



Frequently Asked Questions About Research Involving Human Subjects

Click on a question to go to its answer.

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M What is the purpose of the Institutional Review Board (IRB)?

M What activities count as research?

M When is research exempt from review? What does it mean when research is exempt from review?

M When can review be expedited? What does this mean?

M Are there special requirements if the research involves children?

M What is the difference between "consent", "permission", and "assent"?



F A Q
R E Q U E S T I O N S
U R G E N T L Y

M Are there special requirements if the research involves prisoners?

M Are there special requirements if the research involves pregnant women?

M Are there special requirements for other groups of subjects?

M What is The Belmont Report?

M What if my department does not have a Departmental Review Committee (DRC)? What if the DRC is not available right now to review my protocol?

M What sort of review is needed for a pilot project?

M What sort of review is needed for a class project?

M Telephone Survey - What sort of review is needed? What sort of consent is required?

M What sorts of things are likely to keep my proposal from being approved or delay its approval?

M How *complete* do I have to be in describing my research project?



M What is the difference between "anonymous" and "confidential"?

M What special issues arise when I am audiotaping or videotaping?

M What issues are involved in data storage and reuse?

F A Q

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Click [here](#) to go to a list of web sites dealing with Ethics in Research.

REVISED: January 6, 2001



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What is the purpose of the Institutional Review Board (IRB)?

Institutional Review Boards were mandated by Federal Regulation for two purposes: (1) to implement federal guidelines and (2) to disseminate information about the guidelines throughout the institution. In the best institutions, however, they have taken on more than a legalistic function, serving as the forum for developing the institution's own principles for the ethical conduct of research involving human subjects.

WANT MORE INFORMATION? CLICK [HERE](#) AND YOU WILL BE TRANSPORTED TO THE RELEVANT SECTION OF THE IRB GUIDEBOOK. CLICK ON THE BACK BUTTON ON THE ADOBE ACROBAT CONTROLS TO RETURN HERE.



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What activities count as research?

The shortest answer is "any systematic attempt to gain generalizable knowledge about humans." Federal regulations define *research* as "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge." [45 CFR 46.102(b)], and they define *human subject* as "a living individual, about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information." [45 CRF 46.102(f)].

So, unless you are willing to say that your work does not produce generalizable knowledge or you can prove that you are not using human subjects or identifiable information about humans, you qualify as doing research.

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[CLICK HERE](#) TO GO TO AN INTERACTIVE GUIDE TO THE DEFINITION OF RESEARCH TO DETERMINE WHETHER YOUR PROJECT FALLS UNDER THE JURISDICTION OF THE IRB.



FAQ R S U E K E Q E S U D T E I N O T N L Y S

When is research exempt from review? What does it mean when research is exempt from review?

WHEN: Federal regulations list certain categories of research that can be exempt from review. Those are set out in the IRB Guidebook *.(Click below to go to this section..)* In addition to federal requirements, UT specifies that only research conducted without external funding qualifies for exemption.

WHAT DOES IT MEAN?: In typical bureaucratic fashion, "exempt from review" does not mean that you avoid review. "Exempt" projects must be reviewed by **SOMEBODY** to determine that they **ARE** exempt. At UT, we delegate this review to the Departmental Review Committee – with requirements for reporting to and oversight by the IRB. What it is exempt from, then, is review by the **FULL** campus IRB or its staff.

Exempt research also requires a less extensive documentation. You submit "Form A" instead of "Form B."
(See the IRB Guidebook for examples of both forms and instructions.)

Do not assume, however, that the requirements for protection of subject welfare is relaxed just because the review requirements are relaxed. You are still fully responsible for obtaining fully informed consent from subjects **AND** for taking every reasonable precaution to protect the welfare of subjects.

Also remember that you must not gather any data until the project has been approved by the DRC and reported by them to the IRB.

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[CLICK HERE](#) TO GO TO AN INTERACTIVE GUIDE TO THE EXEMPT CATEGORIES TO DETERMINE WHETHER YOUR PROJECT COULD QUALIFY.



FAQ R S U E K E Q E S U D T E I N O T N L S Y

When can review be expedited? What does this mean?

WHEN: Federal regulations list certain categories of research for which review can be "expedited." These, too, are set out in the IRB Guidebook. (*Click below to go to this section..*) In addition, we are preparing an interactive guide to these categories to make it easier for you to determine when your activity qualifies. WATCH this space for a link to that site.

WHAT DOES IT MEAN?: Expedited review is delegated by the full IRB to one or more of its members. The practical advantage is that this can be conducted in a matter of days instead of waiting for the monthly meeting of the full IRB. It is not reasonable, however, to expect it to be conducted in a matter of HOURS – it takes time to transmit the protocol to the designated reviewers, for them to read it and think it through, and for them to communicate with each other (*if there is more than one reviewer designated*) and with the IRB staff.

As with exempt review, none of the protections are relaxed. The investigator is still responsible for obtaining fully informed consent from subjects and for taking every reasonable precaution to protect the welfare of subjects.

Since the stakes are somewhat higher with the research that fits into these categories, more extensive documentation is required – i.e., Form B. (*See Section 10 of the IRB Guidebook for a sample Form B and Section 8 for instructions for completing it.*)

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[CLICK HERE](#) TO GO TO AN INTERACTIVE GUIDE TO THE EXPEDITED REVIEW CATEGORIES TO DETERMINE WHETHER YOUR PROJECT COULD QUALIFY FOR EXPEDITED REVIEW.



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Are there special requirements if the research involves children?

YES. Children are regarded as a "vulnerable" population and therefore special protections are required.

Children are also incapable of giving legally valid consent for participation, so parental "permission" sometimes substitutes for and sometimes accompanies child "assent" (*See question below on the distinction between consent / permission / assent, as well as Section 9 of the IRB Guidebook.*)

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What is the difference between "consent", "permission", and "assent"?

Consent is a legal as well as an ethical concept. In the law, no one under the age of majority (18 in Tennessee) is capable of giving consent. Federal guidelines provide for this by setting up a system of parental *permission* for children to participate in research. When children are capable of a role of their own in the consent process, their agreement to participate is called *assent*. It is left to each IRB to determine the age and circumstances in which children play roles in the consent process. Our general policy is that children 7 or older must give assent to supplement the permission of their parents; and above about 14, the assent of the child should be sought **prior to** the permission of the parents.

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Are there special requirements if the research involves prisoners?

YES. Prisoners are another population regarded as "vulnerable" – due to their total dependence on the correctional facility in which they are incarcerated – so special protections are required. One feature of the regulations that makes things sticky here is that your research is required to incorporate these special protections even if your subject BECOMES a prisoner AFTER being enlisted as a subject. So, for long-term studies, there may be some obligation to keep in touch with your subjects.

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Are there special requirements if the research involves pregnant women?

YES. Pregnant women are another "vulnerable" population.

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Are there special requirements for other groups of subjects?

YES. Another group labeled as "vulnerable" in federal guidelines are mentally disabled individuals. Furthermore, the local IRB can designate groups as requiring special protections. The UT IRB has made this designation for (a) HIV-positive individuals and (b) residents of battered women's shelters. Other groups might be designated as "vulnerable" in the future.

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What is The Belmont Report?

After the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research had drafted the basic guidelines for the protection of human subjects, they attempted to state the principles on which their rules were grounded. The result is The Belmont Report (named for the retreat center at which it was written).

In Section 10 of Form B, investigators promise that they "subscribe to the principles stated in The Belmont Report" – so it would be a good idea to read the report in order to know what you are subscribing to.

WANT MORE INFORMATION? CLICK [HERE](#) AND YOU WILL BE TRANSPORTED TO AN ON-LINE VERSION OF THE BELMONT REPORT. THIS WILL OPEN A NEW BROWSER WINDOW. YOU MUST CLOSE THAT WINDOW TO RETURN HERE.



F A Q
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What if my department does not have a Departmental Review Committee (DRC)? What if the DRC is not available right now to review my protocol?

The BEST thing to do would be to use this occasion to CREATE a DRC for your department. Contact the Compliances Section for any assistance you might need.

If time does not permit creating a DRC, or if the DRC members are not available in the time-frame you need (for example, during the Summer months), the Department Head has the authority to review the protocol on behalf of the DRC. In that case, a Dean of your College must conduct the oversight review and sign the form in the place where the Department Head usually signs.

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What sort of review is needed for a pilot project?

A pilot project does not receive any special consideration just because it is not the "final, official" study. It must be reviewed through the regular process just as any other study.

That said, there are a couple of caveats here: (1) If you are conducting the pilot study prior to applying for external funding, the pilot study might be eligible for classification as exempt from review (*See Section 5 of the IRB Guidebook for the criteria for exemption*) though review will be required of the final, externally-funded study.

(2) The Compliances staff will be happy to work with you to avoid unnecessary duplication of efforts on both our parts. For example, if your pilot project aims to develop a survey instrument which will later be administered to a larger population, it might be possible to structure your Form B in such a way that the developed-instrument is treated as a CHANGE in the project (*Form D*) instead of having to be approved as a separate study.



FAQ R E Q U E S T I O N S R E Q U E S T I O N S R E Q U E S T I O N S

Telephone Survey - What sort of review is needed? What sort of consent is required?

It is obviously very difficult to obtain a signed consent form in a telephone exchange. (In these days of ubiquitous fax machines, it is not IMPOSSIBLE to do this; but it would be complicated and awkward.) Generally, verbal consent is adequate. However, it must still involve ALL the elements of fully informed consent. In order to verify this, the IRB must review a script of just what will be said to each potential subject to obtain their consent.

The IRB must also review the script for the telephone survey, as well as a description of the process of identifying potential subjects and measures to protect the confidentiality of participants.



FAQ R E S U E S Q U E S T I O N S D I F F I C U L T T O A N S W E R

What sorts of things are likely to keep my proposal from being approved or delay its approval?

The Top Ten Reasons Why Protocols are Delayed and/or Disapproved:

1. Missing signatures
2. Duplicate signatures - no one person can sign in two places (e.g., PI & DRC Chair)
3. Missing letters of approval from research sites
4. Sections of Form B omitted
5. Copies of research instruments not supplied
6. Unclear what part of the activity is experimental and what part is the service being evaluated
7. Description of activity unclear or incomplete
8. Inconsistencies between project description in protocol and in informed consent
9. Consent form unclear or incomplete
10. Improper request to exempt or expedite project



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How *complete* do I have to be in describing my research project?

You need to describe the project in enough detail that reviewers can understand just what is to be done. It is best to describe the process step-by-step, so you don't leave something out and/or the reviewer does not confuse one step with another. Remember, the reviewers may not be familiar with the jargon of your field of research. Explain things in terms that an educated layperson can readily understand. If you are in doubt as to whether to include an element in the description, **PUT IT IN**. Better redundancy and **over**description than gaps in your account.

WANT MORE INFORMATION? [CLICK HERE](#) AND YOU WILL BE TRANSPORTED TO THE RELEVANT SECTION OF THE IRB **GUIDEBOOK**. **CLICK ON THE BACK BUTTON ON THE ADOBE ACROBAT CONTROLS TO RETURN HERE.**



What is the difference between "anonymous" and "confidential"?

A response is *anonymous* if NOBODY but the respondent knows who it came from. For example, a survey questionnaire which is returned without any identifiers at all is anonymous. In contrast, a *confidential* situation is one in which someone KNOWS the identity of the respondent but that information is protected by some measure(s). For example, if you promise to remove the name from a survey questionnaire and to substitute code numbers, you are protecting confidentiality; but, as long as YOU saw the name, you cannot claim it is anonymous.

It is important to remember that names are not the only identifiers. If you have only one senior citizen in your class, for example, then a questionnaire passed out to the class which asked for age would **not** be anonymous. There must be **no** identifiers for the data to qualify as anonymous; data cannot be **made** anonymous by stripping identifiers (since whoever stripped the identifiers had an opportunity to know the identities).

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What special issues arise when I am audiotaping or videotaping?

First, anonymity is impossible if the voice and/or image of the participant is recorded. You can promise confidentiality if you transcribe tapes removing all identifiers and then destroy the tapes, but (a) you must have all those involved in the transcription process sign a pledge of confidentiality and (b) you should inform the participant as to who will have access to the tapes themselves (i.e., transcriptionist(s), dissertation committee member(s), data analysis team).

