Southeastern University Institutional Review Board Standard Operating Procedures		
Expedited Review	**SOP #**	**RR 102**
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1. POLICY

An expedited review procedure consists of a review of research involving human subjects by one or more of the Permanent Members (PMs) of the IRB and one or more reviewers designated by the Chair from among members of the IRB without convening a meeting of the full IRB. The IRB Chair or Co-Chair will disseminate the applications based on the experience and expertise of the respective IRB members. The categories of research that may be reviewed by the IRB through an expedited review procedure include research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the categories authorized by 45 CFR 46.110 and listed in section 1.1 of this policy.

Specific Procedures

1.1 Determining Expedited Review Status

The expedited review procedure may not be used when 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. Furthermore, the expedited review procedure may not be used for classified research involving human subjects.

1.1.1 Definition of Minimal Risk

Minimal risk is defined as "...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(i)).

1.1.2 Expedited Research Categories

The activities listed herein should not be deemed to be of minimal risk simply because they are included on the list of eligible research. Inclusion on this 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.

1.1.2.1 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.

1.1.2.2. 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 of body weight in an 8 week period and collection may not occur more frequently than 2 times per week.

1.1.2.3. Prospective collection of biological specimens for research purposes by noninvasive means. For example:

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 gum base 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
j. washings;
k. sputum collected after saline mist nebulization;
l. vaginal swabs that do not go beyond the cervical os;
m. rectal swabs that do not go beyond the rectum;
n. nasal swabs that do not go beyond the nares.

1.1.2.4. 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 include:

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.

1.1.2.5. 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.)

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

1.1.2.7. 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.)

1.1.2.8. 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.

1.1.2.9. 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.

NOTE: ***The expedited review procedure may not be used with human subjects research involving prisoners.***

1.2 Submission

1.2.1 The investigator makes a preliminary determination that a research application (here after referred to as IRB application or an application) is eligible for expedited review based on the categories presented in 1.1. The IRB makes the final determination regarding whether an application qualifies for expedited status.

1.2.2 The investigator submits one copy of a completed IRB application form requesting review at the

expedited level to the University IRB.

1.2.3 Upon receipt of the application form it is entered into the IRB tracking system and assigned an IRB number by the IRB Chair or Co-Chair.

1.3 Pre-Review

1.3.1 Research applications submitted by investigators who request expedited review will be evaluated by one or more of the PMs, or their designee, who will determine if the project qualifies for expedited review.

1.3.2 If the protocol does not meet the criteria for expedited review, the PM will change and initial the review designation on the application form, which will be processed for review at the appropriate level.

1.3.3 The IRB Chair or Co-Chair will distribute each application to one or more PM and one or more reviewers designated by the Chair from among members of the IRB. Reviewers are assigned based on their experience and expertise in the area of research proposed in the application and on any required special representation. If no members of the board possess the required expertise, the IRB Chair or Co-Chair will solicit an external reviewer to serve as a consultant to the IRB member reviewing the application and the IRB.

1.3.4 The IRB Chair or Co-Chair prepares review materials to be distributed to each reviewer. The reviewers receives a transmittal email with the desired return date, a complete copy of the application, the appropriate IRB Member Review Sheet to document their review and decision regarding approval. The reviewers are given seven days to review the application and respond.

1.4 Review

1.4.1 The expedited reviewer exercises all of the authority of the IRB except that the reviewer may not disapprove research. The IRB may only disapprove a research application in accord with the non-expedited review procedures set forth in federal regulations 45 CFR 46.108(b). Any one reviewer may request review of an application by the IRB at a convened meeting.

1.4.2 The reviewers must return a copy (electronic or hard copy) of the IRB Review Form with their approval decision and any comments to the IRB Chair or Co-Chair.

