
Research Involving Human Subjects

Institutional Review Board (IRB) Requirements

Principal Investigator Training Manual

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Introduction

This training manual has been prepared to provide guidance for researchers whose projects involve human subjects. It contains information that will enable you to determine what steps need to be taken to comply with UTC policies and adhere to the federal regulations governing the use of humans in research. It also outlines the basic principles of UTC's IRB process and will provide information that will enable you to determine if your research requires IRB approval and, if so, the steps that are required to prepare your application for IRB review and approval. Should you need additional information or should you like to discuss specific aspects of your research, please contact the Compliance Division of the Office of Grants and Program Review at (423) 425-4443.

Frequently Asked Questions

1. Does the project meet the definition of research with human subjects?

Research is defined as: "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities, which meet this definition, constitute research for purposes of this policy, whether they are conducted or supported under a program, which is considered research for other purposes. For example, some demonstration and service programs may include research activities" (Code of Federal Regulations, 45 CFR 46.102d).

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" (Code of Federal Regulations, 45 CFR 46.102f).

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

If your project meets the definition of research involving human subjects and it is not exempt (see below), you will need to complete an application and submit it to the Institutional Review Board (IRB) for review.

2. Are there any types of research involving human subjects that do not require IRB approval?

There are a few categories of research that may involve human subjects but do not require IRB applications and/or approval. These include:

- UTC teacher and student evaluations
- Program evaluation research to benefit UTC and carried out by UTC administrative officials and/or their designees

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- Projects designed to enhance or improve curricula offerings at UTC
 - UTC employee performance evaluations
 - State of Tennessee mandated program evaluations
 - Marketing research (designed to market the institution as a product)

Except for the examples listed above, all other research involving human subjects *must* obtain IRB approval. If the principal investigator has any doubt about whether or not his or her project meets these criteria, it is his or her responsibility to contact the IRB Chair for clarification. 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. It is preferable to err on the side of caution and to file an application for approval if there is any doubt about the criteria. Any secondary analyses of this data used for scholarly publication requires IRB approval.

3. What are the categories of review?

There are five categories of review for projects involving human subjects in research settings. These categories include:

- Exempt Review
- Expedited Review
- Full Board Review
- Continuing or Annual Renewal
- Classroom Exemption Projects

Generally speaking, new applications will be submitted as exempt or expedited reviews. A small number of cases might qualify for full board review, although researchers should consult the IRB Chair or Director of Research Integrity before proceeding with this type of application. Applications that involve more than minimal risk to participants automatically require full board review. In most cases, if a full board review is required, it will be initiated by the IRB Committee based on an expedited review application. Continuing or annual renewal applications apply only to projects that have previous IRB approval. Classroom assignment applications may only be submitted by faculty members on a limited basis for projects that are not necessarily research in nature but are designed to familiarize students (through assignments) with the process of research.

4. What type of research is considered exempt?

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

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 this determination. Researchers must submit an exempt application to ensure that the research meets the criteria for an exemption.*

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. The investigator must receive a letter from the IRB Chair stating that the research is exempt before the proposed research may proceed. *There is no such thing as an emergency exemption. No university official other than the IRB Chair may designate research as exempt.*

5. What type of research is eligible for expedited review?

Federal regulations and institutional policy 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). Much of the research in the social and behavioral sciences has no more than minimal risk and will be eligible for expedited review. The greatest risk is often a breach of confidentiality. Certain specific medical procedures also are deemed by federal policy to involve only minimal risk (such as gathering blood samples and certain other non-invasive methods of specimen collection). Investigators should see the full UTC IRB policy for a list of these specific procedures. In addition, if subjects will be randomized to treatment and control groups, the study does not qualify for expedited review (and will need a full board hearing). Expedited review is also 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.

6. 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 or the Director of Research Integrity prior to submitting a full board review application. In some instances the IRB Chair or IRB Committee members may feel that an application requires a full board hearing. In those instances, the IRB Chair will notify the principal investigator and request additional information if needed.

7. What type of research requires annual or continuation review?

IRB approval is valid for one year. 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. Projects approved as exempt do not require annual review. Projects approved as expedited or by full board review must file a Form C before their project anniversary date to note that the project is complete or to request a renewal if the project is ongoing. Projects approved under the full board review process require an annual review by the full board committee membership.

8. What type of research qualifies as a classroom exemption project?

In some instances, faculty members may wish to require students to complete research projects in order to learn about the process of conducting research. These projects do not meet the definition of research as outlined in the IRB policy; however, there is a need to ensure that these class assignments do not compromise any of the principles outlined in the UTC IRB policy. It is also essential that students be socialized to the ethical and procedural concerns associated with institutional review practices and the need to protect human subjects. Classroom assignment exemption does not apply to independent study projects, honors projects, theses, or dissertations.

