

NIDDK Centers
Program Review –
DRAFT

NIDDK Centers Program Review – DRAFT

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1 INTRODUCTION

2 **Purpose of the Centers Program Review**

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

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

- 15
- 16 • examine synergies between centers;
- 17 • encourage interactions between centers, including fostering regional and national cores;
- 18 • enhance access to center resources;
- 19 • examine the value of the Pilot and Feasibility (P&F) program; and
- 20 • examine changes implemented in response to the NIDDK's 2003 centers review based on
21 recommendations that the Institute expand its centers’ P&F program and shift some types
22 of centers from P50 to P30 grants.
- 23

24 **Overview of the NIDDK Centers Program**

25 NIDDK Research Center grants are awarded to extramural research institutions to provide
26 support for long-term multidisciplinary programs of medical research within the NIDDK
27 mission. They also support the development of research resources, aim to integrate basic
28 research with applied research and technology transfer activities, and promote research in areas
29 of clinical applications with an emphasis on intervention, including prototype development and
30 refinement of products, techniques, processes, methods, and practices. Other NIH components
31 also support center programs related to their research missions.

32
33 ***Common Center Characteristics:*** Because NIDDK centers are organizationally and
34 operationally diverse, there is no such thing as a “typical” center. Furthermore, not all centers
35 have the same goals or organizational structure. However, there are common features that are
36 often found in centers, such as:

- 37 • Dozens of member principal investigators (PIs) with related research interests;
- 38 • Administrative and scientific cores;
- 39 • P&F programs;
- 40 • Enrichment activities; and
- 41 • Foster an environment that is conducive to collaboration and training.
- 42

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

8 Table A shows the various types of NIDDK-supported centers, along with the year that each
9 program began (left column) and the number of centers of each type in 2010 (right column). The
10 2010 numbers include centers that were established that year, but did not receive funding until
11 2011; and does not include some centers that received funding in 2010, but which would not
12 receive funds in 2011. In total, NIDDK supported 87 centers in 2010.

NIDDK Centers: Legislative History

13
14
15 Title III, section 301 of the Public Health Service Act (now covered under Title 42 , Chapter 6a,
16 Subchapter II, Part A, Sec. 241) has historically been used by the NIH as a broad-based and
17 open-ended research authority to pursue research activities beyond those generally or specifically
18 authorized in the NIH specific part of the Act. The Diabetes Endocrinology Research Center
19 (DERC) program was thus initiated in Fiscal Year (FY) 1972 under authority of Title III. Five
20 DERCs were first awarded in FY 1973 and FY 1974.

21
22 The first specific statutory authority provided by Congress for the award of centers grants by
23 NIDDK derived from the National Diabetes Mellitus Research and Education Act (Public Law
24 [P.L.]. 93-354), enacted July 23, 1974. This law provided for Diabetes Research and Training
25 Centers (DRTCs) and authorized funds to be appropriated for FY 1975 through FY 1977. The
26 first such grants were awarded in September, 1977. The authority for these centers was
27 subsequently extended by P.L. 94-562 (October 19, 1976) and P.L. 96-538 (December 17, 1980).

28
29 Authority was further extended by the Health Research Extension Act of 1985 (P.L. 99-158),
30 enacted November 20, 1985, which also broadened the authority to include centers in all three
31 modern programmatic divisions of the Institute. The language established in this Act remains
32 unaltered today in Title 42 of the U.S. Code, chapter 6a (the Public Health Service Act). The
33 portion of this law authorizing the NIDDK and describing its statutory mission is section 285c.
34 As written, the authority described extends to “centers for research and training in diabetes
35 mellitus and related endocrine and metabolic diseases”; “centers for research in digestive
36 diseases and related functional, congenital, metabolic disorders, and normal development of the
37 digestive tract”; “centers for research in kidney and urologic diseases” to be named for the
38 Honorable George O’Brien of Illinois; and “centers for research and training
39 regarding nutritional disorders, including obesity.”

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

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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	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	Digestive Diseases Research Development Centers: DDRDCs	4
2005	Cystic Fibrosis Research and Translation Core Centers**	5

*This 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 DRTCs.

**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 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.

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1 **Table B: Activity Codes of Centers Under Consideration in Review Process**

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

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

10
 11 **Table C: Activity Codes of Centers not Under Consideration in Review Process**

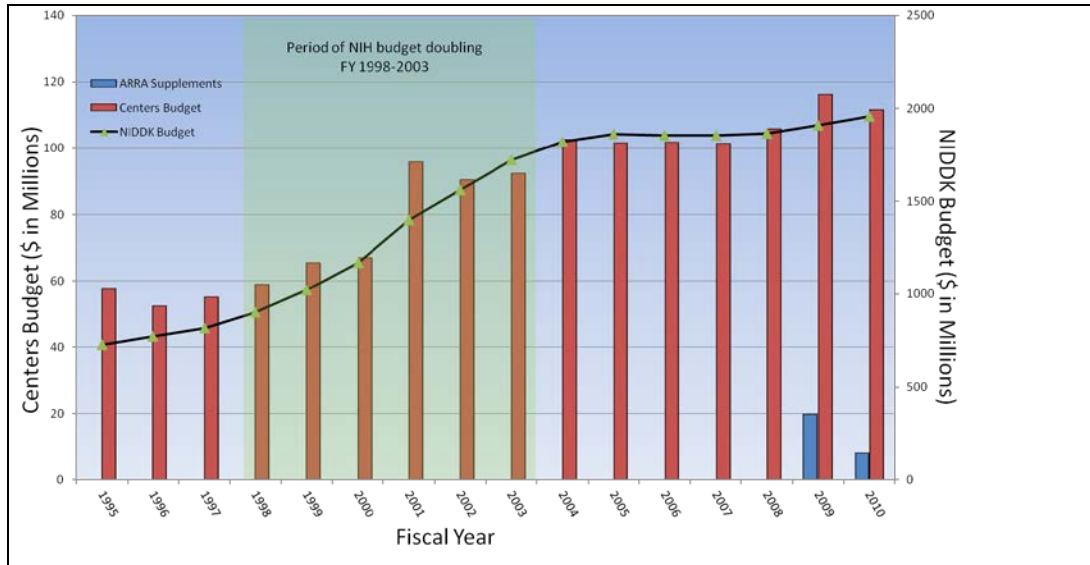
Activity Code	Title	Rationale for Exclusion from Review Process
P20	Center Core Grants Planning Centers for Interdisciplinary Research in Benign Urology	New program in 2010, so too early to examine its implementation and success
U54	Rare Diseases Clinical Research Consortia	FOA issued by NIH Office of 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

