IRB Review of Human Subjects Research - Expedited
Complete the following to determine
If the proposed study meets one or more categories for Expedited

Purpose

The purpose of this Worksheet is to describe the eligibility criteria for expedited review. It is also intended as a reference for investigators.

1. Initial Review before commencing any research procedures **(Check ☑ that apply)**

Researcher's opinion	Research Category
☐	1.1. The research activities present no more than minimal risk *(see definition)* to subjects.
☐	1.2. Identification of the subjects or their responses will not reasonably place them at risk of criminal or civil liability or be damaging to their financial standing, employability, insurability, reputation, or be stigmatizing.
	1.3. The initial review of research falls into one or more of the following categories: **(Check ☑ all that apply)**
☐	1.3.1.a. Clinical studies of ***marketed drugs*** *that are not significantly increases the risks or decreases the acceptability of the risks associated with the use of the product.*
☐	1.3.1.b. Clinical studies of medical devices for which is cleared/approved for marketing and is being used in accordance with its cleared/approved labeling.
☐	1.3.2.a. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from **healthy, non-pregnant adults who weigh >110 pounds** where the amount drawn is <550 ml/8 week period and collection occurs at most 2 times/week. *Multiple withdrawals of blood from an indwelling venous line are more than one collection.*
☐	1.3.2.b. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture from **other adults and children, considering the age, weight, and health of the subjects**, the amount of blood to be collected (at most 550 ml or **3 ml/kg/8 week period**), and the frequency with which it will be collected (**at most 2 times/week**.)

Researcher's opinion	Research Category
☐	1.3.3. Prospective collection of biological specimens for research purposes by noninvasive means. *Non-invasive procedures include, but are not limited to: (1) vaginal swabs that do not go beyond the cervical os; (2) rectal swabs that do not go beyond the rectum; and (3) nasal swabs that do not go beyond the nares.* *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 gum-base 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.*
☐	1.3.4. 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**. *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) weight or testing sensory acuity;* *(c) magnetic resonance imaging;* *(d) electrocardiography, electroencephalography, thermograph, 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.*
☐	1.3.5. Research involving materials (data, documents, records, or specimens) that **have been collected for any purpose**, or will be collected solely for **non-research purposes**.
☐	1.3.6. Collection of data from voice, video, digital, or image recordings made for research purposes.

Researcher's opinion	Research Category
☐	1.3.7. Research on individual or group characteristics or behavior or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. *Examples:* *(a) Research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior; or* *(b) Research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies.*

2. Continuing Review

Researcher's opinion	Research Category
2.1. Continuing review of research previously approved by the convened IRB	
☐	2.1.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. *For a multi-center protocol, an expedited review procedure may be used by the IRB at a particular site whenever these conditions are satisfied for that site.*
☐	2.1.b. where no subjects have ever been enrolled at a particular site and neither the investigator nor the IRB at a particular site has identified any additional risks from any site or other relevant source.
☐	2.1.c. where the remaining research activities are limited to data analysis, **beginning from time when the researcher identifies the activities as limited to only data analysis.** *For a multi-center protocol, an expedited review procedure may be used by the IRB at a particular site whenever these conditions are satisfied for that site.* *The IRB may make this determination at any time, including at the same time as initial approval of a project – i.e., that future continuing review can be conducted by expedited review.*
☐	2.2. Continuing review of research, where all of the following criteria are met: • The research is not conducted under an investigational new drug application or investigational device exemption; • The IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk (this could be during initial review, or later); • The IRB chair or designee has made a determination that no additional risks have been identified.
☐	2.3. Continuing review of the use of a Humanitarian Use Device, when the device is used solely for clinical purposes and the IRB determines that expedited continuing review is appropriate.

❖ Definition

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.

Minor change. A change that will neither

(1) materially increase risk nor materially decrease benefit, when considered in light of any changes proposed to mitigate risk and improve benefit; nor

(2) materially decrease scientific merit; nor

(3) adversely affect the assessment of the research.