NATIONAL HUMAN GENOME RESEARCH INSTITUTE

FUNDING POLICY FOR FISCAL YEAR 2009

Background

The extramural research program of the National Human Genome Research Institute (NHGRI) is developed and guided by periodic planning processes that involve many scientists in the extramural community, and are overseen by and approved by the National Advisory Council for Human Genome Research. The results of the most recent program planning effort are described in "A Vision for the Future of Genomics Research" (http://www.genome.gov/11007524). In addition to our major program planning efforts, in projects where the NHGRI has significant investments (such as, ENCODE [Encyclopedia of DNA Elements], medical sequencing, etc,) these programs are subject to regular assessment and periodic review to ensure that they remain at the leading edge of biomedical research and technology.

Within the scope of this overall guidance, a plan for funding NHGRI's research and training and career development programs is developed for each Fiscal Year. There are several factors that affect this funding plan, including commitments from prior years, special initiatives that implement objectives described in the Vision document through Requests for Applications and other solicitations, emerging scientific opportunities, and available funds. The NHGRI strongly encourages prospective applicants and grantees to discuss their research ideas with the appropriate staff as soon as possible during the earliest stages of preparing an application to ensure that any submitted application is responsive to the NHGRI's mission.

Commitment to New Investigators

NHGRI is highly supportive of NIH's most recent initiative to encourage the support of new investigators in the early stages of their careers (http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-121.html). To facilitate the implementation of this NIH-wide policy, NHGRI is very flexible in the support of early stage investigators (ESIs) by: (1) funding applications that might have a priority score beyond the range of applications from established investigators; (2) not reducing council-recommended budgets beyond what is required by the NIH fiscal year grants policy; (3) supporting new investigators for four or five years, if requested, unless specific circumstances require otherwise; (4) supporting early stage investigators who are applying for their first competitive renewal; and (5) encouraging the use of the Pathway to Independence Awards to support postdoctoral fellows preparing for a career in academia. By contrast, most grants to established investigators awarded by NHGRI are for three years in order to give NHGRI the flexibility to fund unanticipated and new ideas in the rapidly developing field of genomics.

Beyond these policies, NHGRI staff is aware that the early career years and career transitions are fraught with uncertainties, so we make special efforts to work with trainees and young investigators. Our contact with potential new investigators begins with postdoctoral fellows and career development awardees. In the initial phases of the fellowship or career award, NHGRI staff discusses with fellows and awardees the importance of obtaining strong mentorship, learning from peer relationships and generating quality publications. During the last year of the award, staff counsels fellows and awardees about the various options for furthering their research careers, whether through a career development award or an investigator-initiated grant. In addition, staff is always available to answer their questions about program priorities, how to prepare a meritorious grant application, how the peer review process works, and how to work within the NIH system.

Research Project and Center Grants

At the present time, NIH is operating under a Continuing Resolution (CR) until May 2009. The following policy is in effect currently, but may be changed depending on the Institute's fiscal budget for 2009.

Non-Competing Applications:
- No reductions will be applied to R03, R13, R15 and R21 applications.
- Applications with direct costs of $350,000 or less that were previously reduced in FY 07 and FY08 will not be reduced.
- Applications with direct costs of $350,000 or less that were previously reduced in FY08 only, and applications with budgets greater than $350,000 direct costs will receive a reduction of up to ten percent per NIH NOT-OD-09-002, Non-Competing Grant Awards under the Current Continuing Resolution [http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-002.html] . Any further adjustments will be based on the final NIH appropriation and the FY09 NIH Fiscal Policy for Grant Awards.
- The budgets of center and resource applications may be adjusted beyond the NIH approved FY09 reduction to allow new activities in areas of higher program priority.

Competing Applications:

- The Institute will pay special attention to applications from early stage investigators by giving priority to the potential of the principal investigator, by providing support for four or five years, by ensuring that the budget is sufficient to support the proposed research, and by .
- The institute is aware that principal investigators who submit their first renewal applications may be at-risk for funding, so special consideration is given to such applications during the development of funding plans.