12 **NIDDK Centers Budget:** Figure 1 shows the NIDDK centers budget from FY95-10 (red bars,
 13 corresponding to left axis). The annual centers budget was roughly \$60 million from FY95-00.
 14 The budget increased in 2001—during the period of the NIH budget doubling—to over \$90
 15 million. The budget topped \$100 million in 2004, and remained relatively flat through 2008—
 16 coinciding with a flat overall NIDDK budget (black line, corresponding to right axis). In FY09-
 17 10, in addition to receiving funds from the regular NIH appropriations, centers received funding
 18 from the American Recovery and Reinvestment Act of 2009 (ARRA; blue bars, corresponding to

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1 left axis). In FY09-10, the centers received approximately \$20 million and \$8 million,
2 respectively, of ARRA funds. The ARRA funds enabled centers to support activities such as
3 making additional P&F awards, updating or replacing old equipment in the research cores, and
4 supporting summer research experiences for students.

5

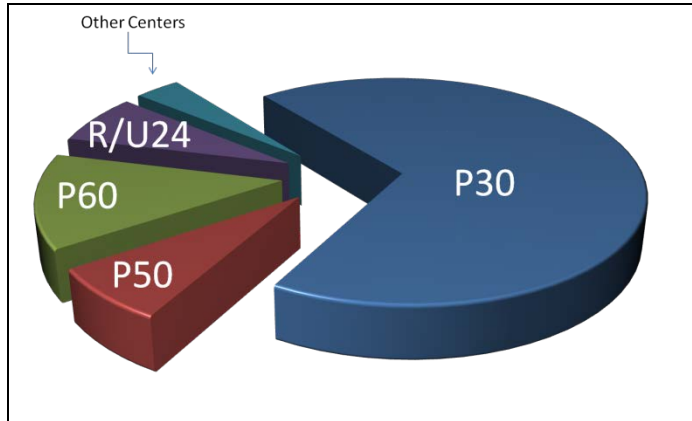


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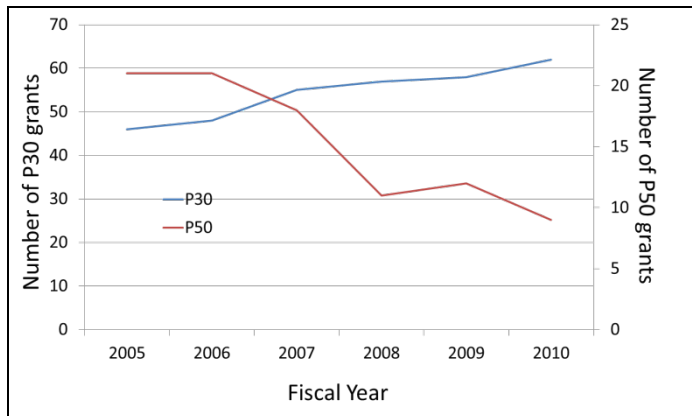
7 **Figure 1—NIDDK Centers Budget:** The centers budget shown in red (corresponding to the Centers
8 Budget axis on the left) includes fiscal year NIDDK spending on P20, P30, P50, P60, U42, PL1, and U54
9 activity codes, as well as the Mouse Metabolic Phenotyping Centers (U24) and Digestive Diseases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

15 Figure 2 shows the NIDDK FY10 budget breakdown by centers activity code. The majority of
16 the FY10 NIDDK centers budget supported P30 grants. This reflects a general trend, since a
17 2003 NIDDK centers review, to move away from the P50 activity code and toward the P30.
18 That trend is also visible in Figure 3, which shows the numbers of both types of grants supported
19 by NIDDK from FY05-10. Since the Centers review was initiated in FY10, NIDDK has
20 discontinued use of the P60 activity code. A new P30 program, the NIDDK Centers for Diabetes
21 Translation Research, was designed to fulfill some of the same program goals.

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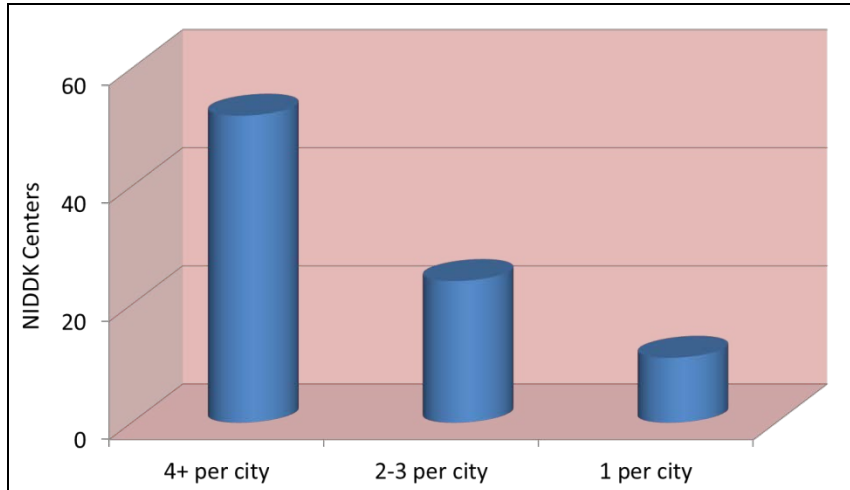
1
2 **Figure 2—Centers Activity Codes in the NIDDK FY2010 Budget***: The size of the wedges is
3 proportional to dollars spent on each activity code in FY10. “Other Centers” refers to the centers detailed
4 in Table C and represents 3.5 percent of the total. *These totals do not include ARRA funds.



5
6
7 **Figure 3—Trends in NIDDK Use of the P50 and P30 Activity Codes, FY05-10**: Number of NIDDK-
8 supported P30 and P50 center grants over time, from FY05-10 (note that the graph has separate axes for
9 P30 and P50 grants). Data show a decline in the number of P50 grants and an increase in P30 grants over
10 this time period.

