

**The University of Tennessee**  
**Office of Research**  
**Research Compliance Services**

**THE HUMAN SUBJECTS RESEARCH REVIEW SYSTEM**

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**HISTORICAL BACKGROUND**

For many years, state and federal laws were silent on the issue of human research and experimentation. The situation changed, however, in 1971 with the first of a series of federal regulations. The then US Department of Health, Education and Welfare (DHEW) issued **The Institutional Guide to DHEW Policy on Protection of Human Subjects**. These guidelines set the initial review criteria into motion. Three years later, on July 12, 1974, Public Law 93-348 (known as the "National Research Act of 1974") was signed into law, creating the National Commission for the Protection of Human Subjects in Biomedical and Behavioral Research, and set the definitive standards of the Institutional Review Board. Section 212 of the law specified, in part, that:

"The Secretary of DHEW shall by regulation require that each entity which applies for a grant or contract under this Act for any project or program which involves the conduct of biomedical or behavioral research involving human subjects submit in or with its application assurances satisfactory to the Secretary that it has established a board (to be known as an "Institutional Review Board") to review biomedical and behavioral research involving human subjects...in order to protect the rights of the human subjects of such research."

The Belmont Report was published on April 18, 1979, by the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research. The report was an outgrowth of intensive discussions held in February 1976 at the Smithsonian

Institution's Belmont Conference Center that were supplemented by the monthly deliberations of the Commission that were held over a period of three years. **The Belmont Report** is a statement of basic ethical principles and guidelines meant to assist individuals in resolving ethical problems that surround the conduct of research with human subjects.

Two years later, on January 27, 1981, the Food and Drug Administration (FDA) and the National Institutes of Health set the regulatory standards in place for the Protection of Human Subjects and for the Operating Standards of the Institutional Review Boards.

On March 8, 1983, the US Department of Health and Human Services (DHHS), in response to the Belmont Report and the FDA's standards, extensively revised its 1974 basic policy and added new regulations governing additional protection for special classes of human subjects -- fetuses, pregnant women, in vitro fertilization, prisoners, children, mental and physical disabled or institutionalized individuals, and the elderly.

In April 1989, the White House Office of Science and Technology ordered all governmental agencies to adopt the DHHS policy as their own, with the Office for Human Research Protections (OHRP) of the National Institutes of Health as the coordinating agency. On June 18, 1991, OHRP issued its revised policies for the Protection of Human Subjects and two months later, on August 19, 1991, the regulations became effective, with OHRP becoming the coordinating agency for 19 US governmental agencies to ensure that institutions comply with the federal regulations which protect human subjects in research. The regulations are known as the **Model Federal Policy of 1991** or simply by its legal citation, 45 CFR 46.

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## **INSTITUTIONAL ASSURANCE OF COMPLIANCE**

To certify that UT complies with these federal regulations, the Office of Research (OR) at UT filed a five-year **Institutional Assurance of Compliance with DHHS Regulations** with OHRP. The assurance includes a statement of ethical principles and institutional policy, a detailed identification of UT's responsibilities, OR's general procedures, the Institutional Review Board's policies and procedures, and the general responsibilities of the research investigator. As part of its assurance, UT's IRB reviews all research involving human subjects regardless of sponsorship.

The current **Institutional Assurance of Compliance** at UT is in effect from June 24, 1999 through June 23, 2004. The Assurance number assigned to UT is M-1081.

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## **THE INSTITUTIONAL REVIEW BOARD**

The Institutional Review Board (IRB) of The University of Tennessee (UT) operates under the US Department of Health and Human Services regulations for the Protection of

Human Research Subjects (Title 45 of the Code of Federal Regulations, Part 46 (45 CFR 46). The IRB is guided by the ethical principles regarding all research involving humans as subjects as set forth in the April 18, 1979, report of the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, entitled: "Ethical Principles and Guidelines for the Protection of Human Subjects of Research," commonly referred to as The Belmont Report).

The IRB has been in existence at UT since 1966. It was originally called the Committee on Research Participation (CRP). In February 1995, the name was formally changed to the Institutional Review Board (IRB) to provide an identity with its counterparts in other institutions throughout the country. Its range of responsibility and authority has shifted over the years with the evolution of federal regulations. However, its fundamental goal has not changed -- *to ensure that vital research of the University can be conducted in full compliance with both the letter and the spirit of regulations designed to protect the rights and welfare of human subjects.*

The IRB is composed of at least 16 members, although the annual membership may vary between 16 and 21. These members (mostly UT faculty) come from diverse backgrounds in order to promote the review of human subjects research activities and to provide the professional competency necessary for this review. The Associate Vice President for Research at UT is responsible for the selection of members for the IRB. Members are selected with consideration to their experience and expertise, their racial and cultural backgrounds, and their sensitivity to such issues as community attitudes.

