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SOP-Research: Non-Human Subject Research

PURPOSE

The purpose of this procedure is to provide standard operating guidelines for determining and providing a determination for non-human subjects research (NHSR). It is intended that this NHSR 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**) adheres to 45 CFR 46 Subpart A 102 (e) and (l) for non-human subjects research review guidelines.

   A. For the full policy on NHSR 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). All study submissions will be reviewed in their entirety by the IRB Office.

II. Researchers may not make an independent official determination of whether a research study is non-human subjects research. The authority to determine whether a study is NHSR from review is vested solely with the IRB Office.

III. All NHSR reviews will be completed within 5 business days of submission, with the exception of unusual circumstances, as determined by the IRB Office.

IV. The IRB Administrator will check all submissions for completeness 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.

V. Non-Human Subjects Research is anything that does not involve research, a human subject, or a clinical investigation as defined by **DHHS** and the **FDA** (see Research That Must Be Reviewed by the IRB Policy).

VI. The IRB Administrator or designee (IRB member) will review the study and complete a worksheet (see IRB SharePoint) to determine if the study is non-human subjects research. The worksheet will be stored in IRBNet under the IRB Administrator's review. If the study meets the qualifications for non-human subjects research, the IRB Administrator will provide a determination letter that states the study is NHSR and does not require IRB review. If a study meets the guidelines for human subjects research, it must undergo exempt, expedited or full IRB review. If exempt or expedited review is required, see SOP-Research: Exempt Review and SOP-Research: Expedited Review.

   A. NHSR reviewers conduct an in-depth review of all submitted materials as they apply to the study.

   B. Reviewers are expected to self-identify conflicts of interest and refer the research study to another reviewer if a conflict exists.

   C. Reviewers will confirm that the research satisfies the conditions of NHSR and document it in IRBNet.

   D. If the reviewer determines that the proposed research does not meet the criteria for non-human subjects research, the study will be reviewed as exempt research, or referred to an expedited reviewer or the full convened IRB for review.

      1. The reviewer may determine that the project:

         a. Meets the requirements for NHSR and does not require IRB review and approval;

         b. Requires more information to make a determination;

         c. Will be referred for exempt review, expedited review or to the full convened IRB

      2. The reviewer may not disapprove the study.

   E. The IRB Administrator will notify the investigator in writing of the determination to approve the study as NHSR or refer the study for another level of review. The IRB Administrator will generate a letter in IRBNet with the following information:

      1. Date of review
      2. Type of review (administrative)
      3. Documents that were reviewed
      4. The level of review the submission received (NHSR, unless the study was referred for another level of review)

5. The determination of the reviewer (i.e. that the study is non-human subjects research)
6. Modifications and/or additional information may be required to determine if the study qualifies as NHSR. If the study qualifies as NHSR, modifications/additional information may be requested to make the official determination. If this is required, the IRB Office will provide:
    a. A description of the required modifications/additional information
    b. The basis for requiring modifications/additional information
    c. The process for submitting the modifications/additional information and how the subsequent review will be conducted.

F. If modifications are required to secure a NHSR determination, the IRB Administrator will communicate with the Primary Investigator/study coordinator until the study is determined to be NHSR.

G. 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.

H. 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.

VII. NHSR studies do not require continuing review. Primary Investigators should submit a request to close the study in IRBNet when the study is finished.

DEFINITIONS

DHHS: Department of Health and Human Services

FDA: Food and Drug Administration

IRB: Institutional Review Board

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. IRB Checklists | CHOP Institutional Review Board

II. Non-Human Subject Research - IRB - The University of Utah
III. 2018 Requirements (2018 Common Rule) | HHS.gov

Approval Signatures

Step Description	Approver	Date
	Deana Nelson: 4080 SVP - Administration and Corporate Initiative	06/2025
	Renee Reed: 4064 Senior Attorney	06/2025
	Georgia Ann Keriazes: 0729 QI/ Due Pharmacist	05/2025
	Andrew Bugajski: 4387 AVP - Research and Sponsored Studies	04/2025
	Andrew Bugajski: 4387 AVP - Research and Sponsored Studies	04/2025