Pre-Application Webinar

RFA-HG-24-026: Building Partnerships and Broadening Perspectives to Advance ELSI Research (BBAER) Program (UM1)

Rene Sterling, PhD, MHA

NHGRI ELSI Research Program

August 28, 2024

Webinar Logistics

- Webinar is being recorded

- Slides are available on webinar event page

- Recording, Q&As, and resource list will be posted within 7-10 days

- The Zoom Chat has been disabled

- You can enter questions in the Zoom Q&A

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Presentation

- Will review key aspects of the Notice of Funding Opportunity (NOFO)

- Will **<u>not</u>** review all NOFO requirements, expectations, recommendations, terms, or policies

Be sure to **read the entire NOFO** before preparing your application

NHGRI Contacts for BBAER Program

Scientific/Research (Program)
Rene Sterling, Ph.D., M.H.A.

Financial/Grants Management
Devon Bumbray-Quarles

Peer Review
Sarah Wheelan, M.D., Ph.D.

Chief Grants Management Officer
Deanna Ingersoll

Agenda

- Background
- Goal, Eligibility, and Elements
- Cooperative Agreements
- Awards & Budget
- Peer Review
- Resources and Q&A

Background
Goal, Eligibility, and Elements
Cooperative Agreements
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What is ELSI?

"Ethical, **l**egal, and **s**ocial implications"

- A lens, perspective, or framework used to assess, examine or evaluate the field of genetics and genomics

- A research program established at NIH in 1990 as part of the U.S. Human Genome Project

ELSI Research

Key tenets:

- Anticipate implications

- Develop and assess policy or societal options

- Evaluate impact or effect of options chosen

A critical area of research that can benefit from:

- Community engagement

- New organizations, scholars, and other partners

- New expertise, perspectives, and approaches

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BBAER Goal

Advance ELSI research by broadening the types of knowledge, skills, experience, expertise, and perspectives brought to bear

Source: Shutterstock

Eligible Applicants

Domestic U.S. organizations that received less than **$30 million** in total NIH funding per year for the past three fiscal years

Eligibility criteria apply to the <u>applicant organization</u>

Applicants may propose partners (organizations or individuals) that do not meet the criteria

Foreign components are allowed

BBAER Elements

A) Vision & Strategic Management

B) Transdisciplinary ELSI Research

C) Relevant Communities & Team-Based Approach

D) ELSI Research Capacity Building

E) ELSI Workforce Development

A) Vision & Strategic Management

- Compelling vision and specific goals (A1)

- Plan for strategic management (A2-A4)
  - Leadership style, management structure, oversight
  - Communication, collaboration, decision-making
  - Monitoring, planning, evaluation

- Plan for sustainability post-BBAER (A5)

B) Transdisciplinary ELSI Research

- **Transdisciplinary** – Integrates knowledge and approaches from different disciplines to generate new frameworks, hypotheses, theories, models, or methods

- **Timely** – Currently interrogated or anticipated at time of application

- **Complex** – Necessitates collaboration across academic disciplines or areas of knowledge

- **Understudied** – Fills gap in knowledge

B) Transdisciplinary ELSI Research

Research Areas (B1)

Genomics in Context

Roles and limitations of genetics and genomics in understanding health

Equity and Justice in Genomics

Define and achieve equity in group, community or population health

Genomics and Identity

How genomics impacts identities and identities impact views on genomics

Genomic Landscape

Use and direction of genomics beyond health

B) Transdisciplinary ELSI Research

Research Projects (B2)

- Can vary in duration and topics

- Two or more academic disciplines or fields of knowledge

- Multiple research approaches

- Optional: Unifying theme

Population Descriptors (B3)

- Used to describe or distinguish people based on perceived or actual differences
    - Race, ethnicity, genealogical ancestry, and genetic ancestry
    - Sex, gender, gender identity, and sexual orientation

Consider phenomena of interest

Name and define

Provide a rationale

Tie to research questions

Describe assumptions or limitations

C) Relevant Communities & Team-Based Approach

Representatives from **relevant communities** as research team members (C1)

Group or groups of people who are:
1. **affiliated** by geographic proximity, special interest, or similar situations, and
2. affected by and have **interest in** the research topics understudy.

C) Relevant Communities & Team-Based Approach

- **Team-Based** Approach (C2)
  - o Substantive and ongoing involvement
  - o Respect and value different types of knowledge
  - o Bidirectional learning
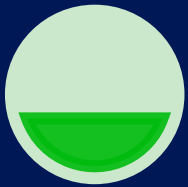 - o Equip and empower team members
  - o Opportunities for benefit sharing

D) Research Capacity Building

- <u>Needs Assessment (D1)</u>

  - Assess resources, capabilities, strengths, opportunities

  - Identify gaps and inform benchmarks

- <u>Capacity Building (D2)</u>

  - Informed by needs assessment

  - Build capacity to establish, enhance, and sustain ELSI research

Capacity building must occur within the applicant organization
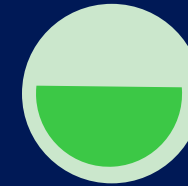
D) Research Capacity Building

