University of Tennessee Institutional Review Board Guide for
Faculty, Staff and Students - Revised December 2010

Introduction

This guide was prepared to help researchers comply with the University of Tennessee, Knoxville (UT Knoxville) policies and procedures, as well as federal regulations concerning the involvement of humans in research.

This guide sets out the basic policies and procedures of the UT Knoxville system of project review. If you need more information or would like to discuss specific aspects of your research with someone from the UT Knoxville Institutional Review Board (IRB), please contact the IRB Administration Office at 974-3466 or visit the office at 1534 White Avenue.

Fundamental UT Knoxville Policy on Human Research
Participant Protection

All UT Knoxville research involving human participants must be reviewed following UT Knoxville IRB policies and procedures. It must be approved prior to the initiation of research activity such as contact with potential human participants. The place to start this process is with your Departmental Review Committee (DRC). Although certain research is exempt from review, these projects must be certified as exempt by (a) your DRC, (b) your Department Head, and, finally, (c) the UT Knoxville IRB or its representative. Federal regulations allow no exceptions to this policy.

Guide Revisions and Additional Information Sources

The information in this guide is considered to be in full compliance with all applicable federal and state laws and regulations and UT Knoxville policies concerning the use of human participants in research. As changes in laws and policies occur, the guide will be revised. In addition, suggestions for improving information contained in the guide and its presentation are always welcomed. Major revisions of this guide will be posted on the IRB Administration Web site http://research.utk.edu/humansubjects/.

Tips for Using This Guide

This guide contains a tremendous amount of information about many different aspects of the protection of human participants in research. You may not need to read the whole guide, but you should read all sections that pertain to your research project. Use the following steps as you initiate your application process:

• Read Sections 1 and 2 to obtain a basic understanding about the protection of human participants in
• Use the information in **Section 3** to determine which application procedure (Form A or Form B\(^1\)) is appropriate for your research project.

• Read **Section 4** to learn more about informed consent procedures and documents.

• Read **Section 5, 6, or 7** to obtain information about completing your application form.

• **Section 8** presents step-by-step instructions for preparing a Form B application.

• If you intend to involve children, pregnant women, decisionally impaired individuals, or prisoners in your research, read **Section 9**.

• If you intend to use participatory action research (PAR) techniques, read **Section 10**.

• **Section 11** describes the continuing oversight function of the UT Knoxville IRB.

• **Section 12** describes operational policies and procedures of the IRB. It is of interest primarily to members and staff of the IRB. We include it here in the interest of transparency.

• **Section 13** is a glossary of key terms used throughout the document.

If you have any questions about the preparation of your application, after reading this guide, please contact the IRB Administration Office at 974-3466.

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\(^1\)To find IRB forms online, go to: [http://research.utk.edu/forms/index.shtml#c4](http://research.utk.edu/forms/index.shtml#c4)
Institutional Review Boards: The Basics

What Do Institutional Review Boards Do?

The responsibilities of IRBs fall into three main categories: (A) initial review, (B) oversight, and (C) continuing review of research involving human participants.

A. Initial Review: IRBs review and approve a research plan before the research can be carried out. This review encompasses the research protocol, the informed consent document to be signed by participants, any advertisements, e-mails, web postings, or other materials to be used in recruiting participants, and other relevant documents. In carrying out this review, IRBs seek to ensure that:
(a) risks to participants are minimized,
(b) any risks participants may incur are warranted in relation to the anticipated benefits;
(c) informed consent documents clearly convey the risks and the true nature of the research;
(d) recruiting materials are fully informative and not misleading; and
(e) the selection of participants is equitable and justified.

IRBs focus much attention on the informed consent document because it is the vehicle for providing information to potential research participants.

B. Oversight: The IRB is charged by federal regulations with ensuring that the research is carried out following the guidelines that were approved. To this end, representatives of the IRB may conduct periodic audits - interviewing study personnel, examining study documents, perhaps observing the consent process.

C. Continuing Review: The continuing review process is multifaceted and includes required reviews "at an interval appropriate to the degree of risk but not less than once per year." In addition to this continuing review, study amendments and reports of unexpected adverse experiences by participants are received and reviewed to ensure that the risk-benefit ratio of the research remains acceptable.

Why Were IRBs Established?

As public awareness and concern about the treatment of human participants in research increased, the need for additional review mechanism was evident. These concerns grew from accounts of the abuse of prisoners revealed during the World War II trials at Nuremberg, the introduction of thalidomide in Europe resulting in numerous children born with birth defects, the so-called "Tuskegee Syphilis Study" in which African-American men with syphilis were denied possible treatment in order to study the natural history of the disease, the administration of cancer cells to chronically ill and senile patients at a hospital in New York, and other controversial research. The formal requirements for the establishment of IRBs were outlined in regulations stemming from the National Research Act of 1974 and in FDA regulations first issued in 1981.
How Are IRBs Organized?

Federal regulations require that boards have at least five members with varying backgrounds. At least one member must have primarily scientific interests, one must have primarily nonscientific interests, and one must be otherwise unaffiliated with the institution in which the IRB resides. Most IRBs are associated with hospitals and/or academic institutions, although a few "central" or commercial IRBs have been established in recent years.

How Does the Department of Health and Human Services (DHHS) Oversee IRBs?

Two agencies within DHHS share responsibility for IRB oversight: the Office for Human Research Protections (OHRP)\(^2\) and the Food and Drug Administration (FDA)\(^3\). Basic federal regulations are set out in 45 Code of Federal Regulations (CFR) 46, the first part of which - referred to as "the Common Rule" - has been adopted by 17 federal agencies\(^4\).

Additional regulations for research involving drugs and devices regulated by the FDA are set out in 21 CFR 50 and 21 CFR 56. Since there is a great deal of overlap between OHRP and FDA documents, these procedures will reference primarily the regulations in 45 CFR 46.

The OHRP's main tool for oversight is the process of registration and the assurance document. Any institution that intends to conduct DHHS-funded research must have a registered IRB of its own or else an association with a registered IRB. The federal-wide assurance (FWA) is a commitment by the institution that it will comply with federal regulations. The OHRP also conducts a small number of site visits.

The FDA's main mechanism for IRB oversight is the inspection process. The FDA also inspects research sponsors and research investigators.

Other federal agencies that adopt the Common Rule may add special requirements to those basic regulations. If you are proposing to apply for funding to those agencies, you should check with them and with the IRB Administration to get information about any such requirements.

Do You Have Additional Questions About the UT Knoxville IRB?

Please review the information contained in this guide, or contact the IRB Administration Office at 974-3466.

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\(^2\)See [http://www.hhs.gov/ohrp/index.html](http://www.hhs.gov/ohrp/index.html)

\(^3\)See [http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/default.htm](http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/default.htm)

\(^4\)The following agencies adopted the Common Rule: Department of Agriculture; Department of Energy; National Aeronautics and Space Administration; Department of Commerce; Consumer Product Safety Commission; International Development Cooperation Agency-Agency for International Development; Department of Housing and Urban Development; Department of Justice; Department of Defense; Department of Health and Human Services; Department of Education; Department of Veterans Affairs; Environmental Protection Agency; National Science Foundation; Department of Transportation; Central Intelligence Agency; and the Social Security Administration.
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Section 1. Basic Overview of the UT Knoxville IRB

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1.1 Activities of the UT Knoxville IRB and Federal Regulations

The University of Tennessee, Knoxville Institutional Review Board (UT Knoxville IRB) implements the regulatory requirements mandated by the U.S. Department of Health and Human Services (DHHS) as presented in the "Federal Policy for the Protection of Human Subjects." This document incorporates the "Protection of Human Research Subjects," (45 Code of Federal Regulations (CFR) Part 46) of the DHHS, "Protection of Human Subjects" (21CFR 50), and "Institutional Review Boards" (21 CFR56) of the U.S. Food and Drug Administration (FDA). The UT Knoxville IRB operates under the University of Tennessee "Federal-Wide Assurance (FWA)." The UT-Federal-Wide Assurance is an agreement between UT Knoxville, represented by the Vice Chancellor for Research (who serves as our officially designated "institutional official"), and the DHHS, represented by the Office for Human Research Protections (OHRP).

1.2 Fundamental Principles

The specifics of federal regulations are grounded in fundamental values and principles of ethics. One important statement of these is in a document that has come to be known as "the Belmont Report." Officially entitled "Ethical Principles and Guidelines for the Protection of Human Subjects of Research," this report was written by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research (the same entity that developed the initial version of the Common Rule). The report identifies three basic principles that underlie measures to protect human participants: respect for persons, beneficence, and justice. A link to the Belmont Report can be found on the IRB Administration website.

Many scholarly disciplines have developed codes of ethics or statements of principles regarding research practices to deal with issues that arise in their areas of research. The IRB Administration website has links to many of these. If the documents in your discipline are not referenced there, please notify the IRB Administration Office of the web link, and we will add them.

1.3 Jurisdiction of the UT Knoxville IRB

The UT Knoxville IRB was established to protect the rights and welfare of human participants in research conducted under the auspices of any unit of UT Knoxville, the Institute of Agriculture, and UT Space Institute.
The UT Knoxville IRB has the authority to approve, disapprove, or require modifications in research activities that fall within its jurisdiction. The UT Knoxville IRB may work in conjunction with other university committees, but it reviews research protocols independently, determining whether human participants are adequately protected.

Prior to preparing a research application, investigators should determine (1) whether the project involves research, as defined in federal regulations, and (2) whether the project will involve human participants.

1.4 Human Participants

"Human subjects"¹ are defined in the regulations [45 CFR 46.102(f)] as "living individuals about whom an investigator conducting research obtains (a) data through intervention or interaction, or (b) identifiable private information."

What counts a “private” information is not well-defined. In general, we understand it as information that others could not readily find out about a person. Thus, name, address, occupation are not private information; but personal attitudes and behaviors are. With regard to what is “identifiable,” look at our discussions of privacy and confidentiality below.

What counts as an “intervention or interaction”? An “intervention” is something that changes one’s behavior - for example, asking you to perform a certain activity or eat a certain food or the like. An “interaction” would include asking you to fill out a questionnaire or observing your behavior in a certain setting.

1.5 Definition of Research

Research is defined in the federal regulations as: "a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge." [45 CFR 46.102(d)]

In other words, research is systematic observation and data collection which:

- is intended for release to the scientific community as a contribution to knowledge (e.g., Investigators undertake work that they anticipate might be shared in published form or otherwise made public), and/or
- is portrayed (explicitly or implicitly) by university students, faculty, or staff as "research" or "experimental" investigation, and/or
- is intended to fulfill requirements for a masters thesis, doctoral dissertation, or other research requirements at the University.

If a proposed activity can be defined as "research" by one or more of these criteria, the protocol must receive the appropriate review by the Departmental Review Committee (DRC) and by the UT Knoxville IRB.

If a proposed activity cannot be defined as "research" by one or more of these criteria, then the

¹The term used in the regulations is "human subject." We prefer the term "participant," and that is what we will use throughout this document. When you see the term "human subject" in this guide, it will be a direct quotation from the federal regulations or similar document.
Examples of observation or data collection activities involving human participants that do not require DRC or IRB review include:

- Data collection for internal departmental or other university administrative purposes (e.g., teaching evaluations, student evaluations, and staff evaluations).
- Program evaluation carried out under independent contract for an external organization that is for their internal purposes only. Examples of program evaluation include: personnel studies, staff effectiveness studies, human cost benefit analysis, treatment effectiveness studies, or human engineering studies.

It sometimes happens that data gathered in these ways prove to be of wider scholarly interest. To enable publication of these findings in such cases, it is wise to fulfill the fundamental requirements for research involving human participants even when the activity is not strictly "research" under this definition. In particular, it is wise to obtain informed consent from participants that includes an agreement that the data could be made available in scholarly publications or presentations. If the data is obtained on the basis of an explicit promise that it will not be used for purposes other than internal evaluation, then it is not appropriate to use it in scholarly reports later.

1.6 Participant Data and Identity Confidentiality Considerations

Federal regulations say: "When appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data." [45 CFR 46.111(a)(7) - our emphasis] There are times when confidentiality is not an issue. For example, in collecting oral histories of a neighborhood, the participants might want their names to be identified with their contribution. Defining the domain of privacy and confidentiality is a matter of judgment, and thus the IRB must make its own judgment about each protocol we review, both about the need for limits and protective measures and about the adequacy of those that have been proposed. Confidentiality is a matter of degree. If all ten members of a research team know the identities of participants, there is less confidentiality than if that information is restricted to the PI and the Co-PI.

Whenever researchers promise participants that their responses and data will be maintained in confidence, all research project members (investigators, directors, transcribers, students, and staff) are required to prevent accidental and intentional breaches of confidentiality. In most cases, confidentiality can be assured by following fairly simple practices (e.g., substituting codes for identifiers, removing survey cover sheets that contain names and addresses, limiting access to identified data, and/or storing research records in locked cabinets). All measures used to assure confidentiality of data need to be understood by all research staff before research is initiated, and followed once research is underway. Confidentiality procedures must be described in detail in research applications that come before the UT Knoxville IRB.

Researchers proposing projects that will address sensitive, stigmatizing, or illegal topics must explicitly outline the steps they will take to assure that any information linking participants to the study is maintained in confidence.

The requirement of signed consent forms is often waived in sensitive studies, if the consent document is the only written record linking participants to the project and a breach of confidentiality presents the principal risk of harm anticipated in that research. This makes participation anonymous, which is the strongest protection possible of privacy. Our understanding is that participation and data are anonymous only if no one could possibly identify the individual participant. If anyone knows, or could ascertain their identity, then confidentiality is the name of the measures taken to protect others from learning their identity.
The Privacy Rule of the Health Insurance Portability and Accountability Act (HIPAA) imposes some additional safeguards on confidentiality for research in health care institutions (including the UT Knoxville Student Health Service, the Psychological Clinic, and the Speech and Hearing Center on campus). See Section 4 of this guide for further details.

The Family Educational Rights and Privacy Act (FERPA) imposes some additional safeguards on confidentiality for research in educational settings. For further information, consult the U.S. Department of Education FERPA web site: http://www2.ed.gov/policy/gen/guid/fpco/ferpa/index.html (See also Section 9.2.4.3 below for guidelines on the use of educational records.)

If there is any chance that data or participants' identities might be sought by law enforcement agencies or subpoenaed by a court, a certificate of confidentiality should be obtained. Under federal law (Public Health Act 301(d)), researchers, prior to the initiation of the research project, may request certificates of confidentiality to protect against forced data and participant identity disclosures. These provide protection for specific research projects where such protection is judged necessary to achieve the research objectives. If you believe your research project may require a certificate of confidentiality, please contact your Departmental Review Committee (DRC) Chair or the IRB Administration at 974-3466 or go to the NIH Certificates of Confidentiality kiosk at http://grants.nih.gov/grants/policy/coc/.

1.7 Research Methods Instruction

Course activities that involve the use of human participants, but have no connection with research beyond the instructional function do not require certification or IRB review. However, efforts that lead to presentation outside of the classroom, and/or the publicizing of the student-prepared documents in any manner are considered research. If the investigator intends to use the data from such activities as the basis for a scientific contribution, or portrays the activity as "research" or "experiment," then the activity will be considered research involving human participants and will be subject to DRC and UT Knoxville IRB review. If the investigator intends to use the data for purposes of a masters thesis or doctoral dissertation, then the activity will be considered research involving human participants and will be subject to DRC and IRB review.
Section 2. Review System and Responsibilities

2.1 Description of the Review Process

All research involving human participants, including projects considered to be "exempt" from full IRB review must be reviewed and approved prior to commencement of the research. The following units are responsible for submitting research proposals to the UT Knoxville IRB:

- All departments and units of the University of Tennessee Knoxville (UT Knoxville);
- All units of the University of Tennessee Space Institute;
- All units of the Institute of Agriculture; and
- All other off-campus units of UT Knoxville or units formally associated with UT Knoxville or units located in Knoxville, except
  - the University of Tennessee Medical Center, Knoxville
  - the University of Tennessee Graduate School of Medicine
  - the Department of Audiology and Speech Pathology.

The UT Knoxville IRB does not review research proposals from individuals, organizations, or units not affiliated with the University of Tennessee, unless they are enlisting UT Knoxville students, faculty, and/or staff as participants. (See Section 3.8.2 for further information about research conducted on the Knoxville campus by outside researchers.)

2.2 Investigators' Responsibilities

It is the responsibility of investigators (including students, faculty advisors, co/principal
investigators, etc.) to provide the appropriate review documents (Form A or B1) to their Departmental Review Committee chairs as soon as they know the extent to which humans will serve as participants in their research. It is the responsibility of the investigators to design and implement research so as to exclude or minimize risks to human participants, and to adhere to the highest standards of research design and procedure within the discipline of the proposed research. It is the responsibility of the investigators to adhere to the principles of the Belmont Report and to applicable codes of professional ethics for the discipline of the proposed research, and to ensure the use of appropriate professional competence and adequate support facilities for all research involving human participants. Investigators must adhere to the principles and procedures for the review of research described in this Guide.

Once the protocol has been approved, it is the responsibility of the investigators to carry out the protocol as approved, to notify the IRB of any significant changes that are planned and to await approval before implementing them, to notify the IRB of any adverse events and work with the IRB to develop a plan to prevent a recurrence, and to instruct all students and staff working on the project in the proper procedures and the importance of showing respect for the human participants.

2.3 Departmental Review of Research Projects

The Departmental Review Committee (DRC) will review all research projects involving human participants initiated by faculty, staff, and students in its department for scientific merit and also for compliance with legal, regulatory, and ethical provisions for the protection of research participants' rights. Applicable ethical standards include principles of the Belmont Report and codes of professional ethics governing the discipline(s) involved. The DRC will apply the same standards applied by the IRB. (See Section 12.3 below.)

If the research includes recruiting student participants and offering course credit or extra-credit as an incentive, the DRC must determine (a) whether the procedure follows departmental guidelines for recruitment and (b) whether alternative means of earning equivalent course credit is available to the student, as required by regulations.

2.3.1 Research Center Reviews

Principal investigators or project directors in Research Centers that are not contained in or do not report to an academic department at the university should submit their research protocols to the DRC in the department where their academic appointments are maintained. If project investigators and directors are not affiliated with UT Knoxville academic departments or units, then their research protocols should be submitted to the DRCs in departments or units in which their Center Directors are affiliated.

2.4 Department Head's Responsibilities

The responsibilities of Department Heads include assisting faculty, staff, and students in meeting the requirements of law, regulations, policy, and procedures (as well as applicable standards of professional ethics) for research involving human participants. Departmental Review Committees review research protocols involving human participants on behalf of the Department Head. However, Department Heads cannot assign their legal, regulatory, policy or ethical responsibilities to the DRC. By signing off on a protocol, the Department Head attests to both the scientific merit of the proposal as well as

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1To find IRB forms online, go to: [http://research.utk.edu/forms/index.shtml#c4](http://research.utk.edu/forms/index.shtml#c4)

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as its compliance with legal, regulatory, and ethical provisions for the protection of research participants' rights.

The Department Head is also responsible for monitoring and managing possible conflicts of interest on the part of the researchers.

2.5 Departmental Review Committee Appointments

If research involving human participants is a normal activity of the discipline, however regular or irregular its occurrence within the Department, the Department Head will appoint a DRC. The Head will report the names of the members of the DRC to the IRB Administrator on Form E annually. The size of the DRC may vary, but minimum recommended membership is three, with alternates available so that members may avoid reviewing their own research or projects in which they may have either an active role or a conflict of interest.

2.6 Important Departmental Files

Each department should maintain a file consisting of the following documents:

- This Guide, copies of current University IRB Forms (e.g., A, B, and D), the Belmont Report, and copies of the DHHS regulations presented in 45 CFR 46, and FDA regulations presented in 21 CFR 50 and 56;
- Copies of other federal regulations relevant to research conducted in the department; and
- Copies of standards of professional ethics applicable to departmental research.

2.7 Departmental Review Committee Recommendations

Prior to submission to the IRB, a research proposal must have DRC approval.

2.7.1 Scientific merit

One of the criteria for approval of a research project specified in federal regulations is: "Risks to subjects are minimized: (i) by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes." [46 CFR 46.111(a)]

Sound research design is to some extent discipline-specific. Therefore colleagues in the discipline are uniquely qualified to evaluate the research design and to consider whether there are alternatives that might minimize risk to subjects even further than what is proposed.

By recommending IRB approval of the protocol, the DRC attests that they have evaluated the research design and that (a) it meets the standards of sound research design in their discipline and (b) no alternative method exists that would minimize risk to the subjects further.

2.7.2 Form A

The DRC will evaluate the Form A protocol in accordance with the guidelines set out in Section 5

1To find IRB forms online, go to: [http://research.utk.edu/forms/index.shtml#c4](http://research.utk.edu/forms/index.shtml#c4)
2.7.3 Form B

Departmental Review Committees conduct the initial reviews of Form B applications and indicate their approval by making one of the following recommendations to the IRB.

2.7.4 Possible DRC Recommendations for Form B Projects

- **Recommendation for Expedited Review**: This recommendation signifies that the project has been reviewed in accordance with the provisions of Section 6 of this Guide and is judged to be eligible for expedited review and approval by the designated representative(s) of the UT Knoxville IRB. The DRC Chair must identify the specific category(ies) under which the project qualifies for expedited review in the signature bloc of the Form B. Please note that the Department Head, the IRB Administration, or an expedited-process reviewer may override this recommendation and refer the project to the full IRB for review.

- **Recommendation for Full IRB Review**: This recommendation indicates that the DRC has reviewed the project in accordance with the provisions of Section 7 of this Guide and found the project eligible for review and approval by the UT Knoxville IRB.

- If the DRC judges that the project is not suitable for approval, it should be returned to the researcher(s) with suggestions as to how (if at all) it might be reworked to make it suitable.

The DRC does not have authority to disapprove a protocol categorically. Only the IRB can do that. If the DRC is uncomfortable with the protocol even after modifications, they should forward it to the Department Head and then on to the IRB with their reservations indicated in writing. The protocol will then be automatically scheduled for full board review, where it is possible for a categorical disapproval to be voted.

2.8 University Responsibilities

The University of Tennessee Federal-wide Assurance outlines the university’s responsibilities with respect to research involving human participants that is conducted by university faculty, staff, and students. In addition, the university, through the Office of Research, provides administrative services necessary for the IRB Administration and UT Knoxville IRB to carry out their duties.

2.9 IRB Administration Responsibilities

The IRB Administration serves as the focal point for the review and approval of all UT Knoxville research involving human participants. The IRB Administration is part of the UT Knoxville Office of Research and administratively answers to the Associate Vice Chancellor for Research. The IRB Administration serves as a clearinghouse for compliance and regulatory information. The staff of this office may consult and aid investigators in the preparation of Form A and B applications.

As requested by Department Heads or DRC Chairs, IRB Administration staff conduct training
seminars concerning applicable human participant research policies and procedures for UT Knoxville faculty and students. The office also maintains two course management (Blackboard) sites dealing with aspects of responsible conduct of research that can be employed for training of students and research personnel.

The IRB Administration maintains this Guide and in consultation with the UT Knoxville IRB and the Associate Vice Chancellor for Research institutes policy and procedural changes for the review of research involving human participants. All policy and procedural changes are required to conform to current applicable regulations, institutional requirements, and UT Knoxville IRB experience.

The IRB Administration maintains records of all UT Knoxville research involving human participants for a period of ten years following the termination of the research project. The IRB Administration also maintains records of all UT Knoxville IRB proceedings and decisions.

The IRB Administration, through the Office of Research, is responsible for reports to the Office for Human Research Protection (OHRP) of DHHS concerning unanticipated risks or injuries to research participants.

### 2.10 Institutional Review Board Responsibilities

The UT Knoxville IRB is the review board for all units of the university in the Knoxville area, except for the University of Tennessee Medical Center, the Graduate School of Medicine, and the Department of Audiology and Speech Pathology. The UT Knoxville IRB is required to report the profession, relationship to the University and the qualifications of its membership to DHHS annually.

#### 2.10.1 Composition of the Institutional Review Board

The composition of the board meets the requirements set forth by the DHHS (45 CFR 46.107).

- Members, including the Chair and Vice-Chair, are appointed by the Associate Vice Chancellor for Research.
- The length of appointment is five years.
- The UT Knoxville IRB consists of at least sixteen members chosen to ensure compliance with the following standards:
  - Members come from diverse backgrounds to promote complete and adequate review of research activities and to provide the professional competence necessary to review specific research activities;
  - Members are selected with consideration to their experience and expertise, their racial and cultural backgrounds, their sensitivity to such issues as community attitudes;
  - The IRB includes male and female members who represent a variety of professions and includes at least one member whose primary expertise is in a nonscientific area and at least one member who is not otherwise affiliated with the University; and
  - When research involving vulnerable participants (e.g., prisoners, children, or individuals who may be decisionally impaired) is reviewed, the IRB will include one or more members (or a consultant) who have primary concern for and knowledge about the welfare of these participants.

#### 2.10.2 IRB Rulings

The IRB issues the following rulings:

- approve
• approve conditional upon modifications required to secure approval (the specifics to be communicated
to the PI in writing)
  ○ for minor modifications the adequacy of the modifications to be verified by the IRB administration
  ○ for more significant modifications, the adequacy of the modifications to be reviewed by a
    subcommittee of the IRB (typically the primary reviewers plus others who had particular concerns
    about the protocol)
• revise and resubmit to the full board for re-review (here again, specific concerns and/or suggestions for
  modifications will be communicated to the PI in writing)
• disapprove (If the IRB decides to disapprove a research activity, it shall include in its written
  notification a statement of the reasons for its decision and give the investigator an opportunity to
  respond in person or in writing and/or to appeal the decision (see section 2.11 just below)) [45 CFR
  46.109(d)]

2.11 Appeals Procedures for UT Knoxville IRB Actions

Principal and co-principal investigators must try to resolve concerns about UT Knoxville IRB
decisions regarding their research protocols by discussing their concerns with the Chair of the UT
Knoxville IRB, the IRB Administrator, and the Associate Vice Chancellor for Research. If their
concerns cannot be resolved through those discussions, they can petition the Associate Vice Chancellor
for Research to establish and convene a UT Knoxville IRB Appeals Board.

Any action of the UT Knoxville IRB, including actions on exempt, expedited, and full board
protocols, can be appealed by principal and co-principal investigators. However, these appeal
procedures do not apply to actions taken by Departmental Review Committees. Actions of the DRC
would be appealed to the IRB.

Investigators wishing to appeal UT Knoxville IRB decisions should address a formal letter
requesting an appeal to the IRB Administrator. The formal letter requesting an appeal should:
  • Identify the project,
  • Identify the UT Knoxville IRB action in question,
  • Describe any steps that have already been taken to attempt to resolve the concern, and
  • List the reasons for appealing the UT Knoxville IRB decision.