9. What if I have a change in the project?

The first thing to do is determine whether the change will be a minor or major change to the project. A minor change will have no impact upon the original goals and protocol outlined in the original application; will not affect the overall harm-benefit profile of the study; and will not affect the willingness of subjects to participate. A major change involves substantial change to the research protocol including changes in the purpose or process of the research project (refer to the full UTC IRB policy for examples). If a minor change is required a Form C should be completed and submitted to the IRB. If a major change is required the investigator must complete a new Form B and submit it to the IRB for review.

10. Do individuals have to consent to participate in the project?

Voluntary participation and informed consent is at the very core of the need for IRB oversight. It ensures respect for people by providing the opportunity for thoughtful consent to ensure that participation is voluntary. How consent is achieved varies on the research design and the level of review. The IRB will seek to ensure that the following general requirements of informed consent are satisfied in all studies:

- Informed consent must be obtained from the participants or their legally authorized representatives.
- Information must be conveyed in understandable language.
- 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 do so.

11. Are there exceptions or situations where a signed informed consent form is not acceptable?

Yes. The IRB Committee may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds that:

- The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality;
- Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
- The research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.

For most anonymous surveys and other exempt applications a signed informed consent form is not required. In fact, an application that requires a signed consent form in this situation may be rejected since it compromises the anonymity of the research subjects. In this case, however, researchers still have an ethical responsibility to ensure that informed consent occurs. In cases where the documentation requirement is waived, the IRB will require the investigator to provide subjects with a written statement regarding the research. This written statement may take the form of an information sheet or cover letter and must include most or all of the same elements as a consent form, without requiring the signature of the subject.

12. What do I need to do when a signed consent form is not required?

If a signed consent form is not required, the primary investigator should provide research subjects with a written statement in the form of a cover letter or introductory remarks (e.g., at the beginning of a survey) that provide: a reference to UTC and the title of the research project; the identity of the principal investigator(s) and their contact information; an introduction to the study; the aims of the study; a brief summary of the background or reason for the project; a summary of why the individual has been asked to participate in the study; a description of the type of participation requested and any procedures; an outline of any risks; an overview of how confidentiality will be maintained; a discussion of any benefits; a description of any alternatives to participation; a discussion of any costs; and a method of securing additional information or asking questions.

13. How do I get consent from subjects who cannot give consent for themselves?

If the study involves subjects who cannot give consent for themselves (e.g., minors, unconscious patients, individuals with Alzheimer's Disease), and the IRB accepts the justification for their inclusion in the study, a separate signature should be obtained for the purpose of third party consent. For studies involving minors, the signature of the parent(s) or guardian(s) is needed. In studies where a legally authorized representative will give consent for the subject, an appropriately labeled signature line should be used. If the study involves minors, an assent line also should be included for minors to sign when appropriate. Generally speaking, assent is required only for students in grade three and above.

14. What about research that involves the use of health information?

Research in health settings using health data have additional considerations to comply with Health Insurance Portability and Accountability Act (HIPAA) regulations. HIPAA regulations are quite complex. Researchers using health information should consult the full UTC IRB policy for additional guidance.

15. What is HIPAA and how does it apply to research?

HIPAA establishes conditions under which protected health information (PHI) may be used or disclosed by covered entities for research purposes [45 CFR §§ 164.501, 164.508(f), 164.512(i)]. The Privacy Rule outlined in HIPAA defines the means by which individuals are informed of how medical information about them will be used or disclosed. The Privacy Rule also defines the individuals' rights with regard to gaining access to information about them when such information is held by covered entities. Under the Privacy Rule, covered entities are permitted to use and disclose protected

health information for research with individual authorization, or without individual authorization under limited circumstances. Typically, a research participant's authorization will be sought for clinical trials and some research involving records. In these instances, specific elements must be included in the informed consent form (see UTC IRB policy).

