is a radio button in the Basic Search Options section that allows you to include only Roadmap applications in your search.

Direct Cost Recommended: In the Review/Program Section, you can search for applications based on specified budget amounts. For example, entering **1000000** and selecting “Greater Than or Equal To” from the drop-down menu will retrieve a list of applications with budgets of one million dollars or more.

Special Selects: The Special Selects Section provides options for searching on several different criteria. You may search on one criterion or a combination of criteria. **Foreign applications** are those applications from organizations outside the boundaries and territories of the United States. In the Special Selects Section, check the box ‘Foreign Grants’ to retrieve a list of summary statements of all foreign applications. **Phase 3 Clinical Trials** are identified by the Initial Review Group. **AIDS** identifies applications involving AIDS-related research. You may also search for applications with various human or animals subjects concerns.

COMPLETING YOUR SEARCH

Once you are satisfied with the search criteria, click the Search button at the top of the page. **Please note** that there is a default score range of 0 to 30 PERCENTILE and 100 to 300 PRIORITY SCORE. If you need to search ALL applications, please **clear** these values prior to running your search.

SEARCH RESULTS

When a search is completed a hit list will be displayed with the search criteria listed at the top. The hit list will include all data on all applications that meet the search criteria you have selected. The search criteria will be listed at the top of the list of applications for easy reference.

The hit list is compiled as a table with one application per line. You may increase or decrease the number of applications displayed on the page by using the Set Records per page display in the upper left corner. The list contains the following information for each application:

Count	Sequence number of applications as retrieved
Email	A link to the Program Officer’s email address
Project Number	Type, activity, and serial number
RFA/PA	The RFA or PA announcement number, if any, with a link to the Program Announcement in the NIH Guide for Grants and Contracts
PI Name	Name of Principal Investigator
Percentile	Percentile rank
Priority	Priority score
Project Title	Title of research application
Study Section	Scientific Review Group, with a link to the Study Section roster
IC-Prog Code	Program Class Code for the primary IC
Institution	Applicant organization

VIEWING SUMMARY STATEMENTS

To view a particular summary statement click on the project number. The next screen will be the complete summary statement. **Note:** Each hit list will list all applications that satisfy the search criteria whether or not the summary statement is currently available. For Netscape users, the grant number will be a different color (usually blue) and underlined if the summary statement is available.

Also, there will be a check box on the left margin (see instructions below on downloading one or more summary statements for offline reading).

The Electronic Council Book allows you to retrieve and download groups of summary statements. In addition, the user now has the ability to selectively "tag" and "untag" items in the hit list by checking the boxes on the left margin. This allows the user to create highly customized hit lists for the purpose of downloading summary statements.

Summary statements may be retrieved in several ways:

- Download one or more summary statements as a single PDF file that can be printed locally (you will need Adobe Acrobat Reader on your computer to use this feature). To download a group of summary statements as a single PDF, check the boxes on the left margin for all applications you wish to include.
- Download a collection of summary statements as a "Zip" file from which individual summary statements can be viewed or printed. You will need a program that extracts Zip files in order to view the summary statements. To download a group of summary statements as a single Zip file, check the boxes on the left margin for all applications you wish to include.
- View individual summary statements in the browser without distracting page headers embedded in the text. To view a single summary statement in your browser window, click on the project number.

VIEWING IRG/SRG ROSTERS

To view the roster of members for a particular Study Section, simply click on the SRG identifier on the hit list. The IRG identifier is adjacent to the application of interest.

For assistance please contact:

Teresa Lindquist, lindquit@nidDK.nih.gov or 301-451-6418.

National Diabetes and Digestive and Kidney Diseases Advisory Council: Advisory Council Operating Procedures (Pending Approval of NDDKAC)

February 2014

Expiration: February 2015

A. Purpose

This documents operating procedures established annually by the National Diabetes and Digestive and Kidney Diseases Advisory Council (NDDKAC) for use of council-delegated authorities. These authorities establish program management and council review procedures for the Institute's extramural programs and establish authorities for management actions undertaken by staff.

In general, the Council makes three types of recommendations relating to second level review of scientific review group (SRG) actions: (1) the Council can concur with the SRG critique; (2) it can suggest a different budget and/or a different length of the grant period; and (3) it can advise deferral of an application for re-review. Specific procedures are given below for each of these types of actions. These procedures are meant to ensure a level of uniformity and comparability across the Council's three subcommittees, which are aligned with the Institute's programmatic divisions. Those subcommittees of Council are free to develop and utilize their own procedures with the understanding that they be consistent with the operating procedures.

B. Background

The National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) and other National Institutes of Health (NIH) awarding Institutes are required by policy to establish procedures for interactions between Advisory Councils and the staff responsible for the day-to-day management of extramural portfolios. These procedures, referred to as Council-delegated authorities, govern staff and NDDKAC responsibilities with regard to grant portfolio management.

C. Definitions

1) Council Delegated Authorities: Those actions negotiated between the NDDKAC and the Director, NIDDK that govern management of the Institute's extramural program portfolio.

2) En Bloc Action: An action taken by Council on a group of applications under review rather than on specific individual applications being presented to NDDKAC for review.

3) Staff Actions: Actions that, based on policy and procedures, do not require a specific action on the part of the NDDKAC. These actions include, but may not necessarily be limited to: (a) change of grantee institution, (b) change of principal investigator, (c) administrative supplements, (d) no-cost extensions, and (e) phase-out or interim support.

4) Communication Letter: A communication between an applicant and Institute staff that is included for NDDKAC information purposes. Communication letters may or may not be acted upon by Council and need not be brought up for special discussion.

D. Policy and Implementation Procedures

The NDDKAC by approval has delegated authority to the NIDDK Director for staff to negotiate adjustments in dollars and/or the terms and conditions of grant and cooperative agreement awards recommended by the Council. In general, these operational guidelines for administrative actions are

developed to provide a day-to-day framework for the smooth and effective operations necessary after review of grant applications by the Council. They are principally intended to enhance the administration of the federal assistance portfolio by the NIDDK.

NIDDK program and grants management staff analyze and review applications, i.e., noncompeting continuation applications and competing applications (new, resubmission (amended) renewal, or revision (supplemental)) before issuing a grant award. NIDDK staff negotiates appropriate adjustments, when applicable, for such changes as the base used for recovery of facilities and administrative costs and/or legislatively imposed salary or other limits. Also, staff can make adjustments to reconcile inconsistencies between SRG recommended budgets and approved activities.

Administrative requests for increases in direct costs, which are the result of marked expansion or significant change in scientific content after formal peer review, will be referred to the Council for advice and recommendation. The NIDDK Director will determine whether the urgency is sufficient to warrant interim consultation with the Council by mail, e-mail, facsimile or telephone, instead of delaying action until the next Council meeting, or by mutual agreement, in rare instances the NIDDK Director may act on behalf of the Council as a whole.

Actions not requiring NDDKAC review or advice are: (1) change of grantee institution, (2) change of principal investigator, (3) administrative supplements to provide additional support either to meet the increased cost of maintaining the level of research previously recommended, or to accommodate activities or to meet needs judged by staff to be within the scope of the previously peer reviewed project, or (4) phase-out or interim support. The Council will be provided with notice of general solicitations for administrative supplements if they apply to an entire class of applications. In addition, NIDDK staff may restore requested time and support which were deleted by the initial review group when the principal investigator has provided justification in a communication letter, and the restoration is in the best interest of the Institute and the project is of high programmatic relevance. Staff will record the action taken and its justification in a memo to the file. In addition, restorations will be summarized for Council information at the next regular scheduled meeting.

Each Council round Council will be provided a list of competing applications that meet the criteria for Special Council Review (SCR) under NIH policy. For each application on the list that may actually be funded, NIDDK staff will provide information about the other funding for the PI that brings his/her direct cost total to the \$1 million threshold and a justification for considering funding. Council members will review these cases and indicate whether or not they have concerns.

NIH, in an effort to improve the efficiency of making awards, authorized the use of an expedited en bloc concurrence Council review process. NIDDK makes use of an expedited concurrence of en bloc actions to provide NIDDK staff with the opportunity to make awards meeting specific circumstances in a more timely, responsive and responsible manner.

All grant and cooperative agreement applications, excluding those from foreign organizations, which have no concerns noted that would represent an administrative bar to award (e.g., for human subjects, animal welfare, biohazards or inclusion of women, children and appropriate minority distribution) or need SCR, will follow a process of expedited concurrence whereby the review of applications is delegated by the Chairman of the Advisory Council to designated Council members acting on behalf of the Advisory Council as a whole. The concurrence committee shall consist of the Council Executive Secretary (non-voting) and six members of the NDDK Advisory Council. Two members will be selected from each subcommittee of the NDDK Advisory Council.

The Executive Secretary will alert the concurrence committee members with responsibility for expedited concurrence when review outcomes for eligible applications are available in the Electronic Council Book. The Electronic Council Book enables members to access: Application Number, Principal Investigator, Project Title and Percentile/Priority Score. Typically this will occur once each Council round, several weeks before the scheduled NDDKAC meeting, however circumstances may arise that will require an additional, earlier expedited concurrence review to allow a set of applications to be funded in a timely manner to optimize the initiation or continuation of the proposed research. In the event of an earlier expedited concurrence review the same procedures described below will be followed including the involvement of the full NDDKAC.

Electronic or written concurrence by a minimum of two members with no votes for non-concurrence within seven days of notification of posting is required for expedited concurrence approval. Any member may bring an application to full NDDKAC consideration without the need for justification. Any single vote for non-concurrence within the allotted time period will result in that application going for regular consideration to the NDDKAC under its normal procedures for concurrence. Members not acting upon an application within the allotted time period after posting will be considered to have abstained from a vote on that application. Expedited listings lacking enough votes for final action will be presented to the regular NDDKAC meeting for review.

The full NDDKAC will be provided with a list of all applications eligible for expedited concurrence, as well as the outcome of the vote by the concurrence committee members on those applications. The Executive Secretary will report the expedited concurrence recommendations during the closed session of the full Advisory Council meeting when reviewed applications are discussed.

The NDDKAC also advises the Institute on: The adequacy of the initial review process, including appeals to grant application review; nominations for and extensions of, Method to Extend Research in Time (MERIT) awards; and, funding of applications with Special Emphasis dollars. Finally, the NDDKAC will receive a report annually on the activities of the NIDDK Board of Scientific Counselors.

E. Exceptional Situations

As circumstances require, based on programmatic considerations, the Director, NIDDK after consultation with Council, may make exceptions to these guidelines.

Exceptions to these procedures should be extremely rare because there needs to be consistent application of these procedures across extramural divisions. Nonetheless, circumstances may require the deviation from the prescribed procedure in order to achieve the mission of the NIDDK. By NDDKAC delegated procedures, the Director, NIDDK has authority to act upon unusual or extenuating

circumstances. These actions are usually discussed by a subset of Council members selected by the Director and Executive Secretary of NDDKAC. Any actions of this exceptional nature must be appropriately documented as necessary for the official record, and should be reported to Council at its next scheduled meeting.

F. References

- 1) Public Health Service Act as amended, 42 USC 52h, 42 USC 241, 42 USC 284a
- 2) NIH Manual Chapter 1805, Use of Advisors in Program and Project Review and Management (<http://www1.od.nih.gov/oma/manualchapters/management/1805/>)

- 3) NIH Manual Chapter 1810-1, Procedures for Avoiding Conflict of Interest for NIH Special Government Employee SGE Advisory Committee Members
(<http://www1.od.nih.gov/oma/manualchapters/management/1810-1/>)
- 4) NIH Manual Chapter 3005, Review and Evaluation of Intramural Programs
(<http://www1.od.nih.gov/oma/manualchapters/intramural/3005/>)
- 5) NIH Manual Chapter 4204-204B, Peer Review Process
(<http://oma.od.nih.gov/manualchapters/grants/4204-204B/>)
- 6) NIH Manual Chapter 54104, NIH Research Grants Involving Foreign Institutions and International Organizations (<http://oma.od.nih.gov/manualchapters/grants/54104/>)
- 7) NIH Manual Chapter 54206, Responsibility for Care and Use of Animals
(<http://oma.od.nih.gov/manualchapters/contracts/6380-2/>)
- 8) NIH Manual Chapter 54513, Management and Procedures of National Advisory Councils and Boards in Their Review of Extramural Activities (<http://oma.od.nih.gov/manualchapters/grants/54513/>)
- 9) NIH Manual Chapter 7410, Review and Documentation of Protections for Human Subjects in Grant Applications and Contract Proposals (<http://oma.od.nih.gov/manualchapters/comgc/7410/>)
- 10) OER Policy & Guidance: Inclusion of Women and Minorities as Participants in Research Involving Human Subjects – Policy Implementation Page
(http://grants.nih.gov/grants/funding/women_min/women_min.htm)
- 11) OER Policy & Guidance: Inclusion of Children Policy Implementation
(<http://grants.nih.gov/grants/funding/children/children.htm>)
- 12) NOT-OD-12-140: Notice of Special Council Review of Research Applications from PDs/PIs with More than \$1.0 Million Direct Costs in Annual NIH Support (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-140.html>)

9/16/14

NATIONAL DIABETES AND DIGESTIVE AND KIDNEY
DISEASES ADVISORY COUNCIL
(All terms end October 31)

National Institute of Diabetes and Digestive and Kidney Diseases
National Institutes of Health
Department of Health and Human Services

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Advisory Council Meetings Dates: 2015 - 2016

2015

January 28-29 (Wednesday and Thursday)

May 13-14 (Wednesday and Thursday)

September 9-10 (Wednesday and Thursday)

Building 31, Conference Rooms 10, 6 and 7

2016

January 27-28 (Wednesday and Thursday)

May 18-19 (Wednesday and Thursday)

September 7-8 (Wednesday and Thursday)

Building 31, Conference Rooms 10, 6 and 7



**197th Meeting of the
NATIONAL DIABETES AND DIGESTIVE AND KIDNEY
DISEASES ADVISORY COUNCIL**

Building 31, C Wing, 6th Floor, Conference Room 10

January 28, 2015

OPEN SESSION 8:30 a.m. to 12:00 noon

- | | | |
|-------------|---|--------------------|
| I. | CALL TO ORDER | Dr. Rodgers |
| II. | CONSIDERATION OF SUMMARY
MINUTES OF THE 196th COUNCIL MEETING | Dr. Rodgers |
| III. | FUTURE COUNCIL DATES | Dr. Rodgers |

2015

January 28-29 (Wednesday and Thursday)
May 13-14 (Wednesday and Thursday)
September 9-10 (Wednesday and Thursday)

2016

January 27-28 (Wednesday and Thursday)
May 18-19 (Wednesday and Thursday)
September 7-8 (Wednesday and Thursday)

All meetings will be held in Building 31, Conference Rooms 10, 6 and 7

- | | | |
|-------------|--|----------------------|
| IV. | ANNOUNCEMENTS
Confidentiality/Conflict of Interest | Dr. Stanfield |
| V. | REPORT FROM THE NIDDK DIRECTOR | Dr. Rodgers |
| VI. | UPDATE FROM THE DIRECTOR, NIEHS:
Vision for NIEHS and Possible Interactions with NIDDK | Dr. Birnbaum |
| VII. | COFFEE BREAK <u>10:00 a.m.</u> | |

VIII. BIG DATA AND INFORMATICS

Barriers to and Career Paths for Integrating Big Data
Into Traditional Science and Traditional Science into Big Data

Dr. Brenner
Dr. Kaushansky

IX. SCIENTIFIC PRESENTATION

Metabolism: SNO in the Forecast

Dr. Schaffer

X. SUBCOMMITTEE MEETINGS**1:00 to 4:00 p.m.**

Diabetes, Endocrinology, and Metabolic Diseases
Building 31, C Wing 6th Floor Conference Center, Room 10
Closed Session: 1:00 p.m. – 2:00 p.m.
Open Session: 2:00 p.m. – 4:00 p.m.

Digestive Diseases and Nutrition
Building 31, C Wing 6th Floor Conference Center, Room 6
Open Session: 1:00 p.m. – 2:30 p.m.
Closed Session: 2:30 p.m. – 4:00 p.m.

Kidney, Urologic, and Hematologic Diseases
Building 31, C Wing 6th Floor Conference Center, Room 7
Open Session: 1:00 p.m. – 3:00 p.m.
Closed Session: 3:00 p.m. – 4:00 p.m.

CLOSED SESSION 4:15 p.m. to 4:30 p.m.**XI. REPORTS OF SUBCOMMITTEES:
CONSIDERATION OF APPLICATIONS**

Dr. Stanfield

Diabetes, Endocrinology, and Metabolic Diseases
Digestive Diseases and Nutrition
Kidney, Urologic, and Hematologic Diseases

XII. ADJOURNMENT

Dr. Rodgers

Meeting Minutes
Department of Health and Human Services
National Institutes of Health
National Institute of Diabetes and Digestive and Kidney Diseases Advisory Council

I. CALL TO ORDER*Dr. Rodgers*

Dr. Rodgers called to order the 195th meeting of the National Diabetes and Digestive and Kidney Diseases Advisory Council at 8:30 a.m., May 14, 2014, in Conference Room 10, Building 31, the NIH Campus, Bethesda, Maryland.

