



Genomics and Society Working Group: Update and Report

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GSWG Members

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Arti Rai	Duke University
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*term ended 2016

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The Genomics and Society Working Group

NHGRI Research Funding Divisions

Division of Extramural
Operations

Division of Genome Sciences

Division of Genomic Medicine

**Division of Genomics and
Society**

Division Outreach and
Activities

Division Planning and
Evaluation

Division Staff

The ELSI Research
Program

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-working-group/>

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

R21 Sample Applications and Summary Statements

The R21 grant mechanism is intended for projects that are primarily exploratory in nature or designed to generate pilot data in preparation for a larger study. The R21 mechanism provides a total of up to \$275,000 in direct costs over two years. The Program Announcement for Ethical, Legal, and Social Implications (ELSI) of Genomic Research Exploratory/Developmental Research Program (R21) is available [here](#).

Principal Investigator	Application Resources
Cinnamon Bloss <i>Response to Testing Among Individual Consumers of DTC Personal Genomics Service</i>	Summary Statement Full Application
Ellen Clayton <i>Returning Research Results of Pediatric Genomic Research to Participants</i>	Summary Statement Full Application
Christian Simon, David Klein, and Helen Schartz <i>Interactive Multimedia and Biorepository Informed Consent</i>	Summary Statement Full Application

R03 Sample Applications and Summary Statements

The R03 grant mechanism is intended for small, self-contained research projects, such as those that involve single investigators. The R03 mechanism provides a total of up to \$50,000 in direct costs a year for two years. The Program Announcement for Ethical, Legal, and Social Implications (ELSI) of Genomic Research Small Research Grant Program (R03) is available [here](#).

Principal Investigator	Application Resources
Maxwell Mehlman <i>Ethical, Legal, and Social Implications in Military Genomics</i>	Summary Statement Full Application
Mark Sagoff <i>Ecological Concepts of Human Identity in Microbiome and Metagenomic Research</i>	Summary Statement Full Application

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



National Human Genome
Research Institute

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



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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