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Informational Session on the Renewed ELSI Funding Opportunities

Dave Kaufman, Nicole Lockhart, Rene Sterling, and Zo Bly

Division of Genomics and Society

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National Human Genome
Research Institute

The **Forefront**
of **Genomics**[®]

NHGRI Contacts for ELSI NOFOs



Dave Kaufman
Program Director



Nicole Lockhart
Program Director



Rene Sterling
Program Director



Deanna Ingersoll
Chief,
Grants Management

What is the ELSI Research Program?

- NHGRI's Ethical, Legal, and Social Implications (ELSI) Research Program was created in 1990
- Supports research into the ethical, legal and social implications of genomics
- Examines new, unexpected ways genomics and society interact

ELSI Research

Key Features

Anticipatory

Identify and address issues on the horizon

Multidisciplinary

Carried out by researchers in genetics, bioethics, law, public policy, philosophy, humanities, social and political sciences, medicine, behavioral science, public health *to name a few*

Various Methods and Study Designs

To help 'cover all the angles'

Renewed ELSI Notice of Funding Opportunities (NOFOs)

- 3 funding opportunities:
 - PAR-23-293 , R01 Research Project
 - PAR-23-294 , R21 Exploratory/Developmental Grants
 - PAR-23-295 , R03 Small Research Grants
- Each funding opportunity has 3 receipt dates per year in February, June and October
- First due dates: Mid-February 2024
- Expire in November 2026

Purpose

- Invites research applications to study the ethical, legal and social implications (ELSI) of human genetics and genomics
- Research studies that identify, examine, and address the ELSI of genomics for individuals, families, communities, groups, institutions, and society
- Wide range of topics expected

Participating Institutes & Offices

	R01	R21	R03
Fogarty International Center		Y	Y
National Cancer Institute	Y	Y	Y
National Eye Institute	Y	Y	
National Institute of Allergy and Infectious Disease*	Y	Y	Y
National Institute of Child Health and Human Development*	Y	Y	Y
National Institute on Drug Abuse*	Y	Y	Y
National Institute on Deafness and Other Communication Disorders*	Y	Y	Y
National Institute of Dental and Craniofacial Research*		Y	Y
National Institute of Environmental Health Sciences	Y	Y	Y
National Institute of Mental Health	Y	Y	Y
National Institute on Minority Health and Health Disparities	Y		
National Institute of Neurological Disorders and Stroke	Y	Y	
Office of Behavioral and Social Sciences Research	Y	Y	Y
Office of Data Science Strategy*			Y
Office of Research on Women's Health*	Y	Y	Y

Participating Institutes & Offices

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At the top of announcement webpages – list of participants:

Department of Health and Human Services

Part 1. Overview Information

Participating Organization(s) National Institutes of Health (NIH)

Components of Participating Organizations

- National Human Genome Research Institute (NHGRI)
- National Eye Institute (NEI)
- National Institute of Allergy and Infectious Diseases (NIAID)
- Eunice Kennedy Shriver National Institute of Child Health and Human Development (NICHD)
- National Institute on Deafness and Other Communication Disorders (NIDCD)
- National Institute on Drug Abuse (NIDA)
- National Institute of Environmental Health Sciences (NIEHS)
- National Institute of Mental Health (NIMH)
- National Institute of Neurological Disorders and Stroke (NINDS)
- National Institute on Minority Health and Health Disparities (NIMHD)
- National Cancer Institute (NCI)

All applications to this funding opportunity announcement should fall within the mission of the Institutes/Centers. The following NIH Offices may co-fund applications assigned to those Institutes/Centers.

- Office of Behavioral and Social Sciences Research (OBSSR)
- Office of Research on Women's Health (ORWH)



Program Officers' Contact Information

Found at bottom of announcement webpages

Section VII. Agency Contacts

We encourage inquiries concerning this funding opportunity and welcome the opportunity to answer questions from potential applicants.

