Status **Active** PolicyStat ID **13626636**

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| Origination | 05/2022 | Owner | Trudy Wittenberg: 4388 Institutional Review Board Administrator |
| Last Approved | 03/2024 | | |
| Effective | 03/2024 | Department | HRPP/Research |
| Next Review | 03/2026 | | |

# SOP-Research: Full Board Review



## PURPOSE

The purpose of this policy is to provide standard operating guidelines for research studies undergoing full board review by the Institutional Review Board. It is intended that this full board 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 policy applies to Lakeland Regional Health's **Workforce** and **Research Personnel** engaged in research.

## POLICY

I. All studies that meet the definition of human subject research (see Research that Must be Reviewed by the IRB Policy) requiring full board review will be reviewed by the **IRB** Committee at a convened meeting at which quorum is present (see SOP-Research: IRB Members).

   A. For the full policy on full board review, see Policy (see Levels of Review Policy).

## PROCEDURE

I. Investigators are required to submit a complete application via IRBNet, including all required supporting documentation (see submission checklist), by the posted deadline date. All study submissions will be reviewed in their entirety by the IRB Administrative Office prior to being assigned a meeting date to be reviewed by the full board.

II. **Pre-Review Procedures:**

   A. 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.

B. The IRB Administrator or designee will check all submissions for completeness (link submission checklist) 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.

C. The IRB Administrator or designee will complete a worksheet verifying that all of the required documents are in the submission and upload it into IRBNet.

D. The IRB Administrator or designee will send out the packet containing the relevant documents for the meeting 9 days prior to the IRB meeting to all of the IRB members. Their reviews must be complete by the Tuesday prior to the IRB meeting (2 days before).

1. Documents provided to all IRB members include:
    i. The complete protocol (initial and renewal applications)
    ii. Central IRB approval (if applicable)
    iii. Investigator Brochure (if applicable)
    iv. Meeting agenda
    v. Proposed/current approved informed consent document
    vi. Continuing review/renewal material (for continuing review)
    vii. Progress reports (for continuing review)
    viii. Any amendments (for continuing review)
    ix. All necessary HIPAA authorizations, alterations, or waivers
    x. Copies of surveys or questionnaires
    xi. Recruitment materials and advertisements intended to be seen or heard by potential subjects
    xii. Study personnel list
    xiii. Training certifications and CV of the primary investigator



III. **Review Procedures:**

A. In order for non-exempt human subjects research to be approved, the IRB must make a number of findings.

1. Meets the criteria of 45 CFR 46.111 and 21 CFR 56.111.
    i. Risks to subjects are minimized:
        a. By using procedures that are consistent with sound research design and which do not unnecessarily expose subjects to undue risk, and
        b. Whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.

ii. Risks to subjects are reasonable in relation to anticipated benefits, if any, to subjects, and the importance of the knowledge that may be expected to result.

    a. In evaluating risks and benefits, the IRB will consider only those risks and benefits that may result from the research (as distinguished from risks and benefits of therapies that subjects would receive even if not participating in the research). The IRB will not consider possible long-range effects of applying knowledge gained in the research (for example, the possible effects of the research on public policy) as among those research risks that fall within the purview of its responsibility.

iii. Selection of subjects is equitable. In making this assessment the IRB will take into account the following:

    a. The purposes of the research.

    b. The applicable population with the disorder or condition.

    c. The setting in which the research will be conducted.

    d. The IRB will be particularly cognizant of the special problems of research involving potentially vulnerable populations, such as children, prisoners, pregnant women or individuals with impaired decision-making capacity, or economically or educationally disadvantaged persons.



iv. Informed consent will be sought from each prospective subject or their legally authorized representative (LAR), in accordance with and to the extent required by appropriate local, state and federal regulations (see Research: Informed Consent, Assent, Re-Consenting, Parental Permission, Remote Consent and Remote Assent Process- CL.0218).

v. Informed consent will be appropriately documented as required by local, state and federal regulations (see Waiver of Informed Consent Policy).

vi. Where appropriate, the research plan makes adequate provisions for monitoring the data collected to ensure the safety of subjects (see Data Management Policy).

vii. Where appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of the data.

viii. When some or all of the subjects, such as children, prisoners, pregnant women, individuals with impaired-decision making capacity, or economically or educationally disadvantaged

persons, are likely to be vulnerable to coercion or undue influence, additional safeguards have been included in the study and in the IRB review process, to protect the rights and welfare of these subjects.

ix. Studies are reviewed at periods appropriate to the degree of risk that research subjects are exposed due to their participation in the study, in accordance with regulatory requirements.

