UNIVERSITY OF SOUTHERN MAINE
Office of Research Integrity & Outreach

Procedure #:	HRPP-027
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Reviewed By:	IRB Chairs; IRBs; ORIO
Procedure Title:	Expedited Initial Review

1.0 Objective

1.1. To describe the policies and procedures for the University of Southern Maine (USM) Institutional Review Board (IRB) to conduct expedited initial review of human subjects research.

2.0 General Description

2.1. Expedited review procedures allow the IRB to review and approve studies that meet the categories adopted by the U.S. Department of Health and Human Services (HHS) or the Food and Drug Administration (FDA) that involve no greater than minimal risk without convening a meeting of the full IRB.

2.2. The expedited review procedure may also be used for approving minor changes in previously approved research during the period (of one year or less) for which approval is authorized. (See *HRPP-040 IRB Review of Modifications*)

2.3. The expedited review process may also be used for the approval of revisions from a contingent approval of the convened IRB for non-substantive clarifications or modifications. This approval may be conducted by the IRB Chair or designee. (See *HRPP-040 IRB Review of Modifications*)

2.4. The expedited review procedure cannot be used in any of the following circumstances:

2.4.1. Research study involves more than minimal risk;

2.4.2. Research study involves minimal risk but does not appear in the categories of research eligible for expedited review;

2.4.3. When research is classified (such as for national security purposes by the sponsor);

2.4.4. If any of the above conditions exists, the research study may not undergo an expedited review procedure and must undergo a full review.

2.5. Expedited reviewers only approve research that meets the federal criteria for approval as specified in 45 CFR 46.111 and 21 CFR 56.111.

2.6. Expedited reviewers ensure that the study's informed consent process and documentation meet the requirements as specified in 45 CFR 46.116 and 21 CFR 50.25 unless the IRB waives the requirements in accord with federal regulations. (See *HRPP-029 Informed Consent*.)

2.7. Expedited reviewers exercise all the authority of the IRB except that the reviewers may not disapprove the research. In this case the protocol would be reviewed by the convened IRB.

2.8. The IRB agenda for convened meetings advises the IRB of research studies approved using expedited review procedures since the prior IRB meeting.

2.9. The limited IRB review that is required for certain exempt research may be conducted using expedited review procedures. For limited IRB the reviewer will receive the information related to privacy and confidentiality and the Broad Consent document when appropriate.

2.10. The IRB has determined that continuing review of research is required for all research that qualifies for expedited review due to the unique nature of a multi-institution Collaborative IRB.

2.10.1. This rational will be documented in all applicable research records.

3.0 Responsibility

3.1. It is the responsibility of the Office of Research Integrity and Outreach (ORIO) staff, Research Compliance Administrator (RCA), Institutional Review Board (IRB), and investigators to execute this SOP.

4.0 Definitions

4.1. **Minimal Risk** means 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. (45 CFR 46.102(j))

5.0 Categories

5.1. Category 1. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.

5.1.1. (a) Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required.

5.1.1.1. 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.

5.1.2. (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.

5.2. Category 2. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:

5.2.1. (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 two (2) times per week; or

5.2.2. (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 two (2) times per week.

5.3. Category 3. Prospective collection of biological specimens for research purposes by noninvasive means. Examples:

5.3.1. (a) Hair and nail clippings in a non-disfiguring manner;

5.3.2. (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction;

5.3.3. (c) permanent teeth if routine patient care indicates a need for extraction;

5.3.4. (d) excreta and external secretions (including sweat);

5.3.5. (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;

5.3.6. (f) placenta removed at delivery;

5.3.7. (g) amniotic fluid obtained at the time of rupture of the membrane prior to or during labor;

5.3.8. (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;

5.3.9. (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings;

5.3.10. (j) sputum collected after saline mist nebulization.

5.4. Category 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:

5.4.1. (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;

5.4.2. (b) weighing or testing sensory acuity;

5.4.3. (c) magnetic resonance imaging;

5.4.4. (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, Doppler blood flow, and echocardiography;

5.4.5. (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

5.5. Category 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).

5.5.1. Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects. 45 CFR 46.104(d)(4). This listing refers only to research that is not exempt.

