Status **Active** PolicyStat ID **13481338**

Origination	03/2022
Last Approved	03/2024
Effective	03/2024
Next Review	03/2026
Owner	Trudy Wittenberg: 4388 Institutional Review Board Administrator
Department	HRPP/Research

SOP-Research: Expedited Review

PURPOSE

The purpose of this policy is to provide standard operating guidelines for expedited review for research studies. It is intended that this expedited review SOP be consistent with Food and Drug Administration federal regulations, the Common Rule, HIPAA, and good clinical practice, each as amended from time to time. Our policies guide our practices and ensure that we place people at the heart of all we do to deliver the best outcomes and safest care.

APPLICABILITY

This standard operating procedure applies to Lakeland Regional Health's **Workforce** and Research Personnel engaged in research.

POLICY

I. Lakeland Regional Health Institutional Review Board **(IRB**) adheres to 45 CFR 46.110 for expedited review guidelines.

   A. For the full policy on expedited review, see Policy (see **Research: Levels of Review-AD.0167**).

PROCEDURE

I. All expedited reviews will be completed within 10 business days of the complete submission (as verified by the IRB Office), with the exception of unusual circumstances, as determined by the IRB Administrative Office.

II. Pre-Review Procedures:

   A. The IRB Administrator will check all submissions for completeness (link submission checklist) and if anything is missing, the IRB Administrator will communicate with the PI and study team until the submission is complete and ready for review.

B. The IRB Administrator will complete a worksheet determining which category of expedited review applies to the study. If the submission qualifies for expedited review according to 45 CFR 46.110, the IRB Administrator will determine the expedited reviewer in congruence with the IRB Chair.

C. The IRB Administrator will determine if special representation, such as a prisoner representative, is needed as a secondary reviewer on the study. If special representation is needed, this will be communicated to the IRB Chair for designation.

D. Expedited reviews will be conducted by an experienced scientific member of the IRB. An experienced scientific member is one who has a minimum of one year of IRB-related experience (either through service on the IRB or in full-time research) and has sound knowledge of the federal regulations and local guidelines. The IRB Chair may appoint expedited reviewers.

E. One or more expedited reviews may be appointed to a study.

III. Review Procedures:

A. To qualify for expedited review, a study must meet both of the following requirements:

1. Involves no greater than **minimal risk**, AND
2. Fits into one (or more) of the specific expedited review categories (see **Research: Levels of Review- AD.0167**)

B. Expedited reviewers conduct an in-depth review of the following materials as they apply to the proposed study:

1. Protocol
2. Proposed consent document(s)
3. Progress reports
4. All necessary HIPAA authorizations, alterations, or waivers
5. Copies of surveys or questionnaires
6. Recruitment materials and advertisements intended to be seen or heard by potential subjects

C. Reviewers are expected to self-identify conflicts of interest.

D. For review of modifications to previously approved research – the reviewer determines that the proposed modification represents a minor change (include criteria to judge whether a modification represents a minor change).

E. For Department of Health and Human Services (**DHHS**)- and **FDA**-regulated research, reviewers will confirm that the research meets the applicability criteria.

F. If the reviewer disagrees with the IRB Administrator's determination and determines that the proposed research does not meet the criteria for expedited review, they will confer with the IRB Administrator for deliberation, and then refer the study for full IRB review if no consensus can be made.

G. The reviewer's decision to approve a new or continuing expedited review study is

based on the criteria for IRB approval of research.

1. Approved: The protocol and accompanying documents are approved by the expedited reviewer as submitted.
2. Approved with Conditions: The protocol and accompanying documents are approved, provided the investigator concurs with the changes or requests for additional documentation/information required by the expedited reviewer. The letter will outline the changes required. Once the changes are submitted and verified, the IRB Administrator will provide a notification letter to the PI that the study is approved and can proceed without further review by the IRB.
3. Information Required/Modifications Required: Changes or clarifications are required for the expedited reviewer to determine that the research meets the regulatory criteria for IRB approval. The PI must submit the required changes/information to the IRB Administrator who will send it to the expedited reviewer for review.
4. Refer to Full Board: The expedited reviewer may refer the study to the full convened IRB, only after conferring with the IRB Administrator (see III.F).
5. The reviewer may not disapprove research.

H. The expedited reviewer will determine if the study is a minimal risk study and document the determination in IRBNet.

I. The expedited reviewer will determine if and how often the study requires Continuing Review.

1. For minimal risk studies in categories 1-8, annual continuing review is generally not required. However, if the reviewer determines that continuing review is required, the frequency will be documented with the reason included. (45 CFR 46.109 (f)(1)). Reasons to require continuing review may include but are not limited to conflict of interest monitoring, international studies, etc.