16. When is Protected Health Information (PHI) authorization not required?

There are four circumstances that allow researchers to use and disclose PHI for research purposes without authorization by research subjects. These are:

- Waiver of authorization
- Review of PHI preparatory to research
- Research involving a decedent's information
- Use involving limited data sets

17. Do HIPAA regulations apply to data sets with health information?

Yes. Regulations permit covered entities (usually the agency providing the data) to disclose health information for research purposes without authorization by the research subject if the use or disclosure involves a "limited data set" and the covered entity enters into a data use agreement with the researcher. A "limited data set" is protected health information that excludes the following direct identifiers of the individual or of relatives, employers, or household members of the individual subjects:

- Names
- Postal address information, other than town or city, state and zip code
- Telephone numbers
- Fax numbers
- Email addresses
- Social security numbers
- Health plan beneficiary numbers
- Account numbers
- Certificate/license numbers
- Vehicle identifiers and serial numbers
- Device identifiers and serial numbers
- Web universal resources locators (URLs)
- Internet protocol (IP) address numbers
- Biometrics identifiers, including finger and voice prints
- Full face photographic images and any comparable images

A limited data set may, however, include other indirect identifiers, especially dates of birth, treatment, discharge, or death.

Investigators may use a limited data set for research without subject authorization if they have completed a Limited Data Use Agreement with the entity releasing the data. Investigators in this situation should complete a Form K and provide a copy of this form and the Limited Data Use Agreement to the Director of Research Integrity. (Normally, the entity releasing the data will provide the Limited Data Use Agreement; however, if the entity does not have such a form the investigator should contact the IRB Chair for examples of acceptable forms.)

PHI can be released freely if it does not contain "individually identifiable information" as defined in the section above. PHI is not individually identified if the subject is not identified, directly or indirectly, and if the subject has no reasonable basis to believe that the information can be used to identify them.

18. What if I collected data that includes protected health information?

If an investigator maintains a database containing PHI then the investigator has an obligation to ensure that the use and disclosure of PHI is in compliance with federal guidelines and UTC policy. The investigator is responsible for:

- Maintaining applicable security for the database, including physical security and access control,
- Controlling and managing the access, use and disclosure of PHI, including verifying appropriate IRB approvals and patient authorizations, and
- Ensuring that any PHI in the database used for treatment or payment purposes must be a duplicate of the original included in the patient's medical record.

Databases created prior to April 14, 2003 are grandfathered in and do not have to meet the Privacy Act policies. Studies involving subjects that have enrolled prior to April 14, 2003 will not be required to re-consent. Investigators may continue to collect and use data gathered from these subjects and no new documentation is required.

19. What is an adverse event?

An adverse event occurs when:

- There is a serious injury or other event that adversely affects a participant;
- There is a problem that involves the conduct of individuals associated with the study; or

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- There is a breach of human subject protections that an investigator becomes aware of that is associated with the research activities conducted by UTC or partnering investigators.

If you have a question about whether an adverse event has occurred please contact the Director of Research Integrity or the IRB Chair.

20. If an adverse event does occur, what do I do?

To report an adverse event you will complete a Form F and submit it to the IRB for review. Please refer to the UTC IRB policy for additional details.

If you should have a question that has not been addressed in this section, please contact the Director of Research Integrity or the IRB Chair.

Guidelines for Selecting the Appropriate Review Procedures

1. Exempt Research Categories (Form A)

Research projects that meet one of the six exemption categories (listed below) may be "exempted" from full or expedited IRB review, if (a) the projects are not externally funded and (b) they place participants at no more than minimal risk. Please refer to the full UTC IRB policy for additional details.

The following exemptions do not apply to research involving minors (participants who are under 18 years old), prisoners, fetuses, or pregnant women.

Definition of Minimal Risk

Minimal risk is a key factor in determining whether a research activity can be exempt from formal review. Minimal risk in a research activity is defined as an *anticipated risk of harm in a proposed research that is no greater, considering probability and magnitude, than risks ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.*

- **Category 1: (Federal Regulation 46.101(b)1)**
Research conducted in established or commonly accepted educational settings, involving normal educational practices such as research on regular and special education instructional strategies, or research on the effectiveness of or the comparison among instructional techniques, curricula or classroom management methods.
- **Category 2: (Federal Regulation 46.101(b)2)**
Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement) including survey procedures, interviews, or observation of public behavior.
- **Category 3: (Federal Regulation 46.101(b)3)**
Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that would not be exempt under Category 2 may be exempt if participants are elected officials, appointed public officials, or candidates for public office; or federal statute(s) require(s) without exception that the

confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

- **Category 4: (Federal Regulation 46.101(b)4)**
Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens may be exempt if these sources are publicly available or if the information is recorded by the investigator in such a manner that participants cannot be identified, directly or through identifiers linked to the participants.
- **Category 5: (Federal Regulation 46.101(b)5)**
Research and demonstration projects which are conducted by or subject to the approval of federal department or agency heads, and which are designed to study, evaluate, or otherwise examine: public benefit or service programs; procedures for obtaining benefits or services under those programs; possible changes in or alternatives to those programs or procedures; or possible changes in methods or levels of payment for benefits or services under those programs.
- **Category 6: (Federal Regulation 46.101(b)6)**
Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods *without* additives are consumed, or (ii) foods are consumed that contain a food ingredient *at or below the level and for a use found to be safe*, or agricultural chemical or environmental contaminant *at or below the level found to be safe* by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

If you have any questions about completing your Form A please contact the Director of Research Integrity or the IRB Chair.

