

## **Defining “Best Practices” for the Process of Managing Pilot and Feasibility Awards at the NIDDK Diabetes Research Centers**

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Prepared on behalf of the Diabetes Centers Executive Committee by Pinchas Cohen (UCLA), with the participation of Sally Radovick (Johns Hopkins), Doris Stoffers (U Penn), Larry Chan (Baylor), Stu Frank (UAB), and Denis Baskin (UW).

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### **Introduction**

A central part of the mission of the Diabetes Centers is to support a Pilot and Feasibility (P&F) Program designed to foster the development of new investigators and to provide seed-support for innovative high-risk projects; typically, at least 20% of the Center direct costs are for support of P&F projects. Thus, the P&F Program Directors are critical to the operations of the diabetes centers. In 2008, a Diabetes Centers Directors’ Meeting was held with an open discussion among P&F Program Directors revealing a substantial variability among the practices of the various Centers regarding the operations of the P&F programs. It is also apparent that some P&F directors take on this responsibility for the first time and have only minimal experience in running the complex process of reviewing and awarding these grants. This document has been put together in order to establish general guidelines for P&F Program management as well as to describe the scope of heterogeneity amongst the various Centers. It should be noted that this document is a general guideline to assist Program Directors rather than an enforceable policy and that there is plenty of room for Centers to establish their own specific policies on the number and scope of P&F grants and on the process of reviewing and awarding them.

Furthermore, additional information about the vision and scope of the P&F program can be found in the Diabetes Centers website: <http://diabetescenters.org/pilotfeasibility>, as well as in the NIH guidelines for submission of Diabetes Center Grants: <http://grants.nih.gov/grants/guide/rfa-files/RFA-DK-08-008.html>

### **Overall goal of P&F grants**

To be considered a viable P&F program, the Center must support a minimum of two pilot projects, and typically at least 20% of the Center direct costs, exclusive of equipment, should be for support of P&F projects. In addition, DRTC applicants will be expected to include and provide for a substantial focus on prevention and control projects in the DRTC P&F program.

Monetary awards funded by the P&F program provide limited support to develop preliminary data sufficient for funding of a research grant application or to test an innovative hypothesis which might have important implications or yield significant results for diabetes-related research

### **Categories of P&F grants**

- (Category 1) New investigators without current or past non-mentored NIH research support as a principal investigator (current or past support from other sources being modest).
- (Category 2) Established investigators with no previous work in diabetes that wish to apply their expertise to a problem in this area.
- (Category 3) Established investigators in diabetes/endocrinology research who propose testing innovative ideas that represent clear departure from ongoing research interests.

### **The Process and timetable of advertising and processing the P&F grants**

Each Center has a wide email distribution list that is used to send various announcements. Notices advertising P&F award competitions (or RFA's) are sent approximately 3-months, 1-month, and 1-week prior to the grant deadline, which is typically 2-3-months prior to the anticipated funding start date. Center faculty members on the distribution lists are encouraged to share this announcement with fellow faculty who may be eligible to participate. Along with this general announcement, this notice is posted on the Center website for general viewers to see

### **Eligibility:**

The P&F program is particularly directed at new investigators and established investigators new to diabetes research. Established diabetes investigators pursuing high impact/high risk projects or projects that are a significant departure from their usual work are also eligible for support under the Diabetes Center P&F program. P&F programs may also be structured to provide support for establishing interdisciplinary collaborations and to help forge new partnerships between basic scientists and clinical researchers. While the distribution of P&F funds to be used in each award category is ultimately at the discretion of the Center P&F committee, it is expected that the Center P&F program will, where possible, place particular emphasis on funding innovative clinical and translational research projects, particularly by young investigators.

- All eligible investigators must have faculty appointments (at the commencement of the award) at the Center (or be Center-Affiliates from a collaborating institution) and be independent investigators. Senior fellows are eligible if they provide a letter from their Chairman insuring that they will become faculty at the time the P&F award commences.
- As the definition of faculty appointment varies, one is eligible for a P&F grant if they are eligible to submit an R01 as a PI at the start of the grant period. A joint appointment at an affiliated institution is allowed. Applications for collaborative projects are strongly encouraged.
- Applications are welcomed from basic, clinical and translational investigators.
- A second P&F grant on a separate topic is allowed for previous awardees (but only once and typically only for young investigators who demonstrated success as a result of their first P&F)

### **Submission Requirements:**

Some Centers employ a two-tier approach soliciting a 1-page LOI followed by an invitation to submit a full proposal; however, most Centers solicit full applications in a single step.