Upon receipt of the letter formally requesting an appeal, the IRB Administrator will notify the UT
Knoxville IRB Chair and the Associate Vice Chancellor for Research. If investigators have exhausted
all other avenues of resolution, the Associate Vice Chancellor for Research will establish and convene
an Appeals Board and serve as the Board's Chair.

The UT Knoxville IRB Appeals Board will meet at a time and location designated by the Board's
Chair. Quorum and procedural rules for the Appeals Board will be the same as those governing the UT
Knoxville IRB. The Appeals Board will review the investigators' appeal, review the UT Knoxville IRB
decision in question, and receive additional appropriate information from other relevant sources.

The Appeals Board cannot override a decision of the UT Knoxville IRB. It can only make
recommendations to the UT Knoxville IRB for reconsideration of their ruling. The Board serves as an
appellate body and can take the following actions:
  • Confirm the decision of the UT Knoxville IRB,
  • Request modification of the proposed research activities and recommend review of the modified
    protocol by the UT Knoxville IRB,
• Request modification of the UT Knoxville IRB decision in question and recommend further review by
the UT Knoxville IRB to consider these recommendations, or
• Request disapproval of research activities previously approved by the UT Knoxville IRB and
recommend further review by the UT Knoxville IRB to consider this recommendation.

If the Appeals Board recommends any changes in the UT Knoxville IRB decision, it must submit its
recommendation with reasons in writing to the UT Knoxville IRB. Any Appeals Board recommendation
to the UT Knoxville IRB will initiate a new full-board review of the research activities in question
which shall address all Appeals Board recommendations. The results of this full-board review will be
sustained without further appeal.

2.11.1 Composition of the Appeals Board

The UT Knoxville IRB Appeals Board is appointed when the need arises by the Associate Vice
Chancellor for Research. The composition of the UT Knoxville IRB Appeals Board is designed to meet
the federal membership criteria for IRBs set forth in 45 CFR 46.107. Appeals Board membership
includes the following individuals:

- Associate Vice Chancellor for Research,
- IRB Administrator
- UT Knoxville IRB Chair,
- Five assigned current or former Board Members.

The five assigned Appeals Board members will be selected by the Associate Vice Chancellor from
a set of senior and former UT Knoxville IRB members. The UT Knoxville IRB will be notified about
Appeals Board assignments by the Associate Vice Chancellor for Research, but the UT Knoxville IRB
has no control over the selection of members. Appeals Board members are assigned to the Board for the
period designated by the Associate Vice Chancellor for Research.
There are three categories of review by the UT Knoxville IRB:

- **Exemption**: Research that does not require formal review by the UT Knoxville IRB process, nor does it require continuing review. However, a description of this research must be examined by the DRC, Department Head, and the IRB or its representative in order to certify that it meets the criteria for exemption. Furthermore, no interaction with participants is exempt from the basic moral principles of the Belmont Report as applied in the process of informed consent and other elements of research design.

- **Expedited**: Research in this category may be reviewed by one or more representatives of the IRB instead of being reviewed by the full board at a convened meeting. One important advantage is that the review can be completed much faster since it does not have to wait for the monthly convened meeting of the full board.

- **Full Board Review**: Research in this category must be reviewed by the full board at a convened meeting. Three primary reviewers study the application especially carefully and present it to the other members of the board along with a recommendation about approval, but all members of the IRB are expected to review the protocol before the meeting and to participate in discussion of and vote on the application.
3.1 Definition of Minimal Risk

Estimation of risk is an initial screening tool in classifying research.

- Research projects must present no more than minimal risk to human participants in order to be considered for exemption from either full board or expedited review.
- Similarly, research projects to be reviewed through an expedited procedure must present no more than minimal risk to human participants.
- Research projects that receive full board review may include those that pose no more than minimal risk, as well as those that pose greater than minimal risk.

Minimal risk in a research activity is defined in federal regulations [45 CFR 46.102(I)] as an anticipated risk of harm or discomfort 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.

This is obviously a judgment call. Researchers should present enough information about research procedures that the members of the IRB can make an informed judgment about the level of risk.

3.2 Exempt Research Categories (Form A)

Research projects that meet one of the following exemption categories may be "exempted" from full or expedited IRB review, if (a) they place participants at no more than minimal risk, and (b) they do not involve minors (i.e., participants who are under 18 years of age), prisoners, fetuses or neonates, or pregnant women. Refer to Section 5 of this guide for more information about this category of review (See especially section 5.3 for some further explanation of these categories, including some examples.).

Category 1: [45 CFR 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: [45 CFR 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: [45 CFR 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.

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1 To find IRB forms online, go to: [http://research.utk.edu/forms/index.shtml#c4](http://research.utk.edu/forms/index.shtml#c4)

2 The exclusion of research involving minors from exemption is not dictated by federal regulations. It is a policy decision made by the UT Knoxville IRB that research involving minors should be given no less than the "expedited" level of review in which one of the reviewers has expertise in child development.
Category 4: [45 CFR 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: [45 CFR 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: (45 CFR 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.

3.3 Expedited Research Categories (expedited Form B¹)

Minimal risk research that may be reviewed using expedited review procedures by the UT Knoxville IRB must fall under one of the following categories specified in federal guidelines:

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
   a. 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.)
   b. 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.

2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
   a. From healthy, nonpregnant 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
   b. From other adults and children² considering the age, weight, and health of the subjects, the

¹To find IRB forms online, go to: [http://research.utk.edu/forms/index.shtml#c4](http://research.utk.edu/forms/index.shtml#c4)

²Children are defined in the HHS regulations as "persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted." [45 CFR 46.402(a)]
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.

3. Prospective collection of biological specimens for research purposes by noninvasive means.

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 cleared/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:
   a. 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;
   b. weighing or testing sensory acuity;
   c. magnetic resonance imaging;
   d. electrocardiography, electroencephalography, thermography, detection of naturally occurring
      radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and
      echocardiography; or
   e. moderate exercise, muscular strength testing, body composition assessment, and flexibility testing
      where appropriate given the age, weight, and health of the individual.

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.)

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

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.)

8. Continuing review of research previously approved by the convened IRB as follows:
   a. 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; or
   b. Where no subjects have been enrolled and no additional risks have been identified; or
   c. Where the remaining research activities are limited to data analysis.
9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where the following conditions apply:
   a. Categories two (2) through eight (8) do not apply; and
   b. 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.

Refer to Section 6 of this guide for further information about the expedited review procedure.

3.4 Categories of Full IRB Reviewed Research (Form B)\(^1\)

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

- Most projects requiring the use of deception.
- Involvement of prisoners, pregnant women, fetuses or neonates, the seriously ill, decisionally impaired individuals, or others for whom a determination of vulnerability must be made.
- 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.
- Collection of information regarding sensitive aspects of the participant's behavior such as: drug and alcohol use, illegal conduct, or sexual behavior.
- Clinical trials
- Projects which include procedures that present more than minimal risk to participants.

Please refer to Section 7 of this guide for more information about projects requiring full-IRB review.

3.5 Audio- and Videorecording Considerations

Videorecording and audiorecording research participants are valid and useful data collection methods. However, the use of audio- or videorecordings makes all the more important an investigator's need to clearly specify the steps taken to maintain the confidentiality of this identifiable information.

Investigators meet this need by describing - both in their Form B applications, and in their informed consent forms - the steps they will take to protect the confidentiality of research audio- or videorecordings. All research in which participants will be audio- or videorecorded requires the use of a Form B application. Expedited reviews of Form B applications are possible when the research does not involve vulnerable participants and the information collected is not of a sensitive nature (e.g., sexual behavior, illegal activities, etc.).

3.5.1 Form B Application Information

Section IV (the Methods and Procedures section) of an investigator's Form B should clearly specify the purposes and uses of the audio- or videorecordings. Investigators should directly relate the purposes and uses of the audio- or videorecordings to achieving the objectives of the project stated in Section II of the Form B. The investigator's audio- or videorecording procedures should be described in detail along with a discussion of the measures used to avoid the inclusion of nonparticipants on the audio- or videorecordings. Investigators should describe audio- or videorecordings storage procedures, the storage

\(^1\)To find IRB forms online, go to: http://research.utk.edu/forms/index.shtml#c4
location, and the duration of storage. If the session is to be transcribed, the qualifications of the
transcriber should be explained, along with a copy of the pledge of confidentiality the transcriber(s) will
sign.\(^1\) Section IV should also contain a description of the investigator's procedures for controlling access
to and use of the audio- or videorecordings, and the disposal of the audio- or videorecordings once the
research use is completed.

Section VII (the "Methods for Obtaining Informed Consent From Participants" section) of a Form
B should clearly specify the investigator's consent procedures. Usually the IRB requires full informed
consent when audio- or videorecording procedures are used. However, the IRB may authorize the use of
deception or incomplete disclosure about the real purpose of the research in the informed consent, if the
proposed consent procedures are essential to the investigator's ability to carry out the research, and
participants are exposed to no more than minimal risk.

If incomplete or deceptive consent procedures are used, then the investigator should address her/his
plan for giving participants full information about their participation following the completion of their
involvement in the study (i.e., what is called "debriefing"). If no debriefing is planned, a justification for
its omission is necessary.

### 3.5.2 Informed Consent Form Information

In addition to all other basic elements of informed consent, a full informed consent should identify
the purposes and uses of the audio- or videorecordings. The informed consent should provide
information about who will have access to the audio- or videorecordings and how access will be
controlled. Audio- or videorecordings storage information should state how long the investigator will
store the audio- or videorecordings and what will be done with the audio- or videorecordings at the end
of the storage period. The information provided in the informed consent should match the information
provided in the Form B application. We recommend a separate signature bloc on the consent form to
grant permission to be audio- or videorecorded in the course of the research. If audio- or videorecording
is so integral to the study that participation is impossible without it, that can be explained in the consent
bloc.

Because the contents of audio- or videorecordings are identifiable, participants must give their
explicit consent for any public use of audio- or videorecordings, such as use in the classroom or use in a
public presentation of research results. The informed consent form or a separate release form must be
used to obtain a participant's explicit consent for the public use of her or his voice and/or image on
audio- or videorecording. Audio- or videorecordings of participants in studies using limited or deceptive
informed consent procedures may not be publicly used without the explicit written consent of the
participant, after full disclosure. Audio- or videorecordings or images of children may not be released
for use on a website, nor may they be reproduced.

### 3.5.3 Storage and Future Use Considerations

If the researcher expects to store audio- or videorecordings in ways that will enable others to use
them, or if the researcher expects to use the audio- or videorecordings in additional research projects
that are not directly related to the objectives of the study under which they were initially created, these
expectations must be clearly stated in the protocol and in the informed consent form. Given that the

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\(^1\) A sample confidentiality pledge can be found on the IRB forms page:
http://research.utk.edu/forms/index.shtml#c4
identities of participants do remain on the audio- or videorecordings until the recordings are erased or
destroyed, participants must be informed about the possibility that others may use the audio- or
videorecordings or that the audio- or videorecordings may be used in additional research projects. There
are many legitimate reasons why one might want to use the audio- or videorecordings in future research
projects, or to allow others to use the audio- or videorecordings, but the participants in the initial study
need to know about these uses when they consent to participate. We recommend a separate signature
bloc for consent for archiving audio- or videorecordings. A participant should be able to refuse the
archiving of these materials while still approving their use in the present study. This is an implication of
their right to withdraw from the study at any time.

If it is anticipated that other researchers may use the audio- or videorecordings outside the present
research project, then the procedures that will be used to grant other researchers access to these audio-
or videorecordings must be specified in the Form B. The participant’s informed consent form should
state that other researchers may use the audio- or videorecordings in the future, indicating in clear terms
the scope of possible future uses. We recommend yet another separate signature bloc for consent for
uses that are outside the scope of the present study to make it clear that the participant may decline this
use while still participating in the present study.

If there is a plan to archive the audio- or videorecordings in a manner in which access to the
recordings will be controlled by other individuals, libraries, or collections, the qualifications of the
guardians of the audio- or videorecordings must be explicitly stated, as must procedures they will follow
to protect the confidentiality of the participants when other researchers request access to the audio- or
videorecordings. The participants in the study need to know when they consent to participate about any
plans to allow others to control future access to the audio- or videorecordings, and these plans should be
clearly stated in the protocol and informed consent form.

The passage of time does not diminish the responsibility to protect the confidentiality of the
participants in research. The rights of a participant do not expire at the end of a research project, or after
any other period of time. Audio- or videorecordings cannot be considered usable secondary data as long
as they contain identifiable information. Please note that new research projects using the archived audio-
or videorecordings will require a new Form B application if the new project was not described in the
originally approved Form B and consent form. If the new research use was noted, but only partially
described in the originally approved Form B application and informed consent form, then a Form D\(^1\)
that fully describes the new research use may be submitted. In either case, the audio- or videorecordings
may not be used until final IRB approval is received.

If you have any questions about the development of Form B application for a project involving
audio- or videorecordings, please contact the IRB Administration at 974-3466.

### 3.6 Internet Research

The internet can be a powerful research tool, but it also poses some special challenges.

#### 3.6.1 Presentation of Research Findings on the Internet

The web can be a good place to disseminate research findings, but, once material is placed on the

\(^1\)To find IRB forms online, go to: [http://research.utk.edu/forms/index.shtml#c4](http://research.utk.edu/forms/index.shtml#c4)
internet, we lose control of it. Someone else can download it and reuse it or even alter it and then reuse it. This can especially be a problem with images. As attractive as it can be to enhance one's presentation with images of participants, it is essential that there be willing consent for using them based on a full understanding of the consequences. Given the endurance of images and the possibility of altering them, the UT Knoxville IRB is not comfortable approving plans for parental permission for posting images of small children on the web. Children are likely to be more aware of the possibilities of web images than their parents are. Only when the child himself or herself is old enough to give an educated approval is the posting of their image acceptable.

3.6.2 Electronic Transmission and Storage

Researchers who plan to transmit data electronically and/or to store it on computers have a responsibility to investigate security issues such as encryption and the use of passwords. The UT Knoxville IRB expects the protocol to contain enough detail about security measures to enable a judgment about the risks to privacy and confidentiality. This can be explained in either the section of the Form B on "Risks and Protection Measures" or the section on "Facilities and Equipment." It is not enough, for example, to say that the computer on which the data is stored is "password protected." How secure is this password? Explain just how many people will have access to this password. If the computer is a laptop, explain what steps will be taken to ensure that it is not lost or stolen, especially when it is transported. The U.S. (as well as the European Union and a growing number of other countries) have rules and laws (privacy laws) governing the online storage and transmission of information which may be considered private or individually identifiable.

3.6.3 The Internet and "Public Behavior"

The internet has greatly complicated drawing the distinction between "public" and "private" behavior. There may be some chat rooms in which participants have no expectation of privacy and are aware of the presence of "lurkers," and thus observing behavior there may not be troublesome as long as nothing is recorded that would identify the participant.

However, there are internet environments which participants consider to be at least somewhat private - for example, a chat room dedicated to those with a certain medical condition; and they would consider it an invasion of their privacy to have their conversations reported beyond that environment.

In some cases, the content of the information being collected may warrant its designation as private, even if it is being collected from public sources. Any discussion of illegal behavior, for example, should be considered as inherently private; and special measures should be taken to disguise any identifying details.

The burden of proof falls on the investigator to provide evidence that participants in a given web environment have no reasonable expectation of privacy. Relevant language from the site's own description of itself and/or communications with those who manage the site should be quoted in the Form B.

3.6.4 Recruitment in Internet Research

The use of web resources for recruitment must also be handled carefully. To go into a chat room or to send messages to contributors to a listserv or bulletin board which the participants consider private and then to solicit participation in one's research is no less an intrusion than it would be for a researcher to walk into an Oncologist's waiting room or the Oncology wing of a hospital and begin soliciting
participation. In the medical setting, it is customary to ask the physician to make first contact with patients and give them information that would allow them to contact the researcher if they are interested in participating in the research. A similar strategy should be used online. A message to the manager of the chat room, listserv, or bulletin board asking them to pass along information about the research (complete with contact information for the researcher) is more appropriate than direct contact.

As with other research, recruitment material and strategies must be reviewed and approved by the IRB before being implemented. This should include a list of internet sites to be approached, with enough information about each one to enable a judgment as to the appropriateness of the strategy.

### 3.6.5 Privacy and Confidentiality in Internet Research

Use of the screenname chosen by a participant cannot be considered to confer anonymity. People sometimes incorporate into their screenname a part of their name or something descriptive about them that might allow them to be identified. And, even if it could never be correlated with their "offline" (real-world) identity, there can be questions of violating the privacy of their online persona - revealing something about them to others to whom they have chosen not to disclose this. A new pseudonym, unrelated to the self-chosen one, should be substituted in publications and presentations.

It is not strictly true to say: "participants cannot be identified because it is a web-based survey." There are often ways to trace back to the particular computer from which the survey was taken, and this might identify the participant if she or he is the sole user of that computer or if a computer-lab log might reveal who was using a certain computer at a given time. A more complete protection is for the researchers to promise solemnly that they will make no attempt to trace the identity of the respondent. (This might especially be a problem if the survey led the respondent to describe behavior that the researcher might be legally required to report, such as child abuse.)

If contact information is to be gathered in order to direct an incentive such as a gift card, care must be taken to separate this information from the responses to the questionnaire. Gathering this information in a separate file may not be enough to preserve anonymity - if, for example, a print-out of the contact list could be matched one-on-one to a list of the responses. It may be necessary to scramble the order of one of these files to prevent linking the respondent to the response.

If identifying information is retained (to allow a follow-up survey at a later date, for example) care must be taken to separate any files that would link respondent to response - the lists should be kept on different strong-password-protected computers or, at the very least, in different directories of a computer with each directory having a different strong password.

True anonymity is possible only if no identifying information is gathered (or traced). However, be advised that the request to waive documentation of consent in this way requires some specific findings on the part of the IRB. See Section 4.7 of this Guide for details.


### 3.6.6 Skype

Interviews conducted via Skype (or other internet audio- and/or video-device) are not anonymous since the individual can be identified by image and/or voice. Confidentiality can be maintained if no identifying details are given in research notes on the exchange. If voice or image is recorded, then all the issues raised above about audio- and video-recording come into play.
3.6.7 Informed Consent Online

An informed consent document does not serve its purpose unless it is read. There may be a temptation on the part of potential participants to skip reading a lengthy consent document (like we all do with the user agreements we are often confronted with in connection with new software). Some researchers avoid this by mechanisms like placing checkboxes beside each paragraph to be checked after that paragraph is read.

3.6.8 Risk in Internet Research

In a face-to-face interview, it will be pretty obvious if the respondent becomes upset at a question. Even if the respondent is filling out a questionnaire in a classroom, an observant researcher can notice signs of agitation - and there is someone ready at hand for the participant to turn to. However, these clues are not available when a participant is filling out an online survey. When sensitive subjects are being dealt with, provision must be made to offer online support to participants who become emotionally distraught. We propose that a list of resources - including local resources if possible - be no more than one click away at every point in the survey.

3.7 Procedures for Projects that Require Approval from Other UT Knoxville Compliance Committees

Projects that involve the use of animals, radioactive substances, or biological dangers in addition to human participants require approval from separate UT Knoxville institutional committees. These committees share in the responsibility for protecting participants and researchers, but the final authority with respect to the protection of human participants rests with the UT Knoxville IRB.

If your project requires approval from another institutional committee, the appropriate applications may be submitted to all the UT Knoxville institutional committees at the same time. However, final UT Knoxville IRB approval to move forward with participant contact, recruitment, and enrollment will be contingent on project approval from the other UT Knoxville institutional committees, as well as approval from the UT Knoxville IRB. If you have questions about the need to submit project applications to more than one UT Knoxville institutional compliance committee, please contact the IRB Administration at 974-3466.

3.8 Application Procedures for Off-Campus Research

If your project involves the use of non-UT Knoxville facilities as research sites or recruitment sites, then you must obtain letters of compliance from authorized individuals or committees, and/or IRB approvals at those sites. Letters of compliance are obtained when the facility does not have its own approved Federal-Wide Assurance (FWA) and IRB. These letters must be on the facility's letterhead, and contain the statement that the organization will review and comply with procedures approved by the UT Knoxville IRB. If the facility has an approved FWA and IRB, then that IRB must also review and approve your project application before it receives final approval from the UT Knoxville IRB.

If your project requires letters of compliance or approval from an IRB at another facility, you may submit your Form A or B to the UT Knoxville IRB before you receive approval from the non-UT Knoxville facilities. However, final UT Knoxville IRB approval to move forward with participant contact, recruitment, and enrollment will be contingent on project approval from the other IRB, or the IRB Administration's receipt of an acceptable letter of compliance, as well as approval from the UT

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Knoxville IRB. If you have questions about the need to obtain letters of compliance or IRB approvals from non-UT Knoxville facilities, please contact the IRB Administration at 974-3466.

3.8.1 Relationship with the Graduate School of Medicine IRB

If the research is to be conducted at the UT Medical Center at Knoxville, the Graduate School of Medicine IRB should be listed as first review. A second IRB application should be submitted to the UT Knoxville IRB for review as well. In most (but not all) cases, this IRB will accept the review of the Graduate School of Medicine to expedite our review and approval. We reserve the right to refer the proposal to full board review if it raises concerns in the mind of the expedited-process reviewer.

If the only involvement of the UT Knoxville campus in the study is to recruit participants from among students or staff for a study being conducted in the clinical facilities at UT Medical Center at Knoxville, then a copy of the IRB form and consent form submitted to the Graduate School of Medicine IRB should be submitted to the IRB Administrator for review and recommendations.

3.8.2 Research Conducted on the Knoxville Campus by Outside Researchers

The UT Knoxville IRB must approve any research conducted on the Knoxville campus, whether by researchers from our own institution or by those from other institutions. A copy of the protocol that was approved by the researcher's home institution, along with the letter of approval, should be submitted to the IRB Administrator. We do not generally require that a separate Form B be prepared. The IRB Administrator will contact the unit on this campus where participation is being requested to make certain that they are agreeable to having the research conducted within their unit. If they are, the protocol can generally be approved through expedited review. However, if the proposed research raises any concerns, the protocol will be referred to full board review (and, at this point, a Form B may be required).

3.8.3 International Research

Federal regulations specify that research conducted in foreign countries must follow U.S. guidelines, even when they are more stringent than the requirements of the host country. In addition, review mechanisms and requirements of the host country must also be honored. Accordingly, the UT Knoxville IRB will require documentation that host country guidelines are being followed in the same way we require documentation from another institution in the U.S. where research is being conducted.

OHRP maintains a listing of over 1,000 laws, regulations, and guidelines on human subjects protections in over 100 countries and from several international organizations at http://www.hhs.gov/ohrp/international/index.html.

3.9 Advertising to Recruit Participants

All advertisements, posters, flyers, and correspondence aimed at attracting potential research participants must be provided as a part of Form A or Form B applications. If these materials are not available when the research application is submitted, they must be submitted and reviewed before final approval can be granted. Only reviewed and approved recruiting materials may be used.

In general, recruiting materials should contain contact information, an accurate and brief description of the research objectives, and basic eligibility criteria. The documents should also indicate whether participants will be paid or receive free treatments as an incentive to participate.
3.10 General Policy on the use of Children in Research

Federal regulations [Title 45 CFR Part 46, Subpart D] require that the researchers explicitly address the measures taken to protect the welfare and rights of children participating in research projects. At the University of Tennessee, the adequacy of these measures is assessed by the UT Knoxville IRB during the review process. Because of the potential vulnerability of children, a higher standard of protection must be demonstrated for approval. As a result, all research involving children requires expedited or full-IRB review of Form B applications. Minimal risk projects that would normally be considered exempt from IRB review (Form A applications) are not exempt when children are involved.

Please note that you may not initiate contact with potential child-participants, or begin data collection, before you have received final approval from the IRB. Although Form B applications take longer to prepare and review than Form A applications, most Form B applications are reviewed and approved within three weeks of submission (expedited review). However, the approval process sometimes takes longer than this, especially if significant revisions are required. Therefore, please give yourself adequate time to prepare and submit your application. Please understand that the complexity of your project and the initial quality of your application affect the time required for approval.

Section 9.2 of this guide addresses several significant areas of concern that commonly arise during IRB reviews of research involving children. When preparing your Form B application, follow the Form B Application Guidelines in. Section 8 of this guide.

If you have additional questions about your specific research project or need further clarification, please contact the IRB Administration at 974-3466.

3.11 General Policy on the use of Vulnerable Individuals in Research

The UT Knoxville IRB is required to determine that the selection of research participants is equitable.

In addition to children, the U.S. Department of Health and Human Services (DHHS) recognizes three other groups as vulnerable populations: pregnant women, prisoners, and individuals who may be decisionally impaired. The DHHS also considers other individuals vulnerable if they are identified as potential participants because of their availability, compromised positions, or potential susceptibility to manipulation (e.g., students, subordinate employees, economically or educationally disadvantaged individuals) rather than for reasons directly related to the objectives of the study. As a result, the UT Knoxville IRB must also determine that the identification and selection of potential research participants from vulnerable populations is reasonable and not opportunistic.

This added scrutiny should not be interpreted as a signal to avoid the use of individuals from vulnerable populations in your research. Adequate representation of individuals from all vulnerable populations is important, especially in research that relates directly to issues, disorders, or conditions that disproportionately affect members of vulnerable populations. The other side of the IRBs mandate to ensure that selection of participants is equitable is to question whether people are excluded from participation for reasons that amount to discrimination against them.

Please note that Form B applications must be used for research involving persons from vulnerable populations. As researchers prepare their Form B applications, they should state why their research requires or justifies using individuals from vulnerable populations, and identify any special risks posed by the research methods. When appropriate, researchers should specify mechanisms that will be used to reduce pressures on susceptible or compromised populations. For additional information about the UT
Knoxville IRB policies concerning projects that will use vulnerable individuals as research participants, please refer to Section 9 of this guide. If you have additional questions, please contact the IRB Administration at 974-3466.
4.1 General Policy on Informed Consent

Informed consent is a core element in the protection of research participants' rights and welfare. Investigators must also recognize that informed consent is an ongoing process that assures participants are provided information about the research needed to knowledgeably and voluntarily decide whether to participate and to continue to participate. Investigators should seek consent only under circumstances which provide the prospective participants sufficient opportunity to consider whether to participate, and which minimize the possibility of coercion or undue influence. Consent and information forms must be written in language that is understandable and clear to potential participants. The consent process may not include exculpatory statements through which participants waive or appear to waive any legal rights, or release or appear to release the investigator, sponsor, institution, or agents from liability for negligence.

For research involving children, see parental permission and assent procedures described in Section 9.2.3 of this guide.

4.2 Basic Elements of Informed Consent

As you develop your consent form or procedure, federal regulations [45 CFR 46.116(a)] require that you include the following information.

