CARILION CLINIC INSTITUTIONAL REVIEW BOARD
Standard Operating Guidelines

Title: 2.5: Review of Research: EXPEDITED REVIEW	
Original Date: January 2006	**Date of Last Revision:** 02-07, 01-08, 04-08, 8-14, 8-23
Primary Sponsor: Human Research Protections Office	**Approved By:** Director of the Human Research Protections Office

Objective:

To provide guidance regarding what types of research proposals will quality for expedited review in accordance with the guidelines followed by the Carilion Institutional Review Board (IRB).

General Description:

Research activities that present no more than minimal risk to human subjects and involve only procedures listed in one or more of the following categories may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110.

Procedure:

All research is submitted to the Carilion IRB on the IRB Research Application, which can be found in the Carilion Clinic IRB submission system PRIS3M. All appropriate sections of the form must be filled out prior to submission.

If it is believed that research may be expedited (see attached pages), the following information must be uploaded with the PRIS3M submission:

- IRB Research Application*
- Consent form or research subject information sheet, if applicable
- Any additional literature or information
- Any surveys or data collection tools to be used with research, if applicable
- Principal Investigator's Curriculum Vitae received within 2 years from study submission
- All other study related materials, as applicable

**Note: Unless the study is sponsored or if the researcher will use a separate protocol to conduct his or her research, the IRB will consider the IRB Research Application to be the study protocol.*

The IRB may request additional information as it determines to be appropriate.

The expedited review procedure allows for approval of the research by the IRB chairperson or his/her designee(s). Designees include the Director of the Human Research Protections Office, the Vice-Chairperson of the IRB, the IRB Regulatory Affairs Administrator, or any other member so designated. The reviewer may approve the study, or may request modification, but the reviewer may not deny approval of research. The reviewer reserves the right to choose not to

expedite review of the research study and refer it to the convened IRB for review. If full IRB review is required, the full IRB review process must be followed.

If the review is expedited, a letter will be sent to the principal investigator stating that the research has been approved in an expedited manner. Copies of this letter will be sent to the Research & Development Department, the Institutional Official, and other involved departments, if appropriate.

The following pages contain a supplemental sheet to the Code of Federal Regulations (CFR) detailing research activities that may receive an expedited review.

Categories of Research That May Be Reviewed by the IRB through an Expedited Review Procedure

Applicability

Research activities that present no more than minimal risk to human subjects and involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR 46.110 and 21 CFR 56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.

The categories in this list apply regardless of the age of subjects, except as noted.

The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or civil liability or be damaging to the 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 expedited review procedure may not be used for classified research involving human subjects.

IRBs are reminded that the standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review--expedited or convened--utilized by the IRB.

Categories one through seven pertain to both initial and continuing IRB review.

Research Categories

(1) Clinical studies of drugs and medical devices only when the:
   (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 risks associated with the use of the product is not eligible for expedited review; or
   (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.

(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; 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 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.) 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 from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(4). This listing refers only to research that is not 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 from the HHS regulations for the protection of human subjects. 45 CFR 46.101(b)(2) and (b)(3). This listing refers only to research that is not exempt.)

(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.

(9) Continuing review of research, not conducted under an investigational new drug application or investigational device exemption where categories two (2) through eight (8) do not apply but the IRB has determined and documented at a convened meeting that the research involves no greater than minimal risk and no additional risks have been identified.