
Menopause and the NIH: Part 2—The Postreview Process

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The process for obtaining NIH funding for menopause-related research does not end when the application is submitted. Various steps can be taken by the applicant even after an application has been reviewed. Taking the time to learn about the factors considered when funding decisions are made is an important part of a proactive approach to securing funding for much-needed menopause-related research.

Introduction and Review

Part 1 of this article (“Menopause and the NIH: Part 1—Research Needs and Funding Mechanisms,” January/February 2002, pages 13-15,18-21) addressed the need for menopause-related research, and detailed the process involved in obtaining funding for such research through the National Institutes of Health (NIH). Funding mechanisms were described and pointers given for increasing the chances of receiving funding through the grant application process.

Part 2 of this article addresses the postreview process; specifically, it explains what occurs once an application for funding has been reviewed, describes the recourse available when funding is denied and discusses the considerations involved in making funding decisions at the NIH. Also included in the present article is an overview of the career development awards—the K series of grant mechanisms—available through the NIH.

Study Section Review Outcomes

Usually within a week or two after the study section meets, applicants receive notification by mail of the score and percentile ranking of their application.

Unscored applications. An unscored application (i.e., not discussed or scored during the review meeting) means that the assigned reviewers felt it ranked in the lower half of the applications being considered at the current meeting; it also means that no other study section member asked that the application be discussed. Applicants will, however, receive a summary statement describing the assigned reviewers’ opinions of the proposed research plan. Applicants may revise and resubmit the application without prejudice in subsequent reviews, provided it has not already been revised twice.

Scored applications. Applications that are discussed receive a score and some, as explained below, receive a percentile. The percentile is meant to normalize scores across many Center for Scientific Review (CSR) study sections with potentially widely divergent average levels of enthusiasm for their assigned applications. The percentile is the primary indicator of scientific quality used for funding decisions by NIH Institutes. Percentiles are usually derived based on scores of applications reviewed in the current and two previous review cycles. Not all applications receive a percentile; usually, all R01 applications

reviewed by CSR study sections do, but R01s reviewed for requests for applications (RFAs) or in other Institute-based study sections might not. Other mechanisms that are generally not “percentiled” include career awards, fellowships and conference grants.

Summary statement. The only official record of the study section decision which, in turn, provides the basis for the resulting score, is the summary statement. The applicant generally receives the summary statement within 4 to 6 weeks after the study section meets.

The summary statement contains the following:

- the name of and contact information for the primary program administrator for the application (upper left-hand corner);
- a resumé of the discussion that occurred during the meeting;
- verbatim comments from the assigned reviewers;
- information related to suggested changes in budget and/or length of funding; and
- administrative notes detailing any observed problems or shortcomings re-

garding human or animal research issues, or inclusion of women, minorities and children in clinical research.

It is important to read the summary statement carefully and, perhaps, to discuss it with the program administrator. The scientific review administrator (SRA) of the study section will not provide any further information than that already contained in the summary statement, and contact with any members of the study section is *not* permitted. Even if an apparently fundable score is received, questions can arise from the Institute program staff prior to funding, based on comments therein. If funding is not achieved, the summary statement serves as the main source of information on which to base an amended application.

Appealing the Review

With success rates (number of funded applications divided by the total number of applications) generally no higher than the 30% range (not to be confused with percentile ranking!) across NIH Institutes, most applications in any given council round* are not funded. After carefully reading the summary statement, applicants may appeal the results of the review if:

- they find errors of fact in the summary statement regarding information contained in the application, or
- for some reason, other than a difference of scientific opinion, they feel the review was flawed (e.g., not having the proper expertise on the study section).

Although this avenue (appeal) is available, applicants are usually not advised to utilize it. The very best outcome that

can be achieved with an appeal is a “re-review” of the identical application, with no additional or updated information; this process can take up to two council rounds (about 8 months). In general, applicants are better served by revising and resubmitting the application by responding to the criticisms of the reviewers, as expressed in the summary statement, and by including additional preliminary data and a revised experimental plan.

Funding Decisions

Contrary to popular opinion, study sections do not make “funding” decisions. The intended role of the study section is to rank applications according to their overall scientific merit, independent of whether or not they are funded. Scientific merit, while a major indicator of potential funding, is not the sole basis for making a funding decision. In addition to scientific merit, funding decisions include such “programmatic” considerations as how well the proposed research fits with the mission of the Institute, with perceived gaps in research, and with the ongoing research already funded by that Institute.