2. Expedited Research Categories (Expedited Form B)

Research categories that may be reviewed using expedited review procedures include the following:

- **Category 1:**
Clinical studies of drugs and medical devices only when either of the following conditions are met:
 - Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (Note: Research on marketed drugs that significantly

increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)

- Research on medical devices for which (i) an investigational device exemption application (21 CFR Part 812) is not required; or (ii) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

- **Category 2:**
Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
 - From healthy, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
 - From other adults and children considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.

- **Category 3:**
Prospective collection of biological specimens for research purposes by noninvasive means.

- **Category 4:**
Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be either cleared or approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications.) Examples:
 - Physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy
 - Weighing or testing sensory acuity
 - Magnetic resonance imaging
 - Electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography

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- Moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual

 - **Category 5:**
Research involving materials (data, documents, records, or specimens) that have been collected or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis). (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)

 - **Category 6:**
Collection of data from voice, video, digital, or image recordings made for research purposes.

 - **Category 7:**
Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. (Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects 45 CFR 46.101 (b)(2) and (b)(3). This listing refers only to research that is not exempt.)

 - **Category 8:**
Continuing review of research previously approved by the convened IRB as follows:
 - Where (i) the research is permanently closed to the enrollment of new subjects; (ii) all subjects have completed all research-related interventions; and (iii) the research remains active only for long-term follow-up of subjects;
 - Where no subjects have been enrolled and no additional risks have been identified;
 - Where the remaining research activities are limited to data analysis.

 - **Category 9:**
Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where the following conditions apply:
 - Categories 2 through 8 do not apply; and
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- The IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.

3. Categories of Full IRB Reviewed Research (Full Board Form B)

Categories of research that always require full IRB Committee review include:

- **Category 1:**
Projects requiring the use of deception.
- **Category 2:**
Use of prisoners, pregnant women, fetuses, the seriously ill, or persons with mental disabilities, or incompetent individuals.
- **Category 3:**
Collection of information or recording of behavior which, if known outside the research, could reasonably place the subject at risk of civil, or criminal liability or damage the participant's social standing, financial standing, or employability.
- **Category 4:**
Collection of information regarding sensitive aspects of the participant's behavior such as: drug and alcohol use, illegal conduct, or sexual behavior.
- **Category 5:**
The project includes procedures that present more than minimal risk to participants.

Audio- and Videotaping Considerations

Videotaping and audio-taping research participants are valid and useful data collection methods; however, the use of audio- or videotapes increases an investigator's need to clearly specify the steps taken to maintain the confidentiality of this identifiable information. Investigators meet this need by describing the steps they will take to protect the confidentiality of research audio- or videotapes in their Form B applications, and in their informed consent forms. All research in which participants will be audio- or videotaped requires the use of a Form B application. Expedited reviews of Form B applications are possible when the research does not involve participants from vulnerable populations and the information collected is not of a sensitive nature (e.g., sexual behavior, illegal activities, etc.).

If you have any questions about the development of your Form B application, please contact the Director of Research Integrity or the IRB Chair.

4. Classroom Exemption Projects (Form D)

Faculty members may elect to use the procedure outlined in this section of the policy for student research projects that involve classroom assignments (at both the graduate and undergraduate level) when all of the criteria listed below can be met:

- The assignment is part of a regular class which meets weekly (by any format; i.e., in person or electronically).
- The assignment will be completed during the semester in which the student has registered for the course (and therefore has faculty supervision).
- The purpose of the assignment is for students to learn about the process of engaging in research and not to actually engage in research which would be used for publication, formal reports, or other formal means that would add to the body of knowledge in a particular field.
- 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 training and has filed their certificate of completion with the Chair of the IRB Board. (Available at <http://ohrp-ed.od.nih.gov/CBTs/Assurance/login.asp>.)

