

NATIONAL HUMAN GENOME RESEARCH INSTITUTE

FUNDING POLICY FOR FISCAL YEAR 2016

INTRODUCTION

The 2011 National Human Genome Research Institute (NHGRI) strategic plan- [*Charting a course for genomic medicine from base pairs to bedside*](#) (*Nature* **470**: 204 – 213; <http://www.genome.gov/27543215>) – articulates a vision for genomics research and describes the path to an era of genomic medicine. To implement this vision, NHGRI will support the development of: resources; methods and technologies that will accelerate research in understanding the structure of genomes; understanding the biology of genomes; understanding the biology of disease; advancing the science of medicine; and improving the effectiveness of healthcare. NHGRI will also support research in several cross-cutting areas, including the societal implications of genomics research and clinical implementation of genomics, bioinformatics, technology development, and research training and career development.

EXTRAMURAL FUNDING STRATEGY

The NHGRI Extramural Research Program is developed and guided by periodic planning processes, as reflected in the strategic plan referred to above, as well as earlier, similar documents. NHGRI's development of a strategic plan involves participation by many scientists in the extramural research community, as well as other scholars and members of the public, and is overseen and approved by the National Advisory Council for Human Genome Research (NACHGR). With guidance from the NACHGR, the program staff develops research initiatives to carry out the Institute's mission. Many of the NHGRI programs [such as the Genomics of Gene Regulation (GGR), Large-scale Sequencing, Electronic Medical Records and Genomics (eMERGE), Clinical Sequencing Exploratory Research (CSER), Centers of Excellence in ELSI Research (CEER), training and career development programs and several others] are regularly assessed and periodically reviewed by the NACHGR and its working groups to ensure that they remain at the leading edge of biomedical research and technology and so that the Institute has a means for expanding into new areas of opportunity as they arise.

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 or as a result of the strategic plan through Requests for Applications and other solicitations, emerging scientific opportunities and available funds.

Because NHGRI's research mission is dynamic, the Institute staff strongly encourages prospective applicants and grantees to discuss their proposed research ideas with the

appropriate staff during the concept development and preparation of an application, to ensure that any submitted application is responsive to NHGRI's research, training and career development mission.

FUNDING GUIDELINES

Research Project and Center Grants

NHGRI will make efforts to keep the average size of awards mostly constant at Fiscal Year (FY) 2015 levels and the number of competing awards will likely be increased modestly compared to the number of competing awards in FY 2015. Consistent with NIH-wide policies, no inflationary increases will be allowed for future years. Other select budgetary considerations are noted below.

Non-Competing Grants:

- Generally, non-competing awards will be funded at the previously committed FY 2016 level. However, in very select cases, NHGRI reserves the right to reduce FY 2016 commitments to meet programmatic objectives.
- No reductions will be applied to "small grants" with FY 2016 commitments of \$250,000 total costs or less (typically R03 and R21 grants).
- Other select programs may be exempt from these reductions, or receive further reductions, based on program priority.
- Non-competing grants administered by NHGRI for Common Fund and other NIH initiatives may have specific FY 2016 reductions determined for those programs.

Competing Applications:

- Applications that address issues relevant to the strategic plan will be given the highest priority for funding considerations. The strategic plan identifies the following criteria for high priority: technology development; methods development; comprehensiveness; ability to scale; and approaches generalizable across diseases and biological systems of higher order organisms.
- The budgets of new competing applications will be evaluated rigorously to assess the appropriateness of the budget to the timeliness of the research goals and the available budget.
- In general, most research 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, and the level of risk.
- 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.

- Inflationary increases for competing continuation applications must be well justified and will be granted on a case-by-case basis. Requests for future year budget increases due to programmatic needs (e.g., equipment, additional personnel, etc.) will be considered only if well justified.
- Innovation, impact 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.
- NHGRI will encourage early stage investigators to become established investigators by generally providing them support for four or five years and by ensuring that budgets are sufficient to support the proposed research.
- NHGRI is aware that principal investigators who submit their first renewal applications may be at-risk for a gap in funding, so special consideration will be given to such applications during the development of funding plans.
- NHGRI has always encouraged and supported innovative research, and will continue these efforts. Special attention will be given to applications that are innovative, but whose overall impact scores would otherwise preclude them as candidates for funding.

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

Non-competing Applications:

SBIR and STTR grants will generally be issued at the FY 2016 committed level.

Competing Applications:

- Funding levels will be awarded in accordance with the NIH implementation of the SBIR/STTR Reauthorization Act of 2011 (P.L. 112-81).
- Applications that address issues relevant to the strategic plan will be given the highest priority for funding consideration. The strategic plan identifies the following criteria for high priority: technology development; methods development; comprehensiveness; and ability to scale.
- The impact score, timeliness of the project, and program priorities will be major considerations in funding applications that may be 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

Consistent with the 2016 Consolidated Appropriations Act and with the recommendations of the Advisory Committee to the Director regarding the Biomedical Research Workforce, the NIH will increase NRSA stipends by approximately 2 percent on average. The full range of stipend adjustments for FY 2016 is described at NOT-OD-16-047.

