



NIDDK Centers Program Review

September 2012

NIDDK Centers Program Review

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EXECUTIVE SUMMARY

Background: Through its Research Centers Program, the NIDDK provides critical support and services for research on diabetes, endocrinology, digestive diseases, kidney diseases, obesity and nutrition, cystic fibrosis, molecular therapy, urology, and hematology. Because the Centers Program is such an important part of its research portfolio, the NIDDK periodically reviews the program in consultation with the National Diabetes and Digestive and Kidney Diseases Advisory Council.

Process: A review of the NIDDK Centers Program began at the February 2010 Advisory Council meeting, at which Council members recommended that the NIDDK examine synergies between centers; encourage interactions between centers; enhance access to center resources; examine the value of the Pilot and Feasibility (P&F) program; and examine changes implemented in response to the NIDDK's 2003 Centers review. To address these recommendations, NIDDK staff made site visits to five universities, each of which has five NIDDK-supported Centers. The NIDDK shared its interim status report and preliminary findings from these visits with the Advisory Council at its May 2011 meeting. So that all Centers had an opportunity to be involved in the review process, the NIDDK invited Centers to provide input on the interim report. To ensure the broadest possible stakeholder input, a draft report was then posted on the NIDDK website for a month-long period of public comment. The final report was presented to the Institute's Advisory Council at its September 2012 meeting.

Data Collection: At the site visits, the NIDDK observed diverse operations. Tangible examples of synergy included retreats and courses co-sponsored by different centers, multiple centers supporting a common core, investigators that were members of more than one center due to cross-cutting research interests, and Center Directors with administrative duties that cut across the centers at their institutions. At many sites, the NIDDK site visit was the first interaction for all the NIDDK centers at a site, and the site visits were an opportunity for all NIDDK staff overseeing centers programs to come together and share experiences and knowledge. During the comment periods, the commenters provided input on discussion topics under consideration by the Institute, and suggested ways that the NIDDK could enhance its centers program.

Outcomes: The NIDDK has modified its centers program and is making recommendations to strengthen the program further. For example, the NIDDK has already modified some centers to promote the establishment of regional/national resources to serve a wider scientific community; modified some centers' guidelines for reporting the research base to make reviewers aware when members belong to more than one center at an institution; enhanced information sharing among centers and with the scientific community, such as through creation of a website; and implemented novel approaches to enhance access to center cores.

The NIDDK is also considering other ways to strengthen the centers program. For example, NIDDK staff are meeting on a regular basis to identify opportunities for enhancing synergy and center value, which may include using web-based tools, identifying ways to incentivize centers to build networks and share resources, enhancing opportunities for training through the centers, and identifying ways to link other NIDDK programs to the centers. The NIDDK also plans to provide guidance and information to the centers through "best practices" documents on the P&F

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program, core business models, and center membership. Other areas under consideration focus on support of small centers and institutional cores, and approaches to broaden access to center resources.

Conclusions: This review has identified many strengths in the NIDDK centers program and showcased how the centers are advancing research progress on diseases within the NIDDK mission. The review has also identified areas that could be strengthened, and some changes have already been made while other changes are under consideration.

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1. INTRODUCTION

1.a. Purpose of the Centers Program Review

Through the NIDDK Research Centers program, NIDDK provides critical support and services for research on diabetes, endocrinology, digestive diseases, kidney diseases, obesity and nutrition, cystic fibrosis, molecular therapy, urology, and hematology. Because the centers program is such an important part of its research portfolio, the NIDDK periodically reviews the program in consultation with its Advisory Council.

The centers program was last evaluated in 2003, an exercise that led to several changes in the NIDDK approach to centers. The findings and effects of the 2003 effort are briefly addressed in this report. The current effort, which began at the February 2010 meeting of the National Diabetes and Digestive and Kidney Diseases (NDDK) Advisory Council, is intended in part to determine whether the program can be further strengthened to advance the Institute's scientific mission more rapidly. The current review focuses on several areas recommended by the Institute's Advisory Council at the February 2010 meeting:

- examine synergies between centers;
- encourage interactions between centers, including fostering regional and national cores;
- enhance access to center resources;
- examine the value of the Pilot and Feasibility (P&F) program; and
- examine changes implemented in response to the NIDDK's 2003 centers review based on recommendations that the Institute expand its centers' P&F program and shift some types of centers from P50 to P30 grants.

1.b. Overview of the NIDDK Centers Program

NIDDK Research Center grants are awarded to extramural research institutions to provide support for long-term multidisciplinary programs of medical research within the NIDDK mission. They also support the development of research resources, aim to integrate basic research with applied research and technology transfer activities, and promote research in areas of clinical applications with an emphasis on intervention, including prototype development and refinement of products, techniques, processes, methods, and practices. Another important goal of the centers is to create synergy. That is, they should enable researchers to address key scientific questions and to make more substantial scientific progress than would otherwise be possible by the individual components of a center. In other words, the sum should be greater than the individual parts. Synergy can be generated within the center itself, as well as through collaborations between/among centers, cross-fertilization between centers and other NIDDK programs, utilization of center resources by the broader NIDDK research community, and other means. Other NIH components also support center programs related to their research missions.

Common Center Characteristics: Because NIDDK centers are organizationally and operationally diverse, there is no such thing as a “typical” center. Furthermore, not all centers have the same goals or organizational structure. However, there are common features that are often found in centers, such as:

- Dozens of member principal investigators (PIs) with related research interests;
- Administrative and scientific cores;

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- P&F programs;
- Enrichment activities; and
- Foster an environment that is conducive to collaboration and training.

Legislative History and Historical Perspective: The NIH Revitalization Act of 1993, Public Law (P.L.) 103-43, now codified in Section 431 of the Public Health Service Act, provides the NIDDK with broad authority to establish centers for diabetes mellitus and related endocrine and metabolic diseases; digestive diseases and related functional, congenital, metabolic disorders, and normal development of the digestive tract; kidney and urologic disorders; and nutritional disorders, including obesity. Authorities for specific types of centers are described in the “NIDDK Centers: Legislative History” box insert.

Table A shows the various types of NIDDK-supported centers, along with the year that each program began (left column) and the number of centers of each type in 2010 (right column). The 2010 numbers include centers that were established that year, but did not receive funding until 2011; and does not include some centers that received funding in 2010, but which would not receive funds in 2011. In total, NIDDK supported 87 centers in 2010.

NIDDK Centers: Legislative History

Title III, section 301 of the Public Health Service Act (now covered under Title 42, Chapter 6a, Subchapter II, Part A, Sec. 241) has historically been used by the NIH as a broad-based and open-ended research authority to pursue research activities beyond those generally or specifically authorized in the NIH specific part of the Act. The Diabetes Endocrinology Research Center (DERC) program was thus initiated in Fiscal Year (FY) 1972 under authority of Title III. Five DERCs were first awarded in FY 1973 and FY 1974.

The first specific statutory authority provided by Congress for the award of centers grants by NIDDK derived from the National Diabetes Mellitus Research and Education Act (Public Law [P.L.]. 93-354), enacted July 23, 1974. This law provided for Diabetes Research and Training Centers (DRTCs) and authorized funds to be appropriated for FY 1975 through FY 1977. The first such grants were awarded in September, 1977. The authority for these centers was subsequently extended by P.L. 94-562 (October 19, 1976) and P.L. 96-538 (December 17, 1980).

Authority was further extended by the Health Research Extension Act of 1985 (P.L. 99-158), enacted November 20, 1985, which also broadened the authority to include centers in all three modern programmatic divisions of the Institute. The language established in this Act remains unaltered today in Title 42 of the U.S. Code, chapter 6a (the Public Health Service Act). The portion of this law authorizing the NIDDK and describing its statutory mission is section 285c. As written, the authority described extends to “centers for research and training in diabetes mellitus and related endocrine and metabolic diseases”; “centers for research in digestive diseases and related functional, congenital, metabolic disorders, and normal development of the digestive tract”; “centers for research in kidney and urologic diseases” to be named for the Honorable George O’Brien of Illinois; and “centers for research and training regarding nutritional disorders, including obesity.”

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Accordingly, the NIDDK published a request for research center applications (P50), to establish Kidney and Urological Research Centers on August 8, 1986. The initial awards of digestive diseases centers actually preceded P.L. 99-158. The NIDDK published requests for applications for Digestive Diseases Core Centers to be initiated in FY 1984, consistent with House Appropriations Report language for that fiscal year.

Other centers programs supported by the NIDDK are addressed in report language from the House and Senate Appropriations Committees and Authorization Committees dating from the 1970s, and authorized nonspecifically through Title III, section 301 of the Public Health Service Act.