- State that the study involves research.
- Explain the purposes of the research and the expected duration of the participants' participation.
- Describe the procedures that directly involve human participants, and identify any procedures that are
4.2.1 Additional Elements of Informed Consent

The following are among the additional elements of informed consent that may be required in certain situations, as determined by the IRB [45 CFR 46.116(b)]:

- A statement that the particular treatment or procedure may involve risks to the participant that are unforeseeable.
- Anticipated circumstances under which a participant's participation may be terminated by the investigator without regard to the participant's consent.
- Any additional costs to the participant or to their health insurance that may result from participation in the research.
- The consequences of a participant's decision to withdraw from the research, and procedures for orderly

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1 It is also helpful to identify what elements are NOT experimental. For example, in a study to test certain innovative approaches to math instruction, the student who declines to participate in the research may be spared taking certain tests whose sole purpose is to evaluate the effectiveness of this approach and, perhaps the student will by-pass certain supplemental instruction - but the student needs to know that she or he will NOT be able to by-pass math class or regular math tests by declining to participate in the research.

2 It is important to distinguish benefits from incentives. Incentives are things (e.g., cash payments, gifts, parking passes, course extra credit) which participants receive to entice them to agree to participate. Benefits stem from the research activity itself - e.g., better math skills. To say something like “participants will gain an understanding of the process of research” is also somewhat extraneous to the specific research. Any benefits that might stem from these particular research activities are the key things to indicate here.

3 It is safest not to tell participants exactly WHERE on the Knoxville campus material will be stored - although the IRB expects that specific information in the Form B.

4 The phrase “or loss of benefits to which you are otherwise entitled” should be used only in situations in which there are benefits to which participants are otherwise entitled - e.g., service settings. If part or all of promised incentives will be withheld from those who withdraw before the research activities are completed, this must be clearly stated.
termination of participation.

- 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.

If you have any questions about preparing an informed consent form or procedure, please check with your Departmental Review Committee or the IRB Administration at (974-3466).

4.3 Sample Informed Consent Document

(Include or exclude information as applicable)

================================= Beginning of Sample Consent ===========================

INFORMED CONSENT STATEMENT

[List project title here]

INTRODUCTION

State that participants are invited to participate in a research study. State the purpose/objectives of the study.

INFORMATION ABOUT PARTICIPANTS' INVOLVEMENT IN THE STUDY

List all procedures, preferably in chronological order, that will be employed in the study. Point out any procedures that are considered experimental. Clearly explain technical and medical terminology using nontechnical language. Explain all procedures using language that is appropriate for the expected reading level of your participants.

State the amount of time required of participants per session and for the total duration of the study.

If audiorecording or videorecording procedures are going to be used, provide information about the use of these procedures. (If applicable, please review section 3.5 of this Guide.)

If you are planning to include children in your study, please review Section 9.2 of this Guide.

For other vulnerable participants, consult the appropriate sub-section of Section 9.

RISKS AND PROTECTIONS

List all reasonably foreseeable risks, if any, of each of the procedures to be used in the study, and any measures that will be used to minimize the risks.¹

¹Virtually no activity is entirely free from risk. In filling out a benign questionnaire, the participant might experience a paper cut. Thus, “This research carries minimal risk.” is more appropriate than “This research poses no risk.”
BENEFITS

List the benefits you anticipate will be achieved from this research, either for the participants, for others, and/or for the body of knowledge.

COMPENSATION (If applicable to your study, add compensation information here)

Indicate what compensation (including course credit) participants will receive for their participation in this study. Indicate other ways participants can earn the same amount of course credit. State whether participants will be eligible for compensation if they withdraw from the study prior to its completion. If compensation is pro-rated over the period of the participant's involvement, indicate the points/stages at which compensation changes during the study.

CONFIDENTIALITY

If appropriate, state that the information in the study records will be kept confidential. Data will be stored securely and will be made available only to persons conducting the study. State that no reference will be made in oral or written reports which could link participants to the study.¹

Specify who will have access to potentially identifiable data (e.g., transcriptionist, qualitative research group) and make it clear that they will pledge confidentiality.

EMERGENCY MEDICAL TREATMENT (appropriate only if there is some risk of harm or injury as a result of the study) The University's General Counsel recommends the following language here:

The University of Tennessee does not "automatically" reimburse participants for medical claims. If harm or injury is suffered in the course of research, please notify the investigator in charge. (List investigator's name and telephone number).

CONTACT INFORMATION

If you have questions at any time about the study or the procedures, (or you experience adverse effects as a result of participating in this study,) you may contact the researcher, [Name], at [Office Address], [Office Phone Number] or [e-mail address]. If you have questions about your rights as a participant, contact the IRB Administrator in the Office of Research at (865) 974-3466 or blawson@utk.edu.

{Note: Although we encourage the use of an office phone number and discourage the use of a home phone number, we recognize that many people nowadays use a cell phone as their primary contact number and thus we will approve substitution of a cell phone number if given a satisfactory rationale for its use.}

¹If you would like to identify participants in publications (as might be the plan, for example, in an oral history in which participants would want to be identified with their stories), you should add to this sentence the phrase: "unless participants specifically give permission in writing to do otherwise" and then add a section below the general consent to participate in the study requesting consent to use the persons' name (and perhaps offering to use a pseudonym of the person's choosing as an alternative).
PARTICIPATION

Your participation in this study is voluntary; you may decline to participate without penalty. If you decide to participate, you may withdraw from the study at anytime without penalty and without loss of benefits to which you are otherwise entitled.

Explain what will be done with the data already collected if the participant withdraws from the research.

Say something like EITHER

"If you withdraw from the study before data collection is completed, your data will be returned to you or destroyed"

OR

"If you withdraw from the study, data gathered to that point will be retained for analysis to the extent necessary for completing the research."

Explain to the IRB (in the Methods section of the Form B) the basis of the need to retain it.

(Note: Please delineate the "Consent" section of the Informed Consent Form by drawing a line across the page. This delineation is especially important when your consent form grammar shifts from second person to first person, as shown in this example.)

CONSENT

I have read the above information and had all my questions answered. I have received a copy of this form. I agree to participate in this study.

_____________________________________________        ________________________

Participant's signature                  Date

============= End of Sample Consent ===============

4.3.1 Additional Notes to Investigators:

- Researchers are urged by the Committee to use the wording in the checklist and follow the format in the sample, unless researcher-supported reasons are provided for alternative wording. Use of alternative wording or different format may slow down the review process. All sections of the consent form, except the "Consent Section" should be written in second person ("You are invited..."). Use of first person ("I") can be interpreted as suggestive and coercive.

- Be sure to follow the directions for preparing the signature lines. Separate forms should be prepared when minors are used; one for the minor’s assent and one for the parent’s permission. See Section 9.2.3 of this guide for further instructions about preparing these forms.

- If your form is more than one page, there should be a line at the bottom of each page for the subject's initials, except for the last page where the signature is obtained.

- Be sure to include all elements of informed consent that are appropriate to your study. If they apply to your study, they must be included. On the other hand, sections like the “Emergency Medical Treatment” section do not need to be included unless the nature of the research poses some risk of physical injury. For example, filling out a questionnaire is unlikely to involve such a risk.
Statements like “This project has been approved by the University of Tennessee Knoxville Institutional Review Board” are not appropriate in the consent form. This might suggest a stronger endorsement by the IRB than is warranted. All we actually do is to rule that your proposal meets minimal standards of acceptability.

4.4 Sample Short Form Consent Document

There are times when it is most appropriate to conduct the consent procedure orally rather than in a written document. To allow for this, regulations permit the IRB to authorize the use of a "short form" in place of the standard consent form. [45 CFR 46.117(b)(2)] The short form states that the details of the project have been explained orally and the person consents to participate.

================================ BEGIN Sample Short Form ==========================

Consent to Participate in Research

You are being asked to participate in a research study. Before you agree, the investigator must tell you about (i) the purposes, procedures, and duration of the research; (ii) any procedures which are experimental; (iii) any reasonably foreseeable risks, discomforts, and benefits of the research; (iv) any potentially beneficial alternative procedures or treatments; and (v) how confidentiality will be maintained.

Where applicable, the investigator must also tell you about (i) any available compensation or medical treatment if injury occurs; (ii) the possibility of unforeseeable risks; (iii) circumstances when the investigator may halt your participation; (iv) any added costs to you or your insurance; (v) what happens if you decide to stop participating; (vi) when you will be told about new findings which may affect your willingness to participate; and (vii) how many people will be in the study.

If you agree to participate, you must be given a signed copy of this document and a written summary of the research.

You may contact the researcher, [Name], at [Office Address], [Office Phone Number] or [e-mail address] any time you have questions about the research or what to do if you are injured.

You may contact the UT Knoxville IRB Administrator at (865) 974-3466 or blawson@utk.edu if you have questions about your rights as a research participant.

Your participation in this research is voluntary, and you will not be penalized or lose benefits if you refuse to participate or decide to stop.

Signing this document means that the research study, including the above information, has been described to you orally, and that you voluntarily agree to participate.

___________________________________________ ____________
Signature of participant  date

___________________________________________ ____________
Signature of witness  date

================================ END Sample Short Form ==========================
NOTE the line provided for a witness. This is required by federal regulations. The witness attests to both the fact that a detailed oral explanation of the research was provided and that the participant willingly consented.

4.4.1 Sample Information Sheet

The regulations require that a written summary of the oral presentation be provided. A copy must be included in the Form B so the IRB can evaluate its adequacy, and a copy must also be made available to the participant following the oral presentation. We recommend the following format for this summary.

================================ BEGIN Sample Information Sheet ===========================

Sample Information Sheet

Include or exclude information as applicable.
If you have any questions, please contact the IRB Administration at 974-3466.

[List title of study here]

INTRODUCTION
State that participants are invited to participate in a research study. State the purpose/objectives of the study.

INFORMATION ABOUT PARTICIPANTS’ INVOLVEMENT IN THE STUDY
List all procedures, preferably in chronological order, that will be employed in the study. Point out any procedures that are considered experimental. Clearly explain technical and medical terminology using nontechnical language. Explain all procedures using language that is appropriate for the expected reading level of your participants.

State the amount of time required of the participant per session and for the total duration of the study.

RISKS
List all reasonably foreseeable risks, if any, of each of the procedures to be used in the study, and any measures that will be used to minimize the risks.

BENEFITS
List the benefits you anticipate will be achieved from this research, either to the participants, others, or the body of knowledge.

COMPENSATION (If applicable to your study, add compensation information here)
Indicate what compensation (including course credit) participants will receive for their participation in this study. Indicate other ways participants can earn the same amount of course credit. State whether participants will be eligible for compensation if they withdraw from the study prior to its completion. If compensation is pro-rated over the period of the participant's involvement, indicate the points/stages at which compensation changes during the study.

CONFIDENTIALITY (This section can be omitted for anonymous surveys.)

State that the information in the study records will be kept confidential. Data will be stored securely and will be made available only to persons conducting the study unless participants specifically give permission in writing to do otherwise. No reference will be made in oral or written reports which could link participants to the study.

Specify who will have access to potentially identifiable data (e.g., transcriptionist, qualitative research group) and make it clear that they will pledge confidentiality.

CONTACT (Use the following contact information format in your information sheet)

If you have questions at any time about the study or the procedures, you may contact the researcher, [Name], at [Office Address], or [Office Phone Number] or [e-mail address]. If you have questions about your rights as a participant, contact the IRB Administration at (865) 974-3466 of blawson@utk.edu.

PARTICIPATION (Use the following voluntary participation information in your information sheet.)

Your participation in this study is voluntary, you may decline to participate without penalty. If you decide to participate, you may withdraw from the study at anytime without penalty and without loss of benefits to which you are otherwise entitled.

Explain what will be done with the data already collected if the participant withdraws from the research.

Say something like EITHER

"If you withdraw from the study before data collection is completed, your data will be returned to you or destroyed"

OR

"If you withdraw from the study, data gathered to that point will be retained for analysis to the extent necessary for completing the research."

Explain to the IRB (in the Methods section of the Form B) the basis of the need to retain it.

===================== END of Sample Information Sheet ========================
4.5 Pregnancy and Consent

For any research which includes procedures or elements that might pose a risk to the fetus, the consent form should include a sentence along the lines of the following: "You are not pregnant, nor are you likely to become pregnant during the course of this research."

4.6 Waiving or Altering Elements of Informed Consent

The IRB can authorize a consent procedure which does not include or which alters some or all the elements of consent or even waive the requirement to obtain consent, but only if the following four conditions are met: [45 CFR 46.116(d)]

1. The research involves no more than minimal risk to the subjects;
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
3. The research could not practicably be carried out without the waiver or alteration; and
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

The Form B should contain an explicit request for the waiver or alteration, an explanation of the rationale for it, and documentation that the four conditions above are met.

If de-briefing is planned following the research activities to provide additional pertinent information after participation, a script for the de-briefing should be included with the Form B. If de-briefing is not planned, a rationale should be included for its omission.

There can be several reasons for altering consent procedures. In some cases, the research design requires that participants not be given full information about the focus of the investigation or even that they be deceived as to its real purpose.

4.7 Waiving the Requirement of Written Documentation of Informed Consent

The IRB can waive the requirement for a signed consent form when either of the following conditions is met: [45 CFR 46.117(c)]

1. (a) the only record linking the participant and the research would be the consent document and (b) the principal risk would be potential harm resulting from a breach of confidentiality. In general, each participant will be asked whether she or he wants documentation linking them with the research, and the participant's wishes will govern; or
2. the research presents no more than minimal risk of harm to participants and involves no procedures for which written consent is normally required outside of the research context.

In cases in which the documentation requirement is waived, the IRB may require the investigator to provide participants with a written statement regarding the research (see the Information Sheet discussed above in Section 4.4.1).

Cases in which this sort of waiver is especially appropriate include

- surveys dealing with sensitive issues in which no individually identifiable information is gathered, so participation would be anonymous without a signed consent form. A statement should be included on the survey form that says something like "Completion of this survey constitutes consent for participation in this study."
- interviews that will be audiorecorded and then transcribed and the recording destroyed so that, although the recorded voice precludes anonymity, identification of the participant will no longer be possible after
the destruction of the recording. In these cases, the participant can voice consent at the beginning of the recording. The researcher's explanation of the research may also be recorded.

4.8 Health Insurance Portability and Accountability Act (HIPAA)

The Privacy Rule which was developed under this legislation puts significant limitations and regulations on the disclosure of Protected Health Information (PHI). The Rule applies only to health care entities which engage in electronic transactions (e.g., filing claims to insurance companies electronically). These are called “Covered Entities” in the regulation.

On the UT Knoxville campus, there is only one covered entity: the Student Health Service. However, two additional entities have agreed to voluntarily comply with the Privacy Rule regulations in order to train their students in the regulations and to extend this further protection to their clients. These two units are: the Psychological Clinic and the Speech and Hearing Center.

The HIPAA Privacy Rule stipulates that patients must give explicit consent for the release of any PHI. Here is the wording we suggest to convey the information that is required:

4.8.1 Subject Authorization to Use and Disclose Individually Identifiable Health Information in Research

CONFIDENTIALITY

1. Provide a statement explaining how individual identifiers will be used in maintaining the research records. (E.g., "Your research record will be labeled with your name." or "Your research record will be labeled with a code number. A master key that links your name and the code number will be maintained in a separate and secure location.")

2. If the study involves the use of a federal Certificate of Confidentiality, provide the information about the certificate and how it protects subject information from re-disclosure.

3. If information about the subject's participation in the study or the results of procedures performed in the study will be placed in the subject's clinic record (as contrasted with the research record), then this should be explained. Indicate that information placed in the medical record may be available to the participant's insurer.

4. State that individual subjects will not be identified in any presentations or publications based on the results of the research study.

5. Insert the HIPAA authorization portion of the confidentiality section. [template below]

BEGIN Template for Confidentiality Section

__________________________ BEGIN Template for Confidentiality Section _______________________

TEMPLATE FOR HIPAA PORTION OF THE CONFIDENTIALITY SECTION OF THE STUDY CONSENT FORM

The subject authorization language provided below should be inserted at the appropriate location in the confidentiality section of the study consent form. The language in the template should be precisely followed. The material in Roman type is the required authorization language. The italicized material in parentheses provides directions for including material that may or may not be relevant for particular studies. Material in bold italics indicates

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specifications to be added.

Under federal privacy regulations, you have the right to determine who has access to your personal health information (called "protected health information" or PHI). PHI collected in this study may include [specify what information will be shared with researchers], as well as basic demographic information. By signing this consent form, you are authorizing the research team at the University of Tennessee to have access to your PHI collected in this study (if the study will use PHI in the possession of another covered entity, add) and to receive your PHI from (either) your physician (and/or) facilities where you have received health care. (If the study is multi-institutional, add the following sentence.) In addition, your PHI may be shared with other persons involved in the conduct or oversight of this research, including researchers at [name of the institution(s)]. The Institutional Review Board (IRB) at the University of Tennessee Knoxville may review your PHI as part of its responsibility to protect the rights and welfare of research subjects. Your PHI will not be used or disclosed to any other person or entity, except as required by law, or for authorized oversight of this research study by other regulatory agencies, or for other research for which the use and disclosure of your PHI has been approved by the IRB. Your PHI will be used only for the research purposes described in this consent form. Your PHI will be used (either) until the study is completed (or until [insert ending date]) (or if the data is to be archived and made available for future studies within the scope specified in the consent form) indefinitely.¹

You may cancel this authorization in writing at any time by contacting the principal investigator listed on this consent form. If you cancel the authorization, continued use of your PHI is permitted if it was obtained before the cancellation and its use is necessary in completing the research. However, PHI collected after your cancellation may not be used in the study. If you refuse to provide this authorization, you will not be able to participate in the research study. If you cancel the authorization, then you will be withdrawn from the study. Finally, the federal regulations allow you to obtain access to your PHI collected or used in this study. (If the research study includes a component that would be kept secret from participants while it is being conducted, add the following sentences.) However, in order to complete the research, your access to this PHI may be temporarily suspended while the research is in progress. When the study is completed, your right of access to this information will be reinstated.

========== END Template for Confidentiality Section ===========

UT Knoxville faculty, staff, and students may encounter HIPAA regulations when they conduct research at off-campus covered entities. Researchers are advised to check with appropriate officials of those institutions to see if they require specific HIPAA language which differs from that suggested here.

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¹A rationale must be presented in the Form B for retaining data indefinitely. We recommend a separate signature bloc on the consent form to authorize retention, which includes a statement of the scope of the uses that will be made of the data.
The UT Knoxville IRB will need to review and approve any substitutions.

4.9 Foreign-Language Consent

Federal regulations require that information be provided "in language understandable to the subject" [45 CFR 46.116]. Researchers must supply both the English-language version and the translated version of the consent form or information sheet with the Form B. In addition, the IRB is required to arrange an independent translation of the foreign-language document back into English. It may take some time to find foreign-language-speakers to provide these back-translations, so researchers with foreign-language documents should allow extra time for IRB review.
Section 5. Research Exempt from Review: Form A Applications

5.1 Exempt Research Overview

The human subjects regulations from the U.S. Department of Health and Human Services (DHHS) exempt certain types of research from formal review by Institutional Review Boards (IRB). [45 CFR 46.101(b)]

However, the judgment as to whether a given research project falls under one of these exemption categories, or whether instead it requires formal review remains a responsibility of the UT Knoxville IRB. A fundamental principle of the federal regulations is that someone other than the researcher must make these judgments. The policy of the UT Knoxville IRB is to assign the first determination as to whether the research fits under exemption categories to the appropriate Departmental Review Committee (DRC), with the decision to be certified by the IRB Administration.

Thus, the term "exempt" is somewhat misleading because it only means that a research activity is exempt from formal (full or expedited) review by the UT Knoxville IRB.

This process of DRC review and certification by the IRB Administration must be completed prior to commencement of the research. It is the responsibility of investigators to provide the appropriate review documents to their DRC as soon as they know the extent to which humans will serve as participants in their research and then to see that the documents are forwarded to the IRB Administration after DRC review.

5.2 Minimal Risk Definition

The first criterion for exemption from formal review is that the research be estimated to involve no greater than "minimal risk." Minimal risk in a research activity is defined in the regulations as an anticipated risk of harm 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. [45 CFR 46.102(I)]

5.3 Exempt Research Categories

Research projects that place participants at no more than minimal risk may be "exempted" from full or expedited IRB review if they meet one of the following exemption categories:

The following exemptions do not apply to research involving minors\(^1\) (participants under 18 years old), prisoners, fetuses or neonates, or pregnant women.

Departmental Review Committees should use the following category descriptions to determine whether a proposed research project meets the exemption criteria. The DRC report should specify the category that is judged to apply on the approval line of the Form A. If you need clarification or would like representative examples, please contact the IRB Administration at 974-3466:

**Category 1: [45 CFR 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,
- research on the effectiveness of or the comparison among instructional techniques, curricula or classroom management methods.

**Category 2: [45 CFR 46.101(b)2]**

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interviews, or observation of public behavior.

**Category 3: [45 CFR 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: [45 CFR 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.

\(^1\)The exclusion of research involving minors from exemption is not dictated by federal regulations. It is a policy decision made by the UT Knoxville IRB that research involving minors should be given no less than the "expedited" level of review in which one of the reviewers has expertise in child development.
Limitations to Category 4 - The requirement for consent of the participants is waived if the data, documents, records, or specimens are publicly available. The authorization of the custodian of the data or documents, together with the process of removing identifiers, can serve in lieu of specific participant consent for access to the data, in cases in which the data, or records are not publicly available. However, the investigator and the UT Knoxville IRB must be satisfied that the custodian is authorized to release the data for research purposes. Note that some records are by nature confidential (e.g., school records) and others are the property of clients only held in trust by an institution (e.g., patient records). Special care must be taken to ensure that the researcher has the right to access these records - usually requiring the consent of the subject of the records or their legally authorized representative as well as the custodian.

Category 5: [45 CFR 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: [45 CFR 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.

5.4 Preparing an Exempt Research Protocol (Form A)
Use the Form A application to provide your DRC with the information it needs to determine if your project qualifies as an exempt research activity. You may obtain a copy of the current Form A from your DRC Chair, the IRB Administration at 1534 White Avenue, or by downloading it from the Web site: http://research.utk.edu/forms/index.shtml#c4

Objectives: Briefly state the purpose of the research, with special reference to and emphasis upon the exact procedures in which human subjects will be involved. If the research occurs in a larger context, such as a training program, clearly separate out the research component, describing the remainder as the context of the research.

Subjects: Briefly describe the participants, the criteria of selection or exclusion, the population from which they will be selected, methods of recruitment, the duration of involvement, and any special characteristics they have or must have relative to the research. Form A research is restricted to adults and must not involve persons the IRB classifies as vulnerable (e.g., pregnant women, neonates, persons of questionable decisional capacity). If you make use of a control group as well as an experimental group, be sure to specify the selection methods and source populations for both.

Methods or Procedures: Briefly enumerate, using nontechnical language, the research methods that will involve the use of human subjects. List any potential risks to the subjects along with the
protective measures you will apply to minimize those risks. Give enough information to enable
members of the DRC and the IRB Administration to make an informed judgment of the level of risk. If
the subjects will remain anonymous, describe how you will accomplish this. Describe how you will
secure the confidentiality of the data and the subject identities (if applicable), and note where materials
with names will be stored, along with the names of the persons who will have access to the names and
data.

In this section, also mention what appropriate method of obtaining informed consent you will use.
If consent is to be waived, provide a short justification either in the space available or on an attached
sheet. There are certain determinations which must be made in order to waive or alter any aspect of
informed consent or its documentation. You must provide enough information in the Form A for the
DRC, Department Head, and IRB to certify these determinations. See Sections 4.6 and 4.7 above for
lists of the determinations which are required.

**Category:** Referring to the list in Section 5.3 of this document or to the list of exempt categories of
research on the reverse side of Form A, cite the paragraph number that you deem entitles your research
project to exemption from review by the IRB. If uncertain which paragraph applies to the proposed
research, consult with Chair of the Departmental Review Committee or the IRB Administration.

### 5.5 Review Procedures for Form A Applications

Procedures used to review Form A applications vary between departments. However, all research
activities qualify for exemption, if they meet these four criteria:

- Participants will be subject to no more than minimal risk;
- The project satisfies the fundamental requirements for the protection of and respect for human
  participants, including minimizing risk, informed consent, and equitable selection of subjects
- The participants are not minors (under 18 years old), prisoners, fetuses or neonates, or pregnant; and
- The research activities proposed meet the definitions of one or more the federally approved exempt
categories (Section 5.3).

### 5.6 Final Approval Procedures

A DRC can take the following actions:

- Request modifications to the proposed research project or Form A application.
- Recommend final certification of exempt status for a Form A application.

*This recommendation signifies that the project has been reviewed against the provisions of this section
and certification is recommended by the DRC. However, final certification must be granted by the UT
Knoxville IRB Administration. The DRC should forward the original signed Form A to the UT Knoxville
IRB Administration only after it reviews and recommends approval of a Form A.*

*Form A applications will either be approved or returned to the DRC for clarification within five
working days of receipt by the UT Knoxville IRB Administration. Participant recruitment and data
collection may not begin until final certification of exempt status has been granted by the UT Knoxville
IRB Administration.*

- Reject the Form A application.

*This recommendation should be used when the DRC does not believe the proposed research is
contained within the scope of the outlined exempt categories. The researcher is then free to resubmit a
Form B for the project, requesting either expedited or full board review. The DRC should take this occasion to communicate to the researcher whether they judge it to be eligible for expedited review.

5.7 IRB Certification

Once the DRC and the Department Head have signed the Form A recommending exemption from full board review, the Form A must be forwarded to the University's Institutional Review Board (IRB) at the IRB Administration Office at 1534 White Avenue. Please note that your department's policy may be that you are responsible for delivering your own application to the IRB Administration, so check your department's procedures to avoid an unnecessary delay.

The paper copy of the Form A application submitted to the IRB Administration must contain original signatures. Once the full application has been received in either paper or electronic format, the IRB Administration staff reviews the application and determines whether it can be certified for exemption.

Once the IRB certifies that your project qualifies as exempt, you may initiate your research. If you make significant changes to your research protocol after the Form A has been approved, you should contact the DRC. They may approve minor changes that preserve exempt status. If they determine that the changes are such that they nullify exempt status, contact the IRB Administration staff. You may need to submit additional information about the substance of your project changes and you may even need to complete a Form B at this point. Also, if unforeseen risks to subjects arise as you conduct your research, contact the IRB Administration immediately.

If the IRB Administration staff determines that the application must receive either an expedited or full IRB committee review, you and your DRC will be notified of this change in review procedures and you will be asked to complete a Form B for your project. Full IRB committee reviews may take over a month to complete.

If revisions are requested in your original plan, you will be given a list of items that must be addressed prior to submission of the Form B to the IRB. You will need to submit your Form B application to your DRC for review. The IRB Administration staff can assist you during the revision process. Consultation is encouraged to speed the process.

