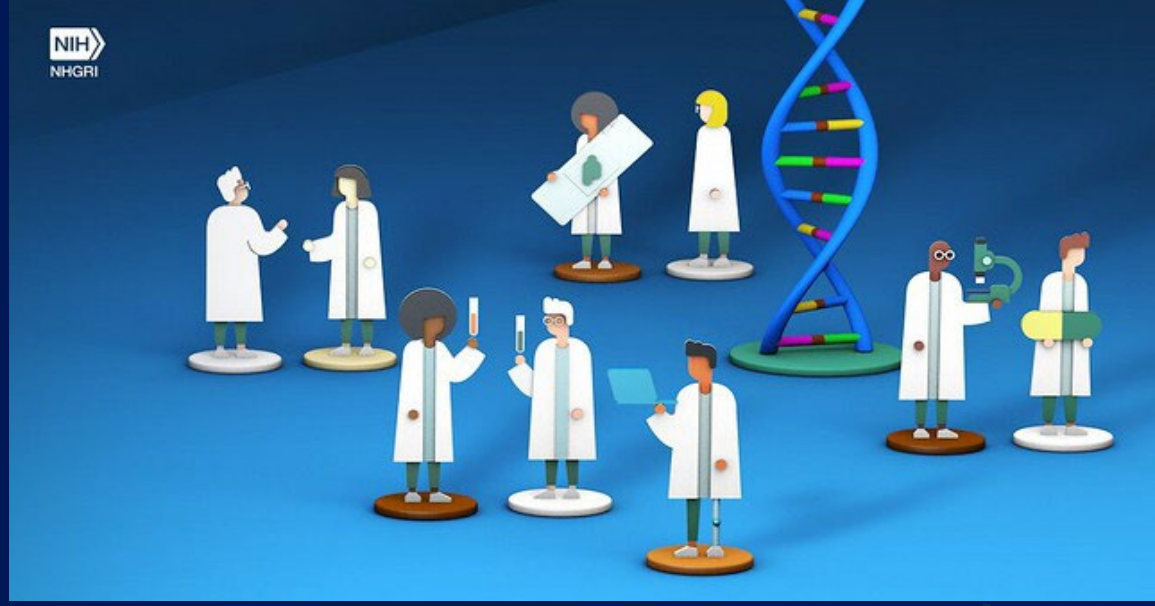


Diversity Centers for Genome Research

RFA-HG-22-026 U54

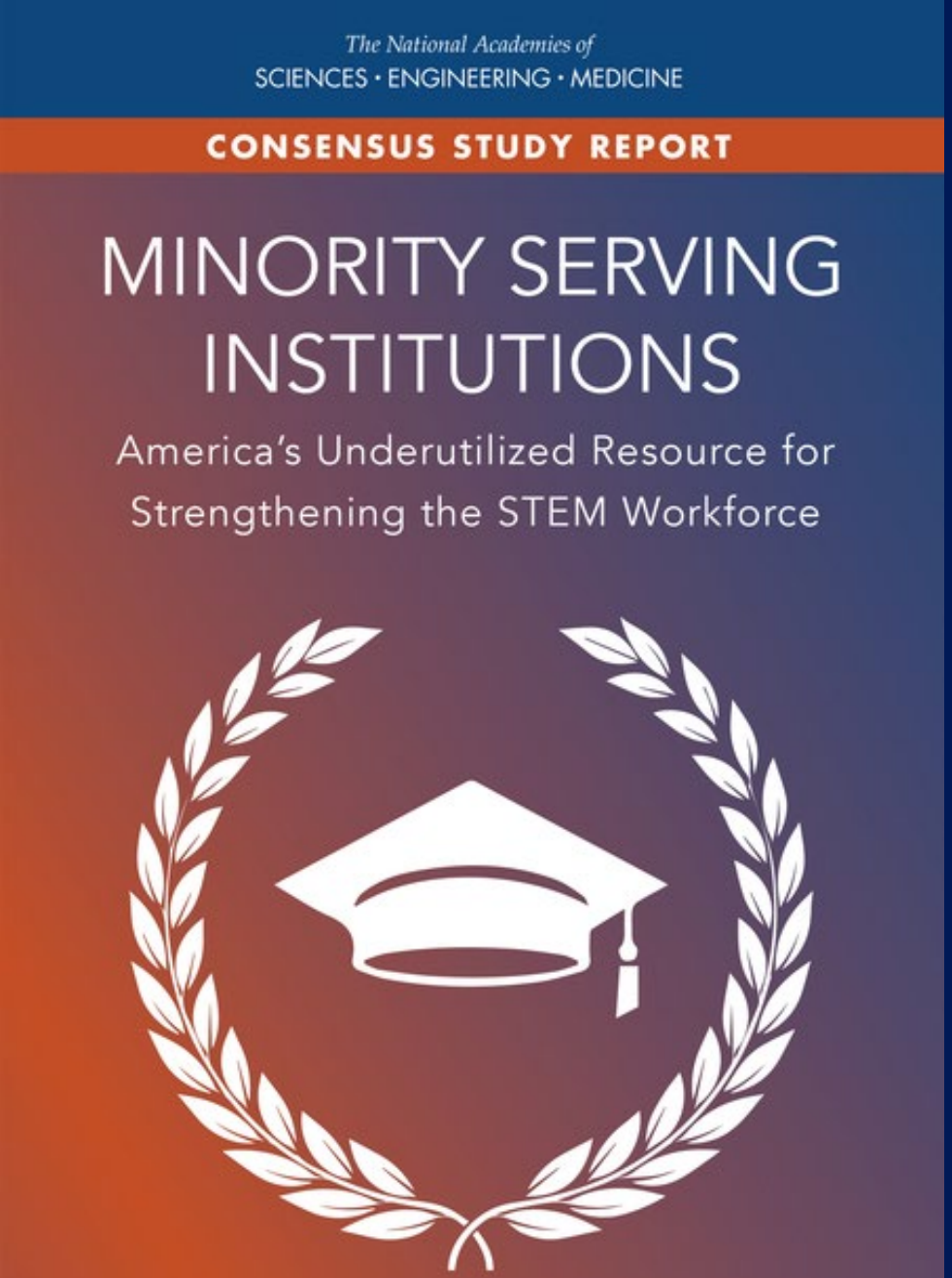
RFA-HG-22-027 UG3/UH3

National Human Genome Research Institute

The Forefront of Genomics®

Webinar Agenda

1. Goals and objectives of the FOAs
2. Eligibility criteria
3. Overview of RFA-HG-22-026 (U54) FOA
4. Overview of RFA-HG-22-027 (UG3/UH3) FOA
5. Application submission process
6. Questions and Answers



Background

- Genomics workforce is not a reflection of the US population
- Diverse investigators bring innovative ideas and increase objectivity in research
- MSIs award 25% of all science PhDs, MDs, and health profession degrees to Black and Hispanic students each year

Goals and Objectives

- Enhance diversity in genomics research by establishing Centers at MSIs with a mission to serve historically underrepresented populations to carry out innovative, state-of-the-art genomic research studies
- Foster genomic research career development and enhancement for trainees and investigators at all career levels
- Enhance the genomic infrastructure, computational, analytical and ELSI research capability
- Establish sustainable partnerships and disseminate resources and findings

