

Appalachian State University Research Protections and Institutional Review Board Standard Operating Procedures		
SOP #5 Rev. 2	Expedited Review of Research	Date Effective: 1.21.2019
Approved by IRB Chair	<i>R. S. Grand</i>	Date 1/21/2019
Approved by RP Director	<i>Robin Schuman Mendenhall</i>	Date 1/21/2019

PURPOSE

To describe the procedures for conducting expedited review of human subject research.

GENERAL DESCRIPTION

45 CFR 46 regulates the ethical oversight of human participants in research. While the regulations were originally written for studies to be required by a convened IRB, the regulations allow for “expedited” review of studies that are determined to be no more than minimal risk and fit into one of the categories for expedited review. The expedited review procedure may not be used for classified research involving human subjects.

The IRB Chairperson or one or more experienced reviewers from among the IRB membership (regular and alternate members) conducts expedited reviews. Expedited reviewers exercise all of the authority of the IRB except that the reviewers may not disapprove the research application.

Only the convened IRB may disapprove a research activity in accord with non-expedited procedures set forth in the DHHS and FDA regulations.

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

RESPONSIBILITY

Execution of SOP: IRB Chair, IRB administrators Research Protections (RP) Staff, Principal Investigator (PI)/Study Personnel.

PROCEDURES

1. IRB administrators make a preliminary determination that an initial protocol review, Limited Review, continuing IRB review (CR), or a proposed modification to an approved protocol, is eligible for expedited review based on an assessment of the level of risk and the DHHS review categories and FDA requirements.
 - a. If the sponsor or the PI specifically requests full Board review procedures, a full Board review is conducted.
 - b. Minor changes (e.g., modifications/addendums) to approved protocols can be reviewed by expedited review. The Board defines a minor change as one which makes no substantial alteration in:

- i. The level of risks to subjects;
 - ii. The research design or methodology;
 - iii. The subject population;
 - iv. Qualifications of the research team;
 - v. The facilities available to support the safe conduct of the research; or
 - vi. Any other factor that would warrant review of the proposed changes by the convened IRB.
2. IRB administrators conduct a preliminary review of the study and add it to the agenda for the weekly IRB Chair meeting. The study is discussed at the meeting which may include the following:
 - a. an assessment of the risk level and the expedited or limited review category;
 - b. any special considerations (e.g., need for additional expertise, prisoner representative review, other institutional reviews, HIPAA or FERPA concerns); and
 - c. whether an addition members of an experienced IRB member with a specific expertise to conduct the IRB review.
 - d. The review may included additional considerations such as FDA applicability, application of the practice of medicine under NC state law, conflicts of interest or other reviews which may be needed.
3. The IRB Chair, or designee, reviews the RP staff recommendations and makes a final decision that the review request meets the expedited review criteria and appoints a primary expedited reviewer or expert reviewer from experienced IRB membership, or external experts as needed.
 - a. An experienced IRB member is a member who has completed the required IRB training, reviewed the training materials provided to each member, served on the IRB for 1 month, and has sufficient expertise to assess the risk level of the research.
 - b. Experienced IRB members are recommended as expedited reviewers based on the member's familiarity with IRB issues, experience, and expertise.
4. RP staff contact the appointed expedited reviewer(s), and any other appointed experts, to confirm that they do not have a conflict of interest and the review can be completed in a timely manner (i.e., within 2 weeks).
 - a. Reviewers access the study and materials in IRBIS and are provided a reviewer checklist. Reviewers who do not have access to IRBIS are sent copies of the application and other provided documentation.
 - b. The appointed expedited reviewer(s) reviews the study according to the criteria for approval and the primary expedited reviewer makes a final determination that the research meets the expedited review criteria.
5. The primary expedited reviewer, in consultation with any other expedited reviewer and experts, makes one of the following determinations:
 - a. Approval: The study can be approved if the primary reviewer finds that