1.5 Review Outcomes

1.5.1 The reviewer makes one of the following determinations or recommendations by completing the IRB Review form:

> *Approved*: The research procedures and associated documents meet the criteria for approval with no further revision needed.
>
> *Approved with Conditions*: The research procedures and associated documents meet the criteria for approval with no further revision needed. However, final approval is contingent upon receiving external documentation as specified (i.e., school permissions, other committee approvals, second IRB approval documentation, etc.).
>
> *Pending Revision*: Minor revisions which do not involve substantive issues must be made before

the research can be approved. The investigator must submit the revisions for review.

Designated for full board review: The reviewer determines that the application should be reviewed at a convened meeting of the IRB or via expedited review.

1.5.2 The approval period for the application is determined at the time of review. The approval period will be appropriate to the degree of risk, but no longer than one year. The following factors are considered in determining the criteria for which applications require review more frequently than one year and what the review frequency will be:

a. Probability and magnitude of anticipated risks to participants;

b. Specific experience of the investigator(s) and other members of the research team in conducting similar research;

c. Nature and frequency of adverse events observed in similar research; vulnerability of the subjects;

d. Any other factors the IRB deems relevant.

The start of the approval period (i.e. approval date) is the date the approval letter is generated by the IRB Chair or Co-Chair.

1.5.3 When an application is placed in *Pending Revision* status, the IRB Chair or Co-Chair will document the approval status and any suggested revisions in the tracking system. The IRB Chair or Co-Chair will generate an email to the investigator(s) transmitting the revisions requested by the IRB.

1.5.4 Investigators are responsible for submitting any requested revisions to the IRB. The IRB Chair or Co-Chair reviews the response to the request for revisions to determine if the investigator's response is appropriate. If the response is deemed appropriate, the IRB Chair or Co-Chair documents that the protocol is approved in the tracking system.

1.5.5 If the IRB Chair or Co-Chair determines that the revisions are inappropriate or insufficient, the investigator will be asked via email to make further revisions. This review and revision process will continue until the application is approved or reassigned to a different review level (e.g., exempt or full board).

1.5.6 When an application is approved with conditions, the IRB Chair or Co-Chair will generate a "conditionally approved" letter that will be sent to the investigator stipulating the documents that are needed prior to final approval. Upon receipt of the requested documentation, an approval letter will be issued as described in 1.5.7.

1.5.7 When an application is approved, the IRB Chair or Co-Chair will generate the approval letter with the IRB Chair signature and attach all recruiting, consent and debriefing documents (as applicable) with the IRB approval stamp affixed with the valid dates of IRB approval. The IRB Chair or Co-Chair will send the signed approval letter and other appropriate documents to the investigator(s).

1.5.8 If the investigator has concerns regarding the IRB decision/recommendations for changes in the research, he/she may submit his/her concerns to the IRB reviewer, if known to him/her, and/or the IRB

Chair via a written document that includes justification for changing the IRB decision. The reviewer and the Chair will agree on a final resolution. If the investigator is still dissatisfied with the IRB decision, the application will be sent to the convened IRB for review.

1.6 Notification of the IRB

IRB applications that undergo expedited review are documented monthly by the IRB Chair or Co-Chair and a list is made available to all members via the IRB email and presented to the Board at the next convened meeting.

2. SCOPE

This procedure applies to research applications submitted for expedited review.

3. RESPONSIBILITY

Investigators are responsible for making a preliminary determination that their applications are eligible for expedited review. The IRB Chair or Co-Chair is responsible for receiving applications from investigators who are requesting expedited review, tracking the application review, reviewing and documenting expedited status, reviewing and approving revisions, and generating correspondence. The IRB Chair or Co-Chair is responsible for reviewing and documenting expedited status as needed, changing review level if appropriate, and reviewing and approving revisions.

4. APPLICABLE REGULATIONS AND GUIDELINES

Minimal Risk:
45 CFR 46.102
21 CFR 56.102
Expedited Review:
45 CFR 46.110
21 CFR 56.110

5. REFERENCES TO OTHER APPLICABLE SOPS

This SOP affects all other SOPs

6. ATTACHMENTS

None