

EXPEDITED REVIEW: THE IRB APPLICATION

(PLEASE TYPE)

Principal Investigator

Title of Project

Please indicate, by checking the appropriate space below, the category or categories into which you believe your project falls:

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 (21CFR 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 an investigational device exemption application (21CFR Part 812) is not required; or the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

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.

____ (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:

____ (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.

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.)

_____ (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 nonresearch purposes (such as medical treatment or diagnosis). (NOTE: some research in this category may qualify for exempt from informed consent.)

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 qualify for exempt from informed consent approval.)
8. Continuing review of research previously approved by the full IRB as follows:
 - _____ (a) where the research is permanently closed to the enrollment of new subjects, all subjects have completed all research-related interventions, and 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.
9. Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two through eight do not apply but the IRB has determined and documented at a convened meeting that research involves no greater than minimal risk and no additional risks have been identified.

Signature of Investigator

Date

Department

Office

THIS SPACE FOR IRB USE ONLY

Reviewer's Comments:

Signature of Reviewer

Date

EXPEDITED REVIEW: THE HUMAN SUBJECTS PROTOCOL

(PLEASE TYPE)

Title of Project

A. General Information (Additional pages acceptable unless noted)

1. Investigator

(a) Name of Principal Investigator

Signature of Principal Investigator Date

Department Office

Qualifications of Investigator

(b) List the name, rank, and major departmental appointment of other investigators participating in this project, if any.

None Others

(c) If medical supervision is necessary, give the name of the physician who will be responsible for supervision.

Physician Phone

2. Type of proposal or activity: New Renewal

If renewal, date of last IRB approval

If this proposal is part of a grant, please indicate the following:

Name of Grant:

Principal Investigator of Grant:

3. Source of Funds - State specific name of funding source.

None

Governmental Agency

Foundation(s)

Corporation(s)

Organization(s)

Individual(s)

B. Number and Type of Subjects and Controls

1. Number of subjects and controls

2. Type of subjects and controls

3. Populations from which derived

4. Please check if population includes any of the following:

None

Prisoners

Fetuses

Mentally Retarded

Abortuses

Mentally Disabled

Pregnant Women

Minors under 14 years of age

If any of the populations above are involved, attach a statement indicating the reasons for using these groups.

5. Will any of the subjects be from the Veteran's Administration Hospital?

Yes

No

C. Duration of Study

Probable duration of entire study:

Total amount of time each subject will be involved:

Duration of each phase in which subject will be involved

