RESEARCH INVOLVING HUMAN SUBJECTS

The Role and Methods of the Institutional Review Board at UTC
WHAT IS THE INSTITUTIONAL REVIEW BOARD (IRB)?

Committee composed of a diverse group of faculty members and professionals representing a broad range of professional and academic disciplines.

Purpose: To determine if the rights and welfare of human participants in research are adequately protected.

Reviews and approves all research activities involving human subjects.
How do you know if you’re doing research?

**Research:**
A systematic investigation designed to develop or contribute to generalizable knowledge or to contribute to the general body of knowledge.
HOW DO YOU KNOW IF YOU ARE USING HUMAN PARTICIPANTS?

**Human Participants:**
Living individuals about whom an investigator conducting research obtains:

- Data through intervention or interaction with the individual, or
- Identifiable private information
Does your project meet the definition of research with human subjects?

All of the following activities may be considered research:

- Interviews
- Surveys
- Observation
- Case studies
- Analysis of existing data
What about Student Research?

Ask yourself these questions:

- Will the research be conducted outside of the classroom or off campus?
- Do the results have the 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?

If the answer is “Yes” to any of these questions, the student should submit an application to the IRB.
EXAMPLES OF CLASS-RELATED PROJECTS THAT MAY REQUIRE IRB APPROVAL

- A doctoral dissertation that studies the efficacy of a certain medical procedure or treatment.
- Senior-Year Departmental Honors Project that interviews students regarding their views on domestic violence, the results of which will be presented at a regional conference.
- “Capstone” research project that involves observation in local classrooms and will result in a paper on teaching strategies that may be published.
CLASS-RELATED ACTIVITIES THAT DO NOT REQUIRE REVIEW

- Course activities that involve human participants, but have no connection to research beyond the instructional function
- The collection of information from respondents for the purpose of class discussions or for the purpose of training in research or research methods.

In these situations, instructors are responsible for the protection of human subjects. Faculty instructors must have completed IRB training and have filed a classroom activity application with the IRB.

No project that involves more than minimal risk to the participants may be dealt with under this procedure.
What does the IRB look for in a research project?

- Risks are minimized
- Risk vs. benefits ratio
- Equitable participant selection
- Informed consent process is appropriate
- Privacy, confidentiality, and safety are maximized
- Safeguards are in place to protect vulnerable subjects
What You Need to Know

All faculty, staff, and students who conduct research involving human subjects are required to have prior approval from the IRB BEFORE research begins.

Projects must be approved regardless of whether or not the research is funded.
So you need IRB approval. What do you do next?
HOW TO APPLY FOR IRB APPROVAL

Application for Review of Research Involving Human Subjects (Form A)

Forms may be downloaded from the IRB website:

www.utc.edu/irb/forms
PURPOSE/OBJECTIVES OF RESEARCH

- State the purpose of the research and the problem to be investigated. When possible, state specific hypotheses to be tested or specific research questions to be answered. For pilot or exploratory studies, discuss the way in which the information obtained will be used in future studies so that the long term benefits can be assessed.
RELEVANT BACKGROUND AND RATIONALE FOR THE RESEARCH

- This section should present the context of the work by explaining the relation of the proposed research to previous investigations in the field. Include citations for relevant research.
- Provide at least twice as many peer reviewed citations as “lay” citations.
METHODS/PROCEDURES

Discuss your research methods which directly involve use of human subjects. Discuss how the methods employed will allow you to address your hypotheses and/or research question(s).
**Subject Population**

- Provide the number of participants that will be involved in the research.
- State who the study participants will be and how they will be recruited.
- If you are doing research with vulnerable populations, check the appropriate box on the application (children, mentally impaired, pregnant women, etc.).
INCENTIVES

- **What incentives will be offered, if any?**
  (Indicate whether or not subjects are to be paid, how and when they will be paid, amount, and the rationale for payment. Payment should not be so great as to encourage participation that would not otherwise be undertaken.

- **Extra credit – discouraged!**
Risks/Benefits to Participants and Precautions to be Taken

- Discuss all possible risks and discomforts from participation in the study, indicating both severity and likelihood of occurrence for each.
- The methods that will be used to minimize these risks should also be discussed.
- Many studies hold the potential for loss of privacy and confidentiality. These concerns should be noted in this section.
- If subjects are vulnerable populations, or if risks are more than minimal, please describe what additional safeguards will be taken.
Describe how the privacy/confidentiality of the participant will be maintained.

How will the instruments/data be stored securely?

Who will have access to the data?

What will happen to the data following the study?

Example: The survey will be stored in a securely locked cabinet that can only be accessed by the researcher. There will be no identifiers linked to the surveys and each will be assigned a numeric code.
HOW TO APPLY FOR IRB APPROVAL

Applications are completed and submitted electronically to: instrb@utc.edu

For student projects, faculty advisor approval is required.

Submit the application to the faculty advisor first, then he or she can submit it and all applicable attachments to the IRB.
HOW LONG WILL IT TAKE TO HAVE MY PROJECT APPROVED?

The length of time for review depends on a number of factors:

- The category of review required
- The completeness of your application
- The volume of applications being reviewed by the IRB
WHAT ARE THE CATEGORIES OF REVIEW?

1. Exempt
2. Expedited
3. Full Board Review
4. Continuing or Annual Renewal
5. Classroom Assignments
AVERAGE REVIEW TIMES

Exempt
• 5-7 days

Expedited
• 7-10 days

Full Board Review
• up to a month
**How is the category of review determined?**

The IRB determines the category of review based on the following factors:

- The level of potential risk to the participants
- The vulnerability of the participant population
- The selection process of the participants
- Whether sensitive or medical information will be collected
Consider These Risks

- Physical risks
- Financial risk
- Stigmatization
- Embarrassment
- Criminal/civil liability
- Employment risk
- Insurability
What type of research is considered exempt?