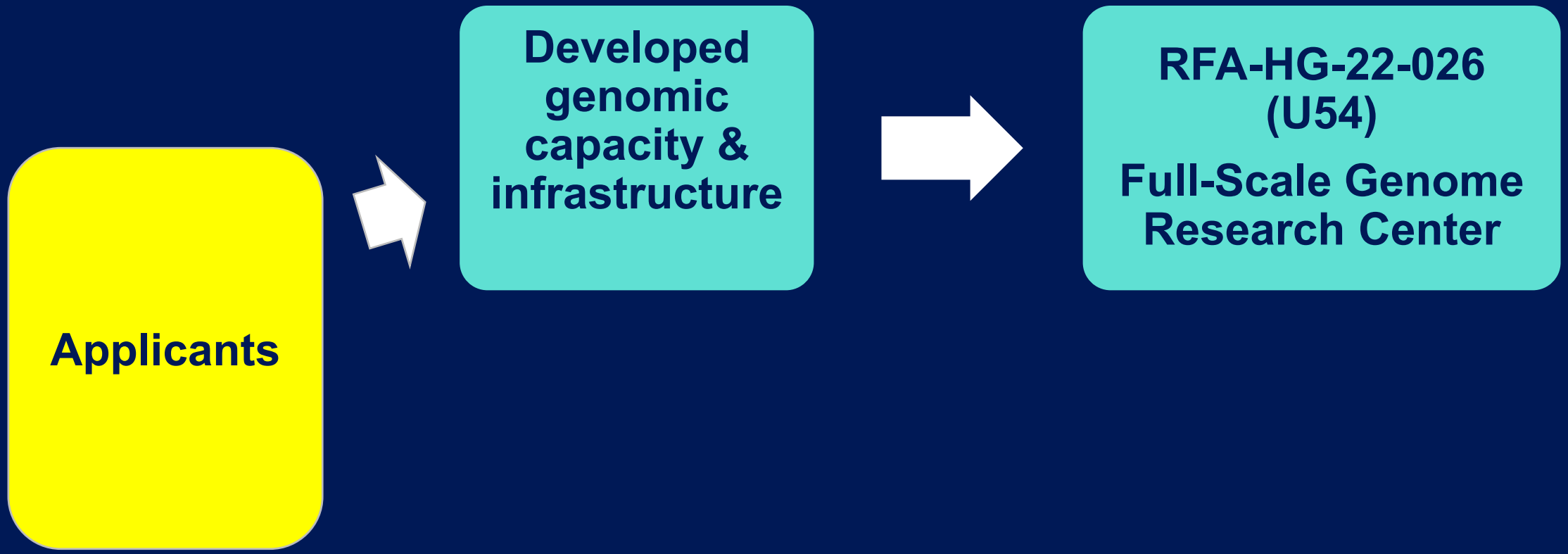
Eligibility Criteria

- Applicant institution must be a domestic institution located in the United States and its territories which:
  - Has received an average of less than $50 million per year in NIH support and less than $25 million per year of R01 total cost of NIH support for the past three fiscal years
  - Awards doctorate degrees in the health professions or the sciences related to health and
  - Has a documented historical and current mission to educate students from any of the populations that have been identified as underrepresented in biomedical research as defined by the National Science Foundation NSF (http://www.nsf.gov/statistics/wmpd/)

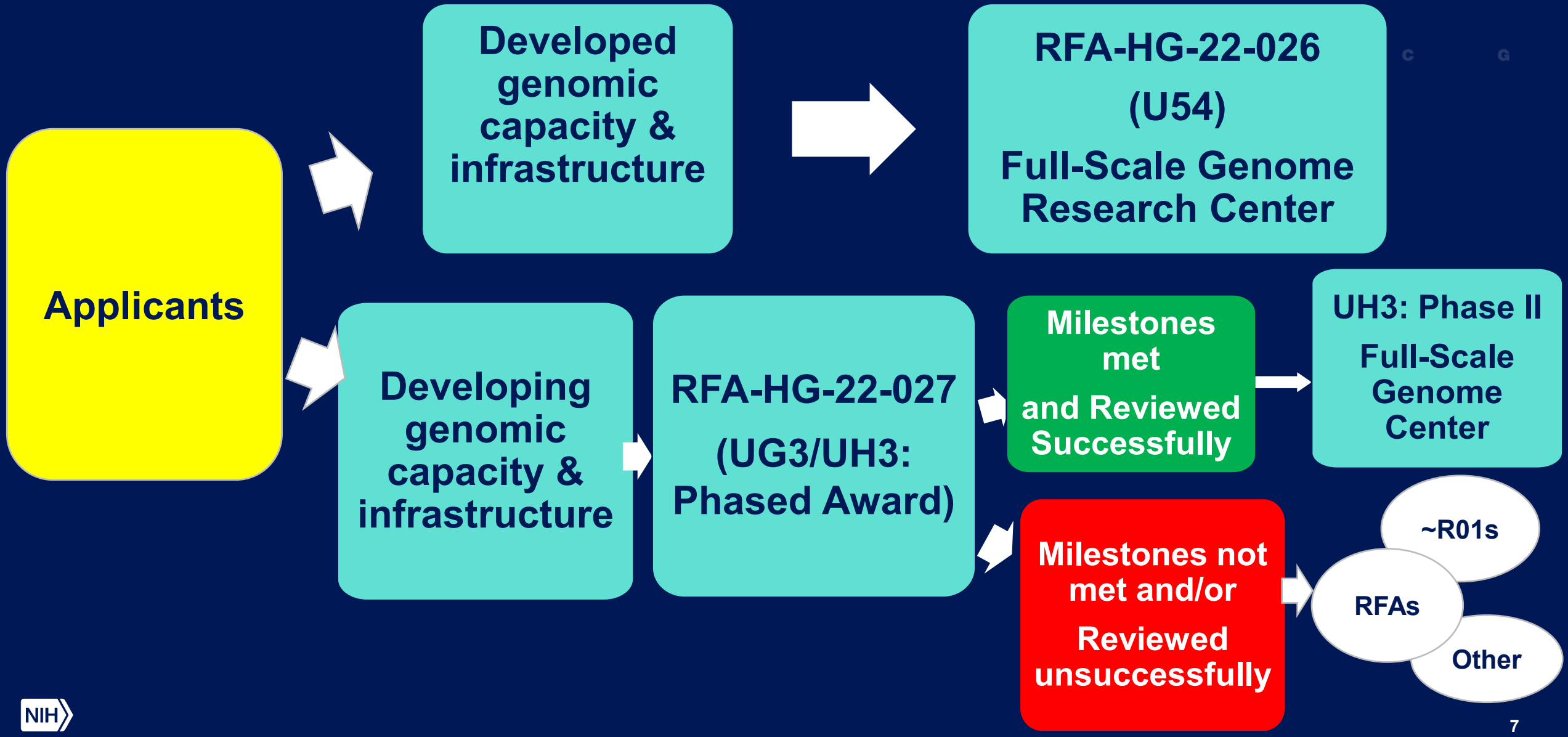
    or has a documented record of:

