

IACUC & IRB: Protecting *Living* Subjects

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Outline

- Key terms
- When and how to submit
- Similarities and differences
- IACUC/IRB/Grant lifecycle
- Questions



Key Terms

Animal– live, vertebrate animals used in research and teaching

Human Subject – A living individual about whom an investigator conducting research obtains (1) data through intervention or interaction with the individual or (2) identifiable, private information

Research - A systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge

When does an application need to be submitted?

IACUC

➤ Whenever you involve a live animal in research or teaching at Harvard

IRB

➤ Whenever you involve a human subject in research

How do you submit?

IACUC

eProtocol: <https://harvard.keyusa.net/>

IRB

ESTR (Electronic Submission, Tracking & Reporting):

<http://irb.harvard.edu>

About ESTR:

<http://cuhs.harvard.edu/estr>

Ethical Principles

U.S. Government Principles for the Utilization and Care of Vertebrate Animals Used in Testing, Research, and Training

- I. Transportation, care and use of animals
- II. Relevance of procedures to human or animal health
- III. Appropriate animal species, quality, and minimum number required
- IV. Avoidance or minimization of discomfort, pain and stress

The Belmont Report

Ethical Principles and Guidelines for the Protection of Human Subjects of Research

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research

The Belmont Report

Ethical Principles and Guidelines for the Protection of Human Subjects of Research

The National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research
April 18, 1979

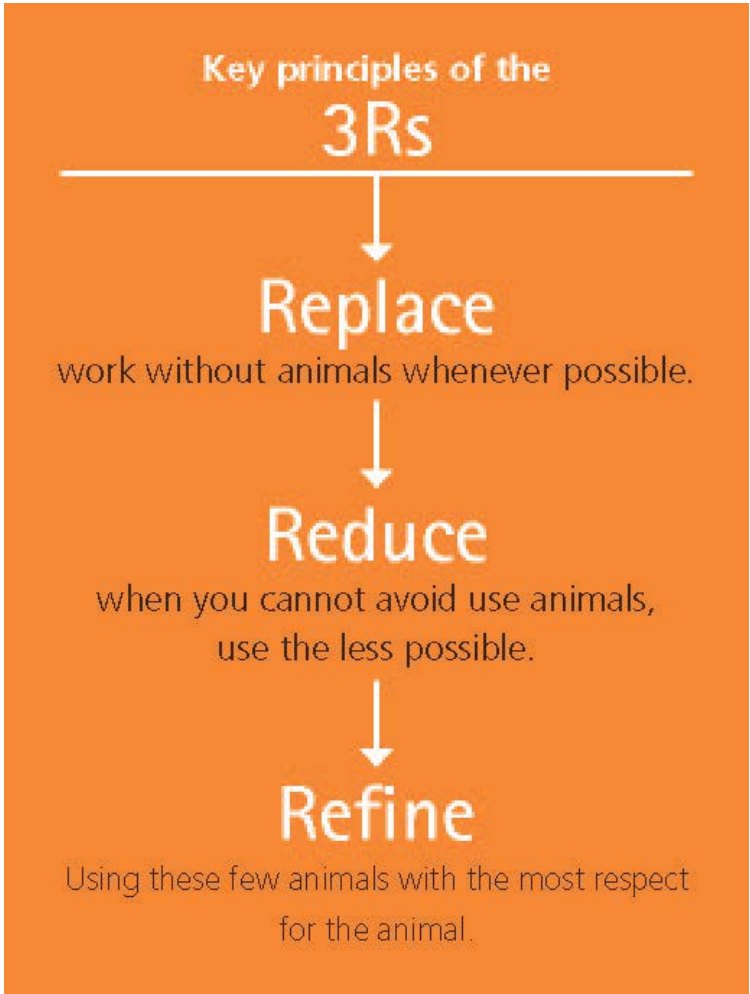
DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
Office of the Secretary

Division of Human Subjects

Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research, Report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research

AGENCY: Department of Health, Education, and Welfare
OFFICE: Office of Support for Public Programs