A negative final funding decision cannot be appealed within the NIH system. The National Advisory Council for the funding Institute, which constitutes the second level of review, must approve potential funding before any application can be funded, but the Council is not usually directly involved in generating the list of the applications that are actually funded. If the percentile is beyond the funding line for the primary Institute, you should query your program contact at the secondary Institute(s) to which the application is assigned, to see if the score lies within its funding line and level of interest in the subject matter of the research. Be aware that the various Institutes have different sensitivities to considering secondary-assigned applications for funding; on average, probably well less than 5% of all funded grants were funded by Institutes with secondary assignments. Applications remain active for a year, unless a revised application is received; if not funded in the council round during which

it was submitted, the application may be considered for funding at the next two council rounds over the period of a year.

NIH Career Development Award Mechanisms: The K Series

Career development awards, or the K series of grant mechanisms, are designed primarily to provide salary support for the awardee so that he/she can have protected time to conduct research. Those at the early stages of their career development have access to mentored awards, in which the individual receiving the award is mentored in a specific area of research by a senior investigator. For mentored awards, the awardee, but not the mentor, will receive a salary from the award. The salary is usually capped, but increases in the cap occur periodically. Limited funds are provided for research in the mentored awards.

The more senior K awards do not require mentors, and usually necessitate a separate source of research funds, typically an R01 grant to support the research. A listing and brief description of the K award series is provided in the Table (on page 15). Keep in mind that all K applications are reviewed by the Institute’s review groups, so that the Institute’s mission plays a large role in the scoring of those applications.

Some K awards are designed for specific purposes, rather than for general career development. For example, the K23 and K24 are intended to promote research careers in patient-oriented research, the K25 is intended to promote careers in research in the quantitative sciences relevant to biomedical research, and the K26 for development of mouse pathobiologists. The K07 provides funds for a senior investigator to develop a specific academic program of interest to the funding Institute at the investigator’s institution, and the K30 involves a senior investigator developing a clinical research curriculum at his/her institution.

The NIH Web page (<http://grants.nih.gov/grants/guide/index.html>) contains complete information about all of these mechanisms, and the Table includes Web addresses for access to more infor-

*A “council round” is the period of time between the application receipt date and the National Advisory Council meeting during which the application is considered for funding (usually 7-8 months after the application is received). There are three council rounds per year, and they are partly overlapping in that applications received for a given council round arrive at about the time the applications from the previous council round are being reviewed in study sections.

Table.
NIH Career Development Award Descriptions

Mentored Awards

	Applicant	Goal	What the National Institute on Aging Provides
K01	Early- to midcareer with prior postdoctoral experience	New area of research	3-5 yrs of support; requires min. of 75% effort; salary up to \$75,000 plus fringe; \$20,000 in research costs
K08	Junior clinician with little to moderate research training	Clinician-scientist	3-5 yrs of support; requires min. of 75% effort; salary up to \$75,000 plus fringe; \$20,000 in research costs
K12	Junior clinician with little to moderate research training	Clinician-scientist	Institutional version of the K08
K23	Junior clinician with little to moderate research training	Clinician-scientist trained in patient-oriented research	3-5 yrs of support; requires min. of 75% effort; salary up to \$75,000 plus fringe; up to \$20,000 in research costs (\$50,000 in exceptional cases)
K25	Relatively junior scientist trained in quantitative or engineering discipline	Develop career in biomedical research	3-5 yrs of support; requires min. of 75% effort; salary up to \$75,000 plus fringe; up to \$40,000 in research costs

Regular Awards for Early- to Midcareer Applicants

	Applicant	Goal	What the National Institute on Aging Provides
K02	Early- to midcareer with previous grant funding	Become a leader in research field	5 yrs of support; requires min. of 75% effort; salary up to \$75,000 plus fringe; no research expenses
K24	Midcareer clinician-scientists	More time for patient-oriented research; mentoring junior clinicians in patient-oriented research	3-5 yrs; 25 to 50% effort; salary up to \$70,650; \$25,000 in research costs
K26	Midcareer with experience in mouse pathobiology research	More time for mouse pathobiology research and to mentor junior investigators	3-5 yrs; 25 to 50% effort; salary up to \$70,650; \$25,000 in research costs

Regular Awards for Senior Applicants

	Applicant	Goal	What the National Institute on Aging Provides
K07	Acknowledged research leader	Infrastructure building for institution	2-5 yrs; 25 to 75% effort; requires institutional sponsorship; salary up to \$50,000 plus fringe; direct costs limited to \$100,000
K30	Acknowledged clinical research leader	Develop clinical research curriculum	NIA does not sponsor this award; for other NIH Institutes: Institutional award; 5 yrs; up to \$200,000 per year

For further information:

1. NIH Web page for K awards (includes "career award wizard"): <http://grants.nih.gov/training/careerdevelopmentawards.htm>

2. Web page for NIA-supported K awards: <http://www.nia.nih.gov/funding/training/rcd.htm>

mation about the various K mechanisms. Because not all Institutes fund all of the K awards, applicants are advised to consult Institute Web pages to determine if the Institute whose mission includes their research supports the K mechanism of interest to them.