B. The submission and related study materials are distributed to the primary reviewers, secondary reviewers, and all Board members sufficiently in advance of the meeting date to allow review of the material, generally nine (9) days prior to each scheduled meeting, with completed reviews due two (2) days before the meeting.

C. The primary and secondary reviewers 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 policies 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 the minutes in IRBNet will be communicated to and required to be addressed by the investigator.

D. All members are expected to review and be familiar with all protocols.

E. Members are expected to provide comments for review into the IRBNet application.

F. The primary reviewers are responsible for providing a brief summary of the study at the convened meeting and identifying concerns. Secondary reviewers may also provide their concerns at the meeting.

1. Primary reviewers will present any identified weaknesses and strengths in the study to the full board.
2. Secondary reviewers will present any additional weaknesses and strengths not already named by the primary reviewer.
3. The primary and secondary reviewer will discuss the weaknesses with the full board and come to a resolution, then a vote will be taken by the full board.

G. All members are expected to participate in the discussion of the significant concerns, raise additional concerns, provide necessary clarifications and/or propose resolutions.

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

I. The convened full IRB Committee may make one of the determinations listed below. Votes are taken by show of hands and/or voice vote by members participating by teleconference. The IRB Chair and Vice Chair participate as voting members.

1. Approved: The protocol and accompanying documents are approved by the IRB 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 IRB. 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 IRB to determine that the research meets the regulatory criteria for IRB approval. Please submit the required changes/ information to the IRB Administrator who will notify you when the study is placed on the IRB agenda for next review. Depending on criteria for review and IRB determinations – review of changes may be expedited or full board.
4. Not Approved: The submission fails to meet one or more criteria required by the IRB for approval of research. Significant modifications to the study design and/or protocols are required. Please contact the IRB Administrator or IRB Chair for further clarification.

J. At the time of the IRB determination, the minutes will reflect the individual(s) responsible for verifying that the conditions for approval have been met. Approval verification will be documented by the responsible individual(s) in IRBNet.

K. **Continuing Review:**

1. Continuing review is a time for study teams to tell the IRB what has happened since the IRB's previous review & approval, which could be the IRB's initial approval. At time of continuing review, the IRB ensures that the study still meets all of the regulatory criteria for approval, including the additional protections for vulnerable populations, such as for children (when applicable).
2. The IRB's continuing review of research must be substantive and meaningful. To do that, the IRB must receive sufficient information to conduct its review. The LRH IRB provides a continuing review checklist for continuing review submissions (link Continuing Review Checklist). The frequency of continuing review for the research is determined by the IRB.
3. Based on the 2018 Common Rule, the following types of studies still require continuing review:
    i. **FDA** regulated research;
    ii. Greater than **minimal risk** research (including research reviewed under Expedited category 8(b));
    iii. Minimal risk research reviewed under Expedited category 9; or
    iv. Research where the IRB has determined that Continuing Review is required (i.e. any study with an expiration date).
4. The following types of studies do NOT require continuing review:
    i. Minimal risk research;
    ii. Greater than minimal risk research where remaining activities

are limited to data analysis/long-term follow up and the IRB has determined that Continuing Review is no longer required (e.g. no expiration date); or

iii. Exempt studies.

