Western Carolina University
Office of Research Administration
Institutional Review Board Standard Operating Procedures

SOP# 204.1	TITLE: Expedited Review	Date Effective: 01/01/2022 Last Revision Date: 06/30/2021

I. Purpose

This sets forth the expedited project review process and criteria for approval.

II. Definitions

Certain categories of minimal risk research may be reviewed by the IRB using an expedited review process. Expedited review allows the IRB to approve research projects without convening the full board using designated reviewers. The chair, or an experienced designee from the IRB, may serve as the designated reviewer. Designated reviewers hold all the authority granted to the convened IRB, except that the reviewer may not individually disapprove a project.

Designated reviewers may only approve research that meets the criteria for approval outlined in 45 CFR § 46.111 and must ensure the study meets the requirement for informed consent outlined in 45 CFR §§ 46.116 and 46.117 unless the study meets the requirements for waiver of consent or documentation. A list of all projects approved using expedited review procedures will be shared with the entire IRB prior to each convened meeting. Any IRB member may request to review the records of an expedited study.

The expedited review categories as listed by the DHHS are as follows:

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 is not required
   b) Research on medical devices for which (i) and investigational device exemption application 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.

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.

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).

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.

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 and investigational new drug application or investigational device exemption where categories two through eight 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

III. Procedure

Submission and Screening

1. Investigators must submit a *Request for Initial Review of Research* in and include all applicable supplemental documents required.

2. The IRB administrator receives the package in InfoEd and conducts an initial review for completeness as described in SOP 201. The IRB administrator conducts a preliminary assessment as to whether the project meets the criteria for expedited review.

3. The IRB administrator evaluates the project topic and selects the IRB member with the most appropriate background and expertise to evaluate the study. If additional expertise is necessary to conduct the review, the IRB administrator will assist the reviewer in finding a consultant with relevant experience.

4. If the project does not qualify for expedited review, the IRB administrator processes the application as a full board review – see SOP 205.

Assigning Reviewers

1. Any experienced member of the IRB may serve as an expedited reviewer. Experienced members have served on the board for at least one month and have undergone training with the IRB administrator, chair, or designated IRB mentor.

2. Any reviewer who receives a study may request that it be reassigned for any reason or may request that the project undergo full-board review.

3. Expedited reviewers may not review projects for which they have a conflict of interest. Examples of a conflict of interest include a situation where the reviewer is a committee member on a student

investigator's thesis committee, the reviewer has a romantic relationship with an investigator, or the reviewer has a financial interest in the research.

IRB Expedited Review

1. The expedited reviewer is sent the project through Infoed.

2. The reviewer conducts an in-depth review to determine whether the research meets the regulatory requirements for approval described in 45 CFR § 46.111.

3. The reviewer evaluates the informed consent process and documentation to be sure they meet the requirements described in 45 CFR §§46.116 and 46.117. If the project involves an FDA regulated device, the informed consent process and documentation will meet the requirements in 21 CFR §§ 50.25 and 50.27.

Review Outcomes

1. The expedited reviewer makes one of the following four determinations:
   a) Modifications Required: The reviewer requests additional information or requires modifications to the project before granting approval. Modifications must be directly related to the criteria for approval. Requests for modification to the project will be sent through InfoEd. Modifications may be requested as many times as necessary to meet the regulatory requirements.
   b) Approved: The expedited reviewer has completed their evaluation and determined that the project meets all criteria for approval. The IRB administrator issues an *Approval Letter* through InfoEd.
   c) Full-Review Required: The expedited reviewer determines that the project requires review by the full-board at a convened meeting. As described in 46.115(a)(3), the IRB reviewer of the expedited application must provide a rationale for the determination that research that appears on the expedited review list presents more than minimal risk.

2. The expedited reviewer may alternatively determine that the project is eligible for exemption or does not qualify as human subjects research. The expedited reviewer will notify the IRB administrator who will issue the appropriate documentation.

3. The investigator is notified of the outcome of the review in writing. The Office of Research Administration retains all records and correspondence related to the project.

4. Expedited research approval is not required to undergo continuing review. However, the IRB may, at its discretion, choose to require continuing review for certain projects. If continuing review is required, a rationale for this decision will provided to the investigator in writing.

5. Modifications to expedited projects must be submitted to the IRB, prior to implementation. Modifications may be reviewed using the expedited review process, or may require full-board review.

IV. Responsibilities
IRB administrators, IRB members, Investigators

V. References
45 CFR §§ 46.109, 46.110, 46.111, 46.115, 46.116, 46.117
21 CFR §§ 56.110, 56.111
21 CFR §§ 50.20, 50.25, 50.27