
Levels of IRB Review

The UTHSC IRB new project application will ask you which level of IRB review you are requesting, **Full Board** review, **Expedited** review, **Exempt** or **Not Human Subjects Research (NHSR)** determination.

The level of review reflects the level of risk to the subject and other stipulations set by federal regulations. “Minimal risk” is defined by the federal regulations:

Minimal risk is the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests (45.CFR.46.102(j)).

Greater than minimal risk studies require review by the Full Board, while minimal risk studies *may* be eligible for Expedited or Exempt review, or a NHSR determination.

Full Board Review

These types of studies are greater than minimal risk and require review by the full convened IRB. The UTHSC IRB meeting and submission schedule is available at <http://www.uthsc.edu/research/compliance/irb/researchers/meeting-schedule.php>.

Examples of studies and research interventions/interactions that require Full Board review:

- Behavioral studies involving risky interventions, observations of illegal behavior, or deception
- Blood draw
 - Healthy nonpregnant adults weighing at least 110 lbs – the amount to be collected exceeds 550 ml in an 8-week period and the collection is more than 2x/week
 - Other adults and children considering age, weight, and health, – the amount to be collected is greater of 50 ml or 3 ml per kg in an 8-week period and collection is more than 2x/week
- CT Scan
- DXA scan
- Disclosure of information that could require mandatory legal reporting (e.g. child/elder abuse, etc)
- Electromyography (EMG) (intramuscular)
- Investigational drug administration
- Investigational device testing
- Nasal swabs that go beyond the nares

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- Prisoners – if a study will include interactions/interventions that pose more than minimal risk to the subjects who are prisoners
Prisoners = individuals sentenced to an institution under a criminal or civil statute; individuals detained in other facilities by virtue of statutes or commitment procedures which provide alternatives to criminal prosecution or incarceration in a penal institution; an individual detained pending arraignment, trial, or sentencing; etc.
 - Randomized treatment studies
 - Rectal swabs that go beyond the rectum
 - Some kinds of genetic testing
 - Vaginal swabs that go beyond the cervical os
 - When privacy and confidentiality protections may be questionable: Disclosure of illegal activities, sexual attitudes, genetics, religious beliefs, mental health that could place subjects at risk of criminal or civil liability, could be damaging to the subject's financial standing, employability, insurability, reputation, or could be stigmatizing
 - Depression and mental health disorders
 - Sexual abuse
 - Violent crimes or other criminal behavior
 - Opinions about employers
 - X-rays (any type) taken for research purposes

Expedited Review

These types of studies only involve minimal risk to subjects and fit into one or more of the specific Expedited review categories. This type of research does not require review by the full convened IRB. The IRB review is conducted by the IRB Chair or one or more experienced reviewers designated from among the members of the IRB.

Category 1: Approved drug or device being used for its approved indication

- 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.

Note: The drug or device must be approved and used exactly according to its labeling. All study procedures other than use of the drug or device must themselves be of minimal risk for the study to qualify for expedited review.

Category 2: Blood Collection

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

- a. (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, 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: Noninvasive specimen collection

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.

Additional Examples:

- a. Nasal swabs that do not go beyond the nares
- b. Rectal swabs that do not go beyond the rectum
- c. Vaginal swabs that do not go beyond the cervical os

Category 4: Non-invasive procedures

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. Body composition assessment (not DXA)
- b. Detection of naturally occurring radioactivity
- c. Diagnostic infrared imaging
- d. Doppler blood flow
- e. Echocardiography
- f. Electrocardiography
- g. Electroencephalography
- h. Electromyography (EMG) (electrodes only)
- i. Electroretinography
- j. Flexibility testing where appropriate given the age, weight, and health of the individual
- k. Magnetic resonance imaging (MRI)
- l. Moderate exercise
- m. Muscular strength testing
- n. 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
- o. Thermography
- p. Ultrasound
- q. Weighing or testing sensory acuity

Additional Examples:

- a. fMRI
- b. Force plate
- c. Tendon tapping
- d. Vision testing/evaluation
- e. Vital signs (blood pressure, heart rate, respirations, etc.)

Category 5: Use of data, records, or specimens collected for non-research purposes

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).

Examples:

- a. Retrospective or prospective chart review
- b. Analysis of specimens that contain any of the 16 direct HIPAA identifiers (e.g., name, MRN, etc.)

Category 6: Collection of data from voice, video, digital, or image recordings made for research purposes

Example: Using video recordings to examine communication styles between faculty and students

Category 7: Behavioral research

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.

Example: Survey research

Exempt/Non-Human Subjects Research (NHSR)

Under UTHSC IRB policy, determination of whether a study qualifies for NHSR or Exempt status must be made by the Chair or other senior member of the IRB via a new project submission in iMedRIS.

NHSR projects do not meet the federal regulatory definitions of “research” and/or “human subject”.