Second, archiving tapes for future use requires an explicit explanation to and consent from the participant. We recommend that this be separate from consent to participate in the research – although it could be incorporated into the same consent form, it should be structured to require a separate act of consent (i.e., a separate signature).

Third, even with the consent of the participant, discretion should be exercised in making use of tapes – especially in the classroom setting or in local conferences. People known to the subject may identify them inadvertently.

WANT MORE INFORMATION? CLICK [HERE](#) AND YOU WILL BE TRANSPORTED TO THE RELEVANT SECTION OF THE IRB GUIDEBOOK. CLICK ON THE BACK BUTTON ON THE ADOBE ACROBAT CONTROLS TO RETURN HERE.



FAQ R E S U E K E S Q U E S T I O N S T L Y

What issues are involved in data storage and reuse?

If you know in advance that you want to retain the data you are collecting, you should inform the prospective subjects and get their consent for this. We recommend that the consent to archive the data be separate from consent to contribute it for the present research project.

Data for thesis and dissertation projects should be retained by UT faculty. It is the UT IRB that would have to vouch for the protection of this data if we were audited, and we cannot pass this responsibility off to the individual researcher or to another institution.

Federal Regulations define *research* as "a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge" [45 CFR 46.102(d)]

If your project satisfies ANY ONE of the descriptions below, click on the **YES** box; if it satisfies NONE of the descriptions below, click on the **NO** box:

- systematic observation and data collection which is intended for release to the scientific community as a contribution to knowledge (i.e., thorough publication, presentation to a professional group, or other form of dissemination)
- systematic observation and data collection which is portrayed (explicitly or implicitly) by university students, faculty, or staff as "research" or "experimental" investigation
- systematic observation and data collection intended to fulfil the requirements for a master's thesis, doctoral dissertation, or other research requirements at the

YES

at least **ONE** of the descriptions above is true of my project

NO

NONE of the descriptions above is true of my project

If your project satisfies EITHER of the descriptions below, click on the **YES** box; if it satisfies NEITHER of the descriptions below, click on the **NO** box:

- data collection for internal departmental or other university administrative purposes (e.g., teaching evaluations, student evaluations, and staff evaluations)
- *program evaluation carried out under contract for an external organization that is for their internal purposes only (i.e., no external reporting to any funding or public agency or plans to publish the findings or otherwise disseminate them). Examples of program evaluation include: personnel studies, staff effectiveness studies, human cost benefit analysis, treatment effectiveness studies, or human engineering studies.*

YES

at least **ONE** of the descriptions
above is true of my project

NO

NEITHER of the descriptions above
is true of my project

Federal regulations define a *human subject* as "a living individual, about whom an investigator (whether professional or student) conducting research obtains (1) data through intervention or interaction with the individual, or (2) identifiable private information" [45 CFR 46.102(f)]

If your project does NOT involve living individuals or information about them in **any** way, click NO below; otherwise, click on YES.

YES

NO

Intervention is defined to include "both physical procedures, by which data are gathered (for example, venipuncture), and manipulations of the subject or the subject's environment that are performed for research purposes."

Interaction "includes communication or interpersonal contact between investigator and subject." [45CFR 46.102(f)]

If your project does not involve **any** form of intervention **or** interaction with human subjects, as defined here, click on NO; otherwise, click on YES.

YES

NO

Private information "includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and 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). Private information must be individually identifiable (i.e., the identity of the subject is or may be readily be ascertained by the investigator or associated with the information)" [45 CFR 46.102(f)]

If your project does not involve **any** gathering of private information about individuals, as defined here, click on NO below; otherwise, click on YES.

YES

NO

It appears that your project does NOT constitute research involving human subjects. Hence it is not subject to the authority of the IRB.

Best wishes in conducting your research project.

Of course, this does not remove the ethical imperative to safeguard the welfare of any persons with whom you come into contact in the course of your project. It is just that this is now your personal and professional responsibility, not the purview of the IRB.

Your project **DOES** constitute research involving human subjects and hence it does come under the jurisdiction of the IRB.

Click on the appropriate box below to proceed to determine whether your project might be exempt from review by the IRB or eligible for expedited review.

EXEMPT

EXPEDITED

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Is your project externally funded?

YES

NO

Your project does NOT qualify as exempt from review.
Click on the link below to proceed to the determination
of whether it might be eligible for EXPEDITED review.

EXPEDITED

Does the project involve more than "minimal risk" for subjects?

Federal regulations define *minimal risk* as "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(i)]

If you are CONFIDENT that no more than "minimal risk" is involved, click on NO; if there is any question, click on YES.
WARNING: If you say "no" and the departmental review committee disagrees, you will be required to fill out more paperwork for an IRB review.

YES

NO

Does your project involve

- prisoners
- fetuses
- pregnant women

or

in vitro fertilization?

If ANY of these are involved, click YES; if NONE of them, click NO.

YES

NO

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Does your project involve CHILDREN (i.e., any subject under 18 years of age)?

YES

NO

Does the project consist of observation of public behavior of the children in which the investigator does **not** participate in the activities being observed and the behavior is **not** audiotaped or videotaped?

YES

NO

Click on the box below that represents the category of research involved in your project.

Research conducted in established or commonly accepted educational settings involving normal educational practices, such as research on regular and special educational instructional strategies, or research on the effectiveness or, or comparison among instructional techniques, curricula, or classroom management methods.

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

Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens.

Research and demonstration projects which are conducted by or subject to the approval of Department or Agency heads, **and** which are designed to study, evaluate or otherwise examine (i) public benefit or service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures, or (iv) possible changes in methods or levels of payment for benefits or services under those programs.

Taste and food quality evaluation and consumer acceptance studies.

None of the above.

Your project involves: Research conducted in established or commonly accepted educational settings involving normal educational practices, such as research on regular and special educational instructional strategies, or research on the effectiveness or, or comparison among instructional techniques, curricula, or classroom management methods.

Federal regulations require that confidentiality of identifiable information must be maintained without the express permission of the participants to do otherwise.

Do you **either** have express permission to reveal identities **or** adequate measures to protect confidentiality?

YES

NO

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

If **both** of the following conditions are satisfied, click on YES; otherwise click on NO:

- information obtained is recorded in such a manner that human subjects can be identified, directly or through identifiers linked to the subjects, **and**
- any disclosure of the human subjects' responses outside the research could reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, or reputation.

YES

BOTH are true

NO

one or both are false

If **either** of the following conditions applies to your project, click on YES; otherwise click on NO.

- the human subjects are elected or appointed public officials or candidates for public office; **or**
- federal statute(s) require without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

YES

at least one of these applies

NO

neither applies

Your project involves: Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens.

If **either** of the following conditions are true of your project, click on YES; otherwise, click on NO.

- these sources are publicly available
- the information is recorded by the investigator in such a manner that subjects cannot be identified, directly or through identifiers linked to the subjects.

YES

at least one of these applies

NO

neither applies

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Your project involves: Taste and food quality evaluation and consumer acceptance studies.

Are the foods involved wholesome foods without additives?

YES

NO

Your project involves: Taste and food quality evaluation and consumer acceptance studies.

Does the food to be consumed contain only:

- 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?

YES

NO

CONGRATULATIONS!

Your project appears to be eligible for exemption from IRB review.

You need to complete an IRB **Form A** and submit it to your Departmental Review Committee (DRC). Be sure to **document** the basis for the exemption in detail so the DRC can review it.

REMEMBER: You must not enroll any subjects or gather any data until the DRC has approved your project and forwarded it to the Compliances Office.

Click [here](#) and you will be transported to a sample **Form A**, complete with instructions for filling it out.

Does the project involve more than "minimal risk" for subjects?

Federal regulations define *minimal risk* as "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(i)]

If you are CONFIDENT that no more than "minimal risk" is involved, click on NO; if there is any question, click on YES.

YES

NO

Your project does NOT qualify for expedited review.
Prepare the number of copies to submit for full
committee review.

Click [here](#) for instructions about full IRB review.

Is the data you are gathering such that 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, or reputation?

YES

NO

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Do you have concrete plans to implement reasonable and appropriate protections so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal?

YES

NO

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Is your research CLASSIFIED?

YES

NO

Is the **ONLY** procedure involved in your project:

(1) Clinical studies of drugs and/or medical devices

YES

NO

EXPEDITED?

Does it consist in research on drugs for which an investigational new drug application (21 CFR Part 312) is **not** required?

YES

NO

Can you assure the IRB that this research does **not** significantly increase the risk or decrease the acceptability of the risks associated with the use of the product?

NOTE: Be prepared to support these claims with documentation!

YES

NO

Does it consist on research on medical devices for which

1. An investigational device exemption application (21 CFR Part 812) is **not** required; **or**
2. The medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling?

YES

NO

Is the **ONLY** procedure involved in your project:

(2) collection of blood samples by finger stick, heel stick, ear stick, or venipuncture

YES

NO

Is the collection of blood samples:

- from healthy, nonpregnant adults who weigh at least 110 pounds **and**
- the amounts drawn will not exceed 550 ml in an 8 week period **and**
- collection will not occur more frequently than 2 times per week?

YES

NO

Is the collection of blood samples:

- from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected
- the amount drawn will not exceed *the lesser of* 50 ml or 3 ml per kg in an 8 week period and
- collection will not occur more frequently than 2 times per week

YES

NO

Is the **ONLY** procedure involved in your project:
(3) Prospective collection of biological specimens for
research purposes by noninvasive means.

EXAMPLES: (a) hair and nail clippings in a nondisfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gumbase or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with established prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

YES

NO

Is the ONLY procedure involved in your project:

(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.)

Click [here](#) to see some examples of this category.

YES

NO

Is the ONLY procedure involved in your project:

(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).

YES

NO

Is the **ONLY** procedure involved in your project:

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

YES

NO

Is the **ONLY** procedure involved in your project:

(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?

YES

NO

If no ONE of the categories described your research, is it the case that your project involves **two or more** of the categories listed **and no other elements**?

YES

NO

CONGRATULATIONS!

Your project appears to be eligible for expedited review. You need to complete an IRB **Form B** and submit it to your Departmental Review Committee (DRC) and then to the Compliances office. Be sure to **document** the basis for your judgment that review is expeditable, so the DRC and the IRB staff can review it.

REMEMBER: You must not enroll any subjects or gather any data until your project has been approved and you have made any changes recommend and had **those** approved.

Click [here](#) and you will be transported to a the section of the IRB Guidebook which explains the procedures for expedited review.

**University of Tennessee
Institutional Review Board**

**Instruction Guide
for Faculty, Staff, and
Students**

Revised June 1999

**Compliances Section Office
404 Andy Holt Tower
University of Tennessee
(865) 974-3466**

www.ra.utk.edu/ora/sections/compliances/humsub/toc.html

University of Tennessee Institutional Review Board Instruction Guide for Faculty, Staff and Students - Revised June 1999

Introduction

This guide was prepared to help researchers comply with the University of Tennessee, (UT) policies, and federal regulations concerning the use of humans in research. This guide outlines the basic policies and procedures on which the UT system of project review is based. If you need more information or would like to discuss specific aspects of your research with someone from the UT Institutional Review Board (IRB), please contact the Compliances Section Office at 974-3466.

Fundamental UT Policy on Human Research Participant Protection

All UT research involving human participants must be reviewed following UT-IRB procedures and approved prior to the initiation of research activity and contact with potential human participants. The best 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 the UT-IRB. There are 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 laws and regulations, and UT policies concerning the use of human participants in research. However, 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 sent to Departmental Review Committees, Department Heads, and posted on the Compliances Section Web site www.ra.utk.edu/ora/sections/compliances/humsub/toc.html. The most current version of the guide can be found on the Compliances Section Web site.

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:

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

3. Read Section 4 to learn more about informed consent procedures and documents.
4. Read Section 5, 6, or 7 to obtain information about completing your application form.
5. Section 8 presents step-by-step instructions for preparing a Form B application.
6. If you intend to use children, pregnant women, mentally disabled individuals, or prisoners, read Section 9.
7. If you intend to use participatory action research (PAR) techniques, read Section 10.
8. If you need copies of UT-IRB Forms, read Section 11. You may also want to contact your Departmental Review Committee Chair or the Compliances Section Office at 974-3466 to obtain the current versions of UT-IRB Forms. Current versions of UT-IRB Forms can be obtained Compliances Section Web site www.ra.utk.edu/ora/sections/compliances/humsub/toc.html.
9. If you have any questions about the preparation of your application, after reading this guide, please contact the Compliances Section Office at 974-3466.