    1) recruiting, training and/or educating, and graduating underrepresented students as defined by NSF , which has resulted in increasing the institution's contribution to the national pool of graduates from underrepresented backgrounds who pursue biomedical research careers and,
    2) for institutions that deliver health care services, providing clinical services to medically underserved communities

Diversity Genome Research Centers



Diversity Centers for Genome Research



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RFA-HG-22-026 (U54)

- Budget limit: $1.4 Million direct costs/year for up to 5 years
- Full-Scale Genome Center includes:
  - Administrative Core
  - Genomic Workforce Development Core
  - Community Engagement Core
  - 2-3 interrelated, innovative genomic research projects that address critical issues in genomics
  - External advisory committee and internal advisory committee, if warranted
  - Evaluation plan

Administrative Core

- Provide overall management of administrative, fiscal, education, training, and scientific activities
- Foster synergy with other ongoing genomic career development activities at the institution
- Develop and monitor core and project milestones including evaluating each proposed activity/core

Genomic Workforce Development Core

- Provide genomic research experiences, genomic career development opportunities and genomic education enhancement activities to students, fellows, and/or investigators in order to develop and/or enhance expertise in genomics
- Develop creative approaches for recruitment and retention of individuals from diverse backgrounds
- Take advantage of unique aspects of the research projects, investigators' talents, and other institutional resources

Community Engagement Core

- Facilitate engagement of the community all aspects of the genomic research including but not limited to:

  - Development of materials for genomic education and training
  - Research design
  - Analyses
  - Outcome assessment
  - Data sharing
  - Translation and dissemination of study results

Research Projects

- The Center should be structured around 2-3 research projects that address one or more critical issues in genomic technology and methods development; genome structure; genome function; genomics of disease; use and impact of genomic information in clinical care; ethical, legal, and social implications of genomics research; genomics and health equity; data science and/or computational genomics
- Centers should bring together different areas of expertise and approaches to provide synergy and allow each project to accomplish more than it would be able to on its own

RFA-HG-22-027 (UG3/UH3)

UG3 (Phase I)

- Budget limit: $300,000 direct costs/year for 1 – 3 years
- Activities:
  - Enhance plans for the organization, implementation and evaluation of a full-scale genomic research center including plans for providing research experiences, courses, and career development opportunities
  - Recruit and retain relevant faculty and trainees
  - Perform training on software and equipment
  - Test and implement protocols and procedures
  - Identify and provide solutions for any logistical problems that can be foreseen
- Encourage collaboration with full-scale Centers

NIH NHGRI

Criteria for Transition to Phase II (UH3)

- Identification and commitment of faculty and staff for Center cores and proposed projects
- Completion of training for all planned software and equipment
- Assessment of mechanisms proposed for regular communication and coordination among investigators
- EAC review and approval of all procedures and protocols
- Successful achievement of the defined milestones for Phase I
- Potential for establishing a full-scale Genome Research Center
- Encouraging results of genomic capacity building activities in Phase I
- Appropriateness of the research and equipment space
- The availability of funds

