

Human Research Compliance

Samara Wisniewski, J.D.
Director of Regulatory Compliance
Department for Human Research Protections
The University of Toledo

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Approval to Conduct Human Subject Research

UT researchers must obtain IRB approval for all “human subject research”

- Human Subject:
 - living individual, and
 - data through intervention or interaction, or
 - identifiable private information
- Research:
 - systematic investigation
 - designed to develop or contribute to generalizable knowledge

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What is an IRB?

- An **Institutional Review Board** is a board established under federal regulatory requirements to review and monitor research involving human subjects
- Purpose - protect rights and welfare of humans participating in research
- Has authority to approve, require modifications, or disapprove research

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IRB Basics

- Guided by federal regulations, ethical principles of The Belmont Report, standards of professional practice, and institutional policy
- Decisions to disapprove cannot be reversed by administration
- Must re-approve research at least annually
- Cannot grant retrospective approval

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UT Institutional Review Boards

- Two IRBs serve UT on campus
 - Biomedical IRB
 - Social, Behavioral & Educational IRB
- Designated External IRBs
 - SVMMC Peds IRB –pediatric biomedical research
 - WIRB – alternative to Biomedical IRB for industry sponsored phase III and IV biomedical research

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Why Is IRB Approval Required?

- Federal Regulations for the Protection of Human Subjects – 45 CFR 46
- The Federalwide Assurance (FWA)
 - Written agreement between UT and OHRP
 - Required by federal regulations for all institutions “engaged in research” conducted or supported by a federal department or agency
 - Assurance that UT will follow all requirements in federal regulations unless research is “exempt”

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Federal Regulations, the FWA and Terms of the Assurance Serve As the Basis for UT Institutional Review Boards' Policies and Procedures

The Goal of UT Department for Human Research Protections and the IRBs is to facilitate research under regulatory requirements and ethical guidelines

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Key Components of the UT Federalwide Assurance (FWA)

- All UT research will:
 - Be guided by The Belmont Report
 - Comply with UT's Terms of Assurance
 - Reviewed by an IRB designated in the FWA
 - Provide education to IRB members, researchers and relevant staff
- Signed by UT's Signatory Official - Dr. Lloyd Jacobs

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Topics Addressed By 45 CFR 46

- Applicability of regulations and exemptions
- Assuring compliance with the regulations - FWA
- IRB membership requirements
- IRB authority (approve, disapprove, require modifications prior to approval)
- Review of approved research by institutional officials
- Procedures for expedited review - specified research

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Topics Addressed By 45 CFR 46

- Informed consent requirements & elements
- Suspension or termination of IRB approval
- Cooperative research (institutional or individual)
- IRB recordkeeping
- Requirement for continuing review
- Criteria for approval of research

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When Is IRB Review Required?

- Prior to Beginning “Human Subject” Research
- Continuing Review Until Data Analysis Complete
 - IRB must review on-going projects at least annually, depending on degree of risk to subjects

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Levels of IRB Review

- **Convened** – fully-convened IRB committee discusses the study and makes a decision about approval. Used for studies involving greater than minimal risk to subjects.
- **Expedited** – qualified member of the IRB reviews the appropriate materials, consults with the investigator if necessary, and decides whether to approve or refer to convened IRB. Utilized for studies that fit into an expedited review category and involve minimal risk to subjects
- **Exempt** – Study screened to determine if it fits into an exempt category of research and is low risk to subjects. If designated exempt, IRB issues exemption letter.

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Common Categories of Expedited Research

- Surveys, interviews, oral histories, individual or group behavior (could be exempt or expedited)
- Materials (e.g. data, documents) collected for non-research purposes
- Data obtained through non-invasive means (e.g. EEG, MRI, moderate exercise monitoring)
- Biological samples obtained non-invasively
- Minor changes to approved research

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Common Exempt Research Categories - 45 CFR 46.101

- Collection or study of existing data, documents, pathological specimens if the information is:
 - Publicly available, or
 - Recorded so that participants cannot be directly or indirectly identified (coded information)
- Educational tests (cognitive, aptitude, achievement)
- Survey or interview procedures if participants are not identified, or disclosure would not be harmful
- **Observation** of public behavior

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Educational Training Requirements for Researchers

- Web Based Training for Research Teams,
- FWA and Terms of Assurance, and
- The Belmont Report

- Researchers accessing PHI must also complete HIPAA training

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Why is Educational Training Required?

- Researchers Must Understand Relevant Ethical Principles and Regulatory Requirements
- FWA provides written assurance to OHRP that UT research will be conducted under principles of:
 - The Belmont Report
 - 45 CFR 46
 - Institutional Policies & Procedures

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UT DHRP and IRB Policies and Procedures

- Required by FWA and Federal Regulations
- Content guided by federal regulations and OHRP
- Explains IRB requirements and procedures for researchers, IRB staff, and IRB members
- Describes compliance monitoring activities

On The Web:
http://www.utoledo.edu/research/RC/HumanSubs_Menu.html

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UT DHRP Compliance Activities

- Compliance Support Visits
 - Random
 - Interview investigator; review files
 - Compliance education and support
- Compliance Audits
 - For cause, or credible evidence of non-compliance

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Reporting Non-Compliance to Institutional Officials and OHRP

