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Lakeland Regional Health

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

Research: Levels of IRB Review- AD.0167

PURPOSE

The purpose of this policy is to provide guidelines for the different levels of **IRB** review for research studies. It is intended that this policy be consistent with FDA, 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. There are five (5) different levels of review that a research study submitted to the IRB can receive:
   A. Full Board Review;
   B. Expedited Review;
   C. Exempt Review;
   D. Non-Human Subjects Research Determination; and
   E. Ceded Review.

II. For all levels of review, the principal investigator (PI) is expected to submit a complete application to the IRB and supply all applicable documents, including but not limited to:
   A. Resumes or curriculum vitaes and current human subject protection education certifications for the PI, co-investigators, and research team members for the purpose of demonstrating that the investigators have the appropriate experience, staff and facilities to conduct the research;
   B. Full protocol/thesis/dissertation/project summary;
   C. Informed consent documents, Parental Permission, Assent forms, pre-screening verbal scripts, as applicable (see Informed Consent- AD.0122 and Research: Waiver of Elements of Consent, Waiver of Documentation of Informed Consent, and Waiver of Written Authorization- AD.0168);
   D. Investigator's brochure(s);

E. Supporting documentation for IND/IDE or HDE;

F. Product labeling or package insert (drug and device);

G. Recruitment and advertising materials, including brochures and flyers;

H. Grant application for research supported by DHHS;

I. Letter of support from non-affiliate sites;

J. Interview or focus group questions;

K. Questionnaires or survey instruments;

L. Data collection form(s);

M. Conflict of Interest statements; and

N. Any other relevant study documentation.

III. Full Board Review

A. The LRH IRB is responsible for reviewing and approving research involving human subjects as defined in the federal regulations and state and local laws. Studies requiring full board review will be reviewed by the IRB Committee at a convened meeting. Studies that require full board review are:

1. Greater than **Minimal Risk**; and
2. Studies that are Minimal Risk, but do not fit in an expedited review category.
    a. The IRB Chair may, if necessary, request full board review of studies that may otherwise qualify for lower levels of review.

B. Full Board review is conducted at convened meetings at which a quorum consisting of the majority of the members of the IRB is present, including at least one member whose primary concerns are in nonscientific areas.

C. The IRB has full authority to approve, approve with conditions, require modifications in, disapprove, terminate, or suspend all research activities that fall within its jurisdiction as specified by both the federal regulations and local institutional policy.

D. The LRH IRB shall utilize a primary and secondary reviewer system for reviewing full board protocols (see SOP-Research: Full Board Review).

IV. Expedited Review

A. To qualify for expedited review, a study must meet both of the following requirements:

1. Involves no greater than Minimal Risk; and
2. Fits into one (or more) of the specific expedited review categories (see IV.B.5).

B. LRH IRB adheres to 45 CFR 46.110 for expedited review guidelines.

1. Research activities that (1) present no more than minimal risk to human subjects, and (2) involve only procedures listed in one or more of the following categories, may be reviewed by the IRB through the expedited review procedure authorized by 45 CFR §46.110 and 21 CFR §56.110. The activities listed should not be deemed to be of minimal risk simply because they are included on this list. Inclusion on this list merely means that the activity is eligible for review through the expedited review procedure when the specific circumstances of the proposed research involve no more than minimal risk to human subjects.
2. The expedited review procedure may not be used where identification of the subjects and/or their responses would reasonably place them at risk of criminal or

civil liability or be damaging to the subjects' financial standing, employability, insurability, reputation, or be stigmatizing, unless reasonable and appropriate protections will be implemented so that risks related to invasion of privacy and breach of confidentiality are no greater than minimal.