A. ATTENDANCE – COUNCIL MEMBERS PRESENT

Dr. Domenico Accili	Dr. Jean Schaffer
Dr. Gopal Badlani	Dr. Alan Shuldiner
Dr. David Brenner	Dr. Irving Smokler
Dr. Eugene Chang	Dr. Bruce Spiegelman
Ms. Cindy Hahn	Dr. William Steers
Dr. Kenneth Kaushansky	Mr. John Walsh
Ms. Ellen Leake	Dr. David Klurfeld
Ms. Robin Nwankwo	Dr. Robert Vigersky
Dr. Jerry Palmer	Dr. Mark Zeidel
Dr. Thomas Robinson	

Also Present:

Dr. Gregory Germino, Deputy Director, NIDDK
 Dr. Brent Stanfield, Executive Secretary, NIDDK Advisory Council

B. NIDDK STAFF AND GUESTS

Agodoa, Lawrence - NIDDK	Copeland, Randy - NIDDK
Andersen, Dana - NIDDK	Cowie, Catherine - NIDDK
Appel, Michael - NIDDK	Davila-Bloom, Maria - NIDDK
Barnard, Michele - NIDDK	Densmore, Christine - NIDDK
Begum, Najma - NIDDK	Dirks, Dale – Health and Medicine Counsel
Bishop, Terry - NIDDK	Doherty, Dee - NIDDK
Bleasdale, John - CSR	Donohue, Patrick - NIDDK
Blondel, Olivier - NIDDK	Drew, Devon - NIDDK
Bourne, Phil – NIH OD	Duggan, Emily - NIDDK
Bourque, Sharon – NIDDK	Eggerman, Thomas - NIDDK
Bremer, Andrew – NIDDK	Evans, Mary - NIDDK
Brown, Sherry - NIDDK	Farishian, Richard - NIDDK
Buchanan, Sarah - Health and Medicine Counsel	Feld, Carol - NIDDK
Byrd-Holt, Danita – Soc. and Sci. Sys., Inc.	Flessner, Michael - NIDDK
Calvo, Francisco - NIDDK	Fonville, Olaf - NIDDK
Carrington, Jill - NIDDK	Fradkin, Judith - NIDDK
Castle, Arthur - NIDDK	Gallivan, Joanne - NIDDK
Cerio, Rebecca - NIDDK	Gansheroff, Lisa - NIDDK

Garcia, Martha - CSR
 Garofolo, Robert - CSR
 Goter-Robinson, Carol - NIDDK
 Graves, Reed - CSR
 Grey, Michael - NIDDK
 Guo, Xiaodu - NIDDK
 Guyer, Mark - NHGRI
 Haft, Carol - NIDDK
 Hamilton, Frank - NIDDK
 Hanlon, Mary - NIDDK
 Hoff, Eleanor - NIDDK
 Hoofnagle, Jay - NIDDK
 Hoover, Camille - NIDDK
 Horlick, Mary - NIDDK
 Hoshizaki, Deborah - NIDDK
 Hubbard, Van - NIDDK
 Hunter, Christine - NIDDK
 Hyde, James - NIDDK
 Imrie, Anne - Soc. and Sci. Sys., Inc.
 Irvins, Jon - CSR
 James, Stephen - NIDDK
 Jerkins, Ann - NIDDK
 Jones, Teresa - NIDDK
 Karp, Robert - NIDDK
 Ketchum, Christian - NIDDK
 Kimmel, Paul - NIDDK
 Kirkali, Ziya - NIDDK
 Kranzfelder, Kathy - NIDDK
 Kuczmarski, Robert - NIDDK
 Kurian, Ravee - NIDDK
 Kusek, John - NIDDK
 Laakso, Joseph - Endocrine Society
 Larkin, Jennie - NIH OD
 Laughlin, Maren - NIDDK
 Leschek, Ellen - NIDDK
 Linder, Barbara - NIDDK
 Malozowski, Saul - NIDDK
 Margolis, Ronald - NIDDK
 Martey, Louis - NIDDK
 Maruvada, Padma - NIDDK
 Mowrer, Karen - Lewis-Burke Associates
 Moxey-Mims, Marva - NIDDK
 Narva, Andrew - NIDDK
 Newman, Eileen - NIDDK
 Nurik, Jody - NIDDK
 Pawlyk, Aaron - NIDDK
 Perry-Jones, Aretina - NIDDK
 Pike, Robert - NIDDK
 Podskalny, Judith - NIDDK
 Polglase, William - NIDDK
 Rankin, Tracy - NIDDK
 Rasooly, Rebekah - NIDDK
 Reiter, Amy - NIDDK
 Roberts, Tibor - NIDDK
 Rosenberg, Mary Kay - NIDDK
 Rosendorf, Marilyn - NIDDK
 Rushing, Paul - NIDDK
 Rys-Sikora, Krystyna - NIDDK
 Sato, Sheryl - NIDDK
 Savage, Peter - NIDDK
 Scanlon, Elizabeth - NIDDK
 Sechi, Salvatore - NIDDK
 Serrano, Jose - NIDDK
 Sheard, Nancy - CSR
 Shepherd, Aliecia - NIDDK
 Sherker, Averell - NIDDK
 Silva, Corinne - NIDDK
 Smith, Philip - NIDDK
 Spain, Lisa - NIDDK
 Star, Robert - NIDDK
 Tatham, Thomas - NIDDK
 Teff, Karen - NIDDK
 Tilghman, Robert - NIDDK
 Torrance, Rebecca - NIDDK
 Tuncer, Diane - NIDDK
 Turner, Linda - NIDDK
 Wallace, Julie - NIDDK
 Wellner, Robert - NIDDK
 Wright, Elizabeth - NIDDK
 Yang, Jian - NIDDK
 Yanovski, Susan - NIDDK

C. ANNOUNCEMENTS

NIDDK-Funded Scientists Recently Elected to the National Academy of Sciences

Marius Clore, a researcher in the NIDDK Intramural Research Program, is an NIH Distinguished Investigator within the Institute's Laboratory of Chemical Physics, the Protein Nuclear Magnetic Resonance Section. His laboratory studies the structure and dynamics of proteins, protein-protein complexes, and protein-nucleic acid complexes

using multidimensional nuclear magnetic resonance (NMR) spectroscopy. It develops and applies novel NMR and computational methods to further these studies.

Dr. Martin R. Pollak, an NIDDK grantee, is the Chief of the Renal Division at Beth Israel Deaconess Medical Center in Boston, Massachusetts, and also a member of the Cancer Genetics Program at the Dana-Farber/Harvard Cancer Center. His laboratory studies the genetic basis of kidney disease, with particular emphasis on proteinuria and glomerulosclerosis. His research team also works to identify genes involved in the development of focal segmental glomerulosclerosis (FSGS) in minority populations. Dr. Pollak has several active NIDDK R01 awards in addition to an NIDDK MERIT award.

International Congress on Obesity (ISO) Awards

Dr. Rudy Leibel, former NIDDK Council member and grantee, received the Werthheimer Award for basic research at the International Congress on Obesity (ICO) of the World Obesity Federation. Dr. Leibel is the Christopher J. Murphy Professor of Diabetes Research in the Departments of Pediatrics and Medicine at Columbia University. He is also Co-director of the Naomi Berrie Diabetes Center and head of the Division of Molecular Genetics at Columbia.

Dr. Steven Blair, a former member of the NIDDK Clinical Obesity Research Panel, received the ICO's Population Science and Public Health Award. The award was established in 2006 to recognize an individual who has made outstanding contributions to the field of obesity. Dr. Blair is a Professor at the Arnold School of Public Health at the University of South Carolina.

"In Memoriam"

Dr. Richard W. Hanson, an NIDDK grantee for nearly 40 years, died in February 2014. He was the Leonard and Jean Skeggs Professor of Biochemistry and Distinguished University Professor at Case Western Reserve School of Medicine. A brilliant scientist and award-winning teacher, Dr. Hanson was known to his friends and colleagues as the "maestro of metabolism." Dr. Hanson served as a member of the NIDDK's Board of Scientific Counselors (BSC) from 1995 to 1997, and as its Chair from 1997 to 2000.

NIDDK Staff Members

Dr. Catherine McKeon, the NIDDK Senior Advisor for Genetic Research, retired in early May 2014, after a thirty-three year career at the Institute. She made major contributions to advancing NIDDK-funded research on the genetics of type 2 diabetes, genetic metabolic diseases, and cystic fibrosis, as well as gene therapy research. Her work in developing a consortium to find genes for type 2 diabetes is an important part of the foundation for a new NIH initiative, "Accelerating Medicines Partnership (AMP)." Her leadership of cystic fibrosis research furthered the development of new therapies for the disease, and was recognized with the NIH Director's Award. In 2013, Dr. McKeon,

and the late Dr. Sonia Skarlatos of the NHLBI, received the first Distinguished Service Award from the American Society of Gene and Cell Therapy.

Dr. Peter Perrin joined the NIDDK Division of Digestive Disease and Nutrition in May 2014. His program is evolving, and will include gastrointestinal immunology, microbiology and epithelial biology. Dr. Perrin received his Ph.D. from the University of Pennsylvania, where he studied the immunopathology of granuloma formation in the liver. During his research career, he has held positions at the Naval Medical Research Institute, the Uniformed Services University of the Health Sciences, and the University of Pennsylvania, where he continued investigating various aspects of immunology. He received NIH and private foundation support for his work. More recently, Dr. Perrin was a Scientific Review Officer (SRO) within the Digestive, Kidney, and Urological Systems Integrated Review Group of the NIH Center for Scientific Review (CSR).

NIDDK Information Network (dkNET)

The formal launch of the NIDDK Information Network, or dkNET, is planned for May 2014. This Network is intended to further the transition of biomedical research data into a digital enterprise including data, software, patient records, and publications. The dkNET will seek to foster centralized *in silico* discovery of data and resources in ways designed to inform stakeholders and to lead to new research advances. As a first step, the NIDDK has developed a highly linked digital data warehouse--starting with many of the Institute's basic science consortia, together with several human genetics databases. A web portal enables users to search through datasets and resources to enhance ongoing work, thereby facilitating research advances (www.dkNET.org). Where appropriate, links to related sources of data take the user to the broader universe of online digital networks. By creating an index of NIDDK-supported research, the dkNET has anticipated the more comprehensive NIH Initiative, "Big Data to Knowledge (BD2K)," which will enhance scientific discovery through the broader use of data. Dr. Rodgers acknowledged the many contributions of Drs. Ron Margolis, Art Castle, Kristin Abraham and other NIDDK staff to establishing dkNet.

II. CONSIDERATION OF SUMMARY MINUTES OF THE 194th COUNCIL MEETING

Dr. Rodgers

Following the motion of a Council member, the Council approved, by voice vote, the Summary Minutes of the 194th Council meeting, which had been sent to members in advance for review.

III. FUTURE COUNCIL DATES

Dr. Rodgers

Dr. Rodgers directed the Council members to the following future Council dates in the agenda.

2014

September 3-4 (Wednesday and Thursday)
Building 31, Conference Rooms 10, 6 and 7

2015

January 28-29 (Wednesday and Thursday)
May 13-14 (Wednesday and Thursday)
September 9-10 (Wednesday and Thursday)
Building 31, Conference Rooms 10, 6 and 7

2016

January 27-28 (Wednesday and Thursday)
May 18-19 (Wednesday and Thursday)
September 7-8 (Wednesday and Thursday)
Building 31, Conference Rooms 10, 6 and 7

The expectation is that meetings will be a single day. However, Council members were asked to hold two days on their calendars to ensure flexibility should a situation arise where a longer meeting is required.

IV. ANNOUNCEMENTS

Dr. Stanfield

Confidentiality

Dr. Stanfield reminded the Council that material furnished for review purposes and discussion during the closed portion of the meeting is considered confidential. The content of discussions taking place during the closed session may be disclosed only by the staff and only under appropriate circumstances. Any communication from investigators to Council members regarding actions on an application must be referred to the Institute. Any attempts by Council members to handle questions from applicants could create difficult or embarrassing situations for the members, the Institute, and/or the investigators.

Conflict of Interest

Dr. Stanfield reminded the Council that advisors and consultants serving as members of public advisory committees, such as the NIDDK National Advisory Council, may not participate in situations in which any violation of conflict of interest laws and regulations may occur. Responsible NIDDK staff shall assist Council members to help ensure that a member does not participate in, and is not present during review of applications or projects in which, to the member's knowledge, any of the following has a financial interest: the member, or his or her spouse, minor child, partner (including close professional associates), or an organization with which the member is connected.

To ensure that a Council member does not participate in the discussion of, nor vote on, an application in which he/she is in conflict, a written certification is required. A statement is provided for the signature of the member, and this statement becomes a part of the meeting file. Dr. Stanfield noted that each Council member's folder contained a statement regarding conflict of interest in his or her review of applications. He said that each Council member should read it carefully, sign it, and return it to the NIDDK before leaving the meeting.

Dr. Stanfield said that, at Council meetings when applications are reviewed in groups without discussion, that is, "en bloc" action, all Council members may be present and may participate. The vote of an individual member in such instances does not apply to applications for which the member might be in conflict. With respect to multi-campus institutions of higher education, Dr. Stanfield said that: An employee may participate in any particular matter affecting one campus of a multi-campus institution of higher education, if the employee's financial interest is solely employment in a position at a separate campus of the same multi-campus institution, and the employee has no multi-campus responsibilities.

NIH Resubmission Policy

Dr. Stanfield announced a change in the NIH resubmission policy for application due dates after April 16, 2014. (<http://grants.nih.gov/grants/policy/amendedapps.htm>) Following an unsuccessful resubmission (A1) application, applicants may submit the same idea as a new (A0) application for the next appropriate due date. The NIH will not assess the similarity of the science in the new (A0) application to any previously reviewed submission when accepting an application for review. Dr. Stanfield noted that this policy change will likely reduce the number of appeals that the Council will have to consider.

Expected Change in Biosketch

Dr. Stanfield said that the NIH is likely to change the Biosketch requirements for applicants. The concept is to replace the current listing of publications with a section entitled "Contributions to Science." In this new section, each applicant would provide a short description of up to five significant contributions, his or her role in these contributions, and reference to a few publications documenting that role. This idea will take the form of a pilot for a number of reviews scheduled in the fall of 2014. It is likely to be fully implemented for applications submitted after January 1, 2015.

V. REPORT FROM THE NIDDK DIRECTOR

Dr. Rodgers

FY 2014 Operating Plan

The NIH is currently operating at a total program level of \$30.15 billion. The NIH amount is an increase of \$1 billion over the agency's comparable FY 2013 level, but below its FY 2012 level. For the NIDDK, the total program level is approximately \$1.88 billion--an increase of about \$46 million over the Institute's FY 2013 funding level. This NIDDK figure includes about \$139 million for the congressionally-mandated Special Statutory Funding Program for Type 1 Diabetes Research, which the Institute administers on behalf of the Department of Health and Human Services in collaboration with other NIH components and the CDC.

The NIDDK plans to use the additional funds provided to support more research project grants, research training grants, and special emphasis grants than last year, and perhaps to undertake one or more new initiatives. Consistent with the Institute's core principles, the highest NIDDK priority is to raise paylines for investigator-initiated R01 research project grants. In general, the NIDDK will try to reach a 13th percentile payline for awards supporting new competing R01 grants (Type 1s) or competing continuations (Type 2s). The NIDDK will prioritize R01 applications that have a primary assignment to the Institute, request less than \$500,000 in direct costs per year, and score at or better than the 13th percentile through the peer review process. A more stringent payline will be applied to R01 applications requesting \$500,000 or more in direct costs for any year. Special emphasis will be placed on supporting Early Stage Investigators (ESIs). In addition, when possible and appropriate, the full period of recommended support will be awarded to ESIs. The NIDDK's FY 2014 Award Funding Policy is posted on the Institute's website (<http://www.niddk.nih.gov/research-funding/process/award-funding-policy>).

FY 2015 President's Budget Request

The President's FY 2015 budget request for the total program of the NIH is about \$210 million above the agency's FY 2014 operating level. For the NIDDK, the request is about \$12 million above the FY 2014 level. House and Senate hearings on the proposed budget were held on March 26 and April 2, respectively, by the appropriations subcommittees with jurisdiction over the NIH. The written testimony of NIH Director Francis Collins is posted on the NIH website (<http://www.nih.gov/about/director/budgetrequest/fy2015testimony.htm>).

During the hearings, subcommittee members encouraged Dr. Collins to share examples of research advances widely so that the public can learn more about the contributions of the NIH to fighting disease and improving health. Several members expressed support for the NIH mission and for increased funding. Dr. Collins noted that the future of biomedical research has never been brighter. He highlighted three examples of scientific opportunity: developing a universal flu vaccine; undertaking the "Brain Research through Advancing Innovative Neurotechnologies (BRAIN) Initiative;" and developing targeted cancer treatments. In response to a question about whether it would be better to have sustained, steady growth in funding for the NIH or a "Manhattan Project" approach to research, Dr. Collins said it would be most helpful for the research community to be able to count on a stable trajectory of funding increases.

Delays in finalizing the FY 2014 budget resulted in delays in submission of the FY 2015 budget. Since the hearings, a few appropriations bills have passed the House, but none has yet passed the Senate. It is hoped that the Congress will pass all 12 regular appropriations bills during the summer and send them to the President for signature before October 1, 2014--the start of FY 2015. If that does not happen, FY 2015 funding for some agencies will likely be provided through one or more continuing resolutions or an omnibus spending bill.

Extension of Special Statutory Funding Program for Type 1 Diabetes Research

This congressionally-mandated program has been extended for an additional year, through FY 2015. Because the program is considered mandatory, it will continue to be subject to a sequestration process that is not being applied to discretionary programs. As a result, the program's actual funding level in FY 2015 will be about \$139 million, instead of the full \$150 million authorized in the legislative extension. Funding plans include moving forward the most promising research on development of an artificial-pancreas from the level of single-site, short-duration studies to the level of multi-center, longer-term studies. Plans are also under way to integrate the various large data sets in genomics, proteomics, metabolomics, and the microbiome that are emerging from the trial, "The Environmental Determinants of Diabetes in the Young (TEDDY)."

"Accelerating Medicines Partnership (AMP)"

In February 2014, NIH Director Francis Collins announced the formation of a new initiative, the "Accelerating Medicines Partnership" (AMP), to be managed through the Foundation for the NIH (FNIH; <http://www.nih.gov/science/amp/index.htm>). The AMP is a joint effort involving the NIH, 10 biopharmaceutical companies, and several non-profit organizations. The AMP is intended to transform the current model for developing new diagnostics and treatments through the collaborative identification and validation of promising biological targets of disease. The ultimate goals are to increase the number of new diagnostics and therapies for patients, and to reduce the time and cost of developing them. Through the cross-sector partnership of the AMP, the NIH and industry will share expertise and resources in an integrated governance structure that will enable the best informed contributions to science from all participants. A critical component of the undertaking is that industry partners have agreed to make the AMP data and analyses publicly accessible to the broad biomedical research community. The AMP will begin with three pilot projects to pursue research plans developed by NIH and industry scientists for characterizing effective molecular indicators of disease (biomarkers) and for distinguishing biological targets that are most likely to respond to new therapies. These pilot projects will set the stage for broadening the AMP to other diseases and conditions.

Type 2 diabetes will be the focus of one of the three pilot projects. That pilot will build on the NIDDK's substantial investment in diabetes research. To date, scientists have identified nearly 80 genes known to have common variants that raise or lower the risk of type 2 diabetes. Advances in technology have enabled the study of these genes in

hundreds of thousands of people with and without diabetes in order to identify rare mutations that can significantly reduce the risk of developing the disease. Two objectives of the AMP's type 2 diabetes pilot project are to support deep sequencing studies of diabetes genes, and to set up a diabetes genetics knowledge portal. The portal will be designed to aggregate, organize, and facilitate the interpretation of massive amounts of genetic information, and thus make it more rapidly and easily usable for drug development purposes. Dr. Rodgers acknowledged the contributions of the NIDDK's Dr. Phil Smith, who has served as the co-director of the steering committee for the type 2 diabetes pilot project.

Following the NIH Director's announcement of the AMP, staff the House and Senate authorizing committees for the NIH requested briefings. Dr. Rodgers said that he described the type 2 diabetes project at a briefing in March 2014.

VI. BRAIN RESEARCH THROUGH ADVANCING INNOVATIVE NEUROTECHNOLOGIES (BRAIN) INITIATIVE

Dr. Story Landis, Director, National Institute for Neurological Disorders and Stroke (NINDS)

Dr. Rodgers introduced Dr. Story Landis, who has been Director of the National Institute for Neurological Disorders and Stroke (NINDS) since 2003. Dr. Landis received her Ph.D. from Harvard University. After postdoctoral work at Harvard, she served on the faculty of the Department of Neurobiology there. In 1985, she joined the faculty of Case Western Reserve University School of Medicine, where she created the Department of Neurosciences which, under her leadership, achieved an international reputation for excellence. Throughout her research career, Dr. Landis has made fundamental contributions to the understanding of nervous system development. Dr. Landis has garnered many honors, is an elected fellow of the Institute of Medicine, the Academy of Arts and Sciences, the American Association for the Advancement of Science, and the American Neurological Association, and in 2002, she was elected President of the Society for Neuroscience.

Research Needs and Opportunities

Dr. Landis provided an overview of the new "Brain Research through Advancing Innovative Neurotechnologies" Initiative (BRAIN), which President Obama announced at the White House on April 2, 2013 (<http://www.nih.gov/science/brain/>). The President said that the BRAIN initiative will give scientists "the tools they need to get a dynamic picture of the brain in action, and to better understand how we think and how we learn and how we remember." Through the Initiative, scientists will learn the language of the brain.

Identified as a high-priority "Grand Challenge" by the Office of Science and Technology Policy, the initiative currently includes the participation of several NIH Institutes: the National Institute of Neurological Disorders and Stroke (NINDS), the National Institute of Mental Health (NIMH), the National Institute on Drug Abuse (NIDA), the National

Institute of Biomedical Imaging and Bioengineering (NIBIB), and the NIH components that are participating in the “Blueprint for Neuroscience Research.” Participants also include the National Science Foundation (NSF), the Food and Drug Administration (FDA), and the Defense Advanced Research Projects Agency (DARPA) of the Department of Defense. The President envisions the BRAIN Initiative as a broad national effort and is therefore also interested in discussions with companies, philanthropies, foundations, non-profits, universities and state governments to explore the possible contributions they can make to leverage expertise and resources.

