NATIONAL HUMAN GENOME RESEARCH INSTITUTE

FUNDING POLICY FOR FISCAL YEAR 2011

INTRODUCTION

The National Human Genome Research Institute (NHGRI) supports the development of resources and technology that will accelerate genome research and its application to human health. A critical part of the NHGRI mission continues to be the study of the ethical, legal and social implications (ELSI) of genome research. NHGRI also supports the training of investigators and the dissemination of genome information to the public and to health professionals. In 2011, NHGRI launched a new strategic plan — <u>Charting a course for genomic</u> <u>medicine from base pairs to bedside</u> (http://www.genome.gov/27543215)-articulating a new vision for the future of genomics research and describing the path towards an era of genomic medicine. Additional information about NHGRI can be found at: <u>http://www.genome.gov</u>.

FUNDING

Strategy

The extramural research program of the National Human Genome Research Institute (NHGRI) is developed and guided by periodic planning processes, as described above, and involves many scientists in the extramural community, and is overseen and approved by the National Advisory Council for Human Genome Research. In addition to our major program planning efforts, projects in which NHGRI has significant investments, such as, the Encyclopedia of DNA Elements (ENCODE), medical sequencing, etc, 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 each Fiscal Year. Some factors that affect this funding plan include commitments from prior years, special initiatives that implement objectives described in the 2011 strategic plan 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.

Guidelines

Research Project and Center Grants

The Department of Defense and Full-Year Continuing Appropriations Act of 2011 (P.L. 112-10) provides NIH with 1 percent less than the total FY 2010 NIH budget (See <u>http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-068.html</u>). Consistent with NIH-wide policies, NHGRI's FY 2011 non-competing research portfolio will be evaluated to remove escalation from FY 2011 committed levels, and will then be reduced by 1 percent; future fiscal year commitments will also receive a 1 percent reduction, unless otherwise noted below.

Non-Competing Grants:

- No reductions will be applied to R03, R13, R15, R21, R00 and those applications under \$250,000 total costs.
- Modular research grants other than the mechanisms listed above will receive a 1% reduction from the FY11 level.
- Center and resource grants will generally be awarded at the FY11 level, with out-years reduced by 1 percent.
- Select programs may potentially receive further reductions to support activities in areas of higher program priority.

Competing Applications:

- 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.
- Institute-negotiated cost reductions for new and competing RPG and Center applications, 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.
- A maximum of 2% escalation will be considered for recurring costs.
- Innovation, impact/priority score, timeliness of the project, program priorities, and whether the applicant is an early stage investigator or a firsttime competing renewal principal investigator will be major considerations in funding applications that are taken out of priority score order.

- 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.
- 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.
- The Institute has always encouraged and supported innovative research. We intend to increase these efforts by supporting applications that receive highly meritorious scores for innovation, but may have overall impact/priority scores that are lower that what is currently being funded.

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 2011 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 impact/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-bycase basis.
- A maximum of 2% escalation will be considered for recurring costs.

Research Career and Research Training Awards

Information about NIH's policy on Ruth L. Kirschstein National Research Service Award (NRSA) Stipends, Tuition/Fees and Other Budgetary Levels Effective for Fiscal Year 2011 can be found at: http://grants.nih.gov/grants/guide/notice-files/NOT-OD-11-067.html

Non-competing Applications:

• Ruth L. Kirschstein National Research Service Awards (NRSA) applications (fellowship (F) and training (T), will be awarded with a two

(2) percent increase of all stipend levels per the NIH Guide Notice NOT-OD-11-067 noted above.

- Career Development (K) will be awarded at the full 2011 commitment levels.
- Supplements for diversity and re-entry candidates will be awarded at the full 2011 commitment levels.

Competing Applications:

Research Career Development Awards

- 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, impact/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.

Research Training (Ts and Fs)

- 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 impact/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-bycase basis.

Conferences and Courses

The National Human Genome Research Institute is committed to disseminating the latest information and technologies through courses and conference grants. However, our investment in this type of research will be limited (in research areas and dollars) and will be targeted to areas that seek to increase the capabilities of US scientists, especially those who are seeking to significantly enhance their skills in genomics and proteomics and scholarly studies of the ethical, legal and social implications of research (ELSI).

COMMITMENT TO NEW INVESTIGATORS

NHGRI is highly supportive of NIH's efforts to encourage the support of new investigators in the early stages of their careers

(http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-013.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 postdoctoral fellows to accelerate their independence in academia through the use of the Pathway to Independence Awards. 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.

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 .