Table A: NIDDK Centers—Year Established and Number of Centers in FY2010

Year Established	Name	Number in FY2010
1973	Diabetes Research Centers*	16
1979	Clinical Nutrition Research Units and Obesity Nutrition Research Centers (combined to form Nutrition Obesity Research Centers [NORCs])	12
1982	Cystic Fibrosis Core Centers**	N/A
1984	Silvio O. Conte Digestive Diseases Research Core Centers: DDRCCs	17
1987	George O'Brien Kidney Research Centers	8
1987	George O'Brien Urology Research Centers	4
1990	Specialized Centers for Cystic Fibrosis Research**	N/A
1991	Pediatric Nephrology Research Centers	2
1993	Molecular Therapy Core Centers**	3
1994	Molecular Hematology Research Centers	5
1999	Polycystic Kidney Disease Research Centers	4
2001	Mouse Metabolic Phenotyping Centers: MMPCs	4
2002	Specialized Centers on Women's Health Research (with ORWH)	3
2003	Silvio O. Conte Digestive Diseases Research Development Centers: DDRDCs	4
2005	Cystic Fibrosis Research and Translation Core Centers**	5

*The first Diabetes Research Centers were DERCs, established in 1973. The first DRTC grants were awarded in 1977. The FY2010 number shown in the table includes both DERCs and DRDCs.

**This table shows the different types of centers conducting cystic fibrosis (CF) research that have existed since the program's inception in 1982. The configuration of this program has been adapted to meet the evolving needs of the CF research community. The CF Core Centers (1982) and Specialized Centers for CF Research (1990) funding opportunities were therefore allowed to expire, and although they are presented here for historical completeness, there were no centers in FY2010.

Activity Codes of NIDDK-supported Centers: The NIH uses “activity codes” to differentiate the wide variety of research-related programs it supports. The NIH defines “centers” as any and all grants—excepting National Library of Medicine grants—with the following activity codes: G12, M01, P20, P30, P40, P41, P50, P51, P60, PL1, U30, U41, U42, U50, U51, U54, and R07.

The types of NIDDK centers considered in this exercise are listed by activity code in Table B. The R24 and U24 mechanisms are not classified as “centers” by the NIH. However, NIDDK

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uses those mechanisms to support center-like activities and thus they were included in this exercise. Two types of centers use the P50 (“Specialized Centers”) activity code. The Specialized Centers of Research (SCOR) Funding Opportunity Announcement (FOA) is issued by the NIH Office of Research on Women’s Health (ORWH), not by NIDDK, and is distinct in some respects from other NIDDK-supported centers. For example, it does not specify the use of funds for P&F programs.

Table B: Activity Codes of Centers Under Consideration in Review

Activity Code	Title	Description
P30	Center Core Grants	Research cores, P&F projects
P50	Specialized Centers	Research cores, P&F projects, research projects
P50	Specialized Centers of Research (SCOR)	Co-funded with NIH Office of Research on Women’s Health; do not use funds for P&F programs
P60	Comprehensive Centers	Research cores, P&F, Prevention and Control (translational) core
R24	Resource-Related Research Projects	Support for research cores directly related to funded research projects; do not have administrative cores, P&F, or enrichment program
U24	Cooperative Agreements	Mouse Metabolic Phenotyping Centers (MMPCs) are the only “center” U24s

The types of NIDDK centers not considered in this exercise are listed by activity code in Table C. The P20 Planning Centers are comparatively small grants that may lead to establishment of full centers. However, because it is a new program, NIDDK considered it too early to examine its implementation and success, and thus excluded these grants from the review. NIDDK did not issue the FOAs for the other centers listed in Table C; those FOAs were issued by the NIH Office of the Director or by other NIH components. Therefore, the NIDDK has somewhat less freedom to modify those programs than its own centers program, so those centers were not included in this review.

Table C: Activity Codes of Centers not Under Consideration in Review

Activity Code	Title	Rationale for Exclusion from Review
P20	Center Core Grants Planning Centers for Interdisciplinary Research in Benign Urology	New program in 2010, so too early to examine its implementation and success
U54	Rare Diseases Clinical Research Consortia	FOA issued by NIH Office of the Director, not NIDDK
PL1	Linked Center Core Grants	FOA issued by NIH Office of the Director, not NIDDK; administered by NIDDK on behalf of NIH Office of the Director, but receive very little NIDDK funding
Centers led by other NIH components -- various activity codes	Various	FOAs issued by other NIH Institutes and Centers, not NIDDK

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NIDDK Centers Budget: Figure 1 shows the NIDDK centers budget from FY95-10 (red bars, corresponding to left axis). The annual centers budget was roughly \$60 million from FY95-00. The budget increased in 2001—during the period of the NIH budget doubling—to over \$90 million. The budget topped \$100 million in 2004, and remained relatively flat through 2008—coinciding with a flat overall NIDDK budget (black line, corresponding to right axis). In FY09-10, in addition to receiving funds from the regular NIH appropriations, centers received funding from the American Recovery and Reinvestment Act of 2009 (ARRA; blue bars, corresponding to left axis). In FY09-10, the centers received approximately \$20 million and \$8 million, respectively, of ARRA funds. The ARRA funds enabled centers to support activities such as making additional P&F awards, updating or replacing old equipment in the research cores, and supporting summer research experiences for students.

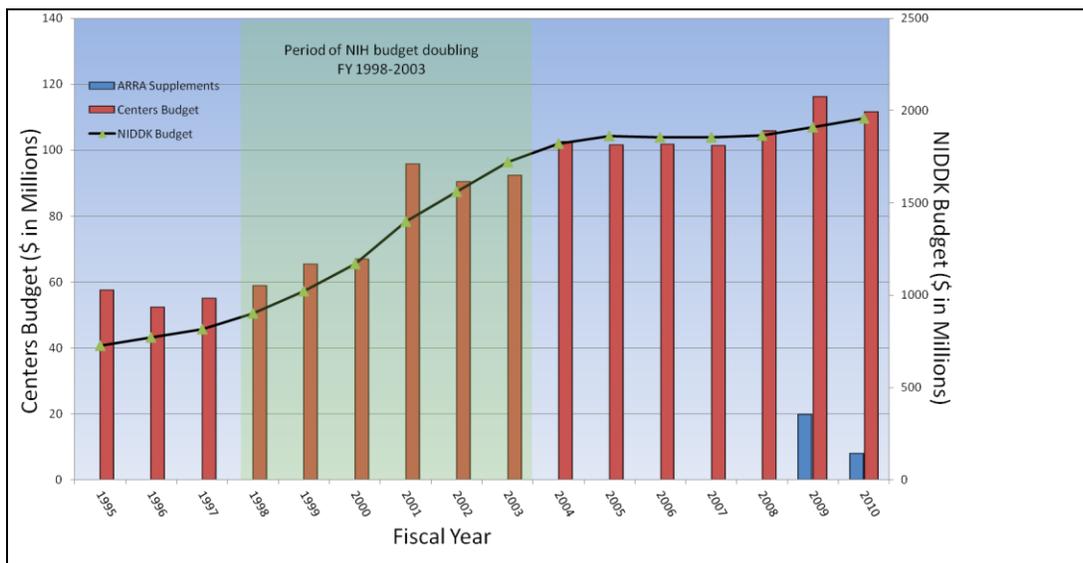


Figure 1—NIDDK Centers Budget: The centers budget shown in red (corresponding to the Centers Budget axis on the left) includes fiscal year NIDDK spending on P20, P30, P50, P60, U42, PL1, and U54 activity codes, as well as the Mouse Metabolic Phenotyping Centers (U24) and Digestive Diseases Research Development Centers (R24). This includes regularly appropriated funds, as well as money from the *Special Statutory Funding Program for Type 1 Diabetes Research*, but excludes spending made possible by the American Recovery and Reinvestment Act of 2009, which is shown separately in blue (with the same axis). The green triangles and black curve show the overall NIDDK budget, and correspond to the axis on the right.

Figure 2 shows the NIDDK FY10 budget breakdown by centers activity code. The majority of the FY10 NIDDK centers budget supported P30 grants. This reflects a general trend, since a 2003 NIDDK centers review, to move away from the P50 activity code and toward the P30. That trend is also visible in Figure 3, which shows the numbers of both types of grants supported by NIDDK from FY05-10. Since the Centers review was initiated in FY10, NIDDK has discontinued use of the P60 activity code. A new P30 program, the NIDDK Centers for Diabetes Translation Research, was designed to fulfill some of the same program goals.

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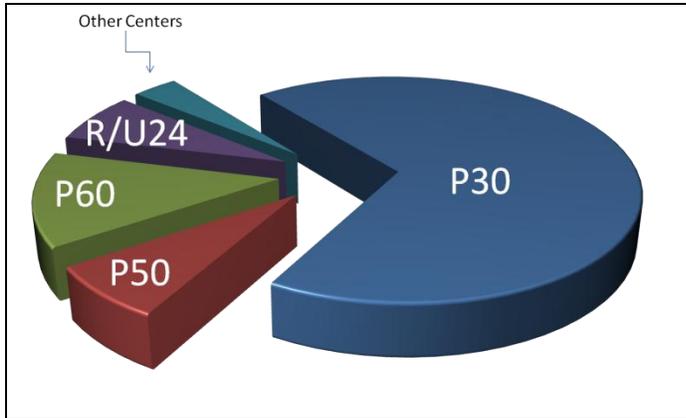


Figure 2—Centers Activity Codes in the NIDDK FY2010 Budget*: The size of the wedges is proportional to dollars spent on each activity code in FY10. “Other Centers” refers to the centers detailed in Table C and represents 3.5 percent of the total. *These totals do not include ARRA funds.