Submit with Application

Needs Assessment Plan

- Structured, detailed, and comprehensive plan

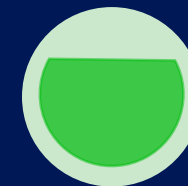- Describe current environment and infrastructure

Overall Approach for Capacity Building

- *NOTE: Plan not required*

Within **12 months** of award

- Implement Needs Assessment Plan

- Submit Needs Assessment Findings

Within **18 months** of award

- Submit Capacity Building Plan

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E) ELSI Workforce Development

Various activities to increase exposure to and experience with ELSI research

- Must include **early career scholars**, such as undergraduates, post-baccalaureates, graduate students, postdoctoral trainees, and/or junior faculty

- **May** include BBAER research team members and other project staff

Background
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Cooperative Agreements
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Peer Review
Resources and Q&A

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Cooperative Agreement

- Substantial NIH programmatic involvement anticipated.

    - To support and stimulate activities by involvement in or working jointly with the recipients in a partnership role.

    - **Not** to assume direction, prime responsibility, or a dominant role.

- Specific terms listed in NOFO

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Awards

- NHGRI intends to commit up to $4,800,000 in FY 2025 to fund up to 4 awards.

- Application budgets are limited to $650,000 direct costs per year for a maximum of 5 years.

- Subawards are limited to 40% of direct costs.

- Budget needs reflect actual needs of the proposed project.

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Budgets

- A single budget is required, with a budget justification delineated by Element.

- Include funds to support all aspects and phases of work.

- Level of Effort:

  - <u>Program Director(s)/Principal Investigators(s)</u> at least 2.4 calendar months. If multiple PDs/PIs, then at least one PI with at least 1.2 calendar months.

  - <u>Element Leaders</u> at least 2.0 calendar months per Element. If multiple Leaders/co-Leaders, then at least one Leader with at least 1.0 calendar month.

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Peer Review

- Peer review by an expert panel convened by NHGRI specifically for BBAER.

- See Section V of NOFO for review criteria, including the standard criteria and the **"*Specific to this NOFO*"** criteria.

- Include sufficient detail in your application to allow reviewers to assess each and every criterion.

- Scores and summary statement provided following review.

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Be sure to review the entire NOFO

RFA-HG-24-026: Building Partnerships and Broadening Perspectives to Advance ELSI Research (BBAER) NOFO Diagram (UM1)

Section I — NOFO Description

Background

Program Goals and Requirements (including Elements)

Section II — Award Info

Funds Available and Anticipated Number of Awards

Award Budget

Section III — Eligibility Info

Eligible Applicants: *Domestic organizations located in the U.S. and its territories that have received less than $30 million per year for the past three fiscal years in total NIH funding*

Section V — Review Information

Review Criteria

Section VII — Agency Contacts

Scientific/Research Contact: *Rene Sterling, NHGRI, rene.sterling@nih.gov*

Section IV: Application and Submission Information

Letter of Intent, Page Limitations

Instructions for Application Submission: *Forms, Attachments, Budget, Subaward budget, Cover Page, Research Plan, Resource Sharing Plan, Data Management and Sharing Plan, Human Subjects, PHS Assignment Request Form for application assignment and review preferences*

Element A: Vision & Strategic Management
Up to 6 pages

- Vision & Goals for BBAER Site
- Approach for Establishing Site
- Collaborators, if any
- Expected Outcomes or Impact
- Leadership & Oversight, including Organizational Charts
- Communication, Collaboration, & Decision-Making
- Planning & Monitoring
- Evaluation & Quality Improvement
- Sustainability

Element B: Research Projects
Up to 12 pages

Research Area:
1. Genomics in Context
2. Equity and Justice in Genomics
3. Genomics & Identity
4. Genomic Landscape

Transdisciplinary ELSI Research Projects

Use of Population Descriptors, if any

Element C: Relevant Communities & Team Approach
Up to 6 pages

Relevant Communities: *Group or groups of people 1) affiliated by geographic proximity, special interest, or similar situations; and 2) affected by and have an interest in proposed research*

Community Experts on Research Teams

Team-Based Approach

Element D: Research Capacity Building
Up to 6 pages

Research Capacity Building Needs Assessment

Research Capacity Building Approach

Element E: Workforce Development
Up to 6 pages

Workforce Development Participants: *Must include early career scholars. May also include research team members and project staff.*

Workforce Development Activities

NOTES: (1) One budget per application with justification broken down by Elements. (2) One set of criterion scores and one overall impact score. (3) Please see **Research Instructions for NIH and Other PHS Agencies** for How to Apply Application Guide