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

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1
2 **Figure 4—Geographical Clustering of NIDDK Centers, FY10:** Of the 87 NIDDK-funded centers, 52
3 were in cities with 4 or more centers (not always at the same institution); 24/87 centers were in cities with
4 2 to 3; and 11 were in cities with no other NIDDK center.

5 6 **PROCESS FOR NIDDK CENTERS PROGRAM REVIEW**

7
8 The NIDDK has engaged in a collaborative process for reviewing its centers program, which has
9 included discussions with and input from the Institute’s Advisory Council, scientists
10 participating in the centers program, and the broader scientific community. This section
11 describes the process for conducting the centers review.

12 **Presentation at February 2010 Advisory Council Meeting**

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

- 16 • examining synergies between centers;
- 17 • encouraging interactions between centers, including fostering regional and national cores;
- 18 • enhancing access to center resources;
- 19 • examining the value of the P&F program; and
- 20 • examining changes implemented in response to the NIDDK's 2003 centers review, which
21 included expanding the centers’ P&F program and shifting some types of centers from
22 P50 to P30 grants.
23

24 **Center Site Visits, 2010-2011**

25 The NIDDK determined that it would begin to address the Advisory Council recommendations
26 by conducting site visits to institutions with multiple NIDDK-supported centers. From
27 December 2010 through March 2011, NIDDK visited five institutions that each had five
28 NIDDK-supported centers, in order to visit a broad representation of the types of centers
29 supported by the NIDDK, and also to permit the Institute to examine synergies and interactions
30 among centers. Detailed information on the site visits is found in the “Site Visits to NIDDK-

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1 supported Centers” section of this report. The NIDDK also alerted other centers that were not
2 visited via email that the site visits were occurring.

3 **Presentation at May 2011 Advisory Council Meeting**

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

7 **Soliciting Input from NIDDK Centers**

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

15 This modified interim report slideset was distributed to all NIDDK-supported centers—including
16 centers that participated in the site visit. In total, 112 centers were invited to provide comment.
17 That number is higher than the total number of centers (87) shown in Table A, because NIDDK
18 also contacted: (1) new centers that had been awarded as of early November 2011; (2) centers
19 that were active at the beginning of the review process, but were no longer active and thus not
20 counted in the numbers reported in Table A; and (3) the P20 centers that were not included in the
21 review process because they were new centers. The centers were invited to provide comment
22 through an online form from November 10-December 21, 2011. The NIDDK received 24
23 responses, which are summarized in the section titled “Summary of Input from Centers.”

24 The NIDDK invited input from the centers first, before inviting comment from the public,
25 because the centers have first-hand experience with the discussion topics of particular interest to
26 NIDDK and would be affected by any changes to the centers program. However, because it is
27 important to the NIDDK to consider input from multiple perspectives, including from scientists
28 not participating in centers, the NIDDK is also inviting public comment on this draft report (see
29 next section).

30 **Soliciting Public Input**

31 To be as inclusive as possible during the centers review process, the NIDDK is next inviting
32 input from the broader scientific community and other interested members of the public by
33 posting this draft report on the Institute’s website. Input received during this public comment
34 period will be considered before finalizing the report.

35 **Finalizing Report for Submission to the Advisory Council**

36 With consideration of input from the Advisory Council, scientists participating in the centers
37 program, the scientific community, and the public, the NIDDK will finalize this report, submit it
38 to its Advisory Council, and post it on the Institute’s website.

1 **SITE VISITS TO NIDDK-SUPPORTED CENTERS**

2
3 This section describes the process and findings from the site visits to NIDDK-supported centers
4 conducted as part of the review.

5 **Purpose of Visits**

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

12 **Centers Visited**

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

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

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

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1 **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
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
Digestive Diseases Research Development Centers: DDRDCs	4	0
Cystic Fibrosis Research and Translation Core Centers	5	1
Total Visited		25

2

3 **NIDDK Personnel Attending Site Visits**

4 The following NIDDK staff members attended the site visits:

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

10 **Summary of Site Visit Process**

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

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

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

20

21 The core visits included presentations by Core Directors and tours of the facilities. In most
22 cases, the NIDDK group toured the core laboratory or facility, saw the instrumentation, and
23 heard about how the core operates. In other cases, such as animal facilities that require visitors
24 to wear special garments, core personnel sometimes opted to give a presentation rather than to
25 take the NIDDK visitors through the actual facility.

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

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

17
18 **Day 2** – On the second day, the visit focused on in-depth information on the centers provided by
19 the institutions through a series of presentations and discussions. The day began with
20 introductory remarks given by the NIDDK Director or Deputy Director, followed by an
21 institutional overview, given by a Center Director, Dean, or Vice-Dean. After the institutional
22 overview, presentations from each Center Director provided detailed information on his or her
23 Center, including its members, organization, cores, scientific accomplishments, and training or
24 enrichment programs. NIDDK and university staff then had a discussion that focused around
25 three topics: (1) membership of the centers; (2) cores; (3) and interactions between centers. The
26 discussion was followed by presentations by recipients of P&F awards, who described the impact
27 of the awards on their research careers. The site visit closed with an open discussion about any
28 other questions that came up during the site visit, and provided an opportunity for the institutions
29 and grantees to provide input on how NIDDK can enhance its centers program.

30 To help frame the discussions during Day 2 of each site visit, the NIDDK provided centers with
31 a list of discussion questions before the site visits. Those questions are listed below, organized
32 by agenda item.
33

Day 2 Discussion Questions

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

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

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

- 43
- 44
- 45 • What is the Center's mission?

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

18 **Focused Discussions—NIDDK and Institutions**

19 Center Membership

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

26 Cores

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

37 Interactions Between Centers

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

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1 **Findings from Site Visits**

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

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

9
10 In most cases, the cores were open access and available to scientists outside of the Center,
11 including non-members at the institution and, in some cases, investigators at other institutions.
12 In some instances, Center membership was a requirement to use a core, but obtaining
13 membership was generally an easy process for investigators (see “Research Cores—Operations”
14 below for more information on core usage). A policy common to many of the visited centers
15 was that investigators were required to have federal funding and a need for one or more center
16 cores to obtain center membership.

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

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

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

33
34 At institutions where a NIDDK Center Director was involved in the leadership of the CTSA,
35 there appeared to be interaction and synergy between that Director’s Center and the CTSA. Both
36 the CTSA and the NIDDK center appeared to benefit from this interaction.