3. The expedited review procedure may not be used for **Classified Research** involving human subjects.
4. Expedited review will be conducted by an **Experienced Scientific Member** of the IRB. The IRB Chair may appoint expedited reviewers.
5. The IRB may use the expedited review procedure to review some or all of the research appearing on the list described below, unless the reviewer determines that the study involves more than Minimum Risk. Categories one (i) through seven (vii) pertain to both initial and continuing IRB review. Categories eight (viii) and nine (ix) pertain to continuing IRB review only. Categories ten (x) through twenty-two (xxii) pertain to amendments.
    a. Clinical studies of drugs and medical devices only when condition (a) or (b) is met.
        i. Research on drugs for which an investigational new drug application (21 CFR Part 312) is not required. (note: research on marketed drugs that significantly increases the risks or decreases the acceptability of the risks associated with the use of the product is not eligible for expedited review.)
        ii. Research on medical devices for which (a) an investigational device exemption application (21 CFR Part 812) is not required; or (b) the medical device is cleared/approved for marketing and the medical device is being used in accordance with its cleared/approved labeling.

    b. Collection of blood samples by finger stick, heel stick, ear stick, or venipuncture as follows:
        i. From healthy, nonpregnant adults who weigh at least 110 pounds. For these subjects, the amounts drawn may not exceed 550 ml in an eight (8) week period and collection may not occur more frequently than two (2) times per week; or
        ii. From other adults and children, considering the age, weight, and health of the subjects, the collection procedure, the amount of blood to be collected, and the frequency with which it will be collected. For these subjects, the amount drawn may not exceed the lesser of 50 ml or 3 ml per kg in an eight (8) week period and collection may not occur more frequently than two (2) times per week.

    c. Prospective collection of biological specimens for research purposes by noninvasive means. Examples: (a) hair and nail clippings in a non-disfiguring manner; (b) deciduous teeth at time of exfoliation or if routine patient care indicates a need for extraction; (c) permanent teeth if routine patient care indicates a need for extraction; (d) excreta and external secretions (including sweat); (e) uncannulated saliva collected either in an unstimulated fashion or stimulated by chewing gum base or wax or by applying a dilute citric solution to the tongue; (f) placenta removed at delivery; (g) amniotic fluid obtained at the time of rupture of the

membrane prior to or during labor; (h) supra- and subgingival dental plaque and calculus, provided the collection procedure is not more invasive than routine prophylactic scaling of the teeth and the process is accomplished in accordance with accepted prophylactic techniques; (i) mucosal and skin cells collected by buccal scraping or swab, skin swab, or mouth washings; (j) sputum collected after saline mist nebulization.

d. Collection of data through noninvasive procedures (not involving general anesthesia or sedation) routinely employed in clinical practice, excluding procedures involving x-rays or microwaves. Where medical devices are employed, they must be cleared/approved for marketing. (Studies intended to evaluate the safety and effectiveness of the medical device are not generally eligible for expedited review, including studies of cleared medical devices for new indications). Examples: (a) physical sensors that are applied either to the surface of the body or at a distance and do not involve input of significant amounts of energy into the subject or an invasion of the subject's privacy; (b) weighing or testing sensory acuity; (c) magnetic resonance imaging; (d) electrocardiography, electroencephalography, thermography, detection of naturally occurring radioactivity, electroretinography, ultrasound, diagnostic infrared imaging, doppler blood flow, and echocardiography; (e) moderate exercise, muscular strength testing, body composition assessment, and flexibility testing where appropriate given the age, weight, and health of the individual.

e. Research involving materials (data, documents, records, or specimens) that have been collected, or will be collected solely for non-research purposes (such as medical treatment or diagnosis). Some research in this category may be exempt from the HHS regulations for the protection of human subjects. This listing refers only to research that is not exempt. Examples include:

    i. Secondary analyses of existing or future data sets, such as databases containing medical records, criminal justice system records, education records, or survey data. These analyses may include studies where one or more data sets are combined. For example:

        1. An analysis of student educational records to explore the relationship between student mobility from district to district and student academic achievement for students from various economic and ethnic backgrounds.
        2. A study of prison administration records to explore the relationship between inmates' individual background characteristics, type of criminal violation, and acquisition of a Graduation Equivalent Development credential.
        3. A study of medical records and survey data to compare individuals' weight with the cultural attitudes of different subpopulations toward diet and exercise.