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Element A: Vision & Strategic Management	Element B: Research Projects	Element C: Relevant Communities & Team Approach	Element D: Research Capacity Building	Element E: Workforce Development
Up to 6 pages	Up to 12 pages	Up to 6 pages	Up to 6 pages	Up to 6 pages
Vision & Goals for BBAER Site	Research Area:	Relevant Communities:	Research Capacity Building Needs Assessment	Workforce Development Participants:
Approach for Establishing Site	1. Genomics in Context	*Group or groups of people 1) affiliated by geographic proximity, special interest, or similar situations; and 2) affected by and have an interest in proposed research*		*Must include early career scholars. May also include research team members and project staff.*
Collaborators, if any	2. Equity and Justice in Genomics		Research Capacity Building Approach	
Expected Outcomes or Impact	3. Genomics & Identity			
	4. Genomic Landscape			
Leadership & Oversight, including Organizational Charts				
	Transdisciplinary ELSI Research Projects			
Communication, Collaboration, & Decision-Making				
	Use of Population Descriptors, if any	Community Experts on Research Teams		Workforce Development Activities
Planning & Monitoring				
Evaluation & Quality Improvement		Team-Based Approach		
Sustainability				

Presentation focused on Sections I-III

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Section IV outlines how to prepare your application and all required components. Keep in mind:

- **Letters of Intent to Apply are encouraged**

- **Resource Sharing Plan** *(sharing of <u>research findings and products</u>)* **and Data Management and Sharing Plan** *(management and sharing of <u>scientific data</u>)* **are both required**

Element A: Strategic Management
Up to 6 pages

Vision & Goals for BBAER Site

Approach for Establishing Site

Collaborators, if any

Leadership & Oversight, including Organizational Charts

Communications & Decision-Making

Planning & Monitoring

Evaluation & Quality Improvement

Sustainability

Element B: Community-Engaged Research Projects
Up to 12 pages

Research Area:
1. Genomics in Context
2. Genomics
3. Genomics & Identity
4. Social Impact of Genomics

Community-Engaged Research Projects

Use of Population Descriptors, if any

Element C: Community & Team Approach
Up to 6 pages

Relevant Communities:
Group or groups of people connected by geographic proximity, special interest, or similar situations who are affected by and have an interest in proposed research

Community Experts on Research Teams

Team-Based Approach

Element D: Research Capacity Building
Up to 6 pages

Research Capacity Building Needs Assessment

Research Capacity Building Approach

Element E: Workforce Development
Up to 6 pages

Workforce Development Participants:
Must include early career scholars, research team members and project staff

Workforce Development Activities

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Section IV
outlines what
to include in the
Research Plan
for each
Element.

Specific Aims
page should
cover the entire
project.

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Up to 6 pages	**Up to 12 pages**	**Up to 6 pages**	**Up to 6 pages**	**Up to 6 pages**

Element A:

Vision & Goals for BBAER Site

Approach for Establishing Site

Collaborators, if any

Expected Outcomes or Impact

Leadership & Oversight, including Organizational Charts

Communication, Collaboration, & Decision-Making

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Element B:

Research Area:
1. Genomics in Context
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Transdisciplinary ELSI Research Projects

Use of Population Descriptors, if any

Element C:

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Research Capacity Building Approach

Element E:

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Up to 6 pages	**Up to 12 pages**	**Up to 6 pages**	**Up to 6 pages**	**Up to 6 pages**

Element A:

Vision & Goals for BBAER Site

Approach for Establishing Site

Collaborators, if any

Expected Outcomes or Impact

==Leadership & Oversight, including Organizational Charts==

Communication, Collaboration, & Decision-Making

Planning & Monitoring

Evaluation & Quality Improvement

Sustainability

"Other Attachments" requires a single file with two organizational charts/diagrams

- one chart for applicant organization management and Element Leaders/co-Leaders (leadership chart)

- one chart for all positions, roles, and relationships (BBAER site chart)

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Resources

- **How to Apply (to an NIH grant) – Video Tutorials**
  https://grants.nih.gov/grants/how-to-apply-application-guide/video/index.htm

- **How to Register Your Organization (to apply for NIH grants)**
  https://grants.nih.gov/grants/how-to-apply-application-guide/prepare-to-apply-and-register/register.htm

- **NIH Subaward Requirements: Domestic and Foreign**
  https://grants.nih.gov/learning-center/nih-subaward-requirements

- **Grant Writing for Success**
  https://www.youtube.com/watch?v=xlSinsu7meI

- **The Writing and Uses of Specific Aims**
  https://elsihub.org/video/traineehub-grantsmanship-series-writing-and-uses-specific-aims

KEEP CALM AND START EARLY

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With what types of organizations can an applicant collaborate?

- Applicants may partner with a variety of organizations, groups, communities, or individuals

- Partners do not have to meet application eligibility criteria

- Applicants should choose partners that add value

- If proposed, include letters of support

How can I find an eligible organization to partner with?

What is an appropriate role for organizations that cannot apply but would like to support an eligible organization?

- At the discretion of the applicant

- Should be a discussion between applicant and potential collaborators

- Examples provided in NOFO

How do I budget for capacity building when I am not sure what I need?

- Include your best estimate

- Identify all ***necessary*** and ***reasonable*** costs

- Peer reviewers will assess whether request is justified by proposed aims and approach

Thank you for your interest

Please email me with any questions or ideas you may have

Rene Sterling, PhD, MHA (she/her)

ELSI Research Program, NHGRI

rene.sterling@nih.gov