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 Institute on Aging (NIA)

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 Research on Women's Health (ORWH)

All of Us Research Program, Office of the Director, National Institutes of Health (PRECMED)

Funding Opportunity Title

Investigator-Initiated Research in Genomics and Health Equity (R21 Clinical Trial Optional)

Activity Code

R21 Exploratory/Developmental Research Grant

Announcement Type

New

Related Notices

- **November 8, 2023** - Notice of Extension of the First Receipt Date of RFA-HG-23-018: Investigator-Initiated Research in Genomics and Health Equity (R21 Clinical Trial (Clinical Trial Optional). See Notice NOT-HG-24-008
- **August 9, 2023** - Notice of Pre-Application Webinar for the Investigator-Initiated Research in Genomics and Health Equity: RFA-HG-23-017 (R01 Clinical Trial Optional) and RFA-HG-23-018 (R21 Clinical Trial Optional). See Notice NOT-HG-23-049.
- **June 5, 2023** - Investigator-Initiated Research in Genomics and Health Equity (R01 Clinical Trial Optional). See NOFO RFA-HG-23-017.
- **October 26, 2022** - Reminder: FORMS-H Grant Application Forms & Instructions Must be Used for Due Dates On or After January 25, 2023 - New Grant Application Instructions Now Available. See Notice NOT-

OD-23-012.

- **August 31, 2022** - Implementation Changes for Genomic Data Sharing Plans Included with Applications Due on or after January 25, 2023. See Notice NOT-OD-22-198.
- **August 8, 2022** - New NIH "FORMS-H" Grant Application Forms and Instructions Coming for Due Dates on or after January 25, 2023. See Notice NOT-OD-22-195.
- **August 5, 2022** - Implementation Details for the NIH Data Management and Sharing Policy. See Notice NOT-OD-22-189.

Notice of Funding Opportunity (NOFO) Number

RFA-HG-23-018

Companion Funding Opportunity

None

Number of Applications

See Section III. 3. Additional Information on Eligibility.

Assistance Listing Number(s)

93.172, 93.313, 93.866, 93.368

Funding Opportunity Purpose

The purpose of this initiative is to support investigator-initiated research in genomics and health equity, with the ultimate goal of developing approaches, generating and disseminating data, and implementing metrics or interventions that will advance the equitable use of genomics to improve health in U.S. populations. Awardees will conduct innovative and generalizable research in genomics and health equity spanning across genomic research areas and will incorporate a plan for enhancing diverse perspectives.This R21 Notice of Funding Opportunity (NOFO) will support small research projects that can be carried out in a short period of time with limited resources. The R21 grant mechanism supports different types of projects including pilot and feasibility studies; secondary analysis of existing data; small, self-contained research projects; development of research methodology; and development of new research technology. Applications supporting New or Early Stage Investigators from diverse backgrounds, including those from groups traditionally underrepresented in the biomedical, behavioral, and clinical research workforce, as described in the NIH Notice of Interest in Diversity (NOT-OD-20-031), are encouraged.

This Notice of Funding Opportunity (NOFO) requires a Plan for Enhancing Diverse Perspectives (PEDP) as part of the application. Applications without a PEDP will not be reviewed.

Key Dates

Posted Date

June 05, 2023

Open Date (Earliest Submission Date)

October 08, 2023

Letter of Intent Due Date(s)

30 days prior to the application receipt date.

Application Due Dates			Review and Award Cycles		
New	Renewal / Resubmission / Revision (as allowed)	AIDS	Scientific Merit Review	Advisory Council Review	Earliest Start Date
December 19, 2023	Not Applicable	Not Applicable	March 2024	May 2024	July 2024
July 08, 2024	July 08, 2024	Not Applicable	November 2024	January 2025	April 2025
July 08, 2025	July 08, 2025	Not Applicable	November 2025	January 2026	April 2026

All applications are due by 5:00 PM local time of applicant organization.

Applicants are encouraged to apply early to allow adequate time to make any corrections to errors found in the application during the submission process by the due date.

Expiration Date

July 09, 2025

Due Dates for E.O. 12372

Not Applicable

Required Application Instructions

It is critical that applicants follow the instructions in the Research (R) Instructions in the SF424 (R&R) Application Guide, except where instructed to do otherwise (in this NOFO or in a Notice from NIH Guide for Grants and Contracts).

Conformance to all requirements (both in the Application Guide and the NOFO) is required and strictly enforced. Applicants must read and follow all application instructions in the Application Guide as well as any program-specific instructions noted in Section IV. When the program-specific instructions deviate from those in the Application Guide, follow the program-specific instructions.

Applications that do not comply with these instructions may be delayed or not accepted for review.

There are several options available to submit your application through Grants.gov to NIH and Department of Health and Human Services partners. You **must** use one of these submission options to access the application forms for this opportunity.

1. Use the NIH ASSIST system to prepare, submit and track your application online.
   Apply Online Using ASSIST

2. Use an institutional system-to-system (S2S) solution to prepare and submit your application to Grants.gov and eRA Commons to track your application. Check with your institutional officials regarding availability.

3. Use Grants.gov Workspace to prepare and submit your application and eRA Commons to track your application.

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Part 2. Full Text of Announcement

Section I. Notice of Funding Opportunity Description

Background

Although advances in genomic discovery and technology have fueled the application of genomics to improve understanding of human health and disease, not all groups have benefitted equitably. Without equity in research, resource allocation, and clinical practice, disparities in the benefits of genomic research and its applications will persist. The 2020 NHGRI Strategic Vision includes a bold prediction that within the next 10 years, individuals from ancestrally diverse and underrepresented backgrounds will benefit equitably from advances in human genomics. In April 2022, NHGRI held a virtual public workshop to understand the gaps and opportunities in genomic health equity research and identify research directions that will help to alleviate health disparities and advance health equity. The workshop report, which includes recommendations from attendees, inform the scope and objectives of this RFA.

Program Description

Scope and objectives

This NOFO, together with RFA-HG-23-017, will support investigator-initiated research in genomics and health equity. NIH recognizes the importance of innovative, nimble, and focused approaches that originate from independent researchers and their teams. By supporting both R01 and R21 applications, independent research based on either mature scientific ideas with preliminary data (R01) or at the exploratory or developmental level (R21) is encouraged. All supported investigators are expected to actively participate in one annual meeting in which substantial information sharing is anticipated. This approach will allow for independent but synergistic efforts among supported investigators and promote rapid sharing of successful approaches and resulting data.

Health equity is relevant across all aspects of genomic research. This initiative will solicit applications to conduct

research that addresses health equity in the areas in genomics that are related to the research missions of NHGRI, NIA, *All of Us*, and ORWH. The research supported by this initiative will address broader implications of health equity beyond demonstrated health outcomes in individuals. Applicants are encouraged to include NIH-designated populations or communities that experience health disparities, such as racial or ethnic minority groups, people with lower socioeconomic (SES) status, underserved rural communities, and sexual and gender minority groups. The research supported by this initiative also includes women and individuals with disabilities, as relevant to the scientific question to be investigated. Efforts related to rigorous community engagement preceding or as part of the research are encouraged. However, the application must go beyond simple inclusion of women, a health disparity or disability population and show evidence that the research will address health equity in genomics.

Addressing health disparities and health equity through a genomic lens relates to a number of research areas, including but not limited to the following examples.