f. Collection of data from voice, video, digital, or image recordings made for research purposes. Examples include:

i. Observational studies of human behavior and characteristics where personal identifiers are recorded and the data are not particularly sensitive in nature. For example:

1. A study using video recordings to examine communication styles used by cooperating employees in a variety of business organizations.
2. A laboratory study comparing patterns of eye movement and reading comprehension performance among novice and competent readers.

g. Research on individual or group characteristics or behavior (including, but not limited to, research on perception, cognition, motivation, identity, language, communication, cultural beliefs or practices, and social behavior) or research employing survey, interview, oral history, focus group, program evaluation, human factors evaluation, or quality assurance methodologies. Some research in this category may be exempt from the HHS regulations for the protection of human subjects. This listing refers only to research that is not exempt. Examples include:

i. Experimental studies of human behavior, attitudes, opinions, and decisions, where the experimental manipulation consists of subjects reacting to hypothetical or contrived situations that are not expected to have significant lasting effects on the subjects. For example:

1. A study in experimental economics in which people play an economic game that involves offering and/or accepting amounts of cash provided as part of the experiment.
2. A study of adults' ability to identify accurately the perpetrators of staged thefts.
3. A study attempting to validate a previously tested measure of extroversion/introversion with members of a previously untested cultural group.

ii. Survey research where the respondents are approached in a natural setting, either personally or through a communications medium (e.g., by mail, telephone, or the internet), and participation is voluntary. For example:

1. A research study using telephone surveys of persons who provide their names and information about their background characteristics, political beliefs, and voting behavior.
2. An online internet study in which undergraduate students view a video clip about economic theory and then respond to computer-simulated scenarios about individual spending decisions.

iii. Evolving research activities (such as ethnographic studies or focus group research) where the research activity is refined in various ways in response to earlier data collection, and the topics are not especially sensitive. For example:

1. An ethnographic field study using un-structured interviews to explore the interrelationship between family life and involvement in religious activities.
2. An ethnographic study using participant-observation where the researcher participates in the subject's activities of daily life, such as an anthropologist studying an agrarian market place by sitting in the respondent's market stall, observing interactions and sometimes selling items to help out.
3. A participatory action research project in which middle school teachers and students use group discussions, surveys, and interviews to evaluate the school's social studies curriculum and develop recommendations for improvements.

h. Continuing review of research previously approved by the convened IRB as follows:
    i. Where (a) the research is permanently closed to the enrollment of new subjects; (b) all subjects have completed all research-related interventions; and (c) the research remains active only for long-term follow-up of subjects; or
    ii. Where no subjects have been enrolled and no additional risks have been identified; or
    iii. Where the remaining research activities are limited to data analysis.

i. Continuing review of research not conducted under an investigational new drug application or investigational device exemption, where categories IV.B.ii through IV.B.viii do not apply, and the IRB has determined and documented (at a convened meeting) that the research involves no greater than minimal risk and no additional risks have been identified.

j. **Minor changes** in previously approved research during the period for which approval is authorized;
    i. Examples of minor changes to a protocol include but are not limited to, the following:
        1. A change in equally qualified PIs;
        2. A new media advertisement that is submitted after the research is approved, such as a new newspaper, Internet, or radio advertisement;
        3. Adding a new procedure to a research study when that procedure is on the expedited list and involves no more than minor risk;
        4. Changing the order of questions in a study questionnaire;
        5. Changing wording in the consent form that does not increase risk or decrease benefit (e.g., changing "nausea" to "nausea and stomach upset");
        6. Correcting grammatical or typographical errors in the

consent form;

7. Deletion from the protocol of a research biopsy that, without impairing scientific merit, materially decreases risk for study subjects;
8. Minor decreases in the number of subjects;
9. Replacing old case report forms with essentially equivalent new case report forms as noted in a revised protocol; and
10. Changes that neither materially increase risk, nor materially decrease benefit, nor materially decrease scientific merit.

k. Changes to research that were initially approved through expedited review will qualify for expedited review unless the change increases the overall risk.