5.8 Informed Consent Considerations for Exempt Research

Full compliance with regulations includes securing voluntary informed consent from all participants of research prior to the conduct of the research activity involving them. A discussion of informed consent appears in Section 4 of this guide. UT Knoxville investigators conducting exempt research are not exempt from informed consent process or requirements (another way in which the term "exempt" is misleading).

If the only document linking the identities of the participants to the research would be the informed consent document, then the requirement for written consent may be waived upon request and justification within Form A. Verbal consent is still required after providing the subject with a fair and reasonable explanation of the research, the participant's role in it, anticipated risks and protection measures, and a statement that the participant is free to withdraw at any time without penalty. (The information to be given to the potential participant verbally must be conveyed to the IRB in written form for review. The format we recommend is the Information Sheet discussed in Section 4.4.1 of this guide.)

The potential subject should understand that her or his participation is voluntary, and he/she should
have an opportunity to ask questions about the research. These requirements apply to all direct contacts with subjects and also to research methods such as telephone surveys that are less direct.

With mail questionnaires and drop-box surveys, where the respondent remains anonymous, the researcher should provide a similar explanation about the purpose of the research and the procedures for completing the questionnaire. This material may be contained in the cover letter accompanying the questionnaire or at the head of the questionnaire itself. The explanation should close with a statement to the effect that "return of the questionnaire will constitute your informed consent to participate."

Online questionnaires may be treated in the same way, even though they are not, strictly speaking, anonymous since it is possible in principle to trace the IP address of the computer from which they take the survey and this may sometimes amount to identifying the individual. Researchers should include an assurance in the information sheet that they will not make any attempt to trace the identity of the respondent.

If the participant does not remain anonymous – that is, if the investigator can initially identify each return with a participant – as is often the case where follow-up questionnaires may be planned – this fact should be revealed to the subject and written consent procedures used.

5.9 Investigator Responsibilities

By signing a Form A, you commit yourself to abiding by the regulations governing research involving human participants, including those provisions specifying the means of obtaining informed consent. In addition, you commit yourself to abiding by the applicable ethical standards of your discipline and those found in the Belmont Report.

Research design should meet applicable research ethics standards of the investigator's professional association or society. In all cases, the standards of respect for persons, beneficence, and justice enumerated by the Ethical Principles and Guidelines for the Protection of Human Subjects of Research (the Belmont Report\(^1\)) apply to all research involving human participants conducted at UT Knoxville.

If your project will make use of the facilities of another institution or a business, obtain letters (on their letterhead) of permission, cooperation, or support to use them and to interact with personnel there. If the institution requires its own research review, you must comply with their review procedures. In such cases, you should note the submission on your Form A and provide a copy of the other location's IRB approval (along with any project modifications the external institution may require) for your UT Knoxville IRB and DRC files.

If any participants suffer adverse reactions occurring during your research, you must notify your DRC and the UT Knoxville IRB. You should also take immediate steps to prevent further problems and indicate those steps taken in your statements to your DRC and the UT Knoxville IRB.

5.10 Graduate Students and Advisors

The Graduate School requires every student to verify that they have complied with the appropriate UT Knoxville approval procedures prior to initiation of their thesis- or dissertation-related research. Students should consult with their advisors as they develop research projects and begin to prepare Form A applications. Advisors indicate their review of the student's research project by signing the Form A. An advisor's signature also certifies that the student's research plan was approved by the appropriate

\(^1\)http://ohsr.od.nih.gov/guidelines/belmont.html
graduate committee.

5.11 Renewal and Termination Procedures for Exempt Projects

5.11.1 Renewal

Certification of exemption from review is not subject to routine continuing review. Unless your research moves in a new direction (e.g., major changes in the objectives or involvement of human participants which would make it no longer eligible for exemption), your department will have responsibility for reviewing and approving changes in your research. Investigators and their DRC are responsible for determining whether the changes will affect the current status of the project or will require a Form B to be submitted for IRB review. If there is any uncertainty about this, consult the IRB Administration at 974-3466.

5.11.2 Termination

Orderly termination of your project is important. When you complete your research, file a Form D\(^1\) and check the termination box. This will allow your DRC and the UT Knoxville IRB Administration to close your project files.

We would appreciate receiving a copy of any publications that result from the project for the IRB files.

If you have further questions about exempt research, contact the Chair of your Departmental Review Committee, call the UT Knoxville IRB Administration (974-3466), or visit the IRB Administration Office at 1534 White Avenue.

\(^1\)To find IRB forms online, go to: [http://research.utk.edu/forms/index.shtml#c4](http://research.utk.edu/forms/index.shtml#c4)
Section 6. Research Eligible for Expedited Review: Expedited Form B Applications

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6.1 General Information about Expedited Review

An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson and/or by one or more experienced reviewers designated by the chairperson from among members of the IRB in accordance with the requirements set forth in 45 CFR 46.110.

For OHRP Guidance about the use of this procedure, see:
http://www.hhs.gov/ohrp/humansubjects/guidance/exprev.htm

6.2 Expedited Review Categories

(List effective November 9, 1998)
http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm

For further explanation of the categories that apply especially to social and behavioral research activities, check out the nifty brochure developed by a unit of the National Science Foundation. Go to:

Research categories that may be reviewed using expedited review procedures by the UT Knoxville Institutional Review Board (IRB):

1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
   a. 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.)
   b. 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.
2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
   a. From healthy, nonpregnant 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
   b. From other adults and children\(^1\) 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.

3. Prospective collection of biological specimens for research purposes by noninvasive means.

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 cleared/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:
   a. 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;
   b. weighing or testing sensory acuity;
   c. magnetic resonance imaging;
   d. electrocardiography, electroencephalography, thermography, detection of naturally occurring
   radioactivity, electoretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and
   echocardiography; or
   e. moderate exercise, muscular strength testing, body composition assessment, and flexibility testing
   where appropriate given the age, weight, and health of the individual.

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.)

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

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.)

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\(^1\)Children are defined in the HHS regulations as "persons who have not attained the legal age for consent to
treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be
carried out." [45 CFR 46.402(a)].
8. Continuing review of research previously approved by the convened IRB as follows:
    a. 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; or
    b. Where no subjects have been enrolled and no additional risks have been identified; or
    c. Where the remaining research activities are limited to data analysis.

9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where the following conditions apply:
    a. Categories two (2) through eight (8) do not apply; and
    b. 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.

6.3 Applicability of Expedited Review Categories

    A. Research activities may be eligible for expedited review if they present no more than minimal risk to human subjects, and involve only procedures listed in one or more of the nine listed categories. The nine categories of activities listed should not be considered to be of minimal risk simply because they are listed. Inclusion on this list means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human participants.

    B. The categories in this list apply regardless of the age of subjects, except as noted (i.e., 2(b)).

    C. The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, incurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

    D. The expedited review procedure may not be used for classified research involving human subjects.

    E. The standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review – expedited or convened-meeting – utilized by the IRB. The expedited-process reviewer would have to document that each of the conditions necessary for waiver are satisfied.

    F. Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

6.4 Expedited Review Procedures

    Once you have completed your Form B application, your application will move through the following steps on its way toward approval. Please keep in mind that the review process takes time, and

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1To find IRB forms online, go to: http://research.utk.edu/forms/index.shtml#c4
you may not initiate your research until your Form B application is approved.

6.4.1 Form B

Your Form B application should include the following items:

- A copy of the Form B with original signatures from all relevant parties
- Copies of all instruments (e.g., questionnaires, tests, etc.) that will be used in the project. If you plan to conduct qualitative research, include a list of expected questions or topic areas that may be addressed
- Copies of all informed consent forms and/or procedures
- Copies of all applicable letters of permission, cooperation, or support, and approvals from other IRB's and/or cooperating institutions.
- Copies of applicable technical sections of grant applications or contracts
- Copies of all recruiting materials (i.e., letters, e-mails, posters, advertisements)

6.4.2 Departmental Review:

Departments or units that regularly conduct research involving human subjects utilize a Departmental Review Committee (DRC) to review all Form A and B applications. Form B applications must be approved for expedited review by the DRC before the department head will indicate her/his approval by signing the Form B. For students, the faculty advisor's signature is also required.

When the DRC approves an expeditable Form B, it must identify the expedited-process category (1 - 9) under which it believes the research falls. The expedited-process category classification must be listed on the signature page of the Form B application.

If the DRC or department head does not approve the application for expedited review, the researcher should receive an explanation. The review comments from the DRC and Department Head can be used to revise the application. In many/some cases the chair or members of the DRC may be willing to assist in revising the Form B application. If researchers need additional assistance, they should contact the IRB Administration staff at 974-3466.

6.4.3 Institutional Review Board Review:

Once the DRC approves an expeditable Form B application and the appropriate signatures are on the original application, the application will be forwarded to the University's Institutional Review Board (IRB) at the IRB Administration Office at 1534 White Avenue. Please note that your department's policy may be that you are responsible for delivering your own application to the IRB Administration, so check your department's procedures to avoid an unnecessary delay.

The paper copy of the Form B application submitted to the Compliance Section must contain original signatures. In addition, you must submit an electronic copy of all parts of the application in either Microsoft Word or Adobe Acrobat format (or a mixture of the two). The electronic copy may be e-mailed and thus it may arrive before the paper copy. Once the full application has been received in either format, the IRB Administration staff reviews the application and determines whether it can be given an expedited review. Expedited reviews take about a week to complete. If the IRB Administration staff determines that the Form B application must receive a full IRB committee review, you and your DRC will be notified of this change in review procedures. Full IRB committee reviews may take a month or longer to complete.
Once the UT Knoxville IRB review is completed, the IRB Administration staff will notify you about the results of the review. If revisions are requested, you will be given a list of items that must be addressed prior to resubmission to the IRB. (Unless you are requested to do so, you will not have to resubmit your Form B application to your DRC, nor will new signatures need to be obtained.) The IRB Administration staff can assist you during the revision process. Consultation is encouraged to speed the process.

Once the IRB gives final approval to your Form B application, you may initiate your research. If you make significant changes to your research protocol after the Form B has been approved, contact the IRB Administration staff. You may need to submit additional information about the substance of your project changes on a Form D¹. Also, if unforeseen risks to subjects arise as you conduct your research, contact the IRB Administration immediately.

6.5 Informed Consent Considerations for Expedited Review

Informed consent is a core element in the protection of research participants' rights and welfare. Investigators must also recognize that informed consent is an ongoing process that assures participants have been provided information about the research needed to knowledgeably and voluntarily decide whether to participate. Investigators should seek consent only under circumstances that provide the prospective participants sufficient opportunity to consider whether to participate, and minimize the possibility of coercion or undue influence. Consent and information forms must be written in language that is clear and understandable to potential participants. The consent process may not include statements through which participants waive or appear to waive any legal rights, or release or appear to release the investigator, sponsor, institution, or agents from liability for negligence.

As you prepare your consent form or procedure, please refer to Section 4 of this guide. If your research involves children, please review consent and assent procedures described in Section 9.2.3 of this guide.

6.6 Investigators' Responsibilities

By signing a Form B, you commit yourself to abiding by the regulations governing research involving human participants, including those provisions specifying the means of obtaining informed consent. In addition, you commit yourself to abiding by the applicable ethical standards of your discipline and those found in the Belmont Report².

Research design should meet applicable research ethics standards of the investigator's professional association or society. In all cases, the standards of respect for persons, beneficence, and justice enumerated by the Ethical Principles and Guidelines for the Protection of Human Subjects of Research (the Belmont Report²) apply to all research involving human participants conducted at UT Knoxville.

If your project will make use of the facilities of another institution or a business, obtain letters (on their letterhead) of permission, cooperation, or support to use them and to interact with personnel there (refer to section 3.8 of this guide for more information). If the institution requires its own research review, you must comply with their review procedures. In such cases, you should note the submission on your Form B and provide a copy of the other location's IRB approval (along with any project

¹To find IRB forms online, go to: [http://research.utk.edu/forms/index.shtml#c4](http://research.utk.edu/forms/index.shtml#c4)

modifications the external institution may require) for your UT Knoxville IRB and DRC files.

If any participants suffer adverse reactions during your research, you must notify your DRC and the UT Knoxville IRB. You should also take immediate steps to prevent further problems and indicate those steps taken in your statements to your DRC and the UT Knoxville IRB. In some cases, the IRB Administration is required to report adverse events to granting agencies or other federal agencies. In the case of serious adverse events, the IRB may be asked to review your plan to avoid a recurrence.

Research investigators are responsible for providing a copy of the UT Knoxville IRB approved and signed informed consent document to each participant at the time of enrolling them in the study, unless the UT Knoxville IRB has specifically waived this requirement. All signed consent documents are to be retained in a manner approved by the UT Knoxville IRB.

Research investigators will submit proposed changes in previously approved human participant research activities to their DRC and the UT Knoxville IRB using Form D. The proposed changes will not be initiated without DRC and UT Knoxville IRB review and approval, except where necessary to eliminate apparent immediate dangers to the participants.

Research investigators are responsible for reporting progress of approved research to the UT Knoxville IRB, as often as and in the manner prescribed by the UT Knoxville IRB on the basis of risks to participants, but not less than once per year. (See "Renewal" just below.)

Upon termination of the study, researchers will report this fact to the DRC and the IRB so the study files can be closed. (See "Termination" just below.)

6.7 Renewal and Termination Procedures for Expedited Projects

6.7.1 Renewal

Expedited approval is for a limited period of time, as specified in the approval letter. According to federal regulations, a project cannot be approved for a period longer than one calendar year and the IRB might judge that the level and/or type of risk dictates review in a shorter period of time. For example, if the IRB judged that there was significant risk that participants in a certain project might experience emotional distress, we might ask for review in three months to determine whether any participants have had such a reaction by that time and whether the measures included to address this were adequate. If not, the next approval might be for six months, or even for a full year.

Approximately one month before the expiration date of the approval, the principal investigator of every active research project will receive a Form R from the IRB Administration. Principal investigators will use Form R to indicate if their projects remain active and UT Knoxville IRB approval needs to be renewed for another period of time. Unless your research moves in a new direction (e.g., major changes in the objectives or involvement of human participants), or participants have experienced adverse reactions, then renewal is not a major hurdle. Renewal can almost always be expedited, so it need not be delayed until the next convened meeting. Investigators and their DRC are the first level of review to determine whether the changes will affect the current status of the project. If there is any doubt, contact the IRB Administration (974-3466).

Projects that have not been reviewed and approved by the end of the approval period are automatically terminated. All research activity must cease until a new Form B has been reviewed and

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1To find IRB forms online, go to: [http://research.utk.edu/forms/index.shtml#c4](http://research.utk.edu/forms/index.shtml#c4)
6.7.2 Termination

Orderly termination of your project is important. When you complete your research, file a Form D and check the termination box. This will allow your DRC and the UT Knoxville IRB Compliances Section to close your project files.

If you have further questions, contact the Chair of your Departmental Review Committee, call the UT Knoxville IRB Administration (974-3466), or visit in the IRB Administration Office in 1534 White Avenue.

We would appreciate receiving a copy of any publications that result from the project for the IRB files.
Section 7. Research Requiring Full IRB Review: Form B Applications

Section 7 Contents

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7.1 Categories of Full IRB Reviewed Research

Research projects are referred to the full board for review if it is considered that the collective judgment of the group would be helpful in evaluating the proposal and developing suggestions for improvement.

The following types of research projects are among those that typically require full UT Knoxville IRB review:

- Many projects requiring the significant use of deception
- Involvement of prisoners, pregnant women, fetuses or neonates, the seriously ill, or persons with possible decisional incapacity, or other vulnerable individuals
- Collection of information or recording of behavior which, if known outside the research, could reasonably place the participant at risk of civil, or criminal liability or damage their social standing, financial standing, or employability
- Collection of information regarding sensitive aspects of the participant's behavior such as: drug and alcohol use, illegal conduct, or sexual behavior
- Studies in which the anticipated risks exceed minimal risk
- Studies which involve types of risks that have not been examined before
- Clinical trials
- Projects that raise policy issues

7.2 Full IRB Review Process

Once you have completed your Form B application, your application will move through the following steps on its way toward approval. Your Form B application should include the following items:

- Copy of the Form B with original signatures from all relevant parties
- Copies of all instruments (e.g., questionnaires, tests, etc.) that will be used in the project If you plan to conduct qualitative research, include a list of expected questions or topic areas that may be addressed
- Copies of all informed consent forms or procedures
• Copies of all applicable letters of permission, cooperation, or support, and approvals from other IRB's
• Copies of applicable technical sections of grant applications or contracts
• Copies of all recruiting materials: letters, e-mails, flyers, posters, advertisements, etc.

7.2.1 Departmental Review:

A completed Form B application must be approved by the DRC before the department head will indicate her/his approval by signing the Form B. For students, the faculty advisor's signature is also required.

If the DRC or department head does not approve the application in its current form, the researcher should receive an explanation and guidance as to how to revise the application. For additional assistance, the IRB Administration staff can be contacted at 974-3466.

Neither the DRC nor the department head has authority to disapprove an application categorically. If either or both continues to have concerns after the Form B has been revised, it should be forwarded to the IRB Administration with their reservations noted in writing. A categorical disapproval of a project requires review and action by the full IRB.

7.2.2 Institutional Review Board Review:

Once your DRC approves your Form B application and the appropriate signatures are on the original application, your application will be forwarded to the UT Knoxville Institutional Review Board (IRB) at the IRB Administration Office in 1534 White Avenue. Please note that your department's policy may be that you are responsible for delivering your own application to the IRB Administration, so check your department's procedures to avoid an unnecessary delay.

Please keep in mind that the review process takes time, and that you may not initiate your research until your Form B application is approved.

The copy of the Form B application that you submit to the IRB Administration must contain original signatures from all the appropriate parties. In addition, you must submit an electronic copy of all parts of the application in either Microsoft Word or Adobe Acrobat format (or a mixture of the two). The electronic copy may be e-mailed and thus it may arrive before the paper copy. Form B applications must be received by the IRB Administration at 1534 White Avenue two weeks prior to the regular meeting of the UT Knoxville IRB. (The IRB typically meets on the third Thursday of each month; thus the submission deadline is typically the first Thursday of the month.) The meeting and deadline information for the current academic year is available on the following web page:

http://research.utk.edu/humansubjects/irb_dates.shtml

Once the full application has been received in either format, the IRB Administration staff will review the application and determine whether it can be given an Expedited Review, or whether it requires a Full-IRB Committee Review. Expedited Reviews take about a week to complete. Full-IRB Committee Reviews may take a month or longer to complete.

Once the IRB review is completed, the researcher will be notified by the IRB Administration about the results. If revisions are requested, you will be given a list of items that must be addressed prior to resubmission to the IRB. (Unless specifically requested to do so, the Form B application will not have to be resubmitted to the DRC, nor will new signatures need to be obtained.) The IRB Administration staff can assist during the revision process and consultation is encouraged.

Once the IRB gives final approval to your Form B application, you may initiate your research. If you make significant changes to your research protocol after the Form B has been approved, contact the
IRB Administration staff. You may need to submit additional information about the substance of your proposed changes on a Form D. Also, if unforeseen harms to participants arise as you conduct your research, please contact the IRB Administration immediately.

### 7.3 Informed Consent Considerations for Full Board Protocols

Informed consent is a core element in the protection of research participants' rights and welfare. Investigators must also recognize that informed consent is an ongoing process that assures participants have been provided all the information about the research they need in order to knowledgeably and voluntarily decide whether to participate. Investigators should seek consent only under circumstances that provide the prospective participants sufficient opportunity to consider whether to participate, and minimize the possibility of coercion or undue influence. Consent and information forms must be written in language that is understandable and clear to potential participants. The consent process may not include exculpatory statements through which participants waive or appear to waive any legal rights, or release or appear to release the investigator, sponsor, institution, or agents from liability for negligence. As you prepare your consent form or procedure, please refer to Section 4 of this guide.

If your research involves children or individuals who are unable to give informed consent, please review consent and assent procedures discussed in Section 9.2.3 of this guide.

### 7.6 Investigators' Responsibilities

By signing a Form B, the researcher commits herself or himself to abiding by the regulations governing research involving human participants, including those provisions specifying the means of obtaining informed consent. In addition, they commit themselves to abiding by the applicable ethical standards of their discipline and those found in the Belmont Report\(^1\).

Research design should meet applicable research ethics standards of the investigator's professional association or society. In all cases, the standards of respect for persons, beneficence, and justice enumerated by the Ethical Principles and Guidelines for the Protection of Human Subjects of Research (the Belmont Report)\(^1\) apply to all research involving human participants conducted at UT Knoxville.

If the project will make use of the facilities of another institution or a business, letters must be supplied (on their letterhead) of permission, cooperation, or support to use them and to interact with personnel there (refer to Section 3.8 of this guide for more information). If the institution requires its own research review, the researcher must comply with their review procedures. In such cases, the submission should be noted on the Form B and a copy of the other location's IRB approval (along with any project modifications the external institution may require) provided for the UT Knoxville IRB and DRC files.

If any participants suffer adverse events during the research, the researchers must notify their DRC and the UT Knoxville IRB. They should also take immediate steps to prevent further problems and indicate those steps taken in statements to their DRC and the UT Knoxville IRB.

Research investigators acknowledge and accept their responsibility for protecting the rights and welfare of human research participants and for complying with all applicable UT Knoxville IRB policies.

Research investigators are responsible for providing a copy of the UT Knoxville IRB approved and

\(^1\)http://ohsr.od.nih.gov/guidelines/belmont.html
signed informed consent document to each participant at the time of consent, unless the UT Knoxville IRB has specifically waived this requirement. All signed consent documents are to be retained in a manner approved by the UT Knoxville IRB.

Research investigators will promptly report proposed changes in previously approved human participant research activities to their DRC and UT Knoxville IRB on Form D. The proposed changes will not be initiated without DRC and UT Knoxville IRB review and approval, except where necessary to eliminate apparent immediate dangers to the participants.

Research investigators are responsible for reporting progress of approved research to the UT Knoxville IRB, as often as and in the manner prescribed by the UT Knoxville IRB on the basis of risks to participants, but not less than once per year.

7.7 Renewal and Termination Procedures

7.7.1 Renewal

IRB approval is for a limited period of time, as specified in the approval letter. According to federal regulations, a project cannot be approved for a period longer than one calendar year and the IRB might judge that the level and/or type of risk dictates review in a shorter period of time.

Approximately one month before the expiration date of the approval, the principal investigator of every active Form B research project will receive a Form R from the IRB Administration. Principal investigators will use Form R to indicate if their projects remain active and thus UT Knoxville IRB approval needs to be renewed for another period of time. Unless your research moves in a new direction (e.g., major changes in the objectives or involvement of human participants), or participants have experienced adverse reactions, then renewal is not a major hurdle. If there is any doubt, contact the IRB Administration (974-3466).

Projects that have not been reviewed and approved by the end of the approval period are automatically terminated. All research activity must cease until a new Form B has been reviewed and approved.

7.7.2 Termination

Orderly termination of your project is important. When you complete your research, file a Form D and check the termination box. This will allow your DRC and the UT Knoxville IRB Compliances Section to close your project files.

We would appreciate receiving a copy of any publications that result from your project for IRB files.

If you have further questions, contact the Chair of your Departmental Review Committee, call the UT Knoxville IRB Administration (974-3466), or visit in the IRB Administration Office at 1534 White Avenue.

1To find IRB forms online, go to: [http://research.utk.edu/forms/index.shtml#c4](http://research.utk.edu/forms/index.shtml#c4)
Section 8. Instructions for Completing Form B

Researchers: Please discuss your proposed research project with your Departmental Review Committee and/or with the IRB Administration, (865) 974-3466, before you begin preparing a Form B application.

If your project only exposes your subjects to minimal risks and you do not intend to use subjects from vulnerable populations, then it may be possible to use a Form A application. (See section 5 of this guide.)

Remember that all research using human subjects must be approved before the subjects are contacted and research begins. After approval has been granted, you are assured that the research is in compliance with sanctioned university research policies and procedures.