National Human Genome Research Institute (NHGRI)

- Access to high-quality and comprehensive genomic information
    - Improving prediction of molecular variation from genetic variation in admixed populations, in conjunction with biological and social determinants of health
    - Maximizing the utility of genomic, social, and environmental data to address health disparities in women or health disparity or disability populations
    - Addressing challenges to genomic data sharing or data science that impact health equity
    - Integrating genomic data with fine-scale data across multiple dimensions (other -omics, precision environmental health) to better characterize health disparities
- Development of accessible technology and methods
    - Developing and implementing genomic technology for under-resourced laboratories and clinics
- Access to genomic technology or testing; quality or management of genomic testing results
    - Distinguishing the utility of race and other socially defined descriptors from genomic information in determining laboratory reference values and clinical algorithms
    - Identifying the gaps between the prognostic and diagnostic properties that genomic tests need to have to impact health disparities, and the current properties of genomic tests; designing strategies to address those gaps
    - Conducting decision science, economic or healthcare utilization studies around new genomic technologies or genomic testing that impacts equitable allocation of clinical resources
    - Conducting ethical, legal and social implication studies around equitable integration of genomics into clinical care and society for underserved and health disparity populations
- Acceptability of genomic approaches and interventions to the public.
    - Developing and applying metrics of health equity in genomic research that are acceptable and useful to communities, participants, and researchers
    - Identifying and overcoming barriers that limit participation in and benefit from genomic research, particularly barriers stemming from structural and social inequities
    - Developing and evaluating models of engagement and inclusion of communities, particularly women or health disparity or disability populations, in genomics research studies of health equity

Applicants are encouraged to utilize Social Determinants of Health (SDOH) measures in the PhenX Toolkit, as relevant.

***All of Us*:**

The *All of Us* Research Program is soliciting R21 applications to conduct research using the *All of Us* Researcher Workbench to advance genomic research and health equity. The *All of Us* Research Program is a historic effort to partner with at least one million or more people who reflect the diversity of the United States to build one of the most

diverse biomedical data resources of its kind that can be used by researchers to gain insights into the biological, environmental, and behavioral factors that influence health. This funding opportunity announcement will support applications focused on understanding how social determinants of health influence genomic variations between and within human genetic ancestry groups and contribute to the unequal burden of disease risk, development, disability, severity, and progression across populations historically underrepresented in biomedical research. The *All of Us* Research Program defines underrepresented groups as:

- Race: Individuals who select a single race other than White (e.g., Asian), or who select more than one race
- Ethnicity: Individuals who select an ethnicity other than those listed under the race of White (e.g., Japanese)
- Age: Young people under 18 years old and older adults 65 and above
- Sexual and gender minorities based on the following:
    - Biological sex assigned at birth: Individuals who self-report intersex as their sex at birth
    - Sexual orientation: Individuals who select any sexual orientation choice other than straight (e.g., gay, lesbian, bisexual, queer, asexual, etc.)
    - Gender identity: Individuals who select any gender identity choice other than man or woman (e.g., non-binary, transgender, genderfluid, questioning, etc.)
- Income: Individuals with an annual household income of less than $25,000
- Educational attainment: Individuals without a high school diploma or GED
- Access to care: People who currently need a medical visit, or have needed one in the past 12 months, but cannot readily use the health care system or pay for needed care
- Geography: Residents of established rural and non-metropolitan zip codes, based on the HRSA Federal Office of Rural Health Policy data files
- Disability: Individuals with a physical, functional, cognitive, or other condition that substantially limits one or more life activities

Applications that use community-engaged research approaches to inform the research study and promote data justice (e.g., ensuring that study results are interpreted in a manner that represent study populations fairly and without bias) will be prioritized. Applications only assessing differences in genomic variations, biological processes, etc., across populations without assessing social determinants of health in the study design will be deemed non-responsive. Investigators must register for the *All of Us* Researcher Workbench (https://www.researchallofus.org/register) and complete the data access process to access and analyze *All of Us* data. Additional training is required to access the *All of Us* Controlled Tier, which includes more granular participant data, such as whole genome sequences and genotyping data. Visit the *All of Us* Research Hub (https://www.researchallofus.org/) to learn more about data types, access, and use.

National Institute on Aging

The mission of the National Institute on Aging (NIA) is to support and conduct biological, clinical, behavioral, social, and economic research on Aging; foster the development of research and clinician scientists in Aging; provide research resources to facilitate innovative aging research; and disseminate information about Aging and related advances in research to the public, health care professionals, and the scientific community, among a variety of audiences. NIA will support meritorious applications that focus on aging research as well as Alzheimer's Disease and related dementia (AD/ADRD). Studies that draw data from across the lifespan are especially encouraged and applicants are expected to factor sex as a biological variable into research designs, analyses and reporting in vertebrate animal and human studies. Applicants interesting in submitting applications on aging and AD/ADRD should review the NIA Strategic Directions for Research, 2020 2025 and the AD/ADRD Research milestones for more information on NIA's research priorities.

NIH Office of Research on Women's Health (ORWH)

The Office of Research on Women's Health (ORWH) is part of the NIH Office of the Director, and works in

partnership with the NIH Institutes, Centers, and Offices (ICOs) to ensure that women's health research is part of the NIH scientific framework and supported throughout the biomedical enterprise. ORWH uses a multidimensional framework to represent the intersection of factors that underlie patterns of disease and determinants of health outcomes in populations.

For the purpose of this NOFO, ORWH will support research that focuses on health disparities in genomic research to eliminate health disparities among women, including populations of women who are understudied, underrepresented, and underreported (U3) in research. The evolving conceptualization of factors relevant to the understanding and reduction of health disparities is illustrated in the NIMHD Minority Health and Health Disparities Research Framework. Applying such a framework to genomic research will help to advance community engagement in biomedical research, and acceptability of genomic approaches, and increase access to genomic technology and interventions needed to advance the equitable use of genomic data to improve health in US populations.

There is also a crucial need to address sex and gender influences in genomic research relevant to women's health, and, as appropriate, address the influence of sex as a biological variable (SABV) in the context of genomic research on health and disease. Integrating the purposeful accounting for SABV in biomedical research, from the most basic to the clinical and applied efforts, will fill gaps in our knowledge, and will inform more effective and personalized approaches for everyone. For additional guidance, please review the 2019-2023 Trans-NIH Strategic Plan for the Health of Women.

Data sharing

Recipients must comply with the NIH Data Management and Sharing Policy (NOT-OD-21-013) and NIH Genomic Data Sharing Policy (NOT-OD-14-124). NHGRI supports the broadest appropriate data sharing with timely data release through widely accessible data repositories. Please follow the NIH guidance on writing a Data Management and Sharing (DMS) Plan here, and ensure the Plan is in alignment with NHGRI's data sharing expectations, which are summarized at genome.gov/data-sharing.

Plan for Enhancing Diverse Perspectives (PEDP)

The NIH recognizes that diverse teams working together and capitalizing on innovative ideas and distinct perspectives outperform homogeneous teams. There are many benefits that flow from a diverse scientific workforce, including: fostering scientific innovation, enhancing global competitiveness, contributing to robust learning environments, improving the quality of the research, advancing the likelihood that underserved populations participate in, and benefit from research, and enhancing public trust.

To support the best science, the NIH encourages inclusivity in research. Examples of structures that promote diverse perspectives include but are not limited to:

- Transdisciplinary research projects and collaborations among researchers from different disciplines.
- Engagement from different types of institutions and organizations (e.g., research-intensive, undergraduate-focused, minority-serving, community-based).
- Individual applications and partnerships that enhance geographic and regional heterogeneity.
- Investigators and teams composed of researchers at different career stages.
- Participation of individuals from diverse backgrounds, including groups traditionally underrepresented in the biomedical, behavioral, and clinical research workforce (see NOT-OD-20-031), such as underrepresented racial and ethnic groups, those with disabilities, those from disadvantaged backgrounds, and women.
- Opportunities to enhance the research environment to benefit early- and mid-career investigators.

This NOFO requires a Plan for Enhancing Diverse Perspectives (PEDP) as part of the application (see further below). Applicants are strongly encouraged to read the NOFO instructions carefully and view the available PEDP guidance material.

Applications must include a Plan for Enhancing Diverse Perspectives (PEDP) submitted as Other Project Information as an attachment (see Section IV). The PEDP will be assessed as part of the scientific and technical peer review evaluation.