l. Adding a new procedure to a research study, when that procedure is on the expedited list and involves no more than minor risk.

m. Adding a new minimal risk procedure to a research study, when that procedure is not on the expedited list. For example:

   i. Low dose radiation procedures; and

   ii. Drawing three to five (3-5) blood draws of less than 550 ml from an in-dwelling catheter.

n. A minor change to research that is not on the expedited list, but does not involve the addition of a procedure. Examples include many types of changes to research, such as:

   i. Change in the equally qualified individuals who will do statistical analysis;

   ii. Change in consent form wording that does not increase risk or decrease benefit. For example, changing “nausea” to “nausea and stomach upset,” or fixing a run-on sentence or a comma;

   iii. Replacing old case report forms with essentially equivalent new case report forms, and the change is noted in a revised protocol;

   iv. Changing the order of questions in a psychology study questionnaire; and

   v. Adding the word “approximately” to the table of the lab test schedule.

   vi. A new media advertisement that is submitted after the research is approved, such as a new newspaper or radio advertisement.

   vii. A statistically small change to the number of subjects an investigator will enroll. For instance, in a single site study, a change from 100 to 105 subjects, or in multi-center study, and change from twenty (20) subjects to thirty (30) subjects at one site in a study involving 1,000 subjects. Minor decreases in the number of subjects would also qualify for expedited review.

   viii. A change in equally qualified study personnel (study coordinator,

nurse, technician, transcriptionist for anthropology study), e.g., a person leaves the institution and is replaced.

ix. A change in equally qualified principal investigators. For example, when a principal investigator leaves the institution and a new principal investigator takes over.

x. Adding a new equally qualified investigator at a new site for a multi-site study, overseen by a central IRB.

xi. Deletion from the protocol of a research biopsy that, without impairing scientific merit, materially decreases risk for study subjects.

6. Changes that include additions and removals of study personnel, other than the Principal Investigator, may be reviewed for approval by the IRB Administrator.
7. Protocol corrections that are only administrative in nature (e.g., correction of typographical and spelling errors in the protocol) would not need additional IRB review because **OHRP** does not consider such corrections to be changes to the research. These administrative changes to the protocol need to be clearly distinguished from administrative changes to the consent form, which always need at least expedited review.
    A. Non-material administrative corrections of typographical and spelling errors in the protocol are those that do not change the conduct of the study, alter the meaning, increase the risk to subjects, or require a change to the informed consent.
    B. These changes may be reviewed for approval by the IRB Administrator or an IRB member designated by the IRB Chair, or by the IRB Chair.
8. In reviewing the research, the reviewers may exercise all of the authorities of the IRB except that the reviewers may not disapprove the research. A research activity may be disapproved only after review by the full convened IRB.
9. When the IRB uses an expedited review procedure, the members will be informed at the next IRB meeting of the studies undergoing expedited review and determination(s). 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.

V. Exempt Review

A. Exempt research must be Minimal Risk and fit into one (1) (or more) of the following categories:

1. Research, conducted in established or commonly accepted educational settings, that specifically involves normal educational practices that are not likely to adversely impact students' opportunity to learn required educational content or the assessment of educators who provide instruction. This includes most research on regular and special education instructional strategies, and research on the effectiveness of or the comparison among instructional techniques, curricula, or classroom management methods.
2. Research that only includes interactions involving educational tests (cognitive, diagnostic, aptitude, achievement), survey procedures, interview procedures, or observation of public behavior (including visual or auditory recording) if at least one (1) of the following criteria is met:

a. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

b. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

c. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and the IRB conducts a limited IRB review to make the determination required by 45 CFR §46.111.

