

Introduction to the NHGRI Ethical, Legal, and Social Implications (ELSI) Program

Dave Kaufman

ISCC In-Person Meeting

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ELSI Research Program: Background

- Established in 1990
- Mission: To anticipate and address the ethical, legal, and social implications of genetic and genomic research
- 5% NHGRI extramural budget set-aside
- FY2019 budget ~ \$21M

★ ~50% of ELSI budget dedicated to investigator-initiated research

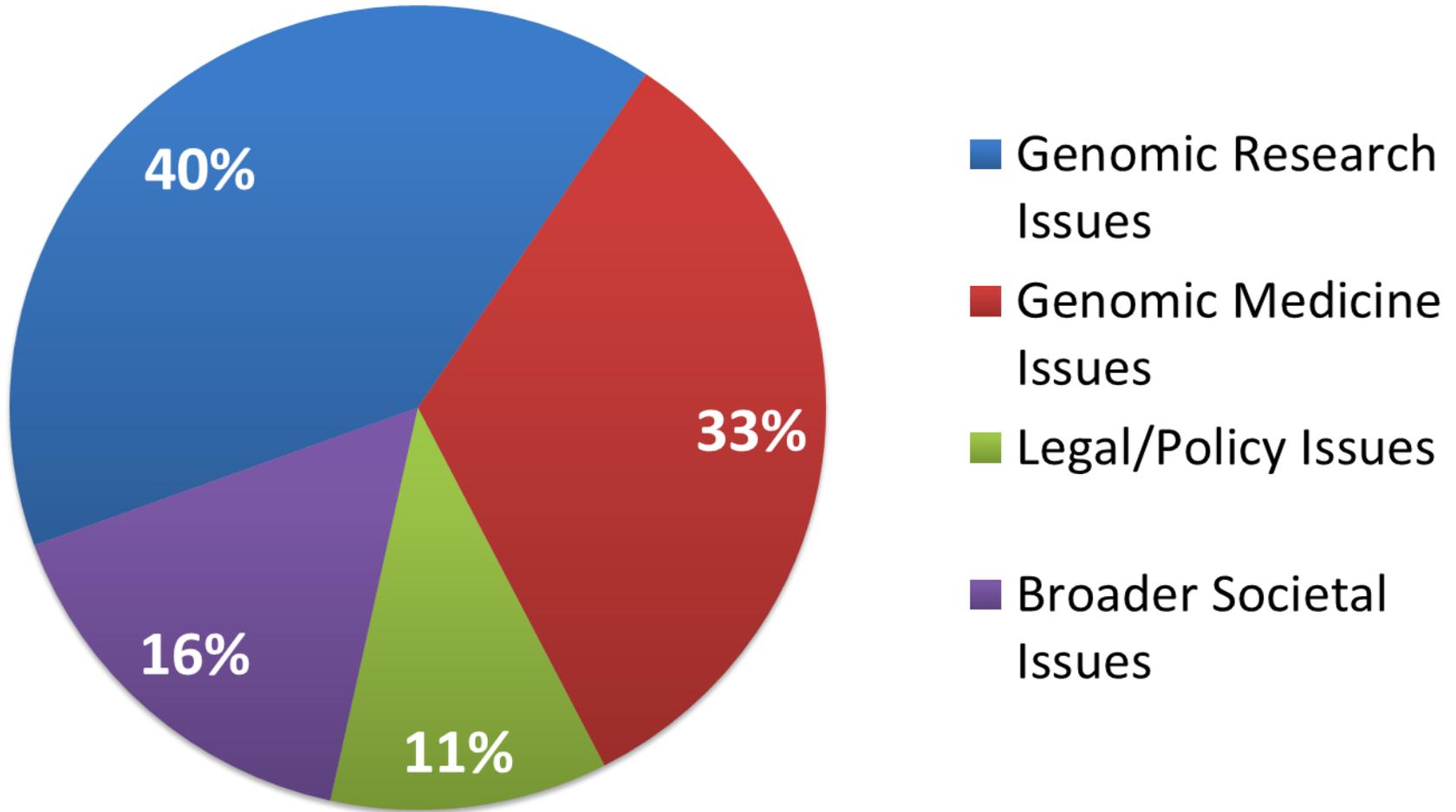
Current Research Priority Areas

- Issues in genetic and genomics research
- Issues in genetic and genomic medicine
- Broader legal, policy and societal issues
- Detailed descriptions available at:

<https://www.genome.gov/Funded-Programs-Projects/ELSI-Research-Program/domains>

Search: ELSI Research Domains

Current Estimated Budget Allocations



Issues Addressed in ELSI Portfolio

- Old issues addressed in new ways
 - *Informed clinical and research consent*
 - *Incidental findings*
 - *Provider and patient understanding of results*
 - *Blurred research/clinical boundaries*
- Emerging issues
 - *Gene editing, gene therapy*
 - *Personal utility*
 - *DTC testing*
 - *Alternatives to in-person counseling*
 - *Re-analysis obligations and practices*
 - *Equity, diversity and clinical genomics*