The NIH recognizes a unique and compelling need to promote diversity in the biomedical, behavioral, clinical and social sciences workforce. The NIH expects efforts to diversify the workforce to lead to the recruitment of the most talented researchers from all groups; to improve the quality of the educational and training environment; to balance and broaden the perspective in setting research priorities; to improve the ability to recruit subjects from minority and other health disparity populations into clinical research protocols; and to improve the Nation's capacity to address and eliminate health disparities. For more information, see Notice of NIH's Interest in Diversity, NOT-OD-20-031 (https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-031.html). Every facet of the United States scientific research enterprise from basic laboratory research to clinical and translational research to policy formation requires superior intellect, creativity and a wide range of skill sets and viewpoints. NIH's ability to help ensure that the nation remains a global leader in scientific discovery and innovation is dependent upon a pool of highly talented scientists from diverse backgrounds who will help to further the NIH mission.

Fostering diversity by addressing underrepresentation in the scientific research workforce is a key component of the NIH strategy to identify, develop, support, and maintain the quality of our scientific human capital. Despite tremendous advancements in scientific research, information, educational and research opportunities are not equally available to all. Investigators from diverse backgrounds, including those from underrepresented groups (e.g., see NOT-OD-20-031, Notice of NIH's Interest in Diversity), are encouraged to work with their institutions to apply for support under this program.

Applications from New or Early Stage Investigators

This initiative will champion a diverse genomics research workforce by supporting New or Early Stage Investigators from diverse backgrounds, including those from underrepresented groups. For the purpose of this RFA, a New Investigator (NI) is an investigator who has not worked with their institution to compete successfully for substantial, independent funding from NIH. An Early Stage Investigator (ESI) is an investigator who has completed their terminal research degree or end of post-graduate clinical training, whichever date is later, within the past 10 years and who has not previously worked with their institution to compete successfully as PD/PI for a substantial NIH independent research award. Additional information on NI/ESI status can be found at https://grants.nih.gov/policy/early-stage/index.htm.

The R01 and R21 applications supported by this initiative will be distinguished by their emphasis on genomics and health equity. NHGRI offers other NOFOs for R01 or R21 applications from New and/or Early Stage Investigators (https://grants.nih.gov/grants/guide/rfa-files/RFA-HG-21-041.html, https://grants.nih.gov/grants/guide/pa-files/PAR-19-222.html, https://grants.nih.gov/grants/guide/rfa-files/RFA-HG-22-001.html). NI or ESI proposing research that addresses other areas of NHGRI's mission, but without a specific focus on health equity, are encouraged to contact the Scientific Contacts for those NOFOs.

Non-responsive applications

Applications with the following properties will be considered non-responsive, and will not be reviewed:

- Applications without a focus on genomics and health equity, even if the research is conducted in women or a health disparity or disability population.
- Applications that do not have a primary focus on genomics research.
- Applications that do not include a Plan for Enhancing Diverse Perspectives (PEDP).

Non-responsive applications will not be reviewed. Applicants are strongly encouraged to reach out to the NOFO scientific/research contact prior to submission to discuss whether their application is responsive.

See Section VIII. Other Information for award authorities and regulations.

Investigators proposing NIH-defined clinical trials may refer to the Research Methods Resources website for information about developing statistical methods and study designs.

Section II. Award Information

Funding Instrument

Grant: A support mechanism providing money, property, or both to an eligible entity to carry out an approved project or activity.

Application Types Allowed

New
Resubmission

The OER Glossary and the SF424 (R&R) Application Guide provide details on these application types. Only those application types listed here are allowed for this NOFO.

Clinical Trial?

Optional: Accepting applications that either propose or do not propose clinical trial(s).

Need help determining whether you are doing a clinical trial?

Funds Available and Anticipated Number of Awards

The following NIH components intend to commit the following amounts in FY2024:

NHGRI intends to commit up to $3.6M in FY24 to support up to six awards from RFA-HG-23-017 and RFA-HG-23-018.

The *All of Us* Research Program will support one R21 application per receipt date, for a total of three R21 applications. New and Early-Stage investigators and investigators from diverse backgrounds are encouraged to apply. Diversity will be defined according to the NIH's Interest in Diversity (NOT-OD-20-031).

Award Budget

Application budgets cannot exceed $200,000 in direct costs per year, and must reflect the actual needs of the proposed project.

Award Project Period

The scope of the proposed project should determine the project period. The maximum project period is 2 years.

NIH grants policies as described in the NIH Grants Policy Statement will apply to the applications submitted and awards made from this NOFO.

Section III. Eligibility Information

1. Eligible Applicants

Eligible Organizations

Higher Education Institutions

- Public/State Controlled Institutions of Higher Education
- Private Institutions of Higher Education

The following types of Higher Education Institutions are always encouraged to apply for NIH support as Public or Private Institutions of Higher Education:

- Hispanic-serving Institutions
- Historically Black Colleges and Universities (HBCUs)
- Tribally Controlled Colleges and Universities (TCCUs)
- Alaska Native and Native Hawaiian Serving Institutions
- Asian American Native American Pacific Islander Serving Institutions (AANAPISIs)

Nonprofits Other Than Institutions of Higher Education

- Nonprofits with 501(c)(3) IRS Status (Other than Institutions of Higher Education)
- Nonprofits without 501(c)(3) IRS Status (Other than Institutions of Higher Education)

For-Profit Organizations

- Small Businesses
- For-Profit Organizations (Other than Small Businesses)

Local Governments

- State Governments
- County Governments
- City or Township Governments
- Special District Governments
- Indian/Native American Tribal Governments (Federally Recognized)
- Indian/Native American Tribal Governments (Other than Federally Recognized)

Federal Governments

- Eligible Agencies of the Federal Government
- U.S. Territory or Possession

Other

- Independent School Districts
- Public Housing Authorities/Indian Housing Authorities
- Native American Tribal Organizations (other than Federally recognized tribal governments)
- Faith-based or Community-based Organizations
- Regional Organizations

Foreign Institutions

Non-domestic (non-U.S.) Entities (Foreign Institutions) **are not** eligible to apply.

Non-domestic (non-U.S.) components of U.S. Organizations **are not** eligible to apply.

Foreign components, as defined in the *NIH Grants Policy Statement*, **are** allowed.

Required Registrations

Applicant Organizations

Applicant organizations must complete and maintain the following registrations as described in the SF 424 (R&R) Application Guide to be eligible to apply for or receive an award. All registrations must be completed prior to the application being submitted. Registration can take 6 weeks or more, so applicants should begin the registration process as soon as possible. The NIH Policy on Late Submission of Grant Applications states that failure to complete registrations in advance of a due date is not a valid reason for a late submission.

- System for Award Management (SAM) Applicants must complete and maintain an active registration, **which requires renewal at least annually**. The renewal process may require as much time as the initial registration. SAM registration includes the assignment of a Commercial and Government Entity (CAGE) Code for domestic organizations which have not already been assigned a CAGE Code.
    - NATO Commercial and Government Entity (NCAGE) Code Foreign organizations must obtain an NCAGE code (in lieu of a CAGE code) in order to register in SAM.
    - Unique Entity Identifier (UEI)- A UEI is issued as part of the SAM.gov registration process. The same UEI must be used for all registrations, as well as on the grant application.
- eRA Commons - Once the unique organization identifier is established, organizations can register with eRA Commons in tandem with completing their Grants.gov registrations; all registrations must be in place by time of submission. eRA Commons requires organizations to identify at least one Signing Official (SO) and at least one Program Director/Principal Investigator (PD/PI) account in order to submit an application.
- Grants.gov Applicants must have an active SAM registration in order to complete the Grants.gov registration.

Program Directors/Principal Investigators (PD(s)/PI(s))

All PD(s)/PI(s) must have an eRA Commons account. PD(s)/PI(s) should work with their organizational officials to either create a new account or to affiliate their existing account with the applicant organization in eRA Commons. If the PD/PI is also the organizational Signing Official, they must have two distinct eRA Commons accounts, one for each role. Obtaining an eRA Commons account can take up to 2 weeks.

