



Appalachian State University Research Protections and Institutional Review Board Standard Operating Procedures		
SOP #5 Revision # 1	TITLE: Expedited Review of Research	Date Effective: 8/8/2012 Revision Date: 9/3/2014
Approved By: IRB Chair	Signature 	Date: 9/3/2014
Approved By: Interim Vice Provost for Research	Signature 	Date: 9/8/2014

PURPOSE

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

GENERAL DESCRIPTION

The Institutional Review Board (IRB) uses an expedited review process to review studies that present no more than minimal risk to human subjects and involve only procedures listed in the categories (copied below) established by the Department of Health and Human Services (DHHS) or the Food and Drug Administration (FDA) that involve no greater than minimal risk.

The IRB defines minimal risk as the probability and magnitude of harm(s) and discomfort(s) anticipated in the research are no greater than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations.

Expedited review 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. The expedited review procedure may not be used for classified research involving human subjects.

Expedited review procedures allow the IRB to review and approve studies without convening a meeting of the full IRB. 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 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

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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, continuing protocol review, 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 notify the IRB Chair, or designee, of the request for review; provide an assessment of the risk level and the expedited review category; convey any special considerations (e.g., need for additional expertise, prisoner representative review, other institutional reviews, HIPAA or FERPA concerns); and recommend experienced members to conduct the IRB review. The IRB Administrator will identify any procedures that meet the practice of medicine under NC state law in order to ensure that licensed medical professional(s) are responsible for all medical procedures in compliance with NC law.
 - 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. Experienced IRB members are recommended as expedited reviewers based on the member’s familiarity with IRB issues, experience, and expertise.
 - b. 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 and other expedited reviewers and external experts as needed.

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3. 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). RP staff sends all study materials, including the approved initial protocol for studies requesting continuing review, and a reviewer checksheet (appended) to the expedited reviewer(s) and experts if appointed.
4. 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 a) the research meets the federal criteria for approval as specified in 45 CFR 46.111 and 21 CFR 56.111; b) 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 c) 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. The IRB may also require that the study investigators meet codes of professional ethics as it deems appropriate.
 - i. Using specific findings from the study, the reviewer documents the findings for the criteria for approval on the reviewer checksheet.
 - ii. The expedited reviewer assigns the approval period at intervals appropriate to the degree of risk and history of compliance of the PI but not more than once per year. The date the expedited reviewer notifies RP staff of approval with a completed checksheet is the date the approval period starts.
 - iii. RP staff process the approval by 1) sending an email notice of approval, with the approval period dates and investigator's responsibilities, to the PI and any research personnel designated to receive IRB correspondence, and 2) sending an email with the approved study documents to the PI and any research personnel designated to receive IRB correspondence. A hard copy of the letter of approval follows within 2 weeks.
 - 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, ASU policies/procedures, or other laws and regulations.

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- i. The expedited reviewer contacts the PI, or requests that RP staff contact the PI via email, for any clarifications needed and documents the issues discussed on a reviewer checksheet.
 - ii. If the expedited reviewer determines revisions are needed, RP staff send the investigator a letter via email describing the revisions requested by the IRB expedited reviewers.
 - iii. The PI responds to revisions requested by the IRB in writing and sends the response to irb@appstate.edu. RP staff confirm receipt and forward responses to the expedited reviewer for further review. The reviewer documents any controverted issues on a reviewer checksheet.
 - 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: 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. If the IRB Chair agrees, those procedures are followed.
6. 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, if not already done;
- conduct a congruency analysis of the IRB request for review with any revised contract/grant; and
- add Sponsored Programs to IRB correspondence regarding continuing review approval, if not already done.

INSTITUTIONAL REVIEW

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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

IRB SOPs

REFERENCES

45 CFR Part 46.103(b)(4)(i), 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), 45 CFR 46.103(b)(4), 45 CFR 46.108(b), 45 CFR 46.109(e), 45 CFR 46.110, 45 CFR 46.111, 45 CFR 46.115(a)(3)&(7), 45 CFR 46.103(a), 21 CFR 56.103(a), and 38 CFR 16.103(a)

The DHHS categories for research eligible for expedited review are:

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, 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
 - (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 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);

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(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 subjects 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.)