37
38 In most instances, preparation for the site visit was the first time all the NIDDK Center Directors
39 at an institution came together in a systematic way. In some cases, institution personnel noted
40 that preparation for the site visit had the unexpected benefit of promoting interaction among the
41 NIDDK centers. The visits also increased the interaction among NIDDK staff overseeing centers
42 programs, making it easier for them to learn from one another’s experiences.

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

10
11 ***Research Cores—Operations:*** Cores of an NIDDK center were often located in adjacent
12 buildings at an institution, but could also be across campus or town. Some cores were housed in
13 stand-alone facilities, while others were located either immediately adjacent to or entirely within
14 investigators' laboratories. NIDDK visited cores that were run by professional staff, tenured
15 faculty, junior faculty, and postdoctoral fellows.

16
17 Commonly, centers decided the access policy to their core services. In other instances, the
18 institutional policy determined that all NIDDK center cores at a site were open to all faculty at
19 the institution, even if they were not members of the center. Thus, cores were generally open
20 access and, in some cases, non-members, including investigators from other institutions or
21 industry, were allowed to use the cores. Cores were generally operated on a first-come, first-
22 served basis with no prioritization to NIDDK center members or other NIDDK-funded
23 investigators. When demand led to a requirement for prioritization, members usually came
24 before non-members and institutional investigators before outside investigators.

25
26 ***Research Cores—Value of Core Services:*** The NIDDK observed that cores provided value in
27 multiple ways, including: through availability of and reduced costs for resources, technologies,
28 equipment, and services; training and support in using facilities; consultations on experimental
29 design and analysis; repositories of reagents; technology development; and opportunities for
30 collaboration.

31
32 Generally, NIDDK center cores did not appear to overlap with other NIH or institutional core
33 services in that the institutional core did not have the equipment required, offer the necessary
34 assays, or have the appropriate expertise. In some cases, centers bought-in to an existing
35 institutional core to gain access to a resource that is needed by center members. In instances
36 where NIDDK center cores did appear to overlap with services available elsewhere, Center
37 Directors were aware of the overlap and noted that other cores were unable to readily supply
38 materials or access due to heavy use.

39
40 NIDDK centers had a mix of standard service cores, such as for mouse transgenic and genomics,
41 and specialized cores with more unique expertise. Standard cores provided a value by reducing
42 the costs and research time for a frequently used service, and may have a larger user base due to
43 their broader service. Specialized cores provided a unique service and, therefore, may have a
44 smaller user base. Center Directors noted that cores evolve in response to the specific needs of a
45 center's research base, leading to a combination of both unique cores and service cores.

46

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1 **Research Cores—Core Business Plans:** The Office of Management and Budget Circular A-21
2 (“Cost Principles for Educational Institutions”) sets accounting rules for educational institutions
3 (see: www.whitehouse.gov/omb/circulars/a021_2004). Visited institutions interpreted this
4 Circular differently, which resulted in centers (or institutions) employing a variety of business
5 plans for the cores. However, generally speaking, few cores had a defined business model. In
6 some instances, cores provided their services with no charge to any user, or the same charge to
7 all users with no specific “discount” for center members or other NIDDK-funded investigators.
8 Some provided a discount for center members, and the discount varied at visited sites. For
9 example, the member could be charged for supplies and materials, but the technical personnel
10 and equipment were paid for by the center; or fees for center members were determined based on
11 the overall usage of the core; or all users were charged the same costs, but center members could
12 receive funds from the center for use at a specific core.

13
14 Efficiencies resulted from multiple centers supporting a core or from centers “buying in” to
15 institutional cores so that center members could utilize existing cores at a lower cost. Not all
16 institutions had a comprehensive list of research cores, including all NIDDK, NIH, or
17 institutionally sponsored cores, but in some cases institutions had or were working towards such
18 a listing (e.g., on a website).

19
20 **Training and Enrichment Programs:** Training is a strength of the centers program, and centers
21 felt that training and development of young scientists’ careers was important to the centers’
22 missions. Of note, dedicated “training funds” are not available to centers from NIDDK to
23 support training of pre- or post-doctoral fellows. However, there are still opportunities to train
24 young scientists without the use of dedicated training funds, such as through Enrichment
25 Programs, P&F awards, and training and consultation provided by core staff.

26
27 Some centers receive limited funds to support Enrichment programs, which are intended to
28 sponsor, for example, seminars, visiting scientists, workshops, and mini-sabbaticals for center
29 members. These activities are aimed at fostering the exchange of ideas with the goal of
30 enhancing the productivity and efficiency of the center and its members. Common activities for
31 Enrichment Programs at the visited sites included research seminars, annual symposia/retreats,
32 and technology seminars/courses. Some centers were attempting to reach a broader audience,
33 such as by videocasting their research seminars to scientists outside of their location. Other
34 examples of how centers were involved in education and training were through summer research
35 programs for high school and undergraduate students, and “year out” programs, in which
36 medical students interrupt their formal coursework to conduct biomedical research.

37
38 **Pilot & Feasibility Award Programs:** Centers demonstrated a strong commitment to P&F
39 programs, which were considered quite valuable by the institutions. These awards are made to
40 new investigators, or established investigators with a new interest in the field or looking to
41 pursue a new research direction. NIDDK did not request specific data on the P&F programs;
42 therefore, information reported by centers was varied. Examples of reported data included
43 information on the P&F programs, such as total number of awards since inception of the center,
44 average number awarded per year, average P&F award size, cap for a P&F request, and amount
45 of funding (R01 or other) that resulted from the P&F support. Thus, there was variability in the
46 way that centers implement the P&F portion of their program.

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1
2 P&F awards are typically distributed internally at an institution, with the issue of transferring
3 indirect costs often cited as the rationale for not making external awards. Some centers have
4 found ways to overcome institutional barriers to broaden their P&F programs to external
5 investigators, but the centers noted that this required significant effort and was cited as a work in
6 progress.

7 **Conclusions**

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

13
14 At many sites, the NIDDK site visit was the first interaction for all the NIDDK centers at a site,
15 and the site visits were an opportunity for all NIDDK staff overseeing centers programs to come
16 together and share experiences and knowledge. This suggests that opportunities for greater
17 synergy may exist both at the grantee institutions and within NIDDK.