5.6. Category 6. Collection of data from voice, video, digital, or image recordings made for research purposes.

5.7. Category 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.

5.7.1. Note: Some research in this category may be exempt from the HHS regulations for the protection of human subjects 45 CFR 46.104(d). This listing refers only to research that is not exempt.

5.8. Category 8. Continuing review of research previously approved by the convened IRB as follows:

5.8.1. (a) Where

5.8.1.1. (i) the research is permanently closed to the enrollment of new subjects;
5.8.1.2. (ii) all subjects have completed all research-related interventions; and
5.8.1.3. (iii) the research remains active only for long-term follow-up of subjects; or

5.8.2. (b) Where no subjects have been enrolled and no additional risks have been identified; or

5.8.3. (c) Where the remaining research activities are limited to data analysis.

5.9. Category 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.

6.0 Procedure

6.1. Submission and Screening

6.1.1. The Principal Investigator (PI) makes a preliminary determination that a protocol is eligible for expedited review based on an assessment of the protocol establishing that it falls into one or more of the categories specified in the federal regulations. The investigator may contact the ORIO with questions.

6.1.1.1. The RCA or designee makes the final determination regarding whether a protocol is eligible for expedited review.

6.1.2. The PI submits a completed IRB application to the ORIO.

6.1.2.1. There is one form for all research regardless of the applicable review categories.

6.1.3. Upon receipt of the application, ORIO staff screen the application including the informed consent process and documentation for completeness and accuracy.

6.1.4. ORIO staff review the PI's expedited category selection for appropriateness.

6.1.4.1. If it is clear to the designated ORIO staff that the application does not meet the criteria for expedited review, the designated ORIO staff contacts the PI and recommends either an exempt or full review application be submitted.

6.1.5. ORIO staff screen for Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule, Family Educational Rights to Privacy Act (FERPA) concerns and/or The Protection of Pupil's Rights Amendment.

6.1.6. ORIO staff contact the PI for any additional information needed for a thorough review.

6.1.7. After screening the application, ORIO staff send the application to the RCA or designee to assign a reviewer.

6.1.7.1. A minimum of one (1) IRB member from among the IRB membership, with the required appropriate scientific or scholarly expertise experience, (regular voting or alternate member) must conduct an in-depth review of the protocol expedited initial review. The reviewer must be one designated as "experienced" to conduct expedited review by the USM IRB.

6.1.7.1.1. An IRB member that completes the IRB member trainings and has served as a second reviewer on at least one prior expedited initial review is considered to have the required experience.

6.2. Assigning Reviewers

6.2.1. The RCA or designee makes initial IRB reviewer assignments based on the member's familiarity with IRB issues and his/her experience and expertise.

6.2.1.1. Any IRB member can request to review an expedited study submission.

6.2.2. Expedited reviewers notify ORIO staff if they are unable to conduct an expedited review during the assigned time period or have a conflict of interest on any protocol as outlined in the HRPP 023 IRB Member and IRB Staff Conflict of Interest SOP.

6.2.2.1. If this occurs, another reviewer is selected by the RCA.

6.2.3. If the RCA or expedited reviewer determines additional expertise or knowledge are required to conduct an in-depth review of the protocol, the RCA will seek a consultant (See *HRPP-022 IRB Use of Additional Expertise).*

6.2.3.1. The RCA will defer IRB review until the appropriate expertise can be obtained.

6.3. Expedited Review Process

6.3.1. Expedited reviewers conduct expedited reviews outside of a convened meeting in accordance with 45 CFR 46.110.

6.3.1.1. The reviewer completes the initial review process within ten (10) days.

6.3.2. The reviewer for expedited protocols receives a completed IRB application which includes the following:

6.3.2.1. Personnel information
6.3.2.2. Study location
6.3.2.3. Funding
6.3.2.4. Purpose
6.3.2.5. Study procedures
6.3.2.6. Background
6.3.2.7. Provisions to monitor data if applicable
6.3.2.8. Investigator experience
6.3.2.9. Subject population
6.3.2.10. Subject compensation and costs
6.3.2.11. Recruitment
6.3.2.12. Potential benefits to participants
6.3.2.13. Risks
6.3.2.14. Provisions to maintain confidentiality of data
6.3.2.15. Provisions to protect privacy interests of participants
6.3.2.16. Informed consent or broad consent if appropriate
6.3.2.17. Informed assent
6.3.2.18. HIPAA
6.3.2.19. Attachments

6.3.3. The reviewer is responsible for reviewing the application upon receipt to determine that research activities:

6.3.3.1. Present no more than minimal risk to human subjects, and
6.3.3.2. Involve only procedures listed in one or more of the categories specified in the federal regulations.