Non-competing Fellowships and Grants:

- Ruth L. Kirschstein National Research Service Awards (NRSA) for fellowships (Fs), training (Ts), and Career Development (Ks) will generally be issued at the FY 2016 committed level with adjustments per NOT-OD-16-062, as appropriate.

Competing Applications:

Research Career Development Awards

- For genomic sciences and genomic medicine applications, funding priority will be given to individuals who seek cross-training in genomic sciences or genomic medicine with emphasis in the quantitative sciences, technology development and computational biology.
- For genomics and society applications, funding priority will be given to individuals that propose to develop a strong foundation in: 1) current developments in genomic science and medicine; 2) core principles and conceptual frameworks in bioethics; 3) qualitative and quantitative behavioral and social science research methodologies; 4) conceptual and analytic research approaches; and 5) the design and implementation of inter- or trans-disciplinary research projects.
- Innovation, impact score, timeliness of the project, mentor(s) supported by NHGRI, availability of genomic resources, and responsiveness to the program priorities will be major considerations in funding applications.

Research Training (Ts and Fs)

- Priority will be given to institutional training grants that emphasize the quantitative sciences, technology development and computational biology and propose to develop scientists who can work independently and as intellectual contributors to interdisciplinary teams.
- Priority will be given to individual fellowships that: (a) focus on genomic sciences or genomic medicine approaches with an emphasis on the quantitative sciences, bioinformatics or technology development or (b) focus on high priority ELSI issues and provide multidisciplinary conceptual and methodological training, and (c) have mentor(s) who are funded by NHGRI.
- The impact score, timeliness of the project, and the program priorities will be major considerations in funding applications that may be taken out of priority order.
- Institute-negotiated cost reductions for new and competing institutional training grant awards, beyond those recommended by peer review and NACHGR, will be handled on a case-by-case 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 research areas relevant to addressing the research issues described in the strategic plan. NHGRI supports a limited number of conferences and courses. Genomic and genetic science is now integrated into many areas of biomedical research. To maintain research focus and accommodate budget constraints, NHGRI must be highly selective when providing funds for conferences/courses. Highest priority in the strategic plan areas structure and biology of genomes, the biology of disease, and bioinformatics and computational biology will be on topics that advance the state of the art of genomics. For clinically-oriented conferences and courses, those with a prominent focus on the application of genomics to improving clinical care will receive the highest priority for consideration. Conferences in the area of ethical, legal and social implications of genomic research will also be supported.

COMMITMENT TO EARLY STAGE AND NEW INVESTIGATORS

NHGRI is highly supportive of NIH's efforts to encourage the support of new investigators in the early stages of their careers. These policies are described at <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-09-013.html> and at http://grants.nih.gov/grants/new_investigators/. 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 an impact 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 and approved by the initial review group, 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 evolving 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 pre-doctoral and 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 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.

COMMITMENT TO INVESTIGATORS FROM UNDERREPRESENTED GROUPS

NHGRI is highly supportive of investigators from underrepresented groups who apply for support in areas addressed by NHGRI's strategic plan. This support encompasses applications for Ph.D. and M.D./Ph.D. support and applications in response to all of NHGRI's funding opportunity announcements (FOAs) and NIH parent FOAs in which NHGRI participates. Underrepresented Minorities (URMs) are also supported at various career levels under NHGRI's Diversity Action Plan that is associated with large grants and as diversity supplements.

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 costs. 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. 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.

Genomic Data Sharing (GDS) Policy

NIH recently announced the final Genomic Data Sharing (GDS) Policy (<http://grants.nih.gov/grants/guide/notice-files/NOT-OD-14-124.html>), which sets forth expectations that ensure the broad and responsible sharing of genomic research data. NHGRI recently published how it plans to implement this policy (<http://www.genome.gov/27562511>). Sharing research data supports the NIH mission and is essential to facilitate the translation of research results into

knowledge, products, and procedures that improve human health. The GDS Policy applies to all NIH-funded research that generates large-scale human or non-human genomic data as well as the use of these data for subsequent research. Large-scale data include genome-wide association studies (GWAS), single nucleotide polymorphisms (SNP) arrays, and genome sequence, transcriptomic, metagenomic, epigenomic, and gene expression data, irrespective of funding level and funding mechanism (e.g., grant, contract, cooperative agreement, or intramural support). This Policy applies to competing grant applications that are submitted to NIH for the January 25, 2015, due date or subsequent due dates.

Salary Limitations on Grants, Cooperative Agreements, and Contracts

NHGRI adheres to the salary limitations for NIH grants, cooperative agreements and contracts. The Executive Level II salary has increased to \$185,100 effective January 10, 2016. For more detailed information, please see [NOT-OD-16-045](#).