DHHS regulations at [45 CFR 46.101](#) identify several different minimal risk research activities in which the only involvement of human subjects will be in one or more categories that are Exempt from federal policy for the protection of human subjects.

These determinations are made through submission and review of the *UTHSC IRB Memphis Form 1: Study/Project Application* via iMedRIS, the IRB electronic system. Once a study has been determined to qualify for NHSR or Exempt status, no further oversight by the IRB is

necessary unless you wish to make revisions to the project. A *Form 2: Change Request & Amendments* form must then be submitted in order for the IRB to determine whether the project remains eligible for NHSR or exempt status, or needs a higher level of review, based on the requested revisions to the project. Further, once the project has been completed, a *Form 7: Study Closure* form must be submitted for IRB review.

The following options are provided in the UTHSC IRB NHSR/Exempt new project application. Numbers 1-4 below are NHSR options, and numbers 5-16 are Exempt options:

1. My project is a case study or series of NO MORE THAN 5 (five) cases AND only involves the review of medical/dental records.
2. The project is an internal evaluation of an institutional or academic program AND the results of the study will NOT be presented professionally or published.
3. The ONLY subjects of this study are persons who are deceased.
4. The study team listed in section 3.0 is NOT VIEWING any individually identifiable private information and/or using any individually identifiable biospecimens.
5. The study involves the review of more than five records that contain identifiable private information or identifiable biospecimens, but ALL are publicly available.
6. The study involves the review of MORE THAN five records that contain identifiable private information, and ALL records are housed in a hospital, clinic, or other healthcare facility. (You may check this box if the research involves both review of this type of record, and the administration of surveys to adult subjects.)
7. The study involves the review of MORE THAN 5 records that contain identifiable private information or the use of MORE THAN 5 identifiable biospecimens. Information about subjects will NOT be abstracted onto a data/master key spreadsheet in a manner that contains identifiable private information about subjects, or with a code linking to identifiers; and the study team does NOT intend to contact subjects or later re-identify them.
8. The research consists of the storage or maintenance of identifiable private information or identifiable biospecimens for potential future research use (e.g., the creation of a repository), PROVIDED THAT the information or biospecimens were or will be initially collected for some other purpose AND consent will be secured using the UTHSC IRB repository consent form template.
9. The research involves the use of identifiable private information or identifiable biospecimens that have been stored for future research, AND prior consent for storage was obtained using the UTHSC IRB repository consent template or equivalent document of another institution, AND the investigator does not include returning individual research results to subjects as part of the study plan.
10. The study involves ONLY the administration of tests (cognitive, diagnostic, aptitude, and achievement), surveys, interviews or focus groups, or observation of public behavior, and ALL subjects doing surveys, interviews or focus groups will be 18 OR OLDER.
11. The study involves public observation of children without the investigator being involved in the activities observed, and without the recording of any information (including audio and visual recordings) in a manner than individually identifies children.
12. The study involves the administration of tests (cognitive, diagnostic, aptitude, and achievement) to children, without the recording of any information (including audio and visual recordings) in a manner than individually identifies children.

13. The research is being conducted in established or commonly accepted educational settings, AND specifically involves an evaluation of normal educational practices that is NOT likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction.
14. The research (OTHER THAN survey research or research on educational practices) involves benign behavioral interventions used to collect information from ADULT subjects through verbal or written responses or audiovisual recordings, AND the subjects prospectively agree verbally or in writing to the activities. (Note: 45 CFR 46.104(d)(3)(ii) states that "For purposes of this provision, benign behavioral interventions are **brief** in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing." *To meet the requirement of brief in duration, the benign behavioral intervention should last a few minutes to a few hours. While it does not have to occur in a single session, the entire time for the intervention should occur on a single day and not exceed a few hours in its entirety.*
15. The research is conducted or supported by a Federal department or agency, or otherwise subject to the approval of department or agency heads AND is designed to study, evaluate, improve, or otherwise examine public benefit or service programs.
16. The study involves taste, food quality, or consumer acceptance testing IF wholesome foods without additives are consumed OR if a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental 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.

Exception to Exemptions: Certain kinds of research with human subject are not eligible for exempt determinations. These include:

Prisoners: research involving prisoners as human subjects is *not* eligible for exemption except for research aimed at involving a broader subject population that only incidentally includes prisoners.

FDA-regulated Research: research using a drug, device or biologic, approved for marketing or not, outlined under 21 CFR 312 (drugs), 21 CFR 812 (devices), and 21 CFR 600 (biologics). FDA regulations for informed consent (21 CFR 50) and Institutional Review Boards (21 CFR 56) also apply.

Minors (Children): Most of the exemption categories can apply to research with minors, except for secondary research involving identifiable data or specimens, surveys, and interviews. Also, research involving educational tests or observations of public behavior can only be exempt when there is no interaction with the researcher.

Contact the IRB office at 901.448.4824 if you are unsure about which level of review is needed.