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SOP-Research: Modifications to Previously Approved Research

PURPOSE

The purpose of this procedure is to describe the process and requirements for investigators when modifications are made to an **IRB** approved research study for research studies undergoing review by the Institutional Review Board. It is intended that this SOP be consistent with Food and Drug Administration federal regulations, HHS, 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. Modification(s) of a research activity, during the period for which IRB approval has already been granted, must be submitted to the IRB, and approved prior to initiation of the modification(s).

II. Changes in approved research may not be initiated without prior IRB review (full or expedited review, as appropriate) and approval, except where necessary to eliminate apparent immediate hazards to human subjects.

   A. When an immediate hazard is present, investigators may take necessary action to mitigate risk to study participants.

   B. The investigators must promptly report all actions taken and changes made in approved research without IRB approval to the IRB.

C. The IRB will review the change to determine whether or not the action was consistent with ensuring the subject's continued welfare.

D. For the full policy on full board review and expedited review, see **Research: Levels of IRB Review- AD.0167**.

PROCEDURE

I. Amendments/Modifications to Approved Research

A. Investigators are required to submit an **amendment**/modification request via IRBNet, including a cover letter detailing the requested modifications, a redline document (if applicable) and a clean copy. All amendment/modification submissions will be reviewed in their entirety by the IRB Administrative Office.

B. For a study submission to be added to the convened IRB meeting, it must be submitted in its entirety in IRBNet by the first (1st) Friday of the month.

1. The IRB Administrator or designee will check all submissions for completeness and if anything is missing, the IRB Administrator will communicate with to the PI and study team until the submission is complete and ready for review. Incomplete applications or those with personnel who are not current regarding training will not be accepted or distributed for review.
2. For all amendments/modifications that qualify for full board review, SOP-Research: Full Board Review will be followed.

C. Modifications to applications previously approved by a convened IRB may be reviewed using the expedited review process if the IRB Office finds:

1. The revision(s) do not pose an increased risk to subjects; and
2. The revision(s) constitute a minor change to previously approved research; and
3. Any added research activity falls within categories 1-7 of the Health and Human Services (HHS) expedited review categories (see SOP-Research: Expedited Review).

D. Modifications to applications previously approved by the expedited review process may be reviewed via expedited review if the IRB Office finds:

1. The research continues to pose no more than **minimal risk** to subjects.
2. Any added research activity falls within categories 1-7 of the HHS expedited review categories (see SOP-Research: Expedited Review).

E. All modifications to previously approved research will be available to all members in IRBNet.

II. IRB Responsibilities

A. The IRB Office will determine the level of review required for the proposed modification(s).

B. The IRB or approved designee will review the proposed modification(s) in accordance with approval criteria and determine whether modifications(s) are consistent with ensuring the subject's continued protection.

C. The IRB or approved designee will review modifications, which were initiated without prior IRB approval in efforts to eliminate apparent immediate hazards to the human subjects, and determine whether each change was consistent with ensuring the participant's continued welfare.

D. The IRB or approved designee will determine that any **Significant New Findings** arising from the review process, and possibly impacting the subject's willingness to continue participation are provided to the subject.

E. The IRB or approved designee will determine if any **new information** resulting from the modification, or from other sources necessitates, an adjustment to the IRB's prior determination(s), such as inclusion of protected or vulnerable populations and findings regarding **FDA**-regulated products.

F. The IRB or approved designee will determine if the proposed modifications to the research require revision of the consent document(s). If so, the IRB will ensure that revised consent documents accurately reflect the modifications.

G. The IRB or approved designee will determine if the modifications warrant re-consenting or notification of subjects including those who have completed research interventions.

H. The IRB will consider whether the interval for continuing review as last determined by the IRB should be adjusted based on the modifications.

I. Once the IRB has made its determination, the IRB Office will notify the Principal Investigator of the findings and determinations via a letter in IRBNet.

III. Reports of New Information During the Approval Period

A. The IRB Office may receive additional materials from the investigative team that constitute a change in the research activity. These materials will be reviewed in order to determine if the materials impact the risk - benefit assessment or conduct of the research at LRH. These additional materials may include, but are not limited to:

    1. Reports generated from a Data and Safety Monitoring Board (DSMB) or study Steering Committees;
    2. Updates to the Investigator's Brochure/Package Insert or investigational device manual;
    3. New publications or news reports related to the research.

IV. IRB Actions in Response to Reports of New Information

A. Reports of new information submitted during the approval period will be reviewed using expedited procedures, as applicable. Based on the initial review, the IRB Chair or designee may determine that the report should be forwarded to a convened IRB for review. The IRB will determine whether the new information should be communicated to research participants and the method of communication (e.g. revised consent form, letter to the subject, conversation

between the investigator and subject).

B. If the event might meet the definition of an unanticipated problem involving risks to subject or others, the study team will be required to report the event in IRBNet in accordance with policy, **Research: Unanticipated Problems & Serious Adverse Events Reporting- AD.0193**.

C. If the event represents non-compliance with the research plan, the event will be managed in accordance with policy, **Research: Protocol Deviations & Non-compliance- AD.0194**.

D. Once the IRB has made its determination, the IRB Office will notify the Principal Investigator of the findings and determinations via a letter in IRBNet.

DEFINITIONS

Amendment: Any change in the research activity from what was approved by the IRB, including, but not limited to, modifications to the protocol, consent document, recruitment material, or information included in the Investigator's Brochure.

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.

Significant Findings/New Information: Information that indicates a significant new serious risk or increased severity of known risk, or a safety issue which requires immediate action.

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

REFERENCES

I. Mayo Clinic - Modifications to Previously Approved Research
II. CHOP - Amendments and Reports of New Findings for Approved Research
III. 45 CFR 46.111
IV. 21 CFR 56.108, 56.111

Approval Signatures

Step Description	Approver	Date

Deana Nelson: 4080 SVP - Administration and Corporate Initiative	06/2025
Renee Reed: 4064 Senior Attorney	06/2025
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