NIH-formatted proposal (submitted on NIH PHS 398 forms limited typically to 5-pages or 3,000 words (not including references) and including:

- Abstract/Project summary
- NIH-formatted biosketch for PI and collaborators
- Some Centers request a Budget and Budget justification. Others do not.
- Grant body including specific aims, innovation, significance, Research Design and Methods, with variable format requirements in various Centers
- References
- Status of Institutional Review Board (IRB) approval for clinical studies, IACUC approval for animal use, etc. if approvals are pending at the time of submission, they must be obtained before funding commences.
- Submission is electronic. Some Centers limit the size of the application to < 2 MB.

**Scope of P&F budgets:**

Budgets for P&F grants usually vary from \$30,000/year to \$50,000/year. In some Centers 1-year grants are awarded, while in others, a second year of funding is possible with demonstrated productivity. Support for a second year is not allowed if the applicant received external funding for the same project. Total support exceeding \$100,000 per candidate is discouraged due to limited funds and a large pool of outstanding candidates in most universities. Some Centers do not encourage, but allow, up to 10% for PI salary+fringe. Exceptions for unique “enhanced” programs that require up to \$100,000 total are made in certain centers where a limited number of proposals may be selected for support as enhanced P&F awards with prior NIDDK approval. Enhanced P&F awards are selected from worthy proposals in three project categories: clinical and translational research awards, clinical and basic research innovative partnership awards, or technology research and development awards. These enhanced awards may be funded at up to \$100,000 direct costs per year and for up to 3 years. Efforts to increase the number of P&F awards and availability of funds for the program through the use of program income or alternative funding sources are particularly encouraged.

**P&F Steering Committee:**

Each Center has a P&F steering committee that is comprised of the P&F director and 3-5 additional Center faculty. They are in charge of the review and award process.

**Awarding Mechanism and timeline:**

After receiving the submissions, the P&F Director will review the applications to ensure that they comply with administrative guidelines. The proposals will then be sent to at least two reviewers (up to 4), from both within and outside the institutions, for peer review.

- Requests for reviewers are sent within 3 weeks of the applications receipt
- Reviews (internal and external) are requested within 4 weeks
- Scores and rankings are tabulated within 2 weeks after reviews are received
- The P&F Steering Committee holds a meeting to review the grants and the scores and agree on the funding decisions (sometimes by conference call)
- Notification of awards occurs 4 weeks prior to the funding start date.

**The P&F grant review process:**

The purpose of the review process is several fold. First and foremost, the goal is to identify the highest quality applications with a high likelihood of developing into NIH R01 funded research programs. Within that framework, the highest priority of the program is to identify promising young faculty who will benefit from support at an early stage of their careers in diabetes research. The next priority is to stimulate and encourage mid-career scientists from other fields to bring their expertise to bear on challenging questions in the search for a cure for diabetes.

The typical review of a Pilot and Feasibility application involves the solicitation of expert reviews from both within and outside of the institution, with provision of variable degree of written feedback that can educate all applicants independent of the funding decision. Reviewers are asked to consider the quality of the science, but also the type of investigator as well as whether the project is likely to lead to sustained funding in the form of an R01, or equivalent, grant. Once the reviews are garnered, a local study section is convened to consider the opinions of the reviewers and to make funding decisions that balance all of the considerations outlined in the previous paragraphs.

Grants that are considered for funding should receive between 2-4 scores from different reviewers and committee members.

### **Selection of internal and external reviewers**

#### **Internal reviewers**

Some Centers send grants to internal and external reviewers simultaneously, while in some Centers there is a first stage, where an internal review group (IRG) composed of mid-senior-level faculty is convened to carry out this evaluation. This IRG typically includes the Diabetes Center PI and the P&F Director, the Steering Committee as well as a mix of diabetes and non-diabetes researchers, most of whom have been part of the IRG in previous years. In addition, new members are added at the request of the P&F Director, based on the need for content area. IRG members include basic scientists, clinical investigators, and some who have expertise in both areas. Each proposal is reviewed by two IRG members, although all members are encouraged to read all grants. Reviewers vote (NIH scale) electronically and all data are tabulated prior to a meeting of the IRG. Those applications with high scores are then reviewed by external reviewers. In most Centers, each application is assigned to two external and two members of the IRG for internal review. Thus, each application receives four reviews and four scores. Again, scores are tabulated electronically prior to a meeting of the IRG to ultimately choose the proposals to be funded. The P&F director notifies all applicants including those not awarded a grant and provides edited written feedback when appropriate. Typically scores and percentiles are not given to the applicants.