Institutional Review Boards: The Basics*

What Do Institutional Review Boards Do?

The responsibilities of IRBs fall into two main categories: initial review and continuing review of research involving human participants.

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 to be used in recruiting participants, and other relevant documents. In carrying out this review, IRBs seek to ensure that: (a) any risks participants may incur are warranted in relation to the anticipated benefits; (b) informed consent documents clearly convey the risks and the true nature of research; (c) advertisements are not misleading; and (d) 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.

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 periodically and reviewed to ensure that the risk-

* Much of this material was originally presented on page 3 of *IRBs: A Time for Reform* (U.S. Department of Health and Human Services publication number OEL-01-97-00193).

benefit ratio of the research has not changed and 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 stories of the abuse of participants during the World War II trials at Nuremburg, the promotional distribution of thalidomide resulting in numerous children born with birth defects, the administration of cancer cells to chronically ill and senile patients at a hospital in New York. The formal requirements for the establishment of IRBs were outlined in regulations stemming from the National Research Act of 1974 and in FDA regulations 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. An estimated 3,000 - 5,000 IRBs exist across the country. Most are associated with hospitals and academic centers.

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

Two agencies within DHHS share responsibility for IRB oversight: the Office for Protection from Research Risks (OPRR) in NIH and the FDA. The OPRR's main tool for oversight is the assurance document. Any institution that intends to conduct DHHS-funded research must have an assurance on file with OPRR. The assurance is a written statement of an institution's requirements for its IRB and human-participant protections. Institutions consistently conducting multiple DHHS-supported studies are eligible for a multiple project assurance (MPA) which can be renewed every five years (a copy of the UT MPA is available from the Compliances Section). The OPRR 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.

Do You Have Additional Questions About the UT-IRB?

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

University of Tennessee Institutional Review Board Guide for Faculty, Staff and Students - Revised June 1999

Outline

	Introduction	
	Fundamental UT Policy on Human Research Participant Protection	i
	Guide Revisions and Additional Information Sources	i
	Tips for Using This Guide	i
	Institutional Review Boards: The Basics	ii
Section 1.	Basic Overview of the UT-IRB	
	Activities of the UT-IRB and Federal Regulations	1
	Jurisdiction of the UT-IRB	1
	Definition of Research	1
	Educational Considerations	2
	Participant Data and Identity Confidentiality Considerations	3
	Classroom-related Activities	3
Section 2.	Review System and Responsibilities	
	Description of the Review Process	4
	Investigators Responsibilities	4
	Departmental Review of Research Projects	5
	Research Center Reviews	5
	Department Head's Responsibilities	5
	University Responsibilities	7
	Compliances Section Responsibilities	7
	Institutional Review Board Responsibilities	8
	Composition of the Appeals Board	10
Section 3.	Guidelines for Selecting the Appropriate UT-IRB Review Procedure	
	Exempt Research Categories (Form A)	11

	Definition of Minimal Risk	12
	Expedited Research Categories (expedited Form B)	12
	Categories of Full IRB Reviewed Research (Form B)	15
	Audio- and Videotaping Considerations	15
	Procedures for Projects that Require Approval from Other UT Compliances Committees	17
	Application Procedures for Off-Campus Research	17
	Advertising to Recruit Participants	18
	General Policy on the use of Children in Research	18
	General Policy on the use of Individuals Selected from Vulnerable Populations in Research	19
Section 4.	Informed Consent Procedures	
	Informed Consent Considerations	20
	Elements of Informed Consent	20
	Additional Elements of Informed Consent	21
	Sample Informed Consent Document	22
	Sample Information Sheet	25
Section 5.	Research Exempt from Review: Form A Applications	
	Exempt Research Overview	27
	Minimal Risk Definition	27
	Exempt Research Categories	28
	Determining if a Research Project Is Exempt	30
	Preparing an Exempt Research Protocol (Form A)	30
	Review Procedures for Form A Applications	31
	Research Funding and Final Approval Procedures	31
	Informed Consent Considerations	32
	Investigator Responsibilities	33
	Graduate Students and Advisors	33
	Renewal and Termination Procedures for Exempt Projects	34

Section 6.	Research Eligible for Expedited Review: Expedited Form B Applications	
	General Information	35
	Expedited Research Categories	35
	Applicability of Expedited Review Categories	37
	Additional Expedited Review Category Information	38
	Expedited Review Procedures	39
	Informed Consent Considerations	40
	Investigators' Responsibilities	41
	Renewal and Termination Procedures for Expedited Projects	42
Section 7.	Research Requiring Full IRB Review: Form B Applications	
	Categories of Full IRB Reviewed Research	43
	Full IRB Review Process	43
	Informed Consent Considerations	45
	Investigators' Responsibilities	45
	Renewal and Termination Procedures	46
Section 8.	Instructions for Completing Form B	48
Section 9.	Research Involving Special or Vulnerable Populations Children	
	General Information	55
	Identifying and Recruiting Potential Child-Participants	56
	Informed Consent Procedures	56
	Risk and Benefit Assessment	58
	Use of Educational Records	59
	Exempt Research Involving Children	60
	Projects Eligible for Expedited Review	60
	Quick Checklist for Research Protocols Involving Children	60

	Mentally Disabled Individuals	
	General Information	61
	Additional Considerations	62
	Minimal Risk Projects	62
	Greater Than Minimal Risk Projects With Expected Direct Participant Benefits	62
	Wards of the State	62
	Greater Than Minimal Risk Projects Without Expected Direct Participant Benefits	63
	Informed Consent Procedures	63
	Pregnant Women	
	Special Considerations	64
	Prisoners	
	General Information	64
	Informed Consent Procedures	64
	IRB Review Procedures	64
Section 10.	Participatory Action Research	
	Project Classifications	66
	Additional Considerations	68
	Background Principles	69
	Basic Ethical Principles	69
Section 11.	Institutional Review Board Forms	
	UT-IRB Form A	71
	UT-IRB Form B	75
	UT-IRB Form D	78

Section 1. Basic Overview of the UT-IRB

Section 1 Contents

Activities of the UT-IRB and Federal Regulations	1
Jurisdiction of the UT-IRB	1
Definition of Research	1
Educational Considerations	2
Participant Data and Identity Confidentiality Considerations	2
Classroom-related Activities	3

Activities of the UT-IRB and Federal Regulations

The University of Tennessee Institutional Review Board (UT-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), "Institutional Review Boards" (21 CFR56), and "Investigational Devices" (21 CFR 412) of the U.S. Food and Drug Administration (FDA). The UT-IRB operates under the principles presented in the University of Tennessee "Multiple Project Assurance." The UT-Multiple Project Assurance is an agreement between the University, represented by the Vice Chancellor of Research, and the DHHS, represented by the Office for Protection from the Research Risk (OPRR) of the National Institutes of Health.

Jurisdiction of the UT-IRB

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

Prior to preparing a research application investigators should determine if (1) the project involves research, and (2) whether the project will involve human participants. Human participants are defined as living individuals about whom an investigator conducting research obtains (a) data through intervention or interaction, or (b) identifiable private information.

Definition of Research

The following definition for human participant research is provided to assist in the process of determining if a project qualifies as human participant research.

Research is defined as 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 or otherwise public form). **or**
- is portrayed (explicitly or implicitly) by university students, faculty, or staff as "research" or "experimental" investigation. **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 possibly by the UT-IRB.

If a proposed activity *cannot* be defined as "research" by one of these criteria, then the protocol does not have to be reviewed by the DRC or UT-IRB.

Examples of observation or data collection activities involving human participants that do not require DRC or UT-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 (i.e., no external reporting to any funding or public agency). Examples of program evaluation include: personnel studies, staff effectiveness studies, human cost benefit analysis, treatment effectiveness studies, or human engineering studies.

Educational Considerations

Research Methods Instruction

Course activities that involve the use of human participants, but have no connection with research beyond the instructional function preclude the need for 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 possibly UT-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 possibly IRB review.

Participant Data and Identity Confidentiality Considerations

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). However, 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 initiated. Confidentiality procedures must be described in research applications that come before the UT-IRB.

Researchers should recognize that the assurance of confidentiality includes keeping the identity of participants confidential. Researchers proposing projects that will address sensitive, stigmatizing, or illegal subjects must explicitly outline the steps they will take to assure 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.

If there is any chance that data or participants' identities might be sought by law enforcement agencies or subpoenaed by a court, a grant of confidentiality should be obtained. Under federal law (Public Health Act § 301(d)), researchers, prior to the initiation of the research project, may request grants of confidentiality to protect against forced data and participant identity disclosures. These grants provide protection for specific research projects where protection is judged necessary to achieve the research objectives. If you believe your research project may require a grant of confidentiality, please contact your Departmental Review Committee Chair or the Compliances Section at 974-3466.

Classroom-Related Activities

The collection of information from respondents for the purpose of class discussion or for the purpose of training in research or research methods does not require IRB review. In this situation, instructors are responsible for the protection of human subjects.

Class-related projects that must be approved:

- All master's theses and doctoral dissertations that involve human subjects.
- All projects for which findings may be published or otherwise disseminated. Since publication will require consent of the participants, it would be prudent to seek IRB review of the informed consent form and other project materials in advance if there is any chance of publication later.
- Class-related projects for which the data collected are archived for any purpose other than administrative evaluations.

Section 2. Review System and Responsibilities

Section 2 Contents

Description of the Review Process	4
Investigator's Responsibilities	4
Departmental Review of Research Projects	5
Research Center Reviews	5
Department Head's Responsibilities	5
University Responsibilities	7
Compliance Section Responsibilities	7
Institutional Review Board Responsibilities	8
Composition of the Appeals Board	10

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-IRB:

- All departments and units of the University of Tennessee (UT);
- All units of the University of Tennessee Space Institute; and
- All other off-campus units of UT or units formally associated with UT, except the University of Tennessee Medical Center.

The UT-IRB does not review research proposals from individuals, organizations, or units not affiliated with the University of Tennessee.

Investigator's Responsibilities

It is the responsibility of investigators (students, faculty advisors, co/principal investigators, etc.) to provide the appropriate review documents (Forms A or B) 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 investigator 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 investigator 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.

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 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.

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 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.

Department Head's Responsibilities

The Assurance of Compliance signed by the University assigns numerous responsibilities to Department Heads. These responsibilities 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 Department Heads. However, Department Heads cannot assign their legal, regulatory, policy or ethical responsibilities to the DRC.

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 or Leader will report the names of the members of DRC to the IRB on Form E annually. The size of 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.

Important Departmental Files

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

1. This Guide, which contains a copy of the [Belmont Report](#), copies of current University IRB Forms (e.g., A, B, and D), a copy of the UT Multiple Project Assurance, and copies of the DHHS regulations presented in 45 CFR 46, and FDA regulations presented in 21 CFR 50 and 56;

2. Copies of federal regulations relevant to research conducted in the department; and
3. Copies of standards of professional ethics applicable to departmental research.

Departmental Review Committee Recommendations

Prior to submission to the IRB, a research proposal must have DRC approval. In addition to the project's research merit, project approval by a DRC is dependent on three factors: i) the level of risk, ii) the characteristics of people who will be asked to participate, and iii) the funding source of the research. Depending on these factors a DRC may require investigators to describe their projects using Form A applications (for minimal risk projects involving nonvulnerable populations), or Form B applications (for greater than minimal risk projects, or projects involving vulnerable populations).

Form A

In general, projects in which participants are exposed to no more than minimal risk and that do not involve minors (under 18 years old), prisoners, fetuses, or pregnant women, can be submitted for review using Form A. Most Form A projects receive "final approval" from the DRC. However, externally funded projects qualifying for Form A consideration must be sent to the Compliances Section for final approval after they have been reviewed by the DRC.

An "externally funded project" is defined as any project that is supported by funds derived from sources outside the university for which a proposal has been prepared and submitted through the Office of Research (OR) Grants and Contracts Section, or the Business Office in the Institute of Agriculture. The proposal must include a set of outcomes or "deliverables" that are intended to be published or shared in some public form.

Examples of projects that are not subject to the "externally funded" definition include student scholarships and fellowships, unrestricted funds from the UT Development Office, UT departmental funds which have been provided under the State Budget, or State of Tennessee contract services. Other funded activities in which data and findings are returned to the sponsor without further dissemination of the data or findings by any UT employee, agent or student are not subject to the externally funded definition.

