

## 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 training of a diverse cadre of new ELSI investigators.

In FY 2004, four Specialized Center (P50) CEERs and three Exploratory Center (P20) CEERs were funded. In FY 2007, two additional P50s were funded, one of which had previously been the recipient of a P20 grant. In FY 2010, the original four P50s were renewed and two new P20s were funded. In FY 2013, one of the eligible P50s funded in 2007 was renewed, one P20 successfully transitioned to a P50 award, and three new P20s were funded. The four original P50s are completing their final year of full funding. In FY 2014, the NHGRI supported five P50s and three P20s with a total budget of \$5.8 million, representing approximately 32% of the FY 2014 ELSI 5% budgetary set aside.

To date, the CEER Program has been highly productive. The Centers' transdisciplinary teams have produced hundreds of peer-reviewed publications, books and book chapters. 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 and the **Newborn Sequencing In Genomic Medicine and Public Health (NSIGHT)** Program. CEER investigators also have written numerous policy briefs, have been consulted on the development of federal and state legislation, have provided written *amicus* briefs in 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).

One of the Program's major achievements has been the provision of training for the next generation of ELSI researchers through the support of graduate, postdoctoral and junior faculty trainees from a wide variety of disciplines (e.g. law, religious studies, philosophy, bioethics, epidemiology, inorganic chemistry, genetics, sociology, anthropology). Approximately 25% of these trainees have been members of underrepresented minority groups. Many CEER trainees have successfully made the transition to tenure track positions and a number have become principle investigators on their own research grants.

## **RESEARCH SCOPE AND OBJECTIVES**

The primary objective of the CEER Program is to support the development of transdisciplinary research teams that have 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 training of the next generation of ELSI investigators, with particular attention given to the recruitment and retention of individuals from under-represented groups.

In order to enhance the focus and cohesiveness of the CEERs, and to decrease the risk that the activities of any given CEER will become too diffuse, each Center will be 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. However, in a departure from the most recent CEER Request for Applications (RFA), this announcement will allow greater flexibility in the selection and design of the primary research project. 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 integrate 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. It is anticipated that this increased flexibility will enhance each Center's ability to respond to new and emerging issues as they arise.

To further enhance the ability of the CEER Program to keep pace with the rapid changes in genomic science, CEER grants will be limited to one four year award, with a possible additional four year renewal, for a total of eight years. This is a modification from the most recent CEER RFA, 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 will allow the Program as a whole to respond more rapidly as new issues emerge. In addition, the direct cost budget for the CEERs funded under this FOA will be set at \$650,000, rather than \$750,000 as under the previous RFA. This will free up funds to allow NHGRI to support additional investigator or program initiated research and training activities.

In another departure from the most recent RFA which focused on postdoctoral training, this announcement will explicitly allow applicants to design a training program that focuses on activities across the training pipeline from undergraduate students to junior faculty. However, the special emphasis on the recruitment and retention of individuals from groups currently underrepresented in ELSI and genomic research will be retained. This more inclusive approach to training is designed to complement the new ELSI NRSA T32 Institutional Training Grant program, which focuses exclusively on pre and postdoctoral trainees.

## **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 a number of 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 that use these conceptual tools and empirical data to inform the development of public-policy options or professional guidelines. In addition, through the Program's training component, the CEERs provide not only transdisciplinary research training, but also training in ways to translate this research so that it might be useful in the development of policies and practices. As mentioned above, this will complement the new ELSI Institutional Training Grant opportunity, which provides a more traditional research training experience for pre and postdoctoral trainees.

## **MECHANISM OF SUPPORT**

This RFA will use the Research Project with Complex Structure (RM1) grant mechanism, rather than the P50 mechanism used previously. This mechanism is specifically designed for large-scale research projects with complex structure and will allow for the submission of more streamlined and well-integrated Center applications. NHGRI will not issue an RFA for Exploratory (P20) grants at this time, but will consider reissuing an Exploratory Grant RFA at a future time so that any new grants issued through such an RFA will be eligible to apply for a full RM1 CEER when the next CEER solicitation is issued.

Investigators will be able to request up to four years of support under the CEER program<sup>1</sup>. The length of award will be determined through the peer review and Council advisory processes. The total period of support for any new Center under this program will not exceed eight years (the initial grant period of up to four years, plus one renewal for up to an additional four 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 \$3,000,000 (total costs) in FY 2016 to fund up to three CEERs in response to this RFA. This will allow the CEER program to maintain a critical mass of up to five centers and will keep the CEER program to approximately 28% 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.

---

<sup>1</sup>CEER grantees submitting applications for competitive continuations will be required to include a progress report and to present a plan describing how the CEER will sustain its activities after it has completed its second, and final, four years of NHGRI funding.