Form B Header: The header on the first page of every Form B should be prepared as follows:

[Note: Please Number the Pages of the Form B Application]

```
FORM B
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IRB # _______ (Leave blank. This number is generated by the IRB Administration)

Date Received in Office of Research _______

THE UNIVERSITY OF TENNESSEE
Application for Review of Research Involving Human Subjects

Body of Form B -- The body of the Form B should include the following information:

(Please note that headings and subheadings printed in blue type must be included in your Form B application even if your response under that heading or subheading is N/A.)

I. IDENTIFICATION OF PROJECT

• Principal Investigator (PI) or Co-Principal Investigators (Co-PI):
  The person or persons responsible for the design and implementation of the research project are considered the PI or CoPIs and should be listed in this section. At UT Knoxville (unlike some institutions), students may be listed as PI and/or CoPI. or each PI or Co-PI, include the name of the college and the name of the department, the mailing address (home or campus), telephone number, and e-mail address. All communications and correspondence will be directed to the first person listed as principal or co-principal investigator, unless otherwise requested and noted on this form.

• Faculty Advisors: For student projects, students should be listed as investigators and their faculty
• Department: State the name of the department located in the college.

• Project Classification: Provide an appropriate description (e.g., Research Project, Dissertation, Thesis, Clinical Trial, etc.)

• Project Title: Provide the title of your project. If a title has not been determined, please provide a tentative title for the project. If external support is sought or has been obtained, use the title of the project listed on the application for external support in creating a title for this project.

• Starting Date: Specify an intended starting date or state "Upon IRB Approval".

• Estimated Completion Date:

• External Funding: (If this project is not externally funded, enter "N/A" and go on to Section II.): If external funding is sought or was obtained for this project, please provide the following information:
  • Grant/Contract Submission Deadline:
  • Funding Agency:
  • Sponsor ID Number (if known):
  • UT Proposal Number (if known):

II. PROJECT OBJECTIVES:

Provide a brief rationale of the project in non-technical language so that reviewers from other disciplines can understand and identify the objectives and goals of the research project. The statement of objectives must be clear and accurate, revealing to reviewers the anticipated significance of the proposed research. If you are seeking external support for this project, the objectives listed in this section must coincide with the objectives and goals in any application for support. In addition, the objectives listed in this section should coincide fully with the objectives described to participants in the consent form. (If investigators have reason to withhold information about the objectives from participants, they must justify this action in Section VII.)

III. DESCRIPTION AND SOURCE OF RESEARCH PARTICIPANTS

1. Describe your participants.
2. How will you gain access to those participants?
3. Include the criteria for selection and exclusion.
4. Include the number of participants you anticipate enlisting.

Explain the rationale for using any special groups, such as children, pregnant women, prisoners, students, cognitively impaired, institutionalized individuals, or any participants whose ability to give voluntary and informed consent may be questioned. (See Sections 3.10, 3.11, and 9 of this Guide for special concerns regarding vulnerable participants.) Give a rationale for projects that restrict participants based on gender, language spoken or any other category that might be regarded as constituting inequitable selection of participants.

Identify the source of your participants (e.g., school systems, hospitals, colleges and universities, private companies, religious groups, governmental entities, community groups, internet groups, etc.) and describe the methods for contacting and recruiting participants. Letters of permission, cooperation, or
support are required from entities other than UT to conduct research at their site and/or to contact their personnel. Letters of permission should authorize the investigators to contact potential participants and/or to use of the facilities and/or records of that entity as appropriate. These letters must accompany the Form B application at the time of submission for review.

Considerations of confidentiality can make recruiting complicated. We consider it a violation of confidentiality, for example, for a medical office or hospital to allow a researcher direct access to patient names and contact information. It is much preferred to have the institution make the first contact with patients and give them information to contact the researcher if they are interested in learning more about the research and/or willing to participate in the research.

Disclose any relationship between researchers and participants - such as, teacher/student; employer/employee; or superintendent/principal/teacher.

If an incentive such as a cash payment is to be provided, identify the incentive for participation, payment procedures, and provide a rationale for using the incentive. Keep in mind that the value of incentives to participants is relative, and reviewers may consider highly valued incentives as undue influence. Make it clear in both the Form B and the consent form how the incentive is affected if the participant withdraws from the study without completing all parts of it.

Investigators who plan to recruit UT students and offer course credit or extra credit for student participation must follow the procedures maintained in the department whose classes are used. Alternative means of earning equivalent credit must be offered. The DRC is responsible for evaluating these measures in their review of the protocol. Departmental procedures must be filed with the IRB and approved before they are instituted.

IV. METHODS AND PROCEDURES

Clearly and concisely describe in non-technical language the data collection and experimental research methods used in this project that will directly involve human participants. This section should be consistent in every detail with the description provided to participants in the consent form or procedure. (Any omission or deviation in the methods and procedures information provided in the consent process must be justified in Section VII.) Include non-technical descriptions of stresses to participants, experimental manipulations, tests or measures, surveys, interviews, observations, photography, and video- and audio recordings. Clearly distinguish between control and comparison, and experimental and treatment participant groups.

If the project involves audiorecording, videorecording or photography of participants, explain the need for these methods and describe how these data will be used. Describe how the photos or recordings will be stored, and when and how they will be destroyed. Identify the individuals who will have access to the recordings or photos, and on what basis they will have access. If the recordings or photos are to be used in the future, explain the procedures for obtaining participants' informed consent for those uses, and the conditions under which the recordings or photos would be used. See Section 3.5 for further discussion of audio- and videorecording.

Describe how you will analyze and interpret the data. For qualitative research, if you plan to use a research group to help analyze the data, describe the composition of the group.

V. SPECIFIC RISKS AND PROTECTION MEASURES

Specify all potential risks to participants of the proposed research. Remember that "risk" refers, not merely to the possibility of physical harm, but also encompasses psychological, social, economic, and
legal harms. Estimate the nature and amount of potential risk, stress, or discomfort, and assess the
likelihood and its seriousness. Describe the precautions you will take to reduce risk and assess the
effectiveness of these protective measures. Identify specific controls, screening methods, and follow-up
to assure no residual physical, psychological, or social damage to the participants. If appropriate,
include a description of the means you will use to assist or treat participants who may incur injury from
one or more of the risks identified in this section. Provide sufficient detail to permit reviewers, who may
not be familiar with your area of study, to evaluate any specific risks to the participants of this research.

Describe how you will protect the privacy of participants. If they are filling out questionnaires in a
group setting, what measures are being taken to prevent others from seeing their answers? If they are
being interviewed, what measures are being taken to prevent others from overhearing their answers?
How is physical privacy being protected if bodily exercises or measuring or the like is involved. To
prevent coercion through peer pressure (real or perceived) on young persons recruited in a group setting,
measures ought to be taken to prevent peers knowing even whether they have agreed to participate in the
research. If the study involves students filling out questionnaires in the classroom, students who
decided to participate in the research ought to be given an alternative activity (e.g., a game worksheet)
that could not be distinguished by their peers from the research activity. If students are being removed
from the classroom for the research activity, an explanation for their leaving should be given that does
not stigmatize them as participating in the research.

Include the methods and provisions by which you will address the issue of anonymity or
confidentiality of data. Note that anonymity is only possible if not even the investigator can discover the
participant's identity from data collected or during the collection process. In either case, describe how
you will maintain the confidentiality of the participants' data. Identify security measures, such as
limiting access to data, purging identifying information from data, securing files, and other appropriate
measures. If files are to be transmitted or stored electronically, describe the security measures such as
encryption, strong-password-protection, etc. Identify all those to whom access is given and all who
might know the password to password-protected computers.

If the confidentiality of the participants' identities or data cannot or will not be protected, please
state how you will inform participants of this fact before their participation. It should be noted that
confidentiality is not a categorical requirement. There may be research projects in which there is no
expectation of privacy or confidentiality. For example, in some oral history projects, respondents want
to be identified as the source of the stories they contribute. (See Section 1.6 of this Guide for a
discussion of privacy and confidentiality.) It is essential that participants know what the status is of
information they provide.

If risks are minimal, state this and give enough information to allow the IRB to make our own
assessment. Federal regulations define "minimal risk" as follows: "Minimal risk means that the
probability and magnitude of harm or discomfort anticipated in the research are not greater in and of
themselves than those ordinarily encountered in daily life or during the performance of routine physical
or psychological examinations or tests." [45CFR46.102(I)]

VI. BENEFITS

Evaluate the reasonableness of the risks stated in Section V in relation to the anticipated benefits
(i.e., desired outcomes), if any, to the participants and/or to society.

Note that in most research projects, the only relevant benefits are those that contribute to
generalizable knowledge in a field of research. In these cases, participant benefits are incidental. Do not
inflate the significance of incidental benefits to participants in your Form B application or your
informed consent procedures.

Note that payment for participation in research is an incentive for participation, and should not be considered a "benefit" of the research.

VII. METHODS FOR OBTAINING "INFORMED CONSENT" FROM PARTICIPANTS

State the methods you will use to obtain legally effective informed consent, assent, and/or permission (as applicable) from participants or participants’ legally authorized representatives. Clearly describe how you will seek consent from participants in a manner that allows them sufficient opportunity to consider whether to participate, and that minimizes the possibility of coercion or undue influence. Indicate that the language used in your informed consent procedure is understandable to your participants or their legally authorized representatives. Describe the setting in which you will obtain consent, the period of time your process allows for potential participants to think about their decision and to ask questions, and the identity and qualifications of the person who will answer their questions and negotiate the consent. As you describe your informed consent procedures, keep in mind that the following procedures are typically used to obtain legally effective informed consent:

1. Use of a written consent document with all the basic elements of informed consent. This form is signed by the participant or a legally authorized representative and an extra copy provided for participant's use and information. A sample consent form is found in Section 4.3 of this guide.

2. Use of a "short form" written consent document indicating that the basic elements of informed consent have been presented orally to each participant or their legally authorized representatives. Written summaries of what is to be said to the participant should be attached to the Form B for approval by the IRB. The "short form" is to be signed by the participant or a legally authorized representative, and by a witness to the oral presentation and participant's signature. An extra copy of the form that was signed and a written copy of the information that was presented orally should be provided for the participant's use and information. A sample Short Form is found in Section 4.4 of this Guide.

3. Information sheet - written consent document containing the basic elements of informed consent. The information sheet is not signed. It can be used either in connection with the Short Form above (for example, for non-English-speaking participants in a situation where a translator is available but there is not time to prepare a written consent form in the prospective participant's language), in a situation in which consent is to be recorded by a verbal statement at the beginning of an audio- or video-recording or in connection with an anonymous survey. A sample study information sheet form is available in Section 4.4.1 of this Guide.

The IRB may approve other procedures, if you explain your need for an alternative consent process. Provision of informed consent by alternative means must be approved by the IRB and recorded in the minutes signed by the IRB Chair. Federal regulations dictate that the following four conditions be satisfied (as documented in the IRB minutes) for an alteration of the consent process to be approved [45 CFR 46.116(d)]:

1. The research involves no more than minimal risk to the participants;
2. The waiver or alteration will not adversely affect the rights and welfare of the participants;
3. The research could not practically be carried out without the waiver or alteration; and
4. Whenever appropriate, the participants will be provided with additional pertinent information after participation.

Complete Section VII by stating the method and place of storage for signed consent documents. During your research project storing signed informed consent forms at locations other than UT may be
appropriate; however, the IRB must approve these sites and security measures. For legal purposes, signed consent documents must be kept on the UT campus for three years following completion of the research and be accessible to authorized personnel (including UT Knoxville IRB members and staff and federal OHRP or FDA staff conducting audits).

As you prepare your consent form or procedure, please include the following basic elements of informed consent: (See also Section 4.2)

1. Provide a statement indicating that the study involves human research.
2. Describe the purposes of the research and state the expected duration of the participant's involvement in the research project. Describe the procedures to be followed that will directly involve human participants, and specifically identify any procedures that are experimental.
3. Identify and describe any reasonably foreseeable risks to the participant or potential discomforts the participant may experience during this research. If you judge the research to be minimal risk, please explain the basis of your assurance that no more than minimal participant risks or discomforts are anticipated. Give enough information that members of the IRB can make an informed judgment of the level of risk.

For research involving children, there is an additional level of risk specified in certain regulations: "a minor increase over minimal risk." Here again, enough information about the specifics of the risks should be included to allow members of the IRB to make an informed judgment.

4. Describe any benefits to the participant (or to others) that may reasonably be expected from this research.
5. Provide a statement disclosing appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant.
6. Provide a statement describing the procedure for maintaining the participant's files/records. Will the records identifying the participant remain confidential? Who will have access to them? Where will they be stored? Describe this in general terms – e.g. "In a locked cabinet inside a locked office on the UT Knoxville campus" – DO NOT specify the room number or building name in the consent form.
7. For research involving more than minimal risk to the participant, state whether any financial compensation or any medical treatments are available should an injury occur. If so, describe the nature and extent of the available compensation and medical treatments. Indicate where further information on this subject may be obtained.
8. Identify the individual who may be contacted for responses to pertinent questions about the research an the rights of the research participant.
9. Indicate that questions about one's rights as a research participant should be directed to Ms. Brenda Lawson, IRB Administrator at 1534 White Avenue (865) 974-3466, or blawson@utk.edu.
10. Include a statement specifically noting the following: (a) participation in the research is voluntary, (b) refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and (c) the participant may withdraw from the research project at any time without penalty of loss of benefits to which he or she is otherwise entitled.¹

¹The phrase "or loss of benefits to which he or she is otherwise entitled" should be used only in settings in which there are such benefits (e.g., a service agency).
Additional elements of informed consent may be required in some cases. (See Section 4.2.1 of this Guide.) Please check with your Departmental Review Committee or the IRB Administration for further information.

VIII. QUALIFICATIONS OF THE INVESTIGATOR(S)

Investigators must specify their relevant qualifications and those of other investigators involved in this project to perform the proposed research. Include qualifications of personnel working on portions of the research where special training, certification, or licensing is required for the performance of their tasks. Be specific! Instead of saying "the students conducting the interviews will receive extensive training"; say "they will receive x hours of training, conducted by y, and the interviewers will be recruited from students who have completed course z (or, perhaps, 'have completed n hours of graduate courses in field a')". Special experience and expertise is required on the part of researchers when involving participants classified as vulnerable, such as children, pregnant women, prisoners, cognitively impaired or institutionalized individuals. Address these special issues.

Those working on the project should be identified by name (and title, if appropriate) and qualifications. If, for example, the particular students who will be working on a project have not been identified at the time the Form B is submitted, this information should be supplied on a Form D as soon as they are selected. Personnel must not become involved in the research until the Form D has been reviewed and approved by the IRB Administrator. This information is important for the audit function of the IRB (see Section 11 of this Guide). We may need to contact selected study personnel in the process of an audit.

IX. FACILITIES AND EQUIPMENT TO BE USED IN THE RESEARCH

Please provide a brief description of the facilities that will be used during the research, with an evaluation of their adequacy for the intended project. Include a brief description of the equipment to be used for storage and analysis of data. Note that computers - including web servers - are pieces of equipment. You need to provide information about the equipment - and especially about its level of security - for any computer or web site on which data will be gathered and/or stored.

If a project is to be conducted in a non-UT facility, an original letter of permission, cooperation, or support to use the non-UT facility must accompany the Form B. These letters must be on the letterhead of the organization and signed by authorized officials. If public school or school system facilities are to be used, letters of permission from authorized officials in the superintendent of schools office, and possibly from school principals must accompany the Form B.

X. RESPONSIBILITY OF THE PRINCIPAL/CO-PRINCIPAL INVESTIGATOR(S)

You must enter the following information verbatim in Section X:

By compliance with the policies established by the Institutional Review Board of The University of Tennessee, the principal investigator(s) subscribe to the principles stated in "The Belmont Report" and standards of professional ethics in all research, development, and related activities involving human participants under the auspices of The University of Tennessee. The principal investigator(s) further agree that:

1. Approval will be obtained from the Institutional Review Board prior to instituting any change in this research project.

2. Development of any unexpected risks will be immediately reported to the IRB
Administration.

3. A continuing review and progress report (Form R) will be completed and submitted when requested by the Institutional Review Board.

4. Signed informed consent documents and all other research data will be kept for the duration of the project and for at least three years thereafter at a location approved by the Institutional Review Board.

XI. SIGNATURES

When you submit your Form B applications for review note that all signatures must be original. As your Form B application moves through the review process, you should maintain two identical Form B applications both of which contain original signatures. As PI or Co-PI, you should keep one copy of the Form B with original signatures and submit the other Form B with original signatures for review.

Use the following format to prepare your signature section (as needed, add signature lines for all Co-Principal Investigators, collaborating and student investigators, faculty advisors, and additional department heads and DRC chairs).

Principal Investigator _____________________________________________
Signature ______________________________ Date ____________________
Co-Principal Investigator __________________________________________
Signature _______________________________ Date ___________________
Student Advisor (if any) ___________________________________________
Signature _______________________________ Date ___________________

DEPARTMENT REVIEW AND APPROVAL

The IRB departmental review committee has reviewed and approved the application described above. The DRC recommends that this application be reviewed as:

[ ] Expedited Review -- Category(s): _____________________________
OR
[ ] Full IRB Review

Chair, DRC ______________________________________________________
Signature ______________________________ Date ____________________
Department Head _________________________________________________
Signature ______________________________ Date ____________________
Protocol sent to IRB Administration for final approval on (Date) _________
Approved:
IRB Administration Office of Research 1534 White Avenue
Signature ______________________________ Date ____________________
Section 9. Research Involving Special or Vulnerable Populations

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9.1 General Issues About Vulnerability

Because most research involves uncertainty and risk, all research participants are vulnerable in some sense. However, it has been suggested that vulnerability, in the context of research, should be understood to be a condition, either intrinsic or situational, of some individuals that puts them at greater risk of being used in ethically inappropriate ways in research.

The National Bioethics Advisory Commission developed an analytical framework, identifying six traits that might especially interfere with participants' ability to protect themselves in research:

1. **Cognitive or communicative vulnerability.** Participants may be insufficiently able to comprehend information, deliberate, and make or express decisions. This could be due to cognitive incapacity or due to circumstances, such as being presented with a consent form during a crisis or in a foreign language. This form of vulnerability may diminish a participant's ability to receive, understand, appreciate, and reason with information and to communicate a clear decision.

2. **Institutional vulnerability.** Individuals (e.g., prisoners or students) may be subjected to the formal authority of others. This increases the risk that participation will not be truly voluntary and that participants may be exploited or recruited solely for convenience.

3. **Deferential vulnerability.** Participants may be informally subordinate to another person. This could be due to traditional roles within a culture or society. For example, in some cultures, women may defer to their husband's wishes regarding participation, or some patients may routinely defer to the expressed or merely perceived wishes of their physician. Again, this increases the risk that participation will not be truly voluntary and that participants may be exploited.

4. **Medical vulnerability.** Individuals may have a serious health condition for which there is no satisfactory standard treatment. This may lead to a perception that research offers the only hope and may contribute to difficulties weighing risks and benefits. Individuals may also suffer from the so-called "therapeutic misconception" in which research is mistaken for individually tailored therapy. This decreases comprehension and appreciation of risk and benefits.

5. **Economic vulnerability.** Individuals may lack access to adequate income, housing, or health care. When research appears to offer benefits that are badly needed and only available to the individual through research participation, decisions may be unduly influenced and voluntariness compromised.

6. **Social vulnerability.** Some members of society may embrace stereotypes of participant groups or disvalue their interests, welfare, and contribution to society. This increases the risk of unfair treatment and stigmatization. For example, if a researcher stereotypes members of some groups as less intelligent, they may be given inadequate information during the consent process. Alternatively, if researchers insufficiently value members of a group, they may be willing to subject them to a risk/benefit ratio that would not be acceptable to the general population.\(^1\)

The UT Knoxville IRB considers each of these dimensions of vulnerability in evaluating protocols. The IRB may make recommendations for specific modifications in the project to address these vulnerabilities.

Federal regulations single out several vulnerable groups for special protections. The UT Knoxville IRB acknowledges the special protections contained in federal regulations:

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9.2 CHILDREN

The information in this section is provided to clarify the Form B preparation and review process for researchers who plan to include children as participants in their research projects. This information is intended to facilitate the compliance approval process. If you have additional questions about your research project, please contact the IRB Administration Office at 974-3466 for further information.

9.2.1 General Information

Federal regulations [45 CFR 46, Subpart D] require that the researchers explicitly address the measures taken to protect the welfare and rights of children participating in research. At UT Knoxville, the adequacy of the protection measures is assessed by the IRB during the approval process. Because of the potential vulnerability of children, a higher standard of protection must be demonstrated for approval. As a result, research involving children is not eligible to be considered exempt. All research involving children requires expedited or full-IRB review of Form B applications; and the expedited-review process always includes a reviewer especially designated to review research involving children due to expertise for dealing with children.

Note that researchers may not initiate contact with potential child-participants, or begin data collection, before having received final approval from the IRB. Although Form B applications take longer to prepare and review than Form A applications, most Form B applications are reviewed and approved within three weeks of submission through the expedited-review process. However, the approval process sometimes takes longer than this, especially if significant revisions are required.

Therefore, please allow adequate time to prepare and submit an application. The complexity of the project and the initial quality of the application affect the time required for approval.

The following section addresses several significant areas of concern that commonly arise during IRB reviews of research involving children. When preparing a Form B application, follow the Form B Application Guidelines described in Section 8.

9.2.2 Identifying and Recruiting Potential Child-Participants

Clearly describe the methods used to identify and recruit potential child-participants. Describe the measures taken to prevent potential concerns about coercion or breaches of confidentiality in the identification and contact stages of your research project. Copies of notices or advertisements that will be used should be included in your application.

Only after permission from the appropriate authorities has been granted in writing may potential child-participants' identities be obtained from school classrooms, care-giving programs, or other agencies. For example, researchers wishing to study students in public school systems must obtain written permission from the school board or its authorized representative and also from the principal(s) of the school(s) to be used before students can be contacted. This approval cannot be used to require teachers or students to participate.

School board or institutional permission is often conditioned upon IRB approval of your project. If your project must receive our approval prior to the granting of any institutional permission, please contact the IRB Administration. This is a common complication that can be easily remedied without delaying the approval process.
9.2.3 Informed Consent Procedures for Children

There are special difficulties with the notion of consent where minors are concerned. One has to reach the age of majority to give legally valid consent; thus minors cannot give "consent" on their own behalf. Furthermore, "consent" is a first-person concept; it does not make sense in legal terms for one person to give "consent" on behalf of another. Thus the language of "consent" is dispensed with in research involving children. Instead, we speak of the "permission" of parents or guardians for the child to participate and the "assent" of the child to take part.

Federal law recommends the assent of the child and requires the permission of the parent(s), or guardian(s), before a child may be involved in a research project. Research involving "mature" or emancipated minors may not need parental permission, but full IRB committee approval must be obtained to waive the parental permission requirement. Federal regulations leave it up to state law to specify under what conditions a minor may give legally valid consent [45 CFR 46.402(a)]. If state law permits a minor to give consent for something (e.g., in Tennessee, a minor may sign themselves in to a drug rehabilitation program), then they may also give consent to participate in research within that program. When the UT Knoxville IRB is in doubt about the appropriateness of consent by minors to a study, we consult the representative of the Office of the General Counsel who serves as a consultant to the IRB. If researchers are aware that their project falls under this exception, it would be helpful to the IRB - and would speed the review process - to supply in the Form B citations to the statutes, regulations, and/or court opinion on which this is based.

9.2.3.1 Permission of Parent or Guardian

Note: A guardian is an individual who is authorized under applicable state or local law to give permission for a child to receive general medical care. The parents are presumed guardians, unless court action has removed this authority from them. [45 CFR, 46.402(3)].

Permission is the explicit agreement of parent(s) or guardian to the participation of their child or ward in research. Failure to object or other forms of passive acquiescence cannot be construed as permission [45 CFR, 46.402(c)].

Both parents must give their permission in any research that places the child-participant at greater than minimal risk [45 CFR, 46.406 and 46.607], unless one parent is deceased, unknown, incompetent, not reasonably available, or when only one parent has legal responsibility for the care and custody of the child [45 CFR 46.408 (b)].

The permission of one parent is sufficient for any research that places that child-participant at no more than minimal risk [45 CFR 46.404]. Furthermore, the UT Knoxville IRB may consider that the permission of one parent is sufficient for research involving greater than minimal risk, if there is a clear prospect of direct benefit to the child-participant [45 CFR 46.408 (b)].

The requirement of parental permission may be waived in those cases where it is clear that the parents' interests do not adequately reflect the child's interests (e.g., research on child abuse or neglect). These cases require investigators to develop special procedures, which must be approved by the full-IRB, that protect the rights and welfare of the children asked to participate.

When permission is required, the information contained in the permission procedure should include all the elements normally required in an informed consent. (Review Section 4 of this guide for more information about informed consent considerations and a listing of the basic elements of informed consent - in Section 4.2.)
9.2.3.2 Assent of the child

Assent is a child's affirmative agreement to participate in research. Assent is an ethical concept. Failure to object cannot be construed as assent [45 CFR, 46.402(b)].

Researchers who include children in their research should be especially mindful of the rights of children participating in their research. Even when assent is not required, researchers are asked to demonstrate a good faith effort to enlist the willing cooperation of children who participate in their research.

It is the responsibility of the IRB to decide whether researchers should seek a child's assent as part of a project's consent procedure. The determination of a child's capacity to provide assent is based on the nature of the research, and the child's age (typically the UT Knoxville IRB requires assent from children age seven and older), maturity, and psychological state of the population of children from whom participants will be drawn. The decision to require assent for a particular protocol depends on the capacity of the children to appreciate the nature, extent, and probable consequences of their participation in a given research project. This decision might be made for all children to be involved in research under a particular protocol, or the IRB might require an assessment of each child individually by someone with the expertise to evaluate the child's capacity [45 CFR 46.408(a)].

Assent is especially important in cases where there is no direct benefit to the child-participants.

The assent procedure should include an explanation of the proposed research in language that is appropriate to the child's age and maturity. The investigator should indicate on their Form B what the children will be told about the research and how the information will be conveyed. The investigator should discuss how the information provided might vary with the age, maturity, and level of experience of the children involved in the study. The assent process should be free from coercion and undue inducements. All children who are capable of providing assent must be informed that they are free to withdraw from participation at any time.