Possible DRC Form A Project Approvals

Please note that the Compliances Section or the UT-IRB may question the eligibility of a Form A application's exemption and require a nonexempt review before research may begin.

Final Approval of Form A Projects at the Departmental Level: This recommendation signifies that the project has been reviewed against the provisions of Section 4 of this Guide and found eligible for final approval by the DRC. Although work may be initiated immediately after approval by the DRC, copies of the signed and approved Form A must be received within five working days of approval by the Compliances Section.

Recommendation of Approval for Externally Funded Form A Projects: This recommendation signifies that the project has been reviewed against the provisions of Section 4 of this Guide and approval is recommended by the DRC. However, final approval must be granted by the Compliances Section. Once a DRC recommends approval of an Externally Funded Form A, the DRC should forward the original signed Form A to the Compliances Section. All externally funded Form A protocols should be approved or returned to the DRC for clarification within five working days of receipt by the Compliances Section. Work may not begin until final approval has been granted by the Compliances Section.

Form B

Projects that expose participants to more than minimal risk, or involve minors, prisoners, fetuses, or pregnant women, must receive final approval from the UT-IRB before the project can be conducted. These projects must be described using the Form B procedures explained in Sections 6 and 7 of this Guide. 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.

Possible DRC Recommendations for Form B Projects

Recommendation for Expedited Review: This recommendation signifies that the project has been reviewed against the provisions of Section 6 of this Guide and found eligible for expedited review by the UT-IRB. The DRC Chair must identify the specific category(ies) under which the project qualifies for expedited review in the signature block of the Form B. Please note that the Compliances Section, or the expedited reviewer may refer the project to the full IRB Committee for approval.

Approval and subsequent Full IRB Review: This recommendation indicates that the DRC reviewed the project against the provisions of Section 7 of this Guide and found the project eligible for approval by the UT-IRB.

University Responsibilities

The University of Tennessee Multiple Assurance Agreement 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 Compliances Section and UT-IRB to carry out their duties.

Compliances Section Responsibilities

The Compliances Section serves as the focal point for the review and approval of all UT research involving human participants. The Compliances Section is part of the UT Office of Research and administratively answers to the Vice Chancellor for Research. The

Compliances Section 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, Unit Leaders, or DRC Chairs, Compliances Section staff conduct training seminars concerning applicable human participant research policies and procedures for UT faculty and students.

The Compliances Section maintains this Guide and in consultation with the UT-IRB and 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-IRB experience.

The Compliances Section is required to maintain records of all UT research involving human participants for a period of three years following the termination of the research project. The Compliances Section also maintains records of all UT-IRB proceedings and decisions.

The Compliances Section, through the Office of Research, is responsible for reports to the U.S. Department of Health and Human Services (DHHS) about investigational new drug and device certification. The Compliances Section, through the Office of Research, also reports to the Office for Protection from Research Risks (OPRR) of DHHS concerning unanticipated risks or injuries to research participants.

Institutional Review Board Responsibilities

The UT-IRB is the review board for all units of the University in the Knoxville area, except for the University of Tennessee Medical Center. The UT-IRB is required to report the profession, relationship to the University and the qualifications of its membership to DHHS and FDA annually.

Composition of the Institutional Review Board

The composition of the board is required to meet the requirements set forth by the DHHS (45 CFR 46.107) and FDA (21 CFR 56.107).

Members, including the Chair and Vice-Chair, are appointed by the Vice Chancellor for Research.

Members are appointed for a three-year term, rotating one-third of the membership each year.

The UT-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 to it;

- 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, and individuals institutionalized as mentally disabled) is reviewed, the IRB will include one or more members who have primary concern for the welfare of these participants.

Appeals Procedures for UT-IRB Actions

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

Any action of the UT-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.

Investigators wishing to appeal UT-IRB decisions should address a formal letter requesting an appeal to the Compliances Office Assistant Coordinator at 404 Andy Holt Tower. The formal letter requesting an appeal should:

- Identify the project,
- Identify the UT-IRB action in question,
- Describe any steps taken to resolve the concern, and
- List the reasons for appealing the UT-IRB decision.

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

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

The Appeals Board cannot override a decision of the UT-IRB. It can only make recommendations for changes to the UT-IRB. The Board serves as an appellate body and can take the following actions:

- Confirm the decision of the UT-IRB,
- Request modification of the proposed research activities and recommend further review by the UT-IRB,
- Request modification of the UT-IRB decision in question and recommend further review by the UT-IRB, or
- Request disapproval of research activities previously approved by the UT-IRB and recommend further review by the UT-IRB.

If the Appeals Board recommends any changes in the UT-IRB decision, it must submit its recommendation with reasons in writing to the UT-IRB. All Appeals Board recommendations to the UT-IRB will initiate full-board reviews of the research activities in question and address all Appeals Board recommendations. The results of these full-board reviews, consistent with the institutional policy and commitment found in the UT Faculty Handbook, will be sustained without further appeal.

Composition of the Appeals Board

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

- Vice Chancellor for Research (Associate Vice Chancellor for Research may serve as a substitute),
- Compliances Office Assistant Coordinator,
- UT-IRB Chair, and
- Five Assigned Board Members.

The five assigned Appeals Board members will be selected by the Vice Chancellor from a set of senior and former UT-IRB members. The UT-IRB will be notified about changes in Appeals Board assignments by the Vice Chancellor for Research each year in August, but the UT-IRB has no control over the selection of members. Appeals Board members are assigned to the Board for the period designated by the Vice Chancellor for Research.

Substitute Appeals Board members may be assigned by the Vice Chancellor for Research to resolve quorum problems, or to provide needed expertise when the research activities in question involve vulnerable populations. Substitute members serve for the period needed to act on a specific appeal.

Section 3. Guidelines for Selecting the Appropriate Review Procedures

Section 3 Contents

Exempt Research Categories (Form A)	11
Definition of Minimal Risk	12
Expedited Research Categories (expedited Form B)	12
Categories of Full IRB Reviewed Research (Form B)	15
Audio- and Videotaping Considerations	15
Procedures for Projects that Require Approval from Other UT Compliances Committees	17
Application Procedures for Off-Campus Research	17
Advertising to Recruit Participants	18
General Policy on the use of Children in Research	18
General Policy on the use of Individuals Selected from Vulnerable Populations in Research	19

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) the projects are not externally funded and (b) they place participants at no more than minimal risk. Please refer to Section 4 of this guide for more information.

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

Category 1: (Federal Regulation 46.101(b)1)

Research conducted in established or commonly accepted educational settings, involving normal educational practices such as, research on regular and special education instructional strategies, or research on the effectiveness of or the comparison among instructional techniques, curricula or classroom management methods.

Category 2: (Federal Regulation 46.101(b)2)

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

Category 3: (Federal Regulation 46.101(b)3)

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that would not be exempt under Category 2 may be exempt if participants are elected officials, appointed public officials, or candidates for public office; or federal statute(s)

require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

Category 4: (Federal Regulation 46.101(b)4)

Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens may be exempt if these sources are publicly available or if the information is recorded by the investigator in such a manner that participants cannot be identified, directly or through identifiers linked to the participants.

Category 5: (Federal Regulation 46.101(b)5)

Research and demonstration projects which are conducted by or subject to the approval of federal department or agency heads, and which are designed to study, evaluate, or otherwise examine:

- public benefit or service programs;
- procedures for obtaining benefits or services under those programs;
- possible changes in or alternatives to those programs or procedures; or
- possible changes in methods or levels of payment for benefits or services under those programs.

Category 6: (Federal Regulation 46.101(b)6)

Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods *without* additives are consumed, or (ii) foods are consumed that contain a food ingredient *at or below the level and for a use found to be safe*, or agricultural chemical or environmental contaminant *at or below the level found to be safe* by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

Definition of Minimal Risk

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

Expedited Research Categories (Expedited Form B)

Research categories that may be reviewed using expedited review procedures by the University of Tennessee Institutional Review Board (IRB) match federal guidelines and include:

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:
 1. 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
 2. From other adults and children² 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.

² 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 conducted." 45 CFR 46.402(a).
 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.

and use of the audio- or videotapes, and the disposal of the audio- or videotapes.

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 videotaping procedures are used. However, the IRB may allow 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. The use of incomplete or deceptive informed consent always requires full-IRB review and approval. 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.

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 videotapes. The informed consent should provide information about who will have access to the audio- or videotapes and how access will be controlled. Audio- or videotape storage information should state how long the investigator will store the audio- or videotapes and what the investigator will do with the audio- or videotapes at the end of the storage period. The information provided in the informed consent should match similar information provided in the Form B application. Because the contents of audio- or videotapes are identifiable, participants must give their explicit consent for any public use of audio- or videotapes, 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 his/her audio- videotape. Audio- or videotapes 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.

Storage and Future Use Considerations

If you expect to store your audio- or videotapes in ways that will enable others to use the audio- or videotapes, or if you expect to use the audio- or videotapes in additional research projects that are not directly related to the objectives of the study under which they were initially created, please explicitly state these expectations in your protocol and in your informed consent form. Given that the identities of your participants remain on the audio- or videotapes until the tapes are erased or destroyed, you must inform participants about the possibility that others may use the audio- or videotapes or that the audio- or videotapes may be used in additional research projects. There are many legitimate reasons why you might want to use the audio- or videotapes in future research projects, or to allow others to use the audio- or videotapes, but the participants in your initial study need to know about these uses when they consent to participate.

If you anticipate that other researcher may use the audio- or videotapes outside your research project, then you must specify the procedures you will use to grant other researchers access

to your audio- or videotapes in the Form B. The participant's informed consent form should state that other researchers may use the audio- or videotapes in the future.

If you expect to archive the audio- or videotapes in a manner in which access to the tapes will be controlled by other individuals, libraries, or collections, please explicitly state the qualifications of the guardians of the audio- or videotapes and the procedures they will follow to protect the confidentiality of the participants when other researchers request access to the audio- or videotapes. The participants in your study need to know about your plans to allow others to control future access to the audio- or videotapes when they consent to participate, and these plans should be clearly stated in your protocol and informed consent.

The passage of time does not diminish your responsibility to protect the confidentiality of the participants in your 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 videotapes cannot be considered secondary data as long as the tapes contain identifiable information. Please note that new research projects using the archive audio- or videotapes 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, then a Form D that fully describes the new research use may be submitted. In either case, the audio- or videotapes may not be used until final IRB approval is received.

If you have any questions about the development of your Form B application, please contact the Compliances Office in 404 Andy Holt Tower at 974-3466.

Procedures for Projects that Require Approval from Other UT Compliances Committees

Projects that involve the use of animals, radioactive substances, or biological hazards in addition to human participants require approval from separate UT 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-IRB.

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

Application Procedures for Off-Campus Research

If your project involves the use of non-UT facilities as research sites or recruitment sites, then you must obtain letters of compliance from authorized individuals or committees, or

IRB approvals at those sites. Letters of compliance are obtained when the facility does not have its own approved Multiple Project Assurance (MPA) or 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-IRB. If the facility has an approved MPA and IRB, then that IRB must also review and approve your project application before it receives final approval from the UT-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-IRB before you receive approval from the non-UT facilities. However, final UT-IRB approval to move forward with participant contact, recruitment and enrollment will be contingent on project approval from the other IRB, or the Compliances Office receipt of an acceptable letter of compliance, and approval from the UT-IRB. If you have questions about the need to obtain letters of compliance or IRB approvals from non-UT facilities, please contact the Compliances Office at 974-3466.

Advertising to Recruit Participants

All advertisements, poster, flyers, and correspondence aimed at attracting potential research participants must be contained in your Form A or Form B applications. If these materials are not available when you submit your research application, they must be submitted before final approval can be granted. Only reviewed and approved recruiting materials may be used in your research.

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 if participants will be paid or receive free treatments.

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-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, almost all research involving children requires expedited or full-IRB review of Form B applications.** The only exception to this rule (discussed in section 7 of this guide) occurs when the research involves observation of public behavior. All other 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. 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.

The following section 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. Copies of the Form B Application Guidelines are available from your DRC Chair and the Compliances Office Web site, www.ra.utk.edu/ora/sections/compliances/humsub/toc.html. If you have additional questions about your specific research project or need further clarification, please contact the Office of Compliance, 404 Andy Holt Tower, at 974-3466.

