

**CONCEPT CLEARANCE**  
**LIMITED COMPETITION RFA**  
**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 issue a Limited Competition Request for Applications (RFA) to provide an opportunity for the continuation of the four Centers of Excellence in ELSI Research (CEERs) that are currently eligible for renewal and score well in the peer review process. This satisfies the NHGRI commitment to offer the RM1 CEERs the opportunity for a maximum of eight years of funding.

**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 2003, a total of 11 Full Centers and 8 Exploratory Centers have been funded. Currently, 5 CEERs are supported with a total budget of \$4.9 million, representing approximately 24% of the FY 2018 ELSI budget. The CEER RFA has been reissued five times, most recently in FY 2017, when the last P50 CEER was renewed as an RM1 for a final four years.

The CEER Program has been highly productive. The Centers have generated hundreds of peer-reviewed publications, books and book chapters. CEER investigators have written numerous policy briefs, consulted on federal and state legislation, written *amicus* briefs for legal cases, and provided expert testimony to the Congress, state legislatures, National Academies committees, and HHS Advisory Committees (often serving as members or chairs of these groups). The CEERs also have developed investigators who successfully integrate genomic and ELSI research. For example, numerous CEER investigators have served as principal investigators, co-investigators or consultants on a number of NHGRI genomic and genetic research consortia (e.g. CSER, eMERGE, NSIGHT).

One of the Program's major achievements has been the cultivation of the next generation of ELSI researchers. CEER support for undergraduate, graduate, postdoctoral and junior faculty fellows from diverse backgrounds has nurtured a talented and diverse cadre of young investigators and contributed to increases in the number of favorably reviewed and highly fundable investigator-initiated grants. This growth of junior ELSI faculty has been accelerated by the substantial increase in NHGRI ELSI funding devoted to Training and Career Development awards (i.e. T32s, Ks and Fs), which grew from \$277,831 or 1.5% of the ELSI budget in FY 2004, when the first CEERs were funded, to \$2.4 million or almost 12% of the budget in FY 2018. Many trainees supported by CEERs have gone on to successfully compete for these Career Development Awards and several have made the transition to tenure track positions and have become principal investigators on their own research grants.

Since the first CEERs were funded in FY 2004, both the genomics and ELSI research landscapes have undergone significant changes. Some of these changes have been facilitated by the success of the CEER program in accomplishing its primary goal of establishing viable research Centers across the country that are well-positioned to respond to calls for ELSI scholarship as an essential part of

the genomic research enterprise. As the ELSI Program prepares to enter the fourth decade of its partnership with human genome research, many of the program's early investments are paying off. Not only is there an impressive cadre of young, talented, diverse investigators, but the partnerships forged with genomic scientists have never been stronger or more effective.

The mandated set-aside for the ELSI Program has ensured that the ELSI budget increases in concert with the rest of NHGRI's budget. NHGRI is the only NIH Institute with dedicated funding for ELSI research. This has provided stability for the ELSI program which is essential to a program that requires both collaboration with and independence from the larger genomic research enterprise. However, since the ELSI research set aside has not increased beyond the 5% stipulated in legislation, the size, duration and future value of all ELSI initiatives, including the CEER program, will need to be considered as the genomics and ELSI research landscapes continue to evolve and additional demands are made on the ELSI research enterprise. This is particularly important now, as the NHGRI engages in a strategic planning process that will help plot the future for genomic and ELSI research activities.

ELSI staff propose to maintain the CEER program at its current level of funding (approximately 24% of the ELSI budget) through FY 2023. This will allow all the currently funded CEERs to compete for their final four-year renewal, without incurring additional commitments beyond 2023. This will help ensure that the ELSI Program can continue to devote a substantial portion of its budget to investigator-initiated research and career development activities and create the flexibility for the possible development of new initiatives tailored to the changing research landscape and based on the ongoing strategic planning process.

## **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.

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 career activities. 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.

The duration of CEER grants has been limited to four-years, with the possibility of a single renewal, for a maximum total funding period of eight years. This RFA will allow the existing RM1 CEERs the opportunity to apply for a renewal for their final 4 years of funding. No new CEERs will be funded under the current announcement.

In keeping with previous RFAs, this announcement will explicitly allow applicants to design research career 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](#) (DAP) grant to enhance their efforts in this area, if they have not already received a DAP award. This 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. Since its inception, ELSI has been committed to supporting high quality investigator-initiated research and has reserved at least 50% of its annual budget to fund this research. CEER investigators are encouraged to seek additional funding and collaborations through these programs as they identify high priority research questions in their area of focus.

The ELSI program has recently initiated and will be funding a new Center for ELSI Research and Analysis (CERA) program that will help coordinate the curation, analysis and dissemination of ELSI research. The CEERs will be expected to make their research tools and findings available to CERA and to participate in analytical and dissemination activities as appropriate. In addition, the ELSI Program supports a National Research Services Award (NRSA) T32 institutional training program that is limited to providing support for pre- and postdoctoral trainees. As noted above, the CEERs have a more flexible career development component which can focus on individuals and activities across the career trajectory.

## **MECHANISM OF SUPPORT**

This RFA will utilize the Research Project with Complex Structure (RM1) grant activity code. The RM1 is specifically designed for large-scale research projects with complex structure and will allow for the development 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 Center funded through this current limited competition FOA will not exceed four years.

## **LIMITED COMPETITION FOA**

The CEER program is dedicated to building sustainable infrastructure to support ELSI activities. Issuing an open competition RFA could result in funding a new center for a single four-year period. A single funding period may not be sufficient to develop truly sustainable transdisciplinary infrastructure, which can be particularly challenging for teams that span several academic schools and/or departments. The 2019 CEER RFA is therefore proposed as a limited competition announcement open only to the existing four CEERs currently eligible for four-year renewals. This will allow these Centers the opportunity to receive eight full years of support and increase the likelihood that they will be able to sustain their activities in the future.

## **FUNDS AVAILABLE**

NHGRI intends to commit approximately \$4,000,000 (total costs) in FY 2020 to fund the renewal of up to four CEERs in response to this RFA. 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. This will allow the CEER program to maintain a critical mass of up to five Centers and will keep the CEER program to approximately 25% 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.