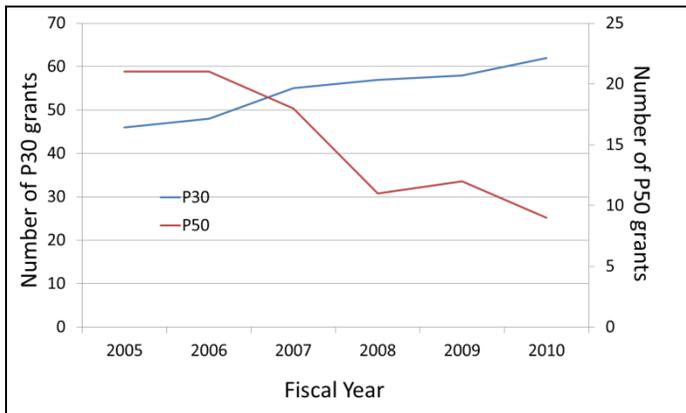


Figure 3—Trends in NIDDK Use of the P50 and P30 Activity Codes, FY05-10: Number of NIDDK-supported P30 and P50 center grants over time, from FY05-10 (note that the graph has separate axes for P30 and P50 grants). Data show a decline in the number of P50 grants and an increase in P30 grants over this time period.

Geographical Clustering of NIDDK Centers: As part of the centers review, the NIDDK examined the geographical clustering of centers, to see how they were distributed across the United States in FY10. Figure 4 highlights an uneven distribution of NIDDK-supported centers. A clear majority of centers (52/87) are in cities with 4 or more centers; these centers are not always at the same institution. Twenty-four of the 87 centers are in cities with 2 to 3, while 11 are in cities with no other NIDDK center. While there is the potential for achieving synergies and/or efficiencies between centers located in proximity to one another, there may be disadvantages to directing resources to a limited number of locations. Grantees at institutions without centers could potentially benefit from access to cores at NIDDK centers, if they have knowledge of them and access to them.

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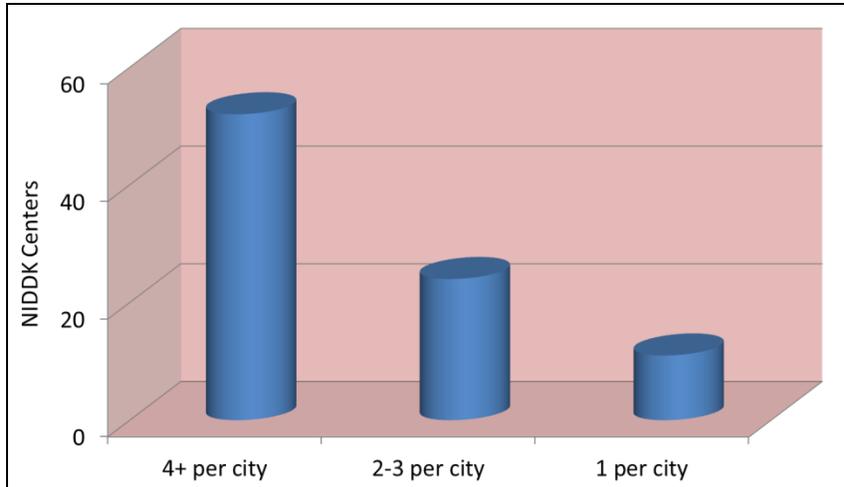


Figure 4—Geographical Clustering of NIDDK Centers, FY10: Of the 87 NIDDK-funded centers, 52 were in cities with 4 or more centers (not always at the same institution); 24/87 centers were in cities with 2 to 3; and 11 were in cities with no other NIDDK center.

2. PROCESS FOR NIDDK CENTERS PROGRAM REVIEW

The NIDDK has engaged in a collaborative process for reviewing its centers program, which has included discussions with and input from the Institute’s Advisory Council, scientists participating in the centers program, and the broader scientific community. This section describes the process for conducting the centers review.

2.a. Presentation at February 2010 Advisory Council Meeting

The centers review began with a presentation made by NIDDK staff at the February 2010 meeting of the NIDDK Advisory Council. At that meeting, the Council members recommended that the Institute further review and strengthen its centers program by:

- examining synergies between centers;
- encouraging interactions between centers, including fostering regional and national cores;
- enhancing access to center resources;
- examining the value of the P&F program; and
- examining changes implemented in response to the NIDDK's 2003 centers review, which included expanding the centers’ P&F program and shifting some types of centers from P50 to P30 grants.

2.b. Center Site Visits, 2010-2011

The NIDDK determined that it would begin to address the Advisory Council recommendations by conducting site visits to institutions with multiple NIDDK-supported centers. From December 2010 through March 2011, NIDDK visited five institutions that each had five NIDDK-supported centers, in order to visit a broad representation of the types of centers supported by the NIDDK, and also to permit the Institute to examine synergies and interactions among centers. Detailed information on the site visits is found in the “Site Visits to NIDDK-supported Centers” section of this report. The NIDDK also alerted other centers that were not visited via email that the site visits were occurring.

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2.c. Presentation at May 2011 Advisory Council Meeting

At the May 2011 meeting of the Advisory Council, the NIDDK Deputy Director presented an interim report of the centers review, including preliminary findings from the site visits. The Council members provided input on the progress and next steps.

2.d. Input on Draft Interim Report Slideset

Because of time and budgetary constraints, the NIDDK visited only a subset of centers during the site visit portion of the centers review described above. However, the Institute wanted to give all centers an opportunity to provide input on the review, not just the centers that participated in the site visits. Toward this goal, the NIDDK modified the interim report slideset presented at the May 2011 Advisory Council meeting by: (1) adding talking points to describe each slide; and (2) adding slides that included specific topics on which NIDDK was particularly interested in receiving input from the centers, including possible changes to the centers program.

This modified interim report slideset was distributed to all NIDDK Center Directors, who have first-hand experience with the discussion topics of particular interest to NIDDK, and would potentially be affected by changes to the centers program. In total, 112 centers were invited to provide comment. That number is higher than the total number of centers (87) shown in Table A, because NIDDK also contacted: (1) new centers that had been awarded as of early November 2011; (2) centers that were active at the beginning of the review, but were no longer active and thus not counted in the numbers reported in Table A; and (3) the P20 centers that were not included in the review because they were new centers. The centers were invited to provide comment through an online form from November 10-December 21, 2011. The NIDDK received 24 responses (a response rate of 21 percent).

2.e. Input on Draft Report

To provide other stakeholders an opportunity to comment, the NIDDK made an earlier draft of this report publicly available for comment on its website and notified all NIDDK grantees to the posting. Because Center Directors are NIDDK grantees, they were also notified of the posting and invited to comment. In total, over 5,400 people were notified via email.

The draft report was developed using the interim report slideset as a guidepost. Importantly, the report included a set of recommendations to enhance the centers program. The recommendations were developed by NIDDK based on the site visits and internal discussions, as well as with consideration of input from the Advisory Council and centers. The NIDDK received 15 responses (a response rate of 0.3 percent), some of which came from center grantees. Input received during both comment periods is summarized in the “Summary of Input from Comment Periods” section of this report.

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3. SITE VISITS TO NIDDK-SUPPORTED CENTERS

This section describes the process and findings from the site visits to NIDDK-supported centers conducted as part of the review.

3.a. Purpose of Visits

Because Council recommendations included enhancing synergies and encouraging interactions between centers, the Institute decided that it would visit institutions that have several NIDDK-supported centers. This approach was also intended to provide a broad picture of the various types of centers supported by the Institute, and to permit the Institute to examine how centers interacted at the same institution, with centers at other institutions, and with scientists outside the centers at a local, regional, and national level.

3.b. Centers Visited

NIDDK staff visited institutions that each had one or more centers supported by each of NIDDK's three programmatic divisions: 1) Division of Diabetes, Endocrinology, and Metabolic Diseases; 2) Division of Digestive Diseases and Nutrition; and 3) Division of Kidney, Urologic, and Hematologic Diseases. The NIDDK determined that five was the largest number of such visits that was practical in the available time and budget. Using these guiding principles, the NIDDK decided to visit the following five institutions that had five NIDDK-supported centers:

- University of Pennsylvania/Children's Hospital of Philadelphia: December 9-10, 2010
- Yale University: December 15-16, 2010
- Washington University in St. Louis: January 27-28, 2011
- University of Washington/Fred Hutchinson Cancer Research Center/Seattle Children's Hospital: February 2-3, 2011
- Vanderbilt University: March 28-29, 2011

By so doing, the NIDDK visited 25 centers in total, including at least one of nearly all types of NIDDK centers (Table D), thereby providing a broad representation of the types of centers supported by the NIDDK.