General Policy on the use of Individuals Selected from Vulnerable Populations in Research

The UT-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 institutionalized as mentally disabled. The DHHS also considers other individuals vulnerable if they are identified as potential participants because of their availability, comprised positions, or potential susceptibility to manipulation (e.g., students, subordinate employees, economically or educationally disadvantaged individuals, et al.) rather than for reasons directly related to the objectives of the study. As a result, the UT-IRB must also determine that the identification and selection of potential research participants from vulnerable populations is reasonable and not opportunistic.

The 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.

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-IRB policies concerning projects that will use children as research participants, please refer to Section 9 of this guide. If you have additional questions, please contact the Compliances Office at 974-3466.

Section 4. Informed Consent Procedures

Section 4 Contents

Informed Consent Considerations	20
Basic Elements of Informed Consent	20
Additional Elements of Informed Consent	21
Sample Informed Consent Document	22
Sample Information Sheet	25

Informed Consent Considerations

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 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.

If your research involves children, please review consent and assent procedures listed in Section 9 of this guide.

Basic Elements of Informed Consent

As you develop your consent form or procedure, please 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 experimental.
- Describe any foreseeable risks or discomforts to participants.
- Describe any benefits to participants or to others that may reasonably be expected from the research.
- Disclose alternative procedures or courses of treatment, if any, which might be advantageous to participants.
- Describe the extent to which confidentiality of records identifying participants will be maintained, that the records will be stored securely on the UT campus, and who will have access to the records.
- For research involving more than minimal risk, explain whether any compensation or medical treatments are available if injury occurs. If compensation or treatments are

available, they should be described. The procedures for obtaining additional compensation/treatment information should be stated.

- Identify the persons participants can contact for answers to pertinent questions about the research, and participants' rights.
- State that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which participants are otherwise entitled, and that participants may discontinue participation at any time without penalty or loss of benefits to which they are otherwise entitled.

Additional Elements of Informed Consent

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

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

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

Sample Informed Consent Document

(Include or exclude the following information as applicable)

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 study.

If **audiotaping, videotaping, or film** procedures are going to be used, provide information about the use of these procedures. (If applicable, please review pages 15 - 17 of this Guide.)

If you are plan to include **children** in your study, please review Section 9 of this Guide.

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.

CONFIDENTIALITY

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.

Participants initials (place on the bottom front page of two-sided consent forms) _____

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

Indicate what participants will receive for their participation in this study. Indicate other ways participants can earn the same amount of credit or compensation. 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.

EMERGENCY MEDICAL TREATMENT

The University of Tennessee does not "automatically" reimburse participants for medical claims. If physical 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], and [Office Phone Number]. If you have questions about your rights as a participant, contact the Compliance Section of the Office of Research at (423) 974-3466.

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

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. I have received a copy of this form. I agree to participate in this study.

Participant's signature _____ Date _____

Investigator's signature _____ Date _____

----- End of Sample Consent -----

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 minors and one for the parents.

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 any elements of informed consent that are appropriate to your study. If they apply to your study, they must be included.

Sample Information Sheet

Include or exclude information as applicable.

If you have any questions, please contact the Compliances Section 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.

CONFIDENTIALITY

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.

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

Indicate what participants will receive for their participation in this study. Indicate other ways participants can earn the same amount of credit or compensation. 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.

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]. If you have questions about your rights as a participant, contact the Compliance Section at (423) 974-3466.

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

Note: In your Form A or B, please indicate whether this information will be presented orally or given to the subjects in written form. The IRB Committee usually requires that the information be provided in written form.

Section 5. Research Exempt from Review: Form A Applications

Section 5 Contents

Exempt Research Overview	27
Minimal Risk Definition	27
Exempt Research Categories	28
Determining if a Research Project Is Exempt	30
Preparing an Exempt Research Protocol (Form A)	30
Review Procedures for Form A Applications	31
Research Funding and Final Approval Procedures	31
Informed Consent Considerations	32
Investigator Responsibilities	33
Graduate Students and Advisors	33
Renewal and Termination Procedures for Exempt Projects	34

Exempt Research Overview

The human subjects regulations (45 CFR 46), the U.S. Department of Health and Human Services (DHHS) exempted certain types of research from review by Institutional Review Boards (IRB). However, judgment of whether a given research project requires formal review remains a responsibility of the UT-IRB. To meet this responsibility the UT-IRB through the judgement of UT Departmental Review Committees (DRC) certifies that every exempt research project involving human participants indeed meets the requirements for exemption of formal review by the UT-IRB. Thus, the term "exempt" is misleading because it only means that a research activity is exempt from formal (full or expedited) review by the UT-IRB.

All research involving human participants conducted by UT faculty, staff, and students or making use of UT facilities must be reviewed by the UT-IRB or certified as exempt from IRB review by your DRC. The research categories listed in this section identify research activities that qualify for exemption under 45 CFR 46. Please note that federally funded projects that would normally receive final approval from a DRC must be given final approval by the UT-IRB.

All research involving human participants, including projects considered to be "exempt" from formal IRB review, **must be reviewed and approved 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.

Minimal Risk Definition

Minimal risk is a key factor in determining whether a research activity can be exempt from formal review. Minimal risk in a research activity is defined as an **anticipated risk of harm in a proposed research that is no greater, considering probability and magnitude, than**

risks ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

Exempt Research Categories

Research projects that meet one of the following exemption categories may be "exempted" from full or expedited IRB review and given final approval at the departmental level, if (a) the projects are not externally funded and (b) they place participants at no more than minimal risk.

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

Use the following category descriptions to determine if a proposed research project meets the exemption criteria. If you need clarification or would like representative examples, please contact the Compliance Section at 974-3466:

Category 1: (Federal Regulation 46.101(b)1)

Research conducted in established or commonly accepted educational settings, involving normal educational practices such as, research on regular and special education instructional strategies, or research on the effectiveness of or the comparison among instructional techniques, curricula or classroom management methods.

Limitations to Category 1 - Confidentiality of identifiable information must be maintained without the express permission of the participants to do otherwise.

Category 2: (Federal Regulation 46.101(b)2)

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

Limitations to Category 2 - This exemption does not apply if the information obtained is recorded in such a manner that participants can be identified, directly or through identifiers linked to participants; and any disclosure of participants' responses outside the research could reasonably place participants at risk of criminal or civil liability or be damaging to participants' financial standing, employability, or reputation. The exemption does not apply to observation of public behavior if the investigator interacts with participants or manipulates the setting in which the observations take place.

Category 3: (Federal Regulation 46.101(b)3)

Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that would not be exempt under Category 2 may be exempt if participants are elected officials, appointed public officials, or candidates for public office; or federal statute(s)

require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.

Limitations to Category 3 - Confidentiality of identifiable information must be maintained without express permission of the participants to do otherwise.

Category 4: (Federal Regulation 46.101(b)4)

Research involving the collection or study of existing data, documents, records, pathological specimens, or diagnostic specimens may be exempt if these sources are publicly available or if the information is recorded by the investigator in such a manner that participants cannot be identified, directly or through identifiers linked to the participants.

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 can serve in lieu of specific participant consent for access to the data, if the data, or records are not publicly available. However, the investigator and the UT-IRB must be satisfied that the custodian is authorized to release the data for research purposes.

Category 5: (Federal Regulation 46.101(b)5)

Research and demonstration projects which are conducted by or subject to the approval of 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.

Limitations to Category 5 - The UT requirements for informed consent may be waived if the research can not be carried out practicably without the waiver.

Category 6: (Federal Regulation 46.101(b)6)

Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods *without* additives are consumed, or (ii) foods are consumed that contain a food ingredient *at or below the level and for a use found to be safe*, or agricultural chemical or environmental contaminant *at or below the level found to be safe* by the Food and Drug Administration or approved by the Environmental Protection Agency or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

With respect to item #4 above (the collection or study of existing data, documents, etc.), please be sure that you have legal access to the materials in question, even if you record the

data without identifiers. 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). These records do not qualify for exemption. However, they may fall under a classification for **expedited review**, which requires the submission of a Form B to legally access data within these records.

Determining if a Research Project Is Exempt

Research activities exempt from formal review must present no greater than minimal risk to participants and meet the definition of one or more of the six categories list above. If you are not certain your proposed research activity qualifies for exempt review, please contact your DRC Chair or the Compliances Office at (974-3466).

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 Compliances Office at 404 Andy Holt Tower, or by downloading it from the Web site <http://www.ra.utk.edu/ora/sections/compliances/humsub/toc.html>.

- **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, emphasize the research component, using the remainder of the work to be done 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, the duration of involvement, and any special characteristics they have or must have relative to the research. Form A research is restricted to adults. 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. If there are no risks, explain why there are none. 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.

- **Category:** Referring to the earlier part 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 OR Coordinator of Compliances.

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 three criteria:

- Participants will be subject to no more than minimal risk;
- The participants are not minors (under 18 years old), prisoners, fetuses, or pregnant; and
- The research activities proposed meet the definitions of one or more the federally approved exempt categories.

Research Funding and Final Approval Procedures

An additional Form A approval consideration is the funding source of the project. If a project is externally funded, final approval for the project must come from the UT-IRB through the Compliances Section.

An "externally funded project" is defined as any project that is supported by funds derived from sources outside the university for which a proposal has been prepared and submitted through the Office of Research (OR) Grants and Contracts Section, or the Business Office in the Institute of Agriculture. The proposal must include a set of outcomes or "deliverables" that are intended to be published or shared in some public form.

Examples of projects that are not subject to this definition include student scholarships and fellowships, unrestricted funds from the UT Development Office, UT departmental funds which have been provided under the State Budget, and State of Tennessee contract services. Other types of funded activities in which data and findings are returned to the sponsor without further dissemination by any UT employees, agents or students are also not subject to this definition.

Once a research project's funding source has been determined, a DRC can take the following actions:

- 1. Provide final approval for the Form A application (projects that are not externally funded).**

This recommendation signifies that the project has been reviewed against the provisions of this section and found eligible for final approval by the DRC.

Although work may be initiated immediately after approval by the DRC, copies of

the signed and approved Form A must be received within five working days of approval by the UT-IRB Compliances Section.

2. **Request modifications to the proposed research project or Form A application.**
3. **Recommend final approval for a Form A application (externally funded projects).**

This recommendation signifies that the project has been reviewed against the provisions of this section and approval is recommended by the DRC. However, final approval must be granted by the UT-IRB Compliances Section. The DRC should forward the original signed Form A to the UT-IRB Compliances Section only after it reviews and recommends approval of an externally funded Form A.

Externally funded Form A applications will be approved or returned to the DRC for clarification within five working days of receipt by the UT-IRB Compliances Section.

Research and data collection may not begin until final approval has been granted by the UT-IRB Compliances Section.

4. **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.

Informed Consent Considerations

Full compliance with regulations includes securing informed consent from all participants of research prior to the conduct of the research activity involving the subject. A discussion of informed consent appears in Section 4 of this guide. **UT investigators conducting exempt research are not necessarily exempt from informed consent requirements.**

If the only document linking the identities of the participants to the research is 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 potential subject should understand that his/her 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 to research methods as telephone surveys.

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."

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

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](#)) apply to all research involving human participants conducted at UT.

If your project will make use of the facilities of another institution or a business, obtain letters (on their letterhead) of permission or cooperation 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-IRB and DRC files.

If any participants suffer adverse reactions occurring during your research, you must notify your DRC and the UT-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-IRB.

Graduate Students and Advisors

The Graduate School requires every student to verify that they have complied with the appropriate UT approval procedures prior to initiation of their thesis- or dissertation-related research, if approval is relevant to the 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 graduate committee.

Renewal and Termination Procedures for Exempt Projects

Renewal

Certification of exemption from review is **not subject to annual review**. Unless your research moves in a new direction (e.g., major changes in the objectives or involvement of human participants), 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.

Termination

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-IRB Compliances Section to close your project files.

If you have further questions, contact the Chair of your Departmental Review Committee, call the UT-IRB Compliances Section (974-3466), or visit in the Compliances Section Office in 404 Andy Holt Tower.

Section 6. Research Eligible for Expedited Review: Expedited Form B Applications

Section 6 Contents

General Information	35
Expedited Research Categories	35
Applicability of Expedited Review Categories	37
Additional Expedited Review Category Information	38
Expedited Review Procedures	39
Informed Consent Issues	40
Investigators' Responsibilities	41
Renewal and Termination Procedures for Expedited Projects	42

General Information

An expedited review procedure consists of a review of research involving human subjects by the IRB chairperson 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.