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Transition to Phase II (UH3)

- Budget limit: $2 million in total costs/year for 4-5 years
- Successful awardees will apply plans for a full-scale Center including the refinement of proposed approaches and tools that occurred during Phase I
- Phase II – Centers will carry-out activities of a full-scale center including all components listed for the U54 Full-Scale Center

*Total length of UG3/UH3 award cannot exceed 7 years

Components of both FOAs

Evaluation Plan

- Each Center must have an evaluation plan
- Metrics should include:
  - Increased collaboration
  - Development of additional research projects, analyses, and tools
  - Increased submission of genomic applications
  - Publications and presentations
  - Enhancement of capacity for conducting genomics research
  - Institutional commitment and collaborations
  - Number of students, trainees, and investigators from other disciplines exposed to genomic research experiences
  - Trajectories toward successful genomic research careers
  - Progress of the research projects

Advisory Committees

- Each Center must have an External Advisory Committee
- Consist of at least 6 members from the target communities and external scientific advisors with relevant expertise
- Responsibilities:
  - Evaluating the progress of the genomic research center
  - Evaluating protocols and procedures
  - Assessing recruitment of faculty and trainees and plans for capacity building
  - Assessing the solutions for logistical problems
  - Reviewing analysis plans and outcomes
- The Center may also have an Internal Advisory Committee with members not directly supported by the Center award

Funds for Equipment

- Grant will provide up to $500,000 in direct costs for genomic technology and equipment in addition to the overall cost cap, only in year one of the award period
  - For the UG3/UH3 applications, genomic technology and equipment funding will occur in the first year of Phase II (UH3 phase)
- Resources include but are not limited to laboratory equipment, supplies, statistical and bioinformatic software including computational equipment and cloud computing resources

Collaborations

- 70% of the budget will need to stay with applicant institution
- Required within the Research Center and encouraged between Centers in the consortium and other NHGRI Consortia
- Must provide the complete capacity needed to carry out the genomic research projects and the didactic and practicum experiences
-

Plan for Enhancing Diverse Perspectives

- Applicants must include a summary of strategies to advance the scientific and technical merit of the Center through expanded inclusivity
- Plan should explain how enhancing diverse perspectives is viewed and supported throughout the application

Plan for Enhancing Diverse Perspectives Examples

- Plan to enhance recruitment of women and individuals from groups traditionally underrepresented in the biomedical research workforce
- Proposed monitoring activities to identify and measure PEDP progress benchmarks
- Plan to utilize the project infrastructure to support career-enhancing research opportunities for diverse junior, early- and mid-career researchers
- Plan to develop transdisciplinary collaboration(s) that require unique expertise and/or solicit diverse perspectives to address research question(s)
- Outreach and planned engagement activities to enhance recruitment of individuals from diverse groups as research participants including those from underrepresented backgrounds

Consortium meetings

- Centers are expected to meet as a consortium with other awardees twice per year to present research progress, discuss challenges, promote collaboration amongst Centers and share best practices
- Centers encouraged to attend other research consortia and network meetings to increase collaborative opportunities.

Institutes Research Interests

NIH National Human Genome Research Institute

The Forefront of Genomics®

NHGRI Interests

- Projects may include applications to a particular disease area, but Centers should demonstrate that the methods and knowledge generated are generalizable
- Studies focused on disease etiology or outcomes should examine the role of both genomic and non-genomic contributors to human health and disease
- If focus in clinical genomics, it should improve assessment and/or outcomes in all populations including underserved populations and/or include technological or computational methods for the production or analysis of diverse data sets
- All applications, regardless of focus, should explain how generalizable, broadly useful, and transformative the findings and approaches will be to the field of genomics

NIMH Interests

NIMH is interested in research programs examining the contribution of genetic and genomic factors to risk and resilience in psychiatric disorders in ancestrally diverse minority health and health disparity populations

NIMH Interests

- Discovery of genetic variants associated with serious mental illness in ancestrally diverse populations
- Interaction of genetic and familial risk with environmental factors that may influence development of serious mental illness, including genetic risk for suicide
- Deep clinical characterization of cohorts from diverse populations including a minimum set of Common Data Elements
- ELSI research to address ethical, legal and social issues for individuals from underserved communities that are underrepresented in psychiatric genetics research

