

# Departmental Review Committee Guidelines

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## **Section I. Introduction**

The following guidelines serve to provide Departmental Review Committees (DRC) criteria for evaluating research protocols that involve the use of human participants, and to identify the human participants' protection responsibilities of Department Heads and DRCs. A more detailed and complete explanation of UT Institutional Review Board (IRB) policies and procedures can be obtained by contacting your Compliance Officer in the Office of Research at (865) 974-3466.

## **Section II. Departmental Review of Research Projects**

The DRC will review of 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.

### **Section II.A Working Definition of Research Involving Human Participants**

Before initiating a DRC or IRB review of any protocol involving the use of human participants, the Principal Investigator/Projector Director (PI/PD) and Department Head

must first determine if the activity to be conducted qualifies as 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.

Human participant research is defined as systematic observation and data collection with humans as its subject, 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 or doctoral dissertation 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 DRC and possibly by the 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 IRB.

Examples of observation or data collection activities involving human participants that do not require DRC or IRB review include:

- Data collection for internal departmental or other University administrative purposes (e.g., teaching evaluations, student evaluations, and staff evaluations).
- Program evaluation carried-out under independent contract for an external organization which 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.

### **Classroom-related Activities**

Course activities that involve the use of human participants, but have no connection with research beyond the instructional function, as defined by federal regulations, preclude the need for certification or IRB review. Efforts that lead to the presentation outside of the classroom, and/or the publicizing of the student-prepared documents in any manner are considered research.

Classroom instructors must clearly describe their projects verbally on the first day of class and indicate alternative assignments for students who opt not to participate. Any sign-up or recruitment materials for said course requirements must not use the word research to external publics.

If the PI/PD intend to use the data from such activities as the basis for a scientific contribution, or portray the activity as "research" or "experiment," or intend 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.

### **Section III. Responsibilities of the Department Head**

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. Listed below are additional duties of department.

### **Section IV. Departmental Review Committee (DRC)**

If research involving human participants is a normal activity of the discipline, however regular or irregular its occurrence within the Department, the Department Head will appoint a DRC. The Head will report the names of the members of DRC to 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.

#### **Section IV.A Research Centers**

Principal investigators or project directors in Research Centers that are not contained 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.

### **Section V. Departmental Review Committee Recommendations**

DRC proceedings may be far more informal than those of IRB, thus lending themselves to direct assistance to the PI/PD over a broad range of matters. Prior to submission to IRB, a research proposal must have departmental approval. In addition to the research merit of the project, the project approval by a DRC is dependent on three factors: i) the level of risk; ii) the types of people who will be asked to participate; and iii) the funding source of the research.

The four types of approval granted by a DRC include:

## **Form A Approvals**

In general, projects in which participants will be subject to no more than minimal risk and that do not involve minors (under 18 years old), prisoners, fetuses, or pregnant women, will utilize Form A Approval Categories. 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 Research Compliance Services.

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) Grant and Contract Services, 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 development office, UT departmental funds which have been provided under the State Budget, State of Tennessee contract services, and other types of 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.

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

## Form B Approvals

Projects that subject participants to more than minimal risk, or involve minors, prisoners, fetuses, or pregnant women, will utilize Form B Approval Categories.

3. **Approval and Subsequent Review by the Full IRB Committee:** Simple approval, after all recommendations to the PI/PD have been carried out, is the minimal requirement for **Full IRB Committee** review.
4. **Recommendation for Expedited Review:** This recommendation signifies that the project has been reviewed against the provisions of Section VI.D and found eligible for expedited review by the Chair of the IRB or a member appointed to review the project on behalf of the full IRB Committee. The reviewer reserves the option of referring the project to the full IRB Committee.

## Section VI. 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.** 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 Committee chairs as soon as they know the extent to which humans will serve as participants in their research.

### Section VI.A. Research Projects Qualifying for Exempt Status (Form A)

Research projects that meet one of the following exemption categories may be "exempted" from full IRB review and given final approval at the departmental level, as long as (a) the projects are not externally funded (see external funds definition in (Section V. of this Guide) and (b) they place the subjects at no more than minimal risk. ***The following exemptions do not apply to research involving minors (participants are 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 Office of Research Compliance Officer at (865) 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 human participants can be identified, directly or through identifiers linked to the participants; and 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. This exemption does not apply to observation of public behavior when the subjects are children and the investigator is a participant.

**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 Departmental Committee 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;
- 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 US Department of Agriculture.

## **Section VI.B. Research Projects Qualifying for Exempt Status (Form A) Requiring Final Approval by Research Compliance**

This approval procedure should be used when projects qualify under one of the six minimal risk categories outlined in Section VI.A **and** the projects are externally funded. External funding is defined as any direct 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) Grant and Contract Services, or the Business Office in the Institute of Agriculture.

## **Section VI.C. Minimal Risk Research Projects Qualifying for Expedited Review Status (Form B)**

Certain forms of research have been deemed of minimal risk by federal notice. For proposed projects involving such forms of research or for cases where a minor alteration is proposed to an already approved project IRB may elect to use expedited procedures of review (contact Research Compliance Services for further information). Eligibility for expedited review in no way reduces PI/PD responsibilities with respect to human participants, and a project submitted for expedited review may be required to receive full IRB Committee review.

Research activities involving no more than minimal risk and in which the only involvement of the human participants will be in one or more of the following categories (carried out through standard methods) may be reviewed by the IRB through the

expedited review procedure. Please note: Projects that typically qualify for expedited review, but involve minors as participants may require full IRB review. Please contact Research Compliance Services (974-3466) for clarification.

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 products 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, non-pregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or
  - b. from other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an 8 week period and collection may not occur more frequently than 2 times per week.
3. Prospective collection of biological specimens for research purposes by noninvasive means.

Examples: (a) hair and nail clippings in a non-disfiguring 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 sub gingival 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 accepted 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.

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) electro-cardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (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 non-research 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. 45CFR46.101 (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. 45CFR46.101 (b)(2) and (b)(3) (<http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm#46.101>). 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 categories two (2) through eight (8) do not apply but 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.

Although not required for sponsored projects involving federal funds, the UT Institutional Review Board includes the following categories for expedited review:

10. audiotaping or videotaping.

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.

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).

### **Section VI.D. Research Projects Qualifying for Review by Full IRB Committee Status (Form B)**

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

- 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;
- the project includes procedures that present more than minimal risk to the subject.

## **Section VII. Additional DRC Responsibilities**

Upon completion of a review, the departmental review committee should send a letter to the investigator(s) and, if appropriate, their academic advisors that authorize the initiation of the project or identify the research protocol conditions that must be met before final approval is granted. Use of human participants in research may begin only after the research protocol is officially approved.

Departmental committees must provide Research Compliance Services with copies of every approved Exempt status protocol (Form A) within one week of approval. Research Compliance Services is required to maintain a database of all approved research projects involving human participants conducted by UT investigators. The departmental committee must retain original copies of any approved Form A and any correspondence between the departmental committee and the investigator(s) for three years after the project is officially completed.

In addition, the decisions and review procedures of every DRC will be reviewed on an annual basis by Research Compliance Services.