ELSI Research Activities Across the NIH

Lawrence Brody
Division of Genomics and Society
14 September 2020
Overview

• NHGRI ELSI Program
• NHGRI other IC collaborations
• Programs at the NIH
• Data Mining
NIH Funding – Bioethics 2020

Search *Bioethics* - 266

Active “R” Awards

82 Research Grants

21 NHGRI
NIH Research

Behavioral

Bioethics

Legal

Social
Genetics and Genomics

Ethical

Social

Legal
NHGRI Research

Genomic Science

- Intellectual Property
- Equitable Access
- Data Privacy
- Genetics of Populations

ELSI

Implementation
- Clinic/ Research Boundaries
- Data Privacy
- Equitable Access

Genomic Medicine
Ethical, Legal and Social Implications Research Program

The ELSI Research Program fosters basic and applied research on the ethical, legal and social implications of genetic and genomic research for individuals, families and communities.
$20M

~ 65 ELSI Grants

500 NHGRI

50,000 NIH
ELSI Connections

- Historical
- Personal
- Tea Time
- NOSIs
- Pedigree
Components of Participating Organizations

National Human Genome Research Institute (NHGRI)
National Cancer Institute (NCI)
National Eye Institute (NEI)
National Heart Lung and Blood Institute (NHLBI)
National Institute on Aging (NIA)
National Institute of Environmental Health Sciences (NIEHS)
National Institute of Mental Health (NIMH)
National Institute on Minority Health and Health Disparities (NIMHD)
National Institute of Neurological Disorders and Stroke (NINDS)
Other “ELSI-oid” Programs at the NIH

• Vary in intent, scope and stability
• Twenty year trend toward more programs
• Large range of research questions
• Research a mixture of stand alone, embedded and supplemental programs
Priority One: Improve the synergy of basic and applied behavioral and social sciences research.

Priority Two: Enhance and promote the research infrastructure, methods, and measures needed to support a more cumulative and integrated approach to behavioral and social sciences research.

Priority Three: Facilitate the adoption of behavioral and social sciences research findings in health research and in practice.
COVID-19 is an emerging, rapidly evolving situation.

- Latest COVID-19 public health information from the U.S. Centers for Disease Control and Prevention (CDC)
- Latest COVID-19 research information from the U.S. National Institutes of Health (NIH)
- COVID-19 resources for global health researchers from Fogarty

Bioethics news, resources and funding for global health researchers

Fogarty aims to strengthen research bioethics expertise in developing countries by providing resources and information to bioethicists, research ethics committee members, researchers, students, and everyone else involved in international health research. In keeping with its wider commitment to building the capacity to conduct research in low- and middle-income countries (LMICs), Fogarty believes it is important to build in-country bioethics capacity. This enables local ethics review of research, improves research into the distinctive ethical problems in LMICs, and increases the representation of different voices in ongoing global discussions of the ethics of health research.

Bioethics Resources

- For Teachers and Students - teaching tools, career path advice, and online education information
- For Investigators and Ethics Committees - regulations, guidelines, practical aids, committee information
- For Bioethics Researchers - journals and granting agencies
- Bioethics Materials in Other Languages - networks, trainings, journals, and guidelines and regulations in a variety of languages
Ethics Consultation Service
14 Research Faculty
14 Trainees
Charlisse Caga-anan, J.D.

Program Director
Genomic Epidemiology Branch,
Epidemiology and Genomics Research Program

Telephone: (240) 276-6738
Fax: (240) 276-7920
E-mail: charlisse.caga-anan@nih.gov

Contact for questions about:

Bio-ethics

Ethical, Legal and Social Implications (ELSI)

Genomic Data Sharing
ICs nominate grants

ICs administer funding

$5,000,000 per annum
National Institute on Drug Abuse

• Predictive modeling: the role of opioid use in suicide risk

National Institute of Nursing Research

• Engaging patients, family members and caregivers in end-of-life and palliative care research: Addressing the bioethical challenges
National Institute of Allergy and Infectious Diseases

- Bioethical Issues in the use of Mobile Phone Data for Public Health Research in Uganda

- Ethical aspects of clinical xenotransplantation: a national survey of African Americans
National Institute of Dental and Craniofacial Research

- Bioethics of syndrome diagnosis using 3D image analysis

- Orofacial Clefts, Whole Genome Sequencing and Incidental Findings: Ethical considerations.
Landscape for Genomics and Genetics?
Research, Condition, and Disease Categorization Program

Grant database with text mining and visualization tools

(and very helpful staff)
2008 to 2020

196 grants

Genetics? 
No 32
Yes 164

ELSI Research?
No 111
Yes 53
Awarded ELSI Projects by IC, 2010-2020

N=53
Awarded ELSI Projects by Activity Code, 2010-2020  (n=53 projects)
Awarded ELSI Projects by RCDC Thesaurus Concepts, 2010-2020 (n=53 unique projects)
Total Cost Across ELSI Projects By Fiscal Year, 2010-2020 (n=153 project-years)
### Total Cost Across ELSI Projects By Fiscal Year, 2010-2020 (n=153 project-years)

<table>
<thead>
<tr>
<th>Fiscal Year</th>
<th>Total Cost</th>
<th>Project-Years</th>
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<tbody>
<tr>
<td>2010</td>
<td>$3,921,418</td>
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<tr>
<td>2011</td>
<td>$1,526,737</td>
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<tr>
<td>2012</td>
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<td>$3,376,670</td>
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<td>2018</td>
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<td>2019</td>
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<td>2020</td>
<td>$8,855,712</td>
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<td><strong>Grand Total</strong></td>
<td><strong>$52,734,441</strong></td>
<td><strong>153</strong></td>
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Bottom Line?

- NHGRI funds the majority of genomics related ELSI research at the NIH
- Some ICs have stable programs
- ELSI research at other ICs “follow projects”
- NHGRI: exemplar, cooperative, collaborative
<table>
<thead>
<tr>
<th>Name</th>
<th>Position</th>
<th>Division</th>
</tr>
</thead>
<tbody>
<tr>
<td>Joy Boyer, B.A.</td>
<td>Program Director</td>
<td>Division of Genomics and Society</td>
</tr>
<tr>
<td>Dave Kaufman, Ph.D.</td>
<td>Program Director</td>
<td>Division of Genomics and Society</td>
</tr>
<tr>
<td>Nicole C. Lockhart, Ph.D.</td>
<td>Health Sciences Administrator</td>
<td>Division of Genomics and Society</td>
</tr>
<tr>
<td>Rene Sterling, Ph.D., M.H.A.</td>
<td>Program Director</td>
<td>Division of Genomics and Society</td>
</tr>
<tr>
<td>Natalie Pino</td>
<td>Scientific Program Analyst</td>
<td>Division of Genome Sciences</td>
</tr>
<tr>
<td>Alex Raphael</td>
<td>Program Analyst</td>
<td>Division of Genome Sciences</td>
</tr>
<tr>
<td>Tasha A. Stewart</td>
<td>Program Assistant</td>
<td>Division of Genomics and Society</td>
</tr>
<tr>
<td>Kathleen Renna</td>
<td>Program Analyst</td>
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The Forefront of Genomics®
Total Cost Across ELSI Projects By Activity Code, 2010-2020 (n=153 project-years)

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<thead>
<tr>
<th>Activity Code</th>
<th>Total Cost</th>
<th>Project-Years</th>
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<td>R01</td>
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<tr>
<td><strong>Grand Total</strong></td>
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<td><strong>153</strong></td>
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