9.2.4 Risk and Benefit Assessment

9.2.4.1 Risk Assessment:

Federal regulations require IRBs to classify research involving children into one of four categories and to document their discussions of the risks and benefits of the proposed research study. The four categories of research involving children that may be approved by the UT Knoxville IRB, based on degree of risk and benefit to individual participants are as follows:

1. **Minimal Risk:** A risk is minimal where the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests [45 CFR 46.404].
   
   *Examples of research in this category might include: research on children's attitudes about food preferences, surveys about play activities, etc.*

2. **Research involving greater than minimal risk, but presenting the prospect of direct benefit to an individual participant.** Research in this category is approvable provided: (a) the risk is justified by the anticipated benefit to the participant; and (b) the relationship of risk to benefit is at least favorable as any available alternative approach [45 CFR 46.405].
   
   *Examples of research in this category might include: research on the coping strategies of children living in foster care, or research on the effectiveness of drug-use intervention programs for children testing positive for drug use.*
3. **Research involving greater than minimal risk with no prospect of direct benefit to individual participants, but likely to yield generalizable knowledge about the participant's disorder or condition.**

   Research in this category is approvable provided: (a) the risk represents a minor increase over minimal risk; (b) the intervention or procedure presents experiences to participants that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational settings; and (c) the intervention or procedure is likely to yield generalizable knowledge about the participant's disorder or condition that is of vital importance for the understanding or amelioration of the participant's disorder or condition [45 CFR 46.406].

   *Examples of research in this category might include: research involving abused children that is designed to identify early warning signs of potential abuse in the general population of school-aged children; or research on the effectiveness of corporal punishment.*

4. **Research that is not otherwise approvable, but which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.** Research that is not approvable under 45 CFR 46.404, 46.405, or 46.406 may be conducted or funded by DHHS provided that the IRB, and the Secretary of Health and Human Services, after consultation with a panel of experts, finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a significant problem affecting the health or welfare of children. The panel of experts must also find that the research will be conducted in accordance with sound ethical principles [45 CFR 46.407].

   *No examples of research in this category are provided because projects in this category are unique and require federal approval.*

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Assessing probable risks is a central consideration of the IRB's approval process. The specific condition of each child must be taken into account in assessing the probability and magnitude of harm. The issue of what is considered as "ordinarily encountered in daily life or during the performance of routine physical or psychological examinations" may vary depending on the circumstances or conditions of the population from which the children are drawn. What hospitalized cancer patients encounter in their daily life is quite different from what a healthy child encounters in attending public school. The UT Knoxville IRB also considers the extent to which research procedures would be a burden to a child. Behavioral interventions likely to cause psychological stress may be considered to exceed minimal risk.

**9.2.4.2 Benefit Assessment:**

In this section of the Form B, carefully identify and describe all reasonably anticipated benefits that may be received by child-participants. As noted in the risk assessment subsection just above, anticipated benefits to child-participants must exceed anticipated risks when research procedures expose child-participants to greater than minimal risk. The Form B should contain enough specific information about risks and possible benefits to provide the IRB a basis for making this determination.

**9.2.4.3 Use of Educational Records**

Federal law [34 CFR 99, especially 99.03 through 99.37] governs the privacy and access to elementary and secondary school records. The primary rights of access to these records are given to parents, guardians – and to students once they have reached 18 years of age. For other than routine administrative purposes, schools must withhold access to personally identifiable information from
educational records except with the written permission of the students' parents, or students themselves once they have reached 18 years of age. To be valid, a written consent for disclosure of educational records must include three items:

- a specification of the records to be disclosed,
- the purpose(s) of the disclosure, and
- the party or class of parties to whom the disclosure will be made.

The requirement for written permission applies to all research, except that conducted by or for educational agencies or institutions developing, validating, or administering predictive tests, administering student aid, or improving instruction (provided reports of these studies will not permit the identification of individual students and that personally identifying data will be destroyed upon completion of the study). For more information on the privacy of student records, go to the following web site: [http://www2.ed.gov/policy/gen/guid/fpco/ferpa/index.html](http://www2.ed.gov/policy/gen/guid/fpco/ferpa/index.html)

### 9.2.5 Protection of Pupil Rights Amendment

Protections contained in the PPRA [20 U.S.C. § 1232h; 34 CFR Part 98] include:

- The right of parents to inspect, upon request, a survey created by a third party before the survey is administered or distributed by a school to students.
- The right of parents to inspect, upon request, any instrument used in the collection of information about:
  - political affiliations or beliefs of the student or the student's parent;
  - mental and psychological problems of the student or the student's family;
  - sex behavior or attitudes;
  - illegal, anti-social, self-incriminating, or demeaning behavior;
  - critical appraisals of other individuals with whom respondents have close family relationships;
  - legally recognized privileged or analogous relationships, such as those of lawyers, physicians, and ministers;
  - religious practices, affiliations, or beliefs of the student or student's parent; or
  - income (other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under such program).
- Arrangements to protect student privacy in the event of the administration of a survey to students, including the right of parents to inspect, upon request, the survey, if the survey contains one or more of the eight items specified just above.
- The right of parents to inspect, upon request, any instructional material used as part of the educational curriculum for students.
- The administration of physical examinations or screenings that the school may administer to students.
- The collection, disclosure, or use of personal information collected from students for the purpose of marketing or selling, or otherwise providing the information to others for that purpose.

For more information about this regulation, go to the following web site: [http://www2.ed.gov/policy/gen/guid/fpco/ppra/index.html](http://www2.ed.gov/policy/gen/guid/fpco/ppra/index.html)

### 9.2.6 Projects Eligible for Expedited Review

Research projects that involve children may be eligible for expedited review if they present no more than minimal risk to children, and involve only procedures listed in one or more of the nine listed categories (See Section 6.2 of this Guide). The categories in this list apply regardless of the age of
Please note that the activities listed should not be considered to be of minimal risk simply because they are listed. Inclusion on this list means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects. An independent assessment of the level of risk is required as part of the review.

9.2.7 Quick Checklist for Protocols Involving Children as Participants

If you have questions as you prepare your Form B, please contact the IRB Administration at 1534 White Avenue or call 974-3466.

1. Are you preparing a Form B application?
2. What is the level of risk?
   a. If your project involves greater than minimal risk to children who participate in your project, then your Form B application will require a full IRB committee review. Allow sufficient time for the preparation and review of your Form B.
   b. If your project involves minimal risk to children who participate in your project and only involves procedures listed in one of the nine expedited review categories listed in Section 6.2 of this guide, then your Form B application may receive an expedited review.
3. Have you adequately described your methodology and procedures using nontechnical language?
4. Have you clearly identified your methods for identifying and recruiting children?
5. Do you intend to recruit children through schools, or conduct your research at schools? If so, your Form B should include written permission to approach children and teachers from the school board and principals in the schools you are targeting. For preadolescent children, at least, parental permission should be obtained before approaching the children.
6. Have you described your parental permission procedures and included a copy of the parental/guardian's permission form in your Form B? If a waiver of parental permission is requested, provide justification, including explanation that each of the four findings listed in Section 4.6 are met. Waiver of parental permission cannot be granted through expedited review, so allow time for full board review.
7. Have you described your child assent procedures? Assent should be sought from children seven years-old and older. If a waiver of children's assent is requested, provide justification showing that the four findings listed in Section 4.6 are met.
8. Have you included an assessment of the probable risks and benefits anticipated in your research?
9. Are you planning to use information from school records? If so, have you included a written consent for disclosure of educational records that specifies the records to be disclosed, the purpose(s) of the disclosure, and the party or class of parties to whom the disclosure will be made?
10. Are you planning to take photographs, audiorecordings, or videorecordings? Check the guidelines in Section 3.5.

9.3 DECISIONALLY IMPAIRED INDIVIDUALS

9.3.1 General Information about Decisionally Impaired Individuals

Research projects that plan to enroll decisionally impaired participants must be submitted as Form B applications. The participation of decisionally impaired individuals in research that would otherwise fall in exempt categories cannot be reviewed using exempt (Form A) procedures. Researchers should
clearly describe their informed consent and assent procedures in their Form B applications.

Individuals are considered "decisionally impaired," if they have a diminished capacity for rationally and autonomously providing informed consent due to a psychiatric, organic, developmental or other disorder that affects cognitive or emotional functions. The diminution of capacity may be a temporary impairment such as from physical trauma or emotional stress; or it may be chronic impairment such as from neurologic, psychiatric or substance abuse problems. The IRB recognizes that some individuals with these disabilities are capable to give informed consent. However, the IRB is not in a position to determine whether an individual identified with a decisional impairment has the capacity to give informed consent. If researchers believe that specific participants, although diagnosed with these or similar conditions, are able to give informed consent, they should fully and explicitly describe in the Form B their reasons for this judgment as well as the measures that will be taken to evaluate the mental capability in each individual case. For any participants who are able to give informed consent, the general IRB review requirements apply.

9.3.2 Additional Considerations

Researchers should clearly describe their participant identification and recruitment procedures. These procedures must take into account the role of guardians or other third-party decisionmakers and the restrictions on access that may be imposed by institutions in which prospective participants may reside or from which they may receive services. The situation of a person whose mental capacity is compromised is in some ways like the situation of a minor; however, no formal regulations to govern the decisionally impaired have been issued by federal agencies.

9.3.3 Minimal Risk Projects

Research that poses no more than minimal risk to participants can be approved without special limits as long as adequate provisions are made for obtaining the assent of the decisionally impaired individual and permission from competent adults who are legally acting on their behalf.

9.3.4 Greater Than Minimal Risk Projects with Expected Direct Participant Benefits

Projects that expose participants to more than minimal risk, but which promise to benefit individual participants will be approved under the following conditions:

a. The risk is justified by the expected benefit to the participant;

b. The relationship between the risk and the benefit is at least as favorable to the participant as any available from alternative approaches; and

c. Adequate provisions are made for obtaining assent of decisionally impaired participants and permission from competent adults who are acting on their behalf.

9.3.5 Greater Than Minimal Risk Projects without Expected Direct Participant Benefits

Research that poses more than minimal risk to decisionally impaired participants and is not expected to offer direct benefits to the participant will only be approved under the following conditions:

1. The risk is only a minor increase over minimal risk;

2. The research will expose the participant to risks that are reasonably commensurate with those in actual or expected medical, dental, psychological, educational, or social situations;
3. The research is likely to yield generalizable knowledge about the participants’ disorder or condition which is important to the understanding or amelioration of that disorder or condition; and
4. Adequate permission and assent procedures are in place.
   If participants are wards of the state, these measures still apply.

9.3.6 Informed Consent Procedures for Decisionally Impaired Individuals

9.3.6.1 Assent of Participants
Researchers should develop reasonable procedures for obtaining assent from decisionally impaired participants. The information that should be provided by the researcher to the participant in the assent process is the same as the information provided when the participants are not decisionally impaired. The methods used to convey the information should reflect sensitivity for the individual’s disorder or condition, and should be written in language that is appropriate for the individual’s level of understanding. The assent requirement may be waived if participants’ abilities to give assent are so limited that they cannot be reasonably consulted.

9.3.6.2 Permission from the Participant's Guardian
Permission must be obtained from the decisionally impaired participant's guardian. If the participants are under the age of 18, their parents are presumed to be their guardians. However, the parents of decisionally impaired participants 18 years of age or older are not necessarily their legal guardians. In all cases, researchers should determine if legal guardians have been appointed for their decisionally impaired participants. If guardians have not been appointed, then the researcher should propose a means for obtaining permission from a competent adult acting solely in the interests of the decisionally impaired individual. The adequacy of these procedures must be consistent with Tennessee and federal law.

The information provided the participant's guardian in the permission process must contain the basic elements of informed consent discussed in Section 4.2 of this Guide. The permission should be documented in written form.

9.4 PREGNANT WOMEN

9.4.1 Special Considerations
A general exclusion of pregnant women from participating in research would be discriminatory and unjustified. However, risks to the fetus as well as to the mother must be assessed and pregnant women should be excluded if the risk to the fetus is greater than minimal. Pregnant women must be fully informed about the research activity and its possible impact on the fetus.

Researchers should obtain informed consent from both the pregnant woman and the father of the fetus. Consent by the father is not necessary if:
1. The purpose of the study is to meet the health needs of the mother;
2. The identity or whereabouts of the father cannot be reasonably ascertained;
3. The father is not reasonably available; or
4. The pregnancy is the result of rape.

9.4.2 Added Protections for Pregnant Women

At least one of the primary reviewers for protocols involving pregnant women will be a health professional with experience and expertise in dealing with pregnancy.

The added protections of 45 CFR 46, Subpart B will be incorporated into the IRB review.

9.4.3 Informed Consent Procedures for Possibly Pregnant Women

For any research which includes procedures or elements that might pose a risk to the fetus, the consent form should include a sentence along the lines of the following: "You are not pregnant, nor are you likely to become pregnant during the course of this research."

9.5 PRISONERS

9.5.1 General Information

Researchers should be aware that prisoners may be under constraints because of their incarceration, and these constraints may affect their ability to make truly voluntary decisions about participation in research projects. As a result, researchers should describe recruitment and identification procedures that are fair to all prisoners and are immune from arbitrary intervention by prison authorities or fellow prisoners. Any incentives used to recruit prisoners may not, when compared to standard prison conditions, be so great that they impair a prisoner's ability to weigh the risks of participation. In general, the IRB will incorporate into its review the added protections set out in 45 CFR 46, Subpart C.

9.5.2 Definition of “Prisoner”

"Prisoner" is defined by HHS regulations at 45 CFR part 46.303(c) as "any individual involuntarily confined or detained in a penal institution. The term is intended to encompass individuals sentenced to such an institution under a criminal or civil statute, individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution, and individuals detained pending arraignment, trial, or sentencing."

The official interpretation from OHRP is that individuals fit under this definition even if they are incarcerated AFTER being enrolled in the study. The assumption is that there might be constraints with regard to their freedom to withdraw from the study if they are confined. This can complicate procedures if, for example, someone enrolled in a study that has nothing to do with any issue of criminal justice is arrested and detained. If the special composition requirements regarding prisoners were not satisfied at the time the study was approved, the researcher will EITHER have to submit a Form D requesting that the study be re-reviewed and these requirements applied OR ELSE the person will have to be dropped from the study.
9.5.3 Definition of Minimal Risk:

The definition of minimal risk in the section of the regulations that applies to prisoners is slightly different from the one in the Common Rule: Here minimal risk is defined as "the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examination of healthy persons" [45 CFR 46.303(d)].

9.5.4 Informed Consent Procedures for Prisoners

The information provided prisoners in the informed consent process must contain the basic elements of informed consent discussed in Section 4.2 of this Guide. Prisoners should also be informed that participation or non-participation will not be reported to parole boards (nor, to the extent possible, to prison authorities).

9.5.5 IRB Review Procedures

The full IRB committee must review all research projects involving prisoners as participants, and thus Form B protocol applications must be used by researchers. Research projects may present no more than minimal risk to prisoner participants.

9.5.6 Permitted Categories of Research

Federal regulations only permit the UT Knoxville IRB to approve research involving prisoners in the following two categories: [45 CFR 46.306(a)(2)]

1. study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

   (Note that the definition of minimal risk for prisoner research at 45 CFR 46.303(d) differs from the definition of minimal risk for other research, contained in 45 CFR 46.102(I))

2. study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to the subjects;

   There are other categories of research that can be approved by action of the Secretary of Health and Human Services [45 CFR 46.306(a) (2)(iii) and 45 CFR 46.306(a) (2)(iv)].

9.5.7 Special IRB Composition Requirements

At least one member of the IRB who is either a prisoner, or prisoners' representative, with appropriate background and experience, must be at the meeting when the Form B application is reviewed. If no current member of the IRB meets the prisoner or prisoners' representative criteria, then the Chair will identify and recruit a qualified individual to fulfill this requirement and advise the IRB. In addition, a majority of the IRB members at the meeting must not be associated with the prison [45 CFR 46.304].

- For research involving prisoners as subjects, the IRB must meet these special composition requirements of for all types of review of the protocol, including initial review, continuing review, review of protocol amendments, and review of reports of unanticipated problems involving risks to subjects.

- If more than one IRB reviews a protocol, only one of them has to meet these special composition requirements.
9.5.8 Seven Required Findings

The IRB must certify the following seven findings for research involving prisoners: [45 CFR 46.305(a)]

1. the research under review represents one of the categories of research permissible under 45 CFR 46.306(a)(2);
2. any possible advantages accruing to the prisoner through his or her participation in the research, when compared to the general living conditions, medical care, quality of food, amenities and opportunity for earnings in the prison, are not of such a magnitude that his or her ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison is impaired;
3. the risks involved in the research are commensurate with risks that would be accepted by nonprisoner volunteers;
4. procedures for the selection of subjects within the prison are fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners. Unless the principal investigator provides to the IRB justification in writing for following some other procedures, control subjects must be selected randomly from the group of available prisoners who meet the characteristics needed for that particular research project;
5. the information is presented in language which is understandable to the subject population;
6. adequate assurance exists that parole boards will not take into account a prisoner's participation in the research in making decisions regarding parole, and each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole; and
7. where the IRB finds there may be a need for follow-up examination or care of participants after the end of their participation, adequate provision has been made for such examination or care, taking into account the varying lengths of individual prisoners' sentences, and for informing participants of this fact.

In preparing your Form B for research involving prisoners, be sure to provide sufficient information on these issues to permit the IRB to make these determinations.

If you have any questions about the recruitment or use of participants from special or vulnerable populations, please contact your DRC Chair, or the IRB Administration Office at 974-3466.
Section 10. Participatory Action Research

10.1 General Considerations

Participatory Action Research (PAR) (also known as "Community-Based Research" or simply "Action Research") is research that does not fit the usual model. Instead of a research plan generated by the researcher who then must enlist participants, PAR begins with research interests or research questions generated within a group. The group may then decide to contact university researchers to help them design the best way to answer the question. Alternatively, the project might arise from a preexisting service collaboration between university faculty and a community, which generates research questions. In cases like this, such elements as informed consent take on a radically different meaning. If the group has been involved in developing the research project, it seems redundant to try to describe the project they already know as well as their faculty partners do in a formal informed consent form. Furthermore, the procedural requirements for submitting a research protocol—although familiar to university researchers—may be daunting to those outside the university community; and the hurdles they pose may discourage the groups from seeking collaboration with university faculty—which would mean a regrettable loss of scientific rigor in the attempt to answer the research questions.

In an attempt to facilitate research of this type—while at the same time preserving the protections embodied in the federal regulations and the Belmont Report—we developed these less formal guidelines for approval of PAR.¹

10.2 Project Classifications

A. For a project for which there are no prospects of publication of the results of the research to anyone other than the group involved in conducting it, EITHER because the project is a class exercise OR because it is being conducted for a group whose interest in the findings is wholly internal, THEN there is no need to seek IRB approval for the project at all.

1. However, a listing of such projects (a) should be maintained by the UT Knoxville unit and (b) should be made available for review by the IRB or its representatives upon request.

2. If confidentiality is not to be maintained (either with regard to the identities of subjects or with regard to information that has been gathered about them), this should be made explicit. If it is to be maintained, participants should be provided with (a) a list of those who will know subject identities and (b) a

¹Special thanks to John Gaventa, both for prodding us to develop these guidelines and for working with us to structure them.

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description of protection measures that will be employed to prevent confidential information from becoming generally known.

3. All those involved in conducting the project should be informed at the outset that a more formal approval by the IRB AND a more formal consent by the participants will be required if a decision is made later to publish project results.

B. For a project classifiable as "contract research" -- i.e., for which the role of the UT Knoxville unit is limited to carrying out a project on behalf of a local group, which was designed and will be interpreted by the group itself, a short-form application will be submitted to the IRB which outlines the limited role of the UT Knoxville unit and describes the nature of the cooperating group.

1. The project information sheet/informed consent form which is given to prospective subjects (a) should NOT contain any statement indicating that the project has been approved by The University of Tennessee, Knoxville IRB and (b) should indicate with some precision the limited role of the UT Knoxville unit in designing, conducting, and/or interpreting this project.

2. Confidentiality provisions similar to those specified in A.2 should be distributed to all those asked to serve as subjects of the research.

3. Future-consent provisions (cf. A.3) should be communicated to all involved.

C. For a project for which the UT Knoxville unit serves a co-equal role with the community group in designing, conducting, and interpreting the research project, EITHER (a) both groups should be listed on information sheets and/or consent forms -- as well as on a Form A or Form B (as appropriate) submitted to the UT Knoxville IRB OR (b) the community partner should have completed an agreement to abide by the fundamental principles of research ethics. (See "Additional Considerations" below for this list.)


2. Plans for publication (if any) should be included in the consent form.

D. For a project for which the UT Knoxville unit is the PREDOMINANT party (e.g., in which the community partner's role is limited to suggesting the research questions and receiving the interpreted results), the UT Knoxville faculty who is carrying out the project will be listed as Project Director and the standard approval process like that for traditional research will be undertaken, using Form A or Form B, as appropriate.

IN ADDITION, we recommend that the community representation on the UT Knoxville IRB be expanded to include at least one representative of the segment of the community that would be involved in projects of this type.

NOTE: These proposals are framed in terms of the following typology of research elements: community participants may have an active role in the research in one or more of the following ways:

• DEFINING the questions to be answered by the research
• DESIGNING the research method to explore the questions
• CONDUCTING the research project -- i.e., choosing subjects, administering questionnaires, etc.
• ANALYZING the data
• INTERPRETING the results -- i.e., evaluating the significance of the data and drawing conclusions about the answers to the initial questions posed.
• DISSEMINATING the results through publication, etc.
(We are indebted to John Gaventa for this helpful listing of the constituent aspects of a research project.)

10.3 Additional Considerations

10.3.1 "Plain English" Principles of Research Ethics

We here acknowledge our acceptance of the following research ethics standards as guiding principles of our activity in partnership with a unit of The University of Tennessee, Knoxville:

A. We will demonstrate our respect for all the people we encounter in the course of this research project by:
   1. Informing them fully of what we are doing;
   2. Answering any questions they may have about the project;
   3. Asking their consent before involving them in any way; and
   4. Reminding them that they are free to refuse to participate.
   5. If someone is not fully capable of understanding what we are asking them to do (young children, for example), we will either not enlist them or we will seek consent from someone authorized to serve as their guardian or surrogate.

B. We will demonstrate our concern for the welfare of all the people we encounter by:
   1. Designing our project in a way that avoids harming them in any way -- including, not only physical harm and emotional turmoil, but also embarrassment that might result from private information about them being made public;
   2. Monitoring how the project affects those involved throughout and inviting them to withdraw from participation if harm results.
   3. If significant harm does result,
      a. instructing the participants affected to withdraw,
      b. helping them deal with the harm (e.g. by obtaining medical help or counseling services), and
      c. informing the UT Knoxville coordinators of the project immediately so they can report it to the appropriate authorities.
   4. At the end of the project, we will help participants deal with any confusion, misunderstanding, or harm of any sort that might remain as a result of their participation.

C. We will demonstrate our concern for justice by:
   1. Designing the project and choosing participants in such a way that no person or group of persons is unduly burdened or placed at risk.

D. We will demonstrate our respect for the enterprise of scientific research by:
   1. Recording all research information accurately;
   2. Interpreting it fair-mindedly;
   3. Reporting it honestly;
4. Honoring the requests of the UT Knoxville coordinators for oversight of the process and allowing them to discuss it with UT Knoxville research compliance authorities as required.

10.3.2 Basic Ethical Principles\(^1\)

**Respect for Persons.**—Respect for persons incorporates at least two ethical convictions:

1) That individuals should be treated as autonomous agents
2) That persons with diminished autonomy are entitled to protection.

An autonomous person is an individual capable of deliberation about personal goals and of acting under the direction of such deliberation. To respect autonomy is to give weight to autonomous persons' considered opinions and choices while refraining from obstructing their actions unless they are clearly detrimental to others. Respect for the immature and the incapacitated may require protecting them as they mature or while they are incapacitated.

**Beneficence.**—Persons are treated in an ethical manner not only by respecting their decisions and protecting them from harm, but also by efforts to secure their well-being. Such treatment falls under the principle of beneficence. The term "beneficence" is often understood to cover acts of kindness or charity that go beyond strict obligation. In this document, beneficence is understood in a stronger sense, as an obligation. Two general rules have been formulated as complementary expressions of beneficent actions in this sense:

1) Do not harm
2) Maximize possible benefits and minimize possible harms

**Justice.**—An injustice occurs when some benefit to which a person is entitled is denied without good reason or when some burden is imposed unduly.

There are several widely accepted formulations of just ways to distribute burdens and benefits. Each formulation mentions some relevant property on the basis of which burdens and benefits should be distributed. These formulations are:

1) to each person an equal share
2) to each person according to individual need
3) to each person according to individual effort
4) to each person according to societal contribution
5) to each person according to merit

Section 11: IRB Oversight Function

11.1 Purpose

It matters little that the Form B describes satisfactory procedures throughout if those procedures are not carried out as planned. The purpose of auditing research projects is to satisfy the IRB that research is being conducted in accordance with approved procedures. Audits also serve an educational function by reviewing with all study personnel the relevant aspects of their protocols.

11.2 Authority

Federal regulations give IRBs the responsibility and the authority, not only to conduct initial review of proposed research and periodic continuing reviews, but also to audit the conduct of the research. [45 CFR 46.109(e)]

11.3 Audit Selection Criteria

Criteria for selecting research projects to audit include (but are not limited to) the following:

- at random
- at the direction of the IRB for any cause
- for projects that have been designated by the IRB as significant risk
- upon report of suspected noncompliance
- research that has been terminated by the IRB due to failure by the researcher to submit a Form D for continuing review or failure to respond to a request for information from the IRB
- to verify continuing review reports (Form R)
- for studies reporting adverse events
- for studies that have requested modifications (Form D)
- for investigators or departments with a history of noncompliance

11.4 Audit Procedure

1. Projects to be audited will be selected by the IRB Administrator in consultation with the IRB Chair.

2. The selection for audit will be announced by the Associate Vice Chancellor for Research to
   a. The researcher
   b. The Chair of the DRC that reviewed the protocol
   c. The Head of the Department
3. The IRB Administrator will contact the Researcher to schedule the date and time for the pre-audit meeting. Required records will be requested at this time.

4. The audit will be conducted by the Chair or a member of the IRB, a member of the IRB administrative staff, and/or a consultant engaged for the purpose. The IRB Auditor(s) will sign a pledge of confidentiality with respect to information about participants they might encounter and information about the research site and personnel that is extraneous to the audit itself.

5. Documents that may be selected for review include, but are not limited to:
   a. Form A or Form B submissions and associated correspondence
   b. Changes in the protocol and associated correspondence
   c. Review of any lapses in IRB approvals
   d. Review of inclusion and exclusion criteria
   e. Review of recruitment materials and procedures
   f. Review of informed consent forms and informed consent procedure
   g. Review of data collection tools and procedures
   h. Review of any adverse event reports
   i. Review of continuing review reports
   j. Review of training materials for research personnel

6. Prior to the audit, the researcher will be requested to provide a list of all study participants to date, identifying them by code or study number only.
