

OFFICE OF THE DIRECTOR BIOETHICS FUNDS

*Concept Clearance for FY 2014 Bioethics
Research*

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What is a concept clearance?

- “Concept” describes the purpose, scope, and objectives of a proposed funding opportunity
- “Clearance” must include advice from the public, which may be obtained through
 - Congressional mandate,
 - Workshops convened specifically for advisory purposes, or
 - Consultation with national advisory councils and advisory boards

What we need from you

Approval of a broad concept for investing OD bioethics funds in FY 14.

OD Funds for Bioethics Research

- The Office of the Director received \$5M for bioethics research beginning in 2010.
- These funds have been dispersed in a number of ways.
- Increasingly, these funds are used to generate data to help inform policy and program development.

Research to Inform Policy

FY 2012 (Competing Supplements)

Research to develop evidence to inform changes to protections for human research subjects

Four Awards

- Easy-to-read consent in high-risk clinical trials
- Harmonized procedures for informed consent for biospecimens and repository operations
- Preferences for consent models for secondary use of biospecimens, including diverse populations
- Tools for consent for data-sharing

Research to Inform Policy

FY 2013 (Administrative Supplements)

Research on (1) preferences for broad consent to use biospecimens and data and (2) ethical issues surrounding standard of care research

Five awards

- Understanding how patients value physician autonomy to choose treatment strategies within the standard of care
- Insight into expected improvements in healthcare (QI) and what constitutes research
- Understanding how patients, general public, IRBs view the ethical implications of randomization within the standard of care
- Understanding how to incorporate genetic information into EHRs for use in genomics research

FY 2014

BIOETHICS RESEARCH

- NIH will fund **\$1.4 million** in new bioethics research in FY2014
- Collected input from the Institutes and Centers
- Propose to fund research in the following areas:
 - Central IRBs overseeing multisite studies
 - Research using clinical records and data

Central IRBs overseeing multisite clinical trials

- Principles to guide the formation and conduct
- SOPs for routine functioning
- Resources or tools to support the operation
- Other ethical or logistical issues

Research using ***clinical records and data***;

- Participant preferences
- Type/duration of consent for research use of data
- Research vs QI
- Privacy *and* data sharing

Proposed FY 2014 Bioethics Research FOA

TIME LINE

DATE	ACTION
December 6, 2013	Concept Clearance – ACD
January 10, 2014	FOA published in NIH Guide
March 10, 2014	Due date for applications
May 2014	Peer review
September 2014	Review of selected applications by relevant IC Advisory Councils
September 2014	Issue awards