Eligible Individuals (Program Director/Principal Investigator)

Any individual(s) with the skills, knowledge, and resources necessary to carry out the proposed research as the Program Director(s)/Principal Investigator(s) (PD(s)/PI(s)) is invited to work with their organization to develop an application for support. Individuals from diverse backgrounds, including underrepresented racial and ethnic groups, individuals with disabilities, and women are always encouraged to apply for NIH support. See, Reminder: Notice of NIH's Encouragement of Applications Supporting Individuals from Underrepresented Ethnic and Racial Groups as well as Individuals with Disabilities, NOT-OD-22-019.

For institutions/organizations proposing multiple PDs/PIs, visit the Multiple Program Director/Principal Investigator Policy and submission details in the Senior/Key Person Profile (Expanded) Component of the SF424 (R&R) Application Guide.

Individuals Applying as NI or ESI

Individuals applying as the PD/PI must meet each eligibility criterion below. For a multiple PDs/PIs application, all of the individuals serving as PDs/PIs are required to meet all of the same eligibility criteria as for a single PD/PI application.

Institutions applying must ensure that individuals identified as the PD/PI meet either the eligibility criteria A. New Investigator or B. Early Stage Investigator below. For applications with multiple PDs/PIs, each individual serving as PD/PI is required to meet at least one of the eligibility criteria A or B, i.e., must be either a New or Early Stage Investigator. New Investigator and Early Stage Investigator status will be verified by NIH at the time of application.

A. New Investigator (NI)

For the purpose of this NOFO, an investigator is considered a New Investigator (NI; https://grants.nih.gov/policy/early-investigators/index.htm) if he/she has not worked with their institution to compete successfully for substantial, NIH independent funding from NIH. A "substantial" research award is a research grant award excluding smaller grants that maintain Early Stage Investigator (ESI)/NI status (see full list of awards here). PD/PI of NIH Training-Related and Mentored Career Awards are still considered New Investigators if the NIH

awards are in any of the following categories: fellowships (F awards), individual or institutional career awards (K awards), loan repayment contracts (L30, L32, L40, L50, L60), and all training grants (T32, T34, T35, T90, D43).

OR

B. Early Stage Investigator

For the purpose of this NOFO, an investigator is considered an Early Stage Investigator (ESI; https://grants.nih.gov/policy/early-stage/index.htm) if they have completed their terminal research degree or end of post-graduate clinical training, whichever date is later, within the past 10 years, and have not worked with their institution to compete successfully for substantial, independent funding from NIH. A "substantial" research award is a research grant award excluding smaller grants that maintain Early Stage Investigator (ESI)/NI status (see full list of awards here). PD/PI of NIH Training-Related and Mentored Career Awards are still considered New Investigators if the NIH awards are in any of the following categories: fellowships (F awards), individual or institutional career awards (K awards), loan repayment contracts (L30, L32, L40, L50, L60), and all training grants (T32, T34, T35, T90, D43).

2. Cost Sharing

This NOFO does not require cost sharing as defined in the NIH Grants Policy Statement.

3. Additional Information on Eligibility

Number of Applications

Applicant organizations may submit more than one application, provided that each application is scientifically distinct.

The NIH will not accept duplicate or highly overlapping applications under review at the same time, per 2.3.7.4 Submission of Resubmission Application. This means that the NIH will not accept:

- A new (A0) application that is submitted before issuance of the summary statement from the review of an overlapping new (A0) or resubmission (A1) application.
- A resubmission (A1) application that is submitted before issuance of the summary statement from the review of the previous new (A0) application.
- An application that has substantial overlap with another application pending appeal of initial peer review (see 2.3.9.4 Similar, Essentially Identical, or Identical Applications).

Section IV. Application and Submission Information

1. Requesting an Application Package

The application forms package specific to this opportunity must be accessed through ASSIST, Grants.gov Workspace or an institutional system-to-system solution. Links to apply using ASSIST or Grants.gov Workspace are available in Part 1 of this NOFO. See your administrative office for instructions if you plan to use an institutional system-to-system solution.

2. Content and Form of Application Submission

It is critical that applicants follow the instructions in the Research (R) Instructions in the SF424 (R&R) Application Guide except where instructed in this notice of funding opportunity to do otherwise. Conformance to the requirements in the Application Guide is required and strictly enforced. Applications that are out of compliance with these instructions may be delayed or not accepted for review.

Letter of Intent

Although a letter of intent is not required, is not binding, and does not enter into the review of a subsequent application, the information that it contains allows IC staff to estimate the potential review workload and plan the review.

By the date listed in Part 1. Overview Information, prospective applicants are asked to submit a letter of intent that includes the following information:

- Descriptive title of proposed activity
- Name(s), address(es), and telephone number(s) of the PD(s)/PI(s)
- Names of other key personnel
- Participating institution(s)
- Number and title of this funding opportunity

The letter of intent should be sent to:

Lucia A. Hindorff, PhD
Telephone: 240-271-1509
Email: hindorffl@mail.nih.gov

Page Limitations

All page limitations described in the SF424 Application Guide and the Table of Page Limits must be followed.

Instructions for Application Submission

The following section supplements the instructions found in the SF424 (R&R) Application Guide and should be used for preparing an application to this NOFO.

SF424(R&R) Cover

All instructions in the SF424 (R&R) Application Guide must be followed.

SF424(R&R) Project/Performance Site Locations

All instructions in the SF424 (R&R) Application Guide must be followed.

SF424(R&R) Other Project Information

All instructions in the SF424 (R&R) Application Guide must be followed.

Other Attachment

Plan for Enhancing Diverse Perspectives (PEDP)

In an "Other Attachment" entitled "Plan for Enhancing Diverse Perspectives," all applicants must include a summary of strategies to advance the scientific and technical merit of the proposed project through expanded inclusivity. The PEDP should provide a holistic and integrated view of how enhancing diverse perspectives is viewed and supported throughout the application and can incorporate elements with relevance to any review criteria (significance, investigator(s), innovation, approach, and environment) as appropriate. Where possible, applicant(s) should align their description with these required elements within the research strategy section. The PEDP will vary depending on the scientific aims, expertise required, the environment and performance site(s), as well as how the project aims are structured. The PEDP may be no more than 1-page in length and should include a timeline and milestones for relevant components that will be considered as part of the review. Examples of items that advance inclusivity in research and may be part of the PEDP can include, but are not limited to:

- Discussion of engagement with different types of institutions and organizations (e.g., research-intensive, undergraduate-focused, minority-serving, community-based).
- Description of any planned partnerships that may enhance geographic and regional diversity.
- Plan to enhance recruiting of women and individuals from groups traditionally under-represented in the biomedical, behavioral, and clinical research workforce.
- Proposed monitoring activities to identify and measure PEDP progress benchmarks.
- Plan to utilize the project infrastructure (i.e., research and structure) to support career-enhancing research

opportunities for diverse junior, early- and mid-career researchers.
- Description of any training and/or mentoring opportunities available to encourage participation of students, postdoctoral researchers and co-investigators from diverse backgrounds.
- Plan to develop transdisciplinary collaboration(s) that require unique expertise and/or solicit diverse perspectives to address research question(s).
- Publication plan that enumerates planned manuscripts and proposed lead authorship.
- Outreach and planned engagement activities to enhance recruitment of individuals from diverse backgrounds in research including those from under-represented groups in research.

For further information on the Plan for Enhancing Diverse Perspectives (PEDP), please see https://braininitiative.nih.gov/about/plan-enhancing-diverse-perspectives-pedp

SF424(R&R) Senior/Key Person Profile

All instructions in the SF424 (R&R) Application Guide must be followed.

R&R or Modular Budget

All instructions in the SF424 (R&R) Application Guide must be followed.

Travel Funds*:* The budget should include funds for the PD/PI to travel to the Bethesda, MD, area each year to participate in a research symposium.

Scientific data sharing: Budgets should include any funds required to support sharing of scientific data under this NOFO. NIH provides guidance on allowable costs for data management and sharing here. For projects generating genomic data derived from research participants, investigators should consider costs associated with complying with the NIH and NHGRI GDS Policy expectations (e.g., obtaining samples with explicit informed consent for future research use and broad data sharing, implementing processes to seek new consent from study participants, etc.).