Expedited Research Categories

(List effective November 9, 1998)

Research categories that may be reviewed using expedited review procedures by the University of Tennessee Institutional Review Board (IRB) match federal guidelines and include:

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 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.

² 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 conducted." 45 CFR 46.402(a).

- 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:

Where

- (a) the research is permanently closed to the enrollment of new subjects;
 - (b) all subjects have completed all research-related interventions; and
 - (c) the research remains active only for long-term follow-up of subjects; or
 - (d) no subjects have been enrolled and no additional risks have been identified; or
 - (e) 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.

Applicability of Expedited Review Categories

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 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.

- The categories in this list apply regardless of the age of subjects, except as noted.
- 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, insurability, 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.
- The expedited review procedure may not be used for classified research involving human subjects.
- IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review--expedited or convened--utilized by the IRB.
- Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

Additional Expedited Review Category Information

- 1) The Federal policy concerning expedited review categories is contained in the Federal Register (Volume 63, Number 216; pages 60364-60367).
- 2) Source of Categories: Department of Health and Human Services - Office for Protection from Research Risks (OPRR), National Institutes of Health, HHS. OPRR and the Food and Drug Administration (FDA) have identical lists of categories of research activities that may be reviewed by the IRB through the expedited review procedure.
- 3) Historical Information: The Federal Policy (Common Rule) for the Protection of Human Subjects was published in the Federal Register on June 18, 1991 (56 FR 28003) and is employed by 17 Executive Branch agencies. This Federal Policy requires adherence to certain requirements by Federal agencies* and institutions receiving support from those

* 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.

- 4) agencies for research activities involving human subjects. The Federal Policy has three cornerstones: review of any research involving human subjects by an IRB with limited exceptions, informed consent of all research subjects; and formal, written assurance of institutional compliance with the Policy. The Department of Health and Human Services' (HHS) codification of the Federal Policy can be found at 45 CFR Part 46, Subpart A.

Section _____ .110 of the Federal Policy provides for expedited review procedures for certain categories of research involving no more than minimal risk, and for minor changes in approved research. This same section gives the Secretary, HHS, the authority to amend and republish the expedited review list as needed after consultation with the departments and agencies that are subject to the Federal Policy. The expedited review list that is referenced in the Federal Policy was originally published by the Secretary, HHS in 1981 (46 FR 8392, 46 FR 8980). It listed categories of research that could be reviewed by the IRB through an expedited review procedure. The FDA also references an expedited review list (21 CFR Part 56) for matters under FDA's jurisdiction. The HHS and FDA lists have differed slightly, in that item nine (9) on the 1981 HHS expedited review list regarding certain types of behavioral research is not included in the list referenced in 21 CFR 56.110.

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 you may not initiate your research until your Form B application is approved.

Your Form B application should include the following items:

- A copy of the Form B with original signatures
- 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 or cooperation, and approvals from other IRBs
- Copies of applicable technical sections of grant applications or contracts

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. If your department has a DRC, then your expedited Form B application must be approved by that DRC before your department head will indicate her/his approval by signing the Form B. If you are a student, your advisor's signature is also required.

When your DRC approves your expedited Form B it must identify the expedited research category (1 - 9) in which it believes your research is contained. The expedited

category classification must be listed on the signature page of your expedited Form B application.

If your DRC or department head does not approve your application, you should receive an explanation. Use the DRC and Department Head/Leader review comments to revise your application. In many/some cases the chair or members of the DRC may be willing to assist you as you revise your Form B application. If you need additional assistance, please contact the Compliance Section staff at 974-3466.

Institutional Review Board Review

Once your DRC approves your expedited Form B application and the appropriate signatures are on the original application, your application will be forwarded to the University's Institutional Review Board (IRB) at the Compliances Section Office in 404 Andy Holt Tower. **Please note that you may be responsible for delivering your own application to the Compliances Section, so check your department's procedures to avoid an unnecessary delay.**

The copy of the Form B application that you submit to the Compliance Section must contain original signatures. Once received, the Compliances Section staff will review your application and determine if it can be given an expedited review. Expedited reviews take about a week to complete. If the Compliances Section staff determines that your 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 over a month to complete.

Once the UT-IRB review is completed, the Compliances Section 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.)** The Compliances Section staff can assist you 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 Compliances Section staff. You may need to submit additional information about the substance of your project changes. Also, if unforeseen risks to subjects arise as you conduct your research, please contact the Compliances Section immediately

Informed Consent Considerations

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 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, please review consent and assent procedures listed in Section 9 of this guide.

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 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](#)) apply to all research involving human participants conducted at UT.

If your project will make use of the facilities of another institution or a business, obtain letters (on their letterhead) of permission or cooperation to use them and to interact with personnel there (refer to section 3 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 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-IRB and DRC files.

- If any participants suffer adverse reactions occur during your research, you must notify your DRC and the UT-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-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-IRB policies.
- Research investigators who intend to involve human research participants will not make the final determination of exemption from applicable Federal regulations or policies of the UT-IRB.
- Research investigators are responsible for providing a copy of the UT-IRB approved and signed informed consent document to each participant at the time of consent,

unless the UT-IRB has specifically waived this requirement. All signed consent documents are to be retained in a manner approved by the UT-IRB.

- Research investigators will promptly report proposed changes in previously approved human participant research activities to their DRC and UT-IRB. The proposed changes will not be initiated without DRC and UT-IRB review and approval, except where necessary to eliminate apparent immediate hazards to the participants.
- Research investigators are responsible for reporting progress of approved research to the UT-IRB, as often as and in the manner prescribed by the UT-IRB on the basis of risks to participants, but not less than once per year.
- Research investigators will promptly report to the UT-IRB any injuries or other unanticipated problems involving risks to participants and others.

Renewal and Termination Procedures for Expedited Projects

Renewal

All expedited Form B approved research is subject to UT-IRB review, at least once a year. Each year the principal investigator of every active research project will receive a Form R from the Compliances Section. Principal investigators will use Form R to indicate if their projects remain active and UT-IRB approval needs to be renewed for another year. 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. Investigators and their DRC are responsible for determining whether the changes will affect the current status of the project.

Termination

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-IRB Compliances Section to close your project files.

If you have further questions, contact the Chair of your Departmental Review Committee, call the UT-IRB Compliances Section (974-3466), or visit in the Compliances Section Office in 404 Andy Holt Tower.

Section 7. Research Requiring Full IRB Review: Form B Applications

Section 7 Contents

Categories of Full IRB Reviewed Research	43
Full IRB Review Process	43
Informed Consent Considerations	45
Investigators' Responsibilities	45
Renewal and Termination Procedures	46

Categories of Full IRB Reviewed Research

The full UT-IRB typically reviews research projects that involve participants selected from groups that are considered especially vulnerable to coercion or undue influence in research settings. These groups include children (including indirectly infants if their nursing mothers are research participants), fetuses, pregnant women, mentally disabled (cognitively impaired) persons, prisoners, and economically or educationally disadvantaged persons. The primary review concerns are that the use of persons from these groups is justified, that risks are minimized, and that additional safeguards are implemented to minimize risks unique each group. If the research risks are greater than minimal risks (those ordinarily encountered in daily life or during routine psychological or physical examinations), then the research must directly benefit participants, and those benefits must exceed the risks.

In addition, the following research projects typically require full UT-IRB review:

- Projects requiring the use of deception.
- Use of prisoners, pregnant women, fetuses, the seriously ill, or persons with mental disabilities, or incompetent individuals.
- 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.
- Studies in which the anticipated risks exceed the minimal risk definition.

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. Please keep in mind that the review process takes time, and you may not initiate your research until your Form B application is approved. Form B applications must be received by the Compliances Section in 404 Andy Holt Tower two weeks prior to the regular meeting of the UT-IRB (the third Thursday of each month). Please contact the Compliances Section for specific deadline information (974-3466).

Your Form B application should include the following items:

- Copy of the Form B with original signatures
- 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 or cooperation, and approvals from other IRBs
- Copies of applicable technical sections of grant applications or contracts

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. If your department has a DRC, then your complete Form B application must be approved by that DRC before your department head will indicate her/his approval by signing the Form B. If you are a student, your advisor's signature is also required.

If your DRC or department head does not approve your application, you should receive an explanation. Use the DRC's and department head's review comments to revise your application. In many/some cases the chair or members of the DRC may be willing to assist you as you revise your Form B application. If you need additional assistance, please contact the Compliance Section staff at 974-3466.

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 University's Institutional Review Board (IRB) at the Compliance Section Office in 404 Andy Holt Tower. Please note that you may be responsible for delivering your own application to the Compliance Section, so check your department's procedures and avoid an unnecessary delay.

The copy of the Form B application that you submit to the Compliance Section must contain original signatures. Once received, the Compliance Section staff will review your application and determine if it can be given an Expedited Review, or requires a Full-IRB Committee Review. Expedited Reviews take about a week to complete. Full-IRB Committee Reviews may take over a month to complete.

Once the IRB review is completed you will be notified by the Compliance Section 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, you are requested to do so, you will not have to resubmit your Form B application to your DRC.) The Compliance Section staff can assist you 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 Compliances Section staff. You may need to submit additional information about the substance of your project changes. Also, if unforeseen risks to participants arise as you conduct your research, please contact the Compliances Section immediately.

Informed Consent Considerations

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 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 listed in Sections 8 and 9 of this guide.

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 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**](#)) apply to all research involving human participants conducted at UT.

If your project will make use of the facilities of another institution or a business, obtain letters (on their letterhead) of permission or cooperation to use them and to interact with personnel there (refer to Section 3 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 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-IRB and DRC files.

- If any participants suffer adverse reactions during your research, you must notify your DRC and the UT-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-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-IRB policies.
- Research investigators who intend to involve human research participants will not make the final determination of exemption from applicable Federal regulations or policies of the UT-IRB.
- Research investigators are responsible for providing a copy of the UT-IRB approved and signed informed consent document to each participant at the time of consent, unless the UT-IRB has specifically waived this requirement. All signed consent documents are to be retained in a manner approved by the UT-IRB.
- Research investigators will promptly report proposed changes in previously approved human participant research activities to their DRC and UT-IRB. The proposed changes will not be initiated without DRC and UT-IRB review and approval, except where necessary to eliminate apparent immediate hazards to the participants.
- Research investigators are responsible for reporting progress of approved research to the UT-IRB, as often as and in the manner prescribed by the UT-IRB on the basis of risks to participants, but not less than once per year.
- Research investigators will promptly report to the UT-IRB any injuries or other unanticipated problems involving risks to participants and others.

Renewal and Termination Procedures

Renewal

All expedited Form B approved research is subject to UT-IRB review, at least once a year. Each year the principal investigator of every active research project will receive a Form R from the Compliance Section. Principal investigators will use Form R to indicate if their projects remain active and UT-IRB approval needs to be renewed for another year. 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. Investigators and their DRC are responsible for determining whether the changes will affect the current status of the project.

Termination

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-IRB Compliances Section to close your project files.

If you have further questions, contact the Chair of your Departmental Review Committee, call the UT-IRB Compliances Section (974-3466), or visit in the Compliances Section Office in 404 Andy Holt Tower.

Section 8. Instructions for Completing Form B

Researchers: Please discuss your proposed research project with your Departmental Review Committee or the Compliances Section of the Office of Research (974-3466) before you begin preparing a Form B application. If your project only exposes your participants to minimal risks and you do not intend to use participants from vulnerable populations, then it may be possible to use a Form A application. ALL RESEARCH UTILIZING HUMAN PARTICIPANTS MUST BE APPROVED BEFORE THE PARTICIPANTS ARE CONTACTED AND RESEARCH BEGINS.

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

FORM B

IRB # _____

Date Received in Office of Research _____

THE UNIVERSITY OF TENNESSEE, KNOXVILLE

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 bold type must be included in your Form B application even if your response under that heading or subheading is N/A.)

1. IDENTIFICATION OF PROJECT

a) 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 Co-PI's and should be listed in this section.

For each PI or Co-PI, include the name of their college and the name of their department or unit, their 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 projects that will form the basis of students' theses and dissertations, students should be listed as investigators and their faculty advisors should be identified in this section. The names of the advisor's college and department or unit, campus address, campus telephone number, and e-mail address should be included. (Please note that faculty advisors are not

automatically considered project investigators unless they are listed as a PI or Co-PI in Section I.)

Other Investigators: If other individuals are involved in this project (Co-Investigators, Collaborating Investigators, Research Associates or Assistants), enter their names and departments only.

