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

SOP-Research: Exempt Review

PURPOSE

The purpose of this procedure is to provide standard operating guidelines for exempt review for research studies. It is intended that this exempt review standard operating procedure (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 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 46.110 for exempt review guidelines.

   A. For the full policy on exempt review, see **Research: Levels of IRB Review- AD.0167**.

PROCEDURE

I. Investigators are required to submit a complete application via IRBNet, including all required supporting documentation (link submission checklist). All study submissions will be reviewed in their entirety by the IRB Office.

II. **Researchers** may not make an independent determination of whether a research study is exempt. The authority to determine whether a study is exempt from review is vested solely with the IRB and/or IRB Office.

III. All exempt 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. Exempt research must be **minimal risk** AND fit into one (or more) of the specific exempt review categories (see **Research: Levels of IRB Review- AD.0167**).

VI. Exempt review will be conducted by an experienced scientific member of the IRB by using a worksheet to determine the exemption category (link IRB SharePoint), which will then be saved with the review in IRBNet. An experienced scientific member is one who has a minimum of one (1) year of experience on the IRB and has sound knowledge of the federal regulations and local guidelines. The IRB Chair may appoint exempt reviewers.

VII. The reviewer has the authority to approve the exemption, ask for clarification to ensure the study meets exempt criteria, or disapprove the research for exempt review status. If a study is not approved for exempt review, it must undergo expedited or full IRB review. If expedited review is required, see SOP-Research: Expedited Review.

A. Exempt reviewers conduct an in-depth review of the following materials as they apply to the study:

1. IRB Exempt Protocol
2. Protocol or research plan
3. Consent document, letter, or script
4. All necessary HIPAA authorizations, alterations, or waivers
5. Copies of surveys or questionnaires
6. Recruitment materials

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

C. Reviewers will confirm that the research satisfies the exempt review categories45 CFR 46.104 and 21 CFR § 56.104) and document the specific category or categories justifying the exempt review in IRBNet using the Exempt Review Worksheet (see **Research: Levels of IRB Review- AD.0167**).

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

E. The reviewer's decision to approve an exempt study is based on the criteria for IRB approval of exempt research.

1. The reviewer may:
    a. Approve the research as submitted
    b. Require modifications or request clarifications to ensure the study qualifies for exempt review
    c. Refer the study for expedited review or to the full convened IRB
2. The reviewer may not disapprove research.

F. When a study is determined to be exempt, the reviewer will then determine if the following additional requirements are met:
    1. The research must involve no more than minimal risk to subjects; and
    2. Selection of subjects is equitable (That is, the research is appropriate for the population being studied); and
    3. If there is recording of identifiable information, there are adequate provisions to maintain the confidentiality of the data; and
    4. There are adequate provisions to maintain the privacy interests of the subjects; and
    5. If there is contact with the research subjects there will be a consent process that meets the following requirements:
        a. The consent process will disclose that the activities involve research
        b. The consent process will disclose the procedures to be performed
        c. The consent process will disclose that participation is voluntary
        d. The consent process will disclose the name and contact information for the investigator

G. The IRB Administrator will notify the investigator in writing of the determination to approve the exemption 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 (exempt, unless the study was referred for another level of review)
    5. The decisions of the reviewer (i.e. that the study is exempt from further review)
    6. The exemption category the study falls into
    7. If modifications are required in order to secure approval:
        a. A description of the required modifications
        b. The basis for requiring modifications
        c. The process for submitting the modifications and how the review will be conducted on them

H. If modifications are required to secure exempt review, the IRB Administrator will communicate with the Primary Investigator/study coordinator until the study is approved as exempt.

I. 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.

J. The reviewer will provide a summary of the review, including the exemption category, 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.

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

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. Exemptions (2018 Requirements) | HHS.gov
II. Minimal Risk | FDA
III. Office of Research Exempt Research - Office of Research (ucdavis.edu)

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