Selected Disciplines of ELSI Applicants

- Ethics and Bioethics
- Law
- Philosophy and Humanities
 - e.g. History, Religion/ Theology
- Public Policy
- **Medicine**
 - e.g. **Clinical Genetics, Psychology/Psychiatry, Nursing, Genetic Counseling, Pediatrics, Oncology**
- Biomedical Sciences
 - e.g. Genetics, Biology, Neuroscience, Pharmacology
- Public Health
 - e.g. Epidemiology, Biostatistics, MCH, Health Policy, Population Health
- Social Sciences
 - e.g. Sociology, Anthropology, Economics, Political Science



Wide Range of Methods Used in ELSI Research

- Archival research
- Textual interpretation
- Legal analysis
- Conceptual/Critical analysis
- Content analysis
- Oral history
- Ethnography
- Focus groups
- Structured Interviews
- Community Based Research
- Network analysis
- Simulation modeling
- Quasi-experimental and experimental trials
- Survey methods
- Discrete choice analysis
- Time series analyses
- Model clinical encounters



Primary Types of Grants

Grant Type	Description	Project Period	Max Direct Cost
R01	Regular research grant	3 - 5 years (generally 3)	Must reflect project needs, generally <\$500K

- NIH Funding Announcements relevant to ELSI and Bioethics are listed on <http://www.genome.gov/ELSI/>

Path and timeline (I)

Planning, Writing and Submitting

Planning:

Start early! Collect preliminary data & establish internal deadlines.

CONTACT US!!



Writing:

Begin writing application several months prior to application due date



Submitting:

Applicant organization submits application using grants.gov & eRA Commons

Path and timeline (II)

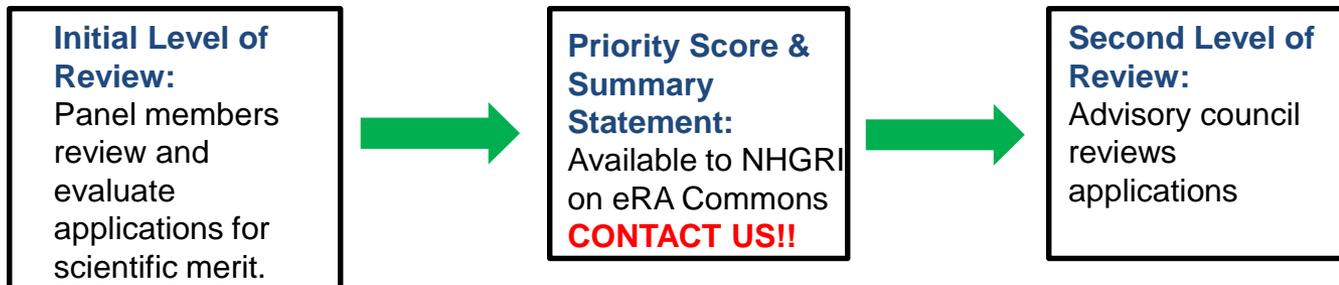
Receipt and Referral

Months 1-3



Peer Review

Months 4-8



Path and timeline (III)

Award

Months 9-12



Or



Revise and Resubmit

NOT-OD-20-038

Notice of Special Interest: Administrative Supplement for Research on Bioethical Issue

<https://grants.nih.gov/grants/guide/notice-files/NOT-OD-20-038.html>

- Funding for one-year supplements to existing grants for bioethics & policy work
- \$100,000 max
- Due March 20

- Pilot work
- 24 Institutes
- Many with specific interests written

Ethical, Legal and Social Implications Research Program

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Research Domains

The ELSI Research Program funds and manages studies, and supports workshops, research consortia and policy conferences related to these topics. For a more in depth exploration of the program, read [The Ethical, Legal and Social Implications Program of the National Human Genome Research Institute](#).

Funding Opportunities

NIH is instituting a number of changes to how it categorizes clinical trial research. Many ELSI studies that previously were not considered clinical trials will now be categorized as such and will be subject to new application, review and reporting requirements. Please visit the [Clinical Trials Definition website](#) for

Sample ELSI Applications and Summary

The grants listed below collectively represent a range of ethical, legal and social implications (ELSI) research. The letter's author, and sam

Program Staff



Joy Boyer, B.A.
Program Director
Division of Genomics and Society



Natalie Pino
Scientific Program Analyst
Division of Genome Sciences



Dave Kaufman, Ph.D.
Program Director
Division of Genomics and Society



Alex Raphael
Program Analyst
Division of Genome Sciences



Nicole C. Lockhart, Ph.D.
Health Sciences Administrator
Division of Genomics and Society



Tasha A. Stewart
Program Assistant
Division of Genomics and Society

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<http://www.genome.gov/elsi/>

30 YEARS OF THE GENOME

Integrating and Applying ELSI Research

ELSICon2020 • 30 Years of the Genome: Integrating and Applying ELSI Research

5th ELSI Congress

June 15-17, 2020

Columbia University, New York

ELSICon2020

More information:

<http://www.genome.gov/ELSI/>

Contact us!!

dave.kaufman@nih.gov

lockhani@mail.nih.gov

boyerj@exchange.nih.gov