

NIDDK Advisory Council: Operating Procedures

January 2019

Expiration: February 2020

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 members 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 members negotiate 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.

Expedited En Bloc Concurrence

NIH, 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, - 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 are included in a category of applications specified as ineligible for expedited *en bloc* concurrence (see below), 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 NDDKAC as a whole. The concurrence committee shall consist of the Council Executive Secretary (non-voting) and six members of the NDDKAC. Two members will be selected from each subcommittee of the NDDKAC.

The Executive Secretary will alert the concurrence committee members 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.

Special Council Review

Each Council round the NDDKAC 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 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.

Specification of Council Action Requirements

Actions requiring NDDKAC review or advice and ***not*** eligible for expedited *en bloc* concurrence are: SCR, applications from foreign institutions, nominations for Method to Extend Research in Time (MERIT) awards and extensions, and unresolved appeals of initial peer review.

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, to otherwise accommodate research 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. 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.

NIDDK staff may restore requested time and support which were deleted by the initial review group when the principal investigator has provided written justification, 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.

The NDDKAC may also advise the Institute on: The adequacy of the initial review process; and, funding of applications out of order (i.e., “Reaches”) and/or 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, generally 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 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 will usually be 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 (<https://oma1.od.nih.gov/manualchapters/management/1805/>)
- 3) NIH Manual Chapter 1810-1, Procedures for Avoiding Conflict of Interest for Special Government and other Federal Employees serving as Advisory Committee Members (<http://oma1.od.nih.gov/manualchapters/management/1810-1/>)
- 4) NIH Manual Chapter 3005, Review and Evaluation of Intramural Programs (<https://oma1.od.nih.gov/manualchapters/intramural/3005/>)
- 5) NIH Manual Chapter 4204-204B, Peer Review Process (<https://oma1.od.nih.gov/manualchapters/grants/4204-204B/>)

- 6) NIH Manual Chapter 54104, NIH Research Grants Involving Foreign Institutions and International Organizations (<https://oma1.od.nih.gov/manualchapters/grants/54104>)
- 7) PHS Policy on Humane Care and Use of Laboratory Animals (<http://grants.nih.gov/grants/olaw/references/PHSPolicyLabAnimals.pdf>)
- 8) NIH Manual Chapter 54513, Management and Procedures of National Advisory Councils and Boards in Their Review of Extramural Activities (<https://oma1.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 (<https://oma1.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>)