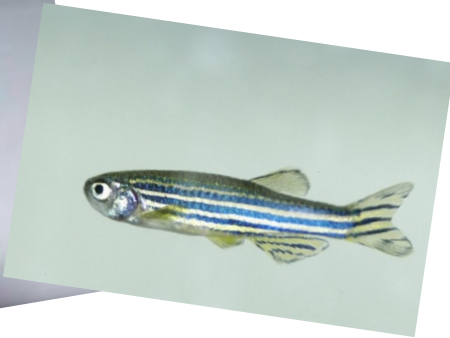
STANDARD: DHEW (OS) 78-0012, The Belmont Report
How to Obtain the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research



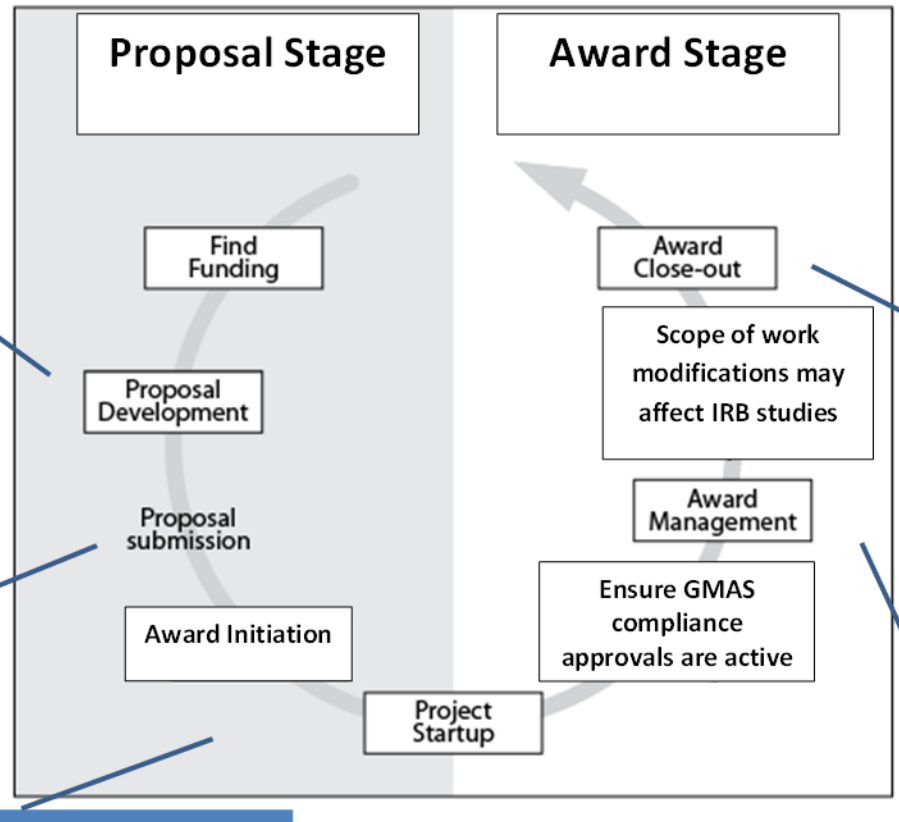
Enforcement - a partnership



Responsibility



Life Cycle



Dept/PI to flag IRB/IACUC Approval(s) in GMAS and in proposal document

Good idea for the PI to contact the IRB/IACUC for consultation

Once submission is received, IRB/IACUC may:
-Provide JIT letter
-Review for regulations
-Compare against contract/grant

[If applicable] PI submits closure request to IRB/IACUC; IRB/IACUC closes study

IRB/IACUC monitors compliance through PI submitting amendments/renewals/etc

Questions



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- CUHS - cuhs@fas.harvard.edu or x6-2847

Useful Links

- FAS RAS IACUC page (<http://iacuc.fas.harvard.edu/>) – **PIN access required -> contact IACUC for access**
- FAS RAS CUHS page (<http://cuhs.harvard.edu/>)