Summary and Conclusions

Continuing research is needed to fully understand biologic and physiologic processes underlying the female reproductive aging process, as manifested by menopause. Women who are still in the early stages of their reproductive lives are likely to appreciate knowing at what age to expect onset of declining fertility and menopause, perhaps based on follicle types and numbers, cyclic patterns, and levels of steroid and peptide hormones across the hypothalamic-pituitary-ovarian axis, cycle regularity and, possibly, new hormones or bioregulatory factors that have not yet been discovered. Research also can provide information and promote understanding that enables clinicians to inform women as early as possible about their specific increased risk for debilitating chronic diseases and conditions associated with the menopause, and more effective preventive and therapeutic options to decrease that risk.

The NIH, with a budget of approximately \$20 billion in fiscal year 2001, provides numerous grant mechanisms for conducting research on menopause, as part of its efforts to best use taxpayers' dollars to improve the health of the nation. A larger number of talented investigators is needed to direct their attention to research on menopause. More creative research approaches are crucial to understanding the underlying mechanisms of menopause and menopause-related health problems.

The concept of the proactive applicant is described in part 1 of this article. This concept involves committed research scientists who are already well trained and knowledgeable about the procedures and methods of high-quality research, or who wish to fully develop an active and productive research career through fellow-

ship and career-development funding mechanisms available through the NIH.

To summarize, proactive applicants will utilize assistance available in the following areas while planning their career development, and in preparing applications for research on menopause, by taking these steps:

- *Heighten their awareness of information available on the Internet.* Regularly consult the *NIH Guide for Grants and Contracts* to keep abreast of grant application updates and changes, of program announcements and RFAs across the NIH, particularly in areas pertinent to menopause-related research. Through NIH Institute/Center home pages, learn research priorities and activities related to the Institutes' missions. Consult the NIH Computer Retrieval of Information on Scientific Projects (CRISP) database to make themselves aware of currently funded grants, use CSR Web pages to keep abreast of scientific areas covered by various study sections, and be aware of the availability of and requirements for various research career-development and training funding mechanisms at various stages of their career.

- *Consult with program administrators in NIH Institutes/Centers.* Consultations with program administrators will help applicants determine the degree of interest of an NIH Institute/Center for the research they are proposing, will allow them to discuss appropriate grant mechanisms for the stage of their research or stage of their career, and will provide access to advice on potential study sections appropriate for their applications. Consulting program administrators also will provide information regarding the locus of review for various grant mechanisms—which can help determine how to “pitch” the application—and will provide assistance in interpreting summary statements and advice regarding appeals of study section reviews. Contacting program administrators at secondary-assigned Institutes/Centers to determine their priorities and interests is suggested if an applicant fails to get funding from the primary-assigned

Institute/Center and if the score of the application might be within the payline of the secondary Institutes/Centers.

- *Consult with review administrators.* Such consultations will assist in determining an appropriate study section and will provide an avenue by which to learn if and when to send additional materials prior to review.

“How to Write a Research Grant Application” is a nicely prepared document that extensively describes many of the topics described in this article, as well as additional topics of interest to the proactive applicant, such as pointers in actually writing his/her application and anticipating questions reviewers typically ask when reviewing applications. This document can be obtained through the home page of the National Institute of Allergy and Infectious Disease (NIAID) (www.niaid.nih.gov/ncn/pdf/howto.pdf).

Research on menopause must go forward to provide important new information that will allow women to better understand and anticipate their menopause experience, and to prevent or ameliorate health problems associated with the menopause, leading to more productive and satisfying lives. ■

Acknowledgments

Once again, I gratefully acknowledge the critical review of this document and the important suggestions made by my NIA colleagues Drs. Huber Warner, Jill Carrington and Sherry Sherman. I also greatly appreciate the helpful suggestions of Dr. Janet Hall of the Massachusetts General Hospital.

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