

INSTITUTIONAL REVIEW BOARD (IRB) PRIMER

Purpose of the IRB

The purpose of the IRB is to review research to be conducted within or by its institution, and determine if the rights and welfare of human subjects involved are adequately protected.

IRB Authority

- IRBs have the authority to approve, require modifications to or disapprove human research.
- IRBs adhere to:
 - Common Rule (45 CFR 46) - adopted in 1991 by 17 federal departments and agencies
 - FDA Regulations
 - OHRP (Office for Human Research Protections) Guidance - formerly known as OPRR
 - State Laws
 - University and Community Standards

When does outcomes management/research require IRB approval?

- If it involves human subjects and you expect to publish it
- If it's sponsored by the federal government (e.g., NIH grant)
- If patient intervention will vary from normal practice
- If you are not sure, always ask! IRBs generally prefer to determine whether or not human research meets federal guidelines for exemption. Check with your own institution's IRB.

Requirements of Informed Consent (Code of Federal Regulations)

- Introduction (with statement that this is research)
- Purpose of study
- Description of study procedures (identifying any that are experimental)
- Duration of subject involvement
- Potential risks or discomforts of participation
- Potential benefits of participation
- Alternatives (medical treatments or other courses of action, if any)
- Confidentiality of records statement
- Compensation for injury statement (for greater than minimal risk studies)
- Contact persons
- Statement of voluntary participation

Resources

- U.S. Office for Human Research Protections (OHRP) website: <http://www.hhs.gov/ohrp>
- Public Responsibility in Medicine and Research website: <http://www.primr.org/resources/human.html>
- Dunn CM, Chadwick G. Protecting Study Volunteers in Research: A Manual for Investigative Sites, 3rd edition. Boston: CenterWatch, Inc.; 2004.