PEDP implementation costs: Applicants may include allowable costs associated with PEDP implementation (as outlined in the Grants Policy Statement section 7: https://grants.nih.gov/grants/policy/nihgps/html5/section_7/7.1_general.htm).

R&R Subaward Budget

All instructions in the SF424 (R&R) Application Guide must be followed.

PHS 398 Cover Page Supplement

All instructions in the SF424 (R&R) Application Guide must be followed.

PHS 398 Research Plan

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions:

Resource Sharing Plan:

Individuals are required to comply with the instructions for the Resource Sharing Plans as provided in the SF424 (R&R) Application Guide.

Other Plan(s):

Note: Effective for due dates on or after January 25, 2023, the Data Management and Sharing Plan will be attached in the Other Plan(s) attachment in FORMS-H application forms packages.

All instructions in the SF424 (R&R) Application Guide must be followed, with the following additional instructions:

- All applicants planning research (funded or conducted in whole or in part by NIH) that results in the

generation of scientific data are required to comply with the instructions for the Data Management and Sharing Plan. All applications, regardless of the amount of direct costs requested for any one year, must address a Data Management and Sharing Plan.

NHGRI recognizes that data sharing is essential to advance genomic research and will expect recipients to comply with the NIH Data Management and Sharing Policy and NIH Genomic Data Sharing Policy. Please follow the NIH guidance on writing a Data Management and Sharing (DMS) Plan here, and ensure the Plan is in alignment with NHGRI's data sharing expectations, which are summarized at genome.gov/data-sharing.

Per NOT-HG-21-022, NHGRI expects applications awarded under this NOFO to share comprehensive metadata and phenotypic, clinical, and environmental exposure data associated with the study; use standardized data collection protocols and survey instruments for capturing data, as appropriate; and use standardized notation for metadata (e.g. controlled vocabularies or ontologies) to enable the harmonization of datasets for secondary research analyses.

To ensure that maximal scientific benefit is derived from this significant public investment, this funding opportunity aims to advance and accelerate research by supporting rapid sharing of the resulting data with the broad scientific community for research use, through submission of all data to the NHGRI Genomic Data Science Analysis, Visualization, and Informatics Lab-space (AnVIL), through submission of variant interpretations to ClinVar, and through publication in the scientific literature. Controlled-access data submitted to the AnVIL will be accessible by the scientific community upon review and approval of a data access request by the NHGRI Data Access Committee. Raw and processed data and metadata, protocols, software code and algorithms, tools, analyses, and methods derived from them, publications, and other products of the consortium are expected to be made available through the AnVIL; other public web sites, as relevant; and/or publication in the scientific literature.

Where human biological samples will be studied, they are expected to have been obtained using a documented informed consent process that allows for future research use and broad data sharing (NOT-HG-20-011). If new human biospecimens will be collected, or if clinical application is included in the application, the consent process should be described at a high level in the Research Plan and detailed in the Human Subjects Section.

NHGRI strongly encourages studies that propose to derive genomic data from human specimens and cell lines to obtain participant consent either for general research use through controlled access or for unrestricted access. Similarly, consent language should avoid both restrictions on the types of users who may access the data and restrictions that add additional requirements to the access request process. NHGRI acknowledges that this will not always be possible or appropriate. In addition, individual participants who do not consent to future research use or broad sharing of their data (i.e., submission of their data to a publicly accessible data repository) may still participate in the primary study if consistent with study design. Additional guidance on informed consent can be found in the NHGRI Informed Consent Resource.

Applicants are encouraged to get feedback from the communities in which the research will be performed regarding plans for how individual level data resulting from the research projects will be shared with the scientific community for research purposes. Feedback and recommendations for data access, protection of participant and patient privacy and confidentiality, and management of health information should be integrated into the project's Data Management and Sharing Plan. Note that any project receiving NIH funding that collects or uses identifiable, sensitive information is automatically deemed issued a Certificate of Confidentiality (CoC).

Appendix:

Only limited Appendix materials are allowed. Follow all instructions for the Appendix as described in the SF424 (R&R) Application Guide.

- No publications or other material, with the exception of blank questionnaires or blank surveys, may be included in the Appendix.

PHS Human Subjects and Clinical Trials Information

When involving human subjects research, clinical research, and/or NIH-defined clinical trials (and when applicable, clinical trials research experience) follow all instructions for the PHS Human Subjects and Clinical Trials Information form in the SF424 (R&R) Application Guide, with the following additional instructions:

If you answered Yes to the question Are Human Subjects Involved? on the R&R Other Project Information form, you must include at least one human subjects study record using the **Study Record: PHS Human Subjects and Clinical Trials Information** form or **Delayed Onset Study** record.

Study Record: PHS Human Subjects and Clinical Trials Information

All instructions in the SF424 (R&R) Application Guide must be followed.

Delayed Onset Study

Note: Delayed onset does NOT apply to a study that can be described but will not start immediately (i.e., delayed start). All instructions in the SF424 (R&R) Application Guide must be followed.

PHS Assignment Request Form

All instructions in the SF424 (R&R) Application Guide must be followed.

3. Unique Entity Identifier and System for Award Management (SAM)

See Part 1. Section III.1 for information regarding the requirement for obtaining a unique entity identifier and for completing and maintaining active registrations in System for Award Management (SAM), NATO Commercial and Government Entity (NCAGE) Code (if applicable), eRA Commons, and Grants.gov

4. Submission Dates and Times

Part I. Overview Information contains information about Key Dates and times. Applicants are encouraged to submit applications before the due date to ensure they have time to make any application corrections that might be necessary for successful submission. When a submission date falls on a weekend or Federal holiday, the application deadline is automatically extended to the next business day.

Organizations must submit applications to Grants.gov (the online portal to find and apply for grants across all Federal agencies). Applicants must then complete the submission process by tracking the status of the application in the eRA Commons, NIH's electronic system for grants administration. NIH and Grants.gov systems check the application against many of the application instructions upon submission. Errors must be corrected and a changed/corrected application must be submitted to Grants.gov on or before the application due date and time. If a Changed/Corrected application is submitted after the deadline, the application will be considered late. Applications that miss the due date and time are subjected to the NIH Policy on Late Application Submission.

Applicants are responsible for viewing their application before the due date in the eRA Commons to ensure accurate and successful submission.

Information on the submission process and a definition of on-time submission are provided in the SF424 (R&R) Application Guide.

5. Intergovernmental Review (E.O. 12372)

This initiative is not subject to intergovernmental review.

6. Funding Restrictions

All NIH awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement.

Pre-award costs are allowable only as described in the NIH Grants Policy Statement.

7. Other Submission Requirements and Information

Applications must be submitted electronically following the instructions described in the SF424 (R&R) Application Guide. Paper applications will not be accepted.

Applicants must complete all required registrations before the application due date. Section III. Eligibility Information contains information about registration.

For assistance with your electronic application or for more information on the electronic submission process, visit How to Apply Application Guide. If you encounter a system issue beyond your control that threatens your ability to complete the submission process on-time, you must follow the Dealing with System Issues guidance. For assistance with application submission, contact the Application Submission Contacts in Section VII.

Important reminders:

All PD(s)/PI(s) must include their eRA Commons ID in the Credential field of the Senior/Key Person Profile form**.** Failure to register in the Commons and to include a valid PD/PI Commons ID in the credential field will prevent the successful submission of an electronic application to NIH. See Section III of this NOFO for information on registration requirements.

The applicant organization must ensure that the unique entity identifier provided on the application is the same identifier used in the organization's profile in the eRA Commons and for the System for Award Management. Additional information may be found in the SF424 (R&R) Application Guide.

See more tips for avoiding common errors.

Upon receipt, applications will be evaluated for completeness and compliance with application instructions by the Center for Scientific Review and responsiveness by NHGRI, NIH. Applications that are incomplete, non-compliant and/or nonresponsive will not be reviewed.

Applications must include a PEDP submitted as Other Project Information as an attachment. Applications that fail to include a PEDP will be considered incomplete and will be withdrawn before review.