NIMHD Interests

- The mission of NIMHD is to lead scientific research to improve minority health and reduce health disparities
- NIMHD encourages genomics projects that use approaches encompassing multiple domains of influence (e.g., biological, behavioral, sociocultural, environmental, physical environment, health system) and multiple levels of influence (e.g., individual, interpersonal, family, peer group, community, societal) to understand and address health disparities

Data Sharing

The NIH Genomic Data Sharing (GDS) Policy

- To comply with the GDS policy, NIH expects that investigators and institutions:
  - Develop and provide a plan for sharing genomic data
  - Provide an Institutional Certification form before the notice of award, if working with human data
  - Share genomic data in a timely manner to an appropriate repository
  - Responsibly use controlled-access data
  - Appropriately cite controlled-access data in publications and presentations

NHGRI GDS Expectations

- SCALE
  - No minimum participant threshold
- CONSENT
  - NHGRI expects explicit consent for future research use and broad sharing (i.e., explicit consent for submission of genomic data to an NIH-designated data repository or via an approved Alternative GDS Plan)
  - Whenever possible, studies should seek consent for General Research Uses of participant data instead of placing disease-specific or other data use limitations on future use of the data. Similarly, whenever possible, there should be no restrictions on the types of users who may access the data (i.e., allow academic, commercial, and government researchers to use the data)
- TIMING
  - Accelerated submission/release timeline for non-human data (aligned with the human data sharing timeline)

Diversity Centers for Genome Research FOA GDS Expectation

- Work with communities when developing the plan for sharing genomic data

"Centers are encouraged to get feedback from the communities in which the research will be performed regarding plans for sharing individual level data resulting from the research projects 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 Center's data sharing plan."

Learn more (links)

- NIH's website:
  - http://sharing.nih.gov
- NHGRI's website:
  - https://www.genome.gov/about-nhgri/Policies-Guidance/Genomic-Data-Sharing
  - Includes FAQs & Key Documents

Review Criteria

- Pay close attention to the review criteria as you develop your application
- Content of the application will be judged against this criteria

Application Submissions

- **Please schedule meeting(s) to discuss potential application and proposed projects with program director(s)**
- Ensure all required components are included
- Give as much detail as possible
- First Application Due Date: December 6, 2022

  Don’t wait until the due date to submit your application
- Try again
  - If not successful on the first try, RESUBMIT
  - Additional receipt dates: June 23, 2023 and June 24, 2024

Successful Diversity Centers for Genome Research

- Carry out innovative genomic research studies
- Enhance institutional genomic research capacity
- Enable investigators to become successful in obtaining competitive extramural support for genomic research
- Foster research career development and enhancement for students and investigators
- Enhance the genomic infrastructure, computational and/or analytical capability within their institutions
- Establish sustainable partnerships with relevant stakeholders to increase collaboration
- Disseminate resources and findings