The IRB includes both male and female members who represent virtually every unit of the University that regularly conducts research involving human subjects. The IRB also includes among its members at least one individual whose primary expertise is in a nonscientific area and at least one individual from the community who has no affiliation with the University other than their involvement with the IRB. In this manner, the composition of the IRB not only meets regulatory requirements but also ensures the expert and sensitive review of all projects submitted.

The IRB members are appointed annually; however, most are reappointed based upon their willingness to serve for an additional year. Several members have served fifteen consecutive years or longer and have a wealth of knowledge and experience. The Coordinator of Research Compliance Services is the only permanent member of the IRB, serving as a voting member of the IRB and as the designated reviewer for expedited research applications. The Associate Vice President for Research is the authorized institutional official and serves as an *ex-officio* (non-voting) member.

The IRB can and does enlist outside expertise whenever it receives especially sensitive projects. For example, when research involves vulnerable subjects (i.e., prisoners, children, institutionalized individuals, mentally handicapped), the IRB includes as a regular member or an expert consultant one or more persons who have primary concern for the welfare of the subjects.

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## THE OFFICE OF RESEARCH, RESEARCH COMPLIANCE SERVICES

The Research Compliance Services section of the UT Office of Research (OR) is responsible for the development of policies and procedures governing the implementation of federal regulations concerning the use of human subjects in research. The Coordinator of Research Compliance Services is responsible for providing full support to the IRB and serving as a liaison between the UT research community and the IRB. Research Compliance Services provides the following services:

- **Preliminary Review and Assistance:** The staff reviews all research projects involving human subjects to determine applicability of federal regulations and institutional policy.
- **Policies and Procedures:** Research Compliance Services develops the policies and procedures for the review of research involving human subjects in consultation with the Institutional Review Board.
- **Education:** The section, in consultation with the IRB, provides information and other educational assistance to departments and to investigators regarding regulations, policies and procedures applicable to research involving human subjects. The IRB and Research Compliance Services provide seminars for faculty, staff, and graduate students. This web site is one example of the educational effort.
- **Records and Files:** Research Compliance Services maintains all IRB records including agendas and minutes, policies, regulations, forms, reference materials, and individual investigator applications. Active, IRB-approved individual application files are maintained for the life of the project. When notification is received that a project has been completed, the files are archived for three years and then destroyed.

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## CATEGORIES OF REVIEW

There are several classifications of research which may involve human subjects but their classification falls outside of the IRB's policies and jurisdiction. Examples include, but are not limited to:

- Teacher and student evaluations;
- Program evaluation research to benefit UT and carried out by UT administrative officials;
- Projects designed to enhance or improve curricula offerings;
- UT employee performance evaluations;
- State of Tennessee mandated program evaluations;
- Marketing research (designed to market the institution as a product); or
- Classroom projects (which do not extend beyond the classroom).

There are four categories of review for projects involving human subjects in research settings. Each successive review category requires more detail than the previous one. The categories include:

**A. Exempted Research:** The federal regulations allow for six classifications of research to be **exempted from IRB review**. For all projects which are not funded by an external sponsor, the responsible Departmental Review Committee may provide final certification for research as "exempted from IRB review." For all projects which are funded (or to be funded) by an external sponsor, only Research Compliance Services of the Office of Research may certify the research as "exempt from IRB review." To determine whether the research qualifies as exempted from IRB review, a Form A and its associated procedures have been developed. The six classifications are:

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 subjects can be identified, directly or through identifiers linked to the subjects; **and** (ii) 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.

*\* PLEASE NOTE: An exemption cannot be used when children are involved for research involving survey or interview procedures or observations of public behavior, except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed. [45 CFR 46.401(b)]*

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 (b)(2) of this section, if: (i) the human subjects 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 subjects cannot be identified, directly or through identifiers linked to the subjects.

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 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.

6. Taste and food quality evaluation and consumer acceptance studies, (i) if wholesome foods without additives are consumed **or** (ii) 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 US Department of Agriculture.

**B. Expedited Review:** The federal regulations and institutional policy require that a full application (Form B) be prepared for one of 9 classifications (revised November 1998) which have been determined to place a human subject at minimal risk in a research setting. However, an application for expedited review may be submitted at any time (no deadlines). On behalf of the IRB, the review and evaluation of proposals for expedited review is conducted by one of Research Compliance Services IRB-designated reviewers within five working days of receipt of the application. This review avoids the necessity for an application to be reviewed, evaluated and approved by the full IRB, which may take as long as two months to complete.

