

National Advisory Council for Human Genome Research
Concept Clearance for RFA
February 13, 2023
Center for ELSI Resources and Analysis (CERA)

Purpose

The Ethical, Legal and Social Implications (ELSI) Research Program of the National Human Genome Research Institute (NHGRI) proposes to issue a Request for Applications (RFA) for the renewal of the Center for ELSI Resources and Analysis (CERA). Building on work completed during the initial funding period, the proposed Center will: 1) provide ELSI researchers with an established and stable platform to share ELSI research products related to genomics; 2) curate and synthesize ELSI research; and 3) facilitate new research collaborations and uptake of ELSI research. Through this work, CERA will help ensure researcher collaboration across disciplines and meaningful involvement of other stakeholders in addressing and disseminating research on new and persistent ELSI topics in genetics and genomics.

Background

Over the last 32 years, the NHGRI ELSI Research Program has funded research addressing a broad array of advances in genomic science and medicine. Research supported by the program is carried out using a wide variety of research methods and approaches, resulting in publications in more than 400 different journals spanning dozens of disciplines and topics. There is no single society or conference that defines the field, nor a single research search engine that covers its scholarship. The heterogeneity of the field is considered a key strength of the program; however, it also poses several challenges. For example, researchers, educators, health practitioners and policy makers often find it challenging to locate, synthesize and act upon ELSI research. Investigators may duplicate efforts or miss opportunities to build on prior work. The effectiveness of regulations, policies or practice guidelines related to genomics might be improved if the evidence-base provided by ELSI research is adequately considered. As the exploration, translation and use of large-scale genomics grows across biomedicine and outside of the health sector, those not actively engaged with the ELSI research community may be less familiar with the range of implications tied to this growth. Ensuring ELSI research is easily found, clearly summarized, and broadly accessible will help mitigate harm and maximize benefit as genomic knowledge, data and technologies grow.

The CERA established in 2019 set out to address these issues by providing ELSI researchers with an established and stable platform to share ELSI research products, including data collection instruments, analytical techniques, study materials, research findings, publications, and other study materials (excluding ELSI data); curate and synthesize ELSI research; and convene a broad set of researchers and other stakeholders to develop a more synergistic and integrated ELSI research community. In November 2020, CERA launched [ELSIhub](#) as an online platform whose key features include searchable databases of publications, research tools, live and archived seminars, and other resources; curated literature collections on foundational and emerging topics; and trainee resources and networking opportunities.

Research Scope and Objectives

This concept proposes to renew the CERA program via an open competition Request for Applications (RFA). This concept is designed to continue and build upon the key functions of

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CERA will also innovate content and expand the reach of the resource. CERA will focus on the ELSI of advances in genomic science and medicine, which is the established focus of the ELSI Research Program. All CERA activities should reflect the interests, needs and perspectives of the broader ELSI research community and other stakeholders, as appropriate.

CERA will provide an established and stable platform for researchers to share ELSI research products. CERA will collect, index, store, and make publicly available ELSI research products. In addition, the CERA will fully develop and maintain a structured and searchable central database of ELSI scholarship. CERA will collaborate with the NHGRI to identify, prioritize, and incentivize the sharing of a broad array of ELSI research products. To avoid duplicating resource-intensive tasks underway elsewhere, CERA will not serve as a repository for ELSI research data and will not be responsible for data curation, storage, or sharing. Rather, CERA will collect and organize information on where and how to access ELSI research data, metadata and the corresponding ELSI research products and present this information in a searchable and easily accessible format.

CERA will curate and synthesize ELSI research. It will plan and facilitate broad overviews of ELSI scholarship through meta-analysis, literature review and other methods. CERA will also develop curated resources on foundational and emerging topics. The processes used to select topics, curate information, and develop and disseminate resources will be fully transparent and allow for input from ELSI researchers and other stakeholders. To accomplish this, CERA will consult members of the broader ELSI research community and other relevant experts as part of this curation process.