Dr. Landis noted that the BRAIN initiative is timely and compelling because it is at the intersection of serious health needs and promising research opportunities. Brain disorders are widespread, and they place a heavy burden on patients, their families and society. For example, the annual cost of dementia care in the U.S. is estimated to be about \$200 billion. The neurodegenerative disorders include Alzheimer’s, Parkinson’s, and Huntington’s diseases, as well as Amyotrophic Lateral Sclerosis (ALS). Cognitive and affective disorders range from schizophrenia and bipolar disorder to depression, anxiety and obsessive compulsive disorder. Among the neurodevelopmental disorders are autism, attention-deficit disorder, epilepsy, and intellectual disability. Injury-induced and insult-induced disorders include Post-Traumatic Stress Disorder (PTSD), traumatic brain injury and stroke. Many Americans are acutely aware of these serious health issues because family members and friends are struggling with them.

To help address these health needs, the BRAIN initiative will focus on tools and technologies to capitalize on new insights into brain structure and function that have been recently achieved through interdisciplinary and integrative research. Neuroscientists are harnessing knowledge from many areas, including chemistry, physics, genetics, nanotechnology, and informatics. Dr. Landis presented a series of visuals that show how new tools and technologies are already deciphering the workings of the brain to reveal the way the nervous system functions in health and disease. Imaging techniques have been particularly important in tracking the processes of brain cells. One technique called “CLARITY” is a revolutionary method for transforming brain tissue by making it transparent, while maintaining important properties, thereby enabling the tissue to be stained and studied more easily than through traditional methods. For example, Dr. Landis noted that this technique has been used for 3D analysis of intact mouse brain tissue. She pointed out that the technique has application not only to brain tissue, but also to tissue of the digestive system or kidneys, which may be of interest to NIDDK investigators (<http://www.nature.com/nature/journal/v497/n7449/full/nature12107.html>).

Guiding and Overseeing the BRAIN Initiative

Although research advances have been remarkable, Dr. Landis said that the ability of scientists is still limited with respect to understanding how the brain encodes, stores, and retrieves information. Additional tools and technologies are therefore needed to assess how the parts of the brain work together to generate patterns of activity; how these patterns are translated into thoughts, behaviors, and emotions; and how experiences alter the brain’s organization. Neural circuitry must be deciphered. In tackling these issues,

the BRAIN Initiative will be guided by a newly established Working Group of the Advisory Committee to the Director, NIH (ACD), co-chaired by Drs. Cornelia Bargmann of The Rockefeller University and William Newsome of Stanford University. The NIH organizational locus for the BRAIN Initiative will be the Office of the NIH Director.

In an Interim Report issued in September 2013, the Working Group of the ACD laid out the framework for the Initiative (<http://www.nih.gov/science/brain/11252013-Interim-Report-Final.pdf>). Based on input obtained by canvassing neuroscientists throughout the country, the Working Group outlined key principles, which include using appropriate experimental systems and models; crossing boundaries in interdisciplinary collaborations; integrating spatial and temporal scales; establishing platforms for sharing data; validating and disseminating technology; and considering ethical implications of neuroscience research. The Working Group also identified the following high-priority research areas: generate a census of cell types; create structural maps of the brain; develop new large-scale, network-recording capabilities; develop a suite of tools for circuit manipulation; link neuronal activity to behavior; integrate theory, modeling, statistics, and computation with experimentation; delineate mechanisms underlying human imaging technologies; create mechanisms to enable collection of human data; and disseminate knowledge and training. The Working Group expects to issue a final report that will be presented to the ACD in June 2014, and made available to the public.

In addition to guidance from the Working Group of the ACD, the Brain Initiative will benefit from expert oversight provided by a Multi-Council Working Group, which is representative of the NIH Institutes and Centers (ICs) that have BRAIN-focused research, as well as *ex officio* representation from other agencies involved in the BRAIN Initiative. The Multi-Council Working Group will integrate BRAIN research across the NIH, and will draft concepts and recommendations for review and consideration by one or more of the National Advisory Councils of the participating NIH components.

NIH Efforts and Planned Funding Levels

Based on the recommendations of the BRAIN Working Group of the ACD, during the winter the NIH issued six Requests for Applications (RFAs) outlining funding opportunities (<http://www.nih.gov/science/brain/funding.htm>). Two of the funding announcements called for developing methods for classifying and accessing the diverse cells and circuits of the brain. Three focused on developing and optimizing technologies for recording and modulating collections of cells that function together as a circuit. One announcement supported the formation of interdisciplinary teams of scientists to develop the next generation of non-invasive imaging technologies for human research. It is expected that the projects funded through these RFAs will be announced in September 2014.

For the NIH, the investment in the Brain Initiative in FY 2014 is estimated to be \$40.7 million. Of that total, an estimated \$22 million is considered “new money” that would not otherwise have been provided to the NIH without the Initiative. The \$40.7 million reflects contributions from several sources, including: \$12.85 million from NIMH;

\$12.85 million from NINDS; \$4 million from NIDA; and \$1 million from NIBIB. The \$40.7 million also includes \$10 million contributed through the NIH “Blueprint for Neuroscience Research,” which involves the participation of several NIH components (NCCAM, NEI, NIA, NIAAA, NIBIB, NICHD, NIDA, NIDCD, NIDCR, NIEHS, NIGMS, NIMH, NINDS, NINR, OBSSR; http://neuroscienceblueprint.nih.gov/blueprint_basics/about_bp.htm).

Dr. Landis emphasized that the \$40.7 million for the BRAIN Initiative is a relatively small part of the total NIH investment in neuroscience research, which is approximately \$5.5 billion annually. She said that the goals of the BRAIN Initiative are already high-priority areas for the participating NIH components; therefore, the Initiative is compatible with existing scientific emphases and objectives. Clearly, neuroscience research--and particularly investigator-initiated regular research grants (R01 grants)--will continue to be supported throughout the NIH beyond the parameters of the BRAIN initiative. Moreover, the BRAIN Initiative is expected to develop innovative tools and technologies that will accelerate other areas of neuroscience research by enhancing scientific capabilities for conducting hypothesis-driven, disease-focused research through R01 grants. Thus, the tools and technologies that will emanate from the BRAIN Initiative will not be ends in themselves, but rather enablers of further research to obtain insights about the workings of the brain in health and disease states.

Dr. Landis pointed out that the President’s Budget for FY 2015 requests approximately \$60 million in additional funds for the BRAIN Initiative, raising the planned total investment to approximately \$100 million for that fiscal year. She is optimistic that funding for the Initiative will continue to increase as the initial projects begin to bear fruit, thereby providing momentum for additional funding to support the development of consortia and other long-term projects.

Planned Efforts of Other Agencies

Dr. Landis gave some examples of the planned contributions of some other agencies to the BRAIN Initiative.

Defense Advanced Research Projects Agency (DARPA): Four efforts are currently planned along the following general lines: (1) development of system-based neurotechnology for emerging therapies; (2) restoration of active memory (RAM) through a wireless device that would repair brain damage and restore memory loss; (3) development of prosthetic hand proprioception and touch interfaces; (4) issuance of an open solicitation for proposals to enable revolutionary advances at the intersection of biology/neurosciences with engineering/physical/computer sciences.

National Science Foundation (NSF): A Science and Technology Center is planned, with a focus on “Brains, Minds, and Machines.” Research Coordination Networks are also planned for organizing the scientific community and for increasing BRAIN Initiative collaborations. The NSF is prioritizing research in three areas: (1) integrative and interdisciplinary research; (2) new theories, computational models, and analytical tools;

and (3) development of innovative technologies and data infrastructure to handle large-scale datasets resulting from this research. Several meetings are planned to help move the BRAIN initiative forward.

Development of Core Bioethical Standards for Neuroscience Research

As part of the BRAIN Initiative, the Presidential Commission for the Study of Bioethical Issues has been charged with proactively identifying a set of core ethical standards to guide not only the Initiative, but the entire area of neuroscience research, and to address ethical dilemmas raised by the application of research findings. To this end, the Commission held public meetings in August and December of 2013, and in February 2014. In May 2014, the Commission issued the first volume of its planned two-part report to respond to ethical issues in this rapidly evolving field. The report is entitled: *Volume I--Gray Matters: Integrative Approaches for Neuroscience, Ethics, and Society*. (<http://bioethics.gov/node/3543>).

Collectively, these and other efforts are expected to further the President's goal of accelerating "the development and application of new technologies that will enable researchers to produce dynamic pictures of the brain that show how individual brain cells and complex neural circuits interact at the speed of thought."

Council Questions and Discussion

Several Council members commended Dr. Landis on her presentation. They noted that it is a very exciting time for brain research, and that the BRAIN Initiative provides a relatively new governance approach for research. The issues raised by the Council members related primarily to funding, and the scientific scope of the BRAIN initiative--specifically, its relationship to the NIDDK research mission.

Sustainability of Initiative: *Will the BRAIN Initiative have a sustainable budget when the first set of funded investigators apply for continued support? Will applications focused on tools and technologies fare well in peer review, given that many reviewers tend to deal with applications that are disease-oriented and translation-oriented?* Dr. Landis replied that the \$40.7 million funding commitment for FY 2014 will not cease when the first set of "starter" grants reach their end dates. The President's budget for FY2015 calls for the total NIH investment in the Initiative to rise from \$40.7 million to about \$100 million that year. Moreover, it is likely that new discoveries will fuel additional funding increases in the future. For example, optogenetics technology is now revolutionizing the neurosciences by enabling the use of light to turn specific subsets of neurons "on" or "off" in circuits within living brain tissue. More than 200 NIH grantees have already obtained supplemental funds to incorporate the technology into their ongoing studies. Optogenetics is the type of tools that can be expected to emerge from the BRAIN initiative to drive the funding of new research and discoveries.

Attracting Capital: *How can the NIH help to prime the pump for the BRAIN Initiative, which appears to be woefully underfunded? Can the Initiative attract non-government*

capital that is sitting uninvested on the sidelines of this country? Dr. Landis responded that many groups and individuals are being considered as potential partners, including the Allen Institute for Brain Science, the Howard Hughes Medical Institute, and the Simons Foundation. In the corporate arena, General Electric, Qualcomm and Google are some of the companies that appear interested in the Initiative. Obtaining non-government support will be essential for the BRAIN Initiative to reach fully operational levels, which could involve the investment of hundreds of millions of dollars annually. Importantly, it is recognized that the Initiative should not disrupt ongoing federal research programs, such as those focused on therapies for neurodegenerative diseases, development of prostheses, functional electrical stimulation for spinal cord injuries, and other clinically-oriented areas. Dr. Landis emphasized that the Initiative will not detract from the NIH funding of investigator-initiated R01 research grants.

NIDDK Metabolic and Obesity Research Relevant to the Brain: *Although the NIDDK is not currently involved in the BRAIN Initiative, it probably should consider participating in some way in light of the Institute's brain-related research in metabolism and other areas. For example, obesity is an important research area for the NIDDK and the NIH generally. This research needs increased funding given that the pharmaceutical industry is retreating from studies of the central nervous system (CNS) as a target for anti-obesity drugs--partly because of increasingly difficult regulatory hurdles. Human obesity is primarily a brain disease, involving many mutated genes whose main action is in the brain. Therefore, human obesity should be included in disease-focused research for which the BRAIN Initiative could have application, and its inclusion could attract renewed investments by the pharmaceutical industry.* Dr. Landis commented that the retreat of the pharmaceutical industry from CNS studies is adversely affecting many disease areas, including the development of therapeutics for psychiatric disorders. However, part of the reason that new drugs with new mechanisms have not emerged in CNS-related areas is because of insufficient fundamental knowledge about the brain. The BRAIN Initiative is a way of investing in the acquisition of that knowledge.

Collaborative Opportunities: *If the BRAIN Initiative becomes a "call to action," then each NIH component may want to consider announcing collaborative funding opportunities, possibly through consortia, in which neuroscientists who are developing new technologies work together on projects with scientists who conduct research on the physiology of diseases related to the brain stem and other parts of the body. These diseases, such as gastrointestinal disorders, represent considerable health burdens and are a huge part of the NIH research portfolio.* Dr. Landis replied that there will be opportunities for the broad research community to adopt technologies generated by the BRAIN Initiative. Collaborations among neuroscientists and other scientists could be furthered through projects that integrate the talents of researchers who have used different strategies to study a particular area, such as neural plasticity. Scientists who are not working on brain issues can probably find highly skilled counterparts in the neuroscience or neurobiology departments of their academic institutions and establish fruitful collaborations. One could also look at research opportunities presented by the variety of mice that express fluorescent proteins and subsets of neurons in somatic tissue.

Assessing Return on NIDDK Investments: *Where can the NIDDK get the highest return on its investment in brain-related research in this time of limited resources? The NIDDK needs to assess carefully the importance of a particular brain-related research area to the Institute's overall mission, and whether the area is really ripe for successful synergistic interactions. Many problems in neuroscience research, such as neurodegeneration, do not seem to be on the brink of resolution. However, in areas such as feeding behavior, the NIDDK has a strong interest and has already had a huge leadership impact. Dr. Landis noted that the NIDDK has an opportunity to join the "Blueprint for Neuroscience Research," which is part of the BRAIN Initiative. However, whether or not the NIDDK formally participates, the BRAIN Initiative will produce tools and technologies likely to be useful in answering questions that are important to the NIDDK research mission.*

Narrow Focus of BRAIN Initiative: *Are there plans to include the social sciences in the BRAIN Initiative given that interactions between biology and social/physical environments are being increasingly recognized as important to brain function and health? Dr. Landis commented that the neuroscience field is an incredibly broad discipline, which includes the social sciences. However, in order to make the BRAIN Initiative workable within the funds provided, it needs to adhere to the narrow focus of tools and technologies to understand brain circuits and how they function, including the use of appropriate model systems. The approximately \$5.5 billion that the NIH is expending on the neurosciences will support other research areas including the social sciences, the potential therapeutic use of stem cells for brain disorders, and the identification of genes that affect the nervous system.*

VII. UPDATE FROM THE NIH ASSOCIATE DIRECTOR FOR DATA SCIENCE: Big Data to Knowledge (BD2K) and Beyond
Dr. Philip Bourne, Associate Director for Data Science, NIH

Dr. Rodgers introduced Dr. Philip Bourne, who very recently joined the NIH as the first permanent NIH Associate Director for Data Science. Dr. Bourne will lead an NIH-wide priority initiative to take greater advantage of the exponential growth of biomedical research datasets. He comes to the NIH from the University of California, San Diego, where he was the Associate Vice Chancellor for Innovation and Industry Alliances, Office of Research Affairs, and Professor in the Department of Pharmacology and the Skaggs School of Pharmacy and Pharmaceutical Sciences. He was also Associate Director of the Research Collaboratory for Structural Bioinformatics (RCSB) Protein Data Bank. Dr. Bourne was trained as a physical chemist and obtained his Ph.D. from The Flinders University in South Australia. His professional interests focus on relevant biological and educational outcomes derived from computation and scholarly communication. This work involves the use of algorithms, text mining, machine learning, metalanguages, biological databases, and visualization applied to problems in systems pharmacology, evolution, cell signaling, apoptosis, immunology, and scientific dissemination. Dr. Bourne has published over 300 papers and five books. One area to which he is especially committed is furthering the free dissemination of science through

new models of publishing and through the better integration and subsequent dissemination of data and results.

Dr. Bourne presented seven factors that favor a system in which scientific data are shared and available in an open way for all potential users.

(1). The era of open data has the potential to deinstitutionalize and democratize science. Dr. Bourne pointed out that the scientific establishment can benefit from “disruptions” in the usual practices and scientific culture with respect to generating, analyzing, and publishing data. He recounted a “disruption” that occurred when a 15-year-old high-school girl was able to produce an innovative scientific paper with her own methodology by using the open literature and available computer resources. According to Dr. Bourne, the NIH should be thinking about how it can take advantage of these types of “disruptions” that come from unexpected people and sources.

(2). It is becoming increasingly difficult to reproduce research findings, even for the investigators who first generated them. It can take a graduate student about 280 hours to reproduce published findings when all the data and software are readily available.

(3). Enormous amounts of data are accumulating. It is estimated that there will be 5,000 gigabytes of information for every person on the planet by the end of the decade.

(4). Little is known about how existing biomedical research data are being used. Yet, companies--such as Google, Amazon, and Netflix--are making very practical connections and marketing decisions based on the way their customers’ use data. More effort could be spent on analyzing the uses of scientific data to facilitate practical connections among people who may be unaware they have common interests.

(5). Some suggest that society is at an inflexion point for change in the acquisition, storage and use of data. For example, commercial companies such as Google are now able to process, in real time, very large amounts of data to get an instantaneous result (*The Second Machine Age: Work, Progress and Prosperity in a Time of Brilliant Technologies* by Eric Brynjolfsson and Andrew McAfee).

(6). Aspects of scholarship appear to be broken. Thousands of scientific citations are never read because they don’t cite data that is meaningful to people. The comparison of scientific papers in different journals based on citations can lead to flawed evaluations. Important data sets can be lost or become inaccessible because scientists lack storage capabilities. Little credit is given to scientists who edit journals. It would be helpful for university administrators to discuss developments in scholarship and share positive changes that represent best practices.

(7). The reward system for scientists is in need of repair. While publishing is important, rewards should also be offered for other forms of scholarship. Many talented young computer scientists don’t have a road toward tenure at academic research institutions and

they are taking positions with private companies where they will receive greater compensation and recognition for their work.

Breaking Down Silos: Concept for a Biomedical Research Data Enterprise

Dr. Bourne described some approaches that could help address problems in data science. One important, positive trend is that the federal government is issuing new policies and regulations calling for the sharing of data acquired through the use of public funds. However, at current resource levels, federal agencies do not have the wherewithal to establish data-sharing systems. Nevertheless, there are other drivers for data sharing, including the establishment of innovative conceptual and organizational approaches.

In that regard, Dr. Bourne presented the concept of a “Biomedical Research Digital Enterprise,” which would break down silos in data science and foster data-sharing efficiencies. The NIH and other partners in the enterprise would coalesce around the programmatic themes of Sustainability, Education, Innovation, Process, and Collaboration. Each theme would have one or more deliverables and features. The NIH would be guided by a Scientific Data Council and External Advisory Board established under the NIH Associate Director for Data Science. Dr. Bourne elaborated on the way the five themes would be pursued.

Sustainability--The Power of the Commons: To realize a sustainable Biomedical Research Digital Enterprise that promotes data-sharing, Dr. Bourne believes that several changes would be required, such as giving more credit to data scientists; changing funding models; promoting more public/private partnerships, interagency coordination, and international cooperation; having better evaluation of and more informed decisions about the use of existing and proposed resources; and promoting the role of institutional data repositories.

The primary deliverable for the Sustainability Theme would be the creation of a digital science “Commons,” which would essentially characterize digital assets and promote their effective and efficient use. The Commons would not be a substitute for the publication of scientific papers, but rather, another means for sharing scientific results and discoveries. Dr. Bourne emphasized that the Commons would be “owned” and managed by the scientific community, with guidance from the NIH. It would be built through agile, incremental steps involving experiments with pilot projects. The Commons would be a way that investigators could store and make their data accessible to others, consistent with new data-sharing policies.