Faculty members who wish to use this procedure must:

1. Submit a Form D to the Chair of the IRB indicating the course, the assignment, and a copy of their certificate of completion of training. This Form must be approved by the IRB Chair prior to any projects proceeding.
2. Require students to submit the appropriate Form A or B for approval by the instructor (instead of the IRB Board).
3. Review and approve the exempt and expedited review forms submitted by the student to the instructor.
4. Submit a Form E at the end of these semester which outlines the student's name, project title, a short description of the project and certifies that the instructor has ensured that all human subjects protections have been met (including informed consent, anonymity, and minimal risk).

These files must be maintained for three years by the faculty member and may be periodically audited by the Director of Research Integrity and/or his/her designee.

The Application Process

1. How do you apply for Approval?

Each level of review has a slightly different review process. Exempt applications require a Form A. Expedited reviews and full board reviews use a Form B. Annual review and minor changes require a Form C. Classroom assignment applications require a Form D.

Applications should be submitted electronically to the email address provided on the form.

If the information on the application seems incomplete or raises any concerns (e.g., regarding eligibility for exempt status, invasion of the subjects' privacy, confidentiality of research records, no consent form included, etc.), the applicant will receive an Action Form from the IRB Chair. The Action Form will outline the concerns that must be addressed in order to continue the review process. It also may indicate that the research does not qualify for the level of review as submitted and ask the investigator to submit a new or revised application.

All applications should be submitted to the email address listed on the form. The IRB office will notify you when your application has been successfully received.

Should you have any questions about how to complete the information that is required on the application, please contact the Director of Research Integrity or the IRB Chair.

Research cannot begin until IRB approval has been received.

- **Exempt Applications**

If an investigator believes his or her study qualifies as exempt from IRB review, a Form A should be completed. You will need to submit the completed application form, consent forms (if applicable), and any research instruments to the IRB for review and approval. Form A requires the investigator to discuss the purpose/objectives of the research, the subject population, methods/procedures, experimental design/methodology, and justification for exemption.

- **Expedited Applications**

Investigators who believe their study qualifies for expedited review should complete a Form B and check the box marked Expedited. You will need to submit

the completed application form, consent forms, and any special attachments (including questionnaires or surveys if applicable) to the IRB for review and approval. Form B requires the investigator to discuss the purpose/objectives of the research, background and rationale for the study, the subject population, methods/procedures, incentives, risks and benefits, and privacy/confidentiality.

- **Full Board Applications**

Investigators who believe their study qualifies for full board review should complete a Form B and check the box for that category. The completed application form, consent forms, and any special attachments (including questionnaires or surveys if applicable) must be submitted for an initial, full board review. The Form B requires the investigator to discuss the purpose/objectives of the research, background and rationale for the study, the subject population, methods/procedures, incentives, risks and benefits, and privacy/confidentiality. Any special requirements and/or attachments must also be included. The IRB Committee meets on an ad hoc basis; therefore, investigators should consult the IRB Chair to ensure that they are scheduled for review.

- **Continuing or Annual Renewal**

Investigators who have a change in their research protocol that they consider to be a minor modification should complete a Form C and submit it to the email address listed on the form for review and approval. Major modification/change requests require that the investigator complete a new Form B noting the modifications to the project and submit it to the IRB.

- **Classroom Assignments**

Faculty members who wish to use this procedure must submit a Form D to the email address listed on the form indicating the course, the assignment, and a copy of their certificate of completion of IRB training. The classroom assignment request must be approved by the IRB Chair prior to the beginning of any projects. Faculty must also require that each student participating in the classroom assignment submit the appropriate Form A or B for approval by the instructor (instead of the IRB Board). A Form E must be submitted at the end of the semester which outlines the student's name, project title, a short description of the project and certifies that the instructor has ensured that all human subjects protections have been met (including informed consent, anonymity, and minimal risk).

- **Action Forms**

If the information on the application seems incomplete or raises any concerns (e.g., regarding eligibility for exempt status, invasion of the subjects' privacy, or confidentiality of research records), the applicant will receive an Action Form from the IRB Chair. The Action Form outlines the concerns that must be addressed in order to continue the review process. It also may indicate that the research does not qualify under the category submitted. Many applications receive an action form because of the failure to address informed consent issues.

2. How will your application be reviewed and how long will the process take?

Three levels of review are utilized to review applications for human subject use: exempt, expedited and full board.

Exempt applications are reviewed and approved by the IRB Chair.

Expedited applications are reviewed and approved by two IRB Committee members.

Full Board review is a review of the proposed research at a convened meeting at which a majority of the membership of the IRB is present, including at least one member whose primary concerns are in non-scientific areas. These reviewers will review the protocol and contact the PI if any additional information or needed revisions. For the research to be approved, it must receive the approval of a majority of those members present at the meetings.