6.3.4. Using the Reviewer Checklist, the reviewer determines and documents:

6.3.4.1. That the research activities meet the federal criteria for IRB approval as outlined in 45 CFR 46.111 and 21 CFR 56.111;
6.3.4.2. That the PI describes the informed consent process and how to obtain documentation of informed consent, as specified in 45 CFR 46.116 and 117 and 21 CFR 50.25 unless the reviewer waives the requirements in accord with federal regulations. (See *HRPP-029 Informed Consent*); and
6.3.4.3. Any specific findings (e.g., requests for a waiver of informed consent or documentation of informed consent, requests for waiver of authorization, and/or Subpart B, C, D findings).

6.3.5. Using the Reviewer Comments, the reviewer:

6.3.5.1. Provides feedback for any clarification needed by the PI;
6.3.5.2. Documents any issues to be addressed by the PI; and
6.3.5.3. Provides questions or comments to the RCA or ORIO staff (as needed).

6.3.6. Using the IRB Approval Notes, the reviewer documents:

6.3.6.1. A determination regarding expedited eligibility;
6.3.6.2. The applicable expedited category (or categories);
6.3.6.3. The policy rationale for requiring continuing review and the approval period (one year or less);
6.3.6.4. Whether the research meets the federal criteria for approval; and
6.3.6.5. One of the following recommendations:
6.3.6.5.1. Approval;
6.3.6.5.2. Revisions and/or Additions Required; or
6.3.6.5.3. Full Board Review Required.

6.4. Review Outcomes

6.4.1. Approval

6.4.1.1. IRB approval indicates that the IRB reviewer(s) concluded that the research and consent forms meet the federal criteria for approval.
6.4.1.2. An approval determination verifies the IRB agrees with the assessment of the protocol and/or specific findings as described by the PI in the application.
6.4.1.3. The RCA or designee processes the determination and the PI is provided with an approval letter and, when applicable, stamped informed consent/assent documents.

6.4.1.3.1. The date the approval letter is issued is the date the approval period starts.

6.4.1.3.1.1. The approval period ends no more than one (1) year from the date of approval.

6.4.1.3.1.2. Continuing review of research is required before the approval period ends for all research that qualifies for expedited review.

6.4.2. Revisions and/or Additions Required

6.4.2.1. The IRB reviewer(s) withhold approval pending submission of revisions/additional information.

6.4.2.2. The RCA or designee returns the protocol to the PI to address concerns/questions provided by the reviewer(s).

6.4.2.3. The PI responds to comments, makes any required changes or additions to the protocol, and re-submits the application within 14 days of receiving the requested revisions.

6.4.2.3.1. Barring extenuating circumstances, if a PI does not respond to requested revisions in the 14-day time-period, the application is administratively withdrawn, and a new protocol submission is required.

6.4.2.4. The RCA or designee assigns the PI's resubmission to the primary expedited reviewer who made the initial determination.

6.4.2.5. This process continues until the reviewer recommends approval or that full review is required.

6.4.3. Full Board Review Required.

6.4.3.1. The primary expedited reviewer may determine that the protocol requires full review by the IRB at a convened meeting.

6.4.4. The expedited reviewer may not recommend disapproval.

7.0 References

7.1. 45 CFR 46.107 – 46.111;
7.2. 45 CFR 46.115 – 46.117;
7.3. 21 CFR 50.23 – 50.24;
7.4. 21 CFR 50.56;
7.5. 21 CFR 56.102;
7.6. 21 CFR 56.110;
7.7. 21 CFR 812.3;
7.8. 63 FR 60364 – 60367;
7.9. Federally Mandated Expedited Review Criteria – Effective November 9, 1998 – Definition of Minimal Risk Guidance to PI and Reviewers.