- b) **Project Classification:** Provide an appropriate description (e.g., Research Project, Dissertation, Thesis, etc.)
- c) **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.
- d) **Starting Date:** Specify an intended starting date or state "Upon IRB Approval"
- e) **External Funding** (If this project is not externally funded, enter "N/A" and go on to Section II.): If external funding is sought or has been obtained for this project, please provide the following information:
 - 1) **Grant/Contract Submission Deadline:**
 - 2) **Funding Agency:**
 - 3) **Sponsor ID Number:** (*if known*)
 - 4) **UT Proposal Number:** (*if known*)

2. PROJECT OBJECTIVES:

In nontechnical terms that reviewers from other disciplines can understand 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. For projects seeking external support, the objectives listed in this section must coincide with the objectives and goals made in the 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.)

3. DESCRIPTION AND SOURCE OF RESEARCH PARTICIPANTS

Describe your participants, include the number of participants you anticipate using, the criteria for selection and exclusion, and how you will gain initial access to those

participants. If you intend to use children, pregnant women, prisoners, cognitively impaired, institutionalized individuals, or any participants whose ability to give voluntary and informed consent may be questioned, please provide a rationale.

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

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

If an incentive is to be used, 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 higher valued incentives coercive.

Investigators who plan to recruit UT students and offer extra course credit for student participation must follow the procedures maintained within the department whose classes are used. Departmental letters of permission must be attached to the Form B application.

4. METHODS AND PROCEDURES

Clearly and concisely describe in nontechnical terms 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 nontechnical 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 audiotaping, videotaping or photography of participants, explain the need for these methods and describe how the data will be used. Describe how the film or tapes will be stored, and when and how they will be destroyed. Identify the individuals who will have access to the tapes or film, and on what basis they will have access. If the tapes or film are to be used in the future, explain the procedures for obtaining participants' informed consent for those uses, and the conditions under which the tapes or film would be used.

Describe how you will analyze and interpret the data.

5. SPECIFIC RISKS AND PROTECTION MEASURES

Specify all potential risks to participants of the proposed research. Estimate the nature and amount of potential risk, stress, or discomfort, and assess the seriousness of it. Describe the precautions you will take to reduce risks, 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.

Include the methods and provisions by which you will either assure the anonymity of the participants or maintain the confidentiality of data. Note that anonymity is only possible if the investigator cannot discover the participant's identity from data collected. In either case, describe how you will maintain the confidentiality of the participants' data. Identify security measures, such as limiting access to data, purging identification information from data, securing files, and other appropriate measures.

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.

6. BENEFITS

Evaluate the reasonableness of the risks stated in Section V in relation to the anticipated benefits (e.g., desired outcomes), if any, to the participants. If the risks are minimal, please state that the risks are minimal and include a statement of anticipated benefits.

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. Please do not inflate the significance of incidental benefits to participants in your Form B application or your informed consent statements.

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

7. METHODS FOR OBTAINING "INFORMED CONSENT" FROM PARTICIPANTS

Please state the methods you will use to obtain legally effective informed consent,

assent, 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.

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.
- 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 should be provided for the participant's use and information.

The IRB will 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 in the minutes and signed by the IRB Chair. Criteria for approval include (but are not limited to) the following:

- 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 practicably 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 necessary, however, the IRB must approve these sites. 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 UT personnel.

As you prepare your consent form or procedure, please include the basic elements of informed consent listed in Section 4 of this guide.

8. 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. Experience and expertise is required when involving participants classified as vulnerable, such as children, pregnant women, prisoners, cognitively impaired or institutionalized individuals.

9. FACILITIES AND EQUIPMENT TO BE USED IN THE RESEARCH

Please provide a brief description of the facilities that will be used during the project 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.

If a project is to be conducted in a non-UT facility, an original letter of permission to use the non-UT facility must accompany the Form B. Letters of permission 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.

10. 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, Knoxville, 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, Knoxville. The principal investigator(s) further agree that:

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

Development of any unexpected risks will be immediately reported to the Compliances Section.

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

Signed informed consent documents 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.

11. 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 _____
(Name)
Signature _____ (Date)

Co-Principal Investigator _____
(Name)
Signature _____ (Date)

Student Advisor (if any) _____
(Name)
Signature _____ (Date)

12. 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(ies): _____

OR

Full IRB Review

Chair, DRC _____
(Name)
Signature _____ (Date)

Department Head _____
(Name)
Signature _____ (Date)

Section 9. Research Involving Special or Vulnerable Populations

Section 9 Contents

Children	
General Information	55
Identifying and Recruiting Potential Child-Participants	56
Informed Consent Procedures	56
Risk and Benefit Assessment	58
Use of Educational Records	59
Exempt Research Involving Children	60
Projects Eligible for Expedited Review	60
Quick Checklist for Research Protocols Involving Children	60
Mentally Disabled Individuals	
General Information	61
Additional Considerations	62
Minimal Risk Projects	62
Greater Than Minimal Risk Projects With Expected Direct Participant Benefits	62
Wards of the State	62
Greater Than Minimal Risk Projects Without Expected Direct Participant Benefits	62
Informed Consent Procedures	63
Pregnant Women	
Special Considerations	64
Prisoners	
General Information	64
Informed Consent Procedures	64
IRB Review Procedures	64

CHILDREN

Special Considerations for the Protection of Children Participating in UT-Sponsored Research

Policy Effective - May 1, 1998

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 Compliance Section Office at 974-3466 for further information.

General Information

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 the protection measures is assessed by the Institutional Review Board (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, almost all research involving children requires expedited or full-IRB review of Form B applications.** The only exception to this rule (discussed on page 59) occurs when the research involves observation of public behavior. All other 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. 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.

The following section 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 described in Section 8.

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 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 approval prior to the granting of any institutional permission, please contact the Compliance Office. This is a common complication that can be easily remedied without delaying the approval process.

Informed Consent Procedures

Federal law recommends the **assent** of the child and requires the **permission** of the parent(s), or guardian(s), in place of consent of the child before a child may be involved in a research

project. Research involving Amature" or emancipated minors may not need parental permission, but full IRB committee approval must be obtained to waive the parental permission requirement.

Note: A **guardian** is an individual who is authorized under applicable state or local law to give permission for a child [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 permission 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]. The UT-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.)

Assent is a child's affirmative agreement to participate in research. Assent is an ethical concept. However, 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 cooperation of children who participate in their research.

It is the responsibility of the IRB to decide if 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 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 depends on the capacity of the children to appreciate the nature, extent, and probable consequences of their participation in a research project.

Assent is especially important in cases where there is no direct benefit to the child-participants. When assent is required, the procedure should include an explanation of the proposed research in language that is appropriate for 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 unfair inducements. All children who are capable of providing assent must be informed that they are free to withdraw from participation at any time.

Risk and Benefit Assessment

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-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 46.606].

Examples of research in this category might include: research using 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 46.604, 46.405, or 46.606 may be conducted or funded by DHHS provided that the IRB, and the Secretary, 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.

Assessing probable risks is a central consideration of the IRB's approval process. The assessment of the probability and magnitude of the risk may differ depending on conditions child-participants may have. The issue of what is considered "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. The IRB 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.

Benefit Assessment: Carefully identify and describe all reasonably anticipated benefits that may be received by child-participants. As noted in the risk assessment subsection, anticipated benefits to child-participants must exceed anticipated risks when research procedures expose child-participants to greater than minimal risk.

Use of Educational Records

Federal law [34 CFR 99, 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). Except for administrative purposes, schools must withhold access to personally identifiable information from educational records except with the written permission of the students' parents, or students 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 such studies will not permit the identification of individual students and that personally identifying data will be destroyed upon completion of the study).

Exempt Research Involving Children

At this time, the only research procedure involving child-participants exempt from IRB review (Form A is the appropriate application form) is observation of public behavior. The definition of observation of public behavior requires that researchers not interact in anyway with the children, record their identities (this includes the use of audio- and videotaping procedures), or place the children at risk.

Examples of Cases when the IRB Exemption Involving Children Does Not Apply

The observation of public behavior exemption does **not** apply when a) the child-participants have a reasonable expectation of privacy (e.g., a private conversation in a public park); b) survey instruments are used (this would constitute an interaction, even if conducted by an independent third-party, such as a teacher); and c) the researcher rearranges or changes the setting/environment in which the public observation takes place.

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 of this Guide). The categories in this list apply regardless of the age of subjects, except as noted.

Please note that the nine categories 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.

Quick Checklist for Protocols Involving Children as Participants

If you have questions as you prepare your Form B, please contact the Compliances Section in 404 Andy Holt Tower or call 974-3466.

1. Are you preparing a Form B application?
2. 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 less than 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, 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.
6. Have you described your parental consent procedures and included a copy of the parental/guardian's informed consent form in your Form B? If a waiver of parental permission is requested, provide justification.
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.
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?

Mentally Disabled Individuals

General Information

Research projects that plan to enroll mentally handicapped participants must be submitted as Form B applications. The participation of mentally disabled individuals in research that would typically fall in exempt categories cannot be reviewed using exempt (Form A) procedures. In addition, projects exposing mentally disabled participants to more than minimal risk will only be approved by the IRB if specific conditions listed on page 6X are met. Researchers should clearly describe their informed consent and assent procedures in their Form B applications.

Individuals are considered Amentally disabled,"if they are unable to give informed consent because of mental illness, mental retardation, emotional disturbance, or senility. The IRB recognizes that some individuals with these disabilities are able to give informed consent.

However, the IRB is not in a position to determine if an individual identified with a mentally disability has the capacity to give informed consent. If researchers believe participants, diagnosed with a mental disability, are able to give informed consent, they should fully and explicitly describe their reasons for this judgement in the Form B. If participants are able to give informed consent, then the general IRB review requirements apply.

Additional Considerations

Researchers should clearly describe their participant identification and recruitment procedures. These procedures should be similar to the identification and recruitment procedures for children discussed on page 55.

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 mentally disabled individual and permission from competent adults are legally acting on their behalf.

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:

- The risk is justified by the expected benefit to the participant;
- The relationship between the risk and the benefit is at least as favorable to the participant as any available from alternative approaches; and
- Adequate provisions are made for obtaining assent of mentally disabled participants and permission from competent adults who are acting on their behalf.

Wards of the State

If the mentally disabled participants are wards of the state, or any other agency, or institution, they may only participate in research that poses more than minimal risk under one of the following conditions:

- A. The research is related to their status as wards; or
- B. The research is conducted in schools, camps, hospitals, or similar settings in which a majority of the participants are not wards of the state. Furthermore, an advocate must be appointed for each mentally disabled individual when the proposed research poses greater than minimal risk. The advocate must have the background and experience to act in, and agree to act in, the best interests of the mentally disabled individual. Advocated cannot be associated in any way with the research, the researchers, or the

guardian institution. The requirement for an advocate is in addition to any other person acting a guardian for the mentally disabled individual.

Greater Than Minimal Risk Projects Without Expected Direct Participant Benefits

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

- The risk is only slightly greater than minimal;
- 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;
- 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
- Adequate permission and assent procedures are in place.

If participants are wards of the state, the measures previously outlined on this page also apply.

Informed Consent Procedures

Assent of Participants: Researchers should develop reasonable procedures for obtaining assent from mentally disabled 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 mentally disabled. The methods used to convey the information should reflect sensitivity for the individual's disorder or condition, and 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.

Permission from the Participant's Guardian: Permission must be obtained from the mentally disabled participant's guardian. If the participants are under the age of 18, their parents are presumed to be their guardians. However, the parents of mentally disabled participants 18 years of age or older are not necessarily their legal guardians. Researchers should determine if legal guardians have been appointed for their mentally disabled 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 mentally disabled 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 of this Guide. The permission should be documented in written form.

Pregnant Women

Special Considerations

In general, pregnant women should not be excluded from research as participants. However, 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:

- The purpose of the study is to meet the health needs of the mother;
- The identity or whereabouts of the father cannot be reasonably ascertained;
- The father is not reasonably available; or
- The pregnancy is the result of rape.

Prisoners

General Information

Researcher 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 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.

Informed Consent Procedures

The information provided prisoners in the informed consent process must contain the basic elements of informed consent discussed in Section 4 of this Guide. Prisoners should also be informed that participation or non-participation does not affect parole board decisions.

IRB Review Procedures

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

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.