18 **SUMMARY OF INPUT FROM CENTERS**

19
20 NIDDK-supported centers were invited to comment on a modified version of the draft interim
21 report slideset presented at the May 2011 NDDK Advisory Council meeting. Included in the
22 slideset were several discussion topics, which outlined specific areas that NIDDK was
23 particularly interested in receiving input. This section describes the discussion topics and
24 summarizes the centers' input. It is not an exhaustive summary of comments received, but
25 includes overarching themes that emerged. The NIDDK has considered all submitted comments
26 in the development of this report and the potential changes to the centers program (see next
27 section on "Outcomes from Centers Review Process"), even if they are not included in the
28 summary section below.

29 **Discussion Topic 1: Enhancing Synergy and Center Value**

30
31 **Background:** The NIDDK is looking for ways to enhance synergy between/among its centers,
32 and to increase utilization of center resources by the broader NIDDK research community.
33 Options to achieve these goals could include supporting more regional and national cores;
34 coordinating core services locally, regionally, or nationally; increasing interactions between
35 centers; promoting collaborations between investigators in different centers; and increasing
36 awareness of center-supported services in the broad NIDDK scientific community.

37
38 With that background, the NIDDK invited input on the following:

- 39 • Do barriers imposed by the institution or by NIDDK interfere with
40 interactions/synergies?
- 41 • Would it be helpful if the NIDDK facilitated (by including funds in centers' budgets) one
42 of the following:
 - 43 ○ National meeting of all NIDDK Center Directors;

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

7
8 ***Input from Centers:*** The centers were supportive of the NIDDK’s overarching goal of
9 increasing synergy. Generally speaking, the centers felt that, especially in times of limited
10 budgets, it is worthwhile examining ways to enhance synergy in order to reduce costs and
11 leverage resources. Centers noted that there are different issues that arise related to increasing
12 synergy between two or more different types of centers at one institution, and between the same
13 type of center at different institutions. For example, simply being in close proximity may make
14 it easier for centers at the same institution to interact, such as by co-supporting a core that may
15 be used by more than one center. However, there are usually more barriers to interactions
16 between institutions (*e.g.*, sense of competition, issue of indirect costs, bringing in
17 samples/animals from other institutions). Some centers reported that they already interact with
18 other centers at their institution, and/or other centers of the same type at different institutions.
19 Other centers reported that they do not interact with other centers within or outside their
20 institution.

21
22 The centers provided ideas for ways that the NIDDK could enhance synergy. The themes that
23 emerged included:

- 24 • *Through an NIDDK Centers Website:* Many centers felt that it could be useful for
25 NIDDK to manage a website dedicated to center activities. For example, the website
26 could include information on cores and their services, so that other centers could see what
27 services are available and potentially prevent duplication. The NIDDK could also post
28 center seminars that may be of broad interest and/or webinars with examples of how
29 different centers manage their cores or P&F programs. This type of information could be
30 particularly useful for new centers. In other words, most centers felt that a “one-stop-
31 shop” for NIDDK-supported center activities would be useful and could help foster
32 synergy across centers.
- 33 • *Through Center Directors Meetings:* The idea of national or regional meetings of Center
34 Directors was well-received by most centers. Even for centers programs that already
35 have regular meetings, some people felt that more time should be dedicated at those
36 meetings to talking about the cores supported by the centers, as a way of sharing
37 information and enhancing coordination.
- 38 • *Through NIDDK Staff Review:* Centers commented that it may be helpful for NIDDK
39 staff to identify areas of overlap or synergies, as a starting point for trying to increase
40 coordination. For example, this could be done with current center programs, such as at a
41 local level to see if there could be cost-sharing for equipment or expertise. Or, it could be
42 done at the time when center grants are reviewed in order to eliminate some aspect that
43 could be served by another center and/or to add unique components to a new center.

1 **Discussion Topic 2: Strengthening the P&F Program**

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

10
11 The site visits highlighted differences in how the P&F programs were administered throughout
12 the centers. For example, there were differences in the number of awards an individual can
13 receive, the size of an individual award, and whether the program was open to investigators
14 outside of the center institution. Because the overarching goals of the P&F program are the same
15 for each center, the NIDDK is considering whether the Institute should develop additional
16 guidelines for implementing the program more uniformly across its centers.

17
18 With that background, the NIDDK invited input on the following:

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

26
27 **Input from Centers:** The centers felt that the P&F programs were a successful component of the
28 centers and had a consensus opinion that the flexibility for centers to manage and administer the
29 program was a strength. They did not think that additional guidelines from NIDDK would
30 improve the program; rather, as long as NIDDK provided clear expectations and goals, the
31 centers could implement successful P&F programs on their own. However, centers did propose
32 several ideas for strengthening the program, which included:

- 33 • *Focusing on mentoring and monitoring progress:* Several centers commented that
34 mentoring was a key component of a successful P&F project. In addition, many felt that
35 it was important to monitor progress of the project, to help ensure success. They
36 recommended that NIDDK place a greater focus on mentoring, such as by requiring that
37 a mentoring plan be submitted with the center application, providing a small amount of
38 funding to a mentor as part of a P&F project, or requiring that P&F award recipients have
39 a mentoring or advisory committee to monitor progress.
- 40 • *Disseminating information on best practices:* Rather than NIDDK providing guidelines
41 on administering P&Fs, many centers thought it would be helpful for NIDDK to provide
42 information on how P&Fs are administered throughout the centers and, for example, post
43 the information on a central NIDDK website (see Discussion Topic 1). Centers could
44 then decide to implement aspects that may work well for their institution. Other centers
45 thought that it would be useful for NIDDK to provide information on a P&F grant review

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1 process that could be used by all centers, and to create a national database of potential
2 reviewers.

