Human Subjects Research and the IRB Process

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Definitions

**Human Subjects**
Living individuals about whom an investigator (professional or student) conducting research obtains data through intervention or interaction with the individual or obtains identifiable private information.

**Research**
A *systematic investigation*, including research development, testing, evaluation, surveys, questionnaires, and/or interviews, designed to develop or contribute to the **knowledge base**.

**Systematic Investigation**
A cohesive approach involving data collection (quantitative and/or qualitative) from one or more individuals for analysis to address a question or test a hypothesis.

**Knowledge Base**
The results or outcomes gained from a systematic investigation that may be published, archived, presented, or viewed in some way as relevant beyond the specific participant population.
The members of the UT Martin Institutional Review Board (IRB) are listed on the ORSP website: [www.utm.edu/departments/rgc/irb.php](http://www.utm.edu/departments/rgc/irb.php)

The purpose of the IRB is to review human subject research to ensure that human subjects are adequately protected.

Duties of the IRB include the following:

- Approve, disapprove, or suggest modifications to human subjects research
- Conduct continuing review
- Observe, monitor, and/or audit human subject research
- Suspend or terminate approval if necessary
IRB Autonomy and Support

The UT Martin IRB has the ultimate approval authority on this campus. Approval by other officials cannot supersede the authority of the university IRB.

45 CFR 46.112 and 21 CFR 56.1
IRB Board Composition

• Minimum of five members, both genders
• Varied professions, scientific and non-scientific
• Minimum of one member not otherwise affiliated with UT Martin
• Experience, expertise, diversity
• Sensitivity to community attitudes
• Knowledge of institutional commitments and regulations, applicable laws, Standards of Professional Conduct
• Knowledgeable and experienced with vulnerable subjects
• Special competencies of Ad Hoc consultants
IRB Applications

If you are planning research involving human subjects, you MUST file an IRB application and receive IRB approval PRIOR to collecting data.

Ethical research practices and federal regulations require IRB approvals in human subject research.

A Federal-wide Assurance binds UT Martin to uphold ethical and regulatory requirements in human subject research, regardless of funding.
Importance of IRB Approvals

Historically, there have been numerous cases in which researchers did not protect their human subjects, resulting in irrevocable harm and deaths resulted.

- Nazi Medical Experiments of WWII
- Dr. Joseph Mengele and the Nuremberg Trials
- Tuskegee Syphilis Study, 1932–1972
- Willowbrook State School, 1956–1963
- San Antonio Birth Control Clinic, 1971
- Phocomelia birth defects, 1950s–1960s
- Milgram Experiments on Obedience to Authority, 1960s
- Jewish Chronic Disease Hospital, 1963
- Human Radiation Experiments, 1940s–1970s
Questions to Consider

- Could this activity lead to a publication?
- Will the results be presented in a professional forum?
- Will the results be archived?
- Does the research project involve an interaction with a living person (face-to-face, by mail, by phone, by email, etc.)?
- During this interaction, will you seek data about the person (i.e., behavior, beliefs, experiences, medical or economic status)?
- Does this research involve archival data about individuals?
- Will identifiable private data be obtained for this research in a form associable with the individual?
Student Research

- Will the research be conducted outside the classroom or off campus?
- Do the results have potential to be published or presented outside the classroom or off campus?
- Is the activity defined as a research project with a research question or hypothesis?
- Since publication requires consent of the participants, it is prudent to seek IRB review of the consent form and other project materials in advance if there is any chance of publication later.
- If a student developed an exemplary research plan and collected data impressive enough that the instructor would like to use it as an example for subsequent projects, this would be archived and subject to IRB approval before it could be used.
- Without IRB approval, these data must be destroyed and cannot serve as an example.
Class-Related Projects and IRB Approval

IRB is required for the following:

- All master’s thesis and research projects involving human subjects
- All projects for which findings may be published or otherwise disseminated
- All class-related projects for which the data collected will be archived for any purposes other than administrative evaluations

Course activities that involve human participants but have no connection to research beyond the instructional function do not require IRB review.

The collection of information from respondents for the purpose of class discussions or for the purpose of training in research or research methods does not require IRB review.

In these situations, instructors are responsible for the protection of human subjects.
Training for Instructors

- The ORSP recommends that instructors who plan to have their students involved in these types of activities complete Human Subjects Research training.
- Training is also available for students.
- Contact the ORSP for instructions to access to this training.
“Ethical lapses are almost never cases of bad people doing bad things, for no good reason. More often they are good people, doing bad things, for good reasons.”

loosely quoting Marcia Angell, MD
(former) Editor-in-Chief, NEJM
“Sometimes, with the best of intentions, scientists and public officials ... working for the benefit of us all, forget that people are people. They concentrate so totally on plans and programs, experiments, statistics, - on abstractions - that people become objects, symbols on paper, figures in a mathematical formula...”

Atlanta Constitution, July 27, 1972
The Belmont Report

Ethical Principles and Guidelines for the Protection of Human Subjects of Research

Respect for Persons
Beneficence
Justice

National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, 1979
Respect for Persons

- Treat individuals as autonomous agents.
- Don’t use people solely as a means to an end.
- Allow people to choose for themselves.
- Recognize a fundamental right to be left alone.
- Extra protections for vulnerable populations.
- **Practical applications:** informed consent and privacy protections.
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Beneficence
• Maximize benefits.
• Minimize risks.
• **Practical applications**: study design, risk-benefit analysis, competent investigators.

