

 Research Integrity Office	Human Research Protection Program Regulatory Sheet	
Title: Expedited Review of Research	Date Effective 4/21/2008	Supersedes P&P dated: N/A
	Identification #	Page 1 of 5

BACKGROUND

An expedited review procedure consists of a review of a research protocol by the IRB chair or by one or more experienced IRB members designated by the chair in accordance with the requirements set forth in the federal Common Rule 45 CFR 46.110 and FDA regulations 21 CFR 56.110. OHRP and the FDA have published parallel guidance describing when expedited initial and continuing review of research is appropriate and a list of categories of research that may be reviewed through and expedited procedure. This process is meant to be a faster way to conduct reviews for studies which are minimal risk or for minor changes to studies.

SCOPE

This policy covers the process and content of expedited review of human subject research.

AUTHORITY

45 CFR 46.110 and 21 CFR 56.110. Expedited review procedures for certain kinds of research involving no more than minimal risk, and for minor changes in approved research.

Expedited Review Categories <http://www.hhs.gov/ohrp/humansubjects/guidance/expedited98.htm> and <http://www.fda.gov/oc/ohrt/IRBs/expeditedreview.html>

OHRP Guidance of the Use of Expedited Review Procedures (2003)

I. POLICY

- A. Expedited review of research includes consideration of all determinations required for approval as defined in applicable federal, state and local regulations per 45 CFR 46.111 and subparts B, C, and D, if applicable. The standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review
- B. Expedited reviews may be carried out by the IRB Chair, an IRB Co-Chair or by one or more experienced reviewers designated by the Chair from among members of the IRB. Consultants may assist the IRB in the review of issues which require expertise beyond, or in addition to, that available on the IRB.
- C. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research.
- D. The expedited review process may be used for the initial review of projects involving:
 1. no more than minimal risk, and
 2. only those procedures listed in one or more of the expedited categories, see Appendix A.
 3. The activities listed should not be deemed to be of minimal risk simply because they are included on this list in Appendix A.
- E. The expedited review procedure for initial review of projects is not 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 are implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

- F. The expedited review procedure may not be used for classified research involving human subjects.
- G. Modifications to previously approved research projects may be expedited if the modification involves only a minor modification to the approved project during the (one year or less) period of approval.
- H. Full board studies may be review using expedited review procedures if the study falls into one of the categories in Appendix B.
- I. The Chair, Co-Chairs or designee retain the right to require full board review when warranted by the nature of the research where there are concerns with regard to subject safety or welfare.
- J. ORIO keeps all IRB members advised of research proposals that have been approved under the expedited review procedure.
- K. Expedited review procedures are typically not used research involving prisoners. However, if an IRB Chair, at its discretion, chooses to use expedited review for research involving prisoners because the activity meets the expedited review criteria, the prisoner representative of the IRB will be one of the designated reviewers.

II. PROCEDURES

- A. Submitting for IRB Review
 - 1. The PI submits proposed studies to the eIRB for review by creating a new study submission.
 - 2. The Initial review questionnaire will prompt if minimal risk review is requested and the PI will make the request if so desired, with careful attention to the description of risk.
- B. Review
 - 1. The managing analyst will conduct an administrative review and assess the PIs application for minimal risk review. If the analyst's assessment yields a different categorization of review, the analyst will query the review team and Chair as necessary and modify the category as appropriate.
 - 2. The managing analyst recommends the study for approval to the Chairs with the expedited review categories indicated.
 - 3. The Chair, co-chair or designee will conduct a complete review of the proposed study including:
 - a. A review of all of the 45 CFR 46.111 approval criteria and subparts B, C, and D, if applicable.
 - b. The standard requirements for informed consent (or its waiver, alteration, or exception) apply regardless of the type of review.
 - 4. The Chairs may refer questions back to the PI for clarification.
 - 5. The Chairs may change the category of review if an error has been made.
- C. Approval
 - 1. When the reviewer approves the study, an approval memo is generated and posted in the eIRB and e-mailed to the PI and review team. The approval memo indicates:
 - a. The approval date
 - b. The expiration date
 - c. The expedited review categories
 - d. Consent requirements
 - e. HIPAA requirements
- D. Continuing Review
 - 1. As with full board studies, all expedited studies must be reviewed at least once per year.
 - 2. Studies that were originally expedited will be likely to continue to be expedited if there are no modifications to the study that alter the risk or procedures in a way that changes the categorization of the study.
 - 3. The reviewers, both analysts and Chairs, use the continuing review as an opportunity to consider the initial analysis and expedited designation. If the review category changes, the PI will be notified via the approval memo (if still expeditable) or when the study is scheduled for full board review.
 - 4. Studies that were full board but now meet one of the expedited review categories for continuing review of full board research (Appendix B) will be reviewed in an expedited manner.
- E. Modifications

1. Minor modifications to full board studies will be reviewed and approved using the same expedited review procedures as an initial approval.
2. The analysts will rely on the IRB Chairs, ORIO Directors and IRB members to determine if a change is minor.

III. DEFINITIONS

Minor Change - is defined as a proposed change in research related activities that does not materially affect an assessment of the risks and benefits of the study and does not substantially change the specific aims or design of the study. Examples of "minor changes" include:

1. Administrative (non-medical) changes
2. Minor changes to consent form, HIPAA form, surveys, questionnaires, brochures or recruitment materials
3. Submission of new consent form, HIPAA form, surveys, questionnaires, brochures or recruitment materials that are easily compared to previously approved forms or materials
4. Editorial changes for purposes of clarification
5. Addition or change of study personnel or study sites

APPENDIX A – PXPEDITED REVIEW 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.
 - i. For these subjects, amounts drawn may not exceed 550 ml in an 8 weeks period and
 - ii. no more 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.
 - i. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml/kg in an 8-week period and
 - ii. 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 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. 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.
 - a. 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.)
 - b. Examples:
 - i. 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;
 - ii. weighing or testing sensory acuity;
 - iii. magnetic resonance imaging;
 - iv. electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography;
 - v. 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).
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.

**APPENDIX B – EXPEDITED REVIEW CATEGORIES
FOR CONTINUING REVIEW OF FULL BOARD RESEARCH**

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), Appendices A and B, 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.