

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

UPenn - Office Of Regulatory Affairs - IRB The Institutional Review Board (IRB) reviews researc - Internet Explorer provided by

http://www.upenn.edu/regulatoryaffairs//index.php?option=com_content&task=view&id=3&Itemid=8

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INSTITUTIONAL REVIEW BOARD

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 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.

IACUC
Penn's Animal Care and Use Committee reviews all research and training activities involving animals

IRB
The Institutional Review Board (IRB) reviews research involving human research participants.

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