3. Research involving benign behavioral interventions in conjunction with the collection of information from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one (1) of the following criteria is met:

    a. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects;

    b. Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing, employability, educational advancement, or reputation; or

    c. The information obtained is recorded by the investigator in such a manner that the identity of the human subjects can readily be ascertained, directly or through identifiers linked to the subjects, and the IRB conducts a limited IRB review to make the determination required by 45 CFR §46.111.

    d. For the purpose of this provision, benign behavioral interventions are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. Provided all such criteria are met, examples of such benign behavioral interventions would include having the subjects play an online game, having them solve puzzles under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.

    e. If the research involves deceiving the subjects regarding the nature or purposes of the research, this exemption is not applicable unless the subject authorizes the deception through a prospective agreement to participate in research in circumstances in which the subject is informed that he or she will be unaware of or misled regarding the nature or purposes of the research.

4. Secondary research for which consent is not required: secondary research uses of identifiable private information or identifiable biospecimens, if at least one (1) of the following criteria is met:

    a. The identifiable private information or identifiable biospecimens are publicly available;

b. Information, which may include information about biospecimens, is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained directly or through identifiers linked to the subjects, the investigator does not contact the subjects, and the investigator will not re-identify subjects;

c. The research involves only information collection and analysis involving the investigator's use of identifiable health information when that use is regulated under 45 CFR parts 160 and 164, subparts A and E, for the purposes of “health care operations” or “research” as those terms are defined at 45 CFR §164.501 or for “public health activities and purposes” as described under 45 CFR §164.512(b); or

d. The research is conducted by, or on behalf of, a Federal department or agency using government-generated or government-collected information obtained for non-research activities, if the research generates identifiable private information that is or will be maintained on information technology that is subject to and in compliance with section 208(b) of the E-Government Act of 2002, §208(b), 116 Stat. 2921. All of the identifiable private information collected, used, or generated as part of the activity will be maintained in systems of records subject to the Privacy Act of 1974, 5 U.S.C. §552a, and, if applicable, subject to the Paperwork Reduction Act of 1995, 44 U.S.C. §3501 et seq.

5. Research and demonstration projects that are conducted or supported by a federal department or agency, or otherwise subject to the approval of department or agency heads (or the approval of the heads of bureaus or other subordinate agencies that have been delegated authority to conduct the research and demonstration projects), and that are designed to study, evaluate, improve, or otherwise examine public benefit or service programs, including procedures for obtaining benefits or services under those programs, possible changes in or alternatives to those programs or procedures, or possible changes in methods or levels of payment for benefits or services under those programs. Such projects include, but are not limited to, internal studies by federal employees, and studies under contracts or consulting arrangements, cooperative agreements, or grants. Exempt projects also include waivers of otherwise mandatory requirements using authorities such as sections 1115 and 1115A of the Social Security Act, as amended.

    a. Each federal department or agency conducting or supporting the research and demonstration projects must establish, on a publicly accessible federal web site or in such other manner as the department or agency head may determine, a list of the research and demonstration projects that the federal department or agency conducts or supports under this provision. The research or demonstration project must be published on this list prior to commencing the research involving human subjects.

6. Taste and food quality evaluation and consumer acceptance studies:

    a. If wholesome foods without additives are consumed, or

    b. If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe, by the FDA or approved by the EPA or the Food Safety and Inspection Service of the U.S. Department of Agriculture.

7. Storage or maintenance for secondary research for which broad consent is required: storage or maintenance of identifiable private information or identifiable biospecimens for potential secondary research may be used if the IRB conducts a limited IRB review and makes the determinations required by 45 CFR §46.111(a)(8).
    a. At this time, the LRH IRB discourages research that requires broad consent.
8. Secondary research for which broad consent is required: Research involving the use of identifiable private information or identifiable biospecimens for secondary research use, if the following criteria are met:
    a. Broad consent for the storage, maintenance, and secondary research use of the identifiable private information or identifiable biospecimens was obtained in accordance with 45 CFR §46.116(a)(1) through (4), (a)(6), and (d);
    b. Documentation of informed consent or waiver of documentation of consent was obtained in accordance with 45 CFR §46.117;
    c. The IRB conducts a limited IRB review and makes the determination required by 45 CFR §46.111(a)(7); and makes the determination that the research to be conducted is within the scope of the broad consent ; and the investigator does not include returning individual research results to subjects as part of the study plan. This provision does not prevent an investigator from abiding by any legal requirements to return individual research results.
    d. At this time, the LRH IRB discourages research that requires broad consent.

