National Advisory Council for Human Genome Research Concept Clearance for PAR February 13, 2023

Ethical, Legal and Social Implications (ELSI) Research (R01/R03/R21, Clinical Trial Optional)

Purpose: The purpose of these renewing funding opportunity announcements is to support investigator-initiated research to study the ethical, legal, and social implications (ELSI) of human genetics and genomics. Studies supported under these three program announcements (PARs) will address <u>four broad research areas</u>:

- Genomics and sociocultural structures and values
- Genomics at the institutional and systems level
- Genomic research design and implementation
- Genomic healthcare

New or renewal/modified initiative: Renewal

As in the past, applications may propose studies using either single or mixed methods. Approaches may include but are not limited to empirical qualitative and quantitative methods, as well as conceptual, legal, and normative analyses. Direct involvement of key stakeholders where appropriate is encouraged.

Minor modifications to the active ELSI Research PARs are proposed. Emphasis will be placed on broadening the wide array of disciplines and lived experiences represented among applicants. The R01 PAR will also recognize that to be successful, communityoriented projects (for example community-based or community-led projects focused on specific demographic, geographic, or stakeholder groups) may require time or funds that exceed the limits stated in the announcement. In keeping with NIH and NHGRI policy, the R01 PAR will encourage applicants who anticipate needing \$500,000 or more in direct costs in any year (excluding consortium F&A), or anticipate needing a fifth year of support, to contact Program Officials before submitting the application to discuss appropriate budget and project period. The R21 will allow for requests including a third year of work. Final project period and budgets will be at the discretion of Program. Finally, to improve the understanding and use of demographic population descriptors (for example measures of race and ethnicity), applicants will specify the proposed demographic variables to be collected, explain the purpose of those variables in data analysis, and briefly justify the proposed plan.

The ELSI Research Program is soliciting participation from all NIH Institutes, Centers and Offices and expects robust involvement.

Current PARs:

PAR-20-254: <u>https://grants.nih.gov/grants/guide/pa-files/par-20-254.html</u> (R01) PAR-20-257: <u>https://grants.nih.gov/grants/guide/pa-files/par-20-257.html</u> (R03) PAR-20-255: <u>https://grants.nih.gov/grants/guide/pa-files/PAR-20-255.html</u> (R21)

Mechanisms of Support: R01, R03, and R21