Brief Introduction to Institutional Review Boards

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Produced by University Communications

What is an Institutional Review Board?

- Federally mandated, institutionally based
- Mission is to protect rights and welfare of human research participants
- Board members must have competence to review specific research activities; apply federal, state, and institutional regulations; apply standards of professional conduct
- UW-Madison has 4 IRBs: Education, Social Behavioral Sciences, Health Sciences, and Health Sciences Minimal Risk

What do IRBs review?

- *Research* involving *human subjects,* e.g.
  - Human testing of drugs, devices, or products
  - Research using medical records
  - Collection of data from surveys, interviews, and observation
  - Use of bodily materials (e.g. cells, blood, urine, organs, hair, nail clippings, DNA)
  - Research using school or corrections records
  - Research using employment information or records of earnings

- IRB oversight required from beginning to end of a research study, unless a project is found to be exempt

What Is a Human Subject?

- According to the "Common Rule" (main regulation governing IRBs), a human subject is a living individual about whom an investigator conducting research obtains:

  (1) data through **intervention** or **interaction** with the individual **OR**

  (2) identifiable **private information** obtained for this research in a form associable with the individual (i.e. the identity of the subject is or may readily be ascertained or associated with information)

- FDA's definition also includes human specimens on which an investigational device is used

What Is Research?

- The Common Rule defines research as "a **systematic** investigation, including research development, testing and evaluation, designed to develop or contribute to **generalizable** knowledge"
  - "**Systematic**" means that research methods are employed to test a hypothesis and draw conclusions
  - "**Generalizable**" refers to the dissemination of or intent to disseminate findings to a scientific or professional audience

Basic ethical principles

Belmont Report (1979) established ethical principles to guide conduct of human subjects research

Respect for Persons:

- Autonomy, informed consent
- Protection for those with limited autonomy (e.g. children, prisoners, cognitively impaired)

Beneficence:

- Maximize benefits of research and minimize potential harm

Justice:

- Fair distribution of both risks and benefits of research

Regulations/policies governing IRB review

- "Common Rule" (45 CFR 46)
- FDA regulations (21 CFR 50), when research involves new drugs, devices
- VA regulations
- HIPAA Privacy Rule (45 CFR 160, 164)
- State law
- UW-Madison policies and guidelines

Basic criteria for IRB review

- Are risks minimized, so that it is as safe as possible for people to take part in the study?
- Does the potential benefit to participants or to society balance the risks?
- Are the right subjects being enrolled to answer the study question?
- Is the study design acceptable?
  - the question posed can be answered by the research
  - the right number of people will be enrolled (not too many or too few), so that as few people are exposed to risk as possible
- Are potential subjects given enough information to make an informed choice about taking part in the research study?

Tips for successful IRB submissions

- Educate yourself about local requirements and procedures
  http://info.gradsch.wisc.edu/research/hrpp/index.html
  http://info.gradsch.wisc.edu/research/hrpp/hsirbs/index.html
- Look at your project through a participant's eyes
  - What will subjects need to know? How will you tell them about the research? What will they have to do? What will procedures be like?
- Explain how the study meets IRB review criteria
  - Provide details and rationale
  - Make all documents complete, clear and consistent
- Consult with IRB staff