The Commons would build on NIH efforts already under way to catalogue existing software and datasets so that they can be “discoverable,” rather than resources that often disappear from use due to storage and accessibility problems. Clearly, a business model would have to be developed for the Commons, which would include public-private partnerships. An example of a community effort that is starting to coalesce around the idea of a Commons is the Global Alliance for Genomics and Health, which has attracted

the interest of private sector companies such as Google, Amazon, and Microsoft (<http://genomicsandhealth.org/>).

Dr. Bourne presented a schematic to display the way the Commons would work, with data science contributions from stakeholders, including NIH awardees, the rest of academia, government, and the private sector. Participants would work collaboratively to make the fruits of scientific discovery openly accessible in an interoperable system that would foster usability, metrics/standards, quality, reproducibility, security/privacy, and sustainable, drop-box-like storage using cloud computing. It is likely that enhanced collaboration and additional scientific discoveries would result from these features, which would promote the cross-fertilization of ideas.

Dr. Bourne described one possible end point of the concept he outlined. A scientist could click on a thumbnail of a figure in a scientific paper to pull up the underlying data, which would be rendered in a way to enable analysis and annotation. The paper would thus become an executable experiment in its own right based on the data associated with it. As more scientists annotated the paper and saw the annotations of others, a database/literature match-up could lead to the development of new collaborations and scientific progress that might not otherwise occur. Papers, data, and data bases would no longer exist as separate enterprises; instead, they would be linked together in a digital enterprise (Bourne, Philip. "The Path to Open Science," *PLoS Comp. Biol.* 2005 1(3) e34. Also: "What Big Data Means to Me" *JAMA* 2014 21:194) .

To explore these ideas, Dr. Bourne intends to bring an NIH data science group together in the spring/summer of 2014 to gather information about the activities and needs of the Institutes and Centers, as well as external communities. He would like the group to discuss shared interests in developing a cloud-based Commons, investigate potential models of sustainability, and consider metrics of usefulness and success.

Education/Training: Another Programmatic Theme in the concept for a Biomedical Research Digital Enterprise is education. Dr. Bourne said that quite a lot of activity is taking place in education/training that may lead to improvements in data science, but more coordination is needed. One possible deliverable is the establishment of training centers along the lines of Cold Spring Harbor. For a week or two, graduate students, faculty, and post-docs could all use standardized data sets to work through some overarching data-science problems, and also have time to work on their own individual data issues.

Innovation--BD2K: The deliverable under the Innovation Theme is the NIH "Big Data to Knowledge" Initiative or B2DK, which is already under way. Data-sharing is a key part of this initiative, which is emblematic of the new directions the NIH can take in digital science. The B2DK initiative seeks to enable biomedical scientists to capitalize more fully on the extensive amount of data generated by the research community. By supporting research, implementation, and training in data science and other relevant fields, B2DK fosters the development of a new infrastructure in which approaches, standards, methods, tools, software, and competencies promote greater, more efficient

use of biomedical research data

(http://bd2k.nih.gov/about_bd2k.html#sthash.BIO6kpfh.dpbs).

Process: The main deliverable under the Process Theme would be modification of the peer review for grant applications involving digital science. Currently, data science tends to be reviewed within applications focused on biological processes and therapeutics; therefore, the reviewers usually do not have the expertise to assess the data-science components. Moreover, best practices in the peer review of data science are not widely disseminated. One suggested change would be to have a standing Study Section for data science. Another possibility would be to have a team of data-science experts who could assist in the review of grants that have data-science elements. Portfolio analyses with respect to data science, as well as the development/dissemination of metrics, would also be useful modifications.

Collaboration: Improved communication among the stakeholders in a Biomedical Research Digital Enterprise would be the deliverable under the Collaboration Theme. One approach would be the convening of meetings to bring stakeholders together to share ideas, reduce inefficiencies, and forge partnerships.

Council Questions and Discussion

Council members found that Dr. Bourne's presentation illuminated many of the challenging issues in data science. For example, on the input side, there is a lack of standardization regarding the way biomedical research studies are conducted and data are collected, thus making it difficult to compare study results. On the output side, enormous quantities of data are being generated, and problems with storage/accessibility are mounting.

Standardization: *What can be done to achieve greater standardization of data?* Dr. Bourne replied that greater standardization will require an evolutionary process within the scientific community, rather than an NIH investment in a monolithic system that may or may not be used by grantees. As a practical matter, the NIH cannot simply define and enforce data standards. Rather, the producers and users of data need to recognize that standards are needed, and then take steps to coalesce in order to define and adopt standards. The NIH role would be to nurture that process, and perhaps maintain the resulting new standards through the National Library of Medicine. As data become increasingly digitized and accessible, scientists would find it easier to reproduce the findings of others or explain the reasons for different findings. Important steps toward greater standardization would include cataloging of existing data, promoting data-sharing policies, and giving credit to software developers.

Interoperability: *Isn't there a need for a strong entity to step in and be a "driver" of interoperability? The reward system in academia reinforces a natural tendency to work in silos. Even the private sector seems incapable of furthering interoperability, as evidenced by the many different commercial systems for maintaining the electronic medical records of patients.* Dr. Bourne said that the issues confronting data science are

so serious right now that economics is the likely driver of change. It is simply not possible for data science to continue in its present state, with so many separate, redundant, functionally different databases and systems. The economic need for efficiencies can be expected to drive improvements in data storage/sharing, standards, and interoperability, and also the creation of partnerships. Undoubtedly, there would be resistance to change, but economic necessity is likely to prevail. Pilot studies and experiments could help lead the way. Ultimately, providing open, facile access to data would not only be efficient, but it would also enable researchers to perceive commonalities with each other, which in turn would spur new scientific collaborations and discoveries.

Role of Medical Associations: *Is there a place for optimizing the sharing of clinical/translational data in the digital enterprise described? If so, should medical associations be part of the circle of partners?* Dr. Bourne replied affirmatively, noting that physician-scientists would probably benefit from greater access to data on very large patient cohorts. He also noted that he is working with the Patient Centered Outcomes Research Institute (PCORI).

Useful Models: *In medical research, institutions have disparate policies on how to handle human studies data, and particularly genetic data. Can lessons be learned from the Network for Excellence in Neuroscience Clinical Trials (NeuroNEXT Network) that provides a robust, standardized, and accessible infrastructure to facilitate clinical trials on neurological disorders?* Dr. Bourne responded that he is very interested in exploring possible models, and that he wants to learn more about the NeuroNEXT Network.

Pilot Studies and Funding Mechanisms: *Could the NIH envision a pilot project wherein it would provide administrative supplements to encourage innovations relative to data analysis?* Dr. Bourne said that funding and review mechanisms would need to be evaluated going forward. For example, while the centers mechanism has been suggested, it may not be optimal for nurturing the entire Biomedical Research Digital Enterprise. There would need to be a reasonable governance model to encourage progress that would benefit the entire research community. Data-science competitions, micro-grants, and open reviews are some ideas for moving data science forward toward the creation of a Biomedical Research Digital Enterprise.

VIII. SCIENTIFIC PRESENTATION: The Good, the Bad, and the Ugly of Intestinal Heat Shock Proteins

Dr. Eugene Chang

Dr. Rodgers introduced the presentation by Council Member Dr. Eugene Chang, the Martin Boyer Professor of Medicine at the University of Chicago. Dr. Chang's research focuses on host-microbial interactions of the intestine. His work includes studies to understand how perturbations or types of enteric flora contribute to the development of digestive diseases, especially inflammatory bowel diseases (IBD). Dr. Chang has defined several novel mechanisms and mediators of action of probiotic organisms that are currently being developed as therapeutic agents. Dr. Chang earned his M.D. at the

University of Chicago Pritzker School of Medicine. He then completed his residency in internal medicine and fellowship in gastroenterology at the University of Chicago before joining the faculty there. He presently has an active NIDDK institutional research training grant award (T32 grant) that supports a program for postdoctoral trainees in digestive diseases and nutrition, and pre-doctoral trainees in metabolism and nutrition.

IX. CONSIDERATION OF REVIEW OF GRANT APPLICATIONS

A total of 1,434 grant applications, requesting support of \$459,506,974 were reviewed for consideration at the May 14, 2014 meeting. Funding for these applications was recommended at the Scientific Review Group recommended level. Prior to the Advisory Council meeting, an additional 932 applications, requesting \$274,771,428 received second-level review through expedited concurrence. All of the expedited concurrence applications were recommended for funding at the Scientific Review Group recommended level. The expedited concurrence actions were reported to the full Advisory Council at the May 14, 2014 meeting.

X. ADJOURNMENT

Dr. Rodgers

Dr. Rodgers expressed appreciation on behalf of the NIDDK to the presenters and discussants. He thanked the Council members for their attendance and valuable input. There being no other business, the 195th meeting of the NIDDK Advisory Council was adjourned at 4:30 p.m. on May 14, 2014.

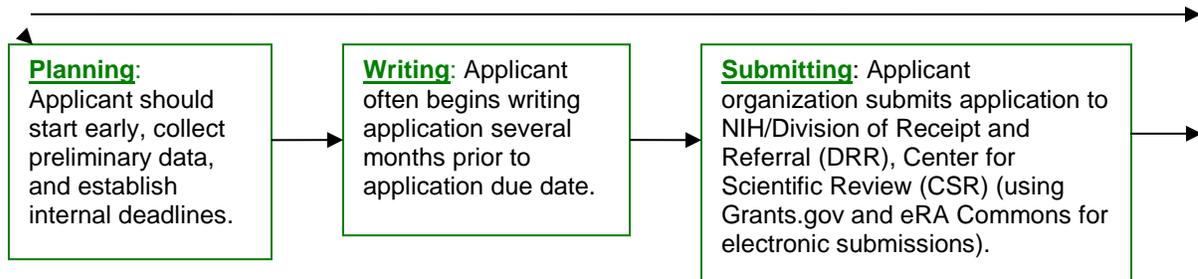
I hereby certify that, to the best of my knowledge, the foregoing summary minutes are accurate and complete.

Griffin P. Rodgers, M.D., M.A.C.P.
Director, National Institute of Diabetes and Digestive and Kidney Diseases, and
Chairman, National Diabetes and Digestive and Kidney Diseases Advisory Council

Grants Process At-A-Glance

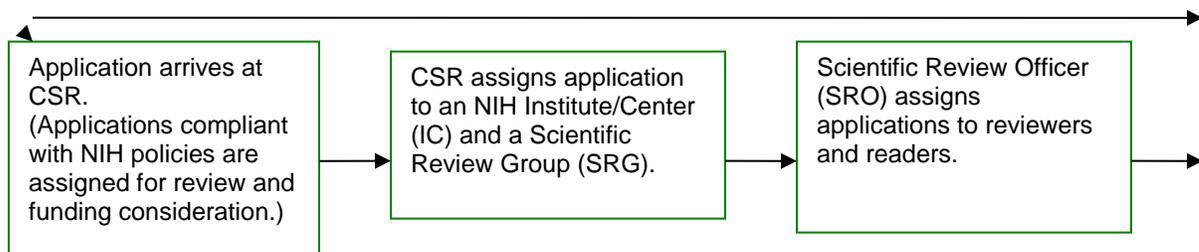
The following NIH "Grants Process At-A-Glance" chart is provided as a sample of the general time element necessary for a competing application to proceed from Receipt and Referral through the Peer Review process to negotiation and award.

Planning, Writing, Submitting



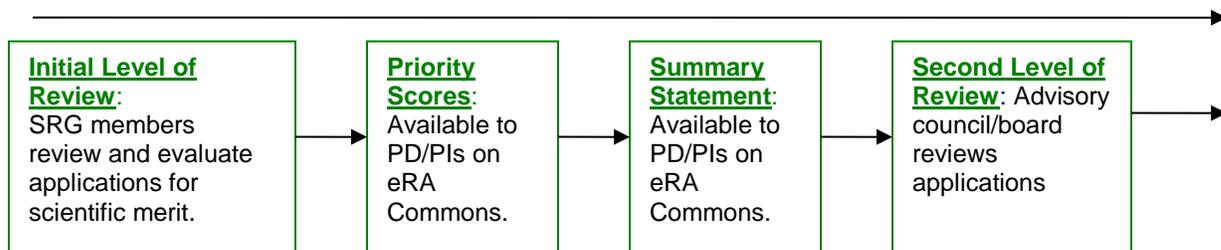
Receipt and Referral

Months 1 to 3



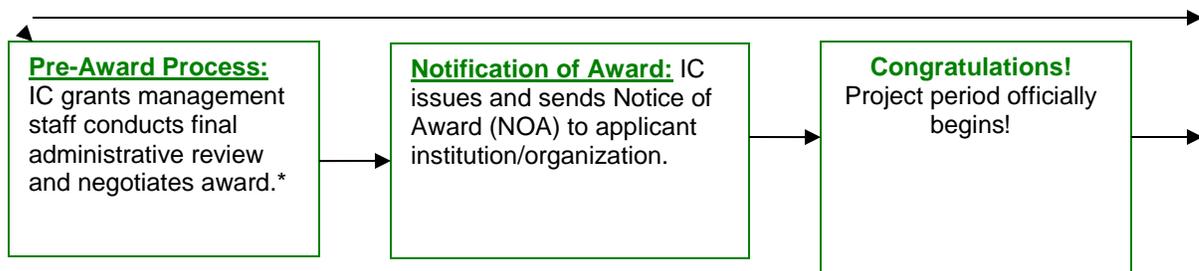
Peer Review

Months 4 to 8



Award (*Requests additional information needed [just-in-time](#) for award.)

Months 9 to 10



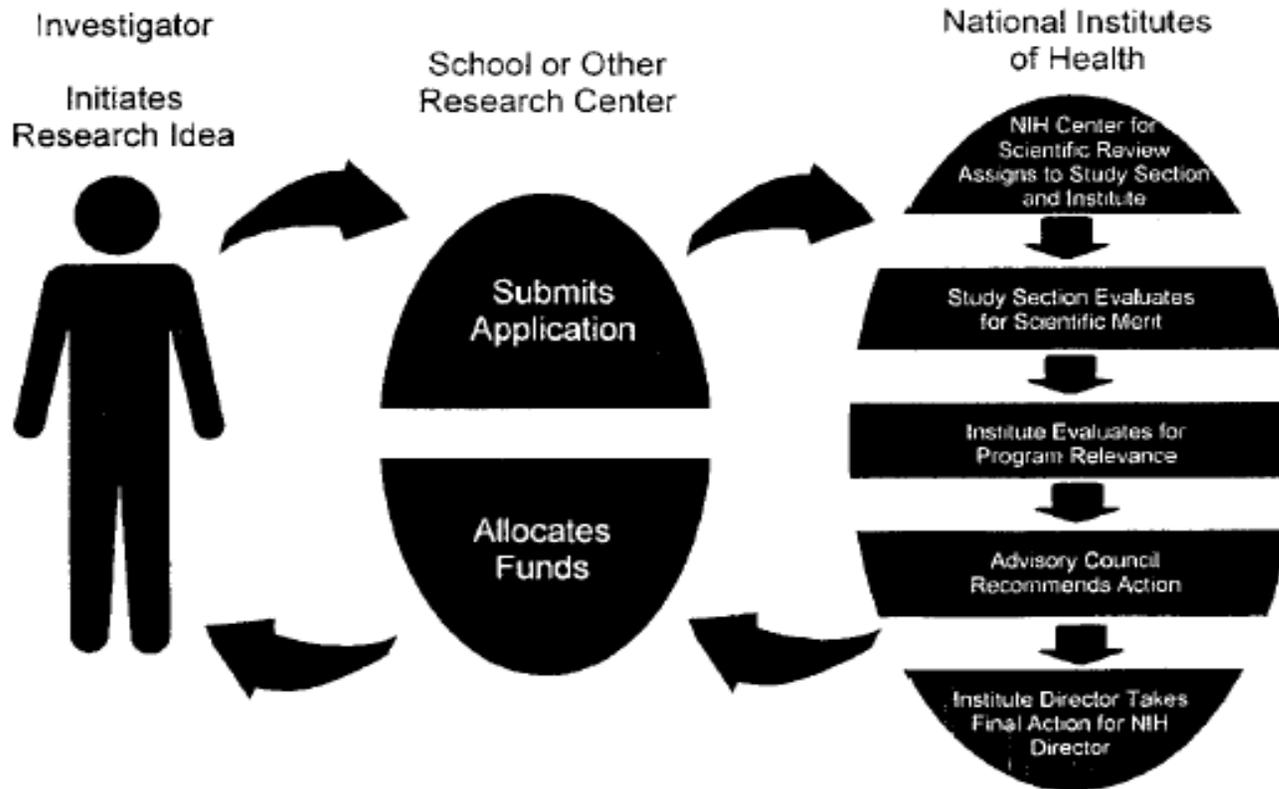
Post-Award Management



Administrative and fiscal monitoring, reporting, and compliance.

Note: Timeline is based on the standard grants process. It does not reflect a shorter timeframe for grants undergoing expedited review.