Some limited types of research are exempt from IRB monitoring; however, federal regulations, funding agencies, and UTC policy prohibit investigators from making this determination on their own.

Only the IRB Chair or his/her designee is allowed to determine exemption, thus researchers must submit an application to ensure that the research meets the criteria for exemption.
Exempt Research

Research may qualify as exempt if:
- Education research
- Tests, surveys, interviews, or public observations
- Research on existing public or anonymous data or specimens
Some Examples of Exempt

Studies of normal educational practices in commonly accepted educational settings

Research involving educational tests or passive observation of public behavior that is anonymous and benign

Research involving surveys or interviews of adults that are anonymous or benign.
EXCEPTIONS

Any study that uses vulnerable populations such as children, cognitively impaired individuals, incarcerated people, or pregnant women is not eligible for exemption. Research on these populations requires expedited review.

The IRB reserves the right to deny exemption if it determines that the study has more than minimal risk, has ethical concerns, or needs additional investigation.
EXEMPT REVIEW PROCEDURES

- The IRB Chairperson determines if research involving human subjects may be considered exempt.

- Exempt research does not require annual review.

- However, if the research design or subject population changes, it is the investigator’s responsibility to contact the IRB to determine if further review is required.
WHAT TYPE OF RESEARCH IS CONSIDERED EXPEDITED?

- Research that is determined to place a human subject at **minimal risk** in a research setting.

- Most social and behavioral science research, certain specific non-invasive methods of specimen collection, and surveys or studies where the participants information will be kept confidential.

Most research at UTC falls into this category.
**EXPEDITED REVIEW EXAMPLES**

- Clinical studies that do not include investigational new drugs or new medical devices
- Surveys or interviews involving minors or other vulnerable populations
- Collection of voice, video, or digital data for research purposes
- Individual or group behavior, surveys, interviews, or oral histories that are confidential, but not anonymous
EXPEDITED REVIEW PROCEDURES

- Review is carried out by two IRB committee members.

- The reviewers may approve the application, request changes, or refer the application to the full committee for review.

- Both reviewers must agree to approve the application or the application will be sent to the full committee for review.
**EXPEDITED REVIEW PROCEDURES**

- Research classified as Expedited is approved for 1 year only. At the end of the year, investigators may apply for renewal if no changes to the study or participant population are anticipated.

- All changes to the research design or the subject population must be reported to the IRB; if deemed substantial, the IRB may require the submission of a new IRB application.
What type of research requires full board review?

Any research that involves more than minimal risk to participants requires full board review.
FULL BOARD REVIEW PROCEDURES

- A full quorum of the IRB is assembled (at least half of the members).
- The investigator(s) will present the research project.
- All members participate in discussion and make comments (plenary review).
- Decision is rendered by a majority of the assembled quorum.
The Board may approve the research, require modifications before approval, or deny the applicant’s request for approval.

Projects approved under the full board review process require an annual review by the full board committee.
INFORMED CONSENT
INFORMED CONSENT

- Voluntary participation and informed consent is at the very core of the IRB.
- Informed consent is a process, not a form.
Core Principles of Informed Consent

- Informed consent must be obtained from the participants or their legally authorized representative before the research begins.
- Information must be understandable.
- Subjects must be given sufficient opportunity to consider whether they want to participate.
- Consent must be given without coercion or undue influence.
- Subjects must not be made to give up legal rights or be given the impression that they are being asked to give up their legal rights.
Exceptions

- For most anonymous surveys and other exempt applications, no signed informed consent form is required. In these situations, a signed informed consent form would be the only record linking the subject and the research and the only risk would result in a breach of confidentiality.

- Researchers must still provide participants with a cover letter or introductory remarks that cover all of the elements of informed consent.
STANDARD ELEMENTS OF INFORMED CONSENT

A. Heading and Title
B. Identify Principal Investigator(s)
C. Purpose and Background
D. Procedures
E. Risks and/or Discomforts
F. Confidentiality
G. Benefits
H. Alternatives
I. Costs/
   Financial Considerations
J. Reimbursement/Payment
K. Questions
L. Tissue and/or Blood Banking or Storage
M. Consent
N. Signature Section
What is HIPAA and how does it apply to research?

The Health Insurance Portability and Accountability Act (HIPAA) establishes conditions under which protected health information (PHI) may be used or disclosed by covered entities for research purposes.
Protected health information (PHI) is any information about health status, provision of health care, or payment for health care that can be linked to a specific individual. This is interpreted rather broadly and includes any part of a patient's medical record or payment history.
Submit a Form H: Research Involving Protected Health Information to determine which forms should be completed and submitted to the IRB.

Use the HIPAA compliant informed consent template on our website.
HIPAA regulations are quite complex.

Researchers using health information should consult the full UTC IRB policy for additional guidance.
Things to Consider
IMPLICATIONS FOR YOU

- The Principal Investigator has ultimate responsibility for ethical conduct.

- Respect the time and process necessary for review. *IRB approvals are not retroactive.*
THINGS TO CONSIDER

If you are involved in research involving human subjects with another university or organization or in an international venue, other considerations and/or procedures may apply.

Contact the IRB to discuss these.
THINGS TO CONSIDER

- The IRB is there 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.
FOR MORE INFORMATION...

UTC IRB Website:

www.utc.edu/irb

- Additional information
- Full UTC IRB policy
- Definitions
- Forms
- Instructions for completing and submitting the application
FOR MORE INFORMATION...

Contact:

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QUESTIONS?