TYPES OF REVIEWS BY THE UT TYLER IRB

Five different types of reviews of protocols are done by the UT Tyler IRB: full board, expedited, exempt, modification requests, and continuing review. Even though an exempt protocol is considered exempt from review, it still must undergo an administrative review to determine it exempt. A PI or co-investigator may not determine the exempt nature of a potential IRB review. Only the IRB can do this.

Any UT Tyler faculty member who is a co-investigator on a research project with another institution must also have UT Tyler approval prior to involvement with the research project. This is a simple process that requires the UT Tyler faculty member to send approval documents (approval letter, IRB application of original institution or proposal) to the UT Tyler IRB. The approval process is usually waived once approval documentation is received.

Students must have a faculty sponsor, and all approvals must be renewed at least annually.

A. Full Board Reviews

1. The IRB as a full committee reviews full board review research proposals (non-exempt, non-expedited). These reviews typically involve more than minimal risk to subjects, and may involve vulnerable populations. All protocols involving prisoners must be full board review.

2. Full board reviews are conducted at monthly meetings, and do not meet criteria for exempt or expedited research. Administrative reviewers may deem an expedited protocol eligible for full board review.

B. Expedited Reviews

1. 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.

2. Approvals of expedited protocols by the IRB Chair or designated person will be reported at the next regularly scheduled IRB meeting

3. Criteria for expedited reviews (additional details are on back of expedited forms):

RESEARCH CATEGORIES

CATEGORY #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.

CATEGORY #2  Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

(a) from healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an 8 week period and collection may not occur more frequently than 2 times per week; or

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

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

**CATEGORY #4**  
Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves.

Where medical devices are employed, they must be 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.

**CATEGORY #5**  
Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

(NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not exempt.)
CATEGORY #6   Collection of data from voice, video, digital, or image recordings made for research purposes.

CATEGORY #7   Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.

(NOTE: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

CATEGORY #8   Continuing review of research previously approved by the convened IRB as follows:

(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.

CATEGORY #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.

C. Exempt Research

1. Exempt research at UT Tyler shall be reviewed for compliance with 45 CFR46.101, http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm
2. Determination of exempt status may only be done by the IRB.
3. An exempt 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, http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.htm

4. Criteria for exempt reviews (additional details on back of exempt forms):

- 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.

- 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.

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

- 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.

- 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, (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 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.

D. Modification Requests

1. Any revisions of previously IRB approved research must be approved first by the UT Tyler IRB before changes can be instituted in the research, except when necessary to eliminate apparent immediate hazards to the subject.

2. Requests may be administratively approved by IRB Chair or designee

3. Approvals of modifications by the IRB Chair or designated person will be reported at the next regularly scheduled IRB meeting

E. Continuing Review

1. All approved proposals must undergo continuing review at least annually, or more often as is deemed necessary by the IRB due to the level of risk to research subjects.

2. Though it is the responsibility of the PI to obtain approval for research studies beyond one year after initial approval, all attempts will be made by the IRB Chair or designee to notify PIs within at least 14 days of the annual due date.

3. No study shall extend beyond the one year date unless approval by IRB Chair or designee is obtained for continuation of study for no more than an additional year or less as specified by the IRB.

4. The Chair or designee shall keep records of all studies where continuing review has been requested, approved or when studies have been terminated through request of the PI.