

**Genomics and Society Working Group  
of the National Advisory Council on Human  
Genome Research: Update and Report**

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**NACHGR  
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# GSWG Members

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# GSWG Report and Update

- ELSI Research Program
  - Boundaries & Priorities
- Societal and Ethical Issues in Research
  - SEIR – ELSI Study section
- DG&S and ELSI Research Program
  - Balance and development

# ESLI Research Program Boundaries

Boundary	Concern/policy	Recommendation
<b>Single disease:</b> Genetics and Alzheimer's Disease, colon cancer, autism	<ul style="list-style-type: none"><li>• Generalizability</li><li>• Acceptable but higher bar</li></ul>	Maintain limit but clarify PA language
<b>Non-medical:</b> Forensic, DTC ancestry testing	<ul style="list-style-type: none"><li>• Important to public</li><li>• Overlap, difficult to predict</li></ul>	Continue support
<b>Beyond genomics:</b> proteomics, stem cells, synthetic biology	<ul style="list-style-type: none"><li>• Fall beyond ELSI scope</li><li>• Requires ongoing assessment</li></ul>	Clarify PA; state restrictions

# ELSI Research Program: Prioritization Criteria

- Criteria used to assess priorities
- How to decide that something is a priority?
  - Do not represent new or additional ways to rank proposals
  - Internal use
  - *Work in progress*

# Prioritization Criteria

## *PROVISIONAL*

Term	Detail
Consequential	Presents an opportunity for impact
Fundamental/basic	Provides necessary basic data or encourage fundamental normative/conceptual analysis
Effective	In light of limited ELSI resources, benefits from ELSI attention
Time Sensitive	Newly emergent or anticipated, or a fleeting or disappearing opportunity
Inclusive	Significant to diverse or understudied communities, or to groups with established health disparities.

# Societal And Ethical Issues In Research Study Section (SEIR)

- Small community & limited pool of reviewers heightens **conflict of interest** issues
  - Removes most knowledgeable reviewers
  - Increases reliance on SEPS & ad hoc members
  - Required expertise—history, philosophy, law—uncommon in CSR pool
- Suggestion
  - ELSI staff look into providing suggestions of reviewers with particular expertise

# Balancing DG&S responsibilities & ELSI Research Program demands

## DG&S

- Oversees broad, integrative genomics & society activities across NHGRI

## ELSI Research Program

- Directs & manages ELSI research

# GSWG Recommendations

- Important transitional phase
  - Affirm distinctive role of ELSI within DG&S
    - ELSI Research Program should be dedicated to research, and;
    - ELSI set-aside should go only to funding research
- GSWG recommends:
  - Add a full time staff member to DG&S
    - Division responsibilities, not ELSI Research Program

# GSWG: What's Next?

## Portfolio Balance of the ELSI Research Program

- Investigator-initiated vs. program-initiated
- Ways to encourage investigator-initiated applications
- Re-envision CEER training component?

## Normative/Conceptual Research

- Scope & role in attaining ELSI goals
- Quantity, breadth & depth
- Assess sufficiency
- Recommend mechanisms to sustain or stimulate research

## Conclude examination of

- Outreach to research community, SEIR related issues

