National Advisory Council for Human Genome Research
Concept Clearance for RFA
February 12, 2024

Building Partnerships and Broadening Perspectives to Advance ELSI Research (BPAER)

Purpose

The National Human Genome Research Institute (NHGRI) proposes a Request for Applications (RFA) to create a new initiative: "Building Partnerships and Broadening Perspectives to Advance ELSI Research" (BPAER). The goal of BPAER is to advance ethical, legal, and societal implications (ELSI) scholarship, enhance ELSI research teams, build ELSI research capacity, and broaden the ELSI workforce. BPAER includes four components: 1) Transdisciplinary ELSI research projects on timely, complex, and understudied topics associated with the advancement of genetics and genomics; 2) Establishment of research teams that include representatives from communities in the general public who are affected by and have an interest in the topic under study (referred to below as "relevant communities") as genuine partners across all phases of the proposed transdisciplinary ELSI research projects; 3) Research capacity building within organizations that are underrepresented in ELSI research; and 4) Workforce development opportunities in ELSI research for undergraduates, post-baccalaureates, graduate students, postdoctoral trainees, and junior faculty (referred to below as "early career scholars"), research project staff, and other members of research teams. Collectively, these four components will broaden the types of knowledge, skills, expertise, experience, and perspectives brought to bear in ELSI research. BPAER also will grow and enhance the pool of competitive applicants for participation in NIH-funded ELSI research.

Background

The increasingly complex and interrelated issues raised by advancing genomics continue to challenge ELSI research. Key tenets from the inception of NHGRI's ELSI Research Program remain relevant and essential today: 1) to anticipate the implications of advances in genomics; 2) to develop and assess policy or societal options for addressing those implications; and 3) to evaluate the impact or effects of options chosen (Juengst 2021). For decades, ELSI scholars have proposed theories, frameworks, guidelines, programmatic approaches, and policy options to prepare for, mitigate, and address current and future issues in genomics.

As applications for new genomic knowledge, data, and technologies multiply, a varied group of relevant communities can help inform and benefit from ELSI research. Representatives from relevant communities are often called upon to serve as human subjects in research but are less frequently involved as partners in the scientific process. Meaningful involvement of relevant communities in the design, conduct, dissemination and translation of ELSI and genomics research could benefit both representatives from relevant communities and ELSI researchers (Ahmed and Palermo 2010, Arumugam et al 2023).

ELSI research can also benefit from the involvement of research organizations that are underrepresented in NHGRI's ELSI Research Program. These research organizations can inspire the use of different theories, approaches, methods, and tools that can add rigor, dimension, and value to ELSI research. They also are part of geographic areas that are not extensively supported by NHGRI's ELSI Research Program, thereby increasing the likelihood of bringing new relevant communities, early career scholars, and research staff into genomics. Supporting the development and strengthening of new partnerships can lead to greater innovation and creativity in how we define, assess, and respond to challenges and

opportunities in genomics. Greater inclusion may improve assessments of whether the promise of genomics is fulfilled and help illuminate the pathway toward greater equity in genomics.

Proposed Scope and Objectives
The BPAER has four required components that collectively are intended to advance ELSI research, including: 1) transdisciplinary ELSI research projects; 2) establishment of research teams with representatives from relevant communities; 3) research capacity building; and 4) workforce development opportunities. Eligible applicants must be domestic organizations that received less than $30 million per year for the past three fiscal years in total NIH funding. In the past, these organizations have not been major recipients of funding for ELSI research and are viable sources of new knowledge, skills, expertise, experience, perspectives, and community connections. BPAER provides an opportunity to bring into the field new research organizations interested in ELSI research and allow them to compete for funding amongst a more similar group of applicants. Organizations that do not meet these criteria are not eligible to apply but may be proposed as collaborators.

