National Advisory Council for Human Genome Research September 16, 2019 Concept Clearance for PAR

Title: Ethical, Legal and Social Implications (ELSI) Research Program

Purpose: The ELSI Research Program supports a broad range of research to anticipate and address the ethical, legal, and social implications (ELSI) of genetics and genomics for individuals, families and communities. Since the mid-1990s the ELSI Program has solicited research through three standing Program Announcements (PA) using three distinct funding activity codes: the Regular Research grant (R01); the Small Research Grant (R03); and the Exploratory or Developmental Research grant (R21).

The current PAs, which include several other NIH Institutes and Center partners, are scheduled to expire in September 2020.

The ELSI program proposes to reissue these funding announcements as Clinical Trial Optional Program Announcements with special receipt, referral and/or review criteria or PARs, rather than PAs. As in the past, applications may propose studies using either single or mixed methods. Approaches may include but are not limited to data-generating qualitative and quantitative approaches, legal, economic and normative analyses, and other types of analytical and conceptual research methodologies, such as those involving the direct engagement of stakeholders.

New or renewal/modified initiative: Renewal of PA-17-444, PA-17-445, PA-17-446

Activity Codes: R01, R03, R21