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Table D: Number of Centers Visited During NIDDK Site Visits, 2010-2011

Name	Number in FY2010	Number Visited
Diabetes Research Centers: DERCs and DRTC	16	5
Clinical Nutrition Research Units and Obesity Nutrition Research Centers (combined to form NORCs)	12	2
Silvio O. Conte Digestive Diseases Research Core Centers: DDRCCs	17	4
George O'Brien Kidney Research Centers	8	3
George O'Brien Urology Research Centers	4	1
Pediatric Nephrology Research Centers	2	1
Molecular Therapy Core Centers	3	1
Molecular Hematology Research Centers	5	2
Polycystic Kidney Disease Research Centers	4	1
Mouse Metabolic Phenotyping Centers: MMPCs	4	3
Specialized Centers on Women's Health Research (with ORWH)	3	1
Silvio O. Conte Digestive Diseases Research Development Centers: DDRDCs	4	0
Cystic Fibrosis Research and Translation Core Centers	5	1
Total Visited		25

3.c. NIDDK Personnel Attending Site Visits

The following NIDDK staff members attended the site visits:

- NIDDK Director or Deputy Director;
- Program Directors managing center programs;
- Director or Deputy Director, NIDDK Division of Extramural Activities; and
- Health Science Policy Analyst, NIDDK Office of Scientific Program and Policy Analysis.

3.d. Summary of Site Visit Process

Each site visit consisted of a 2-day program. The process for each day is described below.

Day 1 – On the first day, NIDDK visited several core facilities that were supported by NIDDK centers. NIDDK did not visit all cores, but rather a subset selected by NIDDK in consultation with the visited institutions. Some of the cores that were visited were supported by more than one center. To summarize:

- The visited centers had an average of 4 cores, while visited cities had an average of 19 total NIDDK-supported cores;
- NIDDK visited an average of 8 cores per site; and
- 42/97 (43%) of the cores were toured.

The core visits included presentations by Core Directors and tours of the facilities. In most cases, the NIDDK group toured the core laboratory or facility, saw the instrumentation, and heard about how the core operates. In other cases, such as animal facilities that require visitors

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to wear special garments, core personnel sometimes opted to give a presentation rather than to take the NIDDK visitors through the actual facility.

The NIDDK sent a list of questions to the centers prior to the visits, to help guide discussions related to the core facilities:

- What services are offered? Which are the most and the least used? Are these services offered elsewhere on campus (if known)? Has the core developed any specialized services/techniques/equipment not available elsewhere on campus?
- What is method of payment for services, *i.e.*, free to members, or others; charge-backs for individual services (and is this scaled for different sets of users); or cost-sharing? Do fellows/trainees/post-docs have free use of core services?
- Who are the users—only center members/associate members; only investigators within the university; others in same city/state; or is this a nationally recognized resource? What is the distribution of users among the groups taking advantage of the core? Is this a centralized facility or is it associated with a single center?
- Is prioritization of services, or of users, necessary, or is the work done on a first-come, first-served basis? Does this apply to all or only some of the core services offered?
- How much institutional support is given to the core? Is this in the form of salaries, cost-sharing, space renovation, or something else?

Day 2 – On the second day, the visit focused on in-depth information on the centers provided by the institutions through a series of presentations and discussions. The day began with introductory remarks given by the NIDDK Director or Deputy Director, followed by an institutional overview, given by a Center Director, Dean, or Vice-Dean. After the institutional overview, presentations from each Center Director provided detailed information on his or her Center, including its members, organization, cores, scientific accomplishments, and training or enrichment programs. NIDDK and university staff then had a discussion that focused around three topics: (1) membership of the centers; (2) cores; (3) and interactions between centers. The discussion was followed by presentations by recipients of P&F awards, who described the impact of the awards on their research careers. The site visit closed with an open discussion about any other questions that came up during the site visit, and provided an opportunity for the institutions and grantees to provide input on how NIDDK can enhance its centers program.

To help frame the discussions during Day 2 of each site visit, the NIDDK provided centers with a list of discussion questions before the site visits. Those questions are listed below, organized by agenda item.

Day 2 Discussion Questions

Institutional Overview—Presented by Center Director, Dean, or Vice-Dean

- Where are the NIDDK Center cores located physically?
- What other NIH-supported cores are located at the institution?
- Who has access to the NIDDK Center cores services? Are fellows, trainees, junior faculty, and/or students given free access to core services and/or consultations?
- Is there an institutional policy on cost management of core services?
- What additional institutional commitment is provided to Centers?

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Overview of each NIDDK-supported Center—Presented by Center Director

- What is the Center's mission?
- How is the Center organized?
- Who does the Center serve (local, regional, national)?
- What is the value of the Center to its members (*e.g.*, cost sharing, instruction, fostering collaborations, enabling technology access/development, access to institutional facilities, use of P&F funds, enrichment activities, etc.)?
- Are there examples of scientific accomplishments that have been achieved that would not have been possible in the absence of a Center?
- What accomplishments have been achieved that arise from synergies created by the Center, which go beyond what could have been achieved by a Research Project grant supported at the same level as a Center?
- For those cores located within an investigator's laboratory: How are core services prioritized? Is there an access problem, *i.e.*, are some Center members disadvantaged by lack of proximity, area of research? Are these services available at multiple locations within the institution?
- For those cores encompassed by an institution-wide facility: How is access prioritized for NIDDK-center members? Is there a cost advantage to using these facilities? Are they convenient for Center members?

Focused Discussions—NIDDK and Institutions

Center Membership

- To what extent do the investigators served by the NIDDK Center cores overlap?
- To what extent do the NIDDK Center investigators interact with one another within their own center, between NIDDK centers, or with other NIH-funded Centers?
- To what extent are the NIDDK Center investigators involved with the institution's Clinical and Translational Science Award (CTSA)?

Cores

- Do any of the core services provided by the NIDDK Center cores at the institution overlap with one another or with other NIH-funded cores or with the institutional cores?
- How many Center cores use fee for service? Can the cost-savings to the Center members be quantified? Are there different 'fees' for different groups, *e.g.*, R01-holders charged but trainees or K-awardees not charged? Is there a centralized electronic billing system?
- To what extent do Centers members use NIDDK Center cores *versus* institutional cores?
- In what cases are the NIDDK cores unique?
- Do you have strategies to promote core usage?
- What services do the Administrative cores provide?

Interactions Between Centers

- Can the Centers synergize to become more cost-effective?
- Do NIDDK Centers interact at a national level with one another? With other investigators at institutions without NIDDK centers? With local institutions?
- Are there barriers to more interactions locally, regionally, or nationally?

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3.e. Findings from Site Visits

This section describes NIDDK observations from the site visits in general terms. Visited centers were told that data would be reported in the aggregate to keep them anonymous.

Center Membership: The visited centers varied in size from 30 to over 100 members. Members could be at the institution or outside the institution. For example, in some cases, investigators could be “external” members in a Center at an institution near their own. Some centers also distinguished between full and associate members—associate members were typically junior investigators.

In most cases, the cores were open access and available to scientists outside of the Center, including non-members at the institution and, in some cases, investigators at other institutions. In some instances, Center membership was a requirement to use a core, but obtaining membership was generally an easy process for investigators (see “Research Cores—Operations” below for more information on core usage). A policy common to many of the visited centers was that investigators were required to have federal funding and a need for one or more center cores to obtain center membership.

It was not uncommon for one person to be a member of two or more centers, though this varied at each site. Center Directors at these sites felt that this dual membership was a natural result of overlap in research interests, particularly with the Diabetes Research Centers and NORCs, or in order to use the unique cores provided by a center.

Synergy among Centers: One key motivation for NIDDK to undertake the site visits was to look at the synergy among centers at sites with multiple NIDDK centers. Every institution visited also had a CTSA as well as other NIH-supported centers.

Common examples of interactions among NIDDK centers at a site included collaborations among investigators (*e.g.*, DERCs and NORCs holding co-retreats; MMPCs organizing courses with DERCs or O’Brien Kidney Centers), coordination of core services (*e.g.*, MMPCs complementing DERC or NORC core services; centers sharing core personnel), and sharing/co-funding of cores. Efficiencies may result not only from having cores share and co-support core personnel, but also from having professional staff running cores. Dedicated core staff may have more time to conduct training, an important mission of NIDDK centers. Interactions also resulted when NIDDK Center Directors were included on another center’s internal advisory committee or as reviewers of another center’s P&F applications at the same site.

At institutions where a NIDDK Center Director was involved in the leadership of the CTSA, there appeared to be productive scientific and/or administrative interaction between that Director’s Center and the CTSA. Both the CTSA and the NIDDK center appeared to benefit from this interaction.

In most instances, preparation for the site visit was the first time all the NIDDK Center Directors at an institution came together in a systematic way. In some cases, institution personnel noted that preparation for the site visit had the unexpected benefit of promoting interaction among the NIDDK centers. The visits also increased the interaction among NIDDK staff overseeing centers programs, making it easier for them to learn from one another’s experiences.

