Office of
Responsible Research Practices

IRB Information Session: EHE Workshop

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Today's Discussion

- Background – Federal requirements/regulations
- Role of the Office of Responsible Research Practices
- Role of Institutional Review Boards/Committees
- Levels of Review

1974 National Research Act

- Institutional Review Boards protect rights and welfare of subjects in research
- IRBs follow the Code of Federal Regulations from the US Department of Health and Human Services (45 CFR 46) and the Food and Drug Administration (21 CFR 50; 56)

The Belmont Report

National Commission for Protection of Human Subjects (1979)

Basic ethical principles

- Respect for persons (autonomy)
- Beneficence (risk vs. benefits)
- Justice (distribution of burdens and benefits)

Role of the Office of Responsible Research Practices

- Federal Wide Assurance (FWA)
- Provides administrative support to the university research community
- Provides support to the committees responsible for research review and oversight.
- Help Ohio State faculty, staff, and student researchers navigate research requirements through education and quality improvement initiatives designed to facilitate research, improve efficiencies, and ensure regulatory compliance.

Role of Institutional Review Boards

Human Subjects Research that is not determined exempt must be reviewed by an Institutional Review Board (IRB)

- Behavioral/Social Sciences IRB
- Biomedical IRB
- Cancer IRB
- Western IRB

Role of Institutional Review Boards

Risks to participants are minimized

Potential for benefit has been maximized

Selection of subjects is equitable

Informed consent is in place when applicable

Adequate provisions to protect a person's privacy and confidentiality of data

Vulnerable populations are protected

Level Of Review

Full committee review

- Convened IRB meeting

Expedited review

- Minimal risk; specified types of research

Exempt review

- One of six categories; no prisoners, no deception

Exempt Review

- One of 6 categories
- Reviewed by an ORRP Analyst
- Must meet same ethical requirements as IRB reviewed studies
- Research cannot be amended

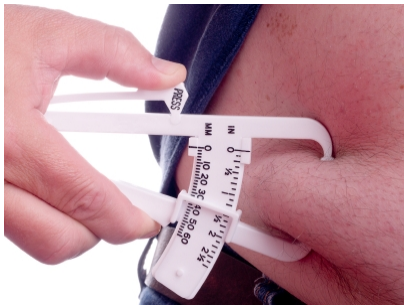
- Category 1: Classroom research
- Category 2: Surveys, Observational studies, interviews, focus groups
- Category 3: #2 with elected officials
- Category 4: Existing data/materials
- Category 5: Federal Agency initiated programs
- Category 6: Food quality and taste

Expedited Review

- Minimal Risk
- One of 7 categories
  - Category 1: Marketed drugs/devices
  - Category 2: Blood draws
  - Category 3: Non-invasive specimen collection
  - Category 4: Non-invasive clinical data collection (e.g., MRI)
  - Category 5: Similar to Exempt #4 (see appendix)
  - Category 6: Audio and video recording
  - Category 7: Research on individual or group characteristics or behavior (most SBS research)
- Reviewed by one IRB member

Expedited Review Examples

- Contact lens studies
- Blood draws
- Buccal swab
- Body composition testing



- Prospective data/specimen collection (medical purposes)
- Most SBS research

http://orrp.osu.edu/irb/initialreview/index.cfm

Full Committee Review

- Usually greater than minimal risk
- Goes to a convened IRB meeting

Examples of Full Review

- Clinical trials or other research with drugs or devices
- Identifiable surveys asking about illegal drug use
- Survey on sex, involving high school students
- Interview of PTSD subjects regarding depression and suicidal tendencies

Office Hours

Behavioral

- 234 PAES building
- Wednesdays
  1:00 p.m. - 3:00 p.m.

Biomedical

- Call for appointment

www.orrp.osu.edu

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