

## Types of IRB Reviews

### 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 face to face meetings, and do not meet criteria for exempt or expedited research. Administrative reviewers may deem an expedited protocol eligible for full board review. Face to face meetings include those with members participating via web conferencing, phone or other device.

### 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. Any protocol that may be covered under “limited IRB review” established as part of the DHHS revised federal regulations for research January 19, 2019 shall be reviewed under expedited review
3. Approvals of expedited protocols by the IRB Chair or designated person will be reported at the next regularly scheduled IRB meeting

#### Expedited reviews include:

1. 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.

2. The categories in this list apply regardless of the age of subjects, except as noted.
3. 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.
4. The expedited review procedure may not be used for classified research involving human subjects.
5. 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.
6. Categories one (1) through seven (7) pertain to both initial and continuing IRB review.

## **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 CFR 46.101](#),
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 (reflects January 19, 2019 federal revisions)

#### **Exemption 1:**

- 1) Normal educational practices in established or commonly accepted educational settings
- 2) Research that involves normal educational practices that are not likely to adversely impact:**
  - a. Students' opportunity to learn required educational content, or
  - b. Assessment of educators who provide instruction  
§\_\_.104(d)(1)

### **Exemption 2:**

- 1) Research that **only includes** interactions involving educational tests, surveys, interviews, and observations of public behavior, exempt when:
  - i. Information recorded cannot be readily linked back to subjects, **or**
  - ii. Any information disclosure would not place subjects at risk of harm, **or**
  - iii. Identifiable information recorded, with limited IRB review for privacy and confidentiality protection under §\_\_.111(a)(7) ; §\_\_.104(d)(2)

### **Exemption #3:**

- i. Research involving benign behavioral interventions (see definition under Related Terms) with adults who prospectively agree, when information collection is limited to verbal or written responses (including data entry) or audiovisual recording, **and**:
- ii. Information recorded cannot be readily linked back to subjects, **or**
- iii. Any information disclosure would not place subjects at risk of harm, **or**
- iv. Identifiable information recorded, with limited IRB review for privacy and confidentiality protection under §\_\_.111(a)(7)

### **Exemption #4:**

**Secondary research use of identifiable private information or identifiable biospecimens if the research falls under one of four provisions.**

- i. Identifiable private information or identifiable biospecimens are publicly available, **OR**
- ii. Information, which may include information about biospecimens, is recorded in unidentifiable manner and the investigator does not contact or re-identify the subjects, **OR**
- iii. Investigator's use is regulated under HIPAA as "health care operations," "research," or "public health", **OR**
- iv. Research is conducted by, or on behalf of, a Federal agency using information collected or generated by the government for non-research purposes, and the information is protected by federal privacy standards

Note: No requirement that all data be “existing” at outset of study  
§\_.104(d)(4)

**Exemption #5:**

Public benefit and service programs research and demonstration projects

- i. Expanded to apply to such federally-supported research; no longer limited to federally-conducted research
- ii. Added requirement that Federal agency publish a list of projects covered by this exemption prior to commencing the research

§\_\_.104(d)(5)

**Exemption #6:**

Taste and food quality evaluation and consumer acceptance studies

**Relevant to Exemptions #7 and #8:**

**IT IS IMPORTANT TO NOTE THAT THE UT TYLER IRB WILL NOT ADOPT THE USE OF BROAD CONSENT AS IT RELATES TO EXEMPTIONS #7 AND #8 BELOW, AND THEREFORE EXEMPTIONS #7 AND #8 WILL NOT APPLY TO ANY PROTOCOL SUBMITTED TO THE UT TYLER IRB.**

**ANY PROTOCOL THAT FALLS UNDER CIRCUMSTANCES STATED IN EXEMPTIONS #7 AND #8 MUST GO THROUGH A FULL BOARD OR EXPEDITED REVIEW.**

**Exemption #7:**

Storage or maintenance of identifiable private information or identifiable biospecimens for secondary research (Requires broad consent and/or limited review)

**Exemption #8:**

Secondary research using identifiable private information or identifiable biospecimens (Requires broad consent and/or limited review) §\_.104(d)(7) and (8)

**NOTE:** While use of broad consent as it applies to Exemptions #7 and #8 is not allowed, use of broad consent may be considered by the IRB under unique circumstances which will be reviewed on an individual basis.

#### **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. While a modification form is required for most protocol alterations, at times a minor modification of a protocol may be approved via email request to the IRB Chair. The IRB Chair will make a determination as to the need for a Modification form.
4. 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 full board approved proposals must undergo continuing review via submission of a renewal form on Cayuse IRB at least annually, or more often as is deemed necessary by the IRB due to the level of risk to research subjects. The IRB may also require annual continuing reviews on other non-full board reviews under certain circumstances. The PI will be notified upon initial approval of a requirement for continuing review. The IRB shall document the rationale for conducting continuing review for non-full board review protocols.
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 full board or other study requiring continuing review 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. All protocols will be verified by the Office of Research & Scholarship on an annual basis regarding their status, and documented as such.
5. The PI is to submit a closure form through Cayuse IRB once their project has concluded
6. 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.