

EXPEDITED REVIEW FORM

PI's Last Name:

Abbreviated Title:

First 4 words of proposal title

EXPEDITED REVIEW CATEGORIES THAT ALLOW EXPEDITED REVIEW OF THIS PROPOSAL. Federal regulations require that projects must pose no more than minimal risk and that one or more of the following blocks (1-7) must be checked in order for research to receive expedited review.

Please underline within each category the applicable section or example. See 63 FR 60364, November 9, 1998 attached to 45 CFR 46 for more information.

(Must be checked). Project involves no more than minimal risk. Minimal risk means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

1. Clinical studies of drugs and medical devices only when certain conditions are met. See 63 FR 60364 for more information.

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) excreta and external secretions (including sweat); (c) 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; (d) placenta removed at delivery; (e) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor; (f) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (g) sputum collected after saline mist nebulization. See 63 FR 60364 for more examples.

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).
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).

Signature of WTAMU Principal Investigator **Date**

Signature of Co-investigator (if applicable) **Date**

Signature of Co-investigator (if applicable) **Date**

Signature of Co-Investigator (if applicable) **Date**