NATIONAL HUMAN GENOME RESEARCH INSTITUTE FUNDING POLICY FOR FISCAL YEAR 2019

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 through the implementation of genomics; and improving the effectiveness of healthcare. NHGRI will also support research in several cross-cutting areas, including the ethical, legal and societal implications of genomics (ELSI) research, clinical implementation of genomics, bioinformatics, technology development, and research training and career development.

The NHGRI is currently in the process of developing a new strategic plan which will be published in Fall 2020. Inputs from various communities--individuals from different and complementary related research disciplines and career--are being sought. (https://www.genome.gov/genomics2020/)

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 Analysis, Visualization and Informatics Lab-space (AnVIL), Implementing Genomics in Practice (IGNITE), Genome Sequencing Program (GSP), 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 genomics 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 before preparing 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) 2018 levels and the number of competing awards will likely be increased modestly compared to the number of competing awards in FY 2018. Consistent with NIH-wide policies, no inflationary increases will be allowed for future years. Other select budgetary considerations are noted below.

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 in genomic sciences and genomic medicine:
 technology development; methods development; comprehensiveness; ability to
 scale; approaches generalizable across diseases and biological systems of
 higher order organisms, and approaches that inform the development and
 implementation of genomics in clinical care.
- 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 or four years.
 Exceptions for longer or shorter periods of time 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.
- 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.

- Institute-negotiated cost reductions for new and competing Research Project Grants (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.
- In general, increases in project costs must be minimal and 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 Impact Score order.

Non-Competing Applications:

Non-competing continuation awards made in FY 2019 will generally be issued at the commitment level indicated on the Notice of Award issued in FY2018 as described in NOT-OD-19-031: Notice of Fiscal Policies in Effect for FY 2019.

Generally, non-competing awards will be funded at the previously committed FY 2019 level. However, in very select cases, NHGRI reserves the right to reduce FY 2019 commitments to meet programmatic objectives.

- No reductions will be applied to "small grants" with FY 2019 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.

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

Competing Applications:

- 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 Impact Score order.
- Funding levels will be awarded in accordance with the NIH implementation of the SBIR/STTR Reauthorization Act of 2016.
- Institute-negotiated cost reductions for new and competing awards, beyond those recommended by peer review, will be handled on a case-by-case basis.

Non-competing Applications:

Non-competing SBIR/STTR applications will be funded at the previously committed FY19 levels.

Research Training and Research Career Development Awards

Ruth L. Kirschstein National Research Service Awards (NRSA)

- Priority will be given to institutional training grants that emphasize the quantitative sciences, technology development, genomic medicine development and implementation, high priority ELSI issues, 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.

The full range of stipend adjustments for FY 2019 is described at NOT-OD-19-036.

Research Career Development Awards

- Funding priority for genomic sciences and genomic medicine applications, 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.
- Funding priority for genomics and society applications 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.

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. Genomic and genetic science and medicine are now integrated into many areas of biomedical research. To maintain research focus and accommodate budget constraints, NHGRI gives priority to courses and conferences that significantly advance the fields of genome sciences, genomic medicine, and genomics and society

COMMITMENT TO EARLY STAGE AND NEW INVESTIGATORS

As described in the <u>NIH's Next Generation Researchers Initiative (NGRI)</u> efforts (https://grants.nih.gov/ngri.htm), NHGRI is committed to providing substantial and sustained support for early stage investigators (ESIs).

NHGRI is highly supportive of NIH's efforts to encourage the support of new investigators in the early stages of their careers, specifically to support new investigators on R01 equivalent awards at success rates comparable to that of established investigators submitting new (Type 1) R01 equivalent applications. To facilitate the implementation of this NIH-wide policy, NHGRI is very flexible in the support of early stage investigators 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 and the NACHGR, 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.

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 institutions having significant investments in NIH funded genomics research that advances the goals of the NHGRI strategic plan.

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 investigatorinitiated applications 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 version of the 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). NHGRI encourages sharing of all data types. However, at this time the NIH GDS Policy and NHGRI implementation plans apply particularly to single nucleotide polymorphism (SNP) array data, genome sequence data, transcriptomic data, epigenomic data, or other molecular data produced by array-based technologies or high-throughput sequencing technologies.

Data pertinent to the interpretation of genomic data-such as associated phenotype data (e.g., clinical information relevant to the disease under study), exposure data, and

descriptive information (*e.g.*, protocols or methodologies used) are expected to be shared. All data sets should include the appropriate metadata to allow efficient sharing and integration with other data sets, irrespective of funding level and funding mechanism (e.g., grant, contract, cooperative agreement, or intramural support).

Salary Limitations on Grants, Cooperative Agreements, and Contracts

NHGRI adheres to the salary limitations for NIH grants, cooperative agreements and contracts. Section 202 of the Consolidated Appropriations Act, 2019 prohibits payments for salaries under grants and other extramural mechanisms in excess of <u>Executive Level II</u> currently set at \$189,600. See NOT-OD-19-030 for additional information.