NIH NHGRI

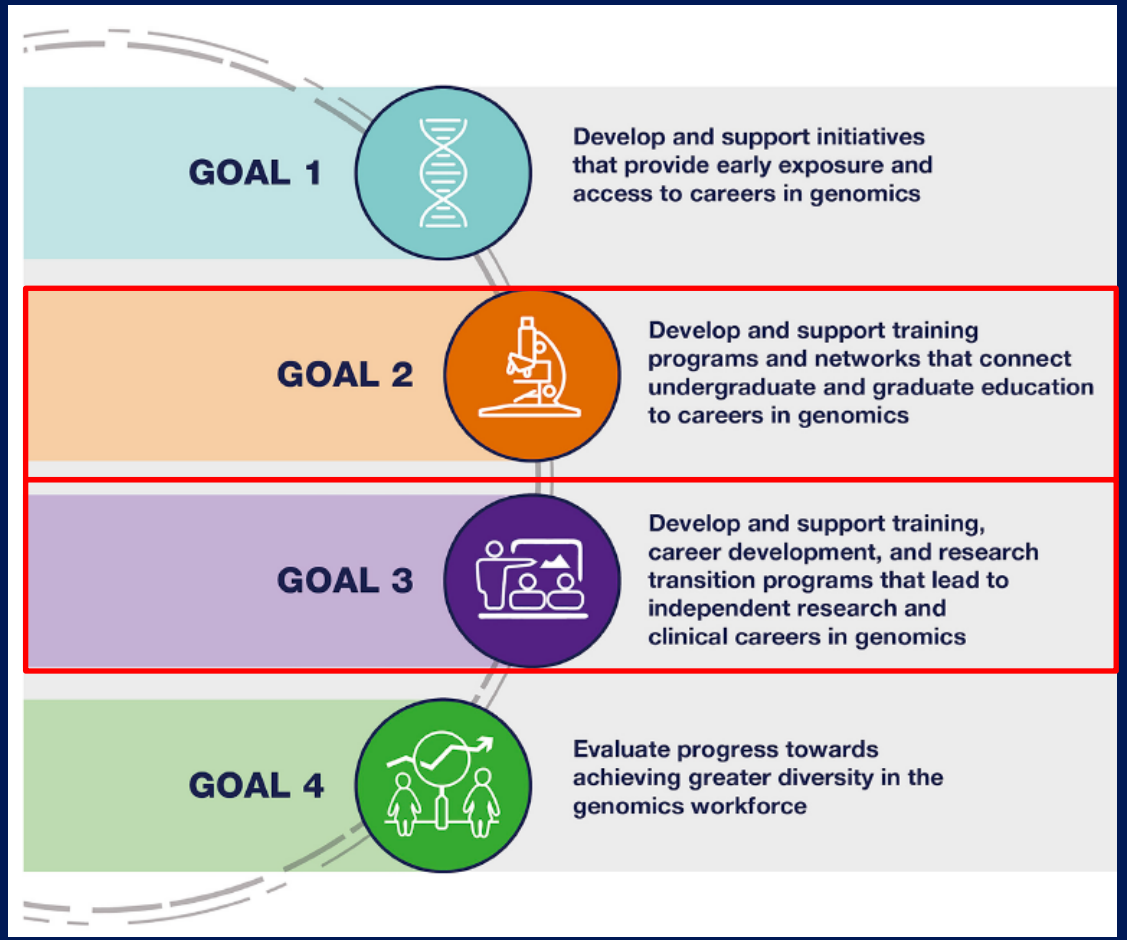
2020 Strategic Vision and Diversity Action Agenda

Box 1

Guiding principles and values for human genomics

- **Maintain an overarching focus on using genomics to understand biology, to enhance knowledge about disease, and to improve human health** — genomics is now foundational across the entire continuum of biomedical research, from deciphering fundamental principles of biology to translating that knowledge into disease prevention and medical advances.
- **Strive for global diversity in all aspects of genomics research, committing to the systematic inclusion of ancestrally diverse and underrepresented individuals in major genomic studies** — attention to diversity in genomics research is both socially just and scientifically essential, which includes meaningful, sustained partnerships with diverse communities in the design and implementation of research studies, the propagation of research findings, and the development and use of new technologies.
- **Maximize the usability of genomics for all members of the public, including the ability to access genomics in healthcare** — engagement, inclusion, and understanding the needs of diverse and medically underserved groups are required to ensure that all members of society benefit equitably from genomic advances, with particular attention given to the equitable use of genomics in healthcare that avoids exacerbating and strives towards reducing health disparities.
- **Champion a diverse genomics workforce** — the promise of genomics cannot be fully achieved without attracting, developing, and retaining a diverse workforce, which includes individuals from groups that are currently underrepresented in the genomics enterprise.
- **Provide a conceptual research framing that consistently examines the role of both genomic and non-genomic contributors to health and disease** — routinely considering the importance of social and environmental factors that influence human health (and the interactions among those components and genomics) will be important for the comprehensive understanding of most human diseases.

- **Promote robust and consistently applied standards in genomics research** — the use of carefully defined standards (for example, those for generating, analysing, storing, and sharing data) has benefited genomics in numerous ways, and this must include appropriate privacy and data-security protections for those participating in genomics research.
- **Embrace the interdisciplinary and team-oriented nature of genomics research** — starting with the Human Genome Project, some of the most challenging genomics endeavours have benefited from the creation and management of large, interdisciplinary research collaborations.
- **Adhere to the highest expectations and requirements related to open science, responsible data sharing, and rigor and reproducibility in genomics research** — the genomics enterprise has a well-respected history of leading in these areas, and that commitment must be built upon and continually reaffirmed.
- **Pursue advances in genomics as part of a vibrant global community of genomics researchers and funders** — the challenges in genomics require the collective energies and creativity of a collaborative international ecosystem that includes partnerships among researchers, funders, and other stakeholders from academia, government, and the commercial sector.



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Thank you for attending

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Questions?