If applications are clear and complete the following estimates apply:

Exempt Review:	5-7 days
Expedited Review:	10-14 days
Full Board Review:	14-30 days

Note: If the project is externally funded, federal regulations require the IRB to review the proposal/grant/award for consistency. This will likely add several days to the above estimates.

3. What happens if you forget to submit an annual review?

The investigator must receive a letter from the IRB Chair stating that the research is renewed *prior* to the anniversary date or the research must be suspended pending an approved renewal notice. Projects which are found to be continuing without IRB

approval are in non-compliance with UTC policy and federal regulations. In these circumstances a non-compliance report will be sent to the Provost for further action.

4. What happens if there are problems that result from the study (e.g., injuries to a subject, breach of confidentiality, failure to follow protocol/research design)?

All investigators conducting research on human subjects must report any injuries or adverse events associated with the study procedures and/or problems involving the conduct of individuals associated with the study which occur during the course of their research project. This is called an adverse event and requires a report be submitted to the IRB (Form G). Further information regarding adverse events may be found in the full UTC IRB policy. Failure to report is a breach of the conditions under which IRB approval is given, and could result in suspension or revocation of approval. Suspension or revocation of approval could result in loss of support by funding agencies and loss of right to publish.

5. What happens if you know that research is being conducted in violation of IRB policy?

Researchers are required to report any possible violations of IRB policy. The IRB will conduct an inquiry following any report of possible misconduct related to human research activities that may come from subjects, study personnel, staff, students, or faculty. If, for instance, a research project is being conducted without IRB approval, or an improper method of recruiting subjects is being used, or undue influence is being placed upon prospective subjects to participate in a study, the IRB has no means of learning about such situations and rectifying them unless it is informed that they are taking place. Thus, in order to fulfill its obligation to protect human subjects in research, the institution depends upon concerned individuals, including investigators, to inform the IRB of any possible misconduct related to research activities of which they become aware.

Such incidents are usually reported by telephone, email, or in writing to the Provost or to the Chair of the IRB Committee. An inquiry is made to the investigator conducting the research activity, maintaining requested anonymity of the individual submitting the report whenever possible. Depending upon the outcome of the IRB's initial inquiry, information about the incident may be forwarded to the Institution Signatory, the Provost, or the Chancellor for appropriate resolution.

The Informed Consent Process

Consent and Information forms must be written in language that is understandable and clear to the potential participants. As you develop your consent form please include the following information:

- **Heading and Title:**
Reference to the University of Tennessee at Chattanooga and notification that a research project is being discussed should be included in the heading of all consent forms. The study title also should be included in the heading of the form.
- **Identify Principal Investigator(s):**
This section should indicate who is conducting the research. Include the first and last names of the principal investigator(s), any applicable titles and/or University departments, and contact information. This information should be at the beginning of the form to clearly indicate who is conducting the study.
- **Purpose and Background:**
This section should introduce the study, state the aim of the study, give a brief summary of the background or reason for the project, discuss the number of subjects expected to participate in the study, and explain why the individual has been asked to participate. The reason a person has been asked to participate should be simply but specifically stated (e.g., "because I have tried to quit smoking in the past but have not been successful," "because I am undergoing surgery and will be given a general anesthetic," "because I am a healthy person"). If the study is sponsored research, the sponsor should be named.
- **Procedures:**
To emphasize the voluntary nature of participation in research, this section should begin with a phrase like, "If I agree to be in this study, the following will happen..." For social and behavioral research, this may involve a simple statement such as: "You will be asked to complete a short survey, participate in an interview, participate in a focus group" etc.

For health related procedures, each procedure should then be listed, preferably in the order in which it occurs, and discussed. If the study involves screening procedures, these should be mentioned first and identified as tests that will determine eligibility to continue in the study. The Procedures section should clearly state what will be done to the individual as a result of participation in the study, and, where appropriate, how this differs from standard treatment or what would happen to the individual if he/she did not participate in the study.

When a study involves randomization, it should be described as a study procedure, and the term "randomization" explained in lay language. Information about the probability of assignment to each treatment or condition should be given. Other terms, which might not be familiar to the average layperson (e.g., "placebo") should be defined the first time they are mentioned.

If a standard medical procedure is being done as part of the study, it should not be referred to as "standard" or "routine" since this could easily imply that the procedure would be done anyway for clinical reasons. Rather, what should be conveyed is that this procedure is an extra laboratory test that is commonly done for clinical purposes, but is being conducted here for research purposes.