If the designated reviewer deems it necessary to submit the application to the full IRB for review, the principal investigator will be notified of the reasons required. In addition, it is the prerogative of the Departmental Review Committee or any member of the IRB to request for full review instead of expedited review.

The classifications for expedited review are:

### **Procedure<sup>1</sup>**

#### Applicability

(A) Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely 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.

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

(C) The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, 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.

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

(E) 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.

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

### Research Categories

(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, 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<sup>2</sup>, 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 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 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) electrocardiography, 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. 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 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.

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<sup>1</sup> 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.

<sup>2</sup> 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).

Source: 63 FR 60364-60367, November 9, 1998.

Applications are prepared utilizing a Form B structure and only one signed, original application must be submitted.

**C. Full IRB Review:** All research projects involving human subjects which do not qualify for any of the above two categories (exempt or expedited) must be reviewed and approved by the full IRB at one of its regular scheduled meetings. The IRB usually meets on the third Thursday of each month (except December, which meets on the second Thursday), with a submission deadline of two weeks prior to the scheduled meeting. Investigators should plan well in advance to avoid processing delays within their own departments. Applications are prepared utilizing a Form B structure and must submit 21 complete copies.

*PLEASE NOTE: Requests for extensions are not usually granted due to the processing time required by Research Compliance Services to obtain primary reviewer comments and make them available to the full IRB in time for the scheduled meeting.*

**D. Acceptance of IRB Approval from Another Institution:** Projects which involve human subjects in research at institutions other than UT may need to be reviewed and approved at that institution's IRB. At the present time, to avoid a dual review situation, the UT IRB accepts the review and approval from the IRB at the UT Medical Center in Knoxville (UTMCK). Investigators planning projects which will utilize UTMCK resources (e.g., patients, medical records, clinics) must first make application to the IRB at UTMCK. When the UT investigator receives approval, submit one copy of the complete UTMCK or Fort Sanders application and the approval letter to Research Compliance Services. UT Research Compliance Services will accept the UTMCK or Fort Sanders approval for approval at UT.

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## THE REVIEW PROCESS

The review process has several steps, for which the investigator must plan accordingly. Not every step will be applicable in every unit, but the following general progression typifies most proposal applications. *Under no circumstances may an investigator undertake research involving human subjects until the project has received approval by the full UT IRB, the responsible Departmental Review Committee (certifying exemption from IRB review) or Research Compliance Services (certifying exemption from IRB review or approval by expedited review).*

**A. The Principal Investigator:** The researcher, as principal investigator, is responsible for preparing either Form A or Form B, as applicable, and for ensuring that it makes its way to Research Compliance Services for review and disposition. The staff in Research Compliance Services are always available to provide assistance to determine the best method of application.

**B. Student Research:**

- **For Research Other Than Thesis or Dissertation:** All students conducting research involving human subjects for course or classroom requirements must have their projects approved by their advisor.
- **Thesis and Dissertation Research:** Graduate students conducting research involving human subjects for theses or dissertations must have their projects approved by their advisor and/or thesis/dissertation committee *before* preparing a Form A or B for submission. Doctoral candidates must append the **Introduction and Methods chapters of the doctoral prospectus** to the Form A or Form B. The thesis/dissertation advisor/chair must sign the form certifying that the committee has approved the research and application.

**C. Departmental Review Committee and Department Head:** The department head is responsible for reviewing and approving research at the department level. Many departments that regularly engage in research involving human subjects have established departmental review committees (DRC) to discharge this responsibility and well as

reviewing the requirements for human subjects in research. Composed of faculty within the department who are familiar with the research methods normally used by each discipline, the DRC can assist the principal investigator(s) in preparing a research proposal that meets all requirements of both the regulations and the applicable canons of research ethics within the discipline. In developing a research plan, the investigator should carefully plan for the time required by departmental review.

In the event that the head of the department is the same as the chair of the departmental review committee or, in the case of students, the advisor, either the vice chair of the department should sign in place in the department head or another member of the departmental review committee should sign in place of the committee chair.

As of January 1997, departmental review committees have final approval authority for non-externally funded projects submitted under Form A.

