

## **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 funding opportunity to support the development or continuation of Centers of Excellence in ELSI Research (CEERs).

#### **BACKGROUND**

The CEER program was initiated in FY 2003 in response to recommendations made during the 2002-2003 NHGRI planning process. It was designed to support the creation of transdisciplinary teams at institutions across the country that would help 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 researchers. 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. Currently, the NHGRI is supporting six P50s and two P20s with a total budget of \$6.4 million, representing approximately 33% of the 2011 ELSI set aside.

To date, the CEER Program has been highly productive, with the Centers' transdisciplinary teams producing hundreds of peer-reviewed publications, books and book chapters. The CEERs have had considerable success in facilitating the integration of 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 the Pharmacogenomics Research Network projects and, most recently, the NHGRI Clinical Sequencing Exploratory Research grants. CEER investigators also have written numerous policy briefs, have been consulted on the development of Federal and State legislation, 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 major achievements of the program is that the CEERs have provided training for more than 80 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 30% of these trainees have been members of underrepresented minority groups. Most CEER postdoctoral and junior faculty fellows have successfully made the transition to tenure track positions and several are now principal investigators with their own research grants. Finally, through their collaborations with researchers from diverse academic and clinical departments, the CEERs have generated considerable interest in and support for transdisciplinary research throughout their home institutions.

#### **RESEARCH SCOPE AND OBJECTIVES**

The primary objective of the CEERs 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 appropriate 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 researchers, 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 decrease the risk that activities of a CEER will become too diffuse, each Center will be expected to identify a clearly defined and highly significant current issue, or set of closely related issues, that will be the focus of its research, policy and training activities. Examples of possible high priority topics are described on the ELSI Research Program's website (<http://www.genome.gov/27543732>). These topics are based on the broad priority areas identified in the Genomics & Society section of NHGRI's 2009 strategic plan for the future of human genome research<sup>1</sup>. They are meant as examples only and should not be considered an exhaustive listing of all possible research areas of focus.

## MECHANISM OF SUPPORT

This RFA will use the Specialized Center (P50) and Exploratory Center (P20) grant mechanisms.

### P50 Specialized Center Grants

Investigators will be able to request up to five years of support under the P50 program<sup>2</sup>. The length of award will be determined through the peer review and Council advisory processes. The total period of support for any new P50 Center under this program will not exceed ten years (the initial grant period of up to five years, plus one renewal for up to an additional five years).

The requested budget for a CEER may be up to \$750,000 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 the subcontracts, which are formally direct costs to the parent institution, will be excluded in considering the \$750,000 cost limit.

### P20 Exploratory Grants

Investigators submitting P20 applications must demonstrate how the proposed planning activities will lead to a P50 application, and describe in substantial detail a vision of the research to be conducted under the subsequent P50 grant. The planning grant budget may request funds for partial salary of key investigators, travel, and some supplies and equipment. Planning grants will be awarded for up to three years and up to \$150,000 direct cost per year. A planning grant is not required as a precursor to a P50 Center application. Funding of a planning grant does not obligate NHGRI to fund a subsequent P50 Center grant.

Because the nature and scope of the proposed research will vary from application to application, it is anticipated that the size and duration of each award will also vary.

## FUNDS AVAILABLE

NHGRI intends to commit approximately \$2,750,000 (total costs) in FY 2013 to fund up to two Specialized Centers (P50s) and up to two Exploratory Centers (P20) in response to this RFA. This will result in a modest reduction in the number of Centers funded in future years. However, it will keep the CEER program to no more than 33% of the projected ELSI program budget and will maximize program planning and budget flexibility in an era of fiscal uncertainty. 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.

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<sup>1</sup>"Charting a course for genomic medicine: from base pairs to bedside" *Nature*. 10 Feb 2011:470;204-13.

<sup>2</sup>CEER grantees who are 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, five years of NHGRI funding.