If patient records will be reviewed for purposes of the study, this should be listed as a procedure.

Amounts of blood or tissue to be taken for study purposes should be specified, using lay equivalents (e.g., teaspoons, ounces) for metric terms.

The number of times a procedure will be done, the time involved for each procedure, and the total amount of time for participation in the study should be specified. The location(s) where the procedures will be done should also be stated.

- **Risks and/or Discomforts:**

The risks and/or possible discomforts of all study procedures should be listed and explained in this section. For social science and behavioral research this might include notifying subjects that there is a possibility that they may be upset by the content of the survey or find an interview embarrassing. For medical and health related studies, this might be a discussion of physical discomfort or pain.

It is usually best to describe the risks of each procedure in a separate point. Risks should be arranged and described according to their severity and the likelihood of their occurrence. Where appropriate, it should be indicated what precautions will be taken to avoid certain side effects or outcomes from occurring, and what will be done should they occur. A statement should be included that significant new findings developed during the course of the research that may relate to the subject's willingness to continue participation will be provided to the subject.

To the extent possible, consent forms should characterize the likelihood of risks using words like "likely," "frequent," "occasional," and "rare." The first time these words are used in a form they should be defined using percentages, as follows:

Likely events: Expected to happen to more than 50% of subjects
Frequent events: Will probably happen to 10-50% of subjects
Occasional events: Will happen to 1-10% of subjects
Rare events: Will happen to less than 1% of subjects

For studies involving investigational agents, or experimental doses or combinations of drugs and/or treatments, subjects should be warned that there may be as yet unknown risks associated with the drug/treatment but that they will be advised if any new information becomes available that may affect their desire to participate in the study.

- **Confidentiality:**

Since one of the risks of participating in research is a loss of privacy, a discussion of confidentiality issues should be included. It should describe briefly how the confidentiality will be protected, i.e., coding of records, limiting access to the study records, not using any individual identifiers in publications or reports resulting from the study.

For all statements regarding confidentiality of research records, it should be kept in mind that there is no legal privilege between investigator and subject as there is between physician and patient or counselor and client. Thus, a guarantee of complete confidentiality, or "strictest confidentiality," should not be given or implied. One should always state instead that confidentiality will be protected "as far as is possible" or "as far as is possible under the law."

- **Benefits:**

Any potential direct benefits to the subject should be described first, followed by potential general benefits (e.g., the group of patients to which the individual belongs, to medical knowledge, etc.). It is usually recommended that the description of possible direct benefits be qualified with the phrase, "... but this cannot be guaranteed." If there is no direct benefit to the subject anticipated from the study, this should be stated at the beginning of the section.

The FDA recommends that possible benefits such as medical or societal benefits resulting from a research study be considered separately from payment for participation in the study. Thus, the discussion of payment or reimbursement should be separated from the benefits statement and placed in its own separately labeled section.

- **Alternatives:**

This section should discuss the various alternatives to participation in the study. This can be a short statement, but it should make clear the possible choices (e.g.,

no treatment, standard therapy, other experimental treatments, or some or all of the protocol treatment, but without participating in the study) that are available if the individual chooses not to participate in the study. When alternative therapies are available, brief objective descriptions of their important benefits and risks should be included.

When the only alternative is to decline participation in the study (e.g., if the study involves only normal, healthy volunteers), this need not be mentioned in a separate section, since the individuals right to choose not to participate will be made clear in the last section of the form.

- **Costs/Financial Considerations:**

When there are no costs at all to be charged to the subject, this should be clearly stated in the form. In some medical situations, however, a simple statement that there are no costs is usually not sufficient and could be misleading. The more typical situations are that the subject will have to pay for the usual costs of his or her medical care but will not be charged any extra for participating in the study or the cost of the study medication will be covered by the study but the subject will have to pay all other charges.

When participation in the study may result in any costs whatsoever to subjects, clear information must be provided in the consent form regarding these costs. Special attention must be paid to this issue in studies in which the subjects are also patients. In such cases, where individuals may be undergoing various procedures, tests, or hospitalizations that are part of their clinical diagnosis and treatment, and others that are part of the research study, the costs section of the consent form should clearly distinguish which costs will be charged to the patient or his third party carrier, and which costs will be covered by the study. In addition, when appropriate, a statement should be included warning subjects that because the therapy is experimental, the insurance carriers may not cover the costs involved.