- i. The research meets the federal criteria for approval as specified in 45 CFR 46.109, 100 and 111 and 21 CFR 56.111;
 - ii. The study's informed consent process and documentation meets 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; and
 - iii. Adequate procedures to protect vulnerable subjects (prisoners, children, pregnant women, seriously ill patients, and mentally incapacitated adults) and any applicable regulatory criteria (Subpart B, C, or D) are met.
 - iv. The IRB may also require that the study investigators meet codes of professional ethics as it deems appropriate.
 - b. Revisions and/or Additional Information Needed: The primary reviewer withholds approval pending submission of clarifications/revisions/additional information. The reviewer only raises controverted issues or clarifications that he/she has determined do not meet the federal criteria for approval, Appalachian State policies/procedures, or other laws and regulations.
 - i. The study is updated with specific requests in IRBIS record and returned to the PI.
 - ii. The PI responds to revisions requested by the IRB in writing and makes the appropriate updates in IRBIS record.
 - iii. RP staff confirm receipt and forward responses to the expedited reviewer for further review if needed. If all requests have been clearly and obviously met, the approval is processed by IRB Administrators.
 - iv. If the PI does not respond with revisions or concerns within 45 days of notification, RP staff send the PI an email noting that the study will be withdrawn in 7 days unless a response with revisions or concerns is received.
 - c. Full Review Required: The IRB expedited reviewer may determine that the protocol requires full board review by the IRB at a convened meeting.
 - d. Request for Review is eligible for a less stringent mechanism of review:
 - i. The reviewer may request clarification from the IRB Chair and IRB administrators about why the study is not eligible for exempt review or that the activities do not fall under the purview of the IRB.
 - ii. If the IRB Chair agrees, those procedures are followed.
6. Approval and continuing review:
- a. The approval date for an expedited study is the date all requests have been addressed and study is ready for approval processing.
 - b. The IRB Administration, in consultation with the IRB Chair, determine whether Continuing Review is required in accordance with 45 CFR 46, other applicable regulations, and SOP#3.
 - c. The IRB office processes approvals through the IRBIS system. A final version of the informed consent and other documents is uploaded.

- i. It is the PI's responsibility to use only the approved versions of documents.
7. Investigator's Right of Appeal: If the PI has concerns regarding the expedited reviewer's decisions, the PI submits the concerns and justification for changing the IRB decision in writing to the reviewer, IRB Administrator, and the IRB Chair for resolution. If the PI is dissatisfied with the final resolution, the request and study are reviewed by the full board.

SPONSORED RESEARCH

For sponsored research, RP staff:

- consult and follow any sponsor IRB review requirements (e.g., the Department of Defense has additional review requirements that must be followed);
- associate the Sponsored Program number with the IRB request for review in IRBIS record, if not already done;
- conduct a brief congruency analysis of the IRB request for review with any revised contract/grant.

INSTITUTIONAL REVIEW

A research application may require institutional review in addition to IRB review (e.g., Institutional Biosafety Council; Radiation Safety Council; Conflict of Interest review). The PI is responsible for informing RP staff about the need for any other institutional reviews. RP staff coordinates additional required reviews to ensure that the research is not conducted until all required reviews have been completed and approved.

SUPPORT PROCESSES AND PROCEDURES

SOP #1 Determination of Activities that Need IRB Review

SOP #2 Requesting IRB Review

SOP #3 Continuing Review

SOP #6 Full IRB Review of Research

SOP #9 Conducting Exempt and Limited Reviews

REFERENCES

45 CFR Part 46, 21 CFR 56.108(a)(1)&(2), 21 CFR 56.109(f), 21 CFR 56.110, 21 CFR 56.111, 21 CFR 56.115(a)(3)&(7), and 38 CFR 16.103(a)

The DHHS categories for research eligible for expedited review are:

Research Categories

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

1. (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.)
2. 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:
 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 2 times per week; or
 2. from other adults and children [2], 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 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 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:
 1. 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
 2. where no subjects have been enrolled and no additional risks have been identified; or
 3. 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.