Each participating Institute lists

- Scientific Contact (Program Officer)
- Grants Management Contact

Start here

NHGRI's ELSI Research Interests

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Genomics and Sociocultural Structures and Values



Genomics at the Institutional and System Level



Genomic Research Design and Implementation



Genomic Healthcare

Other Institutes' Research Interests

Part 2. Full Text of Announcement

Section I. Notice of Funding Opportunity Description

National Institute on Minority Health and Health Disparities

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National Institute of Environmental Health Sciences

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National Institute on Drug Abuse

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National Institute of Allergy and Infectious Diseases

NIAID is NOT interested in supporting clinical trials under this announcement but would consider non-IND trials, e.g., social/behavioral-relevant trials.

NIAID is interested in supporting projects that focus on ethical, legal, and social implications of genomic research that derive from domestic or international research on HIV/AIDS, other infectious diseases including those transmitted by vectors; immunologic and allergic diseases, or organ transplantation; and other ELSI issues arising from genomics that are relevant to NIAID's scientific mission. Applications should consider the following:

- Supporting the integration of bioethics work with genomic research in immunology, allergies, infectious diseases, transplantation, and other topics within NIAID's mission.
- Enhanced engagement of key populations in genomic research on HIV and other infectious disease prevention, treatment, cure; HIV-related comorbidities and co-infections including those transmitted via sexual contact; to improve dissemination and communication of results and mitigate barriers to research participation.
- Representation of key populations in genomic research on immune-mediated diseases and transplantation for disease prevention, treatment, and/or cure; improving dissemination, communication of results, and mitigating barriers.
- Research on genome editing for correcting heritable traits and genetic disorders that impact diseases relevant to NIAID's mission (e.g., inborn errors of immunity, primary immunodeficiencies).
- Investigate perceptions, beliefs, and attitudes towards genomic research among diverse stakeholders including researchers, clinicians, patients, community members, IRB/Ethics committee members, and regulators; analyze ethical implications of these views in planning and conducting NIAID research.
- Research to avoid or mitigate negative consequences of genetic findings on human phenotypes or identity, as well as genetic findings that reveal directionality of disease transmission of pathogens.
- Research to improve the implementation of Artificial Intelligence (AI) and Machine Learning methods to minimize bias in algorithms, coding, and analyses of genomic data.

An array of approaches are possible

- Investigators representing a wide range of lived experiences and perspectives are encouraged
- Variety of methods (e.g. empirical, qualitative, quantitative, conceptual, legal, and normative analyses)
- Single or mixed method studies

Community Involvement



- Community perspectives can inform genomics
- Involvement in any/all phases of study
- May include a range of methods and approaches
- Encouraged but not required



Who can apply?

Section III. Eligibility Information

1. Eligible Applicants

- Ph.D./M.D. not required
- Broad range of organizations
- Foreign organizations are eligible

Foreign Organizations

- **NIH Definition:** An organization located in a country other than the United States and its territories that is subject to the laws of that country
- The organization may be the applicant or a partner
- No requirement to work with specific countries
- Uses the same application forms and instructions
- Additional requirements to register for submission

Additional Criteria for Foreign Applicants

In addition to all review criteria listed in NOFO, NIH considers:

- Relevance to Institute mission and objectives
- Whether the proposal offers an opportunity not readily available in U.S.
- Potential to advance health science in U.S.
- Compliance with human subject, animal welfare, and inclusion requirements

Be sure to reach out to program contacts

Comparing the R01, R21, R03

Type of grant	Description	Direct cost limit	Duration
R01	Larger studies building on preliminary data	\$500K/year	Up to 5 years*
R21	Exploratory projects, may be designed to generate pilot data for a larger study	A total of \$275K across all years	2-3 years
R03	Single investigator projects, e.g. conceptual analyses, or secondary data analyses	\$50K/year	2 years

New requirement – all applications need a Data Management and Sharing Plan (DMSP)

- Applications collecting data require a DMSP plan
- Needed even if you don't plan to share data –to justify that decision
- Applications without a plan will be incomplete
- 2-page attachment
- Summer 2023 ELSI DMSP webinar posted online
- Sample ELSI plan online

New requirement for R01 Plan for Enhancing Diverse Perspectives



A “Plan for Enhancing Diverse Perspectives” (PEDP) is a summary of strategies to advance the scientific and technical merit of the proposed project through inclusivity



