	University of Puerto Rico Medical Sciences Campus Human Research Subjects Protection Office	Effective: 9/1/2008
		Rev. 07/01/2014

PROCEDURES FOR EXPEDITED REVIEW

Federal Regulations (45 CFR 46.110 and 21 CFR 56.110) define expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research. These regulations define *minimal risk* as 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.

Policy:

Certain types of research activities, involving no more than minimal risk may be eligible for expedite review 45 CFR 46.110 and 21 CFR 56.110. The IRB chair or a designated member shall determine if a research activity meets the criteria for expedite review.

Procedure:

General Requirements

All submissions are "pre-screened" by IRB office staff utilizing a checklist of the established categories (45CFR 46 110(a). If the protocol is considered to meet the criteria for an expedited review, it is sent to the correspondent IRB Chair (next scheduled meeting panel) for verification. Under an expedited review procedure, the review may be carried out by the IRB Chair or Vice-Chair, or by an experienced IRB member, as designated by the Chair.

The person(s) conducting the expedited review may either approve, require modifications (to secure approval) or refer the research to the convened

IRB for review in accordance with the non-expedited review procedures, allowing sufficient time for the protocol to be placed on the agenda (24-48 hrs.). In conducting expedited review, the IRB reviewers may exercise all of the authorities of the IRB except that they may not disapprove the research.

The expedite review procedure may not be used where identification of the subject and or their responses would reasonably place them at risk of criminal or civil liability or be damaging the subject's 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.

CFR Defined categories for expedited review

Categories of human subjects research that may qualify for consideration under the expedited review process (as defined in the Federal Regulations) include research activities that (1) present no more than minimal risk to human subjects and (2) involve only procedures listed in one or more of the following categories:

(1) Research on drugs for which an investigational new drug application is not required or research on medical devices for which a) an investigational device exemption application is not required or b) 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, non-pregnant adults, who weigh at least 110 pounds. For these subjects, amounts drawn may not exceed 550 ml in an 8 weeks period and no more 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/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) deciduous teeth at the 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) un-cannulated 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.

(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, electroencelphalography, 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).

(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.

(8) Continuing review of research previously approved by the convened IRB as follows:

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; 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.

Amendments or modifications or reports on approved research activities

Minor changes to ongoing research activities may be reviewed by an expedited review process. Examples of modifications or reports that may be considered minor under approved research are:

(a) Reports of protocol deviations
(b) Editorial changes to consent forms or recruitment materials that improve readability, or correct typographical errors.
(c) Protocol audit reports, site monitoring reports, protocol sponsor waivers, waivers, sponsor reports and data safety monitoring boards.
(d) Inclusion or changes in research staff
(e) Sponsor notifications that do not affect directly the Informed Consent Document
(f) Clinical Investigator Brochures and package inserts
(g) Flyers and promotional materials
(h) Other documents related to the study that does not present more than minimal risk to human subjects.

The expedite review procedures **cannot** be used for research involving prisoners.

Information pertaining to submissions reviewed via an expedited review process will be communicated to the full Board on next convened meeting minutes.