Review Process From Application to Award



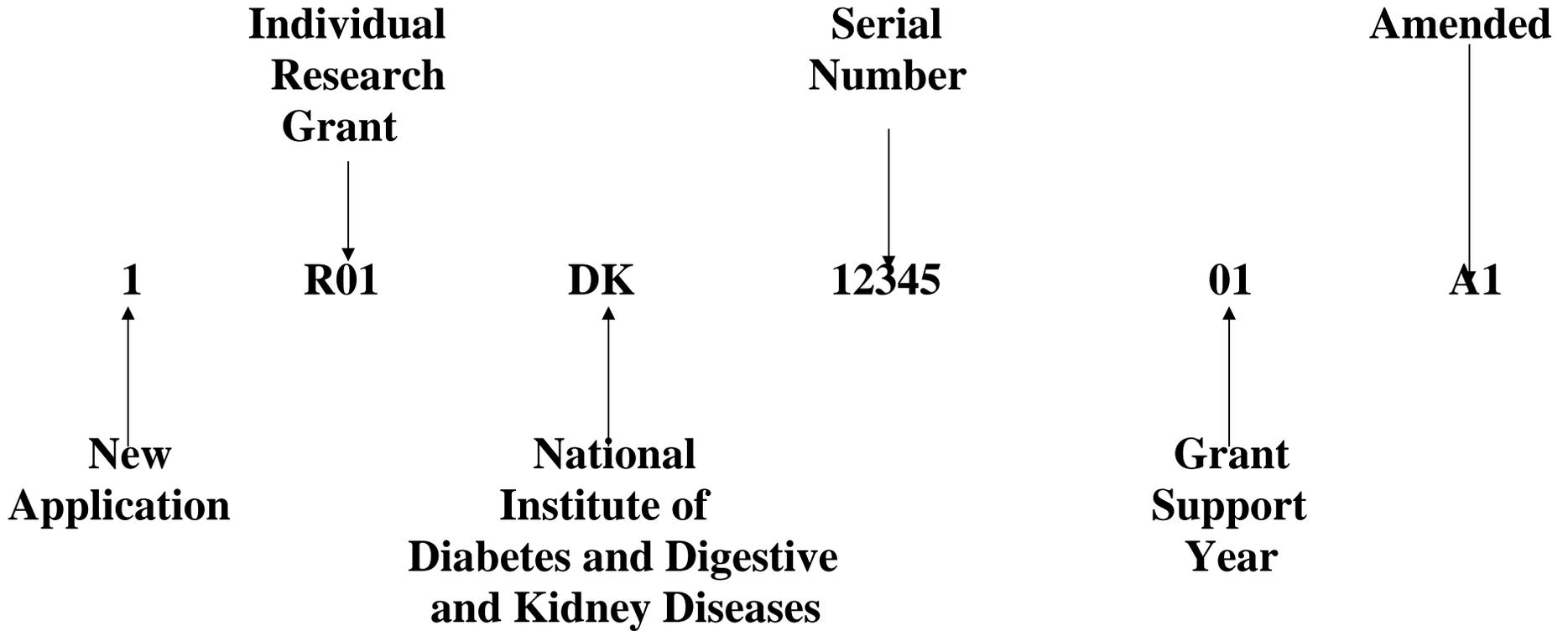
NIH Grant Receipt, Review, and Award Schedule

Jan-May May-Sept Sept-Jan	Receipt Dates
June-July Oct-Nov Feb-Mar	Review Dates
Sept-Oct Jan-Feb May-June	National Advisory Council/Board Dates
Dec 1 Apr 1 July 1	Earliest Possible Beginning Date

NIH Funding Instruments

Grant (NIH as Patron)	Cooperative Agreement (NIH as Partner)	Contract (NIH as Purchaser)
Project Conceived by Investigator	Project Conceived by Investigator or NIH	Project Conceived by NIH
NIH Supports or Assists	NIH Supports or Assists	NIH Acquires Services or Product
Performer Discusses Details and Retains Scientific Control	NIH Participates in Direction	NIH Exercises Direction and Control
NIH Maintains Cognizance	NIH Monitors	NIH Closely Monitors
Accomplishes a Public Purpose	Accomplishes a Public Purpose	For the Direct Benefit of the Government

Sample Application Number



Dual Review System for Grant Applications

First Level of Review

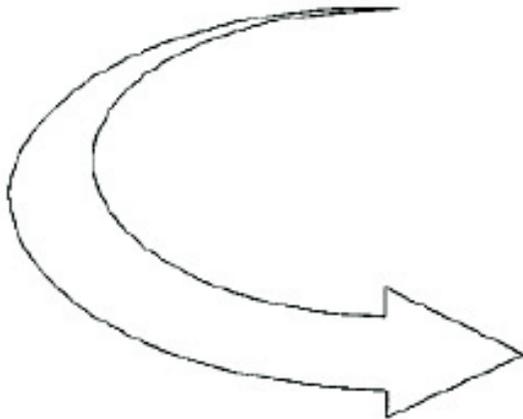
Scientific Review Group (SRG)

- Provides Initial Scientific Merit Review of Grant Applications
- Rates Applications and Makes Recommendations for Appropriate Level of Support and Duration of Award

Second Level of Review

Council

- Assesses quality of SRG Review of Grant Applications (*See Advisory Council Voting Options*)
- Makes Recommendations to Institute Staff on Funding
- Evaluates Program Priorities and Relevance
- Advises on Policy



Second Level of Review: Advisory Council Voting Options

- Concurrence with study section action
- Modification of study section action
- Deferral for re-review

NIDDK Makes Funding Decisions Based on:

- Scientific merit
- Program considerations
- Availability of funds

Initial Review Process

Overview

NIH policy is intended to ensure that grant applications submitted to the NIH are evaluated on the basis of a process that is fair, equitable, timely, and free of bias. The NIH dual peer review system is mandated by statute in accordance with section 492 of the Public Health Service Act and federal regulations governing "Scientific Peer Review of Research Grant Applications and Research and Development Contract Projects."

The first level of review is carried out by a Scientific Review Group (SRG) composed primarily of non-federal scientists who have expertise in relevant scientific disciplines and current research areas. The second level of review is performed by Institute and Center (IC) National Advisory Councils or Boards. Councils are composed of both scientific and lay members chosen for their expertise, interest, or activity in matters related to health and disease. Only applications that are favorably recommended by both the SRG and the Advisory Council may be recommended for funding.

First Level of Review

Initial peer review meetings are administered by either the [Center for Scientific Review \(CSR\)](#) or another [NIH IC](#). The focus of review is specified in the Funding Opportunity Announcement. Peer review meetings are announced in the [Federal Register](#). The meetings are closed to the public, although some meetings may have an open session; the Federal Register provides the details of each meeting.

A. Peer Review Roles and Meeting Overview

[Scientific Review Officer:](#)

Each SRG is led by a Scientific Review Officer (SRO), formerly Scientific Review Administrator (SRA)]. The SRO is an extramural staff scientist and the Designated Federal Official responsible for ensuring that each application receives an objective and fair initial peer review, and that all applicable laws, regulations, and policies are followed.

SROs:

- Analyze the content of each application, and check for completeness.
- Document and manage conflicts of interest. See [NOT-OD-11-120](#) issued on September 26, 2011, and briefly described at end of this chapter.
- Recruit qualified reviewers based on scientific and technical qualifications and other considerations, including:
 - Authority in their scientific field ([42 CFR 52h.4](#))
 - Dedication to high quality, fair, and objective reviews
 - Ability to work collegially in a group setting
 - Experience in research grant review
 - Balanced representation
- Assign applications to reviewers for critique preparation and assignment of individual criterion scores.
- Attend and oversee administrative and regulatory aspects of peer review meetings.
- Prepare summary statements for all applications reviewed.

SRG Members

Chair:

- Serves as moderator of the discussion of scientific and technical merit of the applications under review.
- Is also a peer reviewer for the meeting.

Reviewers:

- Declare Conflicts of Interest (COI) with specific applications following NIH guidance. (See COI section below.)
- Receive access to the grant applications approximately six weeks prior to the peer review meeting.
- Prepare a written critique (using [Review Critique Fill-able Templates](#)) for each application assigned per the SRO, based on [review criteria](#) and judgment of merit.
- Assign a numerical score to each review criterion
- Make recommendations concerning the scientific and technical merit of applications under review, in the form of final written comments and numerical scores.
- Make recommendations concerning protections for human subjects; inclusion of women, minorities, and children in clinical research; welfare of vertebrate animals; and other areas as applicable for the application (see [guidance for reviewers on Human Subjects Protection and Inclusion, Human Embryonic Stem Cells, and Vertebrate Animals](#)).
- Make recommendations concerning appropriateness of budget requests (see [Budget Information for Reviewers](#)).

Other NIH Staff:

- Federal officials who have need-to-know or pertinent related responsibilities are permitted to attend closed review meetings.
- NIH IC or other federal staff members wishing to attend an SRG meeting must have advance approval from the responsible SRO. These individuals may provide programmatic or grants management input at the SRO's discretion.

Peer Review Meeting Procedures

- Applications are reviewed based on established review criteria (see below).
- Assigned reviewers summarize their prepared critiques for the group.
- An open discussion follows.
- Final scoring of overall impact/priority scores is conducted by private ballot.

B. Peer Review Criteria and Considerations

The mission of the NIH is to support science in pursuit of knowledge about the biology and behavior of living systems and to apply that knowledge to extend healthy life and reduce the burdens of illness and disability. As part of this mission, applications submitted to the NIH for grants or cooperative agreements to support biomedical and behavioral research are evaluated for scientific and technical merit through the NIH peer review system.

Review Criteria for Research Grants and Cooperative Agreements

Overall Impact. Reviewers will provide an overall impact/priority score to reflect their assessment of the likelihood for the project to exert a sustained, powerful influence on the research field(s) involved, in consideration of the following review criteria, and additional review criteria (as applicable for the project proposed).

Scored Review Criteria. Reviewers will consider each of the review criteria below in the determination of scientific and technical merit, and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

Significance. Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

Investigator(s). Are the PD/PIs, collaborators, and other researchers well suited to the project? If Early Stage Investigators or New Investigators, or in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

Innovation. Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

Approach. Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed? If the project involves clinical research, are the plans for 1) protection of human subjects from research risks, and 2) inclusion of minorities and members of both sexes/genders, as well as the inclusion of children, justified in terms of the scientific goals and research strategy proposed?

Environment. Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

Additional Review Criteria. As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit and in providing an overall impact/priority score, but will not give separate scores for these items.

- Protections for Human Subjects
- Inclusion of Women, Minorities, and Children
- Vertebrate Animals
- Biohazards
- Resubmission
- Renewal
- Revision

Additional Review Considerations. As applicable for the project proposed, reviewers will consider each of the following items, but will not give scores for these items and should not consider them in providing an overall impact/priority score.

- Applications from Foreign Organizations
- Select Agent
- Resource Sharing Plans
- Budget and Period Support

C. Scoring

The scoring system described below was implemented for applications submitted for funding consideration for FY2010 and thereafter ([NOT-OD-09-024](#))

Before the SRG meeting, each reviewer and discussant assigned to an application will give a separate score for each of five review criteria (i.e., Significance, Investigator(s), Innovation, Approach, and Environment for research grants and cooperative agreements; see above). For all applications, even those not discussed by the full committee, the individual scores of the assigned reviewers and discussant(s) for these criteria are reported to the applicant.

In addition, each reviewer and discussant assigned to an application gives a preliminary overall impact/priority score for that application. The preliminary scores are used to determine which applications will be discussed in full. For each application that is discussed at the meeting, a final impact/priority score is given by each eligible committee member (without conflicts of interest) including the assigned reviewers. Each member's score reflects his/her evaluation of the overall impact that the project is likely to have on the research field(s) involved, rather than being a calculation of the reviewer's scores for each criterion.

The scoring system utilizes a 9-point rating scale (1 = exceptional; 9 = poor). The final overall impact/priority score for each discussed application is determined by calculating the mean score from all the eligible members' impact/priority scores, and multiplying the average by 10; the final overall impact/priority score is reported on the summary statement. Thus, the final overall impact/priority scores range from 10 (high impact) through 90 (low impact). Numerical impact/priority scores are not reported for applications that are not discussed (ND), which may be reported as *.* on the face page of the summary statement and typically rank in the bottom half of the applications.

Applicants should contact the Program Officer for the application to seek additional feedback on the score and summary statement.

An application may be designated Not Recommended for Further Consideration (NRFC) by the Scientific Review Group if it lacks significant and substantial merit; presents serious ethical problems in the protection of human subjects from research risks; or presents serious ethical problems in the use of vertebrate animals, biohazards, and/or select agents. Applications designated as NRFC do not proceed to the second level of peer review (National Advisory Council/Board) because they cannot be funded.

The following guidance has been given to reviewers to determine individual review criterion and overall impact/priority scores:

High Impact Table		
<i>Score</i>	<i>Descriptor</i>	<i>Additional Guidance on Strengths/Weaknesses</i>
1	Exceptional	Exceptionally strong with essentially no weaknesses
2	Outstanding	Extremely strong with negligible weaknesses
3	Excellent	Very strong with only some minor weaknesses
Medium Impact Table		
<i>Score</i>	<i>Descriptor</i>	<i>Additional Guidance on Strengths/Weaknesses</i>
4	Very Good	Strong but with numerous minor weaknesses
5	Good	Strong but with at least one moderate weakness
6	Satisfactory	Some strengths but also some moderate weaknesses
Low Impact Table		
<i>Score</i>	<i>Descriptor</i>	<i>Additional Guidance on Strengths/Weaknesses</i>
7	Fair	Some strengths but with at least one major weakness
8	Marginal	A few strengths and a few major weaknesses
9	Poor	Very few strengths and numerous major weaknesses

Non-numeric score options: NR = Not Recommended for Further Consideration, DF = Deferred, AB = Abstention, CF = Conflict, NP = Not Present, ND = Not Discussed

Minor Weakness: An easily addressable weakness that does not substantially lessen impact

Moderate Weakness: A weakness that lessens impact

Major Weakness: A weakness that severely limits impact

D. [Summary Statement](#)

Applications that are not discussed at the meeting will be given the designation “ND” as an overall impact/priority score, but the applicant, as well as NIH staff, will see the scores from the assigned reviewers and discussants for each of the review criteria as additional feedback on their summary statement.

Understanding the Percentile

- A percentile is the approximate percentage of applications that received a better overall impact/priority score from the study section during the past year.
- All percentiles are reported as whole numbers
- Only a subset of all applications receive percentiles. Which types of applications are percentiled varies across different NIH Institutes and Centers.
- The summary statement will identify the base that was used to determine the percentile.

E. Appeals

To preserve and underscore the fairness of the NIH peer review process, NIH established a peer review appeal system (see NIH Guide Notice [NOT-OD-11-064](#)) to provide investigators and applicant organizations the opportunity to seek reconsideration of the initial review results if, after consideration of the summary statement, they believe the review process was flawed as outlined below. The appeals policy applies to appeal letters received with respect to the initial peer review of all competing applications submitted to the NIH for support for the January 25, 2011 due date and thereafter, including: 1) reviews conducted by the NIH Center for Scientific Review (CSR) and reviews conducted by the NIH Institutes and other NIH Centers; and 2) applications such as fellowship application that typically do not require Council review. This policy does not apply to appeals of the technical evaluation of R&D contract projects through the NIH peer review process, appeals of NIH funding decisions, or appeals of decisions concerning extensions of MERIT award.

An appeal is a written communication from a Project Director/Principal Investigator (PD/PI) and/or official of the applicant institution [not necessarily the Authorized Organization Representative (AOR)] that meets the following four criteria: 1) is received after issuance of the summary statement and up to 30 calendar days after the second level of peer review, 2) describes a flaw in the review process for a particular application, 3) is based on one or more of four allowable issues (described below), and 4) displays concurrence of the AOR. An appeal letter will be accepted only if the letter 1) describes a flaw(s) or perceived flaw(s) in the review process for the application in question, 2) explains the reasons for the appeal, and 3) is based on one or more of the following issues related to the process of the initial peer review:

- Evidence of bias on the part of one or more peer reviewers
- Conflict of interest, as specified in regulation at [42 CFR 52h](#) "Scientific Peer Review of Research Grant Applications and Research and Development Contract Projects", on the part of one or more non-federal peer reviewers
- Lack of appropriate expertise within the SRG
- Factual error(s) made by one or more reviewers that could have altered the outcome of review substantially.

Appeal letters based solely on differences of scientific opinion will not be accepted. A letter that does not meet these criteria and/or does not include the concurrence of the AOR will not be considered an appeal, but rather a grievance. The IC will handle grievances according to IC-specific procedures.

The IC cannot deny the PD/PI and/or the applicant institution the opportunity to have an appeal letter made available to Council, but the IC may determine which appeal letters warrant discussion by the Council members, and Council members may raise certain ones for discussion if they so choose. The Council may concur:

- with the appeal, and recommend that the application be re-reviewed.
- with the SRG's recommendation and deny the appeal.

The recommendation of Council concerning resolution of an appeal is final and will not be considered again by the NIH through this or another process.

Information from http://grants.nih.gov/grants/peer_review_process.htm.

F. Revised Conflict of Interest Policy for Initial Review

The NIH initial peer review process involves the consistent application of standards and procedures that produce fair, equitable, informed, and unbiased examinations of grant and cooperative agreement applications to the National Institutes of Health (NIH). The process, defined in regulation at [42 CFR Part 52h](#), is extended by policy to other types of applications submitted to the agency.

On September 26, 2011, the NIH issued a revised policy on managing conflict of interest (COI) in the initial peer review of NIH grant and cooperative agreement applications: see [NOT-OD-11-120](#). This announcement provides revised policy for managing COI, the appearance of COI, prejudice, bias, or predisposition in the NIH initial peer review process.

The announcement addresses multi-disciplinary and collaborative research and clarifies the role of non-Federal and Federal employees serving as reviewers. Unlike members of NIH Advisory Councils or Boards, reviewers in the initial level of NIH peer review are not appointed as Special Government Employees and do not submit financial disclosure forms. Therefore, SROs are not in a position to collect financial information from reviewers, but can ask about professional relationships and roles as defined in the revised NIH policy and make determinations about potential bias in the initial peer review process.

The overall goal of the revised policy is to increase transparency and to inform the scientific community. With the dramatic increase in internet capability, reviewers may be looking up financial information about investigators on the websites of the investigators' institutions. Although this COI information is available publicly, SROs should instruct reviewers not to consider COI information about applicants in their reviews, discussions, or evaluations.

Similarly, applicants may be looking up financial information about reviewers on their institutions' websites and submitting appeals of initial peer review on the basis of that information. Therefore, it is important that SROs clearly explain the conflict rules for initial peer review to their reviewers.

Second-Level Review Procedures

The Advisory Council/Board of the potential awarding Institute or Center (IC) performs the second level of review. Advisory Councils/Boards are composed of scientists from the extramural research community and public representatives ([NIH Federal Advisory Committee Information](#)). Members are chosen by the respective IC and are approved by the Department of Health and Human Services. For certain committees, members are appointed by the President of the United States.

On June 18, 2010, President Obama issued "Lobbyists on Agency Boards and Commissions," a memorandum directing agencies and departments in the Executive Branch not to appoint or re-appoint federally registered lobbyists to advisory committees and other boards and commissions. On October 5, 2011, the Office of Management and Budget (OMB) issued final guidance to Executive Departments and agencies concerning the appointment of federally registered lobbyists to boards and commissions. This guidance applies not only to advisory committees subject to FACA, but to all other groups as well—even to members of working groups not appointed as SGEs. See [Federal Register / Vol. 76, No. 193 / Wednesday, October 5, 2011/Notices](#) under OFFICE OF MANAGEMENT AND BUDGET, Final Guidance on Appointment of Lobbyists to Federal Boards and Commissions, AGENCY: Office of Management and Budget. ACTION: Notice of Final Guidance.

Second-level review is the assessment of the quality of the initial review of grant applications. By law, NIDDK's Advisory Council must recommend an application before the Institute can fund it. Second-level review is **not a second scientific review**. Rather, the Council looks at applications with potential barriers to funding such as human subjects and animal concerns or special circumstances such as foreign applications and renewal applications requesting more money than the limit.

The Council has three options for recommendations: (1) concurrence with initial review; (2) modify the initial review action (e.g., an adjustment of the budget level and/or project period); or (3) defer an application for re-review. Applications that are brought to the Council subcommittees for closed-session discussion are then reported to the full Council in closed session. The remainder of the applications are considered through an en bloc vote. When Council recommends an application for funding, that doesn't necessarily mean it will receive an award. NIDDK makes the final decision.

Applications Requiring Council Discussion

- Applications from Foreign Institutions

In reviewing and making recommendations on foreign grant applications, the Council members should be aware that ALL of the following criteria must be met in order to be supported by the NIH:

- a. The project presents special opportunities for furthering research programs through the use of unusual talents, resources, populations, or environmental conditions in other countries that are not readily available in the United States or that augment existing United States resources.
 - b. The project has specific relevance to the mission and objectives of NIDDK and has the potential for significantly advancing the health sciences in the United States.
 - c. The application must be approved for funding by the Council.
 - d. The application may be awarded only after assurance that the foreign institution is in compliance with human subject, animal welfare, and gender and minority requirements.
- Applications With Concerns about Human or Animal Subjects and/or Gender and Minority Representation

The Council will be asked to comment on any application(s) recommended for possible funding with unresolved concerns regarding the involvement of human subjects, the use of animals, and/or gender and minority representation. The Council will be asked specifically for concurrence with the Scientific Review Group's (SRG) concern(s).

- Applications That May Not Provide for Appropriate Biosafety, Biocontainment, and Security of Select Agents

The Council will be asked to comment on any applications recommended for possible funding with unresolved concerns regarding biosafety, biocontainment, and security of select agents. The Council will be asked specifically for concurrence with the Scientific Review Group's (SRG) concern.

- Letters of Appeal

The Council reviews appeal letters that were submitted by investigators subsequent to the peer review of their application and were not resolved by program and review staff. It is the responsibility of NIDDK staff to determine whether a letter is an appeal.

An investigator may have concerns about and may wish to appeal a procedural aspect of the peer review process. Only letters concerning procedural aspects of a review are considered an appeal. Procedural issues fall under four categories and the applicant must claim one or more of the following:

- a. The initial review was biased.
- b. A conflict of interest existed.
- c. The review group lacked appropriate scientific expertise.
- d. Factual errors entered into the review.

