

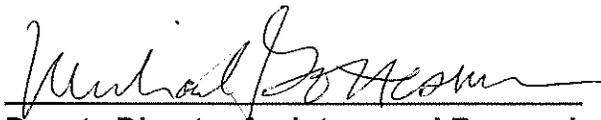
**HRPP STANDARD OPERATING PROCEDURE/POLICY APPROVAL &
IMPLEMENTATION**

OFFICE OF HUMAN SUBJECTS RESEARCH PROTECTIONS

SOP Number: 7A

**SOP Title: REQUIREMENTS FOR EXPEDITED REVIEW OF RESEARCH BY NIH
INSTITUTIONAL REVIEW BOARDS (IRBS)**

**Distribution: Scientific Directors; Clinical Directors; Clinical Investigators, IRB
Chairs, IRB Administrators, Protocol Navigators**

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**SOP 7A – REQUIREMENTS FOR EXPEDITED REVIEW OF RESEARCH BY
NIH INSTITUTIONAL REVIEW BOARDS (IRBS)**

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SOP 7A REQUIREMENTS FOR EXPEDITED REVIEW OF RESEARCH BY NIH INSTITUTIONAL REVIEW BOARDS (IRBS)

7A.1 PURPOSE

This policy provides basic requirements for review of research activities by the expedited review process.

7A.2 POLICY

Research activities that satisfy 45 CFR 46.110 and 21 CFR 56.110 (when applicable), may be reviewed through the expedited review procedure. Like review by the convened IRB, expedited review must fulfill all the requirements of review found at 45 CFR 46.111 and subparts B, C, and D, if applicable.

7A.3 CRITERIA FOR DETERMINATION OF ACTIVITIES ELIGIBLE FOR EXPEDITED REVIEW

Research activities may be reviewed through the expedited review procedure if they are either or both of the following:

- A. Minor changes (see **7A.8.B.2**, below) to previously approved research during the period (of one year or less) for which approval is authorized.
 - 1. For example, expedited review of the short form consent process may be appropriate if the protocol and the full informed consent document have already been approved by the IRB (see SOP 12-Requirements for Informed Consent).

- B. Present no more than minimal risk to subjects and involve only procedures listed in one or more of the allowable research categories authorized by the Secretary of HHS (Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) Through an Expedited Review Procedure, 63 Fed. Reg. 60,364-60,367 (Nov. 8, 1998)). See **Appendix B** for a description of the categories.
 - 1. The allowable research categories should not be deemed to be of minimal risk simply because they are included on the list. Inclusion on the 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.

2. Note that categories (1) through (7) on the Secretary's list pertain to both initial and continuing IRB review.

7A.4 CIRCUMSTANCES IN WHICH THE EXPEDITED PROCEDURE MAY NOT BE USED

- A. 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 or privacy and breach of confidentiality are no greater than minimal.
- B. The expedited review procedure may not be used for U.S. government classified research involving human subjects.
- C. The expedited review procedure may not be used for research involving prisoners.

Note that expedited review is prohibited for certain FDA-regulated research. For more information see SOP 15 - Research Regulated by the Food and Drug Administration (FDA): General Procedures for Both IND and IDE Applications; SOP 15A - Research Regulated by the Food and Drug Administration (FDA): Information and Policies Specific to Research Involving Investigational New Drugs (Including Biological Products); and SOP 15B - Research Regulated by the Food and Drug Administration (FDA): Information and Policies for Investigational Device Exemption (IDE) Applications.

7A.5 PROCEDURES FOR REVIEW OF RESEARCH ACTIVITIES BY THE EXPEDITED PROCESS

- A. Pre-review of Research Activities for Expedited Review: The IRB staff, in consultation with the IRB Chair or designee, pre-reviews all submissions for expedited review, including applications for expedited initial review, expedited continuing review, expedited closure of protocols, and expedited amendments for minor changes to previously approved research. The determination of whether an item is eligible for consideration under the expedited review procedure is made by the IRB Chair or designee. The decision whether to expedite eligible items or to send them for full Board review is at the discretion of the IRB Chair or designee.

B. Selection of Reviewers for Research Activities Eligible for Expedited Review:

1. The IRB Chair, or one or more experienced IRB members designated by the Chair, may review and approve research that meets criteria for expedited review.
2. An experienced IRB member is defined as a regular or alternate member who knows the expedited review categories, and, in the judgment of the Chair, possesses the expertise needed to review the proposed research.