5. In certain situations, continuing review may be performed via expedited review (see SOP-Research: Expedited Review).
6. A complete Continuing Review Application should be submitted at least 30 days before the study approval period ends (expiration date) in order to provide sufficient time for review (see Continuing Review Checklist).
    i. An expiration notice will be sent from IRBNet to the Primary Investigator and study coordinator 60 days and 30 days prior to the study's expiration.
7. Proposed changes to the IRB approved materials may not be included in the continuing review application; investigators must submit these changes as an amendment.
8. The Continuing Review submission must be reviewed and approved by the IRB prior to the expiration date in order for study-related activities involving human subjects to continue. If an investigator fails to provide continuing review information to the IRB or the IRB has not reviewed and approved a research study by the continuing review date specified by the IRB, the human subjects research activities must stop, unless the IRB finds that it is in the best interest of individual subjects to continue participating in the research interventions or interactions.
    i. Enrollment of new subjects or other human subjects activities cannot occur after the expiration of IRB approval.
    ii. No research data can be collected until the Continuing Review Application is reviewed and approved by the IRB, unless determined otherwise by the IRB.
9. Extensions of the due date for continuing review cannot be granted; there is no grace period extending the conduct of the research beyond the expiration date of IRB approval.
10. The convened IRB is responsible for determining which protocols require review more often than annually in order to ensure the continued protection of the rights and welfare of the research subjects. The frequency of review will be documented at the initial IRB review. The IRB shall consider the following factors, along with any other factors deemed relevant by the IRB, in determining the frequency of review:
    i. The nature of the study
    ii. The degree of risk involved
    iii. The vulnerability of the study subject population
    iv. The experience of the clinical investigator in conducting clinical

research

v. Previous experience with the researcher or sponsor (e.g., compliance history, previous problems with the researcher obtaining consent, prior complaints from participants)

vi. The projected rate of enrollment, and

vii. Whether the study involves novel therapies.

11. Continuing IRB review is required as long as the research activity continues to meet the definition of human subjects research and is greater than minimal risk or is FDA regulated. For studies that are not FDA regulated and are minimal risk, continuing review is not required unless the IRB determines and documents why continuing review is needed for a specific study.

12. When continuing review is not required, the LRH IRB still needs a mechanism to track ongoing human subjects research at the institution. Investigators will be required to use the submit a Status Report (link Status Report Checklist) in IRBNet to confirm that a study is ongoing (or request closure) at intervals of 2 years from the last submission to the IRB. This is a requirement for all studies where continuing review is not required, including exempt submissions. Status Reports are automatically acknowledged in IRBNet by the IRB Administrator. Failure to submit a Status Report may result in administrative closure of a study due to inactivity.

13. The IRB will communicate to the investigator in writing and document on the Approval Letter all determinations of requirements for review more often than annually.

14. The full IRB will review all continuing reviews unless a study meets the following qualifications:

    i. The study qualifies for expedited review (see SOP-Research: Expedited Review)

    ii. Research that involves one or both of the following:

        a. Data analysis, including analysis of identifiable private information or identifiable biospecimens, or

        b. Accessing follow-up clinical data from procedures that subjects would undergo as part of clinical care

15. Changes to an approved protocol will generally be reviewed at the same level at which the protocol was first reviewed, either by the expedited review process or by full board review.

    i. Minor changes may undergo expedited review. (see SOP-Research: Expedited Review).

    ii. Significant changes require full IRB review.

L. **Administrative Review:**

1. The IRB Administrator may approve and act upon certain requests that have no impact on research subject safety, yet require IRB review and approval. Such requests include, but are not limited to: verification of criteria for studies “approved with conditions,” study closures, and correction of typographical errors in previously approved study documents or that do not affect the rights and welfare of study subjects, change any aspect of the study or its conduct, or alter the meaning or intent of the document. This extends to all documents.
2. The IRB Administrator will report administrative approvals to the IRB members via an administrative memo prior to the convened meeting.
3. The IRB Administrator will review and approve study closures and report the closures to the IRB on the monthly agendas. The investigator must notify the IRB in writing and attach a final study summary or copies of articles or publications related to the study (as applicable). The IRB Administrator will notify the investigator when the study is officially closed.

IV. **Post-Review Procedures:**

A. The IRB will notify the investigator in writing of its decision to approve, approve with conditions, require modifications, or disapprove 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 IRB
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

B. 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, 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.

C. The Institutional Official and AVP of Research & Sponsored Studies are notified of atypical or important findings and/or actions from IRB meetings via email, when applicable.

# DEFINITIONS

**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. IRBSOP402_ApprovalCriteria _01_22_19 (chop.edu)
II. IRBSOP404 CR 012219 (chop.edu)
III. Full_Committee (ucla.edu)
IV. 45 CFR 46.111
V. 21 CFR 56.108, 56.111




## 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 | 05/2023 |
| | Andrew Bugajski: 4387 AVP - Research and Sponsored Studies | 05/2023 |