Investigators’ Responsibilities in Conducting Human Subjects Research

Dept. of Regulatory Affairs
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Topics in this presentation

• What is human subjects research?
• Review mechanisms
• IRB approval
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What is human subjects research?

- The IRB reviews human subjects research. The activity has to be considered "research" and has to involve "human subjects" for the IRB to review it.
- The DHHS definition of research is "a systematic investigation... designed to develop or contribute to generalizable knowledge."
Systematic investigations include:

- surveys and questionnaires;
- interview and focus groups;
- analysis of existing data or biological specimens;
- epidemiological studies;
- evaluations of social or educational programs;
- cognitive and perceptual experiments; and
- medical chart review studies
• In other words, human subjects research can occur without any intervention or interaction with individuals.
Note that research results do not have to be published or presented at a professional meeting to qualify the experiment or data gathering as research. From DHHS' perspective, the contribution to generalizable (widely applicable) knowledge makes an experiment or data collection research, regardless of publication.
• In addition, a person cannot circumvent the DHHS regulatory definition of research by claiming that there was no intent to develop or contribute to generalizable knowledge. The IRB evaluates the investigator's proposed actions and behavior, rather than the investigator's intent, to discern the design of the activity.
Review mechanisms

• Human subjects research is reviewed via three methods: a convened IRB; expedited review; or is deemed exempt from further IRB review.

• Note that the determination for exemption is made by the IRB, not the investigator.
IRB approval

• You must not conduct human subjects research or implement a modification to approved research without prior IRB review and approval (or an IRB determination that the research is exempt).
• IRB approval occurs when you receive the IRB approval letter.
• IRB approval does not occur:
  – Upon submission to the IRB
  – If the study is “approved pending modifications required to secure approval”
IRB approval

i.e., other Institutional approvals may be required before starting the study. Examples:

- Environmental Health & Radiation Safety (EHRS)
- Institutional Biosafety (IBC)
- Animal Care and Use (IACUC)
- Departmental approval
- City, state, county laws, codes, ordinances, etc.
Consequences

• If the IRB makes a determination of serious non-compliance or continuing noncompliance regarding you or your study:
  – The determination may be reported to the FDA and the Office for Human Research Protections (OHRP).
  – The Senior Vice Provost for Research and Graduate Education and your Department Chairperson and/or Dean will be notified.
• Your research privileges at Temple University or with federal agencies (e.g., FDA) may be restricted.
• The FDA, OHRP, and other monitoring agencies may audit you and your other studies.
• The FDA, OHRP, and other monitoring agencies may audit Temple University.
• The reputation of Temple University may be affected.
• The research enterprise at Temple University may be impacted.
Resources

• You have many resources available to you:
  – The IRB website is a wealth of information: www.temple.edu/research/regaffairs/irb/index.html
  – Some of the highlights:
    • FAQ section
    • Investigator Manual
    • Human Research Protection Program Plan
    • Contact information for IRB staff and Chairpersons
Conclusion

• Don’t violate subjects’ rights.
• Ask the question, “Is this human subjects research?”
• If so, obtain IRB approval before implementation.
• Consult the IRB website and contact the IRB with your questions.
• Don’t risk your and Temple’s reputation.