Differences in scientific opinion that often occur between investigators and reviewers may not be contested through these procedures. In addition, communications from investigators consisting of additional information that was not available to the reviewers are not considered to be appeals.

The Council has two options when reviewing an appeal letter:

- a. To concur with the outcome of the initial peer review as reflected in the summary statement.
- b. To concur with the claims discussed in the applicant's appeal letter and recommend deferral for re-review either by the same or a different review group.

Other letters, termed Council communications, are also made available to the Council at the discretion of NIDDK staff.

Special Council Review of Research Applications from Program Directors/Principal Investigators (PDs/PIs) with more than \$1.0 Million Direct Costs in NIH Support

In an effort to continue responsible stewardship of public funds and to support meritorious and innovative research, NIH has instituted a policy of Special Council Review (SCR) of applications from well-funded investigators: <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-12-140.html>. Pending grants going to Council from PDs/PIs who have more than \$1 million in direct costs from active NIH Research Project Grants (RPGs) grants will be subjected to additional consideration. It is important to recognize that this is a threshold only; investigators who have more research support

may still receive additional awards as warranted. When making funding recommendations, staff will take into account factors such as: how innovative and distinct the pending project is from the PD/PI's other grants; the type of research (since costs requirements differ substantially by field); the public health priority of the research; and how the absence of an award impacts other collaborative or translational research efforts.

The following SCR policy guidance is designed to achieve these goals.

- Criteria Considered by NIDDK Staff for Determining Applications Subject to SCR
 - a. P01s and other Multi-Component RPGs: Only funds acquired¹ through RPGs² should be included when calculating a given PD/PI's support.
 - b. Only competing RPGs (New and Renewals) to be considered for award to investigators with \$1.0M or more of direct cost NIH support are subject to SCR via this policy.
 - c. P01s and other Multi-Component RPGs:
 - i. Competing Multi-Component RPGs are not subject to SCR unless all of the component leaders have \$1.0M or more of NIH support. The rationale for this is that failure to support one or more of the leaders who exceed the limit could significantly detract from the project as a whole.
 - ii. Funded P01s and any other multi-component RPGs, including consortium/sub-award costs, contribute to the \$1.0M threshold of the Program Director and sub-project leaders. Each sub-project leader's total should include the funds provided directly to him/her only through the P01; core costs should not be included.
- Multiple PD/PI Projects:
 - a. Competing Multi-PI applications are only subject to SCR if all the PD/PIs exceed the \$1.0M threshold.
 - b. In calculating the research support available to a PD/PI who participates in a multi-PI award, the direct cost award amount to the institution should be divided evenly among PIs at that institution. Budgets of multi-PIs at other institutions may be determined using the funds allocated to their subcontract costs.
- Requests for Applications (RFAs):
 - a. Pending applications submitted in response to RFAs will not be subjected to SCR. The rationale is that these applications have been solicited by the IC to accomplish a specific purpose. The intent is to award the best proposal(s) designed to achieve the IC's specified goal(s).
 - b. Funds provided through these grants will contribute to the \$1.0M threshold for the investigators' future applications.
- Competing revisions and administrative supplements:
 - a. These types of grants are not expected to be a significant contributing factor in reaching the threshold, since many will not incur future year commitments. However, multi-year supplements are included in grant's out-year commitments and do contribute to the \$1.0M threshold. In order to prevent Re-entry and Diversity Supplements from being an impediment

¹ Funds acquired include active RPG awards for the PD/PI (exclusive of projects in no cost extension) when the application subjected to SCR is pending Council review and funds for multi-year projects allocable to the current Fiscal Year (Multi-Yr: R15, DP2, DP3, DP4, RC3, RC4, R55, RC1)

² Defined as R00, R01, R03, R15, R21, R22, R23, R29, R33, R34, R35, R36, R37, R55, R56, RC1, RC2, RC3, RC4, RL1, RL2, RL5, RL9, P01, P42, PN1, UA5, UC1, UC2, UC4, UC7, UH2, UH3, UH5, UM1, U01, U19, U34, DP1, DP2, DP3, DP4, and DP5.

to an investigator, to the extent possible, these supplements should be excluded from the threshold count.

- Guidelines for Council Consideration (Council role):
 - a. When applied to new projects, SCR will focus on the unique opportunities afforded to the investigator to advance his/her research in directions that are highly promising and distinct from his/her other funded projects.
 - b. SCR of renewal applications may also consider the value of continuing a productive project and the contribution this project makes to the investigator's research program and ongoing collaborations.
 - c. Consideration may also be given to the PD/PI's field of research when evaluating the appropriateness of awarding new grants above the \$1.0M direct cost threshold. The rationales for this consideration are that 1) different types of research (e.g., clinical trials, population sciences) may require larger awards than other fields and 2) non-RPG mechanisms often used for an IC's specialized purposes/goals typically receive separate Council consideration. Since some RPGs, such as U01s, are also used for projects with specialized purposes/goals, each IC, working with its Council, may create defaults for these and other RPG mechanisms or programs to simplify SCR.

NIDDK Implementation of the Second Council Review Policy

Each Council round, the NIDDK Council members will be provided a list of competing applications that meet the criteria for Special Council Review (SCR) under the NIH policy as outlined above. During the closed session, for each application on the list that might actually be funded, NIDDK staff will provide information about the other NIH funding for the PI that brings his/her direct cost total to the \$1 million threshold and a justification for possibly funding the application under consideration. Council members will review these cases and decide whether or not they have concerns.

Recommendation Process

- NIDDK program staff members examine applications, their overall impact/priority scores, percentile rankings, and their summary statements and consider these against NIDDK's needs.
- Program staff provide a grant-funding plan to the Advisory Council.
- The Advisory Council also considers NIDDK's goals and needs and advises the NIDDK Director.
- The NIDDK director makes the final funding decisions based on staff and Advisory Council advice.

Post-Review

- **Not Funded – What Next?**

The NIH receives thousands of applications for each application receipt round. Funding on the first attempt is difficult, but not impossible. If an application does not result in funding, NIH has resources available to help applicants prepare a possible resubmission. Applications in response to a specific initiative with set-aside money typically cannot be resubmitted, but the Program Official should be consulted about next steps.
- **Fundable Score – What Next?**

If an application results in an award, the applicant will be working closely with the NIDDK Program Official on scientific and programmatic matters and a Grants Management Officer on budgetary or administrative issues.

Reviewing Applications Prior to the Meeting: Using the NIH Electronic Council Book (ECB)

(For NIDDK Advisory Council Members Only)

What is the NIH Electronic Council Book

The NIH Electronic Council Book (ECB) provides access to NIH summary statements. Using World Wide Web and Internet capabilities for database search and retrieval, as an NIDDK Advisory Council member you may read, search, sort, and print any or all of the summary statements for a Council round that has either a DK primary or secondary assignment. NIH staff load data and summary statements into the ECB each night, so the ECB is always current.

The data in the ECB, and the codes you use for access to those data, are confidential and must be protected. Since the ECB contains confidential data, you should not leave it unattended. Use it and then disconnect. If for some reason you are inactive for approximately one hour, the system will automatically disconnect, and you will have to login again.

How do I get started?

You or your institution will supply your computer access to the NIH computer, via an Internet connection and a WEB browser (such as Firefox, Netscape Navigator, or Internet Explorer). An NIDDK staff member will give you the information necessary to identify yourself to the NIH computer where the ECB is located. That information includes two codes. The first is called your "USER NAME," the second is your "PASSWORD." Once you have this information, you are ready to start.

Assuming you are already connected to the internet, use your web browser to access the following page: <https://ecb.nih.gov/council/login.cfm>

You will see a screen entitled "**NIH Electronic Council Book**" with two blank boxes for your USER NAME and your PASSWORD. Neither the USER NAME nor the PASSWORD are case sensitive. To log in to the ECB:

- Enter your USER NAME, for example, ECB_JOHNST
- Press Tab or move the mouse cursor to the PASSWORD block
- Enter your PASSWORD
- Click on LOGON

Please note that the password issued to you by NIDDK staff is a temporary password and you must change it before you can login to the ECB. To change your password, go to the ECB login page (see below) and click on the link to the "Council Member Change Password Page." Use the NIDDK-issued password as the "Old Password," and follow the instructions on this page to change your password to a password of your choosing. If you have problems changing your password, please contact Teresa Lindquist (lindquit@nidDK.nih.gov, 301-451-6418).

If you have entered an incorrect USER NAME, you can click on CLEAR, and enter the information again.

How Do I Use the System?

When you log on to the ECB, you will go directly to the Search For Projects tab. The Search Criteria appear in a list on the left of the screen; you can use this menu to move quickly through the sections of the search screen. Clicking on the name of any search item will provide you with help for that item.

PLEASE NOTE that when moving through the screens in the ECB it is best to use the small red arrows in the upper left hand corner of your screen rather than the “Back” button on your browser.

Note that in the Basic Search Options portion of the Search screen, there is an item entitled: **Output Option**. There are two choices: Standard Project List and Resumé Project List. A search using the Standard Project List format will return a list containing the following information:

- Project (or grant) number
- Principal Investigator (PI) name
- Project Title
- Request for Application (RFA) or Program Announcement (PA) number
- Percentile
- Priority score
- Study section name
- Institute or Center (IC) Program Class Code
- PI’s institution.

The Resume Project List retrieves the “Summary of Review and Discussion” section of the summary statement in addition to the items in the Standard Project List. This version of the Project List provides a useful overview of the review of a single application or group of applications.

How do I initiate a search?

Commonly searched items are located near the top of the Search screen. Searching is very flexible. Please note that all searches default to applications on which NIDDK is the primary Institute. If you are looking for an application assigned to another NIH Institute or Center you will need to select either “Primary and Dual Projects” or “Dual Projects only” in the Review/Program Section of the Search screen.

Conduct a search by inserting the particular criteria (Principal Investigator’s name; Application number; Study Section, etc.) (Examples are provided below.)

- **To search for a specific summary statement**, enter either the application number or the Principal Investigator’s last name in the appropriate box. You do not need to enter the entire grant number or full PI name; the system will find all applications that meet your criteria.
- **To search for a group of summary statements that meet certain search criteria** (such as all the applications reviewed by a particular Scientific Review Group (SRG), projects in a range of priority scores or percentiles, or all applications reviewed in response to a particular RFA or any other combination of information), simply enter that information in the appropriate boxes.
- **To search for all applications on a specific scientific topic**, simply enter the appropriate term in the boxes labeled “Summary Text Contains.” This search criterion has two boxes and a drop-down menu between them that allows use of a Boolean logical operator (*AND*, *OR*, and *NOT*) to connect two character strings. Note: If one is searching for a topic such as “endocrine disruptors” consider the two words as a single character string and enter both words in the left box separated by a space rather than one in each box. You may use these fields to search the summary statement, the Project Title, or both of these items.

To initiate a new search, click on the **Clear Criteria** button. This will remove all prior search criteria except for the defaults in percentile and priority score. Clicking on the **Default Criteria** will reset all criteria to their default values.

SEARCH CRITERIA EXAMPLES

Principal Investigator (PI): In the PI/Institution section, enter the first several letters of the PI's last name in the box labeled "Principle Investigator Starts With:" For example, searching for "**Ham**" will return matches for Hamilton, Hammerman, Hammes, Hampe, etc. The more complete the name, the more exact will be the search results.

Scientific Review Group (SRG): In the Review/Program section of the search screen, type the three- or four-character abbreviation of the SRG (e.g., MET, NTN, CVB) in the field labeled "Scientific Review Group Contains". If you are looking for an application that was reviewed in a Special Emphasis Panel, please enter information in the boxes labeled "Special Emphasis Panel." For example, if you enter "DK" in the first box for this search item, the search will return all applications reviewed in NIDDK Special Emphasis Panels (ZDK).

Program Code (PCC): It is important to enter the Program Class Codes correctly. All NIDDK Program Class Codes consist of 8 characters: three characters, a blank space, and then four characters. For example, to search for Obesity Special Projects (Program Class Code = **NBH OBSP**), place **NBH** in the first three boxes. Leave the next box blank and enter OBSP in the remaining 4 boxes.

Application/Grant Number: The identification number is commonly referred to as the application number or grant number, depending on its processing status. The identification number consists of several parts, each having a distinct meaning. The following example shows the parts of an ID number assigned to an amendment (A1) to a supplemental (Type 3) application for a traditional research project (R01) referred to the National Cancer Institute (CA). The number further identifies the application serially as the 65412st new proposal submitted to the National Cancer Institute and indicates that this is the first supplemental application (S1) to the fourth year (-04) of support to this project.

Explanation of Grant application/award identification NUMBERING system:

Application Type	Activity Code	Administering Organization	Serial Number	Suffixes	
				Grant Year	Other
3	R01	CA	65412	08	S1A1

- **Application Type Code:** A single-digit code identifying the type of application received and processed. The codes are as follows:

- 1 New
- 2 Competing Continuation
- 3 Supplement
- 4 Extension
- 5 Noncompeting Continuation
- 6 Change of Institute or Division
- 7 Change of Grantee or Training Institution
- 8 Change of Institute or Division (noncompeting continuation)

9 Change of Institute or Division (competing continuation)

- **Activity Code:** A three-digit code identifying a specific category of extramural activity (e.g., R01, R03, R33, T32, F33, R44, U01).
- **Administering Organization Code** (Also referred to as an IC Code or Admin PHS Org Code): A two-letter code identifying the primary NIH Institute or Center to which the application is assigned. In the above example, "CA" refers to the National Cancer Institute.
- **Serial Number:** A six-digit number generally assigned sequentially to a series within an NIH Institute or Center.
- **Suffixes:** A field composed of the following components:

Grant year. A two-digit number indicates the actual segment or budget period of a project. The grant year number (01, 02, etc.) is preceded by a dash to separate it from the serial number; (e.g., AI 12345-02 or CA 00900-04). The grant year number is increased by one for each succeeding renewal year. Thus, the 04 year suffix in the example above identifies a grant in its fourth year.

Supplement. The letter "S" and related number identify a particular supplemental record (e.g., S1, S2). Supplement designations follow the grant year or the amendment designation, as the case may be (e.g., AI 12345-01S1 and CA 00900-04A1S2).

Amendment. The letter "A" and related number identify each amended application (e.g., A1, A2, etc.). Amendment designations follow the grant year or the supplement designation, as the case may be (e.g., DE 34567-02A1 and HL 45678-01S1A2).

Text Search: A text word search retrieves applications containing one or two search terms. The search is performed against the summary statement narrative and the Project Title and may take slightly longer to return the results. Submitting a search with an entry in the first box will find all summary statements and/or Project Titles containing that single word anywhere in the text. To enter two text words, select the correct Boolean logical operator (*AND*, *OR*, *NOT*) from the drop-down menu between the two text boxes.

Priority Score/Percentile: The system sets a default priority score and percentile to focus on the applications being reviewed by the Advisory Councils. The default for the percentile is between 00 and 30 and for the priority score, between 100 and 300. These defaults can be deleted or changed. Score ranges can be cleared by clicking the "Clear Scores" button below the data entry boxes. If you wish to enter different ranges, highlight the contents of these boxes and enter different numbers.

ADVANCED SEARCH CRITERIA EXAMPLES

Summary Statements Released Since: A frequent user of the system will be able to retrieve summary statements released into the database since the last time the user logged into the system. For example, to retrieve all summary statements since January 15, 2008, the entry would be 01/15/2008 (mm/dd/yyyy). You can also select applications based on whether or not the summary statement has been released by selecting the appropriate option in the drop-down box.

RFA/PA Number: NIDDK will provide its Council members with valid RFA/PA numbers. **Please** use the format as provided on the search screen in the Application ID section. **Please note** that if you are interested in Roadmap applications, there is a radio button in the Basic Search Options section that allows you to include only Roadmap applications in your search.

Direct Cost Recommended: In the Review/Program Section, you can search for applications based on specified budget amounts. For example, entering **1000000** and selecting “Greater Than or Equal To” from the drop-down menu will retrieve a list of applications with budgets of one million dollars or more.

Special Selects: The Special Selects Section provides options for searching on several different criteria. You may search on one criterion or a combination of criteria. **Foreign applications** are those applications from organizations outside the boundaries and territories of the United States. In the Special Selects Section, check the box ‘Foreign Grants’ to retrieve a list of summary statements of all foreign applications. **Phase 3 Clinical Trials** are identified by the Initial Review Group. **AIDS** identifies applications involving AIDS-related research. You may also search for applications with various human or animals subjects concerns.

COMPLETING YOUR SEARCH

Once you are satisfied with the search criteria, click the Search button at the top of the page. **Please note** that there is a default score range of 0 to 30 PERCENTILE and 100 to 300 PRIORITY SCORE. If you need to search ALL applications, please **clear** these values prior to running your search.

SEARCH RESULTS

When a search is completed a hit list will be displayed with the search criteria listed at the top. The hit list will include all data on all applications that meet the search criteria you have selected. The search criteria will be listed at the top of the list of applications for easy reference.

The hit list is compiled as a table with one application per line. You may increase or decrease the number of applications displayed on the page by using the Set Records per page display in the upper left corner. The list contains the following information for each application:

Count	Sequence number of applications as retrieved
Email	A link to the Program Officer’s email address
Project Number	Type, activity, and serial number
RFA/PA	The RFA or PA announcement number, if any, with a link to the Program Announcement in the NIH Guide for Grants and Contracts
PI Name	Name of Principal Investigator
Percentile	Percentile rank
Priority	Priority score
Project Title	Title of research application
Study Section	Scientific Review Group, with a link to the Study Section roster
IC-Prog Code	Program Class Code for the primary IC
Institution	Applicant organization

VIEWING SUMMARY STATEMENTS

To view a particular summary statement click on the project number. The next screen will be the complete summary statement. **Note:** Each hit list will list all applications that satisfy the search criteria whether or not the summary statement is currently available. For Netscape users, the grant number will be a different color (usually blue) and underlined if the summary statement is available. Also, there will be a check box on the left margin (see instructions below on downloading one or more summary statements for offline reading).

The Electronic Council Book allows you to retrieve and download groups of summary statements. In addition, the user now has the ability to selectively "tag" and "untag" items in the hit list by checking the boxes on the left margin. This allows the user to create highly customized hit lists for the purpose of downloading summary statements.

Summary statements may be retrieved in several ways:

- Download one or more summary statements as a single PDF file that can be printed locally (you will need Adobe Acrobat Reader on your computer to use this feature). To download a group of summary statements as a single PDF, check the boxes on the left margin for all applications you wish to include.
- Download a collection of summary statements as a "Zip" file from which individual summary statements can be viewed or printed. You will need a program that extracts Zip files in order to view the summary statements. To download a group of summary statements as a single Zip file, check the boxes on the left margin for all applications you wish to include.
- View individual summary statements in the browser without distracting page headers embedded in the text. To view a single summary statement in your browser window, click on the project number.

VIEWING IRG/SRG ROSTERS

To view the roster of members for a particular Study Section, simply click on the SRG identifier on the hit list. The IRG identifier is adjacent to the application of interest.

For assistance please contact:

Teresa Lindquist, lindquit@niddk.nih.gov or 301-451-6418.

Grant Review-Related Policies

Foreign Organizations

In addition to the regular review criteria, foreign applications are evaluated in terms of special opportunities for furthering research programs through the use of special talents, resources (human subjects, animals, diseases, equipment or technologies), populations or environmental conditions in the applicant country which are not readily available in the United States or which provide augmentation of existing United States resources. In addition, it should be noted whether similar research is being done in the United States and whether there is a need for additional research in the area of the proposal. These special review criteria are not applied to applications from domestic institutions that include a significant foreign component.