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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.

Appendix- Expert Reviewer Checksheet

Project Information			
Criteria	Reviewer Response	Reviewer Comments	
Refer to Sections I- III: Study, Research Personnel, COI			
<ul style="list-style-type: none"> Are research personnel qualified to do the research? Are COI, if any, addressed? 	<input type="checkbox"/> Yes <input type="checkbox"/> No		
Refer to Section IV: The Recruitment and Selection of Subjects			
Selection of subjects is equitable. In making this assessment the IRB should take into account the purposes of the research and the setting in which the research will be conducted.	<input type="checkbox"/> Satisfied <input type="checkbox"/> Not Satisfied		
<ul style="list-style-type: none"> Is recruitment adequately described and are materials included? 	<input type="checkbox"/> Yes <input type="checkbox"/> No		
<ul style="list-style-type: none"> Number of subjects sought? 			
Refer to Section V: Informed Consent			
Informed consent will be sought from each prospective subject or the subject's legally authorized representative (HHS §46.116) Informed consent will be appropriately documented, in accordance with, and to the extent required by (HHS §46.117).	<input type="checkbox"/> Satisfied <input type="checkbox"/> Not Satisfied		
<ul style="list-style-type: none"> Is the Informed Consent process described? 	<input type="checkbox"/> Yes <input type="checkbox"/> No		
<ul style="list-style-type: none"> If any subjects are likely to be vulnerable to coercion or undue influence, (e.g., children, prisoners, pregnant women, mentally disabled persons, or economically or educationally disadvantaged persons), are additional safeguards included to protect the rights and welfare of these subjects? 	<input type="checkbox"/> N/A <input type="checkbox"/> Yes <input type="checkbox"/> No		
Does the consent form include: An explanation of the purposes of the research. <ul style="list-style-type: none"> Description of the procedures of the research in lay language. Description of any reasonably foreseeable risks or discomforts to the participant. Description of any benefits to the participant or to others, which may reasonably be expected from the research. 	<input type="checkbox"/> Yes <input type="checkbox"/> No		
Should these optional elements of consent be included: if the participant is or becomes pregnant, the particular treatment or procedure may involve risks to the embryo or fetus, which are currently unforeseeable. <ul style="list-style-type: none"> Anticipated circumstances under which participation may be terminated without regard to consent. Additional costs to subject from participation. Statement that significant new findings developed during the course of the research, which may relate to subject's willingness to continue participation, will be provided to subject. 	<input type="checkbox"/> Yes <input type="checkbox"/> No		

Refer to Sections VI (Data Collection) & VII (Confidentiality)		
• Are data collection instruments included and procedures adequately described?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
• Could identification of subjects be damaging to employability, insurability, or reputation?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
• If appropriate, does the research plan make adequate provisions for monitoring collected data to ensure safety of subjects, protection of privacy, and confidentiality of the data?	<input type="checkbox"/> Yes <input type="checkbox"/> No	
Refer to Section VIII: Risk & Benefit Analysis		
Risks to subjects are minimized: (i) By using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk, and (ii) whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.	<input type="checkbox"/> Satisfied <input type="checkbox"/> Not Satisfied	
Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may reasonably be expected to result	<input type="checkbox"/> Satisfied <input type="checkbox"/> Not Satisfied	
RISK:	<input type="checkbox"/> Minimal <input type="checkbox"/> Minor Increase Over Minimal Risk <input type="checkbox"/> More than a Minor Increase over Minimal Risk	
BENEFIT:	<input type="checkbox"/> Benefit to Society <input type="checkbox"/> Prospect of a Direct Benefit	
Recommended Level of Review and Category	Exempt:____ Expedited:____ Full Board:____	
Recommendation	<input type="checkbox"/> Approve <input type="checkbox"/> Minor Stipulations <input type="checkbox"/> Return to PI	
I have no conflict of interest with this study. Reviewed By:		Date:
General Comments:		