- 3 • *Changing metrics for success:* Some centers suggested that NIDDK place less emphasis
4 in center review criteria regarding publications and amount of subsequent funding
5 obtained by P&F recipients. They felt that those metrics encouraged centers to make
6 awards to scientists with nearly funded research projects, and discouraged support of
7 scientists with new ideas that are not close to being funded. If new metrics were
8 developed to measure the success of P&F projects, the scientific scope of the projects
9 may be broadened.
- 10 • *Broadening group of eligible investigators:* Some centers thought that other groups of
11 investigators—such as PIs who just missed the payline for NIH funding and need specific
12 data to resubmit an application—should be considered for P&F funding. Some centers
13 thought that consideration should be given to funding larger interdisciplinary
14 collaborative awards.
- 15 • *Opening up P&F program to investigators outside home institution:* Several centers
16 supported the concept of opening up the P&F program to investigators outside of their
17 institution, and some reported already doing so. However, they commented that
18 administrative issues (*e.g.*, indirect costs) were major barriers. Suggestions included
19 permitting co-PIs from outside institutions, requiring that each center have at least one
20 collaboration between two or more NIDDK-funded centers at separate institutions per
21 P&F cycle, supporting external P&F projects that will benefit from use of center cores,
22 and having NIDDK make the P&F award directly. Other centers thought that it was
23 important for the P&F award recipient to be at the home institution, or at least in the local
24 vicinity, because of the importance of mentoring to the success of a project.
25

26 **Discussion Topic 3: Core Support and Access**

27
28 **Background:** The site visits highlighted different types of cores supported by the centers,
29 including highly specialized, unique cores that focus on research specific to the NIDDK mission
30 areas, as well as general institutional cores in which the centers buy in so that their members
31 have access. Both of these models have value, and the NIDDK invited feedback from the centers
32 regarding their perception of the relative value of supporting the two types of cores through the
33 centers.
34

35 In addition, the NIDDK invited input from the centers on the idea of broadening access to
36 specialized core resources to users outside of the center institution, such as at a regional or
37 national level. For example, the NIDDK-supported Mouse Metabolic Phenotyping Centers
38 (MMPCs) provide a national resource of specialized phenotyping services for mouse models of
39 diabetes, diabetic complications, obesity, and related disorders. MMPCs assess mouse mutants
40 sent to them with any of a wide array of complex metabolic tests, on a fee-for-service basis. The
41 NIDDK is considering whether this type of core usage model could be expanded to other
42 NIDDK center cores that provide unique, specialized services that may be of use to investigators
43 at institutions that do not have access to those types of services.
44

45 **Input from Centers:** Input focused around the following themes:

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- 1 • *Core support:* Most centers commented that centers should both support specialized
2 cores and buy in to general institutional cores. They felt that center members needed
3 access to both types of cores, although some centers felt that specialized cores were a
4 higher priority for NIDDK funding.
- 5 • *Broadening access:* Although there was varied input, there was general support for the
6 idea of NIDDK broadening access to specialized core resources to users outside of the
7 center institution, at a regional or national level. It was thought that such cores could be
8 valuable if they provide a specialty service, but would need to be readily accessible,
9 provide a rapid turnaround, and not delay the science. Some concerns about opening up
10 cores to outside users included issues related to bringing in samples/animals from other
11 sites and already having a maxed-out workload at current funding levels. Centers
12 commented that the latter issue could be addressed by using a charge-back system to
13 defray the additional costs. Another suggestion included allowing centers to apply to
14 NIDDK for additional funds to set-up a center-associated core that provides a service to
15 other institutions on a fee-for-service basis.

16
17 Other suggestions from Center Directors in regard to Discussion Topic 3 are summarized
18 elsewhere. (For example, NIDDK developing and disseminating best practices for
19 administrative and financial aspects of cores is addressed under Discussion Topic 4, and sharing
20 information on core resources through a central NIDDK website is addressed under Discussion
21 Topic 1.)
22

23 **Discussion Topic 4: Core Business Models**

24
25 ***Background:*** A variety of business models are in use at the center cores NIDDK visited, and
26 some cores do not have a defined business model. Toward the goals of increasing core access,
27 ensuring the value of core services, and expanding capacity to meet user needs, the NIDDK is
28 considering encouraging center cores to have and implement a defined business model.
29

30 Examples of business models include: free to members; charge-backs based on usage; charge-
31 backs that vary by category of user; and other business models including reinvestment in the core
32 through technology development, training, etc.
33

34 With that background, the NIDDK invited input on:

- 35 • One possible business model is a charge-back system, which can include subsidies for
36 center members. Is this a good model? Why or why not?
- 37 • What would assist your center cores to establish and implement a defined business
38 model?
39

40 ***Input from Centers:*** Most centers felt that a charge-back system was a good business model for
41 cores, and many centers reported using such a system. For example, several centers stated that
42 they have different charges for different levels of users (*e.g.*, members, non-members, industry).
43 However, centers also noted that different types of cores may require different types of business
44 models. The themes that emerged included:

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- 1 • *NIDDK-disseminated information on core business models:* Several centers said that it
2 would be useful for NIDDK to prepare and disseminate information on business models
3 that could potentially be used by the cores. This information could be posted on a central
4 NIDDK website (see Discussion Topic 1) and/or presented by NIDDK staff at Center
5 Directors or Core Directors meetings. Centers generally felt that having this type of
6 approach would be more helpful to them than NIDDK developing specific requirements
7 for core business models.
- 8 • *Policies regarding purchase of equipment:* Some centers commented that it is
9 challenging to purchase, maintain, and upgrade equipment used in cores, and that a
10 limiting factor is the ability to purchase equipment only one time in a 5-year funding
11 cycle. Centers thought that this issue was important to address if cores are expected to
12 have cutting-edge, state-of-the-art technology for use by center members. Centers
13 suggested that NIDDK consider its policies regarding equipment, including the
14 possibility of using charge-backs to maintain/purchase equipment as part of a core
15 business model.
16

17 **Discussion Topic 5: Potential Value of More Small Centers**

18
19 **Background:** The R24 Digestive Diseases Research Development Centers represent a different
20 model, in which the Center supports a relatively small number of investigators at a particular
21 institution. The NIDDK is considering expanding this concept of smaller centers to other
22 mission areas. For example, small centers could serve institutions with fewer users or provide a
23 unique national resource for a specific field. Centers were invited to comment on the idea of
24 expanding the NIDDK centers program to include more small centers.
25

26 **Input from Centers:** The NIDDK received varied input on this topic, both for and against
27 supporting more small centers:

