Genomics and Society Working Group: Update and Report

Lisa S. Parker, PhD
University of Pittsburgh

NACHGR – February 6, 2017
GSWG Members

*Barbara Bernhardt  University of Pennsylvania
^Jeffrey R. Botkin  University of Utah
*Wendy Chung  Columbia University
Gail Henderson  University of North Carolina
Chanita Hughes-Halbert  Medical University of South Carolina
^Sandra Soo-Jin Lee  Stanford University
*Gary Marchant  Arizona State University
Amy McGuire  Baylor College of Medicine
^Melanie F. Myers  University of Cincinnati
Lisa S. Parker (Chair)  University of Pittsburgh
Arti Rai  Duke University
*Pamela Sankar  University of Pennsylvania
David Veenstra  University of Washington

*term ended 2016  ^appointed 2017
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.
ELSIS 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](https://www.genome.gov/27565190/elsi-sample-applications-and-summary-statements/).

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<td>Summary Statement</td>
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<td>Ellen Clayton</td>
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<td>Christian Simon, David Klein, and Helen Schartz</td>
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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](https://www.genome.gov/27565190/elsi-sample-applications-and-summary-statements/).

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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
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

Columbia University
Johns Hopkins University
University of Utah
Vanderbilt University
University of North Carolina at Chapel Hill
Oklahoma University

Genetic research issues
Info flow, IP, commercialization
Behavioral genetics
Genes x Environment translation
Clinical translation / underserved

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
4\textsuperscript{th} 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/
Thanks to ELSI and DG&S staff

- Joy Boyer
- Lawrence Brody
- Erin Currey
- Dave Kaufman
- Nicole C. Lockhart
- Jean McEwen
- Annie Niehaus
- Laura Lyman Rodriguez