National Advisory Council for Human Genome Research
Feb 10-11, 2020
Concept Clearance for RFA

Advancing Genomic Medicine Research (R01, R21)

Purpose:
These FOAs solicit proposals that stimulate innovation and advance understanding of when, where and how best to implement the use of genomic information and technologies in clinical care in all persons irrespective of ancestral origins or sociodemographic status. They will encourage targeted scientific research studies focused on genomic medicine, defined as using genomic information about an individual as part of their clinical care (e.g., for diagnostic or therapeutic decision-making) and the health outcomes and policy implications of that clinical use. Projects will be broadly applicable to genomic medicine as a field; projects proposing to study a specific disease or disease area will need to yield generalizable findings. To promote progress in the genomic medicine field, awardees will be expected to budget for and participate in an annual meeting to share research progress with other awardees and NHGRI staff. A pre-application webinar will be held to promote interest and answer applicant questions.

Background:
NHGRI is currently developing its 2020 strategic plan, which continues to emphasize studies of the implementation of genomics in clinical practice, and in ways that include diverse populations and diverse settings. NHGRI has primarily funded genomic medicine research through multi-disciplinary consortia, which provide rich opportunities for collaboration or ancillary projects and have produced valuable data resources and tools for independent genomic medicine research (For more information about these programs, see https://www.genome.gov/about-nhgri/Division-of-Genomic-Medicine#two). As the field grows, opportunities for focused research projects outside large-scale coordinated consortium approaches are growing as well. These include projects carried out in clinical settings which propose nimble, flexible approaches to problems in application or implementation of genomic medicine.

This funding opportunity builds upon the Investigator-Initiated Genomic Medicine Research R01 and R21 PARs and has a higher cost limit.

Proposed Scope and Objectives:
This concept centers on addressing research gaps related to the use of genomic information to advance the application of genomics to medical science and clinical care.

Investigators new to the field of genomic medicine will be encouraged to apply. Genomic medicine research is a multidisciplinary field, and research teams may include experts from multiple disciplines, including but not limited to the fields of clinical genetics, genetic epidemiology, biostatistics, data science, public health informatics, implementation science, health outcomes research, health economics, health equity and disparities, health policy, molecular genetics, genetic counseling, and nursing. Studies encompassing diversity are encouraged, such as those that include participants from racial or ethnic minority populations, underserved populations, or populations who experience poorer medical outcomes, as well as studies that take place outside major academic research settings or can demonstrate the ability for findings to be transferrable to other settings.

In the context of their relevance to genomic medicine, the following are some examples of the types of research studies that would be appropriate for these FOAs, grouped by category:

Implementing genomic medicine

Implementation research projects would elucidate whether use of genomic information about an individual improves clinical care and/or health outcomes, or how genomic medicine should be implemented.

1. Understanding clinical barriers and bottlenecks in implementation of genomic medicine and pharmacogenomics across broad settings, especially diffusion and sustainability in diverse clinical settings.
2. Identifying and assessing implementation science frameworks that can be used to study genomic medicine in academic clinical settings, community clinical settings, or both.
3. Development of computational, health-economic, or other analytical approaches that identify characteristics of participants likely to derive the greatest (or conversely, the least) value from incorporating various types of genomic data into clinical care. Applicants considering health-economic approaches should review NOT-OD-16-025, Clarifying NIH priorities for Health Economics Research, https://grants.nih.gov/grants/guide/notice-files/NOT-OD-16-025.html.
4. Comparison of health care utilization or disease outcomes after implementation of clinical decision support tools for genomics.

Facilitating analysis of clinical genomic data

The pace and volume of genomic data being generated presents challenges and opportunities for methods and tools that facilitate clinical analysis.

5. Development and evaluation of methods to calculate and communicate complex disease risk.
6. Evaluation of methods that automate or otherwise improve the efficiency of clinical annotation and interpretation of genomic variants, including reanalysis.
7. Integration of genomic data from various sources, with other data types such as environmental data, family history, transcriptomics, epigenomics, functional data, or model organism data and assess genomic data's contribution to and improvements of predictive value, clinical validity or clinical utility. Proposals primarily focused on development of novel approaches to study how genetic variants lead to differences in function and how such functional differences affect health and disease processes should respond to PA-18-868 or PA-18-867.

Improving clinical access to genomic data

8. Assessment of genomic data integration throughout health systems and their influence on healthcare providers, payers, and regulators.
9. Portable genomic data that uses standards for genomic information and allows for iterative use (e.g., integration with EHR apps).

Relationship to Ongoing Activities:
This concept is intended to nurture and expand genomic medicine research by enhancing interactions among grantees and promoting sharing of successful approaches and resulting data. Related applications might also be received through the NIH Parent R01 and R21 announcements, as well as the Dissemination and Implementation PARs (PAR-19-274 and par-19-275), the Ethical, Legal, and Social Implications (ELSI) of Genomics Research PARs (PA-17-444 and PA-17-446), the Novel Approaches for Relating Genetic Variation to Function and Disease PARs (PA-18-868 and PA-18-867), Novel Genomic Technology Development PARs (PAR-18-777 and PAR-18-778), and Investigator-Initiated Research in Computational Genomics and Data Science PARs (PA-18-844 and PAR-18-843). Although these FOAs might receive some applications with relevance to genomic medicine research, none specifically call for genomic medicine research projects.

Mechanism of Support and Funds Anticipated:
R01 (Research Project) up to $600K DC/year, project period of up to 5 years. Total 4 R01s.

R21 (Exploratory/Developmental Research) up to $200K DC/year, project period up to 2 years. Total 4 R21s.

Total cost of program $4.96M/year ramping to $19.84M/yr. Total first five years = $62M.

Alternating receipt dates averaging 2 per year; May 2020, January 2021, September 2021, May 2022, January 2023.

ICs with interest in funding genomic medicine research would be contacted for the possibility of signing-on.