Research Involving Human Subjects

The rights of all human subjects involved in NIH-supported research are of paramount importance to the Federal Government. Safe-guarding these rights is primarily the responsibility of the institution that receives or is accountable for the funds awarded for support of the research. However, NIH also relies on its scientific review groups (SRGs) and National Advisory Councils or Boards to evaluate all applications and proposals involving human subjects for compliance with the Department of Health and Human Services human subject regulations (Code of Federal Regulations, Title 45 Part 46).

There are several considerations for review of applications involving human subjects. These can be clustered into two broad areas: Protection of subjects from research risks; and the inclusiveness of the study population. Protection issues include questions regarding safety and welfare of the subjects, including data and safety monitoring where applicable. Inclusion issues reflect the appropriate involvement of women, minorities and children.

SRGs assign inclusion codes to applications to indicate their judgment as to compliance with these concerns (*see* Inclusion Codes below). The evaluation by Council will take into consideration the risks to the subjects, the adequacy of protection against these risks, the potential benefits of the proposed research to the subjects and others, and the importance of the knowledge to be gained.

NIH will fund research covered by the regulations only if the institution has filed an assurance with the Office for Human Research Protections ([OHRP](#)) and has certified that the research has been approved by an institutional review board (IRB), a board at the requesting institution formed solely for this purpose.

No awards will be made until all expressed concerns about human subjects have been resolved to the satisfaction of the NIH.

More detailed instructions for reviewing grant applications involving human subjects, and exemptions, are available at the following URL: http://grants.nih.gov/grants/peer/hs_review_inst.pdf.

Definitions:

Human subjects: Federal regulations define "human subject" as a "living individual about whom an investigator obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information." The regulations extend to the use of human organs, tissue and body fluids from individually identifiable human subjects as well as to graphic, written, or recorded information

derived from individually identifiable human subjects. A subset of research involving human subjects may qualify for exemption, but justification must be provided under the heading "Protection of Human Subjects from Research Risk". The use of autopsy materials is governed by applicable state and local law and is not directly regulated by the Federal human subject regulations.

Clinical research is defined as: (1) Patient-oriented research, i.e., research conducted with human subjects (or on material of human origin such as tissues, specimens and cognitive phenomena) for which an investigator (or colleague) directly interacts with human subjects. (Excluded from the definition of patient-oriented research are in vitro studies that utilize human tissues that cannot be linked to a living individual.) Patient-oriented research includes: (a) mechanisms of human disease, (b) therapeutic interventions, (c) clinical trials, and (d) development of new technologies; (2) Epidemiologic and behavioral studies; or (3) Outcomes research and health services research.

A Clinical Trial is operationally defined as a prospective biomedical or behavioral study of human subjects that is designed to answer specific questions about biomedical or behavioral interventions.

An NIH-defined Phase III clinical trial is a broadly based prospective clinical investigation, usually involving several hundred or more human subjects, for the purpose of evaluating an experimental intervention in comparison with a standard or control intervention or comparing two or more existing treatments. Often the aim of such investigation is to provide evidence leading to a scientific basis for consideration of a change in health policy or standard of care. The definition includes pharmacologic, non-pharmacologic, and behavioral interventions given for disease prevention, prophylaxis, diagnosis, or therapy. Community trials and other population-based intervention trials are also included.

A **valid analysis** is required in phase III clinical trials. This means an unbiased assessment. Such an assessment will, on average, yield the correct estimate of the difference in outcomes between two groups of subjects. Valid analysis can and should be conducted for both small and large studies. A valid analysis does not need to have a high statistical power for detecting a stated effect. The principal requirements for ensuring a valid analysis are:

- Allocation of study participants of both sexes/genders and different racial/ethnic groups to the intervention and control groups by an unbiased process such as randomization,
- Unbiased evaluation of the outcome(s) of study participants, and
- Use of unbiased statistical analyses and proper methods of inference to estimate and compare the intervention effects among the sex/gender and racial/ethnic groups.

Research Conducted in a Foreign Country: For foreign awards, and domestic awards with a foreign component, the NIH policy on inclusion of women and minority groups in research is the same as that for research conducted in the U.S. If there is scientific rationale for examining subpopulation group differences within the foreign population, investigators should consider designing their studies to accommodate these differences.

Children: For purposes of this policy, a child is an individual under the age of 21 years. This definition does not affect the human subject protection regulations for research on children (45 CFR 46) and their provisions for assent, permission, and consent, which remain unchanged. State laws define what constitutes a "child," for the purpose of determining whether or not a person can legally consent to participate in a research study.

Exemption from Human Subjects Regulations

If the applicant designates an exemption from the human subjects regulations, reviewers should evaluate the information provided to determine if the designated exemption is appropriate. With regard to exemption 4, although reviewers need not evaluate questions related to research risks or the inclusion of women and minorities, the appropriate inclusion of children **DOES** need to be addressed for these applications.

Protection of Human Subjects

If the proposed research involves human subjects, and does not qualify as being exempt, it is considered clinical research (see definition above) and reviewers must evaluate the plan to protect human subjects. The applicant's research plan should include four elements under the heading "Protection of Human Subjects from Research Risk". Reviewers are asked to evaluate each of the four elements:

- *Risks to the subjects*
- *Adequacy of protection against risks*
- *Potential benefit of the proposed research to the subjects and others.*

Additional information concerning the NIH Policy on Inclusion of Women and Minorities as Participants in Research Involving Human Subjects is available at http://grants.nih.gov/grants/funding/women_min/women_min.htm.

Women and Minorities in Study Populations

There are clear scientific and public health reasons for including women and minorities in study populations. Accordingly, the NIH requires that applications for clinical research give appropriate attention to including members of these groups in studies. If this is impossible (for example, because the disease occurs only in men or is prevalent only in one racial or ethnic group), or is inappropriate with respect to the health of the subjects, a strong scientific rationale or other well-supported justification is necessary. Unless the rationale/justification is compelling, NIH will not fund such applications. This policy covers research grants, cooperative agreements, and research contracts.

SRGs assign codes to applications to indicate their judgment as to compliance with these concerns. These inclusion codes, described below, appear on the summary statement.

Council will consider the degree to which the applicants have addressed this policy when it evaluates applications. Applications with inadequate representation of women and minorities and/or inadequate justification may be deferred, approved based on portfolio considerations, or approved with the condition that staff will ensure compliance with the policy before award. Council will be subsequently notified of awards for these types of approvals.

The NIH will not award research grants, cooperative agreements, or contracts to applicants who do not follow this policy.

Inclusion of Children as Participants in Research

To ensure that adequate data is developed to support the treatment of modalities for disorders and conditions that affect children, as well as adults, it is the policy of NIH that children (i.e., individuals

21 years of age and under) must be included in all human subjects research conducted or supported by the NIH. Children will not be excluded from this policy unless there are scientific and ethical reasons not to include them in the research being conducted; well-supported justification for the exclusion will be necessary. This policy applies to all research involving human subjects, **including** research that is otherwise "exempt". Proposals for research involving human subjects **must** include a description of plans for including children. If children will be excluded from the research, the application must present an acceptable justification for the exclusion.

The section in the application titled "Inclusion of Children" should provide either a description of the plans to include children and a rationale for selecting or excluding a specific age range of child, or an explanation of the reason(s) for excluding children as participants in the research. When children are included, the plan **must** also include a description of the expertise of the investigative team for dealing with children at the ages included, of the appropriateness of the available facilities to accommodate the children, and the inclusion of a sufficient number of children to contribute to a meaningful analysis relative to the purpose of the study.

Specific exclusionary circumstances and other pertinent information on the inclusion of children in NIH-supported research may be found at: <http://grants.nih.gov/grants/guide/notice-files/not98-024.html>.

Use of Human Embryonic Stem Cells In NIH-Supported Research

The National Institutes of Health (NIH) has published final "National Institutes of Health Guidelines for Human Stem Cell Research" ([Guidelines](#)).

On March 9, 2009, President Barack H. Obama issued Executive Order 13505: *Removing Barriers to Responsible Scientific Research Involving Human Stem Cells*. The Executive Order states that the Secretary of Health and Human Services, through the Director of NIH, may support and conduct responsible, scientifically worthy human stem cell research, including human embryonic stem cell (hESC) research, to the extent permitted by law.

These Guidelines implement Executive Order 13505, as it pertains to extramural NIH-funded stem cell research, establish policy and procedures under which the NIH will fund such research, and helps ensure that NIH-funded research in this area is ethically responsible, scientifically worthy, and conducted in accordance with applicable law. Internal NIH policies and procedures, consistent with Executive Order 13505 and these Guidelines, will govern the conduct of intramural NIH stem cell research.

EFFECTIVE DATE: These Guidelines are effective on July 7, 2009.

SUMMARY OF PUBLIC COMMENTS ON DRAFT GUIDELINES: On April 23, 2009 the NIH published draft Guidelines for research involving hESCs in the Federal Register for public comment, 74 Fed. Reg. 18578 (April 23, 2009). The comment period ended on May 26, 2009.

The NIH received approximately 49,000 comments from patient advocacy groups, scientists and scientific societies, academic institutions, medical organizations, religious organizations, and private citizens. The NIH also received comments from members of Congress. Read the NIH response to the public comments that addressed provisions of the Guidelines at <http://stemcells.nih.gov/policy/Pages/2009guidelines.aspx>.

NATIONAL INSTITUTES OF HEALTH GUIDELINES FOR RESEARCH USING HUMAN STEM CELLS

I. Scope of Guidelines

These Guidelines apply to the expenditure of National Institutes of Health (NIH) funds for research using human embryonic stem cells (hESCs) and certain uses of induced pluripotent stem cells (See Section IV). The Guidelines implement Executive Order 13505.

Long-standing HHS regulations for Protection of Human Subjects, 45 C.F.R. 46, Subpart A establish safeguards for individuals who are the sources of many human tissues used in research, including non-embryonic human adult stem cells and human induced pluripotent stem cells. *When research* involving human adult stem cells or induced pluripotent stem cells constitutes human subject research, Institutional Review Board review may be required and informed consent may need to be obtained per the requirements detailed in 45 C.F.R. 46, Subpart A. Applicants should consult <http://answers.hhs.gov/ohrp/categories/1562>.

It is also important to note that the HHS regulation, *Protection of Human Subjects*, 45 C.F.R. Part 46, Subpart A, may apply to certain research using hESCs. This regulation applies, among other things, to research involving individually identifiable private information about a living individual, 45 C.F.R. § 46.102(f). The HHS Office for Human Research Protections (OHRP) considers biological material, such as cells derived from human embryos, to be individually identifiable when they can be linked to specific living individuals by the investigators either directly or indirectly through coding systems. Thus, in certain circumstances, IRB review may be required, in addition to compliance with these Guidelines. Applicant institutions are urged to consult OHRP guidances at <http://www.hhs.gov/ohrp/policy/index.html#topics>

To ensure that the greatest number of responsibly derived hESCs are eligible for research using NIH funding, these Guidelines are divided into several sections, which apply specifically to embryos donated in the U.S. and foreign countries, both before and on or after the effective date of these Guidelines. Section II (A) and (B) describe the conditions and review processes for determining hESC eligibility for NIH funds. Further information on these review processes may be found at www.NIH.gov. Sections IV and V describe research that is not eligible for NIH funding.

These guidelines are based on the following principles:

1. Responsible research with hESCs has the potential to improve our understanding of human health and illness and discover new ways to prevent and/or treat illness.
2. Individuals donating embryos for research purposes should do so freely, with voluntary and informed consent.

As directed by Executive Order 13505, the NIH shall review and update these Guidelines periodically, as appropriate.

II. Eligibility of Human Embryonic Stem Cells for Research with NIH Funding

For the purpose of these Guidelines, "human embryonic stem cells (hESCs)" are cells that are derived from the inner cell mass of blastocyst stage human embryos, are capable of dividing without differentiating for a prolonged period in culture, and are known to develop into cells and tissues of the three primary germ layers. Although hESCs are derived from embryos, such stem cells are not themselves human embryos. All of the processes and procedures for review of the eligibility of hESCs will be centralized at the NIH according to the guidelines available at <http://stemcells.nih.gov/policy/Pages/2009guidelines.aspx>.

III. Use of NIH Funds

Prior to the use of NIH funds, funding recipients should provide assurances, when endorsing applications and progress reports submitted to NIH for projects using hESCs, that the hESCs are listed on the NIH registry.

IV. Research Using hESCs and/or Human Induced Pluripotent Stem Cells That, Although the Cells May Come from Eligible Sources, is Nevertheless Ineligible for NIH Funding

This section governs research using hESCs and human induced pluripotent stem cells, i.e., human cells that are capable of dividing without differentiating for a prolonged period in culture, and are known to develop into cells and tissues of the three primary germ layers. Although the cells may come from eligible sources, the following uses of these cells are nevertheless ineligible for NIH funding, as follows:

- A. Research in which hESCs (even if derived from embryos donated in accordance with these Guidelines) or human induced pluripotent stem cells are introduced into non-human primate blastocysts.
- B. Research involving the breeding of animals where the introduction of hESCs (even if derived from embryos donated in accordance with these Guidelines) or human induced pluripotent stem cells may contribute to the germ line.

V. Other Research Not Eligible for NIH Funding

- A. NIH funding of the derivation of stem cells from human embryos is prohibited by the annual appropriations ban on funding of human embryo research (Section 509, Omnibus Appropriations Act, 2009, Pub. L. 111-8, 3/11/09), otherwise known as the Dickey Amendment.
- B. Research using hESCs derived from other sources, including somatic cell nuclear transfer, parthenogenesis, and/or IVF embryos created for research purposes, is not eligible for NIH funding.

Research Involving Vertebrate Animals

Although the recipient institution and investigator bear the major responsibility for the proper care and use of animals, NIH relies on its staff, scientific review groups, and Advisory Councils to share this responsibility and review research activities for compliance with the Public Health Service policy for the care and use of vertebrate animals. The general intent of the law and policy can be summarized as two broad rules:

- The project should be worthwhile and justified on the basis of anticipated results for the good of society and the contribution to knowledge, and the work should be planned and performed by qualified scientists;

- Animals should be confined, restrained, transported, cared for, and used in experimental procedures in a manner to avoid any unnecessary discomfort, pain, or injury. Special attention must be provided when the proposed research involves dogs, cats, nonhuman primates, large numbers of animals, or animals that are in short supply or are costly.

Any comments or concerns that scientific review group members may wish to express regarding the appropriateness of the choice of species and numbers involved, the justification for their use, and the care and maintenance of vertebrate animals used in the project will be discussed in a special note in the summary statement. A "concern" is a scientific review group finding regarding animal care or use that requires resolution by program staff prior to award; a "comment" is a scientific review group observation that will be communicated in the summary statement as a suggestion to the principal investigator. For projects involving animals, the species used is separately identified at the end of the "Description" in the summary statement. Any comments or concerns that members have regarding treatment and welfare of research animals used in the project are explained in a separate paragraph in the summary statement. Any questions Council members may have should be directed to National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) staff.

SRGs assign codes to applications to indicate their judgment as to compliance with these concerns (*see Inclusion Codes below*).

No research involving animals may be conducted or supported by NIH until the institution proposing the research has provided a written assurance acceptable to NIH.

Inclusion Codes

Gender, Minority, and Children Codes

An NIH-Defined CLINICAL TRIAL? Y Or N

GENDER CODE	MINORITY CODE	CHILDREN CODE:
<i>First character = G</i>	<i>First character = M</i>	<i>First character = C</i>
<i>Second character:</i> 1 = Both Genders	<i>Second character:</i> 1 = Minority & Non-minority	<i>Second character:</i> 1 = Both children & adults
2 = Only Women	2 = Only Minority	2 = Only children
3 = Only Men	3 = Only Non-minority	3 = No children included
4 = Gender Unknown	4 = Minority Representation Unknown	4 = Representation of children unknown
<i>Third character:</i> A = Scientifically Acceptable	<i>Third character:</i> A = Scientifically Acceptable	<i>Third character:</i> A = Scientifically Acceptable
U = Scientifically Unacceptable	U = Scientifically Unacceptable	U = Scientifically Unacceptable

Vertebrate Animal Codes

Code 10 No Live Vertebrate Animals Involved

- Code 30 Live Vertebrate Animals Involved, no SRG Comments or Concerns
- Code 44 Animals Involved - Certified - SRG Concerns
- Code 45 Animals Involved - No Assurance - No SRG Comments or Concerns
- Code 47 Animals Involved - No Assurance, SRG Comments
- Code 49 Animals Involved - No Assurance, SRG Concerns

Biomedical Safety

The investigator and the sponsoring institution are responsible for protecting the environment and research personnel from hazardous conditions. As with research involving human subjects, reviewers are expected to apply the collective standards of the professions represented within the scientific review group in identifying potential hazards, such as inappropriate handling of oncogenic viruses, chemical carcinogens, infectious agents, radioactive or explosive materials, or recombinant DNA.

If applications pose special hazards, these hazards will be identified and any concerns about the adequacy of safety procedures highlighted as a special note (**BIOHAZARD**) on the summary statement.

In the case of research involving human immunodeficiency virus, researchers are expected to follow the latest Centers for Disease Control and Prevention recommendations and guidelines for health care workers and laboratory personnel. In research involving recombinant DNA, assessment of an applicant's compliance with Public Health Service guidelines is the responsibility of the NIH Office of Recombinant DNA Activities.

No award will be made until all concerns about hazardous procedures or conditions have been resolved to the satisfaction of the NIH.

Advisory Council Policy/Logistical Documents

Confidentiality

Review materials and proceedings of review meetings are privileged communications prepared for use only by consultants and staff. Members of Council must return the material given to them to the Executive Secretary at the conclusion of the meeting. All materials members have received at home or at their institutions also must be returned for disposition.

There should be no direct communication between members of Council and applicants. In addition to legal considerations, pre-mature notification of recommendations to applicants often leads to misinterpretation and distortion of discussions and recommendations.

As soon after the Council meeting as possible, applicants will be notified by NIDDK staff about the status of their applications.

Conflict of Interest

NIH takes extreme precautions to avoid placing Council members in situations where there might be an actual or apparent conflict of interest. Thus, at each Council meeting, procedures are delineated to avoid such conflicts.

A member must be absent from the meeting room during review of an application submitted by an institution, or a component of a system of institutions, in which the member or member's spouse, parent, child, partner, or close professional associate is an employee, or in which there is a directive or consultative relationship or financial interest. This includes ownership of stock in, or being a consultant for a for-profit organization. A reviewer should also leave the room during discussion of an application if being present would give the **appearance** of a conflict of interest. Examples would be an application from a for-profit organization that provides substantial financial funding to the reviewer's organization or laboratory.

The NIH has been granted a regulatory waiver by the Office of Government Ethics so that faculty of multi-campus institutions of higher education who serve as experts or consultants to DHHS may participate in matters affecting one campus of a state multi-campus institution if the expert's disqualifying financial interest is employment with no multi-campus responsibilities at a separate campus.

Additionally, a Council member should not participate in the deliberations and actions on any application from a recent student, a recent teacher, a recent collaborator, or a close personal friend. Further, a member should not take part in the discussion of an application from a scientist with whom the member has had long-standing differences which reasonably could be viewed as affecting the member's objectivity.

Council members present at each Council meeting sign a statement certifying that they did not participate in the discussion of, or vote on, any application from their own institution or an institution in which they have a financial interest.

Though the staff attempts to identify possible conflicts of interest and bring them to the attention of the Chairperson, the National Diabetes and Digestive and Kidney Diseases Advisory Council needs the assistance of members to ensure that such conflicts do not arise.