C. Responsibilities of Reviewers

1. Reviewers may obtain additional consultation.
2. Reviewers may approve submissions unconditionally or approve with stipulations but may not disapprove research.
 - a. If the reviewer determines that the research is not eligible for expedited review, or even if eligible for approval by expedited review but should still be reviewed by the convened IRB, this recommendation will be forwarded to the IRB Chair for non-expedited review by the convened IRB.
 - b. If the reviewer determines expedited review is appropriate for the research, the reviewer will determine a review interval for approved expedited research not less than once per year (see SOP 7 - Requirements for the Ethical and Regulatory Review of Research by NIH Institutional Review Boards (IRBs).
 - c. A separate risk and benefit assessment must be documented for each cohort involved in the protocol. Documentation for vulnerable populations (children, prisoners, pregnant women, fetuses, employees and individuals unable to provide consent) should also include protocol-specific findings that support and justify the risk and benefit assessment.
 - d. Any stipulations that must be met prior to final approval of expedited research are sent to the investigator by mail or email and documented in the IRB file. Final approval is provided by the IRB Chair or designee when the response to stipulations has been submitted and approved by the designated reviewer.

7A.6 PROCEDURES FOR INITIAL REVIEW BY THE EXPEDITED PROCESS

Only complete submissions that meet the requirements specified in SOP 8 - Procedures and Required Documentation for Submission and Initial Review of Protocols) will be accepted for expedited review. The reviewer(s) will have access to all of the materials submitted for review. Research materials submitted for review must include sufficient detail for the reviewer(s) to determine: (i) that the study qualifies for review by an expedited process, and (ii) that the study meets the approval criteria that are specified in SOP 7 - Requirements for the Ethical and Regulatory Review of Research by NIH Institutional Review Boards (IRBs). In conducting such a review, the reviewers will document the IRB reviewer's determination in the IRB system, which includes a reviewer checklist (**Appendix A**).

7A.7 PROCEDURES AND CRITERIA FOR CONTINUING REVIEW BY THE EXPEDITED PROCESS

The procedures for expedited review for continuing research activities are the same as the procedures for continuing review by the convened IRB as described in SOP 9 - Continuing Review by the Convened IRB except that expedited review must be documented in the IRB system consistent with the requirements specified in Appendix A and the review is to occur consistent with the expedited process explained in **7A.5.B and C**.

A. Continuing Review of a Research Activity Initially Approved by an Expedited Review:

A research activity that is initially approved by expedited review may use an expedited review procedure for continuing review. For this to occur, the research activity must still qualify for expedited review as described in **7A.3** above. If it does not qualify, continuing review at a convened IRB meeting must take place.

B. Continuing Review of Research Activities Previously Approved by the Convened IRB:

Continuing review for research activities previously approved by the convened IRB may be conducted through expedited review provided they meet the criteria for approval as described by expedited review categories (8) and (9) (**Appendix B**) as permitted by 45 CFR 46.110. IRBs are reminded that expedited review usually is not appropriate at the time of continuing review if the research required review by the convened IRB at the time of initial review.

7A.8 PROCEDURES AND CRITERIA FOR EXPEDITED REVIEW OF AMENDMENTS THAT CONSTITUTE A MINOR CHANGE

- A. Procedures: SOP 10 - Amendments to IRB-approved Research contains some requirements for general amendments and expedited review of amendments. Expedited review of amendments that constitute a minor change have additional criteria and NIH policy requires that the reviewer document the IRB reviewer's determination in the IRB system consistent with the requirements specified in **Appendix A**.
- B. Criteria: Criteria for Determination of Eligibility for Expedited Review of Amendments:
 - 1. Amendments to research previously approved by expedited review may be reviewed through the expedited process as long as the amendment does not make the study ineligible for expedited review.
 - 2. Expedited review can be used for amendments making minor changes to previously approved research, whether previously approved via expedited review or not. A minor change is one which, in the judgment of the reviewer, makes no substantial alteration in:
 - a. The risk-benefit profile of the study.
 - b. The presumed willingness of current subjects to remain in the study.
 - c. The scientific validity of the research design or methodology. (Note: adding procedures that are not eligible for expedited review would not be considered a minor change).
 - d. The number of subjects enrolled in the research.
 - e. The qualifications of the research team. (Note: the addition or deletion of investigators usually is a minor change; however, a change in PI may not qualify as a minor change).
 - f. The facilities available to support safe conduct of the research.

7A.9 REPORTING AND DOCUMENTING IRB ACTIONS REGARDING EXPEDITED REVIEW.

- 1. The reviewer of expedited actions documents determinations in the IRB system per **Appendix A**, including the specific expeditable category or categories relevant to the action.

2. IRB members are provided with a written list of all actions approved by the expedited procedure in the next meeting agenda. IRB members may request additional information.
3. The IRB will provide the PI with the outcome of expedited review.
4. Expedited review actions announced at a convened IRB meeting are listed in that meeting's IRB minutes. A separate risk and benefit assessment must be documented for each cohort involved in the protocol. Documentation for vulnerable populations (children, prisoners, pregnant women, fetuses, employees and individuals unable to provide consent) should also include protocol-specific findings that support and justify the risk and benefit assessment.
5. The expedited actions are entered and tracked in the IRB and Office of Protocol Services (OPS) databases in the same way as non-expedited actions.

