

**National Advisory Council for Human Genome Research**  
**September 9-10, 2024**  
**Concept Clearance for RFAs and PARs**

**Advancing Genomic Medicine Research (R01, R21, R03, R41/R42, R43/R44)**

**Purpose:**

This renewal will allow NHGRI to request applications that stimulate innovation and advance understanding of when, where and how best to implement the use and sharing of genomic information and technologies in patient care and in ways that are generalizable and equitable across different populations and settings. The funding announcements will encourage scientific research studies focused on genomic medicine, defined as using genomic information about an individual as part of their medical care (e.g., for screening, diagnostic, or therapeutic decision-making) and examining the health outcomes and policy implications of its use. Projects will be broadly applicable to genomic medicine as a field; applications focusing on a particular disease or organ system should provide clear demonstration that their research is generalizable to multiple diseases and organ systems. To promote progress in the field and encourage broad adoption of successful approaches, awardees will be expected to budget for, participate in, and potentially co-host an annual meeting with other awardees and NHGRI staff.

**Background:**

The past decade has seen a growth in the implementation of genomics in clinical practice. 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. As the field grows, opportunities for focused research projects are growing.

The prior R01, R21, and R03 funding opportunities ([HG-23-032](#), [HG-23-033](#), and [HG-23-048](#)) will be renewed with no significant changes. Small Business applications will be solicited through [Program Announcements with Review \(PAR\)](#) funding opportunities rather than a NOSI. All applications will be reviewed in one Special Emphasis Panel (SEP) at NHGRI. Funding decisions will continue to emphasize programmatic balance across [previously funded awards](#) and emerging scientific priorities. Since its inception, 135 applications have been received and funded awards have spanned all [science emphasis areas](#) in genomic medicine.

**Proposed Scope and Objectives:**

This concept centers on addressing research gaps to advance the application of genomics in patient care that is generalizable and transferable across populations, settings, and disease areas.

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 genetic counseling, nursing, genetic epidemiology, biostatistics, biomedical informatics, data science, electronic health records, public health, implementation science, health outcomes research, health economics, health equity and disparities, health policy, and molecular genetics. Studies addressing or incorporating [health disparities](#), defined as health differences that adversely affect disadvantaged populations, are encouraged. For NIH, populations that experience health disparities are considered to include racial and ethnic minority groups, people with lower socioeconomic status, underserved rural communities, sexual and gender minority groups, and people with disabilities. Studies that take place outside academic research settings or

can demonstrate the ability for findings to be transferrable to other settings are also encouraged. Where applicable, investigators are strongly encouraged to consider various models for community engagement in research and to include a [Plan for Enhancing Diverse Perspectives \(PEDP\)](#). Products resulting from successfully funded projects should take into consideration the ethical legal and social implications of integrating said products into genomic medicine.

In the context of their relevance to genomic medicine, the following are some examples of the areas of research studies that would be appropriate for these NOFOs, 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.
- *Genetic counseling*  
Assessing, innovating, scaling, and/or researching the implementation of novel genetic counseling practices to address the need for more healthcare professionals trained in genetic counseling.
- *Facilitating analysis of clinical genomic data*  
Studies addressing the pace and volume of genomic data being generated and how to facilitate analysis in the context of real-time clinical care.
- *Improving clinical access and sharing of genomic data*  
Clinical access and sharing of genomic data and relevant phenotype data is critical to promoting genomic medicine.

#### **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-22-105](#), [PAR-22-106](#) and [PAR-22-109](#)), the Ethical, Legal, and Social Implications (ELSI) of Genomics Research PARs ([PA-23-293](#), [PAR-23-294](#) and [PAR-23-295](#)), Investigator-Initiated Research in Computational Genomics and Data Science PARs ([PAR-21-254](#) and [PAR-21-255](#)), and [the Small Business NOFOs](#). Although these NOFOs might receive some applications with relevance to genomic medicine research, none specifically calls for genomic medicine research projects. Genomic medicine projects specifically focusing on the development and implementation of clinical informatics tools to enhance patients' use of genomic information should refer to [NOT-HG-22-011](#) for additional guidance.

#### **Mechanism of Support and Funds Anticipated:**

Small Business Funds:

- R41/R42 (STTR) and R43/R44 (SBIR) NOFOs are PARS, which have no set-aside.

Non-Small Business Research Funds:

- R01 (Research Project) up to \$500K DC/yr, project period up to 5yrs. Total 4 R01s.
- R21 (Exploratory/Developmental Research) up to \$250K DC/yr, project period up to 3yrs. Total 2 R21s.
- R03 (Small Grant Program) up to \$50K DC/yr, project period up to 2yrs. Total 1 R03.
- Total cost of research program: \$4.1M/year ramping to \$12.2/yr. Total first five years = \$46.4M.

One receipt date per year; February 2026, February 2027, February 2028.

ICs with interest in funding genomic medicine research will be encouraged to sign on.