Post Submission Materials

Applicants are required to follow the instructions for post-submission materials, as described in the policy

Section V. Application Review Information

1. Criteria

Only the review criteria described below will be considered in the review process. Applications submitted to the NIH in support of the NIH mission are evaluated for scientific and technical merit through the NIH peer review system.

For this particular announcement, note the following:

> The R21 exploratory/developmental grant supports investigation of novel scientific ideas or new model systems, tools, or technologies that have the potential for significant impact on biomedical or biobehavioral research. An R21 grant application need not have extensive background material or preliminary information. Accordingly, reviewers will emphasize the conceptual framework, the level of innovation, and the potential to significantly advance our knowledge or understanding. Appropriate justification for the proposed work can be provided through literature citations, data from other sources, or, when available, from investigator-generated data. Preliminary data are not required for R21 applications; however, they may be included if available.

A proposed Clinical Trial application may include study design, methods, and intervention that are not by themselves innovative but address important questions or unmet needs. Additionally, the results of the clinical trial may indicate that further clinical development of the intervention is unwarranted or lead to new avenues of scientific investigation.

Overall Impact

Reviewers will provide an overall impact score to reflect their assessment of the likelihood for the project to exert a sustained,

powerful influence on the research field(s) involved, in consideration of the following review criteria and additional review criteria (as applicable for the project proposed).

Scored Review Criteria

Reviewers will consider each of the review criteria below in the determination of scientific merit and give a separate score for each. An application does not need to be strong in all categories to be judged likely to have major scientific impact. For example, a project that by its nature is not innovative may be essential to advance a field.

Significance

Does the project address an important problem or a critical barrier to progress in the field? Is the prior research that serves as the key support for the proposed project rigorous? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?

In addition, for applications involving clinical trials

Are the scientific rationale and need for a clinical trial to test the proposed hypothesis or intervention well supported by preliminary data, clinical and/or preclinical studies, or information in the literature or knowledge of biological mechanisms? For trials focusing on clinical or public health endpoints, is this clinical trial necessary for testing the safety, efficacy or effectiveness of an intervention that could lead to a change in clinical practice, community behaviors or health care policy? For trials focusing on mechanistic, behavioral, physiological, biochemical, or other biomedical endpoints, is this trial needed to advance scientific understanding?

Specific to this RFA: How does the proposed project have the potential to improve genomics-related health equity? To what extent do the efforts described in the Plan for Enhancing Diverse Perspectives further the significance of the project?

Investigator(s)

Are the PD(s)/PI(s), collaborators, and other researchers well suited to the project? If Early Stage Investigators or those in the early stages of independent careers, do they have appropriate experience and training? If established, have they demonstrated an ongoing record of accomplishments that have advanced their field(s)? If the project is collaborative or multi-PD/PI, do the investigators have complementary and integrated expertise; are their leadership approach, governance and organizational structure appropriate for the project?

In addition, for applications involving clinical trials

With regard to the proposed leadership for the project, do the PD/PI(s) and key personnel have the expertise, experience, and ability to organize, manage and implement the proposed clinical trial and meet milestones and timelines? Do they have appropriate expertise in study coordination, data management and statistics? For a multicenter trial, is the organizational structure appropriate and does the application identify a core of potential center investigators and staffing for a coordinating center?

Specific to this RFA: To what extent will the efforts described in the Plan for Enhancing Diverse Perspectives strengthen and enhance the expertise required for the project?

Innovation

Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense? Is a refinement, improvement, or new application of theoretical concepts, approaches or methodologies, instrumentation, or interventions proposed?

In addition, for applications involving clinical trials

Does the design/research plan include innovative elements, as appropriate, that enhance its sensitivity, potential for information or potential to advance scientific knowledge or clinical practice?

Specific to this RFA: To what extent will the efforts described in the Plan for Enhancing Diverse Perspectives meaningfully contribute to innovation?

Approach

Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Have the investigators included plans to address weaknesses in the rigor of prior research that serves as the key support for the proposed project? Have the investigators presented strategies to ensure a robust and unbiased approach, as appropriate for the work proposed? Are potential problems, alternative strategies, and benchmarks for success presented? If the project is in the early stages of development, will the strategy establish feasibility and will particularly risky aspects be managed? Have the investigators presented adequate plans to address relevant biological variables, such as sex, for studies in vertebrate animals or human subjects?

If the project involves human subjects and/or NIH-defined clinical research, are the plans to address 1) the protection of human subjects from research risks, and 2) inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion or exclusion of individuals of all ages (including children and older adults), justified in terms of the scientific goals and research strategy proposed?

In addition, for applications involving clinical trials

Does the application adequately address the following, if applicable

Study Design

Is the study design justified and appropriate to address primary and secondary outcome variable(s)/endpoints that will be clear, informative and relevant to the hypothesis being tested? Is the scientific rationale/premise of the study based on previously well-designed preclinical and/or clinical research? Given the methods used to assign participants and deliver interventions, is the study design adequately powered to answer the research question(s), test the proposed hypothesis/hypotheses, and provide interpretable results? Is the trial appropriately designed to conduct the research efficiently? Are the study populations (size, gender, age, demographic group), proposed intervention arms/dose, and duration of the trial, appropriate and well justified?

Are potential ethical issues adequately addressed? Is the process for obtaining informed consent or assent appropriate? Is the eligible population available? Are the plans for recruitment outreach, enrollment, retention, handling dropouts, missed visits, and losses to follow-up appropriate to ensure robust data collection? Are the planned recruitment timelines feasible and is the plan to monitor accrual adequate? Has the need for randomization (or not), masking (if appropriate), controls, and inclusion/exclusion criteria been addressed? Are differences addressed, if applicable, in the intervention effect due to sex/gender and race/ethnicity?

Are the plans to standardize, assure quality of, and monitor adherence to, the trial protocol and data collection or distribution guidelines appropriate? Is there a plan to obtain required study agent(s)? Does the application propose to use existing available resources, as applicable?

Data Management and Statistical Analysis

Are planned analyses and statistical approach appropriate for the proposed study design and methods used to assign participants and deliver interventions? Are the procedures for data management and quality control of data adequate at clinical site(s) or at center laboratories, as applicable? Have the methods for standardization of procedures for data management to assess the effect of the intervention and quality control been addressed? Is there a plan to complete data analysis within the proposed period of the award?

Specific to this RFA: Are the timeline and milestones associated with the Plan for Enhancing Diverse Perspectives well-developed and feasible?

Environment

Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources available to the investigators adequate for the project proposed? Will the project benefit from unique features of the scientific environment, subject populations, or collaborative arrangements?

In addition, for applications involving clinical trials

If proposed, are the administrative, data coordinating, enrollment and laboratory/testing centers, appropriate for the trial proposed?

Does the application adequately address the capability and ability to conduct the trial at the proposed site(s) or centers? Are the plans to add or drop enrollment centers, as needed, appropriate?

If international site(s) is/are proposed, does the application adequately address the complexity of executing the clinical trial?

If multi-sites/centers, is there evidence of the ability of the individual site or center to: (1) enroll the proposed numbers; (2) adhere to the protocol; (3) collect and transmit data in an accurate and timely fashion; and, (4) operate within the proposed organizational structure?

Specific to this RFA: To what extent will features of the environment described in the Plan for Enhancing Diverse Perspectives (e.g., collaborative arrangements, geographic diversity, institutional support) contribute to the success of the project?

Additional Review Criteria

As applicable for the project proposed, reviewers will evaluate the following additional items while determining scientific and technical merit, and in providing an overall impact score, but will not give separate scores for these items.

Study Timeline

Specific to applications involving clinical trials

Is the study timeline described in detail, taking into account start-up activities, the anticipated rate of enrollment, and planned follow-up assessment? Is the projected timeline feasible and well justified? Does the project incorporate efficiencies and utilize existing resources (e.g., CTSAs, practice-based research networks, electronic medical records, administrative database, or patient registries) to increase the efficiency of participant enrollment and data collection, as appropriate?

Are potential challenges and corresponding solutions discussed (e.g., strategies that can be implemented in the event of enrollment shortfalls)?

