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Owner	Trudy Wittenberg: 4388 Institutional Review Board Administrator
Department	HRPP/Research

SOP-Research: Local Context & Ceded Review

PURPOSE

The purpose of this procedure is to provide standard operating guidelines for **local context** review when the Lakeland Regional Health (LRH) Institutional Review Board (**IRB**) is not the IRB of record and is relying on another institution's IRB. It is intended that this local context review standard operating procedure 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 (SOP) applies to Lakeland Regional Health's **Workforce** and **Research Personnel** engaged in research.

POLICY

I. Lakeland Regional Health Institutional Review Board (IRB) is part of the SMART IRB and aligns our SOPs with theirs as appropriate and are amended from time to time.

   A. **Reviewing IRB** - The "IRB of record" (including an IRB Organization, such as Adverra IRB) to which authority for IRB review and oversight has been ceded by LRH for an instance of Research under the SMART IRB Agreement, or another reliance agreement. When LRH is the Reviewing IRB, the LRH IRB will complete the full review (see Levels of Review Policy).

   B. **Relying Institution** - A Participating Institution (in this instance, LRH) that cedes IRB review to a Reviewing IRB for an instance of Research under the SMART IRB Agreement, or another reliance agreement. When LRH is the Relying IRB/Institution, the LRH IRB will **not** complete the full review (see the below sections).

II. When the LRH IRB is relying on another IRB, the LRH PI must provide local context to the

reviewing IRB, so they can perform their review in its entirety.

A. Responsibilities of relying institution (occurring through PI and/or study team):

1. Communicating local considerations to the Reviewing IRB, including requirements of applicable state or local laws, regulations, policies, and ancillary review processes as are relevant to the Research (i.e., the specific study or studies ceded to the Reviewing IRB). These considerations vary by Reviewing IRBs, however an example of how to communicate these considerations can be viewed at SMART IRB (Relying Site Study Team Survey (smartirb.org)).
    i. Upon submission for local review, the local PI may contact the IRB Administrator to obtain the local consideration language.
2. Providing information about local restrictions, stipulations, or requested substitutions to informed consent documents to the Reviewing IRB for its approval, including institution-specific language (such as LRH's standard injury compensation language).
3. Notifying the Reviewing IRB of the following:
    i. Any unanticipated problems or findings of serious and/or continuing noncompliance that occurred on research that has not been ceded under the SMART IRB Agreement but that may have relevance to ceded Research, or
    ii. Any suspension or restriction of the LRH study team member(s) ability to conduct human subjects research.
4. Disclosing any COI related to Research conducted under the SMART IRB agreement and providing applicable management plans to the Reviewing IRB.
5. If the Reviewing IRB requests that LRH conduct an audit, reporting audit findings to the Reviewing IRB within a reasonable timeframe.
6. Reporting to OHRP, federal funding agencies, and/or other federal oversight authorities and other applicable individuals any unanticipated problems involving risks to human subjects or others, serious and/or continuing noncompliance, and/or suspensions or terminations of IRB approval, if the event has occurred at LRH.
7. Notifying the Reviewing IRB(s) of communications regarding Research covered by the SMART IRB Agreement to/from LRH and **FDA**, OHRP, and/or other regulatory agencies (e.g., re. unanticipated problems or serious and/or continuing noncompliance), as applicable.
8. Informing the Reviewing IRB if the LRH ends its participation in the SMART IRB Agreement or a specific study.

III. The LRH IRB office must perform a local review on the study. Local review is performed by the LRH IRB office when the LRH IRB is **not** the reviewing IRB.

A. Local Context Review – is the responsibility of the relying institution. Local review is

not an additional full board review, as this is covered by the reviewing IRB. The LRH IRB office may request modifications to the items provided, but it may not disapprove research. All local context reviews are documented as Ceded Review in IRBNet.