   a. From the list, the IRB Auditor will select at random 20-30% of the study participants. A list of selected subjects will be sent to the site in advance in order to facilitate gathering study instruments to be reviewed.
   b. In the case of a for-cause audit, the IRB may request a 100% audit of study participant's materials.

7. A pre-audit interview may be conducted with the researcher to document the delegation of authority for the following activities:
   a. Writing protocols for submission to the IRB
   b. Ongoing communication with the IRB
   c. Recruitment of study participants
   d. Obtaining informed consent
   e. Administering study instruments
   f. Reporting adverse events, protocol violations and deviations
   g. Reporting injury or other unforeseen event
   h. Maintaining study documentation
   i. Verification of continuing review reports

8. The IRB audit may consist of (but is not necessarily limited to) the following activities:
   a. Examining the relevant documents,
b. Visiting the site to confirm security of storage of study materials and consent forms

c. Interviewing study personnel to verify that they understand their responsibilities and the procedures
that were approved by the IRB

d. Contacting randomly selected participants to review their experience and their understanding of the
study's purpose and procedures

e. Observing a consent process

9. The IRB Auditor(s) will write a report of the audit which will be reviewed by the IRB at the next
convened meeting.

11.5 Follow-up Actions

1. The audit report will be shared with the researcher along with any recommendations the IRB and/or the
auditor(s) may have - with copies to the DRC Chair and the Department Head.

2. Notification of observations of noncompliance will be accompanied with a detailed explanation of the
basis of these findings. This report will be reviewed with the researcher and an opportunity given for a
written response that will accompany the report when submitted to the Associate Vice Chancellor for
Research.

3. If serious noncompliance is observed, procedures for further investigation and possible suspension or
termination of IRB approval may be initiated. (See Section 12.6 below for these procedures.)

4. All correspondence about the audit and the audit report itself will be filed with the research protocol and
retained as other records for this protocol.

11.6 Research Team Training

Subject to personnel availability, IRB Administration personnel who coordinate audits will instruct research
team members at the initiation of a project in the details of the human participant protections measures that were
approved by the IRB - i.e., such things as the specifics of the approved consent procedure and/or the security
measures to protect confidentiality.
Section 12: IRB Operations

12.1 The Membership of UT Knoxville IRB - Appointment of Members

The Associate Vice Chancellor for Research appoints UT Knoxville IRB Chair, Vice Chair, members, and alternates. The length of appointment is 5 years.
### 12.1.1 Regular Members

The UT Knoxville IRB has at least sixteen members including at least one member whose primary concerns are in scientific areas and at least one member whose primary concerns are in nonscientific areas. UT Knoxville IRB members are selected with varying backgrounds of expertise, experience, and diversity to promote complete and adequate review of research activities commonly conducted by the institution. The UT Knoxville IRB includes at least one member who is not otherwise affiliated with the institution and who is not part of the immediate family of a person who is affiliated with the institution. Members drawn from the UT Knoxville community may include faculty, students, or staff.

Membership rosters are maintained by the IRB Administrator and reviewed on an ongoing basis with the IRB Chair to assure that expertise and experience is representative of the research under review including expertise with vulnerable populations including, but not limited to those with mental disabilities or impaired decision-making capacity. When a deficiency is identified, the IRB Administrator conducts directed recruitment of individuals with the needed expertise or experience. Recommendations may come from UT Knoxville IRB Chair, other IRB members, or academic unit Deans, Directors, or Department Heads. Recommendations are reviewed with the Associate Vice Chancellor for Research who makes the final offer of membership.

### 12.1.2 Responsibilities

Responsibilities of members include reviewing human participant application materials in advance of meetings and being prepared to discuss issues related to human participants protections, serving as primary reviewer when requested, and having an understanding of the specific requirements of human participants regulations.

UT Knoxville IRB members serve at the discretion of the Associate Vice Chancellor for Research. Members who do not adequately fulfill their responsibilities as judged by UT Knoxville IRB Chair may be asked to step down from UT IRB membership by the Associate Vice Chancellor for Research. The reasons for this decision will be documented in the IRB files. In other cases, members will be rotated off after a period of service in the interests of bringing fresh perspectives to the deliberations of the IRB.

### 12.1.3 Compensation of UT IRB Members

The Office of Research provides no compensation to members of UT Knoxville IRB with the exception of parking vouchers provided to off-campus members to cover the cost of parking during meetings. Individual colleges are expected to provide members in proportion to the amount and type of research submitted by their faculty, staff, and students. UT Knoxville colleges may independently choose to provide support either to their departments and/or to individuals to meet this expectation. The Chair receives a research fund annually as partial compensation for his or her time commitment to UT Knoxville IRB.

### 12.1.4 Member Liability

UT Knoxville IRB members function as employees and agents of UT Knoxville. As such, when acting in accordance with UT Knoxville IRB standard operating procedures, their actions are covered by UT Knoxville general liability coverage.

### 12.1.5 Alternate IRB Members

Alternate IRB members, if appointed, are designated for a specific member or members. Alternate IRB members are selected to assure comparable qualifications to the primary member based on discipline, expertise, and/or education and professional experience as appropriate. If both the alternate IRB member and the primary IRB member attend a meeting, only one of these two may vote. In these cases, the minutes reflect who is in attendance as a voting IRB member.
12.1.6 Non-Voting Members

The Associate Vice Chancellor for Research may, at her or his discretion, recruit non-voting, ex officio members from among the academic or administrative staff of UT Knoxville whose presence at the meetings of UT Knoxville IRB would aid the IRB in conducting their duties. These members may take part in all meetings of the IRB, participate in the discussions, and make recommendations to influence decisions, but they may not vote on the decisions. Non-voting members are not included in determining or establishing a quorum at the meetings. UT Knoxville IRB meeting minutes reflect the presence of non-voting members.

12.1.7 Consultants/Ad hoc Reviewers

At its discretion, the UT Knoxville IRB may invite scientists or non-scientists from within or outside UT Knoxville, who have special expertise, to function as consultants and ad hoc reviewers of a project application. These individuals have access to all documents submitted to UT Knoxville IRB relevant to the specific project under review, may participate in the deliberations and make recommendations on the project, but may not vote.

12.1.8 Confidentiality

Protocols submitted to the IRB for review are considered confidential. IRB administrative staff and members of the IRB will not share information they have learned through handling and reviewing protocols with anybody outside the circle of the IRB. To underscore this commitment, IRB members (including non-voting members), alternates, and administrative staff will sign a pledge of confidentiality annually. Consultants or ad hoc reviewers will sign a pledge of confidentiality each time they are engaged to review a protocol. Members of appeals boards (see Section 2.11), audit teams (see Section 11), or non-compliance subcommittees (see Section 12.7) will sign a pledge of confidentiality at the beginning of their term of service.

12.1.9 Conflict of Interest

No UT Knoxville IRB member, consultant, or ad hoc reviewer may participate in the IRB review of any project in which the member has a conflict of interest or any other relationship that may be inappropriate for objective review, except to provide information requested by the board. The determination of a conflict is ultimately a matter of judgment by the individual; however, in general it is clear that (a) serving as PI or Co-PI or Faculty Advisor on a project does constitute a conflict of interest and (b) the mere fact that the PI, Co-PI, or Faculty Advisor is a colleague in one's department or a student in one or two of one's classes does not constitute a conflict. Having previously reviewed the project as a member of the DRC does not constitute a conflict. The individual with a conflict can be a member of a UT Knoxville IRB; however, he or she cannot participate in the review and approval process for any project in which she or he has a conflict of interest. This conflict of interest policy includes all types of review (i.e., review by expedited-process, review by the convened IRB, review of unanticipated problems involving risks to participants or others, or review of noncompliance with the regulations or requirements of the IRB). If a member recognizes a conflict with regard to a protocol assigned for expedited-process review, she or he notifies the IRB Administrator immediately so it can be assigned to a different expedited-process reviewer or referred to a full board review. In cases where an assigned primary reviewer has a conflict of interest, she or he notifies the IRB Administrator as soon as the conflict is recognized and that study application is re-assigned to another primary reviewer. When the investigator-member has a conflicting interest, he or she may be present at UT Knoxville IRB meetings, like any investigator, only to provide information requested by the board. He or she must be absent from the meeting room during the subsequent discussion and voting phases of the review and may not vote (e.g., agree, disagree, abstain) on the study. The absent member is not counted towards a quorum when the vote on the study in question is taken. Minutes document that these requirements have been met.
12.2 Management of UT Knoxville IRB Process

12.2.1 UT Knoxville IRB Chair

The UT Knoxville IRB has a Chair, and at the discretion of the Vice Chancellor for Research - a Vice Chair. These individuals are respected, active members of the University community who are well-informed about regulations relevant to the use of human participants in research. The Associate Vice Chancellor for Research appoints the Chair based on their experience in human research protections, professional discipline(s) and achievements, educational background, and their availability to commit the appropriate amount of time and effort to the UT Knoxville IRB program. The term of service is at the discretion of the Associate Vice Chancellor for Research. The Chairs are evaluated formally on an annual basis in meetings with the Associate Vice Chancellor for Research. The Chair's activities are also monitored on an ongoing basis through periodic reports of UT IRB application activity.

Whenever the Chair is not available to conduct UT Knoxville IRB business, the Vice Chair assumes the duties of the Chair. If the Vice Chair is also not available, the Chair is notified so that she or he may designate a board member to assume her or his responsibilities during the period of absence. An IRB Chair designee will be a named member of the IRB roster and will undergo a period of supervision and training for a minimum of three months directly related to the designee's specific role by the IRB Chair prior to assuming designation responsibilities.

12.2.1.1 Responsibilities of the Chair include:

• determining the type of review for initial, continuing review, and modification applications (exempt, expedited, full board) based on regulatory criteria,
• conducting expedited reviews and approvals,
• assigning primary reviewers for and running full board meetings,
• reviewing minutes,
• reviewing specific revisions to protocols/consent documents that are required as conditions of approval,
• signing the application form certifying project approval,
• reviewing reports of unanticipated problems involving risks to subjects or others,
• suspension of research procedures,
• referral to convened IRB for consideration of termination of research procedures.
• reports of unanticipated problems involving risks to subjects or others, of instances involving serious or continuing noncompliance, or of suspension or termination of a research project are made under signature of the Chair.

In addition, the Chair serves as resources for investigators and UT Knoxville IRB members regarding issues related to University and federal policies.

12.2.2 Administrative Support - The IRB Administration Office

UT Knoxville IRB Administration, a unit within the Office of the Research and reporting to the Associate Vice Chancellor for Research, has been established to support the IRB process.

12.2.2.1 The IRB Administration Office:

• assists UT Knoxville IRB in preparing for and monitoring IRB meetings;
• maintains files on all human participant research (including copies of all correspondence between the IRB and investigators) that takes place at UT Knoxville;
• maintains databases for tracking studies;
• assists with preparation of meeting minutes;
• maintains files of minutes of convened full board meetings;
• screens research applications for completeness prior to initiating the IRB review process;
• acts as a resource for investigators on general regulatory information, guidance with forms, and assistance in preparing an application for IRB review;
• maintains the institution's Federal-wide Assurance, the IRB membership rosters, and a resume for each IRB member;
• provides staff support to the IRB for all written correspondence;
• sends notices of approval, study closure (other than closure of the study by the investigator) for externally sponsored projects to UT Knoxville Sponsored Programs Office;
• generates and sends reminder notices to investigators of upcoming continuing reviews;
• maintains information on federal regulations relating to human participants research;
• provides education regarding the IRB process and regulations to the University community;
• maintains a human participants research monitoring program;
• checks the short form consent process for compliance with regulatory requirements;
• maintains all correspondence between the IRB and other compliance committees.

12.2.2.2. Resources

UT Knoxville provides adequate personnel, facilities and equipment to support the operation of UT Knoxville IRB and IRB Administration Office in performing the functions described in this document.

12.3 Functions of UT Knoxville IRB and Scope of Review

After initial review of applications by the IRB Administration for completeness, UT Knoxville IRB convened or expedited-process review of applications is conducted to: [cf. 45 CFR 46.111]
• consider the scientific or scholarly design to determine that the use of human participants is relevant and appropriate to answer the questions being asked;
• consider ethical issues with regard to the study's design and conduct;
• determine that the proposed recruitment and enrollment plan, including the inclusion and exclusion criteria used, afford selection of subjects from the population that is equitable given the potential benefits and risks of the research;
• identify the risks associated with the research, as distinguished from the risks of therapies, teaching plans, or other interventions which the participants would receive even if not participating in research;
• identify level of risk;
• determine that the risks are minimized to the extent possible by using procedures consistent with sound research design and which do not unnecessarily expose participants to risks, and when appropriate, by using procedures which are already performed on participants for non-research diagnostic, treatment, educational or other purposes;
• identify the probable benefits to be derived from the research;
• determine that the risks are reasonable in relation to the anticipated benefits to subjects, if any, and the importance of the knowledge to be gained, considering only those risks and benefits that may result from the research;
• assure that potential subjects are provided with an accurate and fair description of the risks or
discomforts and the anticipated benefits;

- require informed consent be sought and documented from each prospective subject or their legally authorized representative, or determine to waive these requirements according to appropriate regulatory requirements;
- assess any incentives offered for participation to ensure that they do not constitute undue inducement;
- determine intervals of periodic review;
- where appropriate, determine that adequate plans are in place for data and safety monitoring;
- determine the adequacy of the provisions to protect the privacy of participants and to maintain the confidentiality of the data;
- where the subjects are likely to be members of a vulnerable population, determine that appropriate additional safeguards are in place to protect the rights and welfare of these subjects.

12.4 Operations of UT Knoxville IRB - Scheduling of Meetings

The UT Knoxville IRB is scheduled to meet once each month, ordinarily on the third Thursday of the month, with a primary purpose of reviewing new protocols and modifications requiring full board review, as well as conducting continuing reviews. If a scheduled meeting falls on a University holiday or break, the meeting will be rescheduled, usually to the following Thursday.

The IRB Administrator, when assigning protocols to full board IRB meetings makes an initial assessment of the member expertise in relation to the particular protocols requiring review. The IRB chair and/or the IRB Administrator, or their designee, when assigning primary reviewers to protocols, assesses the expertise of the IRB membership and, when relevant, their experience in dealing with vulnerable populations, and can make arrangements for a consultant to be present to advise the IRB if it is judged that additional expertise is required. If a Chair designee assigns primary reviewers to protocols, the IRB Chair will review and grant final approval of all primary reviewer assignments.

Monthly meetings of the IRB may be cancelled by the Chair due to a) insufficient applications requiring full board review, or b) inability to secure a quorum for attendance, or c) other reasons as may arise that make a scheduled meeting unnecessary or otherwise inappropriate.

12.4.1 Submission of Applications

All applications for review are submitted to the IRB Administration, 1534 White Avenue. One paper copy of the application form must be submitted, containing signatures of researcher(s), DRC Chair, and Department Head. An electronic version of the application must also be submitted via email for posting on the IRB Blackboard site and distribution to the primary reviewers.

The review process can begin as soon as the electronic copy is received, even if the paper copy with signatures is still in transit.

As soon as an application is received, it is assigned a UT Knoxville IRB reference number. This unique number remains with the study and is never reassigned to a different study.

Applications are initially screened in the IRB Administration for completeness before determination of the type of review or assignment to a monthly agenda. A complete submission for IRB review includes the following items as applicable:

1. Application form (Form A or Form B)
2. proposed Informed Consent Document(s) or other consenting materials,
3. recruitment materials (including direct advertising materials, e-mails, letters, etc.),
4. survey instruments,
5. pledge of confidentiality from study personnel who might have contact with study materials containing identities of participants,
6. grant application, if applicable
7. other materials specific to the proposed study (e.g., sponsor correspondence, background information relative to determinations of risk)

If the application is incomplete or otherwise not fully prepared for review, it is returned to the investigator or a request is made for necessary changes or to provide additional information.

12.4.2 Determination of Type of Review

The Chair and/or the IRB Administrator and/or an IRB-member designee reviews the entire application, as well as the recommendation for type of review made by the DRC and the Department Head, and makes a determination as to whether the project constitutes human participants research and, if so, the type of review (full board review, expedited review, or exempt). All applications are assigned to full board review unless they pose no more than minimal risk and (1) they meet the criteria for exemption listed in Section 5 of this Guide or (2) they meet the criteria for expedited review listed in Section 6 of this Guide.

12.4.3 Full Board Review Process - Primary Reviewer Assignment

The Chair, or designee, assigns three primary reviewers for each protocol well in advance of a full board meeting (ideally 10 days before the meeting unless special circumstances make this impossible and then primary reviewers must agree to the change of date of distribution). If a Chair designee assigns primary reviewers, the Chair will provide final approval of the primary reviewer assignments to any given IRB agenda. The Chair may, at her or his discretion, serve as primary reviewer. In selecting the three primary reviewers for each protocol, consideration is given to the individual's knowledge of the subject area embodied in the proposal and/or special expertise regarding the participant population (especially if it is deemed to be a vulnerable population).

If, in the opinion of the IRB Chair, the IRB membership or likely attendees for a scheduled meeting does not include someone with the relevant scientific or scholarly expertise to conduct an in-depth review of a particular protocol, the Chair may invite a consultant with the appropriate expertise to attend the meeting as one of the primary reviewers. If the IRB chair chooses to invite a consultant to be a primary reviewer, the consultant would act under the procedures for consultants as described in Sections 12.1.7 and 12.4.4 of this Guide.

For initial reviews, the primary reviewers each review the application, the proposed informed consent document(s) (or parental permission and child assent documents), recruitment materials (including direct advertising materials), study instruments, and, if applicable, the grant application, study protocol, and investigator's brochure.

For continuing review applications, the primary reviewer reviews the complete project application, which includes all materials previously reviewed by UT Knoxville IRB under expedited or full board review, and reports of unanticipated problems involving risks to subjects or others.

The primary reviewers may contact the investigator in advance of or during the board meeting for additional information or clarification. The primary reviewers each present their review and make a recommendation for disposition of the application under review. The primary reviewer must not have a conflict of interest regarding the project under review and is expected to notify the Chair of any conflict. Primary reviewers are provided a worksheet to ensure that all criteria for approval of research have been fulfilled.

12.4.4. Use of Consultants

At the time of preliminary review of a project application, the UT Knoxville IRB Chair and/or UTK Administrator and/or one of the primary reviewers may determine that the study requires further review by a consultant with expertise outside of the current UT Knoxville IRB membership. This determination may be made based on the scientific design of the study, the ethical issues of the study, the potential risks or benefits of the
study, specific privacy and confidentiality concerns, or considerations relative to a particular study population.

Upon identifying the need for a consultant review, the IRB Administrator and/or primary reviewer in consultation with the Chair will identify a consultant based on the particular issues to be addressed. The Chair will determine that the consultant does not have a conflict of interest based on the definition provided in Section 12.1.9 of this Guide.

For issues requiring only simple clarification, a written set of questions will be developed for submission to the consultant or the completion of a primary reviewer checklist may be required of the consultant. A signed confidentiality agreement will be required from the consultant prior to completing the review process. The consultant's written response to these questions will be provided to the full UT Knoxville IRB for review at the time of the convened meeting.

For issues requiring more than simple clarification, the consultant may also be asked to review the project application in its entirety and complete a primary reviewer checklist and be invited to attend the full board meeting during the review of that particular study and to serve as a primary reviewer. Documentation of the discussion with the consultant will be included in the meeting minutes.

12.4.5 Notification of Meetings and Distribution of Materials

The agenda and application materials are posted on the IRB Blackboard site and thereby made available to all UT Knoxville IRB members, the representative of the Office of General Counsel who serves as ex-officio consultant to the IRB, and identified consultants, if applicable. This posting is done sufficiently in advance of the meeting date to allow time for review, generally at least a week in advance. The agenda indicates the date, time, and place of the meeting. Items posted include all the elements of an application, and other materials as determined by the Chair.

For continuing reviews or for modifications to be approved, all the elements submitted to the IRB Administration office will be posted.

The primary reviewers receive materials in advance of the Blackboard posting.

All IRB members are expected to review all materials in sufficient depth to discuss them at the convened meeting.

In addition to the material posted, there is a link to a discussion board within the Blackboard course management system for each protocol. This allows IRB members to post questions and observations about the protocols as they review them. The IRB Administration will review the issues raised in these discussion boards and, if necessary, contact the researchers to seek clarification or supplemental information or materials. The hope is this might lead to clearing up some questions in advance of the convened meeting.

12.4.6 Urgent Review of Applications

Urgent review procedures may be invoked only under unusual circumstances. This does not include urgency that is a result of negligence or delay on the part of the investigator or her or his staff to submit human participants applications in a timely fashion.

On occasion, however, an investigator is faced with an immediate deadline beyond his or her control. If the Chair permits urgent review of a protocol, the materials are distributed as soon as possible to UT IRB members to allow sufficient time for review prior to the meeting.

The investigator may be required to attend the meeting to answer any questions that arise.

12.4.7 Meeting Procedures

UT Knoxville IRB meeting is called to order when a quorum of members is in attendance. A quorum consists of more than half of the number of primary members and must include at least one non-scientist. The meeting ends or is suspended whenever a quorum of members is no longer present. The quorum is monitored throughout the meeting by an IRB Administration staff member or the IRB Chair.
At the discretion of the Chair and/or primary reviewers, the investigator(s) may be invited to attend the meeting for the purpose of additional clarification or discussion. The investigator(s) is (are) required to leave the meeting for subsequent discussion and voting.

At the discretion of the Chair, voting may be by written ballot or a show of hands. The official meeting minutes record a motion from the board and the number of votes which agree or disagree with the motion as well as the number abstaining.

In the event a member of UT Knoxville IRB elects to cast no vote, the minutes record such.

A vote of approval by a member means that member has determined that

- risks to subjects are minimized;
- risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result;
- selection of subjects is equitable,
- informed consent will be sought from each subject or their legally authorized representative (or waived in accordance with the criteria listed in Section 4.6 of this Guide);
- informed consent will be appropriately documented (or documentation waived in accordance with the criteria listed in Section 4.7 of this Guide);
- when appropriate, there are adequate provisions to protect the privacy of subjects and maintain the confidentiality of data; and
- when some or all of the subjects are likely to be vulnerable to coercion or undue influence, additional safeguards have been included in the study to protect their rights and welfare.

A majority vote of the members present at the meeting is required for approval. Investigators are notified in writing of the decision of UT Knoxville IRB and any changes required.

The actions which the IRB may pass are: (cf. Section 2.10.2 of this Guide)

- approve
- approve conditional upon modifications required to secure approval (the specifics to be communicated to the PI in writing)
  - for minor modifications the adequacy of the modifications to be verified by the IRB administration
  - for more significant modifications, the adequacy of the modifications to be reviewed by a subcommittee of the IRB (typically the primary reviewers plus others who had particular concerns about the protocol)
- revise and resubmit to the full board for re-review (here again, specific concerns and/or suggestions for modifications will be communicated to the PI in writing)
- disapprove (If the IRB decides to disapprove a research activity, it shall include in its written notification a statement of the reasons for its decision and give the investigator an opportunity to respond in person or in writing and/or to appeal the decision (see Section 2.11 of this Guide for the appeal procedure and the constitution of the Appeals Board) [45 CFR 46.109(d)].

12.4.8 Studies Designated "Revise and Resubmit to Full Board"

When a study is designated "revise and resubmit to full board" at a meeting (i.e. the majority vote agrees with this motion), the study, after the investigators have addressed the IRB requirements, must be returned to a convened full-board IRB meeting for review. The Full Board Meeting Procedures described above are followed for these protocols. Additional materials distributed to members for tabled studies include the primary reviewer reports, the minutes from the previous meeting, and any response to those minutes from the investigators.

When possible, the primary reviewers from the previous review will be assigned as the primary
12.4.9 Meeting Minutes

Minutes are generated that record the following information:

- attendance at each meeting including those members or alternate members who participated through videoconference or teleconference, and documentation that those members not physically present received all pertinent materials prior to the meeting and were able to participate in all discussions.
- indication by name when members absent themselves from the meeting due to a conflicting interest on individual agenda items and the reason for absenting themselves, or indication by name that a member was not present for discussion and voting on individual agenda items;
- the vote on actions taken by the IRB including the number, for, against, abstaining, and not voting;
- separate deliberations for each action, where applicable;
- actions taken by the board including determinations as required by federal regulations and protocol-specific findings justifying those determinations for waiver or alteration of the consent process, research involving pregnant women, human fetuses, and neonates, research involving prisoners, and research involving children;
- justification of any deletion or substantive modification of information concerning risks or alternative procedures contained in the DHHS-approved sample informed consent document;
- the basis for requiring changes in or disapproving research;
- the length of time of an approval;
- a written summary of the discussion of controverted issues and their resolution;
- specific comments relevant to inclusion of certain populations;
- whenever a significant risk/non-significant risk determination is made, the rationale for significant risk/non-significant risk determinations;
- where appropriate, information regarding expedited approvals, modifications, terminations, unanticipated problems involving risks to subjects or others, and any other business appropriate for board meetings.

If the convened IRB approves research contingent on specific minor conditions and the IRB Administrator, IRB Chair, or a subcommittee consisting of one or more other IRB members designated by the Chair approves the modifications, the approval by the Chair or designee(s) is documented in the minutes of the first IRB meeting that is convened after the date of approval.

Minutes are available for review within three weeks of the meeting date.

After approval by the IRB, the minutes cannot be altered by anyone including a higher authority.

12.4.10 Expedited Review

The expedited review process may be used in accordance with federal regulations for applications that qualify for expedited review [45 CFR 46.110 - also see Section 6 of this Guide]. The UT Knoxville IRB Chair or her or his IRB-member designees (including the IRB Administrator) are responsible for these reviews. The criteria for approval using the expedited procedure are the same as those for review by a convened IRB (See Section 12.3 of this Guide). Approved studies are subject to at least annual review and this information is communicated to the principal investigator in the approval letter.

The IRB Chair or her or his IRB-member designee conducting an expedited review either concurs with the investigator's protocol-specific findings justifying determinations required by the regulations or document such findings themselves prior to approval. These include protocol-specific findings for:
• Waiver or alteration of the consent process (Sections 4.6 and/or 4.7)
• Research involving children (Section 9.2, especially 9.2.7)

The Chair and/or her or his IRB-member designee(s) may approve projects as submitted or require modifications prior to approval. They are not empowered to disapprove projects reviewed through the expedited process; in such cases, the application must be submitted for full board review along with the comments and recommendations of the Chair and/or IRB-member designee(s). In cases where the full board concurs with the recommendation, the investigator may appeal the decision as provided in Section 2.11 of this Guide).

A listing of all protocols that have been reviewed and approved through the expedited process is reviewed at the next convened meeting and posted on the UTK IRB Blackboard site on a monthly basis. These reports include initial reviews, continuing reviews and reviews of modifications to previously approved research.

The expedited review process may be used for the review of projects involving a) no more than minimal risk, and b) only those procedures listed in one or more of the categories set out in Section 6.2 of this Guide.

12.4.11 Exempt Research

When a recommendation for exempt classification is received from the DRC and Department Head, the Form A is reviewed by the IRB Chair and/or a designated member of the IRB Administration staff. If it is determined that the project is eligible for exemption, the PI, DRC Chair, and Department Head are notified immediately by e-mail and/or telephone. The goal is to complete these reviews within 3 working days, even at the busiest times. Participant recruitment and other project activities can begin as soon as certification of exemption by the IRB representative is communicated. PIs will be advised that exempt projects are not subject to routine continuing review, but they may be subject to audit.

If the determination is that this project is not eligible for exemption, the PI is notified immediately by e-mail and/or telephone and advised to resubmit the project on a Form B. At that time, the IRB representative advises the PI whether the protocol is eligible for expedited review or whether it will need to be reviewed by the full board.

A listing of all protocols that have been reviewed and certified to be exempt from expedited or full board review is reviewed at the next convened meeting and posted on the UTK IRB Blackboard site on a monthly basis.

Projects may be certified as exempt only if they involve a) no more than minimal risk, and b) only those procedures listed in one or more of the categories set out in Section 5.3 of this Guide.