Protections for Human Subjects

For research that involves human subjects but does not involve one of the categories of research that are exempt under 45 CFR Part 46, the committee will evaluate the justification for involvement of human subjects and the proposed protections from research risk relating to their participation according to the following five review criteria: 1) risk to subjects, 2) adequacy of protection against risks, 3) potential benefits to the subjects and others, 4) importance of the knowledge to be gained, and 5) data and safety monitoring for clinical trials.

For research that involves human subjects and meets the criteria for one or more of the categories of research that are exempt under 45 CFR Part 46, the committee will evaluate: 1) the justification for the exemption, 2) human subjects involvement and characteristics, and 3) sources of materials. For additional information on review of the Human Subjects section, please refer to the Guidelines for the Review of Human Subjects.

Inclusion of Women, Minorities, and Individuals Across the Lifespan

When the proposed project involves human subjects and/or NIH-defined clinical research, the committee will evaluate the proposed plans for the inclusion (or exclusion) of individuals on the basis of sex/gender, race, and ethnicity, as well as the inclusion (or exclusion) of individuals of all ages (including children and older adults) to determine if it is justified in terms of the scientific goals and research strategy proposed. For additional information on review of the Inclusion section, please refer to the Guidelines for the Review of Inclusion in Clinical Research.

Vertebrate Animals

The committee will evaluate the involvement of live vertebrate animals as part of the scientific assessment according to

the following criteria: (1) description of proposed procedures involving animals, including species, strains, ages, sex, and total number to be used; (2) justifications for the use of animals versus alternative models and for the appropriateness of the species proposed; (3) interventions to minimize discomfort, distress, pain and injury; and (4) justification for euthanasia method if NOT consistent with the AVMA Guidelines for the Euthanasia of Animals. Reviewers will assess the use of chimpanzees as they would any other application proposing the use of vertebrate animals. For additional information on review of the Vertebrate Animals section, please refer to the Worksheet for Review of the Vertebrate Animals Section.

Biohazards

Reviewers will assess whether materials or procedures proposed are potentially hazardous to research personnel and/or the environment, and if needed, determine whether adequate protection is proposed.

Resubmissions

For Resubmissions, the committee will evaluate the application as now presented, taking into consideration the responses to comments from the previous scientific review group and changes made to the project.

Renewals

Not applicable.

Revisions

Not applicable.

Additional Review Considerations

As applicable for the project proposed, reviewers will consider each of the following items, but will not give scores for these items, and should not consider them in providing an overall impact score.

Applications from Foreign Organizations

Reviewers will assess whether the project presents special opportunities for furthering research programs through the use of unusual talent, resources, populations, or environmental conditions that exist in other countries and either are not readily available in the United States or augment existing U.S. resources.

N/A for this RFA.

Select Agent Research

Reviewers will assess the information provided in this section of the application, including 1) the Select Agent(s) to be used in the proposed research, 2) the registration status of all entities where Select Agent(s) will be used, 3) the procedures that will be used to monitor possession use and transfer of Select Agent(s), and 4) plans for appropriate biosafety, biocontainment, and security of the Select Agent(s).

Resource Sharing Plans

Reviewers will comment on whether the Resource Sharing Plan(s) (e.g., Sharing Model Organisms) or the rationale for not sharing the resources, is reasonable.

Authentication of Key Biological and/or Chemical Resources

For projects involving key biological and/or chemical resources, reviewers will comment on the brief plans proposed for identifying and ensuring the validity of those resources.

Budget and Period of Support

Reviewers will consider whether the budget and the requested period of support are fully justified and reasonable in relation to the proposed research.

2. Review and Selection Process

Applications will be evaluated for scientific and technical merit by (an) appropriate Scientific Review Group(s)

convened by NHGRI, NIH, in accordance with NIH peer review policy and procedures, using the stated review criteria. Assignment to a Scientific Review Group will be shown in the eRA Commons.

As part of the scientific peer review, all applications will receive a written critique.

Applications may undergo a selection process in which only those applications deemed to have the highest scientific and technical merit (generally the top half of applications under review) will be discussed and assigned an overall impact score.

Appeals of initial peer review will not be accepted for applications submitted in response to this FOA.

Applications will be assigned on the basis of established PHS referral guidelines to the appropriate NIH Institute or Center. Applications will compete for available funds with all other recommended applications submitted in response to this NOFO. Following initial peer review, recommended applications will receive a second level of review by the National Advisory Council for Human Genome Research. The following will be considered in making funding decisions:

- Scientific and technical merit of the proposed project as determined by scientific peer review.
- Availability of funds.
- Relevance of the proposed project, including the PEDP, to program priorities.

3. Anticipated Announcement and Award Dates

After the peer review of the application is completed, the PD/PI will be able to access his or her Summary Statement (written critique) via the eRA Commons. Refer to Part 1 for dates for peer review, advisory council review, and earliest start date.

Information regarding the disposition of applications is available in the NIH Grants Policy Statement.

Section VI. Award Administration Information

1. Award Notices

If the application is under consideration for funding, NIH will request "just-in-time" information from the applicant as described in the NIH Grants Policy Statement.

A formal notification in the form of a Notice of Award (NoA) will be provided to the applicant organization for successful applications. The NoA signed by the grants management officer is the authorizing document and will be sent via email to the recipient's business official.

Recipients must comply with any funding restrictions described in Section IV.6. Funding Restrictions. Selection of an application for award is not an authorization to begin performance. Any costs incurred before receipt of the NoA are at the recipient's risk. These costs may be reimbursed only to the extent considered allowable pre-award costs.

Any application awarded in response to this NOFO will be subject to terms and conditions found on the Award Conditions and Information for NIH Grants website. This includes any recent legislation and policy applicable to awards that is highlighted on this website.

Individual awards are based on the application submitted to, and as approved by, the NIH and are subject to the IC-specific terms and conditions identified in the NoA.

ClinicalTrials.gov: If an award provides for one or more clinical trials. By law (Title VIII, Section 801 of Public Law 110-85), the "responsible party" must register and submit results information for certain applicable clinical trials on the ClinicalTrials.gov Protocol Registration and Results System Information Website (https://register.clinicaltrials.gov). NIH expects registration and results reporting of all trials whether required under the law or not. For more information, see https://grants.nih.gov/policy/clinical-trials/reporting/index.htm

Institutional Review Board or Independent Ethics Committee Approval: Recipient institutions must ensure that all protocols are reviewed by their IRB or IEC. To help ensure the safety of participants enrolled in NIH-funded studies, the recipient must provide NIH copies of documents related to all major changes in the status of ongoing protocols.

Data and Safety Monitoring Requirements: The NIH policy for data and safety monitoring requires oversight and monitoring of all NIH-conducted or -supported human biomedical and behavioral intervention studies (clinical trials) to ensure the safety of participants and the validity and integrity of the data. Further information concerning these requirements is found at http://grants.nih.gov/grants/policy/hs/data_safety.htm and in the application instructions (SF424 (R&R) and PHS 398).

Investigational New Drug or Investigational Device Exemption Requirements: Consistent with federal regulations, clinical research projects involving the use of investigational therapeutics, vaccines, or other medical interventions (including licensed products and devices for a purpose other than that for which they were licensed) in humans under a research protocol must be performed under a Food and Drug Administration (FDA) investigational new drug (IND) or investigational device exemption (IDE).

2. Administrative and National Policy Requirements

All NIH grant and cooperative agreement awards include the NIH Grants Policy Statement as part of the NoA. For these terms of award, see the NIH Grants Policy Statement Part II: Terms and Conditions of NIH Grant Awards, Subpart A: General and Part II: Terms and Conditions of NIH Grant Awards, Subpart B: Terms and Conditions for Specific Types of Grants, Recipients, and Activities, including of note, but not limited to:

- Federal wide Research Terms and Conditions
- Prohibition on Certain Telecommunications and Video Surveillance Services or Equipment
- Acknowledgment of Federal Funding

If a recipient is successful and receives a Notice of Award, in accepting the award, the recipient agrees that any activities under the award are subject to all provisions currently in effect or implemented during the period of the award, other Department regulations and policies in effect at the time of the award, and applicable statutory provisions.