**D. Research Compliance Services, Office of Research:** After approval by the DRC and the department head, the project goes to Research Compliance Services. For exempt research which is, or will be, funded by an external sponsor, the Form A goes to the Coordinator of Research Compliance Services. Form Bs, for either expedited or full IRB review, also go to the same location. If the project qualifies for expedited review, approval or other response will follow within a few days. Full IRB review takes longer, although the IRB Chair or a staff member of Research Compliance Services may communicate with the principal investigator concerning regulatory details of the proposal.

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## REVIEW CRITERIA

The substance of our concern for research involving human subjects lies in the criteria by which the IRB or Research Compliance Services evaluates proposals. In order to review and approve a project, the IRB must determine that it satisfies the following requirements:

**A. Risks to Subjects:** Risks to the subject are minimized by using procedures that are consistent with sound research and that do not unnecessarily expose the subjects to risks (e.g., physical, psychological, social or economic) and by using, whenever appropriate, procedures already being performed on subjects for diagnostic and treatment purposes.

**B. Risks vs. Benefits:** Risks to the subject are reasonable in relation to anticipated benefits, if any, to subjects, and to the importance of the knowledge that may reasonably be expected to result. In evaluating risks and benefits, the IRB considers only those risks and benefits that may result from the research (as distinguished from the risks and benefits of therapies or services that subjects would receive even if they do not participate in the research). *The IRB does not consider the long-range effects of applying the*

*knowledge gained in the research as among those research risks or benefits that fall within its responsibility.*

**C. Subject Selection:** The selection of subjects must be equitable. In making this assessment, the IRB takes into account the purposes of the research, the setting in which the research will be conducted, and the population from which the subjects will be recruited.

**D. Informed Consent:** Informed consent will be sought from each prospective subject or the subject's legally authorized representative and will be legally documented.

**E. Confidentiality and Privacy:** The research plan must provide for monitoring the data collected to ensure the subjects' privacy and the confidentiality of the data.

**F. Other Considerations:** The IRB also considers the acceptability of the research project in terms of institutional commitments and regulations, applicable law, standards of professional conduct and practice, and special vulnerabilities of the subjects.

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## **IRB REVIEW PROCEDURES AND RESULTS**

Acting on behalf of the IRB, the Coordinator of Research Compliance Services screens all applications to determine whether the proposal should be submitted to the full IRB for review or determine that the proposal qualifies for expedited review. If a proposal was submitted for expedited review, but the Coordinator has determined that it does not qualify for expedited review, the Coordinator has the authority to refer a project to the full IRB for review and action. As part of the initial screening process, the Coordinator of Research Compliance Services may require the principal investigator to revise an application to bring the proposal into compliance with UT guidelines and IRB review criteria.

In preparation for its monthly meeting, the Coordinator of Research Compliance Services appoints three primary reviewers for each project from among the IRB members to be in attendance. All members of the IRB receive the proposal and all attachments. Within three days of the scheduled meeting, the primary reviewers may request the attendance of the principal investigator at the meeting to answer specific questions of concern. A staff member of Research Compliance Services will contact the principal investigator and notify him/her of this request.

The primary reviewers lead the discussion of the project at the meeting, but all members participate fully and freely. If the primary reviewers invited the principal investigator (PI), the PI may attend the first part of a meeting at which his/her project will be reviewed to answer questions from the IRB membership but is not present during the ensuing discussion or the final vote.

After a full discussion, the IRB may take one of the following actions:

**A. Approve without Reservation:** IRB may approve the project as submitted without any changes noted for a maximum period of 12 months.

**B. Approve with Minor Modifications:** The IRB may approve a project contingent upon modifications to be completed by the principal investigator. When the changes are received by the Research Compliance Services section, the Coordinator, acting on behalf of the IRB, will compare the modifications received with the actions requested by the IRB. If the modifications are in compliance with the IRB directives, the Coordinator will approve the project for a maximum period of 12 months.

**C. Table Approval Pending Resubmission:** If the IRB deems that the proposal and/or informed consent as submitted require major revisions, they will require the PI to resubmit the application and attachments with all of the changes required. In some cases, the IRB Chair may request one or more IRB members to assist the PI in resubmitting the application. If no IRB member has been designated, the PI is strongly urged to consult with Research Compliance Services to receive assistance in the preparation of a new application.

