

CONCEPT CLEARANCE

CENTERS OF EXCELLENCE IN ETHICAL, LEGAL, AND SOCIAL IMPLICATIONS (ELSI) RESEARCH (CEERs)

PURPOSE

The Ethical, Legal, and Social Implications (ELSI) Research Program of the National Human Genome Research Institute (NHGRI) proposes to reissue a Request for Applications (RFA) to support the development or continuation of Centers of Excellence in ELSI Research (CEERs).

BACKGROUND

The CEER program was established in FY 2003 in response to recommendations made during the 2002-2003 NHGRI planning process. The Program is designed to support the creation of transdisciplinary teams at institutions across the country that can help to integrate ELSI and genomic research, enable more effective translation of ELSI research findings to inform policy and practice, and support the development of a diverse cadre of new ELSI investigators.

Since the beginning of the program in 2003, a total of 11 Full Centers and 8 Exploratory Centers have been funded. Currently, 6 CEERs are being supported with a total budget of \$6.1 million, representing approximately 33% of the projected FY 2017 ELSI 5% budgetary set aside.

The CEER Program has been highly productive to date. The Centers' transdisciplinary teams have produced hundreds of peer-reviewed publications, books and book chapters. CEER investigators also have written numerous policy briefs, have been consulted on the development of federal and state legislation, have written *amicus* briefs for legal cases, and have been called on to provide expert testimony to the Congress, state legislatures, NRC & IOM committees, and HHS Advisory Committees (often serving as members or chairs of these committees). The CEERs have also had considerable success in integrating genomic and ELSI research. For example, CEER investigators currently serve as principal investigators, co-investigators or consultants on a number of genomic and genetic research studies—including those in the NHGRI Clinical Sequencing Exploratory Research (CSER) Consortium, the Electronic Medical Records and Genomics (eMERGE) Network, and the Newborn Sequencing In Genomic Medicine and Public Health (NSIGHT) Program. In addition, CEERs have been very successful leveraging their CEER experiences to pursue and obtain other funding to broaden and deepen their research, policy and education activities.

One of the Program's major achievements has been the cultivation of the next generation of ELSI researchers through the support of undergraduate, graduate, postdoctoral and junior faculty students and fellows from diverse backgrounds and from a wide variety of disciplines (e.g. law, religious studies, philosophy, bioethics, epidemiology, inorganic chemistry, genetics, sociology, anthropology). Many of these individuals have successfully made the transition to tenure track positions and a number have become principal investigators on their own research grants.

The CEER RFA has been reissued four times, most recently in FY 2015, when a number of changes were implemented regarding the funding mechanism, duration, total budget and training component of CEER applications. These changes are reflected in the current proposed RFA.

RESEARCH SCOPE AND OBJECTIVES

The primary objective of the CEER program is to support the development of sustainable transdisciplinary research centers with the expertise and flexibility to: 1) anticipate, conduct research on, and respond rapidly to a range of ELSI issues related to emerging genome technologies and the increasing availability and use of genomic information; 2) facilitate the translation and dissemination of research findings to maximize their relevance to the development of policies and practices; and 3) contribute to the education and career advancement of the next generation of ELSI investigators.

In order to enhance the focus and cohesiveness within each CEER, and to decrease the risk that the activities of any given CEER will become too diffuse, each Center application is expected to identify a clearly defined and highly significant topic area, or set of closely related topics, as the focus of its research, policy and training activities. While it is expected that potential applicants will identify a tightly focused area of research and provide a detailed plan for how they will pursue this research, the research may take the form of either a single highly integrated trans-disciplinary project or a small number of tightly interwoven projects that incorporate the full spectrum of ELSI research disciplines and methodologies, from data-generating qualitative and quantitative studies to legal and normative analyses, and other analytical or conceptual research methodologies.

To enhance the ability of the CEER program to keep pace with the rapid changes in genomic science, a decision was made in the FY 2015 RFA to limit the duration of CEER grants to four-years, with the possibility of a single renewal, for a maximum total funding period of eight years. This is a modification from the original CEER RFAs, which provided for initial awards of five years and the possibility of renewal for an additional five years, for a total of ten years. This shorter budget period increases the agility of the program and makes it easier to respond rapidly as new issues emerge. As in the 2015 RFA, the direct cost budget limit for the CEERs funded under this FOA will be set at \$650,000.

In addition, consistent with the 2015 RFA, this announcement will explicitly allow applicants to design education programs that focus on activities across the career pipeline from undergraduate students to junior faculty. This FOA also will retain the special emphasis on the recruitment and retention of individuals from groups currently underrepresented in ELSI and genomic research, and all CEERs will be eligible to apply for an [R25 Diversity Action Plan](#) grant to enhance their efforts in this area. This more comprehensive approach to training is designed to complement the [ELSI NRSA T32 Institutional Training Grant](#) program, which focuses exclusively on traditional pre and postdoctoral training.

RELATIONSHIP TO ONGOING ACTIVITIES

The ELSI Program supports a number of investigator-initiated and program-initiated activities. These include the [ELSI Regular Research \(R01\)](#), [Developmental/Exploratory Research \(R21\)](#), and [Small Research \(R03\)](#) grant program announcements as well as several ELSI collaborations embedded in larger clinical sequencing programs. The ELSI program also has recently initiated a T32 institutional training program to provide support for pre and postdoctoral trainees.

The intent of the CEER program is to allow researchers to propose comprehensive, trans-disciplinary approaches that integrate the spectrum of ELSI research methodologies with

translational activities designed to inform the development of public-policy options or professional guidelines. In addition, through the Program's education and career advancement component, the CEERs prepare the next generation of researchers both to conduct ELSI research and to facilitate the translation of the findings of this research to inform the development of sound policies and practices.

MECHANISM OF SUPPORT

This RFA will utilize the Research Project with Complex Structure (RM1) grant mechanism. This mechanism is specifically designed for large-scale research projects with complex structure and will allow for the submission of streamlined and well-integrated Center applications.

Investigators will be able to request up to four years of support. The length of award will be determined through the peer review and Council advisory processes. The total period of support for any new Center funded through this program will not exceed eight years.

The requested budget for a CEER may be up to \$650,000 in direct costs for the first year for continuing operations (e.g., personnel, equipment, supplies, travel and other expenses.) To accommodate collaborations that extend beyond single institutions, Facilities & Administrative (F&A) charges on any subcontracts, which are formally direct costs to the parent institution, will be excluded in considering the \$650,000 cost limit.

FUNDS AVAILABLE

NHGRI intends to commit approximately \$2,000,000 (total costs) in FY 2018 to fund up to two CEERs in response to this RFA. This will allow the CEER program to maintain a critical mass of up to six Centers and will keep the CEER program to approximately 33% of the projected ELSI program budget. Although the financial plans of the NHGRI provide support for this program, awards pursuant to this RFA are contingent upon the availability of funds and the receipt of a sufficient number of meritorious applications.