- Institute-negotiated cost reductions for new and competing RPG and Center awards, beyond those recommended by peer review, will be handled on a case-by-case basis.
- Competing continuation applications that request significant increases over the previous year's budget will be evaluated for the appropriateness of the increases.
- The budgets of new competing applications will be evaluated to assess the appropriateness of the budget to the timeliness of the research goals.
- In general, most projects will be funded for three years; exceptions will be made based on factors such as career stage of the principal investigator, program priorities, needs of the specific research project, how fast the field is changing, the level of risks, etc.
- Applications that focus on (1) technology development and methods development and (2) ELSI topics relevant to the Institute's objectives will be strongly favored.
- Innovation, priority score, timeliness of the project, program priorities, and whether the applicant is an early stage investigator or a first-time competing renewal principal investigator will be major considerations in funding applications that are taken out of priority score order.

Small Business Innovation Research (SBIR) and Small Business Technology Transfer (STTR) Programs

Non-competing Applications:
SBIR and STTR applications will generally be awarded at the 2008 commitment levels, but may be adjusted by staff based on program priorities.

Competing Applications:
- Applications that focus on (1) technology development and methods development in the area of genomics and proteomics and (2) ELSI topics relevant to the Institute's objectives will be strongly favored.
- The priority score, timeliness of the project, and program priorities will be major considerations in funding applications that are taken out of priority order.
- Institute-negotiated cost reductions for new and competing awards, beyond those recommended by peer review, will be handled on a case-by-case basis.

Research Career and Research Training Awards

Non-competing Applications:
- Ruth L. Kirschstein National Research Service Awards (NRSA) applications (fellowship (F) and training (T), will be awarded at the full 2009 commitment levels. NRSA funds for stipends, tuition and training-related expenses will be held at FY 2008 levels until further notice.

- Career Development (K) will be awarded at the full 2009 commitment levels.
- Supplements for diversity and re-entry candidates will be awarded at the full 2009 commitment levels.

Competing Applications:
<u>Research Career Development Awards</u>
- Funding priority will be given to individuals in: (1) non-biological sciences such as chemistry, computer science, engineering, math, physics and other quantitative sciences who wish to pursue multi-disciplinary approaches to problems in genomics research or and (2) physicians who wish to pursue genomics or proteomics research.
- Innovation, priority score, timeliness of the project, mentor and research resources, and the program priorities will be major considerations in funding applications that are taken out of priority order.

<u>Research Training</u>
- Priority will be given to institutional training grants that propose to develop scientists who can work as intellectual contributors to interdisciplinary teams developing technologies for genomics and proteomics.
- Priority for funding of individual fellowships will be given to individuals wishing to pursue (1) the development of genomics and proteomics technologies and (2) Institute-relevant ELSI topics in interdisciplinary research environments.
- The priority score, timeliness of the project, and the program priorities will be major considerations in funding applications that are taken out of priority order.
- Institute-negotiated cost reductions for new and competing awards, beyond those recommended by peer review, will be handled on a case-by-case basis.

Adherence to NIH Policy:

Applications Requesting $500,000 or More in Direct Cost for Any One Year

- NIH requires pre-approval for single applications or for multi-site collaborative studies requesting $500,000 or more in annual direct costs in any year. Applicants are encouraged to interact with NHGRI staff during the concept development of applications that request $500,000 or more in direct cost. Applicants planning large grants should request approval from NIH staff at least six weeks in advance of the planned receipt date. The NIH "Revised Policy On The Acceptance For Review of Unsolicited Applications That Request $500,000 Or More In Direct Costs" (NOT-OD-02-004) may be found at: http://grants.nih.gov/grants/guide/notice-files/not-od-02-004.html.

- The NIH expects and supports the timely release and sharing of final research data from NIH-supported studies for use by other researchers. all investigator-initiated applications with direct costs greater than $500,000 in any single year will be expected to address data sharing in their application. Applicants are encouraged to discuss their data sharing plan with their program contact at the time they negotiate an agreement with the Institute/Center (IC) staff to accept assignment of their application as described above.

Data Obtained in NIH-Supported or Conducted Genome-Wide Association Studies.

The NIH believes that the full value of GWAS to the public can be realized only if the resulting genotype and phenotype datasets are made available as rapidly as possible to a wide range of scientific investigators. Rapid and broad data access is particularly important for GWAS—these studies generally require significant resources; present challenges in analyzing the large datasets; and provide extraordinary opportunities for making comparisons across multiple studies. Additional information about this policy can be found at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-08-013.html .