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Institutional Involvement in Center Activities: The NIDDK observed a range in amount and type of support provided to centers by their home institutions. Some provided little or no institutional oversight of centers, and were not involved in the creation, dissolution, or management of cores. Others provided significant institutional coordination of center activities and cores, including guidance on core operations and other issues. Common examples of institutional support included start-up costs for new core services; space, construction, and renovation costs; equipment purchases; supplemental support of cores; access to administrative resources; and subsidies for institutional core use. Some institutions offered support for billing and for advertising the center core services on websites.

Research Cores—Operations: Cores of an NIDDK center were often located in adjacent buildings at an institution, but could also be across campus or town. Some cores were housed in stand-alone facilities, while others were located either immediately adjacent to or entirely within investigators' laboratories. NIDDK visited cores that were run by professional staff, tenured faculty, junior faculty, and postdoctoral fellows.

Commonly, centers decided the access policy to their core services. In other instances, the institutional policy determined that all NIDDK center cores at a site were open to all faculty at the institution, even if they were not members of the center. Thus, cores were generally open access and, in some cases, non-members, including investigators from other institutions or industry, were allowed to use the cores. Cores were generally operated on a first-come, first-served basis with no prioritization to NIDDK center members or other NIDDK-funded investigators. When demand led to a requirement for prioritization, members usually came before non-members and institutional investigators before outside investigators.

Research Cores—Value of Core Services: The NIDDK observed that cores provided value in multiple ways, including: through availability of and reduced costs for resources, technologies, equipment, and services; training and support in using facilities; consultations on experimental design and analysis; repositories of reagents; technology development; and opportunities for collaboration.

Generally, NIDDK center cores did not appear to overlap with other NIH or institutional core services in that the institutional core did not have the equipment required, offer the necessary assays, or have the appropriate expertise. In some cases, centers bought-in to an existing institutional core to gain access to a resource that is needed by center members. In instances where NIDDK center cores did appear to overlap with services available elsewhere, Center Directors were aware of the overlap and noted that other cores were unable to readily supply materials or access due to heavy use.

NIDDK centers had a mix of standard service cores, such as for mouse transgenic and genomics, and specialized cores with more unique expertise. Standard cores provided a value by reducing the costs and research time for a frequently used service, and may have a larger user base due to their broader service. Specialized cores provided a unique service and, therefore, may have a smaller user base. Center Directors noted that cores evolve in response to the specific needs of a center's research base, leading to a combination of both unique cores and service cores.

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Research Cores—Core Business Plans: The Office of Management and Budget Circular A-21 (“Cost Principles for Educational Institutions”) sets accounting principles for educational institutions (see: www.whitehouse.gov/omb/circulars_a021_2004). Visited institutions interpreted this Circular differently, which resulted in centers (or institutions) employing a variety of business plans for the cores. However, generally speaking, few cores had a defined business model. In some instances, cores provided their services with no charge to any user, or the same charge to all users with no specific “discount” for center members or other NIDDK-funded investigators. Some provided a discount for center members, and the discount varied at visited sites. For example, the member could be charged for supplies and materials, but the technical personnel and equipment were paid for by the center; or fees for center members were determined based on the overall usage of the core; or all users were charged the same costs, but center members could receive funds from the center for use at a specific core.

Efficiencies resulted from multiple centers supporting a core or from centers “buying in” to institutional cores so that center members could utilize existing cores at a lower cost. Not all institutions had a comprehensive list of research cores, including all NIDDK, NIH, or institutionally sponsored cores, but in some cases institutions had or were working toward such a listing (e.g., on a website).

Training and Enrichment Programs: Training is a strength of the centers program, and centers felt that training and development of young scientists’ careers was important to the centers’ missions. Of note, dedicated “training funds” are not available to centers from NIDDK to support directly the research training of pre- or post-doctoral fellows. However, there are still opportunities to train young scientists without the use of dedicated training funds, such as through Enrichment Programs, P&F awards, and training and consultation provided by research core staff.

Some centers receive limited funds to support Enrichment programs, which are intended to sponsor, for example, seminars, visiting scientists, workshops, and mini-sabbaticals for center members. These activities are aimed at fostering the exchange of ideas with the goal of enhancing the productivity and efficiency of the center and its members. Common activities for Enrichment Programs at the visited sites included research seminars, annual symposia/retreats, and technology seminars/courses. Some centers were attempting to reach a broader audience, such as by videocasting their research seminars to scientists outside of their location. Other examples of how centers were involved in education and training were through summer research programs for high school, undergraduate, and medical students, and “year out” programs, in which medical students interrupt their formal coursework to conduct biomedical research.

Pilot & Feasibility Award Programs: Centers demonstrated a strong commitment to P&F programs, which were considered quite valuable by the institutions. These awards are made to new investigators, or established investigators with a new interest in the field or looking to pursue a new research direction. NIDDK did not request specific data on the P&F programs; therefore, information reported by centers was varied. Examples of reported data included information on the P&F programs, such as total number of awards since inception of the center, average number awarded per year, average P&F award size, cap for a P&F request, and amount

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of funding (R01 or other) that resulted from the P&F support. Thus, there was variability in the way that centers implement the P&F portion of their program.

P&F awards are typically distributed internally at an institution, with the issue of transferring indirect costs often cited as the rationale for not making external awards. Some centers have found ways to overcome institutional barriers to broaden their P&F programs to external investigators, but the centers noted that this required significant effort and was cited as a work in progress.

3.f. Conclusions

In conclusion, the NIDDK observed diverse operations at the visited centers. Tangible examples of synergy included retreats and courses co-sponsored by different centers, multiple centers supporting a common core, investigators that were members of more than one center due to cross-cutting research interests, and Center Directors with administrative duties that cut across the centers at their institutions.

At many sites, the NIDDK site visit was the first interaction for all the NIDDK centers at a site, and the site visits were an opportunity for all NIDDK staff overseeing centers programs to come together and share experiences and knowledge. This suggests that opportunities for greater synergy may exist both at the grantee institutions and within NIDDK.

4. SUMMARY OF INPUT FROM COMMENT PERIODS

This section summarizes input received during comment periods described in the “Process for NIDDK Centers Program Review” section. It is organized around discussion topics that were included in earlier forms of this report. It is not an exhaustive summary of comments received, but includes overarching themes that emerged. The NIDDK has considered and appreciates all submitted comments, even if they are not included in the summary section below.

4.a. Discussion Topic 1: Enhancing Synergy and Center Value

Background: The NIDDK is looking for ways to enhance synergy and center value, in particular through collaboration between/among its centers and increased utilization of center resources by the broader NIDDK research community. Options to achieve these goals could include supporting more regional and national cores; coordinating core services locally, regionally, or nationally; increasing interactions between centers; promoting collaborations between investigators in different centers; and increasing awareness of center-supported services in the broad NIDDK scientific community.

With that background, the NIDDK invited input on the following:

- Do barriers imposed by the institution or by NIDDK interfere with interactions/synergies?
- Would it be helpful if the NIDDK facilitated (by including funds in centers’ budgets) one of the following:
 - National meeting of all NIDDK Center Directors;
 - Web-based meetings of all NIDDK-supported centers;

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- Web-based or face-to-face meetings of NIDDK centers within specific geographic regions; or
- Posting webinars on the NIDDK website of center activities that are of broad interest to the scientific community (*e.g.*, scientific talks, career development lectures)?

Summary of Input: The centers were supportive of the NIDDK's overarching goal of increasing synergy. Generally speaking, the centers felt that, especially in times of limited budgets, it is worthwhile examining ways to enhance coordination in order to reduce costs and leverage resources. Centers noted that there are different issues that arise related to increasing collaboration between two or more different types of centers at one institution, and between the same type of center at different institutions. For example, simply being in close proximity may make it easier for centers at the same institution to interact, such as by co-supporting a core that may be used by more than one center. However, there are usually more barriers to interactions between institutions (*e.g.*, sense of competition, issue of indirect costs, bringing in samples/animals from other institutions). Some centers reported that they already interact with other centers at their institution, and/or other centers of the same type at different institutions. Other centers reported that they do not interact with other centers within or outside their institution.