LIST OF APPENDICES

Appendix A: Required Fields for Electronic Documentation of IRB Expedited Review Determinations

Appendix B: List of Research Categories Approved By the Secretary HHS

APPENDIX A- REQUIRED FIELDS FOR ELECTRONIC DOCUMENTATION OF IRB EXPEDITED REVIEW DETERMINATIONS

Each IRB system (PTMS and iRIS™) will be used to document the determination of the reviewer for each expedited action. The system documentation will contain the elements of the determination as specified below. No output from the system will be required but others, such as IRB members and OHSRP staff, will be provided access to these determinations.

EXPEDITED REVIEW: IRB REVIEWER DETERMINATION REQUIREMENTS

- A. The investigator submission will contain the following minimum requirements if not already captured in the applicable IRB system:
1. Date of request
 2. PI Name
 3. Title of Protocol
 4. Institute/Center
 5. Supporting documentation relevant to this request as appropriate to the request (e.g., the protocol, consent document or other information needed to make a determination).
- B. Reviewer's checklist: *(select all that apply)*
1. ____ Minor change(s) in previously approved research during the period for which approval is authorized (45 CFR 46.110(b)(2)). A minor change is one which, in the judgment of the reviewer, makes no substantial alteration in:
 - a. the risk-benefit profile of the study,
 - b. the presumed willingness of current subjects to remain in the study,
 - c. the scientific validity of the research design or methodology. (Note: adding procedures that are not eligible for expedited review would not be considered a minor change.)
 - d. the number of subjects enrolled in the research,
 - e. the qualifications of the research team. (Note: the addition or deletion of investigators usually is a minor change; however, a change in PI may not qualify as a minor change).
 - f. the facilities available to support safe conduct of the research.

2. ____ Research involves no more than minimal risk to subjects and involves only procedures listed in one or more of the allowable research categories on ***the List of Research Categories Approved by the Secretary, HHS*** (45 CFR 46.110(b)(1))¹

C. Reviewer's Determination

I have made the following determination:

1. ____ The activity is not eligible for expedited review and must be reviewed by the convened IRB, explain: *(explanation is optional)*
2. ____ The activity is eligible for expedited review, however the reviewer and IRB Chair determined that the protocol must be reviewed by the convened IRB, explain: *(explanation is optional)*
3. ____ The activity is eligible for expedited review as a minor change in previously approved research and is approved. (45 CFR 46.110(b)(2))
4. ____ The activity is eligible for expedited review for initial or continuing review as research that involves no more than minimal risk to subjects and involves only procedures listed in one or more allowable research categories and is approved under research category number¹ ____ (45 CFR 46.110(b)(1))

For Initial or Continuing Reviews or Amendments to previously approved research, in addition to meeting the regulatory requirements of 45 CFR 45.110², above, all of the following regulatory elements of 45 CFR 46.111 must be satisfied and Subparts B, C or D as applicable:

1. __ Risks to subjects are minimized (45 CFR 46.111(a)(1))
2. __ Risks are reasonable in relationship to anticipated benefits, if any (45 CFR 46.111(a)(2))
3. __ Subject selection is equitable (45 CFR 46.111(a)(3))

¹ For more information about the List of Categories, see **SOP 7A- Appendix B**

² For more information about criteria for approval, see SOP 7 - Requirements for the Ethical and Regulatory Review of Research by NIH Institutional Review Boards (IRBs)

4. ___ Informed consent process is adequate and is appropriately documented (45 CFR 46.111(a)(4), 46.111(a)(5), 46.116 and 46.117)
5. ___ Data will be monitored to ensure safety of subjects (45 CFR 46.111(a)(6))
6. ___ When appropriate, there are adequate provisions for privacy & confidentiality (45 CFR 46.111(a)(7))
7. ___ When appropriate, additional safeguards have been included in the study for vulnerable subjects (45 CFR 46.111(b))

The following elements must be included if not already captured in the IRB system:

1. Stipulations
2. Period of Approval
3. Risk Assessment (*A separate risk assessment must be documented for each cohort involved in the protocol. Documentation for vulnerable populations (children, prisoners, pregnant women, fetuses, employees and individuals unable to provide consent) should also include protocol-specific findings that support and justify the risk assessment.*)
4. Benefit Assessment (*A separate risk assessment must be documented for each cohort involved in the protocol. Documentation for vulnerable populations (children, prisoners, pregnant women, fetuses, employees and individuals unable to provide consent) should also include protocol-specific findings that support and justify the risk assessment.*)
5. Name of Reviewer(s)
6. Reviewer(s) Signature
7. Reviewer(s) Title (Chair, Designated IRB Member)
8. Date of review

APPENDIX B- LIST OF RESEARCH CATEGORIES APPROVED BY THE SECRETARY HHS

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

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.

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 (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 (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, 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.

*Children are defined in the HHS regulations as Persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.” 45 CFR 46.402(a).

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 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.

Source: Categories of Research That May Be Reviewed by the Institutional Review Board (IRB) Through an Expedited Review Procedure, 63 Fed. Reg. 60,364-60,367 (Nov. 8, 1998) as described at <http://www.hhs.gov/ohrp/policy/expedited98.html>.