What is the IRB?
What does the IRB do?

- Oversees all UPenn research on human participants

~INCLUDING~

- Federally funded research [Department of Health and Human Services (DHHS)]
- Industry sponsored research through the Food and Drug Administration (FDA)
- Investigator-initiated research (whether funded or not) conducted by student or faculty
New Submissions

How the IRB reviews research
How does the IRB review research?

♦ Reviews are divided into categories:
  • **Administrative acknowledgment** (not human subjects/not research/or both)
  • **Exempt from IRB review**
  • **Expedited** (minimal risk)
  • **Convened IRB** (greater than minimal risk, reviewed by convened IRB)
NOT RESEARCH OR NOT HUMAN SUBJECTS

♦ IRB submission is **NOT REQUIRED**

♦ Your dissertation chair will help you determine if submission is required.
New Submissions

Exempt & Expedited Reviews
EXEMPT

♦ Must be determined by the IRB staff that the research qualifies

♦ Exempt research examples:
  • Surveys, interviews and observations that do not put subjects at risk of any liabilities
    – Non-sensitive surveys, interviews, oral histories
    – Information that may be sensitive in nature, but identifying information about the subject is not retained
  • and do not involve:
    – Children
    – Prisoners
    – FDA regulation
New Submissions

Convened IRB Review

(Protocol reviewed at the IRB meetings)
IRB WEBSITE

The mission of the IRB is:

- To promote the rights and welfare of human research participants
- To facilitate excellence in human research by providing timely and high quality review of human research
- To provide professional guidance and support to the research community

The University of Pennsylvania is guided by the ethical principles set forth in the Belmont Report (Ethical Principles and Guidelines for the Protection of Human Subjects of Research). The minimum standards are set by the Department of Health and Human Services regulations at 45 CFR 46 and the Food and Drug Administration's regulations at 21 CFR 50 and 21 CFR 56.

In June 2007, Penn's human research protection program (including the IRBs) was awarded full accreditation by the Association for the Accreditation of Human Research Protection Programs. Accreditation standards establish the highest expectations for the conduct and oversight of human research.