Commenters provided ideas for ways that the NIDDK could enhance synergy. The themes that emerged included:

- *Through an NIDDK Centers Website:* Many centers felt that it could be useful for NIDDK to manage a website dedicated to center activities. For example, the website could include information on cores and their services, so that other centers could see what services are available and potentially prevent duplication. The NIDDK could also post center seminars that may be of broad interest and/or webinars with examples of how different centers manage their cores or P&F programs. This type of information could be particularly useful for new centers. In other words, most centers felt that a “one-stop-shop” for NIDDK-supported center activities would be useful and could help foster collaboration across centers.
- *Through Center Directors Meetings:* The idea of national or regional meetings of Center Directors was well-received by most centers. Even for centers programs that already have regular meetings, some people felt that more time should be dedicated at those meetings to talking about the cores supported by the centers, as a way of sharing information and enhancing coordination. Specific topics for discussion could be ways to enhance interactions with the pharmaceutical industry, which has already benefitted some centers, as well as whether there are opportunities to promote use of unique cores by other centers and the scientific community.
- *Through NIDDK Staff Review:* Centers commented that it may be helpful for NIDDK staff to identify areas of overlap or areas for potential collaboration, as a starting point for trying to increase coordination. For example, this could be done with current center programs, such as at a local level to see if there could be cost-sharing for equipment or expertise. Or, it could be done at the time when center grants are reviewed in order to eliminate some aspect that could be served by another center and/or to add unique components to a new center.

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- *Through NIDDK incentivizing centers to build networks and share resources:* Centers suggested that center value could be leveraged by NIDDK incentivizing centers to build networks and share resources.

4.b. Discussion Topic 2: Strengthening the P&F Program

Background: The goals of the NIDDK centers P&F program are to enable investigators to explore a research concept relevant to the center and to collect preliminary data sufficient to support a grant application for independent research support. The P&F program provides a modest amount of time-limited funding to: (1) new investigators; (2) established investigators from other fields exploring new research directions related to the center; and (3) established investigators within the field exploring innovative new ideas that represent a significant departure from their ongoing, funded projects.

The site visits highlighted differences in how the P&F programs were administered throughout the centers. For example, there were differences in the number of awards an individual can receive, the size of an individual award, and whether the program was open to investigators outside of the center institution. Because the overarching goals of the P&F program are the same for each center, the NIDDK is considering whether the Institute should develop additional guidelines for implementing the program more uniformly across its centers.

With that background, the NIDDK invited input on the following:

- What additional goals should NIDDK consider for the P&F program, if any?
- If the NIDDK were to establish more uniform policies for the P&F program, what changes would be most helpful?
- What other changes should NIDDK implement to enhance the P&F program and better meet the program's goals?
- What are the potential pros and cons of opening the P&F program to scientists outside of the center's institution?

Summary of Input: The centers felt that the P&F programs were a successful component of the centers and had a consensus opinion that the flexibility for centers to manage and administer the program was a strength. They did not think that additional guidelines from NIDDK would improve the program; rather, as long as NIDDK provided clear expectations and goals, the centers could implement successful P&F programs on their own. However, centers did propose several ideas for strengthening the program, which included:

- *Focusing on mentoring and monitoring progress:* Several centers commented that mentoring was a key component of a successful P&F project. In addition, many felt that it was important to monitor progress of the project, to help ensure success. They recommended that NIDDK place a greater focus on mentoring, such as by requiring that a mentoring plan be submitted with the center application, providing a small amount of funding to a mentor as part of a P&F project, or requiring that P&F award recipients have a mentoring or advisory committee to monitor progress.
- *Disseminating information on best practices:* Rather than NIDDK providing guidelines on administering P&Fs, many centers thought it would be helpful for NIDDK to provide

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information on how P&Fs are administered throughout the centers and, for example, post the information on a central NIDDK website (see Discussion Topic 1). Centers could then decide to implement aspects that may work well for their institution. Other centers thought that it would be useful for NIDDK to provide information on a P&F grant review process that could be used by all centers, and to create a national database of potential reviewers.

- *Changing metrics for success:* Some centers suggested that NIDDK place less emphasis in center review criteria regarding publications and amount of subsequent funding obtained by P&F recipients. They felt that those metrics encouraged centers to make awards to scientists with nearly funded research projects, and discouraged support of scientists with new ideas that are not close to being funded. If new metrics were developed to measure the success of P&F projects, the scientific scope of the projects may be broadened.
- *Broadening group of eligible investigators:* Some centers thought that other groups of investigators—such as PIs who just missed the payline for NIH funding and need specific data to resubmit an application—should be considered for P&F funding. Some centers thought that consideration should be given to funding larger interdisciplinary collaborative awards.
- *Opening up P&F program to investigators outside home institution:* Several centers supported the concept of opening up the P&F program to investigators outside of their institution, and some reported already doing so. However, they commented that administrative issues (*e.g.*, indirect costs) were major barriers. Suggestions included permitting co-PIs from outside institutions, requiring that each center have at least one collaboration between two or more NIDDK-funded centers at separate institutions per P&F cycle, supporting external P&F projects that will benefit from use of center cores, and having NIDDK make the P&F award directly. Other centers thought that it was important for the P&F award recipient to be at the home institution, or at least in the local vicinity, because of the importance of mentoring to the success of a project.

4.c. Discussion Topic 3: Core Support and Access

Background: The site visits highlighted different types of cores supported by the centers, including highly specialized, unique cores that focus on research specific to the NIDDK mission areas, as well as general institutional cores in which the centers buy in so that their members have access. Both of these models have value, and the NIDDK invited feedback from the centers regarding their perception of the relative value of supporting the two types of cores through the centers.

In addition, the NIDDK invited input from the centers on the idea of broadening access to specialized core resources to users outside of the center institution, such as at a regional or national level. For example, the NIDDK-supported Mouse Metabolic Phenotyping Centers (MMPCs) provide a national resource of specialized phenotyping services for mouse models of diabetes, diabetic complications, obesity, and related disorders. MMPCs assess mouse mutants sent to them with any of a wide array of complex metabolic tests, on a fee-for-service basis. The NIDDK is considering whether this type of core usage model could be expanded to other

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NIDDK center cores that provide unique, specialized services that may be of use to investigators at institutions that do not have access to those types of services.

Summary of Input: Input focused around the following themes:

- **Broadening access:** Several people reported that non-center members had difficulty accessing center cores, particularly if the core was at an external institution, but sometimes even when the core was located at the investigator's home institution. Some commenters were not aware of resources that were available through centers. Others reported a perception in the scientific community that cores are limited to use by individual laboratories (*e.g.*, center leadership), rather than being open to other scientists.

There was general support for the idea of NIDDK broadening access to specialized core resources to users outside of the center institution, at a regional or national level. It was thought that such cores could be valuable if they provide a specialty service, but would need to be readily accessible, provide a rapid turnaround, and not delay the science. Some concerns about opening up cores to outside users included issues related to bringing in samples/animals from other sites, and cores already working at or near capacity at current funding levels. Potential solutions offered included:

- Using a charge-back system to defray additional costs and/or boost capacity;
 - Allowing centers to apply to NIDDK for additional funds to set-up a center-associated core that provides a service to other institutions on a fee-for-service basis;
 - Providing additional NIDDK oversight of centers; and
 - Developing additional NIDDK requirements regarding resource sharing, to ensure that center resources are available to a broader community.
- **Core support:** Commenters generally approved of NIDDK supporting specialized cores. However, there was some disagreement regarding buying in to general institutional cores. Some commenters felt that this enhances access to resources by NIDDK researchers. Others felt that such buy-in may not add value, as center members may have the same access to institutional cores without center support. Indeed, some commenters encouraged NIDDK to ensure that cores at institutions do not overlap, and that there is synergy among the different cores.

Other suggestions related to Discussion Topic 3 are summarized elsewhere. (For example, NIDDK developing and disseminating best practices for administrative and financial aspects of cores is addressed under Discussion Topic 4, and sharing information on core resources through a central NIDDK website is addressed under Discussion Topic 1.)

4.d. Discussion Topic 4: Core Business Models

Background: A variety of business models are in use at the center cores NIDDK visited, and some cores do not have a defined business model. Toward the goals of increasing core access, ensuring the value of core services, and expanding capacity to meet user needs, the NIDDK is considering encouraging center cores to have and implement a defined business model.

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Examples of business models include: free to members; charge-backs based on usage; charge-backs that vary by category of user; and other business models including reinvestment in the core through technology development, training, etc.

With that background, the NIDDK invited input on:

- One possible business model is a charge-back system, which can include subsidies for center members. Is this a good model? Why or why not?
- What would assist your center cores to establish and implement a defined business model?

Summary of Input: Most centers felt that a charge-back system was a good business model for cores, and many centers reported using such a system. For example, several centers stated that they have different charges for different levels of users (*e.g.*, members, non-members, industry), and that use of a charge-back system has been necessary for generating center program income, which has been critical for growing and evolving cores to meet the needs of center members. However, centers also noted that different types of cores may require different types of business models. Thus, there was concern that requiring cores to implement a charge-back business model would hinder the ability of some investigators (*e.g.*, young investigators with limited funding) to access cores, as well as place a large administrative burden on heavily used cores. The themes that emerged included:

- *NIDDK-disseminated information on core business models:* Several centers said that it would be useful for NIDDK to prepare and disseminate information on business models that could potentially be used by the cores. This information could be posted on a central NIDDK website (see Discussion Topic 1) and/or presented by NIDDK staff at Center Directors or Core Directors meetings. Centers generally felt that having this type of approach would be more helpful to them than NIDDK developing specific requirements for core business models.
- *NIDDK guidelines for data collection on core usage:* It was felt that centers are not collecting uniform data on core usage, which can make it difficult for reviewers to compare cores when reviewing new and competing center applications. NIDDK was encouraged to develop guidelines for data collection to increase accountability and provide more definite operational definitions for cores.
- *Policies regarding purchase of equipment:* Some centers commented that it is challenging to purchase, maintain, and upgrade equipment used in cores, and that a limiting factor is the ability to purchase equipment only one time in a 5-year funding cycle. Centers thought that this issue was important to address if cores are expected to have cutting-edge, state-of-the-art technology for use by center members. Centers suggested that NIDDK consider its policies regarding equipment, including the possibility of using charge-backs to maintain/purchase equipment as part of a core business model.

