

Expedited Review Form Institutional Review Board (IRB)

Principal Investigator's Name: _____

Project Title: _____

Expedited Review Categories that Allow Expedited Review of this Proposal. Federal regulations and Union Institute & University IRB policy require that research 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 a research project to receive expedited review. Within each category, please **underline** the applicable section or example. See Expedited Review in the *IRB Handbook for the Protection of Human Research Subjects* for more information.

_____ **(Must be checked).** Research project involves no more than minimal risk. *Minimal risk* means that the probability and magnitude of harm or discomfort 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. Research involving materials (data, documents, records, specimens, voice, video, digital, or image recordings) that were previously collected, or will be collected solely for nonresearch purposes (such as medical treatment or diagnosis).

_____ 2. Collection of data from voice, video, digital, or image records made for research purposes.

_____ 3. 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.

_____ 4. Continuing review of research previously approved by the convened (full) IRB as follows: (1) Where the research (i) 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.

_____ 5. Changes to studies previously approved by the IRB, provided that the proposed changes do not result in more than minimal risk.

Other types of medical and clinical studies also eligible for expedited review include:

_____ 6. Clinical studies of drugs and medical devices only when certain conditions are 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 risk 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.

_____ 7. 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, 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.

- _____ 8. 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.
- _____ 9. 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 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 (MRI); (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.

The expedited review process **may not be used** when identification of subjects and/or their responses would reasonably **place them at risk of criminal or civil liability** or be damaging to 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.

The undersigned certify that they believe that the conduct of the above described research includes risks for subjects that are no more than minimal and are not beyond the ordinary risks of daily life.

_____ Date _____
Signature of Principal Investigator

_____ Date _____
Signature of Faculty Advisor or Dissertation Chair

Note: Form 540 IRB Application and Research Proposal Outline must be completed and submitted to the IRB Coordinator with this form.