Genomics and Society Working Group: Update and Report

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The Genomics and Society Working Group



Provide input about the ELSI Research Program, including input about its relative research priorities, ... and the best use of limited budgetary and staff resources

https://www.genome.gov/27551917/ the-genomics-and-society-workinggroup/

Input re: ELSI Research Program

- Embedded ELSI Research
- Duration of R01 Projects
- Relationship of ELSI & Health Services
 Research
- Steps to encourage high quality applications
 - Post sample applications & summary statements
 - Outreach to (current and potential) ELSI community

Embedded ELSI Research

- •ELSI Research is typically only one component that is incorporated and conducted within the context of a larger project/initiative
 - Examples: eMERGE, CSER, NSIGHT
- GSWG members considered the majority of embedded ELSI research projects successful and a worthwhile investment for the ELSI Program

Embedded ELSI Research: Recommendations

 GSWG recommended continued monitoring of the effectiveness of embedded ELSI research and possible development of productivity metrics

 GSWG stressed the need for the quality of proposed embedded ELSI research to be consistently incorporated into the overall priority score during peer review

Duration of R01 Project Period

- NHGRI default is to fund R01s for 3 years
- Rationale is the fast-paced nature of the field and constantly changing technology
- Longer awards are permitted with justification
 - E.g., longitudinal or multi-site studies

Duration of Award: Recommendations

- Emphasize in Program Announcement and staff communications that project period should correspond to the proposed research
- Encourage applicants to discuss appropriate project length with program staff pre-submission
- NHGRI staff should consider whether additional guidance for New Investigators is warranted, as they may not know about exceptions-with-justification possibility

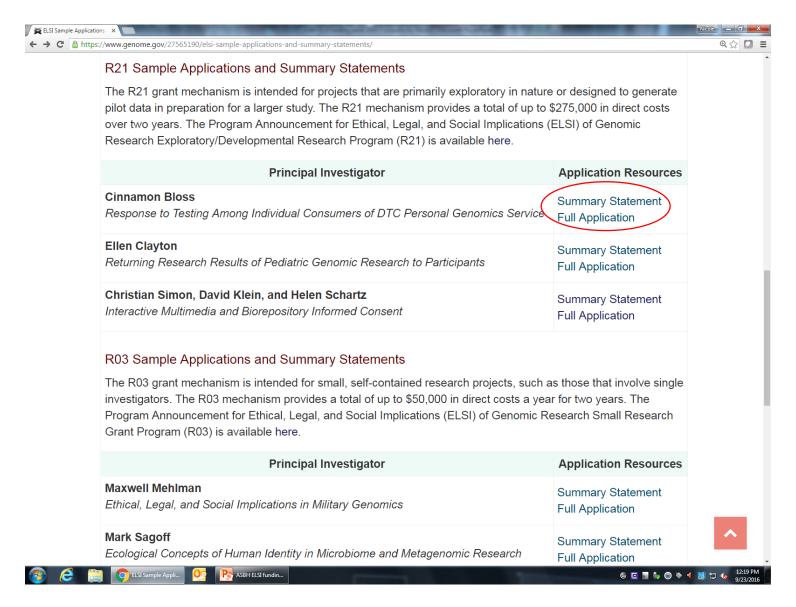
ELSI and Health Services Research

- Topics in HSR have significant ELSI components and implications
- HSR could provide data that call for normative analysis, or that are needed to refine or strengthen the empirical components of an ELSI study
- Conceptual research may inform or clarify components of HSR
- HSR in embedded research projects may encourage the collection of longitudinal data with ELSI input into research questions and study design, thereby catalyzing subsequent ELSI research to address important normative issues

ELSI and HSR: Recommendations

- DG&S should promote HSR and ELSI research in other ICs, Divisions, and within the ELSI Research Program, as appropriate
- GSWG and ELSI Research staff continue to discuss ways to encourage ELSI research on findings from health services research and projects that conceptualize health services issues, and analyze their normative foundations and implications

ELSI Sample Applications and Summary Statements



Outreach: to expand the ELSI research community

 Panels at professional meetings (e.g., American Society for Bioethics & Humanities)

- Ongoing activities:
- Article elucidating the nature & value of empirical, normative, & conceptual ELSI research – targeted to the genomic research community
- Announcements/"explainers" in professional society forums to encourage collaborations & submissions



The Genomics and Society Working Group

Provide input about Division activities in light of changes in genomics, genomic medicine, and the policy landscape, aiming to identify emerging issues or gaps

Identify areas of potential synergy ... between NHGRI and other NIH Institutes and national/international organizations, as well as issues and activities that are more appropriately addressed by other NIH Institutes, or other agencies or organizations

Precision Medicine Initiative

- Memo, endorsed by Council, May 18, 2015
- Offered consultation to Joni Rutter re: PMI-CP/All of Us Research Program
- Published a call & agenda for ELSI research on the PMI-AURP

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Genetics
in Medicine

The Precision Medicine Initiative's All of Us Research Program: an agenda for research on its ethical, legal, and social issues

Pamela L. Sankar, PhD1 and Lisa S. Parker, PhD2

GSWG review of CEERs Centers for Excellence in ELSI Research

Case Western Reserve University

Duke University

Stanford University

Kaiser Permanente/ UCSF

University of Washington

Genetic research issues

Info flow, IP, commercialization

Behavioral genetics

Genes x Environment translation

Clinical translation / underserved



Columbia University

Johns Hopkins University

University of Utah

Vanderbilt University

University of North Carolina at

Chapel Hill

Oklahoma University

Psych, neuro, & behavioral

Precision med / infectious disease

Prenatal & newborn screening

Privacy risks

GeneScreen, sequencing in primary

care

American Indian and Alaska Native communities & health care systems

4th ELSI Congress Genomics and Society: Expanding the ELSI Universe

- June 5 − 7 in Farmington, CT
- Over 190 proposals submitted from 68 institutions
- 28 international submissions representing 10 countries outside of the U.S.
- Registration is now open
- More information at: http://www.elsicon2017.org/

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