

Research Involving Human Subjects

Let's Start with Definitions of Research and Human Subjects

- Research is defined as: “A systematic investigation, including research development, and testing and evaluation, designed to develop or contribute to generalizable knowledge.”
- A Human Subject means: “A living individual about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information.”

Does My Project Meet the Definition of Research with Human Subjects?

- All of the following activities may be considered research:
 - Pilot studies (research development)
 - Interview procedures
 - Surveys
 - Observation
 - Case studies
 - Oral histories
 - Analysis of existing data

Ok, So My Research Involves Human Subjects- What Does That Mean?

- When research is conducted that involves the participation of human subjects we are ethically bound to protect the rights and welfare of these individuals.
- At UTC we are guided by the ethical principles set forth by the National Commission on the Protection of Human Subjects commonly referred to as The Belmont Report.

Institutional Review Board (IRB)

- In order to ensure that research done at UTC is conducted in full compliance with federal and institutional regulations we have established an Institutional Review Board (IRB) whose mission is to ensure that vital university research can be conducted in full compliance with both the letter and the spirit of the regulations designed to protect the rights and welfare of human subjects.

What Does the IRB Do?

What is it?

What do I need to know?

You need IRB approval, what next?

What happens if I don't get approval?

The IRB

- Reviews and has the authority to approve, exempt, require modifications, or disapprove all research activities involving human subjects.

What I Need to Know

- All faculty and staff (both full-time and part-time) using human subjects or identifiable, private information about human subjects to conduct research within the course and scope of their duties are required to have prior approval from the IRB before research is initiated.
- Projects must be approved regardless of whether or not the research is funded and regardless of the source of the funds.
- This policy also applies to students whose research is conducted under the advisement of a faculty member.

- All research proposals must be reviewed by the IRB and no individual, other than the IRB Chair, may exempt a proposal from review. Research that is conducted without IRB approval is not in compliance with UTC policy and federal regulations. In these circumstances a non-compliance report will be sent to the Provost for further action.

What About 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?
- If you answered yes to any of these questions you will need to submit an application to the IRB.

Class-related Projects that Require IRB Approval

- All master's theses 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

Classroom-related Activities that Do Not Require Review

- 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.

You Need IRB Approval. What Do You Do Next?

- What level of review do you need?
- Specific criteria for IRB approval of research are discussed in more detail in the IRB policy; however, the following elements are central to IRB decisions. In order to ascertain the level of review, several factors will be considered including whether:
 - Risks to subjects are minimized;
 - Risks are reasonable in relation to anticipated benefits;
 - Selection of subjects is equitable;
 - Informed consent is sought from each subject; and
 - Informed consent is appropriately documented.

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.

Consider these risks

- Not just physical risk, but
- Criminal/civil liability
- Financial risk
- Employment risk
- Stigmatization
- Insurability
- Embarrassment

What are the Categories for Review?

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

What Type of Research is Considered Exempt?

- 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.

What Type of Research is Considered Exempt? Cont.

- 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 make that determination, thus researchers must submit an application to ensure that the research meets the criteria for an exemption.***

What Type of Research is Considered Exempt? Cont.

- Service projects involving human subjects (including grants and programs that provide services and include an evaluative component that might be determined to be research) are encouraged to contact the IRB Chair and/or submit a proposal to ensure that they are exempt from IRB review.

What Type of Research is Considered Exempt? Cont.

- ***The Investigator must receive a letter from the Director of Research Integrity stating that the research is exempt before the proposed research may proceed. There is no such thing as an emergency exemption, and no university official other than the IRB Chair may designate research as exempt.***

Specific Categories of Exempt Research

- According to federal Department of Health and Human Services (DHHS) regulations for protection of human subjects in 45 CFR 46.101, research may qualify as exempt if:
 - Education research
 - Tests, surveys, interviews, or public observations
 - Research on existing public or anonymous data or specimens
 - Federal demonstration projects
 - Taste and food evaluations

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



The 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.

Expedited



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

Not necessarily.