Justice
• Burdens and benefits of research should be distributed equitably.
• Treat people fairly.
• **Practical applications**: selection of subjects, recruitment, populations under study.
Principles carry equal moral weight.
Tension was anticipated and expected.
Requires subjective judgment calls.
Reasonable people will disagree.
Common Rule

- Federal policy for the Protection of Human Subjects
  - June 18, 1991
  - Adopted by 21 federal agencies
- Based on a system of assurances
Additional Protections for Vulnerable Populations

45 CFR 46

- Subpart B: (1975, 2002) Fetuses, pregnant women, and in vitro fertilization
- Subpart C: (1978) Prisoners
- Subpart D: (1983) Children
- Subpart E: (Proposed) Mentally disabled
Review Continuum

The level of risk determines route of review. All student-involved research at UT Martin involving human subjects is classified as Expedited or Full Review.
Assessment of Exempt

“If I think my research is exempt, then I don’t have to do anything, right?”

Wrong!!!

Exempt does not mean “exempt from review” - it means exempt from Full Review.
Research must fall into one or more of the six categories defined by 45 CFR 46 (32 CFR 219.010) to be exempt.
Researchers must fully explain their selection of category in their application.
Consent and other safeguards may still be required.
Assessment of Exempt Categories

Educational research
Tests, surveys, interviews or public observations
Research on existing public or anonymous data or specimens
Federal demonstration projects
Taste and food evaluations
Examples:
- Studies of normal educational practices in commonly accepted educational settings.
- Research involving educational tests or passive observation of public behavior that is anonymous or benign.
- Research involving surveys or interviews of adults that are anonymous or benign.

Check the Handbook on the ORGC website for limitations and extra circumstances that may apply.
Assessment of Exempt

IRB may still determine
- The study has more than minimal risk, so it cannot be exempt.
- State or local laws may prohibit an exemption.
- Exempt studies may still need consent.
- Exempt studies may have ethical concerns.
Assessment of Minimal Risk

The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves from those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Not only physical risk, but also
- Criminal/civil liability
- Financial risk
- Employment risk
- Stigmatization
- Insurability
- Embarrassment
Assessment of Minimal Risk

“Okay, if my research is not exempt, the IRB can expedite it. This is quick, right?” Not necessarily.

Expedited does not mean quicker. Rigor of review is the same as full review, number of reviewers is different.

Review is carried out by IRB Chair and the IRB secretary.

Both reviewers must agree to approve or the application will be sent to the full committee for review.

Expedited does not mean cursory; documentation of substantial review is essential.

If there are any questions, UT Martin will err on the side of full review.
Assessment of Full Review

- A full quorum is assembled (at least half of the members).
- All members participate in discussion and make comments (plenary review).
- Decision is rendered by a majority of the assembled quorum.
- No member with a conflict of interest participates in the decision.
- Numerical vote is taken and recorded.
Initial Expedited Review

- Clinical studies where IND/IDE are not required
- Blood sample collection (small amounts, routine methods)
- Prospective collection of biological samples - noninvasive means
- Data collected through noninvasive means (routinely practiced in clinical settings)
- Materials (data documents, specimens, etc.) collected for non-research purposes.
- Collection of voice, video, or digital data for research purposes
- Individual or group behavior, surveys, interviews, oral histories
Continuing Expedited Review

- Continuing review of research with no further direct subject participation
- Continuing review of minimal risk research (not under IND or IDE) where no additional risks have been identified.
Criteria for Approval

- 45 CFR 46.111
- Minimized risks (not eliminated)
- Reasonable risk/benefit assessment
- Equitable subject selection
- Informed consent process
- Informed consent documentation
- Data monitored for safety
- Confidentiality/privacy maintained
- Vulnerable populations protected
Consequences of Not Filing IRB

- Your ethics may be called into question.
- You may be subject to a Misconduct of Research and Service investigation.
- Your papers or presentations may be pulled from publication or program proceedings due to the absence of IRB approval.
- Grant funding may be denied.
- Failure to have and follow appropriate procedures for IRB review and approval can also result in federal investigations and sanctions for the university.

If you are involved in human subjects research
- with another university or organization or
- in an international venue,
there are additional considerations and/or procedures that may apply.
Important Reminders

- The Principal Investigator has ultimate responsibility for ethical conduct.
- Respect the time and process necessary for review. IRB approvals are not retroactive.
- The IRB exists to assist by raising issues and asking questions that the PI may have overlooked or failed to consider.
- The researcher and the IRB should be considered collaborators.
Resources

Additional information can be accessed from the UT Martin Office of Research and Sponsored Programs website: [www.utm.edu/departments/rgc/irb.php](http://www.utm.edu/departments/rgc/irb.php)

Information concerning the UT Martin IRB, the UT Martin *Faculty, Staff, and Student Handbook for Studies Involving Human Participants*, definitions, the forms needed to file an IRB application, instructions for completing the application

UT Martin subscribes to an approved online training program regarding Human Subjects Research that is available at no cost to faculty, staff, and students. Contact the UT Martin ORSP for access information.