



Policy Name: <b>Expedited Review of Research Policy and Procedures</b>		
Approved		
Effective Date: <b>01/27/2012</b>	Page 1 of 5	Section: <b>HRPP 3.3</b>
Replaces Policy: Effective 12/01/2009		

## I. POLICY

### A. Introduction

Expedited review procedure consists of a review of research involving human subjects by the IRB Chair or by one or more experienced reviewers designated by the Chairperson from among members of the IRB in accordance with the requirements set forth in 45 CFR 46.110 and 21 CFR 56.110. The review will normally be performed by the Chair, Vice-Chair or IRB member with extensive service on the IRB. If necessitated by unique circumstances in the area of research under consideration (i.e., vulnerable population or novel procedures), the reviewer may solicit input from another IRB member with relevant experience. When reviewing non-exempt human-subjects research and clinical investigations using the expedited review procedure, the reviewer(s) are subject to *IRB Member Conflict of Interest Policy* detailed in **HRPP Guide Section 2.3 Membership of the IRB**.

### B. Limitations to the Use of Expedited Review

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.

### C. IRB Approval Process

The Chair or designee may approve a protocol meeting the requirements of expedited review (documented by completion of the Expedited Review Form) but may not disapprove a protocol meeting these requirements. Any protocol submitted that should be considered for disapproval will be sent to a meeting of the convened IRB for consideration.

### D. Reporting of IRB Approval

Protocols approved by the expedited process will be reported to the full IRB board at a convened meeting. Any board member may request further consideration of any protocol approved by the expedited process

## **II. DEFINITIONS**

As used in this document, human-subjects research encompasses activities that meet the DHHS definitions of *research* and *human subject* and/or the FDA definitions of *clinical investigation* and *human subject*. These definitions are found in HRPP Program Guide Section 1.3 – Definitions of terms.

- A. Research (DHHS)
- B. Human Subject (DHHS)
- C. Clinical Investigation (FDA)
- D. Human Subject (FDA)
- E. Minimal Risk

## **III. APPLICABILITY TO CONSIDER EXPEDITED REVIEW**

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, may be reviewed by the IRB through the expedited review procedure (45 CFR 46.110; 21 CFR 56.110):

## **IV. CATEGORIES OF RESEARCH THAT MAY BE REVIEWED BY THE IRB THROUGH AN EXPEDITED REVIEW (45 CFR 46.111)**

1. Clinical studies of drugs and medical devices only when condition (1) or (2) is 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 risks associated with the use of the product is not eligible for expedited review.)
  - b. Research on medical devices for which (1) an investigational device exemption application (21 CFR Part 812) is not required; or (2) 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, 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 by noninvasive means. Examples: Hair and nail clippings in a nondisfiguring manner; deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; permanent teeth if routine patient care indicates a need for extraction; excreta and external secretions (including sweat); uncannulated saliva collected either in an unstimulated fashion; placenta removed at delivery; amniotic fluid obtained at the time of rupture of the membrane prior to or during labor: supra-and subgingival dental plaque and calculus, provided the collection procedure is no more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; 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: 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: weighing or testing sensory acuity; magnetic resonance imaging; electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, eletroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; 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 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 DHHS regulations for the protection of human subjects 45 CFR46.101 (b) (2) and (b) (3). This listing refers only to research that is not exempt.)

**V. CATEGORIES OF REVIEW OF RESEARCH PREVIOUSLY APPROVED BY THE CONVENED IRB**

8. Continuing review of ongoing research may be expedited when the initial review of the protocol qualified for expedited review,
  - a. Protocol was previously approved by the convened IRB where:
    - i. the research is permanently closed to the enrollment of new subjects;
    - ii. all subjects have completed all research related interventions;
    - iii. the research remains active only for long term follow up of subjects;or
  - b. no subjects have been enrolled and no additional risks have been identified; or
  - c. the remaining research activities are limited to data analysis.
9. Continuing review of research, not conducted under an investigational new drug application or investigation device exemption where categories two (2) through (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.