J. For studies that do not require Continuing Review, an annual status report will be provided to the IRB Office by the study team.

K. Exceptions: Based on the 2018 Common Rule, the following types of studies still require continuing review:

1. FDA regulated research;
2. Greater than minimal risk research (including research reviewed under Expedited category 8(b));
3. Minimal risk research reviewed under Expedited category 9;
4. Research reviewed under the pre-2018 Common Rule; or
5. Research where the IRB has determined that Continuing Review is required (i.e. any study with an expiration date).

L. How often the study requires review via expedited procedures or the convened IRB will be documented in the study records in IRBNet by the IRB Administrator.

M. All expedited studies are subject to the standard requirements for informed consent (or its waiver or alteration).

N. The reviewer will complete checklists or other documentation, as applicable, and document findings and recommendations in IRBNet, including any determinations that are required by LRH's IRB policy and federal regulations for research involving children, prisoners, pregnant women and fetuses; waivers and alterations of consent; and waivers of consent documentation. Only findings and recommendations documented in IRBNet will be communicated to and required to be addressed by the investigator.

IV. Post-Review Procedures:

A. If the study requires annual review, the start date of approval is the date the expedited reviewer approves the study and the last day of the approval period is 364 days later (i.e. January 1, 2021 – December 31, 2021). If the reviewer determines that the study does not require annual review, but requires less frequent review, the start date of approval is the date the expedited reviewer approves the study and the last date of the approval period will be determined on a case-by-case basis.

B. The IRB will notify the investigator in writing of its decision to approve, require modifications, or require full IRB review of the proposed research activity. The IRB Administrator will generate a letter in IRBNet with the following information:

1. Date of review
2. Type of review (initial, continuing, amendment, etc.)
3. Documents that were reviewed
4. The level of review the submission received (full board, expedited, administrative, etc.)
5. The decisions of the reviewer
6. If modifications are required in order to secure approval:
    i. A description of the required modifications
    ii. The basis for requiring modifications
    iii. The process for submitting the modifications and how the review will be conducted on them

C. If modifications are required by the expedited reviewer, the IRB Administrator will communicate with the Primary Investigator/study coordinator.

1. If the requested modifications are minimal and do not involve changes to the research or study design, the changes will be reviewed by the IRB Administrator.
2. If the requested modifications involve changes the research or study design, the study must be reviewed again by the expedited reviewer.

D. **Researchers** should respond to all communication from the IRB in writing, either by submitting a new package in IRBNet (with a cover letter detailing the requested modifications, a redline document (track changes), and/or a review table, along with

a clean copy), or via the messaging feature in IRBNet. If a re-submission is required, a new package should be created in IRBNet and it will receive the appropriate level of review.

E. The reviewer will provide a summary of the review at the next scheduled IRB meeting. The summary does not re-open the study for review by the full board, it is only for full disclosure to the board.

F. The Institutional Official and AVP of Research & Sponsored Studies are notified of findings and actions from reviews using the expedited procedure via email, when applicable.

DEFINITIONS

DHHS: Department of Health and Human Services

FDA: Food and Drug Administration

IRB: Institutional Review Board

Minimal Risk: Minimal risk means that 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.

Researchers/Research Personnel: All individuals designing or directing research, serving as a principal or co-investigator, enrolling research subjects (including obtaining subjects' informed consent or screening potential subjects), or making decisions related to eligibility to participate in research, analyzing or reporting research data, analyzing or reporting adverse events, or submitting manuscripts concerning the research publication

Workforce: All LRH employees, volunteers, trainees/students, contractors, and medical staff.

REFERENCES

I. Expedited Review: Categories of Research that may be Reviewed Through an Expedited Review Procedure (1998) | HHS.gov

II. Attachment B: Approved by SACHRP July 20, 2011 - SACHRP Recommendation regarding definition of a minor change in research under 45 CFR 46 and 21 CFR 56 | HHS.gov

III. Expedited Review of Social and Behavioral Research Activities (nsf.gov)

IV. Minimal Risk | FDA

Approval Signatures

Step Description	Approver	Date

Deana Nelson: 4080 SVP - Administration and Corporate Initiative	03/2024
Georgia Ann Keriazes: 0729 QI/ Due Pharmacist	03/2024
Andrew Bugajski: 4387 AVP - Research and Sponsored Studies	04/2023