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Research: Children as Research Subjects- AD.0154

PURPOSE

The purpose of this policy is to ensure the protection of **children** who are involved as subjects in research. It is intended that this children as research subjects policy be consistent with Food and Drug Administration federal regulations, the Revised Common Rule, HIPAA, and good clinical practice. 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 personnel engaged in research.

POLICY

The LRH IRB will ensure the protection of the rights and welfare of children who are involved as subjects in research under the requirements of 45 CFR 46 Subpart D, 21 CFR 50 Subpart D, and according to the ethical principles of the Belmont Report.

I. Level 1 - Research not involving greater than minimal risk.
    1. LRH may conduct research in which the IRB finds that no greater than minimal risk to children is presented, only if the IRB finds that adequate provisions are made for soliciting the **assent** of the children and the **permission** of their **parents** or **guardians**.

II. Level 2 - Research involving greater than minimal risk, but presenting the prospect of direct benefit to the individual subjects.
    1. LRH may conduct research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well-being, only if the IRB finds that:

i. The risk is justified by the anticipated benefit to the subjects;

ii. The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and

iii. Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians.

III. Level 3 - Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition.

1. LRH will conduct research in which the IRB finds that more than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is not likely to contribute to the well-being of the subject, only if the IRB finds that:

i. The risk represents a minor increase over minimal risk;

ii. The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations;

iii. The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition; and

iv. Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians.

IV. Level 4 - Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses or neonates.

1. The IRB may approve research that the IRB does not believe meets the requirements of 45 CFR 46.204 or 45 CFR 46.205 only if:

i. The IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates; and

ii. The Secretary of HHS or the Commissioner of FDA, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, ethics, law) and following opportunity for public review and comment, including a public meeting announced in the Federal Register, has determined either:

a. That the research in fact satisfies the conditions of 45 CFR 46.404, 45 CFR 46.405, 45 CFR 46.406, 21 CFR 50.51, 21 CFR 50.52 or 21 CFR 50.53 as applicable; or

b. That the following conditions are met:

I. The research presents a reasonable opportunity to

further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;

II. The research will be conducted in accord with sound ethical principles; and

III. Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians, as set forth in 45 CFR 46.408 and 21 CFR 50.55.

V. Requirements for permission by parents or guardians and for assent by children.

1. See: Research: Informed Consent, Assent, Re-Consenting, Parental Permission, Remote Consent and Remote Assent Process- CL.0218.

VI. Wards

1. Children who are wards of the state or any other agency, institution, or entity can be included in research approved under 45 CFR 46.406 or 45 CFR 46.407 only if such research is:
    i. Related to their status as wards; or
    ii. Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.
2. The IRB shall require appointment of an advocate for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in loco parentis. One individual may serve as advocate for more than one child. The advocate shall be an individual who has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research and who is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization.

Additional Guidance

I. Infants - When appropriate, the IRB will determine that studies have been conducted first on animals, adult humans, and then on older children, before involving infants.

PROCEDURE

I. The LRH IRB will ensure compliance with this policy according to the IRB functions and operations specified in 45 CFR 46.108 and the principles of respect for persons, beneficence and justice as described in the Belmont Report.

II. For convened IRB review each member reviews the protocol. For expedited review the IRB chair, or designee reviews the protocol. If greater than minimal risk is identified during an expedited procedure, the reviewer sends the protocol to the convened IRB for review.

III. The IRB full board or member (as appropriate) reviews the proposed research taking into consideration all applicable policies, specifically including the degree of risk involved in the

research, prospects of direct benefits to individual subjects, and likelihood of the research to yield generalizable knowledge.

IV. The IRB approves research only after determining the research may proceed ethically in accordance with the Belmont Principles.

V. The IRB Administrator documents the Children's Research Risk Level as determined by the IRB.

DEFINITIONS

Assent: A child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

Children: Persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

Guardian: An individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

Parent: A child's biological or adoptive parent.

Permission: The agreement of parent(s) or guardian to the participation of their child or ward in research.

Workforce: All LRH employees, volunteers, trainees/students, contractors, and medical staff.

REFERENCES

HHS 45 CFR 46 Subpart D - Additional Protections for Children Involved as Subjects in Research.

FDA 21 CFR 50 Subpart D – Additional Safeguards for Children in Clinical Investigations.

Approval Signatures

Step Description	Approver	Date
	Danielle Drummond: 0001 President & Chief Executive Officer - LRHS	05/2023
	Jonn Hoppe: 1011 Executive VP, Chief Legal Officer-General Cou	05/2023
	Timothy Regan: 0009 President - LRMC/Chief Medical Officer	05/2023
	Renee Reed: 4064 Senior Attorney	05/2023

Lori Williams Shea: 4341 AVP PWC-Business Development & Operations	04/2023
Joy Boyd: 0060 Manager - Patient Care	03/2023
Deana Nelson: 4080 SVP - Administration and Corporate Initiative	03/2023
Georgia Ann Keriazes: 0729 QI/ Due Pharmacist	03/2023
Andrew Bugajski: 4387 AVP - Research and Sponsored Studies	03/2023