**VI. PROCEDURES**

**A. Initial Determination for Expedited Review**

1. The Principal Investigator submits the protocol indicating request for review using the Expedited Procedure, indicates the review Category(s) and submits supporting data as appropriate.
2. All submitted studies are automatically routed to the individual(s) designated by the Principal Investigator's College/ Department/ Division for review and approval. Designated individuals issue electronic approval or request information/clarification from the study team.

3. Studies designated as “Expedited” for which no funding is indicated will be routed to the Associate Provost for Research for review and approval.
4. Ancillary Notification. The following departments receive notification of study submission (if applicable):
  - a) Success Center
  - b) Office of Research and Sponsored Programs
  - c) Grant and Contracts Administration
  - d) Conflict of Interest Committee (only if a COI is reported)
  - e) Gastroenterology (only if the PI is a Fellow in GI)
  - f) MUSC Simulation Center (only if the Simulation Center is indicated as a study site)

The notifications to these departments are for information purposes only. No approval is required from these departments.

5. The IRB Chair or designee will conduct a review of the project to determine if it qualifies for review using the expedited procedure according to IRB policy and human subjects research regulations. Request for revisions and/or clarifications will be entered electronically along with the study team responses. The Chair or designee will complete the IRB Reviewer Checklist for Expedited Initial Application and electronically submit this document along with review notes and decisions.
6. If there are no question/concerns, or if responses are satisfactory, and the research as described on the application fits criteria for review by the expedited process, the Reviewer will electronically approve the application and the approval letter will be generated.
7. If the reviewer makes the decision that the research does not fit the criteria for review by the expedited procedure, then the IRB staff will notify the study staff that the protocol does not meet criteria for review by the expedited procedure. The study staff will be provided with the rationale for this decision and of the need to submit the research study for full board review.
8. The applications submitted for review by the expedited procedure are evaluated based upon the DHHS and FDA criteria for expedited review research determinations in 45 CFR 46.110 et al, 21 CFR 56.110 et al and accompanying guidance documents.
9. At each meeting, minutes of the previous meeting are available to all IRB members. Expedited determinations are included in the

“Report of Expedited, Exempt, Acknowledged Items” of the minutes.

**B. Expedited Continuing Review**

1. The IRB Reviewer completes the Continuing Review Full Board and Expedited Review Protocols Reviewers Checklist and electronically submits these documents along with review notes and decision upon completion of the review.

**C. Expedited Amendments**

1. Changes made to the informed consent, protocol, and HIPAA Authorization must be submitted for prospective IRB review and approval except where necessary to eliminate apparent immediate hazards to subjects. The IRB must be notified immediately of any changes made to protect subjects' immediate safety.
2. The Chair or designee must determine whether the change is minor. Examples of amendments that may be considered minor include advertisements, personnel changes and other, low risk changes.

**VII. MATERIAL PROVIDED TO THE REVIEWER**

- A. IRB Application and the Principal Investigator Statement of Assurance
- B. Informed Consent or Waiver of Informed Consent
- C. Protocol
- D. HIPAA Authorization or HIPAA Waiver of Authorization (if applicable)
- E. Budget
- F. Advertisements (if applicable)
- G. Questionnaires and Surveys (if applicable)
- H. Conflict of Interest Disclosure (if applicable)

**VIII. CHECKLISTS**

- A. IRB Reviewer Checklist for Expedited Initial Application
- B. IRB Reviewer Checklist for Continuing Review Full Board and Expedited Protocols
- C. IRB Reviewer Checklist Informed Consent

**IX. REFERENCES**

- A. [Office for Human Research Protections \(OHRP\) - Expedited Review Categories](http://www.hhs.gov/ohrp/policy/expedited98.html) <http://www.hhs.gov/ohrp/policy/expedited98.html>
- B. FDA Expedited Review Categories – <http://www.fda.gov/ScienceResearch/SpecialTopics/RunningClinicalTrials/ucm119074.htm>