Should the applicant organization successfully compete for an award, recipients of federal financial assistance (FFA) from HHS will be required to complete an HHS Assurance of Compliance form (HHS 690) in which the recipient agrees, as a term and condition of receiving the grant, to administer their programs in compliance with federal civil rights laws that prohibit discrimination on the basis of race, color, national origin, age, sex and disability, and agreeing to comply with federal conscience laws, where applicable. This includes ensuring that entities take meaningful steps to provide meaningful access to persons with limited English proficiency; and ensuring effective communication with persons with disabilities. Where applicable, Title XI and Section 1557 prohibit discrimination on the basis of sexual orientation, and gender identity. The HHS Office for Civil Rights provides guidance on complying with civil rights laws enforced by HHS. Please see https://www.hhs.gov/civil-rights/for-providers/provider-obligations/index.html and https://www.hhs.gov/civil-rights/for-individuals/nondiscrimination/index.html

HHS recognizes that research projects are often limited in scope for many reasons that are nondiscriminatory, such as the principal investigator's scientific interest, funding limitations, recruitment requirements, and other considerations. Thus, criteria in research protocols that target or exclude certain populations are warranted where nondiscriminatory justifications establish that such criteria are appropriate with respect to the health or safety of the subjects, the scientific study design, or the purpose of the research. For additional guidance regarding how the provisions apply to NIH grant programs, please contact the Scientific/Research Contact that is identified in Section VII under Agency Contacts of this NOFO.

- Recipients of FFA must ensure that their programs are accessible to persons with limited English proficiency. For guidance on meeting the legal obligation to take reasonable steps to ensure meaningful access to programs or activities by limited English proficient individuals see https://www.hhs.gov/civil-rights/for-individuals/special-topics/limited-english-proficiency/fact-sheet-guidance/index.html and https://www.lep.gov.
- For information on an institution's specific legal obligations for serving qualified individuals with disabilities, including providing program access, reasonable modifications, and to provide effective communication, see https://www.hhs.gov/civil-rights/for-individuals/disability/index.html.

HHS funded health and education programs must be administered in an environment free of sexual harassment, see https://www.hhs.gov/civil-rights/for-individuals/sex-discrimination/index.html. For information about NIH's commitment to supporting a safe and respectful work environment, who to contact with questions or concerns, and what NIH's expectations are for institutions and the individuals supported on NIH-funded awards, please see https://grants.nih.gov/grants/policy/harassment.htm.

- For guidance on administering programs in compliance with applicable federal religious nondiscrimination laws and applicable federal conscience protection and associated anti-discrimination laws see https://www.hhs.gov/conscience/conscience-protections/index.html and https://www.hhs.gov/conscience/religious-freedom/index.html.

Please contact the HHS Office for Civil Rights for more information about obligations and prohibitions under federal civil rights laws at https://www.hhs.gov/ocr/about-us/contact-us/index.html or call 1-800-368-1019 or TDD 1-800-537-7697.

In accordance with the statutory provisions contained in Section 872 of the Duncan Hunter National Defense Authorization Act of Fiscal Year 2009 (Public Law 110-417), NIH awards will be subject to the Federal Awardee Performance and Integrity Information System (FAPIIS) requirements. FAPIIS requires Federal award making officials to review and consider information about an applicant in the designated integrity and performance system (currently FAPIIS) prior to making an award. An applicant, at its option, may review information in the designated integrity and performance systems accessible through FAPIIS and comment on any information about itself that a federal agency previously entered and is currently in FAPIIS. The Federal awarding agency will consider any comments by the applicant, in addition to other information in FAPIIS, in making a judgement about the applicant's integrity, business ethics, and record of performance under Federal awards when completing the review of risk posed by applicants as described in 45 CFR Part 75.205 and 2 CFR Part 200.206 Federal awarding agency review of risk posed by applicants. This provision will apply to all NIH grants and cooperative agreements except fellowships.

Cooperative Agreement Terms and Conditions of Award

Not Applicable

3. Data Management and Sharing

Note: The NIH Policy for Data Management and Sharing is effective for due dates on or after January 25, 2023.

Consistent with the NIH Policy for Data Management and Sharing, when data management and sharing is applicable to the award, recipients will be required to adhere to the Data Management and Sharing requirements as outlined in the NIH Grants Policy Statement. Upon the approval of a Data Management and Sharing Plan, it is required for recipients to implement the plan as described.

4. Reporting

When multiple years are involved, recipients will be required to submit the Research Performance Progress Report (RPPR) annually and financial statements as required in the NIH Grants Policy Statement.

A final RPPR, invention statement, and the expenditure data portion of the Federal Financial Report are required for closeout of an award, as described in the NIH Grants Policy Statement. NIH NOFOs outline intended research goals and objectives. Post award, NIH will review and measure performance based on the details and outcomes that are shared within the RPPR, as described at 45 CFR Part 75.301 and 2 CFR Part 200.301.

The Federal Funding Accountability and Transparency Act of 2006 (Transparency Act), includes a requirement for recipients of Federal grants to report information about first-tier subawards and executive compensation under Federal assistance awards issued in FY2011 or later. All recipients of applicable NIH grants and cooperative agreements are required to report to the Federal Subaward Reporting System (FSRS) available at www.fsrs.gov on all subawards over the threshold. See the NIH Grants Policy Statement for additional information on this reporting requirement.

In accordance with the regulatory requirements provided at 45 CFR 75.113 and 2 CFR Part 200.113 and Appendix XII to 45 CFR Part 75 and 2 CFR Part 200, recipients that have currently active Federal grants, cooperative agreements, and procurement contracts from all Federal awarding agencies with a cumulative total value greater than $10,000,000 for any period of time during the period of performance of a Federal award, must report and maintain the currency of information reported in the System for Award Management (SAM) about civil, criminal, and administrative proceedings in connection with the award or performance of a Federal award that reached final disposition within the most recent five-year period. The recipient must also make semiannual disclosures regarding such proceedings. Proceedings information will be made publicly available in the designated integrity and performance system (currently FAPIIS). This is a statutory requirement under section 872 of Public Law 110-417, as amended (41 U.S.C. 2313). As required by section 3010 of Public Law 111-212, all information posted in the designated integrity and performance system on or after April 15, 2011, except past performance reviews required for Federal procurement contracts, will be publicly available. Full reporting requirements and procedures are found in Appendix XII to 45 CFR Part 75 and 2 CFR Part 200 Award Term and Condition for Recipient Integrity and Performance Matters.

Section VII. Agency Contacts

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

Application Submission Contacts

eRA Service Desk (Questions regarding ASSIST, eRA Commons, application errors and warnings, documenting system problems that threaten submission by the due date, and post-submission issues)

Finding Help Online: https://www.era.nih.gov/need-help (preferred method of contact)
Telephone: 301-402-7469 or 866-504-9552 (Toll Free)

General Grants Information (Questions regarding application instructions, application processes, and NIH grant resources)
Email: GrantsInfo@nih.gov (preferred method of contact)
Telephone: 301-637-3015

Grants.gov Customer Support (Questions regarding Grants.gov registration and Workspace)
Contact Center Telephone: 800-518-4726
Email: support@grants.gov

Scientific/Research Contact(s)

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Section VIII. Other Information

Recently issued trans-NIH policy notices may affect your application submission. A full list of policy notices published by NIH is provided in the NIH Guide for Grants and Contracts. All awards are subject to the terms and conditions, cost principles, and other considerations described in the NIH Grants Policy Statement.

Authority and Regulations

Awards are made under the authorization of Sections 301 and 405 of the Public Health Service Act as amended (42 USC 241 and 284) and under Federal Regulations 42 CFR Part 52 and 45 CFR Part 75 and 2 CFR Part 200.

Weekly TOC for this Announcement
NIH Funding Opportunities and Notices

National Institutes of Health
Office of Extramural Research
Department of Health
and Human Services (HHS)
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Files.