#### **External Reviewers**

Some Centers offer applicants the option to submit a list of potential reviewers outside of the home institution who the applicant perceives have no conflicts of interest.

The National Diabetes Centers database includes an extensive list of experts who are Diabetes Center members who can serve as reviewers. The P&F Director solicits two external reviewers per application, explaining to potential reviewers that a score and brief written comments are requested, and conflicts of interest should be considered and avoided.

Many Centers request external reviewers to review 4-6 applications each, while some send each grant to only one reviewer. It is felt that having a scope of grants allows reviewers to prioritize and compare the quality of applications. Some Centers rely on certain external reviewers with experience in the field to review grants year after year.

The Diabetes Center reviewer database is part of the main Diabetes Center website, and the reviewer information from all of the Centers is available in the database. Program Directors can easily navigate this site to select among hundreds of reviewers from the different Centers according to key words related to their expertise.

#### **Honorarium for external reviews**

Some Centers offer a small honorarium (\$50-100 per grant) that is paid as a token of appreciation for the external reviewers' efforts.

### **Post-Award responsibilities and reporting duties of awardees**

Once a grant is awarded, the responsibilities of successful applicants include involvement in the local diabetes community through seminar presentations and participation in local events of the diabetes research community, acknowledgment of Diabetes Center support in any publications emanating from the supported project, as well as progress reports and reporting of successful

independent grant applications resulting from the work supported by the Diabetes Center Pilot and Feasibility grant.

- All awardees are asked to acknowledge the Center support in all publications
- They must to notify the director of outside funding when received
- They must report yearly for 5 years and every five years after on publications, grants, awards, patents and promotions and on core utilization

**Data collection by P&F Directors**

Awards are acknowledged on the Center’s website and at the annual Diabetes Center Symposiums.

All Diabetes Centers collect data for use in their progress reports and renewal applications but this process is not uniform across all centers. A National data collection effort has been initiated and Centers are now required to provide information to this database, however, this is still a work in progress. P&F directors recommend that the NIDDK continue to define a common set of guidelines for the gathering of data related to center P&F programs as well as storing the data in a single searchable repository. Such a database would be an invaluable resource to NIDDK for documenting and tracking the success of the P&F Program at each center as well as center-wide. Ideally, some of the data in a centralized P&F Program database could be made available to all centers and possibly to the public.

The types of data that are currently collected and could be entered into such a database should minimally include all of the usual metadata on P&F awardees. These would be names, degrees, faculty ranks, institutions, academic departments, titles of the projects, etc. It would be useful to have abstracts of the projects, dollar amounts awarded, and dates of the award periods; the list of the information and data that potentially might be stored in a common database is open ended and would be defined by NIDDK. We believe that such a database should include publications resulting from P&F awards as well as subsequent funding that results from the P&F supported research as well as the recipients’ subsequent professional positions (e.g., academic, private practice, industry etc.). An added feature that could be very useful would be information on center core use by the awardees. The above are some of the basic elements of a P&F database. More types of data could be included, depending on intended use and resources. For such a database to be useful it would have to be current. NIDDK would, therefore, need to develop a common mechanism for centers to enter new data and update earlier records. To accomplish this efficiently requires a central NIDDK P&F Internet website that has preset online forms and fields in which metadata and other information can be easily entered by each center. The database could be updated at any time by respective centers, but they would be required to update their entries coincident with submission of annual progress reports and renewal applications. A prototype of this is currently tested off-line.

**Proposed Database**

Below is a sample table for a recommended format that can be used to collect data on P&F awardees in a particular Center. These tables should be submitted to the NIH on a regular basis.

Year	Name	Title	Department	Institution	Degree(s)	P&F Application Title	P&F Investigator Type	Type of P&F Research	Amount of P&F Award	Duration of P&F support	Grant Funding Resulting From P&F Support	Current Institution	Current Job Title
(1989-2009)	P&F Awardee's Name (Last Name, First Name)	Academic Title at time of P&F award	at time of P&F award	at time of P&F award	Graduate degrees only		Use code 1, 2, or 3 (New =1, Established =2, or Established and new to diabetes =3)	Basic, Clinical, Translational (may use more than one term)	Total Direct Costs (\$)	(MM'YY - MM'YY)	Role, Source, Amount (total costs), Dates	Current (2009) institution of P&F awardee	Current (2009) job title of P&F awardee
1989	Smith, Jane												
1990													
1991													
Etc													