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

Section 10. Participatory Action Research

Section 10 Contents

Project Classifications	66
Additional Considerations	68
Background Principles	69
Basic Ethical Principles	69

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 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 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 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 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 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 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 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.)

1. Confidentiality provisions outlined in A.2 apply.
2. Plans for publication (if any) should be included in the consent form.

D. For a project for which the UT 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 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 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.)

Additional Considerations

"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:

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 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 coordinators for oversight of the process and allowing them to discuss it with UT research compliance authorities as required.

Background Principles

Responsibility of Project Director

By the Compliance with the policies established by The University of Tennessee, Committee on Research Participation, the project director subscribes to the principles stated in "The Belmont Report" and standards of professional ethics in all research, development, and related activities involving human subjects under the auspices of The University of Tennessee.

- a. Approval will be obtained from the University Committee prior to instituting any change in the research project.
- b. Development of any unexpected risks will be reported to the University Committee.
- c. A status report (Form D) will be submitted at 12-month intervals or as requested attesting to the current status of the project.
- d. Signed consent statements will be kept for the duration of the project and for at least three years thereafter.

Basic Ethical Principles *

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

* National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, Belmont Report - Ethical Principles and Guidelines for the Protection of Human Subjects of Research. **44 FEDERAL REGISTER** 76 (Wednesday, April 18, 1979), pp. 23192-23197.

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. Institutional Review Board Forms

Section 11 Contents

UT-IRB Form A	71
UT-IRB Form B	75
UT-IRB Form D	78

Form A

IRB # _____ Certification for Exemption from IRB Review for Research Involving Human Participants

Date received in OR _____

Please note: The exemptions listed on the second page of this form do not apply to projects that include participants from vulnerable populations, such as children, prisoners, or pregnant women. If your project involves participants from a vulnerable population, submit a Form B.

A. PRINCIPAL INVESTIGATOR(s)and/or CO-PI(s): (List all investigators)

(If this is a student project, list the student(s) and faculty member(s) responsible for directing the project. If faculty members listed in this section are not considered Principal or Co-Principal investigators, then they will sign as the "Advisor" in the signature section below).

B. DEPARTMENT/UNIT:

C. COMPLETE MAILING ADDRESS, E-MAIL ADDRESS, AND PHONE NUMBER OF PI(s) and CO-PI(s):

D. PROJECT TITLE:

E. EXTERNAL FUNDING AGENCY AND ID NUMBER (if applicable): (If this project is federally funded, final approval of this form must be obtained from the IRB):

F. GRANT SUBMISSION DEADLINE: (if applicable)

G. STARTING DATE: (NO RESEARCH MAY BE INITIATED UNTIL CERTIFICATION IS GRANTED.)

H. ESTIMATED COMPLETION DATE (Include all aspects of the research project.):

I. RESEARCH PROJECT:

- a. Objective(s) of Project (use an additional page, if needed):
- b. Participants (use an additional page, if needed):
- c. Methods or Procedures (use an additional page, if needed):
- d. Category for Exempt Research per 45 CFR 46.101 b (see reverse side for categories):

J. CERTIFICATION: The research described herein is in compliance with 45 CFR 46.101(b) and presents participants with no more than minimal risk as defined by applicable regulations.

(Add additional signature lines, if needed)

Principal Investigator _____
Name Signature Date

Co-PI or Advisor _____
(Circle one) Name Signature Date

Dept. Review Comm. Chair _____
Name Signature Date

APPROVED:
Dept. Head _____
Name Signature Date

Revised 05/98

INSTRUCTIONS FOR COMPLETING FORM A

Please type or use a word processing program to complete your Form A application. Provide responses for all items (A - H) using the Form A format. If you need more space, attach additional sheets. Submit one copy of your Form A to the Chair of your Departmental Review Committee for review and approval. Be sure this page is printed on the back of or attached to your Form A application.

ALL SIGNATURES MUST BE ORIGINAL on this form. Once your Form A is signed by your department/unit head, a copy of the signed Form A will be returned to the person identified on the form as the Principal Investigator (PI). A copy of the approved and signed Form A must be sent by the PI to the Compliances Section, 404 Andy Holt Tower, within seven days. If the project is federally funded, final approval must be obtained from the IRB.

In section H of your Form A application, please provide the following information:

- I. **OBJECTIVES:** Briefly state, in nontechnical language, the purpose of the research.
- II. **PARTICIPANTS:** Briefly describe the number of participants to be used, identification and recruitment methods, criteria of selection or exclusion, the population from which participants will be selected, and duration of involvement.
- III. **METHODS OR PROCEDURES:** Briefly enumerate, in nontechnical language, the research methods that directly involve use of human participants. List any potential risks, or lack of such, to participants and any protection measures. Explain how you will maintain confidentiality of identifiable materials or data. List the names of individuals who will have access to participants' names or identifiable information.
- IV. **CATEGORIES FOR EXEMPT RESEARCH PER 45 CFR 46:** Refer to the federal regulation extracts below and cite the category(ies) by number (1, 2, . . .) that you believe entitle this research project to certification as exempt from review by the IRB.

PLEASE NOTE: An exemption may be used for studies in which children are participants only if the research is limited to observation of public behavior. The use of surveys or interviews, review of any records, any direct or indirect interaction by the researcher, or any adjustment of the setting in which the observations take place does not qualify as an observation of public behavior.

45 CFR 46.101(b): Research activities in which the only involvement of human participants will be in one or more of the following categories are exempt from IRB review:

1. Research conducted in established or commonly accepted educational settings, involving normal educational practices, such as: (i) research on regular and special education instructional strategies, or (ii) research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.

2. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures or observation of public behavior, unless: (i) information obtained is recorded in such a manner that human participants can be identified, directly or through identifiers linked to the participants; and (ii) any disclosure of the human participants' responses outside the research could reasonably place the participants at risk of criminal or civil liability or be damaging to the participants' financial standing, employability, or reputation.
3. Research involving the use of educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior that is not exempt under paragraph (2) above, if: (i) the human participants are elected or appointed public officials or candidates for public office; or (ii) Federal statute(s) require(s) without exception that the confidentiality of the personally identifiable information will be maintained throughout the research and thereafter.
4. Research involving the collection or study of existing data, documents, records, pathological specimens or diagnostic specimens, 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.
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: (i) Public benefit or service programs; (ii) procedures of obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) possible changes in methods or levels of payment for benefits or services under those programs.
6. Taste and food quality evaluation and consumer acceptance studies, if wholesome foods without additives are consumed or if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminants 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.

CONTACT THE COMPLIANCES SECTION IN 404 ANDY HOLT TOWER (TELEPHONE: 974-3466) WHEN CHILDREN OR INDIVIDUALS FROM OTHER VULNERABLE POPULATIONS ARE POTENTIAL RESEARCH PARTICIPANTS

FORM B

IRB # _____

Date Received in Office of Research _____

THE UNIVERSITY OF TENNESSEE, KNOXVILLE

Application for Review of Research Involving Human Subjects

I. IDENTIFICATION OF PROJECT

1. Principal Investigator (PI) or Co-Principal Investigators (Co-PI)

Complete name and address including telephone number and e-mail address.

Faculty Advisors: if applicable

Other Investigators: if applicable

Complete name and address including telephone number and e-mail address.

Department

2. Project Classification:

3. Project Title:

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

5. External Funding: (If this project is not externally funded, enter "N/A" and go on to Section II.)

a. **Grant/Contract Submission Deadline:**

b. **Funding Agency:**

c. **Sponsor ID Number (if known):**

d. **UT Proposal Number (if known):**

II. PROJECT OBJECTIVES

III. DESCRIPTION AND SOURCE OF RESEARCH PARTICIPANTS

IV. METHODS AND PROCEDURES

V. SPECIFIC RISKS AND PROTECTION MEASURES

VI. BENEFITS

VII. METHODS FOR OBTAINING "INFORMED CONSENT" FROM PARTICIPANTS

VIII. QUALIFICATIONS OF THE INVESTIGATOR(S)

IX. FACILITIES AND EQUIPMENT TO BE USED IN THE RESEARCH

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

By compliance with the policies established by the Institutional Review Board of The University of Tennessee, Knoxville, 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, Knoxville. 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 Compliances Section.
3. An annual review and progress report (Form R) will be completed and submitted when requested by the Institutional Review Board.
4. Signed informed consent documents 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

Principal Investigator _____
(Name)

Signature _____ (Date)

Co-Principal Investigator _____
(Name)

Signature _____ (Date)

Student Advisor (if any) _____
(Name)

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(ies):

OR

Full IRB Review

Chair, DRC _____
(Name)

Signature _____ (Date)

Department Head _____
(Name)

Signature _____ (Date)

UT-IRB Form D

Status for Changes and/or Project Termination
Form B Approved Research Involving Human Subjects
(Instructions on Next Page)
Compliances Section Office of Research
The University of Tennessee
404 Andy Holt Tower
Knoxville, TN 37996-0140

IRB No. _____

Principal Investigator _____

Department _____

Mailing Address _____

Project Title _____

PLEASE CHECK THE APPROPRIATE LINE(S) BELOW (see instructions on reverse):

- _____ **Change of Project Title**
- _____ **Change of Principal or Co-Principal Investigator(s), Other Collaborators, Student Advisor**
- _____ **Change(s) to Project Which Affect Participation of Human Subjects**
- _____ **Change(s) to Informed Consent Forms and/or Assent Form(s)**
- _____ **Additional Locations for Conducting Project**
- _____ **Unexpected Risks to Subjects**
- _____ **Project Completed B Please Close the IRB Files.**

Signatures:

Principal Investigator _____ Date _____

Student Advisor _____ Date _____

Departmental Review (if required) _____ Date _____

Rev. 9-01-95

INSTRUCTIONS FOR USE

A Form D is used to report completion of a project or to request minor changes in a previously IRB-approved research project which was prepared under a Form B. Such changes may include, but are not limited, to: change of project title, minor grammatical changes to an informed consent and/or child's assent form, addition or deletion of collaborators and/or co-PIs, change in student advisor, additional sites for the performance of the research (include a letter from the authorized individual for a new location), minor project changes which do not change the original goal, and reporting unexpected risks encountered in carrying out the project.

The IRB has directed that the Compliances Section employ an expedited review procedure to determine if approval can be granted outright, if further information is required, whether the change must be reviewed by the full IRB, or if a new application must be submitted for review and approval. When a Form D is approved, it does not affect the renewal date of the overall project.

DO NOT USE THIS FORM FOR MAJOR CHANGES THAT MODIFY THE ORIGINAL GOAL OF THE RESEARCH -- A NEW FORM B MUST BE SUBMITTED!

INSTRUCTIONS FOR FORM D COMPLETION - (*This form may be typed or printed in ink*)

1. Insert the 4-digit IRB number, followed by the letter "B" in accordance with the number and letter assigned on your initial approval letter.
2. Enter the name of the Principal Investigator and Department or Division.
3. Enter your mailing address (if not UT, be sure to include your zip code).
4. Enter the Project Title (exactly as shown on the last approval letter received). *If the Project Title has changed, enter the new title and check box 5. below.*
5. CHECK this box if the project title in item 4. is different from your last approval letter.
6. CHECK this box if there is a change of principal or co-principal investigators, other collaborators or a change in student advisor. Attach a memo delineating the changes in investigators.
7. CHECK this box if there are minor changes to the project. Revise and amend any relevant sections of the Form B and submit these changes with Form D. **No change is too small to report.**
8. CHECK this box if there are changes to informed consent forms and/or assent form(s), and/or assent form(s). Submit the new consent/assent forms with Form D.

9. CHECK this box if there are additional locations or organizations where the research involving human subjects will be conducted. Submit a copy of the letter(s) from those organizations that have given permission for you to conduct your research in their institution. The letters should be on the institution's own letterhead.
10. CHECK this box if you have encountered unexpected risks to research subjects (*e.g., breaches of confidentiality*) or to yourself (*e.g., angry parents, threats of violence*). Submit a copy of the incident(s) with Form D and describe how you have or will resolve the problem.
11. CHECK this box if the project is now completed or if the project will not be conducted at all. For dissertation research: IRB-approved projects should NOT be terminated until the dissertation committee has accepted the dissertation.
12. The primary principal investigator must sign this Form D. If the PI is a student, the student's advisor must also sign. Some departments require that the Form D and its associated changes also be reviewed and approved by the Chair of the Departmental Review Committee. Please consult with your department's requirements.

Rev. 9-01-95