Lobbying

Technically, Council members are Government employees and governed by DHHS standards of conduct during the days they are being paid for duty. Thus, during the full midnight-to-midnight period of each of these days, members cannot transact personal business, enter into personal activities with the Legislative or Executive branches of Government, or discuss with NIH staff matters pertaining to their institution's federally funded activities. During this same period, members of Council also must not discuss with members of Congress proposed or pending legislation or appropriations that concern the Public Health Service or DHHS.

Freedom of Information and Privacy Act

The Freedom of Information Act (FOIA) of 1967 and the Privacy Act of 1974 have significantly affected the NIH review and disclosure processes. Under FOIA, a person may obtain access to any Government record, including records about himself or herself, unless the records fall within one of nine exemptions to the Act. The Privacy Act, on the other hand, is limited to records about individuals which are maintained in a "system of records" from which information is retrieved by his or her name or other personal identifier.

For example, under FOIA, third parties may receive copies of awarded grant applications, but they may not receive copies of applications that were scored but not funded or applications that were not recommended for further consideration. Also, under the Privacy Act, Principal Investigators may have access, upon request, to documents generated during the review of their grant applications. Such documents include site visit reports and summary statements, but not individual reviews. Reviewers' written comments are not retained after their substance has been incorporated into summary statements or site visit reports.

The Freedom of Information and Privacy Acts

	FREEDOM OF INFORMATION REFORM ACT OF 1986 (P.L. 93-570)	PRIVACY ACT OF 1974 (P.L. 93-579, DEC. 1974)
PURPOSE	To allow access by the public to government records.	To provide safeguards for an individual against invasion of personal privacy.
SCOPE	<p>Applies to all Federal agencies, including executive and military departments and independent regulatory agencies.</p> <p>Pertains to:</p> <ul style="list-style-type: none"> • methods whereby public may obtain records; • types of records available to the public; • exemptions that permit agencies to withhold certain types of records 	<p>Applies to all Federal agencies, including executive and military departments and independent regulatory agencies.</p> <p>Pertains to:</p> <ul style="list-style-type: none"> • any system of records from which information is retrieved by an individual’s name, identifying number, or other identifying particular assigned to an individual; • any system of records maintained by a government contractor if the agency provides by contract for the “operation by or on behalf of the agency to accomplish an agency function.”
REQUIREMENTS	<p>Requires Federal agencies to:</p> <ul style="list-style-type: none"> • publish in the Federal Register organizational descriptions and locations of agency records; • make all Agency opinions, orders, policy statements, manuals, and instructions available for public inspection and copying; • publish rules stating time, place, fees (as authorized), and procedure to be followed for requesting records; • make records promptly available to any person following the established guidelines for requesting such records; • make available for public inspection a record of the final votes of each member in every Agency proceeding, except as exempted; • release all portions of records not covered by FOIA exemptions. Exemptions that may apply to grants records include those permitting the deletions of commercial information, information that would invade personal privacy, and internal government options and advice. 	<p>Requires Federal agencies to:</p> <ul style="list-style-type: none"> • permit individuals to determine what records pertaining to them the agency collects, maintains, uses, or disseminates; • permit individuals to prevent records pertaining to them obtained for a particular purpose from being used or made available for another purpose without their consent; • permit individuals to gain access to information pertaining to them in agency records, to have a copy made of their records, and to correct or amend their records; • collect, maintain, use, or disseminate records of identifiable personal information in a manner that assures that such action is for a necessary and lawful purpose, that the information is current and accurate for its intended use, and that adequate safeguards are provided to prevent misuse of information; • be subject to civil or criminal sanctions as a result of willful or intentional actions which violate any individual’s rights under the Act; • publish annually a notice in the Federal Register indicating the existence and character of the system records..
SUMMARY	Makes possible disclosure of policy, procedures, and records to the public.	Safeguards the privacy of individuals in the face of disclosure.

Travel Procedures for NIDDK Advisory Council Members

When you travel to the National Diabetes and Digestive and Kidney Diseases Advisory Council (NDDKAC) meeting, **you are considered a Government employee** of the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK), and therefore traveling on official Government business. Your expenses are reimbursed according to Federal travel regulations.

In order for you to be reimbursed in a timely manner and to ensure that you will be reimbursed for your travel expenses, please be sure to read the information below.

Note: If you will **not be attending** the meeting, please call Dr. Brent Stanfield at (301) 594-8843 to inform him of your absence.

Overview of Expenses and Reimbursement

Allowable consultant expenses for members of NDDKAC are as follows:

Air/Rail Transportation. Round-trip transportation (from home to Bethesda, Maryland, and back).

Ground Transportation. This includes costs for taxis (including a 15 percent tip), shuttle services, parking, tolls, subway fare, and any other reasonable transportation costs.

Travel by Privately Owned Vehicle. If you drive your car to the meeting or to the airport, you will be reimbursed for the miles, tolls, and parking expenses incurred. The current Government rate is \$0.565 per mile.

Hotel. You will be reimbursed for the Government room rate and associated taxes.

Meals and Incidental Expenses (M&IE). This is a fixed rate, currently \$71.00 per day for the Washington, D.C., metropolitan area. You will receive $\frac{3}{4}$ of the M&IE rate for a maximum of 2 travel days. For any non-travel days spent at the meeting, you will receive the full per diem less any meals provided.

Honorarium. You will receive a \$200.00 honorarium for each day or fraction of a day that you attend the Advisory Council meeting. These checks are processed separately using Electronic Funds Transfer.

Travel Instructions

NIDDK will fax an NIH travel order to you prior to your travel.

Per Federal travel regulations, all Government employees are required to use their agency's travel management center. Therefore, **you are required to book your air or train fare through Omega World Travel (OWT) and you must book coach class.** Please mention you are attending the "NIDDK Advisory Council Meeting on _____ (date) _____ in Bethesda, Maryland.

It is the Council member's responsibility to contact Omega Travel at 866-264-8281 (for after-hours emergencies please contact 800-285-6342) to confirm/change the travel reservation. OWT's local number is 301-984-8985' fax is 301-984-9552. All airline tickets will be processed as electronic tickets. When using Omega World Travel, the ticket will be paid for by the National Institutes of Health. When air/rail transportation is used, travelers must use the most economical means. All travel should be by the most direct route.

What do I need to do to make a change on my airfare so I can be reimbursed for additional expenses due to changes?

If you need to make a change on your airfare, you are required to contact OWT (see phone numbers above). **We recommend that you carry their after hours number with you in case you need to make a change to your airfare or train ticket.**

What if I don't contact OWT? How will this affect my reimbursement?

Please note that if you book either business class for airfare and/or a train ticket, you will not be reimbursed. In addition, **you can not pay the difference for a change in your airfare or train ticket by paying the additional money in cash.** Again, you must contact OWT; they will charge additional travel expenses to our government account. *Travelers who choose to not use Omega World Travel to make their travel reservations will not be reimbursed by NIH/NIDDK.*

Will I receive a confirmation from OWT of my airfare or train ticket reservations?

Yes. OWT will process your reservation with an electronic ticket and send you a confirmation notice via email. Retain this confirmation number.

Can I be reimbursed for rental car expenses?

Rental car expenses are rarely approved and must be pre-approved on the travel order. Under no circumstances will rental care expenses be reimbursed without prior authorization.

Can I be reimbursed for the expense of using a sedan instead of a taxi

You can always be reimbursed for taxis but not for use of a sedan.

What documents should I carry with me when I travel?

- OWT's phone numbers in case you need to make a change in your itinerary

OMEGA WORLD TRAVEL After hour's emergency: (800) 285-6342 Outside the local area: (866) 264-8281 Local Area: (301) 984-8985 Fax: (301) 984-9552

- A **government-issued photo ID** (license, passport, etc.)
- A **copy of your electronic ticket** with confirmation number.
- The **NIH travel order** to verify that you are traveling on official Government business. NIDDK will fax the travel order to you prior to your travel.

Hotel Information

NIH/NIDDK books and pays for hotel rooms for all Council members. Hotel room confirmation numbers will be submitted to you prior to your departure. Also please confirm your check-in and check-out dates, especially if arriving late. You will be lodging at the Hyatt Regency Bethesda.

Hyatt Regency Bethesda
7400 Wisconsin Avenue
Bethesda, MD 20814
T: (301) 657-1234
F: (301) 657-6453

http://bethesda.hyatt.com/en/hotel/home.html?src=agn_mls_hr_lclb_blocal_bethe

Expense Reimbursement

After completion of travel, Council members must file a Travel Expense Form (sample attached). It is necessary to include:

- Travel stubs or the travel itinerary showing the price of the ticket
- Other travel related receipts over \$75.00 (e.g., receipts for taxi fares, tolls, parking fees)
- Original hotel bill
- Rental car receipt (reimbursement must be pre-approved).

Travelers are reimbursed for three-quarters of a day's per diem on arrival and departure days. No receipts are needed. (See M&IE above.)

Travel Expense forms and receipts should be sent within 5 days of your complete travel to:

Clairisse Mullsteff, Program Specialist
Division of Extramural Activities
National Institute of Diabetes and Digestive and Kidney Diseases
Two Democracy Plaza, Room 713B
6707 Democracy Boulevard
Bethesda, MD 20892-5452

Once your completed Travel Expense Form with all receipts attached is received, you will be sent a travel voucher for your signature. The travel voucher is a document prepared at the conclusion of your trip itemizing all claims for reimbursement.

After the travel voucher is received at NIH, the payment will be deposited into your banking account within 14 business days in the amount indicated on the travel voucher as "NET TO TRAVELER."

Note: Your honorarium will be processed separately as noted above.

If you have any questions, please do not hesitate to contact Clairisse at 301-594-8843 or email her at mullsteffcy@mail.nih.gov.

NIDDK ADVISORY COUNCIL TRAVEL EXPENSE FORM

(_____ (date) _____ Council Meeting)

REQUIRED RECEIPTS: (Please attach to this form)

- **Travel Stubs/Itinerary** with total price of ticket \$ _____
- **Original Hotel** itemized receipt:
 - Room Rate \$ _____
 - Hotel Taxes \$ _____
 - Phone Calls (\$5.00 per day are reimbursable) \$ _____
- Other travel-related receipts **over \$75.00** \$ _____
- Rental car (reimbursement must be pre-approved) \$ _____

OTHER REIMBURSEABLE EXPENSES:

- Privately-Owned Vehicle (Number of Miles x \$0.565 cents)
\$ _____
- Parking Fees \$ _____
- Taxis:
 - From Residence to Terminal \$ _____
 - From Terminal to Hotel \$ _____
 - From NIH Campus to Terminal \$ _____
 - From Terminal to Residence \$ _____
 - Other \$ _____
- Tolls \$ _____
- Other miscellaneous expenses \$ _____
(Please describe: _____)

DO NOT CLAIM ANY MEALS FOR REIMBURSEMENT. The amount of Meals and Incidental Expenses (M&IE) reimbursed is set at a fixed rate of \$71.00 per day while you are on official government business. You will receive ¾ of the M&IE rate for each day you are in travel.

PRINT NAME: _____

SIGNATURE: _____

DATE: _____

RESPONSIBILITIES OF NIDDK ADVISORY COUNCIL MEMBERS

(A Cheat Sheet for New NIDDK Council Members)

I. Before the meeting

Early Concurrence

- All grant applications (excluding those from foreign organizations) which have no concerns noted that would represent a bar to award (e.g., for human subjects, animal welfare, biohazards, etc.) or need Special Council Review, will follow an expedited concurrence process.
- A few weeks prior to the meeting NIDDK will alert the early concurrence committee members that these applications are available in the Electronic Council Book (ECB).
- As a new member it is unlikely that you will be asked to be a member of the early concurrence committee, but during this process all Council members are provided the list of all applications eligible for early concurrence for review and any member may bring any of these applications to full Council consideration.

Bottom line: *You may wish to spend a little time looking over the early concurrence list to see if you have any concerns--and if you do let Brent Stanfield know A.S.A.P.*

Council Materials

- About ten days before the Council meeting Council Members are notified that materials for the meetings are available for their review.
- These materials are available via the ECB using the same access information that was earlier given for access to the early concurrence list.
- Scientific members are frequently asked in advance to review particular applications or proposed actions in the closed portion of the subcommittee meeting, and they are often provided additional materials.

Bottom line: *Please thoroughly review these materials prior to the meeting & contact the appropriate NIDDK Division Director if you have any concerns or if you would like additional information.*

Additional Requests

- Occasionally a Division Director, or other NIDDK staff member, will contact a Council member to request that they participate as a discussant of a presentation at an open portion of the meeting.
- If available, the slide set or additional materials will usually be provided to the Council member.

Bottom line: *Please review these materials & come to the meeting prepared to participate as requested. Please be sure that you understand & follow any specific guidance — especially when considering appeals. NIDDK needs advice on the merit of the appeal, not the merit of the application.*

Attendance

- Members are encouraged to attend the entire Council meeting. Staff will work with you or your assistant to arrange travel plans that will allow you plenty of time to catch your flight after the meeting.

Bottom line: *Please don't plan on leaving Council meetings early.*

II. At the meeting

Closed Sessions

- Council members are requested to come prepared to fully participate in the closed sessions.
- Members are reminded that all matters discussed or materials available for discussion in closed sessions and the discussions themselves are confidential and should not be shared with anyone outside of the meeting.

Bottom line: *What happens in closed session stays in closed session.*

Open Sessions

- Council members are requested to come prepared to participate fully in the open sessions, including the discussions that follow presentations.
- Members are encouraged to provide specific feedback to NIDDK staff about any of the matters discussed or potential matters or issues they would like to hear discussed at a future meeting.
- Remember that ***members of the public, of advocacy groups, and of the press may attend our Council meetings*** and anything that you say in the open sessions of Council meetings could be reported.

Bottom line: *Please interact & give us your perspective and advice, but be careful about seeming/being too prescriptive in open session and also please be careful in open session not to say anything that you (and we) might regret if it gets reported and appears in print.*

III. After the meeting

Special Requests

- Occasionally Council members may be requested to review certain matters (for example, an appeal that arrived too late for consideration at the meeting) after the meeting.
- Please provide the requested advice within the timeframe allowed and treat all of these matters as confidential, just as you would were they are being considered within closed session.

Bottom line: *These matters are essentially an extension of the closed session.*

What do we really want from you?

- Your scientific expertise
- Your understanding of patient and clinical issues
- Your wise council about our general portfolio
- Your thoughts about NIH/NIDDK policies, the public landscape and help in avoiding pitfalls
- Your outreach and advocacy on behalf of NIH/NIDDK both within your community and to the public to explain the processes, the considerations, the rigor, and the fairness of how we do business and the important work that we support
- Your help in keeping NIDDK at the cutting edge of science and scientific administration

What should you be careful about?

- Keeping closed session materials and discussions confidential
- Paying attention to and avoiding/disclosing any real or apparent conflicts of interest as soon as they arise

- Advocating to elected officials while on official government travel
 - You are a special government employee when you are traveling to attend Council meetings and during this time you are not allowed to advocate!
- Keeping in mind that anything you say in the open sessions of the Council meeting (both the main sessions and open sessions of the sub-councils) could wind up in print
- Not appearing to be too prescriptive in your remarks – You represent NIDDK’s broad community rather than advocating for a particular segment of that community
 - Sparking disease or research area wars is not in anyone’s best interest

NIDDK Advisory Council Orientation Reference Links January, 2015

General background information about Council

- **Advisory Council page on the web:**
<http://www.niddk.nih.gov/about-niddk/advisory-coordinating-committees/national-diabetes-digestive-kidney-disease-advisory-council/Pages/advisory-council.aspx>
- **Advisory Council Charter:**
<http://www.niddk.nih.gov/about-niddk/advisory-coordinating-committees/national-diabetes-digestive-kidney-disease-advisory-council/Documents/2012NIDDKChartersigned.pdf>
- **Advisory Council Operating Procedures:**
<http://www.niddk.nih.gov/about-niddk/advisory-coordinating-committees/national-diabetes-digestive-kidney-disease-advisory-council/operating-procedures/Pages/operating-procedures.aspx>
- **Advisory Council Membership Roster:**
http://www.csr.nih.gov/Roster_proto/members.asp?cid=100532&Title=National+Diabetes+and+Digestive+and+Kidney+Diseases+Advisory+Council&ABBR=DKNAC

General background information about NIDDK and funding

- **NIDDK Mission:**
<http://www.niddk.nih.gov/about-niddk/meet-the-director/mission-vision/Pages/mission-vision.aspx>
- **NIDDK Organization:**
<http://www.niddk.nih.gov/about-niddk/offices-divisions/Pages/default.aspx>
- **NIDDK Division of Extramural Activities:**
<http://www.niddk.nih.gov/about-niddk/offices-divisions/division-extramural-activities/Pages/default.aspx>
- **NIDDK Division of Intramural Research:**
<http://www.niddk.nih.gov/about-niddk/offices-divisions/division-intramural-research/Pages/default.aspx>
- **NIDDK Funding Policy:**
<http://www.niddk.nih.gov/research-funding/process/award-funding-policy/Pages/award-funding-policy.aspx>

Administrative matters regarding Council membership

- **Confidentiality, Conflict of Interest & Lobbying**
(Ethics Training for Special Government Employees):
<http://oge.gov/Education/Education-Resources-for-Federal-Employees/Ethics-Training-for-Special-Government-Employees-WBT/>
- **Procedures for Avoiding Conflict of Interest for Special Government Employees:**
<http://oma1.od.nih.gov/manualchapters/management/1810-1/>

- **Travel Reimbursement:**
<http://www.niddk.nih.gov/about-niddk/advisory-coordinating-committees/national-diabetes-digestive-kidney-disease-advisory-council/travel-expenses-reimbursement/Pages/advisory-travel-expenses-reimbursement.aspx>

The Grant Process

- **NIH Grants Process Overview, from application to award:**
http://grants.nih.gov/grants/grants_process.htm
- **Types of NIH grants:**
http://grants.nih.gov/grants/funding/funding_program.htm
- **Research Project Grant (RPG) mechanisms utilized by NIDDK:**
<http://report.nih.gov/DisplayRePORT.aspx?rid=565>
- **Peer Review Policies & Practices:**
<http://grants.nih.gov/grants/peer/peer.htm>

Grant Policies & Regulations

- **FOIA & Privacy:**
<http://www.nih.gov/icd/od/foia/5usc552.htm>
See also: <http://www.niddk.nih.gov/Pages/niddk-privacy-statement.aspx>
- **NIH Grants Policy & Guidance:**
<http://grants.nih.gov/grants/policy/policy.htm>
- **NIH Intellectual Property Policy:**
<https://grants.nih.gov/grants/intell-property.htm>
- **NIH Invention Reporting (iEdison):**
<https://s-edison.info.nih.gov/iEdison/>
- **NIH Public Access Policy:**
<http://publicaccess.nih.gov/>
- **Research Integrity/Research Misconduct:**
https://grants.nih.gov/grants/research_integrity/index.htm
- **Information about NIH grant applications from foreign countries:**
<http://grants.nih.gov/grants/foreign/index.htm>

Additional Information

- **Information for new Council Members:**
<http://www.niddk.nih.gov/about-niddk/advisory-coordinating-committees/national-diabetes-digestive-kidney-disease-advisory-council/Documents/NIDDKACOrientationHandbook508cRev02112012.pdf>

Recent Notices in the Guide on Policy, etc.:

- **NIH Genomic Data Sharing Policy:**
<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-124.html>
- **Implementation of the NIH Genomic Data Sharing Policy for NIH Grant Applications and Awards:**
<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-111.html>
- **Update: New Biographical Sketch Format Required for NIH and AHRQ Grant Applications Submitted for Due Dates on or After May 25, 2015:**
<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-15-032.html>