- 28 • *For support of more small centers:* Some centers—including those at smaller institutions
29 and those that are not geographically near other major research Centers—were supportive
30 of the idea of NIDDK funding more small centers. Centers commented that NIDDK
31 would need to consider factors such as: requiring a minimum number of productive
32 scientists and a clear research theme; ensuring that small centers are not funded out of
33 proportion to their productivity and are distinct from a multiple PI grant or a P01 grant;
34 and funding small centers that consist of a small team of collaborators who work in close
35 proximity at the same institution. A suggestion was that small centers could be useful
36 especially where a single specialized resource exists.
- 37 • *Against support of more small centers:* Other centers commented that they did not see
38 value in supporting more small centers. A common concern was that they thought it
39 would be difficult for small centers—with correspondingly small budgets—to be efficient
40 or effective. They recommended that, instead of supporting more small centers, NIDDK
41 increase coordination across centers (Discussion Topic 1) and open up cores to outside
42 users, including at institutions without centers (Discussion Topic 3).
43

1 Discussion Topic 6: Center Membership

2
3 **Background:** The site visits showcased that, at institutions with more than one NIDDK-
4 supported center, it is not uncommon for one person to be a member of two or more centers.
5 This overlap could be a natural result of overlap in research interests, particularly with the
6 Diabetes Research Centers and NORCs, or in order to use the unique cores provided by a center.
7 However, this results in scientists being included in the research base for multiple centers in
8 center applications from the same institution. Because applications are reviewed independently,
9 the NIDDK has been considering ways to make reviewers aware of this issue, such as by asking
10 centers to provide a percent effort for members that are listed in the research base of more than
11 one center. However, at the site visits, some centers expressed concerns with that approach and
12 felt that the percent-effort data could not be captured. The NIDDK wants to ensure that the
13 research base for each center is defined in a way that is consistent and fair, and that accurately
14 reflects usage. The Institute invited ideas for how to ask centers to define the research base when
15 members belong to more than one center.

16
17 **Input from Centers:** The NIDDK received varied perspectives on center membership, including:

- 18 • *Members belonging to more than one center:* Centers generally felt that it was acceptable
19 for investigators to be members of more than one center, due to related research interests
20 and/or because investigators pursue research relevant to multiple areas within the NIDDK
21 mission. Centers commented that, during the grant review process, the study section
22 would have the opportunity to evaluate the members' contribution to research relevant to
23 the center's mission. A suggestion was that, for scientists listed on more than one center
24 grant application, the centers be asked to add footnotes to explain the components of
25 research that are supported by the center, rather than trying to define the percent-effort.
- 26 • *Defining "center member:"* Some centers felt that it was best to make membership
27 inclusive, as it is beneficial to get as many people as possible studying the center's
28 research area. Other centers considered membership numbers to be inflated if, for
29 example, centers counted investigators who attended center-sponsored seminars or
30 training activities but had no other involvement in the center. They thought that those
31 types of members were not necessarily active users. Centers suggested addressing this
32 issue by defining center members specifically as "core users." Other centers noted that
33 junior faculty benefit greatly from the centers, but are not counted in the research base
34 because they do not have NIH funding.

35 OUTCOMES FROM CENTERS REVIEW PROCESS

36
37 With careful consideration of input received from its Advisory Council, centers, and other
38 stakeholders during the review process, the NIDDK has enhanced its centers program and is
39 making additional recommendations to strengthen the program further. The NIDDK notes that
40 the recommendations are in draft form and will be informed by input received during the public
41 comment period before they are finalized. The Institute also notes that there could be additional
42 changes made to the centers program that are not outlined here, which could stem from further
43 consideration of this review process and recommendations in this document, assessment of the

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1 centers program in consultation with Advisory Council, input from the extramural scientific
2 community, and strategic planning processes.

3 **Recent Changes Made to Centers Program**

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

10

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

25

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

41

42 ***Increasing Synergy among NIDDK Centers through Information Sharing:*** The NIDDK is
43 implementing approaches to share information among centers and with the scientific community.
44 For example, several centers have developed public websites. The Diabetes Research Centers
45 (<http://www.diabetescenters.org/>) and the Digestive Diseases Centers
46 (<http://www.digestivediseasescenters.org/>) created websites, and the NORCs are in the process

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1 of creating a website. Additionally, at upcoming meetings of Diabetes Research Center
2 Directors, NIDDK staff will present information on other center programs, to make the Center
3 Directors aware of what is happening in other programs and what resources may be available.
4

5 ***Broadening Access to Hematology Centers:*** The Hematology Centers are doing a pilot program
6 in which Center Directors attended the February 2012 “Heme-Net: Nonmalignant Hematology
7 Research Network” meeting and gave presentations about the resources that are available in their
8 Centers. As a next step, the Centers are soliciting applications from hematology researchers
9 interested in doing a summer mini-sabbatical at a Center to use a specific core. The aim of this
10 pilot is to open up the Centers’ resources to other hematology investigators, thereby making the
11 resources available to a broader research community.
12

13 **NIDDK Recommendations To Enhance the Centers Program**

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

18 ***Discussion Topic 1: Enhancing Synergy and Center Value***

19 Input from the centers revolved around three themes:
20

21 *Theme:* Creating an NIDDK centers website

22 *NIDDK Recommendation:* The NIDDK recognizes the importance of web-based tools to provide
23 information about NIDDK-supported centers, such as core facilities, as a way to enhance
24 synergy among centers, as well as to make NIDDK-supported investigators at institutions
25 without centers aware of available resources. The NIDDK is currently redesigning its website,
26 and part of that effort includes improving the section on the centers. Additionally, websites have
27 already been created for both the Diabetes Research Centers and the Digestive Diseases Centers,
28 and will soon be created for NORCs. The NIDDK will continue considering how best to use the
29 web to advance the goal of enhancing synergy and sharing.
30

31 *Theme:* Having trans-NIDDK Center Directors meetings

32 *NIDDK Recommendation:* While most center programs have yearly meetings, NIDDK will
33 consider having all NIDDK-funded centers participate in a meeting if a specific
34 topic/need/challenge is identified as a focus for the meeting.
35

36 *Theme:* Having NIDDK staff identify areas of overlap and opportunities for synergy in NIDDK
37 centers programs

38 *NIDDK Recommendation:* As a result of the review process, NIDDK staff managing center
39 programs are working together to enhance synergy within the Institute, such as by harmonizing
40 FOAs, and the Institute recognizes that there are additional opportunities to do so. NIDDK staff
41 have begun meeting on a regular basis to discuss the centers program and to identify ways to
42 coordinate efforts further. For example, staff plan to discuss the changes that have been made in
43 response to the review process (see previous section), and will consider whether those changes
44 should be considered for other center programs.
45

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

3
4 *Theme:* Promote interaction and synergy between centers and CTSA

5 *NIDDK Recommendation:* The Institute will examine ways to promote enhanced cooperation
6 between NIDDK-supported centers and CTSA.