- When the IRB finds:
 - *Unanticipated problems involving risk to subjects, or*
 - *Serious or continuing non-compliance with federal regulations, UT IRB procedures, or requirements of the UT IRB,*
- the IRB shall report the occurrence to the UT signatory official and OHRP

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OHRP Common Findings of Non-Compliance

- Research conducted without IRB approval
- Failure to obtain continuing approval of previously approved research
- Inappropriate review of research using expedited procedures for non-qualified research
- Failure to obtain approval for changes to protocol
- Failure to obtain informed consent

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OHRP Common Findings of Non-Compliance

- Failure to document informed consent
- Informed consent documents insufficient
- Informed consent language too complex
- Enrollment procedures did not minimize possibility of coercion or undue influence
- Failure of IRB to make findings required by federal regulations prior to approving research

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Student Research Projects

- Requires supervision by faculty member (“faculty advisor”)
- Faculty advisor’s signature is required on IRB application
- Student investigators and faculty advisors share the responsibility for compliance with federal and institutional requirements

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Graduate Research

• Graduate students must complete GRAD form following committee approval of a topic and approach for research

- Signed by student, advisor, committee members (and Dept. Chair for HSC)

• Submit to College of Graduate Studies Office on appropriate campus

TOLEDO

Original Submission Date: _____

RECIPIENT: College of Graduate Studies
Health Service Campus

Main Campus: _____ Health Service Campus: _____

Graduate Research Advisory (GRAD) Committee Approval & Assurances Form

This form requires the Notice of Project, Notice of Thesis, and Assurances of Compliance Forms for Main Campus and/or the Assurances of Compliance Form for the HSC/HSB Research Track. Major Institutional/Departmental Responsibilities Apply for the Health Service Campus.

Instructions: Student must complete this form and receive the required approvals **prior to beginning** research. The principal investigator, advisor, committee members, advisor, student, or department chair must sign and date the required approvals **prior to beginning** research.

For the purposes of this document, the term “investigator” includes both the **Principal Investigator or Faculty Advisor and the Student Investigator**. The completion of this form indicates that a Graduate Committee has approved both a topic and an approach for the research, and is aware of federal requirements for institutional review of human subjects.

This form is signed by the Student, Advisor, Committee Members, and Departmental Chairperson (Health Service Campus) (should be included in the advisor section of the form). Please include Advisor on the form besides “Major Advisor” on the Health Service Campus and “Research Advisor” on the Main Campus.

The respective College of Graduate Studies Office will accept receipt of the form, signifying that institutional review requirements have been met. The Policy Information and Forms page below are available on the following Research & Sponsored Programs Web site: <http://www.utoledo.edu/research/>

Date: _____

Student's Name: _____ Student ID #: _____

Degree Program: _____

Concentration or Track (if applicable): _____

Research track and: Doctoral Project Thesis Dissertation Field Experience

Advisor: _____

Proposed Title: _____

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GRAD Committee Approval and Assurances Form

- Main Campus Graduate Studies Web Page
 - <http://utoledo.edu/graduate/files/gradform.pdf>
- HSC College of Graduate Studies Web Page
 - <http://monitor.utoledo.edu/depts/grad/forms.html>

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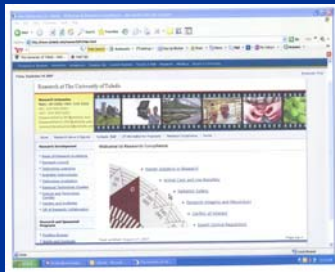
DHRP & IRB

- DHRP
 - Carolyn Pinkston, RN, BS – Director of Operations
 - Samara L. Wisniewski, JD – Director of Regulatory Compliance
- Biomedical IRB
 - Chair – Roland T. Skeel, MD
 - Coordinator – Susan Mates, CMA-C – Coordinator
- SBE IRB
 - Chair – Barbara K. Chesney, PhD
 - Coordinator & Compliance – Jeff Busch, PhD

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IRB Forms

- http://www.utoledo.edu/research/RC/HumanSubs_Menu.html



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Contact Us

<u>Biomedical IRB</u>	<u>SBE IRB</u>
IRB.Biomed@utoledo.edu	IRB.SBE@utoledo.edu
CCE 0105	University Hall 2300
419-383-6796	419-530-6167
MS # 1035	MS # 944

<http://www.utoledo.edu/research/RCMain.html>

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Questions?



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Regarding Social Scientists' Frustrations with the IRB Process

A motivating objective of evaluation science is to benefit individuals by improving social conditions (Rossi, Freeman, and Lipsey 1999). Even evaluations that reveal negative program effects are valuable because they (should) compel decision makers to adjust allocations. Human research subject protections go hand-in-hand with these goals. Although we may occasionally be frustrated by rules, policies, and seemingly inconsistent IRB decisions, we need to remember that just as helping people is central to our science, it is central to IRB oversight. Indeed, the IRB system did not spontaneously appear from the ether to frustrate researchers and create bureaucratic obstacles. The situation today is a direct consequence of many documented violations of very basic ethical standards. That many of these occurred in biomedical investigations only means that social scientists need to ensure such harms never befall their subjects.

RISKS AND WRONGS IN SOCIAL SCIENCE RESEARCH
An Evaluator's Guide to the IRB,
J. MICHAEL OAKES, University of Minnesota (2002)
<http://www.research.umn.edu/irb/studentResearchers/>

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