Expedited Review

- Expedited does not mean quicker.
- Rigor of review is the same as full review, number of reviewers is different.
- Review is carried out by two IRB committee members.
- Both reviewers must agree to approve or the application will be sent to the full committee for review.

What Type of Research is Eligible for Expedited Review?

- Federal regulations and institutional policies allow for expedited review of certain types of research that have been determined to place a human subject at minimal risk in a research setting (45 CFR 46.110 and 21 CFR 56.110).

What Type of Research is Eligible for Expedited Review? Cont.

- Most social and behavioral science research has no more than minimal risk and will be eligible for expedited review.
- Certain specific medical procedures also are deemed by federal policy to involve only minimal risk (such as gathering blood samples and some other non-invasive methods of specimen collection.) Investigators should see the full UTC policy for a list of these specific procedures.

What Type of Research is Eligible for Expedited Review? Cont.

- If subjects will be randomized to treatment and control groups, then the study does not qualify for expedited review (and will need a full board hearing.)
- Expedited review also is prohibited in cases when the identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability; be damaging to the subjects' financial standing, employability, insurability, or reputation; or be stigmatizing unless reasonable and appropriate protections are implemented so that risks related to invasion of privacy and breach of confidentiality are minimal.

Expedited Review Examples

- Clinical studies that do not include investigational new drugs or new medical devices
- Blood sample collection (small amounts, routine methods)
- Prospective collection of biological samples – noninvasive means
- Data collected through noninvasive means (routinely practiced in clinical settings)

Expedited Review Examples

- 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, or oral histories

What Type of Research Requires Full Board Review?

- Any research that involves more than minimal risk to respondents requires full board review. In rare instances, initial applications may require an application for full board review. In most cases, the typical type of research conducted at UTC is eligible for expedited review. Researchers are encouraged to contact the IRB Chair prior to submitting a full board review application. In some instances the IRB Chair or an IRB Committee member may feel that an application requires a full board hearing. In those instances, the IRB Chair will notify the principle investigator on the application and request additional information if needed.

Full Review Means

- 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.

Criteria Used 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.**

What Type of Research Requires Annual or Continuation Review?

- IRB Approval is valid for one year. At that time, investigators must file a Form C noting that the project is complete or request a renewal for projects that required expedited or full board review. Projects approved under the full board review process require an annual review by the full board committee membership. The annual review date is an anniversary date that is one calendar year later than the date on the original IRB formal letter of approval.

What Type of Research Qualifies as a Classroom Assignment? Cont.

- Student research projects may be exempt from IRB review if the assignment meets the criteria outlined below. ***This procedure applies only to class assignments and does not include independent study projects, honors projects, theses, or dissertations.*** These types of research require normal review according to the UTC IRB policy.

What Type of Research Qualifies as a Classroom Assignment? Cont.

- Faculty members may elect to use the procedure outlined in this section of the policy for student research projects (at both the graduate and undergraduate level) that meet all of the following criteria:

Classroom Assignment Criteria

- The assignment is part of a class and is conducted under faculty supervision;
- The purpose of the assignment is for students to learn about the process of engaging in research or applying a pedagogical technique as opposed to engaging in research which is intended to be used for publication, formal reports, or presentations at professional conferences;

Classroom Assignment Criteria Cont.

- The project is eligible for exempt or expedited review (i.e., no project requiring full board approval may be dealt with under this procedure;)
- The instructor has completed the on-line IRB training and has filed their certification of completion with the Director of Research Integrity.

What If I Don't File an IRB Application?

- 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.



Implications for UTC

- Failure to have and follow appropriate procedures for IRB review and approval can also result in federal investigations and sanctions for the university.



Other Considerations That May Apply

- 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.
- Contact the Institutional Review Board to discuss these.

Remember

- The Principal Investigator has ultimate responsibility for ethical conduct.
- Respect the time and process necessary for review. ***IRB approvals are not retroactive.***

Also 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.

Further Information

The following additional information can be accessed from the UTC IRB Website:

www.utc.edu/irb

- Information concerning the UTC IRB,
- The full UTC IRB policy,
- Definitions,
- All forms needed to file an IRB application, and
- Instructions for completing and submitting the application.