B. The IRB Administrator will insure and review the following:
    1. Assuring that the PI and study personnel do not have any conflicts of interest.
    2. Assuring that the PI and all of the study personnel have completed the appropriate CITI training (see Research: Investigator, Research Personnel, IRB Member, IRB Administrator, and Institutional Official Training-AD.0161).
    3. Insuring the following reviews are complete (as applicable):
        i. Feasibility
        ii. Radiation safety
        iii. Bio/DNA safety
        iv. Chemical and environmental
        v. Coverage analysis
        vi. Pharmacy
        vii. Nursing
    4. All local considerations as submitted to the Reviewing IRB, including all institution-specific language (see II.A.1-2).

C. The IRB Administrator will perform a local review on all continuing reviews of ceded studies.
    1. The PI is required to submit in IRBNet:
        i. Renewal letter from Reviewing IRB; and
        ii. Updated COI for each member of the study personnel.

D. The PI is required to submit a request to close the study in IRBNet upon study completion, which will be reviewed, approved, and closed out by the IRB Administrator.

E. The IRB Chair, Vice-Chair or designated scientific member will administratively review the following if/when they are submitted:
    1. All local unanticipated problems, adverse events, noncompliance, and/or suspension or restrictions to the members of the LRH research team (see II.A.3).
    2. All reports submitted to the FDA, OHRP, federal funding agencies, or other federal authorities regarding unanticipated problems, adverse events, or noncompliance (see II.A.6).

PROCEDURE

I. The PI (or local PI) must submit the following information to the LRH IRB office for review through IRBNet:
    A. Study Personnel List
    B. Site PI CV
    C. CITI training for all members of study personnel
    D. Conflict of Interest for all members of study personnel
    E. Confidentiality Agreements for all members of study personnel
    F. Local Context Review Checklist (0.0 - IRB Checklist - Local Context Review.docx (mylrh.org))

II. The LRH IRB office will review the above information and the ancillary reviews (if applicable) via ceded review (see Levels of Review Policy).

III. The review will be documented as "Ceded Review" in IRBNet, whether the review is completed by the IRB Administrator or by the Chair/Vice Chair, and an acknowledgement response letter will be provided in IRBNet to the PI. This process is applicable to initial reviews, continuing reviews, and study closures.

DEFINITIONS

FDA: Food and Drug Administration

IRB: Institutional Review Board

Local Context Information: To help with the Reviewing IRB's determination to serve in such a capacity and to appropriately orient the Reviewing IRB to the Relying Institution, the LRH PI will provide a basic overview of the local community (i.e., cultural, demographic, and economic characteristics, languages spoken, and local educational and/or literacy concerns, and religious, social, and political considerations) as it relates to the protocol being reviewed. This will help the Reviewing IRB ensure that appropriate methods are in place for conducting research within the Relying Institution's community.

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. SMART IRB SOP Manual

II. Protocol-Specific-20180726.pdf (smartirb.org)

III. Relying Site Investigator Checklist (smartirb.org)

IV. Relying Site Study Team Survey (smartirb.org)

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	09/2023
	Andrew Bugajski: 4387 AVP - Research and Sponsored Studies	09/2023

History

Sent for re-approval by Bugajski, Andrew: 4387 AVP - Research and Sponsored Studies on 9/29/2023, 11:31AM EDT

> No changes since last iteration

Last Approved by Bugajski, Andrew: 4387 AVP - Research and Sponsored Studies on 9/29/2023, 11:31AM EDT

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Draft saved by Bugajski, Andrew: 4387 AVP - Research and Sponsored Studies on 1/31/2024, 10:54AM EST

Last Approved by Keriazes, Georgia Ann: 0729 QI/Due Pharmacist on 3/6/2024, 4:02PM EST

> No material changes have been made since the last approval date. Awaiting feedback from the law firm and consulting firm regarding recommended changes to the overall HRPP/Research/IRB

> policies and forms. No recommended edits at this time.

Last Approved by Nelson, Deana: 4080 SVP - Administration and Corporate Initiative on 3/15/2024, 10:49AM EDT

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Draft discarded by Bugajski, Andrew: 4387 AVP - Research and Sponsored Studies on 6/11/2024, 12:43PM EDT

Administrator override by Beatty, Leanne: 0708 Quality Professional on 9/27/2024, 4:40PM EDT

> Policy owner reassigned.