Sources of diverse perspectives include people who do the research, the places where research is done, and the people who participate as part of the study population



The PEDP is submitted as a 1-page “Other Attachment” to be included in **ELSI R01** grant applications

Plan for Enhancing Diverse Perspectives

The PEDP:

- Should provide an integrated view of how enhancing diverse perspectives is supported throughout the application
- Should align where possible with descriptions in the Research Strategy
- Can speak to enhancing the science in many ways – via any review criteria
- Varies depending on scientific goals and study design
- Is considered in scientific peer review

R01s without a PEDP will be withdrawn prior to review

New Review Criterion for R01 and R21 – Population Descriptors

Applications that propose using variables in their analysis that measure race, ethnicity, genealogical ancestry, genetic ancestry, sex, gender, or sexual orientation should:

- Name and define those variables
- Provide the rationale for their use
- Describe how selected variables relate to research questions
- Describe assumptions or limitations
- Consider variables provided in the PhenX Toolkit

Key Differences in Current NOFOs

- | | |
|-------------------|---|
| R01
R21
R03 | <ul style="list-style-type: none">• Requires a Data Management and Sharing Plan, per NIH policy• Encourages community involvement, where appropriate |
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| R01
R21 | <ul style="list-style-type: none">• Requests a description of and rationale for use of population descriptors in analysis; part of peer review |
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| R01 | <ul style="list-style-type: none">• Requires a Plan for Enhancing Diverse Perspectives (PEDP); part of peer review• Applications to NHGRI require prior approval from a Program Officer to apply for a 5-year grant. |
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Reach out to Program Officers

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Early! And often!

Acknowledgments

NHGRI

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NICHD

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NEI

Cheri Wiggs
Karen Robinson Smith

OBSSR

Erica Spotts

ODSS

Shu Hui Chen

NIDCR

Alicia Yesiu Chou
Gabriel Hidalgo
Dana Rutberg

FIC

Barbara Sina
Victoria Tran

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Questions and Answers

Thank you!



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Q&A Session



What are NHGRI priorities for funding?

- The NOFOs identify four broad areas of ELSI research that are of interest to NHGRI. Detailed examples are online.
- Applicants may look at ELSI issues associated with any of NHGRI's scientific areas (e.g., genomic technology, data science, genomic medicine)
- For NHGRI, projects focused on a single disease may be of lower priority unless findings are generalizable or transferable
- However, be sure to review research interests of other Institutes and Centers

How do I choose the best funding opportunity?

- A variety of factors can impact funding opportunity selection
- Strongly recommend reaching out to a program officer as soon as possible to discuss
- Considerations:
 - Career stage
 - Short- and long-term goals
 - Research interests
 - Prior work
 - Other NIH funding opportunities

Can I resubmit an application under the new NOFO?

- If a revised application is resubmitted within 37 months of the original, then it can be resubmitted under the new NOFO
- If the revised application is significantly different from the original or you want to separate it from prior review, then it can be submitted as a new application

For more about resubmissions, see:

<https://grants.nih.gov/grants/policy/amendedapps.htm>

Are there special issues pertaining to Tribal communities?

- U.S. Tribal Nations are sovereign nations with their own governments and laws
- NIH is committed to upholding Tribal sovereignty
- Meaningful engagement is valuable and encouraged for studies involving American Indian, Alaska Native, Native Hawaiian or other indigenous groups
- Engagement can address research questions, research protocols, data sharing approaches, return of benefit, and other issues

How can I budget for involvement of community and other interest groups?

- Involvement of communities and other interest groups can take many forms
- Budgets can include costs of compensation and other support needed for successful involvement
- Budget justification should describe role(s) and support needs

What are requirements for LMICs?

- No unique requirements for low to middle income countries (LMICs)
- Follow requirements for foreign and international organizations

https://grants.nih.gov/grants/policy/nihgps/HTML5/section_16/16_grants_to_foreign_institutions_international_organizations_and_domestic_grants_with_foreign_components.htm

- Review 'Tips for International Applicants'

https://grants.nih.gov/grants/ElectronicReceipt/files/Tips_for_International_Applicants.pdf



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