Transdisciplinary ELSI Research Projects. BPAER research projects will focus on timely (anticipated or interrogated in the field at time of application), complex (issues that necessitate collaborative exploration by multiple disciplines) and understudied (fill gaps in knowledge) topics associated with the advancement of genetics and genomics, while building on existing scholarship. Projects will address one or more of the following areas:

a) ***Genomics in Context.*** Addresses the roles, strengths and limitations of genetics and genomics in understanding and improving human health, behavior, disease, and other variable traits. Genomic research is expanding beyond the realm of rare disease to phenotypes with multifactorial etiologies. When genomics is a causal factor, it is seldom sufficient to fully explain outcomes.
b) ***Equity and Justice in Genomics.*** Addresses efforts to define and help achieve equity in genomics for individuals, groups, communities, or populations. Inequities arise from the differential experience of benefit or harm from genomic research participation or genomic discoveries. Definitions and interpretations of risk, harm, and benefit are critical to the examination of issues of justice across communities.
c) ***Genomics and Identity.*** Addresses how genetics and genomics impact conceptions of individual, group, or population identities; and how conceived identities may impact perceptions people have of, or experiences people have with, genomic information and technologies. Concepts of identity can influence how genomic information is generated, communicated, interpreted, and used.
d) ***Genomic Landscape.*** Addresses the use and direction of genetics and genomics by a broad range of entities whose mission, scope and impact go beyond health (e.g., direct-to-consumer testing companies, education system, and national security). The interplay, involvement, and influence of various entities within genomics may create, exacerbate, prevent, mitigate, or resolve different ELSI issues.

Research Teams with Representatives from Relevant Communities. BPAER research projects will be led by teams whose knowledge, skills, expertise, experience, and perspectives are collectively integrated and brought to bear across all phases of proposed projects. Research teams will include representatives from relevant communities and employ a team-based approach that achieves or exceeds the following:

- Ensures substantive involvement in all phases of the project.
- Promotes a culture that respects and values different types of knowledge.
- Facilitates bidirectional learning across researchers and relevant communities.
- Ensures communities are equipped and empowered for success in their role.

- Identifies and implements opportunities for benefit sharing.

Research Capacity Building. BPAER will build ELSI research capacity within underrepresented organizations and address the sustainability of its ELSI research efforts. Capacity building plans will be based on needs assessments and designed to develop or enhance research organization or investigator competitiveness, readiness, sustainability, or partnerships. Capacity building efforts may include, but are not limited to:

- Enhancing competitiveness for securing research funding, including process improvement for grant application, award, and administration.
- Enhancing research readiness through grantsmanship support, workshops for grant writing, sharing research ideas to enhance knowledge of field, and related areas.
- Developing sustainable partnerships with other organizations, such as academic institutions, governmental bodies, community-based organizations, or industry.

Workforce Development. BPAER will support workforce development opportunities for early career scholars interested in ELSI research careers; research project staff; and other members of research teams (referred to below as "project workforce"). BPAER will: 1) increase exposure to ELSI research, 2) provide practical experience working in community involved ELSI research projects, and 3) broaden the pool of individuals participating in the ELSI workforce. BPAER sites will engage their project workforce in various stages of the research process. Other activities may include, but are not limited to, seminar series, workshops, skills development, team building, mentorship, and career planning. Specific approaches will align with the needs and strengths of the BPAER site.

BPAER sites will develop an organizational structure and management plan to show how the site will integrate and coordinate the four required components of BPAER. The management plan will also describe how meaningful involvement of relevant community members will be achieved on proposed research teams, and how the applicant and any collaborators will achieve the goals of the project. All BPAER sites will attend annual meetings to discuss progress, outcomes, lessons learned, sustainability, and other pertinent topics.

Relationship to Ongoing Activities

The NHGRI ELSI Research Program supports investigator-initiated research and training through individual and institutional grant mechanisms, a few program-initiated projects, and some research embedded in larger NHGRI research consortia. BPAER integrates some of the most successful components of the Centers for Excellence in ELSI Research (CEER) program (which sunsets in 2024), including the establishment of a research focus, funding for transdisciplinary research, opportunities for career development, and scholarly exchange across sites. BPAER increases NHGRI's ELSI Research Program's focus on community involvement and adds capacity building efforts to bring genomics to new places. BPAER also supports NHGRI's workforce diversity efforts with support for programming across career stages and research staff. Awardees will collaborate as appropriate with the Center for ELSI Resources and Analysis (CERA) on dissemination, resource sharing, and enhancing accessibility. The NHGRI ELSI Research Program will facilitate opportunities for BPAER to engage with NIH-funded projects focused on community involvement (e.g., AIM-AHEAD and CEAL) and capacity building (e.g., Diversity Centers for Genome Research), as appropriate.

Mechanism of Support: A single RFA using an UM1 (Research Project with Complex Structure, Cooperative Agreement) is anticipated to enable four related components and substantial programmatic involvement. Multiple receipt dates are anticipated.

Anticipated Funds: $650,000 direct costs with a project period up to 5 years. Up to 6 active awards in total.