B. Exempt - Limited IRB Review
    1. Exempt Categories V.2, V.3, V.7 and V.8 have provisions for exempt research that require limited IRB review. This means that when appropriate, there are adequate provisions to protect the privacy of subjects and to maintain the confidentiality of data 45 CFR §46.111(7).
    2. Investigators submitting exempt research that requires limited IRB review will be prompted to complete the appropriate confidentiality sections in the IRB application.

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

VI. Non-Human Subjects Research (NHSR)

The IRB Administrator or designee will review the study and, if the study meets the qualifications for non-human subjects research, will provide a determination letter that states the study is NHSR and does not require IRB review (SOP-Research: Non-Human Subject Research).

VII. Ceded Review

When LRH is relying on another IRB to be the IRB of record, local context review must be performed on the study by LRH. The IRB Administrator or designee will review the study and document the review as a Ceded Review in IRBNet (SOP-Research: Local Context & Ceded Review).

PROCEDURE

I. SOP-Research: Full Board Review
II. SOP-Research: Expedited Review
III. SOP-Research: Exempt Review
IV. SOP-Research: Non-Human Subject Research
V. SOP-Research: Local Context & Ceded Review

DEFINITIONS

Classified Research: Classified research is defined as research that has a security classification established by an authorized agency of the federal government. An entire sponsored research project or a specific section of a research project may be categorized as classified. Classification requirements typically emerge due to certain contractual conditions, but may, in some cases, arise after the research has been conducted as a result of the extreme importance of the research results to national security. Classified Research as a designation is not normally applied to basic research projects. It is more typically used to limit use and dissemination of information about applied research or development efforts.

Experienced Scientific Member: 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.

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.

Minor Change - A minor change for the purposes of research related to the level of risk to subjects, the research design or methodology, the subject population, qualifications of the research team, the facilities available to support the safe conduct of the research and/or, any other factor that warrants review of proposed changes by the convened IRB.

OHRP: Office of Human Research Protections

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. FDA 21 CFR §56.104

II. Expedited Review: Categories of Research that may be Reviewed Through an Expedited Review Procedure (1998) | HHS.gov

III. Exemptions (2018 Requirements) | HHS.gov

IV. Attachment B: Approved by SACHRP July 20, 2011 - SACHRP Recommendation regarding definition of a minor change in research under 45 CFR 46 and 21 CFR 56 | HHS.gov

V. John Hopkins University - https://research.jhu.edu/jhura/wp-content/uploads/sites/2/2017/01/JHU_Classified_Research-Policy.pdf#:~:text=%EE%80%80Classified%EE%80%81%20%EE%80%80research%EE%80%81%20is%20defined%20as%20%EE%80%80research%EE%80%81%20that%20has,a%20%EE%80%80research%EE%80%81%20project%20may%20be%20categorized%20as%20%EE%80%80classified%EE%80%81

VI. Expedited Review of Social and Behavioral Research Activities (nsf.gov)

VII. Guidance on IRB Approval Research with Conditions (hhs.gov)

VIII. Office of Research Exempt Research - Office of Research (ucdavis.edu)

IX. Minimal Risk | FDA

Approval Signatures

Step Description	Approver	Date
	Danielle Drummond: 0001 President & Chief Executive Officer - LRHS	01/2025
	Jonn Hoppe: 1011 Executive VP, Chief Legal Officer-General Cou	01/2025
	Timothy Regan: 0009 President - LRMC/Chief Medical Officer	01/2025
	Deana Nelson: 4080 SVP - Administration and Corporate Initiative	01/2025
	Renee Reed: 4064 Senior Attorney	01/2025
	Andrew Bugajski: 4387 AVP - Research and Sponsored Studies	01/2025
	Georgia Ann Keriazes: 0729 QI/ Due Pharmacist	01/2025
	Trudy Wittenberg: 4388 Institutional Review Board Administrator	01/2025