CERA will facilitate new research collaborations and increase uptake of ELSI research. These dual goals will be accomplished by convening ELSI researchers and other stakeholders and conducting outreach and dissemination activities. To increase rigor, reach and effectiveness, collaborations should include researchers and other stakeholders from a broad range of disciplines, professional backgrounds, and lived experiences. Examples of activities to spur new collaborations could include facilitating special journal issues, holding meetings that generate new scholarship or policy analysis, developing a webinar series, supporting community-based or community-driven discussions, or organizing ELSI panels and presentations at a wide range of conferences. CERA will also seek to increase uptake of ELSI products through dissemination, outreach and translation activities that connect ELSI researchers and their findings to a wide range of stakeholders who might find them useful. Activities coordinated by CERA should reflect the interests, needs and perspectives of its intended users.

CERA will develop innovative strategies to: (a) encourage and incentivize broader stakeholder participation in CERA's work (b) facilitate engagement and collaboration among researchers examining ELSI, including those who self-identify as ELSI researchers and those who do not, (c) ensure that a wide variety of stakeholders directly and indirectly involved in genomics are aware of ELSI research that can be utilized in their work, and (d) inform researchers interested in ELSI research about the expanding genomic landscape. These activities should include efforts aimed at different career stages, including students and trainees interested in ELSI research and trainees in basic and clinical science whose work might involve ELSI considerations. To build and improve upon current efforts, CERA will conduct ongoing usability testing and needs assessments of both current users and relevant potential users. The CERA will propose methods and approaches for assessing uptake and use of all major components. All resources, tools and products developed by the CERA will be portable and easily transferred if needed.

Applicants will include a Plan for Enhancing Diverse Perspectives. This plan will describe how the applicant plans to foster diversity, inclusivity, and accessibility both within the project

team and across the CERA user community. Approaches should consider how diverse perspectives advance CERA goals and are integral to equity and inclusion in the work CERA performs. Examples could include significant involvement of investigators from diverse backgrounds, including groups historically underrepresented in research; engagement with different types of institutions and organizations; training and mentoring opportunities encouraging participation of people from diverse lived experiences and career stages; and multidisciplinary collaborations that require and include unique expertise and diverse perspectives. The Plan for Enhancing Diverse Perspectives should include integration and involvement across all stages of the project and all project goals including needs assessment, planning, implementation, and evaluation. Applicants will also propose how they will ensure that resources and events are accessible to a wide variety of potential users and how they will evaluate these strategies.

Regular input on CERA activities will be provided by an External Scientific Panel with diverse expertise including quantitative and qualitative research methods, training, outreach, engagement strategies, data management, analysis, and dissemination. The External Scientific Panel will provide guidance on all CERA activities and ensure that milestones are achieved, and the needs of the ELSI community are considered in an unbiased manner.

Relationship to Ongoing Activities

The ELSI Research Program supports both investigator-initiated and program-initiated activities. These include the [ELSI Regular Research \(R01\)](#), [Developmental/Exploratory Research \(R21\)](#), and [Small Research \(R03\)](#) grant program announcements and training of new ELSI scholars through several mechanisms. The ELSI program also supports research embedded in larger clinical sequencing programs and in basic genomic sciences programs in collaboration with the Division of Genomic Medicine and the Division of Genome Sciences.

When collecting and organizing information on where and how to access ELSI research data, metadata, and corresponding data collection tools, CERA will collaborate with the NHGRI Analysis, Visualization, and Informatics Lab-space (AnVIL). CERA may collaborate with additional NHGRI programs as appropriate and will provide a central resource of ELSI tools, products, and expertise that could be consulted by other NHGRI programs. CERA will increase the availability and visibility of ELSI products and resources to relevant NIH programs as well as other US-based and international genomics efforts and serve as a source of expertise for the larger research and policy communities, as appropriate.

Mechanism of Support

This renewal of [RFA-HG-18-008](#) Center for ELSI Resources and Analysis is anticipated to use the U24 mechanism of support. The planned duration of support is up to 5 years starting in FY24.

Funds Anticipated

NHGRI anticipates supporting a single award for up to \$6M direct costs over 5 years. It is anticipated that no single year's direct costs will exceed \$1.5M. Co-funding will be sought from other Institutes and Centers interested in ELSI research.