4.e. Discussion Topic 5: Potential Value of More Small Centers

Background: The R24 Digestive Diseases Research Development Centers represent a different model, in which the Center supports a relatively small number of investigators at a particular

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institution. The NIDDK is considering expanding this concept of smaller centers to other mission areas. For example, small centers could serve institutions with fewer users or provide a unique national resource for a specific field. Centers were invited to comment on the idea of expanding the NIDDK centers program to include more small centers.

Summary of Input: The NIDDK received varied input on this topic, both for and against supporting more small centers:

- *In favor of supporting more small centers:* Several commenters were supportive of the idea of NIDDK funding more small centers. It was suggested that smaller centers may be more flexible and allow for more innovation because of their correspondingly smaller administrative structure compared to larger centers. Centers commented that NIDDK would need to consider factors such as: requiring a minimum number of productive scientists and a clear research theme; ensuring that small centers are not funded out of proportion to their productivity and are distinct from a multiple PI grant or a P01 grant; and funding small centers that consist of a small team of collaborators who work in close proximity at the same institution. A suggestion was that small centers could be useful especially where a single specialized resource exists.
- *Opposed to supporting more small centers:* Other commenters said that they did not see value in supporting more small centers. A common concern was that it might be difficult for small centers—with correspondingly small budgets—to be efficient or effective. Some commenters opposed to supporting small centers suggested that the scientific need would be better met through increased NIDDK coordination across centers (Discussion Topic 1), and by opening up cores to outside users, including at institutions without centers (Discussion Topic 3).

4.f. Discussion Topic 6: Center Membership

Background: The site visits showcased that, at institutions with more than one NIDDK-supported center, it is not uncommon for one person to be a member of two or more centers. This overlap could be a natural result of overlap in research interests, particularly with the Diabetes Research Centers and NORCs, or in order to use the unique cores provided by a center. However, this results in scientists being included in the research base for multiple centers in center applications from the same institution. Because applications are reviewed independently, the NIDDK has been considering ways to make reviewers aware of this issue, such as by asking centers to provide a percent effort for members that are listed in the research base of more than one center. However, at the site visits, some centers expressed concerns with that approach and felt that the percent-effort data could not be captured. The NIDDK wants to ensure that the research base for each center is defined in a way that is consistent and fair, and that accurately reflects usage. The Institute invited ideas for how to ask centers to define the research base when members belong to more than one center.

Summary of Input: The NIDDK received varied perspectives on center membership, including:

- *Members belonging to more than one center:* Centers generally felt that it was acceptable for investigators to be members of more than one center, due to related research interests and/or because investigators pursue research relevant to multiple areas within the NIDDK

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mission. Centers commented that, during the grant review process, the study section would have the opportunity to evaluate the members' contribution to research relevant to the center's mission. A suggestion was that, for scientists listed on more than one center grant application, the centers be asked to add footnotes to explain the components of research that are supported by the center, rather than trying to define the percent-effort.

- *Defining "center member:"* Some centers felt that it was best to make membership inclusive, as it is beneficial to get as many people as possible working to advance the center's research area. Other centers felt that membership should be limited to core users. Some commenters thought that membership numbers were inflated if, for example, centers counted investigators who attended center-sponsored seminars or training activities, or were casual users of cores, but had no other involvement in the center. They thought that those types of members were not necessarily active users. Other centers noted that junior faculty benefit greatly from the centers, but are not counted in the research base because they do not have NIH funding. NIDDK was encouraged to ensure that its policies on center membership and research base are consistent with the Institute's goal of increasing scientific cooperation and collaboration.

5. OUTCOMES FROM CENTERS PROGRAM REVIEW

With careful consideration of input received from its Advisory Council, centers, and the broader scientific community during the review, the NIDDK has modified its centers program and is making additional recommendations to strengthen the program further. The NIDDK notes that there could be additional changes made to the centers program that are not outlined here, which could stem from further consideration of this review and recommendations in this document, assessment of the centers program in consultation with Advisory Council, input from the extramural scientific community, and strategic planning processes.

5.a. Recent Changes Made to Centers Program

As a result of the review, the NIDDK has implemented changes to some of its centers programs. The Institute notes that there are differences in the various center programs and their goals, so changes that were made to one program were not necessarily made to others. Additionally, some changes are being piloted in one or two center programs, and, if successful, could be considered for implementation in other centers. Examples of recent changes are described below.

Support of Regional and National Cores through the Diabetes Research Centers: The NIDDK modified its Diabetes Research Centers Program to promote the establishment of regional/national resources that could serve a wider scientific community. In the FOA published in March 2011, the NIDDK invited applicants to provide Diabetes Research Center core services and P&F grant opportunities to diabetes researchers at institutions not served by an NIDDK Diabetes Research Center. Applicants were invited to propose: (1) establishing a regional/national shared resource core located at a different institution; (2) establishing a regional/national shared resource core located at the applicant institution or an affiliated hospital; and/or (3) expanding the P&F program to a different institution(s). Applicants were permitted to request additional funds over the cap for resource cores, if they proposed a regional/national resource. However, the total funding provided by NIDDK for the Diabetes Research Centers program was unchanged, so this approach could result in the funding of fewer Centers or smaller

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awards to Centers not providing regional or national service if multiple Centers successfully compete to serve as a regional/national resource.

Reporting Grants Included in the Research Base of More Than One NIDDK Center: Some institutions have multiple NIDDK-funded centers, and it is not uncommon for one person to be a member of two or more centers. This overlap in membership is often due to overlap in research interests, particularly with the Diabetes Research Centers and NORCs. The NIDDK wanted to make reviewers aware of this issue, so the Institute modified its guidelines for reporting the research base in Diabetes Research Centers and NORC applications. Specifically, the guidelines now require that applicants note whether grants listed in the research base are also listed in the research base of another NIDDK center at the same institution, and if so, which center. Therefore, reviewers will see how many investigators are included in the research base of other NIDDK centers at the applicant institution. The NIDDK considered other approaches to address this issue, such as requiring applicants to report percent-effort for each grant listed in the research base, but many centers expressed concerns with that approach and felt that the percent-effort data could not be captured. Therefore, the NIDDK is using a less burdensome approach to make reviewers aware of investigators that are included in the research base of more than one center at an institution.

Increasing Synergy among NIDDK Centers through Information Sharing: The NIDDK is implementing approaches to share information among centers and with the scientific community. For example, several centers have developed public websites. The Diabetes Research Centers (<http://www.diabetescenters.org/>), the Digestive Diseases Centers (<http://www.digestivediseasescenters.org/>), and the NORCs (www.norccentral.org) created websites. Additionally, at upcoming meetings of Diabetes Research Center Directors, NIDDK staff will present information on other center programs, to make the Center Directors aware of what is happening in other programs and what resources may be available.

Broadening Access to Hematology Centers: Through their Enrichment Programs, Hematology Centers offered summer students the opportunity to test new ideas through the use of core facilities. In FY2011, each Center filled to capacity their short summertime slots. In order to broaden access to the core facilities, Center Directors attended the February 2012 “Heme-Net: Nonmalignant Hematology Research Network” meeting and gave presentations about the resources that are available in their Centers.

5.b. NIDDK Recommendations To Enhance the Centers Program

This section describes NIDDK recommendations for additional ways to strengthen its centers program, organized around the discussion topics and themes presented in the section of this report on “Summary of Input from Comment Periods.” For detailed background on each discussion topic, please refer to that section.

Discussion Topic 1: Enhancing Synergy and Center Value

Input revolved around four themes:

Theme: Creating an NIDDK centers website

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NIDDK Recommendation: The NIDDK recognizes the importance of web-based tools to provide information about NIDDK-supported centers, such as core facilities, as a way to enhance collaboration among centers, as well as to make NIDDK-supported investigators at institutions without centers aware of available resources. The NIDDK is currently redesigning its website, and part of that effort includes improving the section on the centers. Additionally, websites have already been created for the Diabetes Research Centers, the Digestive Diseases Centers, and the NORCs. The NIDDK will continue considering how best to use the web to advance the goal of enhancing synergy and sharing.

Theme: Having trans-NIDDK Center Directors meetings

NIDDK Recommendation: While most center programs have yearly meetings, NIDDK will consider having all NIDDK-funded centers participate in a meeting if a specific topic/need/challenge is identified as a focus for the meeting.