- **Reimbursement/Payment:**

When referring to money that subjects will receive in return for participation in a study, either of the terms "reimbursement" or "payment" may be used. However, the term "compensation" should not be used, since it is used on consent forms to designate compensation for injury. Investigators should avoid connotations of undue influence to participate or that the subject is being employed by the investigator. Rather, the sense should be that subjects will be reimbursed for their time, travel expenses, and the inconvenience of being a research subject. However, unless the subject has actual receipts (e.g., parking, taxi, babysitting),

the person is not being reimbursed in the strictest sense of the word, for either accounting or tax purposes.

This section should state the total dollar amount that the subject will be paid for participation in the study, and should give any other relevant information such as pro-rating if a subject does not complete the study, or bonus payment at the end of the study. If appropriate, a payment schedule should be included in this section. Subjects should not be required to complete the entire study in order to be reimbursed and bonus payments for study completion should be modest. Subjects should be informed how payment will be made (e.g., in cash, by check) and when they will be paid (e.g., immediately after the interview, approximately six weeks after individual completion of the study). Payments for research participation in excess of \$600 per calendar year are considered taxable income. If subjects will be paid more than \$600, the Reimbursement section should explain that the University will report this income to the IRS.

If there will be no payment or reimbursement of subjects for the study participation, this information should be so stated in this section.

- **Questions:**

This section should provide contact information for the subject in case of questions about the study. At least one permanent name and telephone number of one investigator, usually the principal investigator, must be listed in this section. Blank lines to be filled in later may be included for additional contact persons. If the principal investigator is a student, the faculty advisor's name and phone number should be included in this section as subjects often wish to contact the person who is supervising the project.

- **Tissue and/or blood banking or storage:**

Some studies include the option to have tissue specimens or blood stored (or banked) for studies that may come available in the future, future diagnostic testing, or other purposes not yet determined. Subjects should have the option to participate in the study whether or not they agree to tissue banking.

- **Consent:**

This section should state that the subject has been given (not just "offered") a copy of the consent form.

This section should then state that participation in research is voluntary, and explain the individual's right to decline to participate or withdraw from the study at any time. If the subjects are patients, students, or employees, a phrase may be added indicating that refusal or withdrawal will be without jeopardy to status or

care. The investigator may also wish to advise subjects that they may be withdrawn from the study if the investigator deems it in the best interests of the subject or for other reasons that should be specified (e.g., medical interests, failure to keep appointments).

The IRB discourages such wording as "I have read this form and understand it; based on this understanding, I hereby agree to participate," since this does not guarantee an individual's comprehension, legally or otherwise. Rather it is recommended that investigators simply state that if the person wishes to participate in the study, he or she should sign the form; signature will then indicate agreement to participate.

- **Signature Section:**

Unless waiver of signed consent is approved by the IRB, this section should include lines for the subject's signature and the date of signature. The consent form also should include a signature line for the specific individual that secured or was present to obtain consent so that subjects have a record of who explained the study to them.

Additional Elements of Informed Consent

The following are additional elements of informed consent that may be required:

- A statement that the particular treatment or procedure may involve risks to the participant that are unforeseeable.
- Anticipated circumstances under which participation may be terminated by the investigator without regard to the participant's consent.
- Any additional costs to the participant that may result from participation in the research.
- The consequences of a participant's decision to withdraw from the research, and procedures for orderly termination of participation by the participant.
- A statement that significant new findings developed during the course of the research that may relate to the participant's willingness to continue participation will be provided to the participant.
- The approximate number of participants involved in the study.

Examples of acceptable informed consent forms may be found on the IRB website at www.utc.edu/irb.

If you have any questions about preparing an informed consent form or procedure, please check with the Compliance Division of Grants and Program Review at (423) 425-4443 or email instrb@utc.edu.

Forms

- [Form A: Application for Exempt Review](#)
- [Form B: Application for Expedited or Full Board Review](#)
- [Form C: Change Certification For Changes, Annual Review, Or Project Termination/Completion](#)
- [Form D: Application To Proceed With Student Class Projects](#)
- [Form E: Certification Of Completion Of Student Class Projects](#)
- [Form F: Adverse Events Report](#)
- [Form G: Request For Waiver Or Alteration Of Subject Authorization For The Use And Disclosure Of Protected Health Information](#)
- [Form H: Research Involving Private Health Information](#)
- [Form I: Investigator's Access Preparatory To Research](#)
- [Form J: Research Involving Deceased Individuals](#)
- [Form K: De-Identification Certification Form](#)
- [Sample Action Form](#)
- [Sample Consent Form](#)

IRB Policy

The full [IRB Policy](#) is available for review. Follow the link to view the policy in Acrobat PDF format. You may experience extended load times on slower internet connections.