12.4.12 Research approved conditional upon modifications required to secure approval
( the specifics to be communicated to the PI in writing)

The PI will be notified of the modifications the IRB insist on, as well as those recommended but not required and "friendly suggestions" for improvement of the study, within one week of the convened meeting. PIs will be advised that a response is expected within 60 days. Delay beyond that may require the protocol to be re-reviewed as a new submission.

12.4.12.1 for minor modifications the adequacy of the modifications to be verified by the IRB administration
When a response is received from the PI, a designated member of the IRB Administration staff will review it promptly.

If the modifications are determined to be satisfactory, the PI will be notified immediately by e-mail and/or telephone, with a follow-up letter. This action will be communicated to the IRB at the next convened meeting, and it will be posted on the UTK IRB Blackboard site.

If the designated IRB Administration staff have concerns about the response, it will be shared with (a) the IRB Chair and/or (b) those who served as primary reviewers for the protocol. If warranted, the response may be put on the agenda for the next convened IRB meeting for review by the full board.

12.4.12.2 for more significant modifications, the adequacy of the modifications to be reviewed by a subcommittee of the IRB

(typically the primary reviewers plus others who had particular concerns about the protocol)

When a response is received from the PI, the IRB Administration staff will forward it to those who have been designated as the subcommittee to review it. A discussion board will be created on the UTK IRB Blackboard site to facilitate interchange among the subcommittee as they review the response.

If the modifications are determined to be satisfactory by all members of the subcommittee, the PI will be notified immediately by e-mail and/or telephone, with a follow-up letter. This action will be communicated to the IRB at the next convened meeting, and it will be posted on the UTK IRB Blackboard site.

If any members of the subcommittee have concerns about the response, the response will be put on the agenda for the next convened IRB meeting for review by the full board.

12.5 Special Consideration for Projects Involving Vulnerable Populations

The UT Knoxville IRB considers certain groups of human participants to be particularly vulnerable in a research setting. The UT Knoxville IRB considers additional protections for research activities involving pregnant women, human fetuses and neonates, prisoners, children, and persons with impaired decisionmaking capacity. The UT Knoxville IRB may also consider additional protections for those who are educationally or economically disadvantaged, students, or other groups that require special consideration. In reviewing these research projects, the UT Knoxville IRB ascertains that the inclusion of the vulnerable population is adequately justified and that safeguards are implemented to minimize risks unique to each population. Special protections for these individuals are set out in detail in Section 9 of this Guide.

Requests for approval of federally funded research that exposes children to risks that do not meet one of the criteria in 46 CFR 45.404-406 are submitted to the United States Secretary of Health and Human Services for review and approval.

Determinations of approval by UT Knoxville IRB of federally funded research involving prisoners are reported to the DHHS Office of Human Research Protections (OHRP). The UT Knoxville IRB must have present at its meeting a designated prisoner advocate in order to review projects involving the use of prisoners in research. The Chair or her or his IRB-member designee may approve new studies limited to retrospective review of prisoners' records and minor modifications using expedited review procedures after review and comment by the prisoner advocate.
The following restrictions also apply with respect to vulnerable populations:

- Research involving fetuses cannot be approved.
- Research involving in vitro fertilization cannot be approved.
- Research involving children as subjects cannot be approved unless:
  - The study presents no greater than minimal risk.
  - The study meets all requirements of Subpart D of the DHHS or FDA regulations.

12.6 Suspension or Termination of IRB Approval

The UT Knoxville IRB has the authority to suspend or terminate approval of human participants research that is not being conducted in accordance with the UT Knoxville IRB’s requirements or that has been associated with unexpected serious harm to subjects. Any suspension or termination of approval includes a statement of the reasons for the IRB’s action and is reported in writing within 5 working days to the investigator, the Chair of the investigator’s DRC and the Department Head, the Associate Vice Chancellor for Research, and (when the study is externally funded) the Sponsored Programs Office.

Suspensions implemented by the IRB chair will be reported to and reviewed by the convened IRB. The IRB may take actions, within its authority, as deemed appropriate. When suspending or terminating IRB approval on an urgent basis, the IRB (or IRB Chair for suspensions):

- considers actions to protect the rights and welfare of currently enrolled participants.
- considers whether procedures for withdrawal of enrolled participants considered their rights and welfare.
- considers whether participants should be informed of the termination or suspension.
- requires any adverse events or outcomes to be reported to the IRB.

12.7 Noncompliance Investigations and Actions

Human subjects research that deviates from the policies, procedures, stipulations, decisions, state, or federal law is non-compliant and subject to further inquiry by the IRB and the IRB Administration. All reports and complaints of non-compliance should be directed to the IRB Administrator (via email, phone, mail, or in person). The IRB Administrator will immediately investigate all allegations of non-compliance. If necessary, the IRB Administrator will send the investigator(s) in question a notice requesting the immediate suspension of all specified research activities while the issue of non-compliance is reviewed, consistent with Federal Mandate 45 CRF Part 46.113. This initial notice will also include a statement detailing the rationale for the IRB’s action. There are three categories of non-compliance: general, serious, and continuing.

1. **Non-compliance**: Any deviation from UT Knoxville IRB policies and procedures, federal regulations, or state law is “non-compliance.” Failure to follow requirements and determinations of the IRB is also considered “non-compliance.”

2. **Serious Non-compliance**: All non-compliance substantially affecting participants’ rights and / or welfare, or impacting upon the risks or benefits is serious non-compliance.

3. **Continuing Non-Compliance**: Is a pattern of non-compliance that indicates an inability or unwillingness to comply with the regulations or the requirements of the IRB.

4. **Allegation of Non-Compliance**: An assertion of non-compliance that is not yet proven or disproven.

5. **Finding of Non-Compliance**: Non-compliance that is established by a fair process. A finding of non-compliance may exist because there is clear evidence, an admission, or an investigation into an allegation
has determined the allegation to be true.

Allegations of non-compliance will first be investigated by the IRB Chair and the IRB Administrator. If the general non-compliance is clearly neither serious nor continuing, and there is a corrective action plan that can be readily implemented to prevent recurrence, then the matter may be filed and no further action is needed (examples that might fall here include failure to sign the application or consent forms stored at a place other than that specified in the protocol). Otherwise, the IRB Chair will refer allegations and findings of non-compliance to undergo an evaluation by an ad-hoc IRB Non-Compliance Subcommittee, selected by the IRB chair. This subcommittee, composed of two members of the IRB and one staff member from the IRB Administration, will review the nature of the non-compliance and make a recommendation based on each specific case. The subcommittee issues recommendations to the IRB for a vote. For allegations of non-compliance, the subcommittee makes a preliminary determination as to whether the allegation has a basis in fact. When allegations are found not to have a basis in fact, the investigation is closed. For findings of non-compliance, when allegations are substantiated, the subcommittee considers the following recommendations:

- modifying the research protocol;
- modifying the consent process;
- contacting past or current participants with additional information (for current participants whenever that information might affect their willingness to continue to take part in the research);
- re-consenting participants;
- modifying the approval period;
- suspension;
- termination; or
- referring the case to other administrative authorities (e.g., the researcher’s department head or dean, or the Vice Chancellor for Research) for further disciplinary action.

The IRB non-compliance subcommittee will also makes a preliminary determination as to whether the non-compliance was serious or continuing.

The full IRB will review the preliminary findings and the recommendation(s) of the IRB non-compliance subcommittee. All IRB members will be provided with a copy of the approved protocol, current consent documents, and the report of the IRB non-compliance subcommittee with any supporting documents. A member of the IRB non-compliance subcommittee will present the subcommittee’s report. The IRB may accept, modify, or reject the subcommittee’s recommendation(s). The IRB will then assess whether the incident of non-compliance was serious and/or continuing. If necessary, the IRB may request additional information from researchers before issuing determinations. The IRB reserves the right to request any appropriate additional consultation and expertise to resolve non-compliance. Deliberations and determinations of the convened IRB will be fully documented in the IRB files for the project. Every effort will be made to complete each stage of this process as quickly as possible, recognizing that suspension of research may have deleterious effects on the research itself and, for funded research, on the pay of study personnel. The expectation will be that each stage of this process (i.e., initial review, subcommittee investigation, IRB review of subcommittee report,) will be completed within a week's time. All cases of non-compliance which the IRB determines to be serious or continuing noncompliance will be reported to the Associate Vice Chancellor for Research and to such other parties as the Associate Vice Chancellor for Research deems appropriate.
12.8 Review of Unanticipated Problems involving Risks to Subjects or Others

Unanticipated problems involving risk to subjects or others are reported to the IRB by UT investigators. Information reported indicates whether or not the investigator believes the reported event is an unanticipated problem involving risks to subjects or others. The process for review of these reports is as follows:

- The IRB Administrator and/or the IRB Chair compares the content of the report with the previously approved project materials such as applications, informed consent documents, protocols, investigator brochures, or other supporting documents to determine whether this event meets the definition of an unanticipated problem involving risk to subjects or others.

- If the chair agrees the event meets the definition of an unanticipated problem involving risk to subjects or others, the Administrator and/or Chair determines whether the event represents minimal risk of harm or more than minimal risk of harm to subjects enrolled under the UT Knoxville study.

- If the event represents minimal risk of harm, the Chair writes a notation to this effect for the IRB records of this protocol.

- If the event represents more than minimal risk of harm to subjects enrolled under UT Knoxville study, the report is referred for full board review.
  - A primary reviewer is assigned to lead the discussion at the full board meeting.
  - All IRB members including the primary reviewer receive appropriate materials such as the initial report, other communications with the Principal Investigator or other relevant individuals, approved IRB application, consent documents and other documentation from the project files as appropriate, prior to the full board meeting.
  - All IRB members are expected to review and be familiar with all materials.
  - The convened IRB makes a determination whether the event is an unanticipated problem involving risk to subjects or others.
  - If the determination made by the convened IRB differs from that made by the IRB chair, the determination of the convened IRB supersedes that made by the IRB chair.
  - When a quorum of IRB members is present, and after discussion, the IRB shall vote recommended actions.
  - The IRB or IRB Chair may take any of the following actions or other actions as appropriate:
    - Modification of the protocol,
    - Modification of the consent document,
    - Providing additional information to current subjects - this is done whenever the information may relate to the subject's willingness to continue participation,
    - Providing additional information to past subjects,
    - Requiring current subjects to re-consent to participation,
    - More frequent continuing review or monitoring (this can include observation of the research activities and/or the consent process),
    - Requiring additional training of the investigator,
    - Notification of investigators at other sites,
    - Suspension or termination of the research
    - Obtaining additional information
  - The IRB sends written notification of actions taken to the PI. Reports to other entities are made in accordance with procedures described in Section 12.9.2 just below.

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12.9 Reporting

12.9.1. Maintaining FWA and UT IRB Registration

The IRB Administration maintains the FWA and IRB registrations notifies OHRP of any changes in the FWA or IRB membership as they occur.

IRB staff maintains a list of the IRB members (IRB rosters) for the IRB that include the following information:

- The information required by 45 CFR 46.103(b)(3) and 21 CFR 56.115(a)(5).
- Whether the member is a primary member or alternate member.
- The primary member(s) for whom each alternate member could substitute.

12.9.2. IRB Determinations Requiring Reporting

The following policy outlines the procedure for reporting to the appropriate institutional departments and offices, the institutional official, sponsors, and/or the appropriate regulatory agencies of events determined by the IRB to be:

- suspensions or termination of IRB-approval of research (see Section 12.6),
- serious or continuing non-compliance (see Section 12.7), or
- unanticipated problems involving risks to subjects or others (see Section 12.8)

Following an IRB determination of any of the above, the full board IRB Administration staff in collaboration with the IRB Chair prepares a letter for signature by the IRB Chair that contains the following information:

- The nature of the event (whether or not the event was an unanticipated problem involving risks to subjects or others, serious or continuing non-compliance, or a suspension or termination of approval of research or a combination of these events),
- The title of the research project and/or grant proposal in which the problem occurred,
- The name of the principal investigator on the protocol,
- The IRB number assigned to the research project and the number of any applicable federal award(s) such as grants, contracts, or cooperative agreements,
- A short summary of the project,
- A detailed description of the problem including the findings of the organization and the reasons for the IRB’s decision,
- Actions the institution is taking or plans to take to address the problem (e.g. revise the protocol, suspend subject enrollment, terminate the research, revise the informed consent document, inform enrolled subjects, increase monitoring of subjects, increase IRB monitoring of the project, etc.),
- Plans, if any, for any follow-up action.

The IRB Administration staff sends a copy of this letter no more than one month following the review and final determination by the convened IRB to:

- Institutional Entities:
  - The researcher
  - The Chair of the researcher’s DRC and the Department Head
  - The Associate Vice Chancellor for Research
  - UT Knoxville Institutional Official (Office of the Vice Chancellor for Research),
  - Sponsored Programs Office, if appropriate. The IRB Administrator, the Associate Vice Chancellor
for Research, and the Sponsored Programs Office (if appropriate) then determine whether notification of the sponsor or others is required by contract or agreement and notifies the sponsor or appropriate others accordingly.

- Dean of the College of the principal investigator
- Federal Agencies:
  - OHRP, if the study is subject to DHHS regulations or subject to a DHHS Federal wide assurance,
  - FDA, if the study is subject to FDA regulations [21 CFR 50 and 56]
  - If the study is conducted or funded by any Federal Agency other than DHHS that is subject to "The Common Rule" (see Definitions in Section13), the report is sent to OHRP or the head of the agency as required by the agency.
    - NOTE: Reporting to a regulatory agency does not occur if the event occurred at a site that was not subject to the direct oversight of the organization, and the agency has been notified of the event by the investigator, sponsor, another organization, or other mechanisms.
  - The IRB Administration can provide copies to others as deemed appropriate by the Institutional Official.

12.10 Undue Influence

Investigations of attempts to unduly influence any member of UT Knoxville IRB or IRB Administrative Support staff focus on the protection of the independence of the IRB members and support staff so that they can function in the role of protecting research participants. Attempts to unduly influence the IRB can be reported in the following manner.

When an IRB Administrative Support staff member experiences undue influence, she or he should report such an occurrence to the IRB Administrator. These reports of undue influence go to the Associate Vice Chancellor for Research. If the staff member feels that undue influence is coming from the IRB Administrator, she or he reports the occurrence to the Associate Vice Chancellor for Research directly. If the staff member feels the undue influence is coming from any of the above individuals in the reporting chain, the staff member can report the incident to the appropriate UT Knoxville Faculty or Staff Ombudsperson.

When an IRB member experiences undue influence, she or he should first report the occurrence to the IRB Chair. The IRB Chair can then notify the IRB Administrator. The report then goes to the Associate Vice Chancellor for Research. If the IRB member feels that the undue influence is coming from the IRB Chair or the IRB Administrator, the IRB member reports directly to the Associate Vice Chancellor for Research. If the IRB member experiences undue influence from any of the above reporting chain, the IRB member can report the incident to the UT Knoxville Faculty or Staff Ombudsperson. Parties to whom the reports are made will evaluate the allegation and will determine a course of action to be taken. Actions can include additional investigation, internal resolution, or referral to the appropriate dean, the Vice Chancellor for Research, the Provost, the Chancellor, or the Office of Human Resources.

12.11 Tennessee Laws Governing Research Activities

The following are laws of the State of Tennessee that are taken into account in reviewing protocols by the UT Knoxville IRB:

NOTE: Material for this section will be supplied at a later date by the Office of the General
Counsel.
Section 13. Glossary

**Agent of the Organization** Agents include all individuals performing institutionally designated activities or exercising institutionally delegated authority or responsibility.

**Assent** - Affirmative agreement by a child to participate in research, a supplement to the "permission" given by parents or guardian. A partial substitute for consent (since a minor is not legally qualified to give consent on their own behalf).

**Chair** - Chair or Vice-Chair, as designated on UT IRB roster submitted to OHRP, unless otherwise indicated.

**Children (Child)**

DHHS definition: persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.²

FDA definition: persons who have not attained the legal age for consent to treatments or procedures involved in clinical investigations, under the applicable law of the jurisdiction in which the clinical investigation will be conducted.

**Clinical Investigation**

FDA definitions:

- any experiment that involves a test article and one or more human participants and that is one of the following:
  - subject to requirements for prior submission to the Food and Drug Administration under section 505(I) or 520(g) of the act, or
  - is not subject to requirements for prior submission to the Food and Drug Administration under these sections of the act but the results of which are intended to be submitted later to, or held for inspection by, the Food and Drug Administration as part of an application for a research or marketing permit.

The term does not include experiments that are subject to the provision of 21CFR58, regarding nonclinical laboratory studies. (From 21 CFR 50.3(c); 21 CFR 56.102(c)) - any experiment in which a drug is administered or dispensed to, or used involving, one or more human participants. For the purposes of this part, an experiment is any use of a drug except for the use of a marketed drug in the course of medical practice. (From 21 CFR 312.3(b))

(Investigation): a clinical investigation or research involving one or more subjects to determine the safety or effectiveness of a device. (From 21 CFR 812.3(h))

**Confidentiality** the ethical or legal right that information be considered private and be held secret unless consent is provided permitting disclosure. Contrast anonymity, which applies only to cases in which no one does or could know the identity of the participant (i.e., anonymous surveys in which no

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¹Adapted from University of Iowa Institutional Review Board Standard Operating Procedures

http://research.uiowa.edu/hso/downloads/policies/UIIRBSOP.pdf

²In Tennessee, the age of consent is 18 except for certain special circumstances, including
identifying information is reported and the ordinary requirement for signed consent is waived by the IRB.)

**Conflict of Interest** Conflict of interest in research involves situations in which an investigator has a significant financial interest that may compromise, or have the appearance of compromising, professional judgment in the design, conduct, or reporting of research. The terms "investigator" and "significant financial interest" are defined below.

Investigators conducting research funded by the Public Health Service (including National Institutes of Health) and National Science Foundation, as well as those conducting studies regulated by the Food and Drug Administration, are subject to agency specific regulations. These regulations set forth the obligations of investigators, sponsors and institutions for research involving significant financial or other conflicts of interest, and affected parties are advised to review the relevant regulations prior to submission of a research proposal or application.

a. "Investigator" means the principal investigator and any other person, whether faculty, staff, or student, who is responsible for the design, conduct, or reporting of research. "Investigator" also includes the investigator's spouse and dependent children.

b. "Significant financial interest" means anything of monetary value, including, but not limited to, salary or other payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options, or other ownership interests); and intellectual property rights (patents, copyrights, and royalties from such rights) held by an investigator or the investigator's immediate family, individually or in aggregate, when such interest involves:

i. Payments in excess of $10,000 (including salary, consulting fees, royalty or licensing payments from intellectual property, and honoraria and/or gifts) received within the past 12 months or anticipated for the next 12 months (excluding salary and other payments for services from the University);

ii. An equity interest in a publicly traded company worth more than $10,000 or more than 5 percent of the business entity as determined by reference to its publicly listed price (excluding mutual funds);

iii. Any equity interest if the value cannot be determined by reference to publicly listed prices (i.e., an equity interest in a privately held company, such as a start-up company);

iv. A position giving rise to a fiduciary duty, such as director, officer, partner, trustee, employee, or any other position of management; or

v. Intellectual property rights (patents or copyrights) or royalties from such rights whose value may be affected by the outcome of the research, including royalties distributable under University policy or any royalty-sharing agreements involving the University.

For UT Knoxville IRB members only, the following indicate a conflict of interest with a protocol under review: she or he serves as a co-investigator, other member of the research team, or faculty advisor or a member of his or her immediate family serves as a co-investigator, other member of the research team, or faculty advisor.

**Immediate family** means spouse or domestic partner, and dependent children.

Personal agreements between sponsors and investigators, IRB members, or their immediate family members where the amount of compensation (consulting, board honoraria, or any other kind) could change depending on the outcome of a study or any other activity the faculty/IRB member performs as part of their University service are prohibited. In some cases, such arrangements are illegal under state law.

**Continuing Noncompliance** Any noncompliance that occurs repeatedly to the point of suggesting a pattern or an underlying problem. Continuing noncompliance may occur due to lack of knowledge
(unintentional) or due to deliberate choice to ignore regulations or determinations of the IRB (intentional).

**Existing (Data, Documents, Records, Pathological or Diagnostic Specimens)** Existing with regards to these materials means the items must be "on the shelf" or in existence at the time the project is submitted to the IRB for review.

**Federal Agency** Other than DHHS that is subject to "The Common Rule" Any one of the following: Agency for International Development (22 CFR 225); Central Intelligence Agency (Executive Order); Consumer Products Safety Commission (16 CFR 1028); Department of Agriculture (7 CFR 1c); Department of Commerce (15 CFR 27); Department of Defense (32 CFR 219); Department of Education (34 CFR 97); Department of Energy (10 CFR 745); Department of Homeland Security (Public law 108-458 Sec. 8306); Department of Justice (28 CFR 46); Department of Transportation (49 CFR 11); Department of Veteran's Affairs (38 CFR 16); Environmental Protection Agency (40 CFR 26); Housing and Urban Development (24 CFR 60); National Aeronautics and Space Administration (14 CFR 1230); National Science Foundation (45 CFR 690); Office of Science and Technology Policy (Adoption of policy); Social Security Administration (Public law 7.5.26)

**Guardian** a person who is not the parent of a child, but who has been appointed by a court or juvenile court having jurisdiction over the child, to have a permanent self-sustaining relationship with the child and to make important decisions which have a permanent effect on the life and development of that child and to promote the general welfare of that child. A guardian may be a court or a juvenile court.

**Human participant**

*DHHS definition:* a living individual about whom an investigator (whether professional or student) conducting research obtains a) data through intervention or interaction with the individual, or b) identifiable private information. (From 45 CFR 46.102.(d))

*FDA definitions* (human participant): -an individual who is or becomes a participant in research, either as a recipient of the test article or as a control. A participant may be either a healthy human or a patient. (From 21 CFR 50.3(g))

-(Subject): a human who participates in an investigation, either as an individual on whom or on whose specimen an investigational device is used or as a control A subject may be in normal health or may have a medical condition. (From 21 CFR 812.3(p))

**Identifiable Private Information** -private information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and/or information which has been provided for specific purposes by an individual and which the individual can reasonably expect will not be made public (for example, a medical record). This information is considered individually identifiable if the identity of the subject is or may readily be ascertained by the investigator or associated with the information. [45 CFR 46.102(f)(2)]

If information includes Protected Health Information (as defined later under Protected Health Information), identifiable information includes any of the following information for the individual, relative, employer, or household member of the individual:

(1) Names;

(2) all geographic subdivisions smaller than a state, except for the initial three digits of the ZIP code if the geographic unit formed by combining all ZIP codes with the same three initial digits contains more than 20,000 people;

(3) all elements of dates except year, and all ages over 89 or elements indicative of such age;
(4) telephone numbers;
(5) fax numbers;
(6) email addresses;
(7) social security numbers;
(8) medical record numbers;
(9) health plan beneficiary numbers;
(10) account numbers;
(11) certificate or license numbers;
(12) vehicle identifiers and license plate numbers;
(13) device identifiers and serial numbers;
(14) URLs;
(15) IP addresses;
(16) biometric identifiers;
(17) full-face photographs and any comparable images;
(18) any other unique, identifying characteristic or code, except as permitted for re-
identification in the Privacy Rule.

Interaction An interaction includes communication or interpersonal contact between investigator and
participant.

Intervention An intervention includes both physical procedures by which data are gathered (for example,
venipuncture) and manipulations of the participant or the participant’s environment that are
performed for research purposes.

Legally authorized representative (LAR) - an individual or judicial or other body authorized under
applicable law to consent on behalf of a prospective subject to the subject's participation in the
procedure(s) involved in the research.

Minimal risk the probability and magnitude of harm or discomfort anticipated in the research are not
greater in and of themselves than those ordinarily encountered in daily life or during the
performance of routine physical or psychological examinations or tests. [45 CFR 46.102(l) and 21
CFR 50.3(k)]

In research involving prisoners the probability and magnitude of physical or psychological harm
that is normally encountered in the daily lives, or in the routine medical, dental, or psychological
examination of healthy persons. [45 CFR 46.303(d)]

Minor modifications modifications to a research project and/or consent documents that pose no
additional risk to subjects (e.g. changes in title, co-investigator(s), funding sources). If the
modification is an addition or modification of procedures they must fall into one of the categories
eligible for expedited review. To be considered a minor modification, it must also maintain similar
or increased safeguards to protect the subject.

Noncompliance failure to follow the federal regulations with respect to protection of human participants
in research or failure to follow the determinations of the IRB with respect to conduct of the research
as approved by the IRB.

Nonscientist - an individual who has little or no formal scientific or medical training or experience.
Permission - Affirmative agreement by parents or guardians for a child to participate in a research, a partial substitute for consent (since a minor is not legally qualified to give consent on their own behalf). See also "assent."

Privacy freedom from unauthorized intrusion or the state of being let alone and able to keep certain personal information to oneself.

Protected Health Information (PHI) information that:
1. is transmitted or maintained in any form (electronic, oral, paper) by a covered entity, and
2. identifies the individual or could reasonably be used to identify the individual; and
3. relates to the past, present or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present or future payment for the provision of healthcare to an individual. [From 45 CFR 160.103]

Quorum a majority of voting members of an IRB, including at least one member whose primary expertise is in a nonscientific area.

Research - a systematic investigation, including research development, testing and evaluation, designed to develop or contribute to generalizable knowledge. Activities that meet this definition constitute research even if they are a component of a larger non-research activity (e.g., instruction, demonstration.) [From 45 CFR 46.102(d)]

Research Misconduct fabrication, falsification, plagiarism, or other practices that seriously deviate from those that are commonly accepted within the research community for proposing, conducting, or reporting research. It does not include honest error or honest differences in interpretations or judgments of data or creative innovations that are nonetheless ethical, legal and meet professional standards.

Risk the probability of harm or injury (physical, psychological, social, or economic) occurring as a result of participation in a research study. Both the probability and magnitude may vary from minimal to significant.

Serious adverse drug experience Any adverse drug experience (associated with the use of the drug) occurring at any dose that results in any of the following outcomes: death, a life-threatening adverse drug experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse drug experience when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed above. ([rom 21 CFR 312.32(a)]

Serious Noncompliance Noncompliance that materially increases risks or that results in unexpected substantial harm to subjects or others. In addition the following instance(s) of noncompliance, as defined by OHRP, will always be determined as serious noncompliance:
- Non-Exempt human participants research being carried out without IRB review and approval or without appropriate informed consent.
- Substantive modifications to IRB-approved research without IRB approval.

Significant Risk (SR) device study - one that presents a potential for serious risk to the health, safety, or welfare of a subject and (1) is intended as an implant; or (2) is used in supporting or sustaining human life; or (3) is of substantial importance in diagnosing, curing, mitigating or treating disease, or otherwise prevents impairment of human health; or (4) otherwise presents a potential for serious risk to the health, safety, or welfare of a subject. [From 21 CFR 812.3(m)]
Suspension - By requirement of the convened IRB or the IRB Chair, a temporary halt to a selection of research activities being conducted under an IRB-approved project or a temporary halt to the IRB approved project as a whole.

Termination - By requirement of the convened IRB, a permanent halt to some or all research activities in a previously approved IRB project.

Test Article any drug for human use, biological product for human use, medical device for human use, human food additive, color additive, electronic product, or any other article subject to regulation under the Federal Food Drug and Cosmetic Act, or under sections 351 or 354-360F of the Public Health Service Act. (From 21 CFR 50.3(j) and 21 CFR 56.102(l))

Unanticipated adverse device effect Any serious adverse effect on health or safety or any life-threatening problem or death caused by, or associated with, a device, if that effect, problem, or death the frequency, specificity or severity of which has not previously been identified in the investigational plan or application, or any other unanticipated serious problem associated with a device that relates to the rights, safety, or welfare of subjects. [From 21 CFR 812.3(s)]

Unanticipated problem involving risk to subjects or others Any problem or event that:

a. was not expected given the nature of the research, the population under study and the approved procedures or protocol for conduct of the study, impacts the rights, safety, or welfare of subjects or others (e.g. those not directly involved in the research such as research staff or family members), and

b. is related to the research intervention, research procedures, and/or conduct of the research study.

Unexpected adverse drug experience Any adverse drug experience (associated with the use of the drug), the frequency, specificity or severity of which is not consistent with the current investigator brochure; or, if an investigator brochure is not required or available, the specificity or severity of which is not consistent with the risk information provided to subjects and the IRB. [from 21 CFR 312.32(a)]