**D. Disapprove:** The IRB may disapprove a research project if it has determined that the human subjects are at a greater risk than the benefits to be accrued. The IRB will notify the principal investigator, the advisor (if the PI is a student), the chair of the departmental review committee, the department head of the investigator, and the Associate Vice President for Research. Notification will include all of the reasons and rationale behind the disapproval. Upon disapproval, the principal investigator has the option of one or the following two actions:

1. **Revise and resubmit the project, reducing the risks to the subjects; OR**
2. **Appeal the IRB's decision to the Appeals Board [See APPEALS TO IRB DECISIONS]. *Please note: Federal regulations specify that the UT administration cannot approve a project which the IRB has disapproved.***

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## **ANNUAL REVIEW AND PROGRESS REPORTS**

When a proposal is approved by either the full IRB or through expedited review criteria, approval is granted for a maximum of 12 months. Six weeks prior to the expiration of the approval, Research Compliance Services will send a Form R (Annual Renewal and Progress Report Form) to the principal investigator and, in the case of the PI also being a student, to the PI's advisor. Our Institutional Assurance of Compliance with the US Department of Health and Human Services for the Protection of Human Subjects in Research requires at least one annual review by the Institutional Review Board (IRB) of all studies involving human subjects in research.

The Annual Progress Report is a required component for the annual review. The procedures for annual review require submission to the IRB, by the principal investigator, of an annual progress report including descriptions of all adverse effects encountered and any changes contemplated in the research protocol and/or informed assent/consent forms. A used copy of the approved informed consent and/or assent form(s) must accompany the Annual Progress Report. Incomplete or unsigned reports will not be submitted to the IRB for review and approval and will be returned to the Principal investigator for completion. Student principal investigators, whose research is conducted in partial fulfillment for a masters or doctoral degree, must maintain an active, IRB-approved protocol until the thesis or dissertation has been successfully defended.

If the Coordinator of Research Compliance Services, acting on behalf of the IRB, does not receive the Annual Progress Report and one used copy of the approved informed consent/assent form(s) on or before the due date noted on the form, the IRB approval will automatically expire. A notification of expiration of IRB approval is sent to the principal investigator(s), the IRB Chair and, in the case of student principal investigator(s), to the student's advisor and department head.

Projects which are found to be continuing without IRB approval will be considered to be in non-compliance with UT policy and federal regulations. For projects which are under the direction of UT faculty or staff, a non-compliance report will be filed by the Coordinator of Research Compliance Services with the Associate Vice President for Research for further action. For projects which are under the direction of student investigators, the non-compliance report will be sent to the student's advisor and department head for further action.

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## **CHANGES AND OTHER ACTIONS TO APPROVED PROJECTS**

The IRB has regulatory authority to observe, or have observed, the consent process and the research.

Changes to existing approved projects, as well as project terminations, require submission of a Form D to the Coordinator of Research Compliance Services. Such modifications may include, but are not limited to: change of project title, change of principal or co-principal investigator(s) or other collaborators, changes which affect participation of human subjects, changes to informed consent forms and/or assent forms, additional sites for conducting the research, unexpected risks to subjects, or notification of project completion (before the next scheduled annual review). Changes to projects should not be implemented until approval has been granted.

Change of mailing address of the principal investigator may be made at any time without the need for a Form D. Research Compliance Services relies upon the principal investigator to notify them of any change of mailing address.

In the event of unexpected serious harm to subjects or if a project is not being conducted in accordance with the IRB's decisions, conditions, or requirements, the IRB has the authority to suspend or terminate its approval of the research.

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## **APPEALS TO IRB DECISIONS**

In virtually all instances, investigators work with the IRB or the Coordinator of Research Compliance Services to reach agreement on the best ways to meet human subjects' requirements while conducting research. Nevertheless, the University maintains an appeals procedure should these less formal efforts fail to reach an accord. The appeals procedure should be used **ONLY** after all other avenues of discussion have been exhausted.

In the event a principal investigator wishes to appeal a decision of the IRB with respect to approval or to requested modifications in the project, he/she may address a formal request to the Associate Vice President for Research for a meeting of the Appeals Board. The request should contain sufficient information to identify the project, actions of the IRB, the means used to settle outstanding disagreements, and the reasons for the investigator's appeal.

The Associate Vice President for Research will convene the Appeals Board, whose members will include: the Associate Vice President for Research; the Coordinator of Research Compliance Services; the IRB Chair; and four to five knowledgeable members of the research community. The Appeals Board may confirm the decision of the IRB, may require further project modifications, or disapprove projects which were previously approved by the IRB.

If the Appeals Board believes that a disapproved project should be approved or that required modifications or restrictions should be deleted, it may recommend further review by the IRB and provide the IRB with the reasons for its recommendation. The Appeals Board does not have the authority to approve a project which the IRB has disapproved. After subsequent review and action of the IRB, the University will sustain the IRB decision without further appeal.