7
8 *Theme:* Including synergy as a review consideration for NIDDK center applications

9 *NIDDK Recommendation:* By definition, centers are expected to demonstrate synergy among
10 their members. Toward the goal of enhancing synergies among centers, the NIDDK will explore
11 the possibility of asking applicants to address the issue when they submit new or competing
12 applications so that reviewers could assess value-adding scientific relationships with other
13 NIDDK centers or CTSA. For example, the Institute could consider giving “points” for groups
14 that have either successfully established synergistic relationships with other NIH/NIDDK centers
15 or CTSA (for renewals), or have proposed strategies to achieve such recommendations (for new
16 applications). This could potentially be added as a secondary review consideration, but may be
17 regarded as particularly important for applicants from institutions with a CTSA or with one or
18 more other NIDDK centers.

19
20 *Theme:* Enhance opportunities for training through the centers

21 *NIDDK Recommendation:* The NIDDK will consider ways to utilize the centers to enhance
22 opportunities for training. For example, the Diabetes Research Centers support a summer
23 research program for medical students, which is open to all medical students (not just those
24 affiliated with center institutions). The goal of the program is to encourage medical students to
25 consider research in diabetes and its complications as a career and to educate students about
26 diabetes. This type of program could potentially be expanded to other NIDDK centers, as a way
27 to leverage the expertise of the centers and foster the creation of a pipeline of physician scientists
28 conducting research in NIDDK mission areas.

29 ***Discussion Topic 2: Strengthening the P&F Program***

30 Input from the centers revolved around five themes:

31
32 *Theme:* Focusing on mentoring and monitoring progress

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

38
39 *Theme:* Disseminating information on best practices

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

42
43 *Theme:* Changing metrics for success

44 *NIDDK recommendation:* The NIDDK will include recommendations regarding the types of
45 science that should be prioritized when making P&F awards in the best practices document on
46 P&F programs (see above).

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1
2 *Theme:* Broadening group of eligible investigators
3 *NIDDK Recommendation:* The NIDDK does not plan to change the group of eligible
4 investigators for P&F awards. In considering whether to broaden eligibility, the NIDDK came
5 to the conclusion that there are already mechanisms at NIH to support other groups of
6 investigators (e.g., NIH R56 mechanism available to provide funds to investigators who just
7 missed the payline). Therefore, based on feedback from centers about the success of the P&F
8 program, the Institute feels that the current group of eligible investigators is appropriate.

9
10 *Theme:* Opening up P&F program to investigators outside home institution
11 *NIDDK Recommendation:* Although many centers cited the issue of indirect costs as a major
12 barrier to making external P&F awards, the NIDDK notes that the NIH does not impose any
13 requirements related to charging indirect costs when making P&F awards to external institutions.
14 Some Hematology Centers, for example, have identified approaches to make P&F awards to
15 external institutions. The NIDDK could include examples of approaches that have been used by
16 these and other centers in its best practices document. Additionally, as described in the above
17 section on “Recent Changes Made to Centers Program,” the Diabetes Research Centers invited
18 applicants to make P&F awards at external institutions. This approach will be considered for
19 other NIDDK center programs.

20 ***Discussion Topic 3: Core Support and Access***

21 Input from the centers revolved around two themes:

22
23 *Theme:* Core support
24 *NIDDK Recommendation:* NIDDK agrees that there are often compelling justifications for
25 support of institutional cores and these should continue to receive support. The Institute
26 recognizes, though, that unique or specialized cores that provide technology development or
27 support for services that are specific to the NIDDK research community should be a high
28 priority.

29
30 *Theme:* Broadening access
31 *NIDDK Recommendation:* The NIDDK is considering addressing this issue on multiple fronts:
32 (1) the NIDDK will develop information on core business models (see Discussion Topic 4),
33 including a charge-back system, which was cited by centers as a possible way to increase core
34 capacity and broaden core access; (2) the NIDDK is using web-based systems as a way to
35 increase awareness of cores by outside investigators (see Discussion Topic 1); (3) the Diabetes
36 Research Centers have modified their FOA to invite applicants to provide core services to
37 diabetes researchers at institutions not served by an NIDDK Diabetes Research Center. This
38 approach will be considered for other NIDDK centers; and (4) the NIDDK will consider
39 supporting small centers, such as centers that serve as a specialized, national resource (see
40 Discussion Topic 5). The NIDDK will continue considering other avenues to broaden access to
41 cores services to benefit the NIDDK research community.

42 ***Discussion Topic 4: Core Business Models***

43 Input from the centers revolved around two themes:

44
45 *Theme:* NIDDK-disseminated information on core business models

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

3
4 *Theme:* Policies regarding purchase of equipment

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

8 ***Discussion Topic 5: Potential Value of More Small Centers***

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

11
12 *Theme:* Supporting more small centers

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

16 ***Discussion Topic 6: Center Membership***

17 Input from the centers revolved around two themes:

18
19 *Theme:* Members belonging to more than one center

20 *NIDDK Recommendation:* The issue of members belonging to more than one center was
21 primarily related to the Diabetes Research Centers and NORCs because of related research
22 interests. The NIDDK addressed this issue by requiring that Diabetes Research Centers and
23 NORC applicants note whether grants listed in the research base are also listed in the research
24 base of another NIDDK center at the same institution.

25
26 *Theme:* Defining “center member”

27 *NIDDK Recommendation:* The NIDDK will consider defining center members (*e.g.*, R01 PIs that
28 use cores), associate members, etc., as well as clarifying who should be included in the research
29 base investigators of a center.

30 **CONCLUSIONS**

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

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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
ORWH	NIH Office of Research on Women’s Health
P&F	Pilot & Feasibility
PI	principal investigator
PL	public law
SCOR	Specialized Centers of Research