Brief Introduction to Institutional Review Boards

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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