Theme: Having NIDDK staff identify areas of overlap and opportunities for synergy in NIDDK centers programs and with other NIDDK programs

NIDDK Recommendation: As a result of the review, NIDDK staff managing center programs are working together to enhance the centers' program, such as by harmonizing FOAs and Center Guidelines, and the Institute recognizes that there are additional opportunities to do so. NIDDK staff have begun meeting on a regular basis to discuss the centers program and to identify ways to coordinate efforts further. In addition to regular meetings of NIDDK program directors, subcommittees of that group have been formed and are meeting to develop recommendations to be considered by the entire group. Staff plan to discuss the changes that have been made in response to the centers program review (see previous section), and will consider whether those changes should be considered for other center programs. In addition, staff will consider opportunities to link other NIDDK programs to the centers as another way to leverage center expertise and resources.

Theme: Through NIDDK incentivizing centers to build networks and share resources

NIDDK Recommendation: By definition, centers are expected to demonstrate synergy among their members. Toward the goal of enhancing synergies among centers, the NIDDK will explore the possibility of asking applicants to address the issue when they submit new or competing applications so that reviewers could assess value-adding scientific relationships with other NIDDK centers or CTSA. For example, applicants might be asked to describe the types of productive networks they have established or resources they have shared with other NIH/NIDDK centers or CTSA (for renewals) or strategies they propose to achieve such (for new applications). This information could be regarded as particularly important for applicants from institutions with a CTSA or with one or more other NIDDK centers. The Institute may consider these factors when making funding decisions.

In addition to the above four themes, there are two other themes under consideration by NIDDK as approaches to enhance synergy and center value.

Theme: Promote interaction and synergy between centers and CTSA

NIDDK Recommendation: The Institute will explore ways to promote enhanced cooperation between NIDDK-supported centers and CTSA.

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Theme: Enhance opportunities for training through the centers

NIDDK Recommendation: The NIDDK will consider ways to utilize the centers to enhance opportunities for training. For example, the Diabetes Research Centers support a summer research program for medical students, which is open to all medical students (not just those affiliated with center institutions). Most of the funding for this program comes from the NIDDK's National Research Service Award (NRSA) training grant funds; a small amount of Diabetes Research Center funds are used to support the administrative aspects of the program. The goal of the program is to encourage medical students to consider research in diabetes and its complications as a career and to educate students about diabetes. In other examples, Digestive Diseases Centers have leveraged an NIDDK-funded R25 (education project) grant to support undergraduate summer research, and NIDDK has provided funds to Kidney, PKD, Urology, and Hematology Centers to support summer research programs for college and medical students. These types of approaches may be utilized more broadly, as a way to capitalize on the expertise of the centers and foster the creation of a pipeline of scientists conducting research in NIDDK mission areas.

Discussion Topic 2: Strengthening the P&F Program

Input revolved around five themes:

Theme: Focusing on mentoring and monitoring progress

NIDDK Recommendation: The NIDDK recognizes the importance of mentoring and monitoring research progress, particularly for new investigators. The Institute does not plan to provide additional funding to centers for mentoring, as it believes that mentoring falls within institutional responsibility. The NIDDK will address mentoring and monitoring progress in its "best practices" document on P&F programs (see below).

Theme: Disseminating information on best practices

NIDDK Recommendation: The NIDDK will develop a "best practices" document on P&F programs that could be distributed to centers for informational purposes.

Theme: Changing metrics for success

NIDDK recommendation: The NIDDK would like to promote high-risk, high-impact research while balancing the need for career development of young investigators. The Institute will include recommendations regarding prioritization of P&F awards in the best practices document on P&F programs (see above).

Theme: Broadening definition of eligible investigators

NIDDK Recommendation: The NIDDK does not plan to change the current definition of eligible investigators for P&F awards. In considering whether to broaden eligibility, the NIDDK came to the conclusion that there are already mechanisms at NIH to support other groups of investigators (e.g., NIH R56 mechanism available to provide funds to investigators who just missed the payline). Therefore, based on feedback from centers about the success of the P&F program, the Institute feels that the current definition of eligible investigators is appropriate.

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Theme: Opening up P&F program to investigators outside home institution

NIDDK Recommendation: Although many centers cited the issue of indirect costs as a major barrier to making external P&F awards, the NIDDK notes that the NIH does not impose any requirements related to charging indirect costs when making P&F awards to external institutions. Some Hematology Centers, for example, have identified approaches to make P&F awards to external institutions. The NIDDK could include examples of approaches that have been used by these and other centers in its best practices document. Additionally, as described in the above section on “Recent Changes Made to Centers Program,” the Diabetes Research Centers invited applicants to make P&F awards at external institutions. This approach will be considered for other NIDDK center programs.

Discussion Topic 3: Core Support and Access

Input revolved around two themes:

Theme: Broadening access

NIDDK Recommendation: The NIDDK is considering addressing this issue on multiple fronts: (1) the NIDDK will develop information on core business models (see Discussion Topic 4), including a charge-back system, which was cited by centers as a possible way to increase core capacity and broaden core access; (2) the NIDDK is using web-based systems as a way to increase awareness of cores by outside investigators (see Discussion Topic 1); (3) the Diabetes Research Centers FOA has been modified to invite applicants to provide core services to diabetes researchers at institutions not served by an NIDDK Diabetes Research Center. This approach will be considered for other NIDDK centers; and (4) the NIDDK will consider supporting small centers, such as centers that serve as a specialized, national resource (see Discussion Topic 5). The NIDDK will continue considering other avenues to broaden access to core services to benefit the NIDDK research community.

Theme: Core support

NIDDK Recommendation: NIDDK recognizes that there are often compelling justifications for support of institutional cores that need to be balanced with concerns of whether supporting such cores provides added value. The Institute also recognizes that unique or specialized cores that provide technology development or support for services that are specific to the NIDDK research community should be a higher priority.

Discussion Topic 4: Core Business Models

Input revolved around three themes:

Theme: NIDDK-disseminated information on core business models

NIDDK Recommendation: The NIDDK will develop information on core business models and disseminate it to centers for informational purposes.

Theme: NIDDK guidelines for data collection on core usage

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NIDDK Recommendation: The NIDDK will consider how to balance requirements for uniform data collection with increased administrative burden on center applicants.

Theme: Policies regarding purchase of equipment

NIDDK Recommendation: The NIDDK will consider ways to allow more flexibility with respect to center cores, including issues related to equipment purchase, if the center does not currently allow purchase of equipment after the first year.

Discussion Topic 5: Potential Value of More Small Centers

The NIDDK received varied input on this topic, both for and against supporting more small centers.

Theme: Supporting more small centers

NIDDK Recommendation: NIDDK will continue to explore opportunities where small centers may be an appropriate investment. For example, a possible model may be to support a small center that serves as a specialized, national resource.

Discussion Topic 6: Center Membership

Input revolved around two themes:

Theme: Members belonging to more than one center

NIDDK Recommendation: The issue of members belonging to more than one center was primarily related to the Diabetes Research Centers and NORCs because of related research interests. The NIDDK addressed this issue by requiring that Diabetes Research Centers and NORC applicants note whether grants listed in the research base are also listed in the research base of another NIDDK center at the same institution. Other NIDDK centers may also transition to this approach of reporting membership.

Theme: Defining “center member”

NIDDK Recommendation: The NIDDK will develop a best practices document and consider establishing requirements for center membership, as well as clarifying who may be included in the research base investigators of a center and who may use core facilities. Standard definitions may aid reviewers’ ability to compare applications in the review process.

6. CONCLUSIONS

This review has identified many strengths in the NIDDK centers program and showcased how the centers are advancing research progress on diseases within the NIDDK mission. The review has also identified areas that could be strengthened, and some changes have already been made while other changes are under consideration. The NIDDK appreciates the input received during this review. The Institute will continue to invite input from the centers and the NIDDK research community as it considers how best to manage its centers program.

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APPENDIX A: ACKNOWLEDGEMENTS

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APPENDIX B: ACRONYMS

ARRA	American Recovery and Reinvestment Act of 2009
CF	cystic fibrosis
CTSA	Clinical and Translational Science Award
DDRCC	Digestive Diseases Research Core Center
DDRDC	Digestive Diseases Research Development Center
DERC	Diabetes and Endocrinology Research Center
DRTC	Diabetes Research and Training Center
FOA	Funding Opportunity Announcement
FY	fiscal year
MMPC	Mouse Metabolic Phenotyping Centers
NIDDK	National Institute of Diabetes and Digestive and Kidney Diseases
NIH	National Institutes of Health
NDDK Advisory Council	National Diabetes and Digestive and Kidney Diseases Advisory Council
NORC	Nutrition Obesity Research Center
NRSA	National Research Service Award
ORWH	NIH Office of Research on Women's Health
P&F	Pilot & Feasibility
PI	principal investigator
PL	public law
SCOR	Specialized Centers of Research