ORLANDO HEALTH®

1414 Kuhl Ave.
Orlando, Florida 32806
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Type of Policy:	***PROTECTION OF HUMAN RESEARCH PARTICIPANTS***	Category:	**Orlando Health Institutional Review Board (IRB)**

Title:	***Children in Research including Unmarried Pregnant Minors, Unmarried Minor Mothers, Married Minors, and Emancipated Minors***	Policy #:	**0330-1011**
		Replaced #:	ORMC IRB# 6000-400
Page 1 of 5		Issued By:	Orlando Health Institutional Review Board
Issue Date:	**7/19/95**	Approved By:	**SIGNATURE ON FILE** Philip Giordano, MD Institutional Official
Revision Dates:	1/1/01, 3/20/02, 5/17/05, 11/9/07, 9/23/13, 4/24/15, 3/26/18, 4/5/21,1/18/23		

I. PURPOSE:

To impose additional safeguards to protect certain vulnerable classes of human research subjects.

II. DEFINITION:

When used in this policy these terms have the following meanings:

A. Informed consent: A process by which a subject voluntarily confirms his or her willingness to participate in a particular trial, after having been informed of all aspects of the trial that are relevant to the subject's decision to participate. Informed consent is documented by means of a written, signed, and dated informed consent form.
B. Emancipated minor: An individual less than 18 years of age who is married, widowed or divorced, is in the military, is pregnant (as related to the pregnancy), has a child (as related to the child), or whose minor status has been approved by a court of law.
C. Emergency/urgent conditions: When adult/minor is in danger of loss of life or permanent loss of bodily functions.
D. Legal representative: A person who, under applicable law, has the authority to act on behalf of an individual. A legal representative includes a healthcare surrogate, proxy, guardian, or parent or other person acting in place of a parent (in loco parentis) for a non-emancipated minor, or an executor or administrator of an estate.
E. Minor: Any person under the age of 18.
F. Ward: a person for whom a guardian has been appointed and is a child whose welfare is the responsibility of the State or any other agency, institution, or entity
G. Guardian Advocate: is a person appointed by a court to make decisions regarding mental health treatment on behalf of a patient who has been found incompetent to consent to treatment.
H. Assent: A minor's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

III. POLICY:

The Orlando Health Institutional Review Boards (IRB) shall require additional safeguards in research involving children as subjects.

IV. PROCEDURE:

In addition to the responsibilities prescribed in IRB Policy #0330-1017 "Ethical Principles", the IRB will require the following additional duties:

A. Exemption from review for research involving survey or interview procedures or observations of public behavior does not apply, except for research involving observation of public behavior when the investigator(s) do not participate in the activities being observed.

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B. Minimal risk research is allowed if the child assents and the consent of at least one parent or guardian are obtained when required by the IRB.

C. Research involving greater than minimal risk but presenting the prospect of direct benefit to the child is allowed if the IRB finds and documents that:
   1. the risk is justified by the anticipated benefit to the child;
   2. the relation of the benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches; and
   3. adequate provisions are made for soliciting the assent of the child and consent of at least one parent or guardian.

D. Research involving greater than minimal risk and no prospect of direct benefit to the child but likely to yield generalizable knowledge about the child's disorder or condition is allowed if the IRB finds and documents that:
   1. the risk represents a minor increase over minimal risk;
   2. 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 situation;
   3. the research is likely to yield generalizable knowledge about the subjects' condition which is of vital importance for the understanding or amelioration of the subject's condition; and
   4. adequate provisions are made for soliciting assent of the child and consent of both parents or guardians.

E. Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children is allowed if:
   1. the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;
   2. the research will be conducted in accordance with sound ethical principles; and
   3. adequate provisions are made for soliciting the assent of children and the permission of <u>both</u> parents or guardians.

F. Requirements for permission by parents or guardians and for assent by children:
   1. Assent should be documented from children ages 12-17 years old; however, the IRB may require assent from children younger than 12 years old.
   2. The IRB recognizes that under certain circumstances, it might not be possible to obtain assent. If assent is not obtained, the reason why will be documented.
   3. Provisions shall be made for soliciting the assent of the child, when in the judgment of the IRB claims the child is capable of providing assent, taking into account the ages, maturity, and psychological state of the child. If the IRB determines that the capability of some or all of the children is so limited that they cannot reasonably be consulted or that the intervention or procedure involved in the research holds out a prospect

of direct benefit that is important to the health or well-being of the children and is available only in the context of research, the assent of the children is not a necessary condition to proceeding with the research. When assent is required, the IRB must also determine whether and how assent must be documented.

4. If the IRB finds and documents that both parents are required to sign the consent form, then both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child. The IRB requires that an attempt to obtain both parents' signature be sought in non-emergency situations. If one parent's consent is obtained and the other parent cannot be contacted, then the one parent's consent and the documentation of the reasonable attempts to reach the other parent must be documented in the patient's record. If the second parent is not available, the Telephone and Secure Electronic Consent Process as outlined in IRB Policy #0330-1002 "Informed Consent Process" may be followed.
5. A minor may, with IRB approval, legally consent on his/her behalf (as a mature minor) if the research involves a treatment for which a minor's consent is permissible under applicable law (e.g., use of contraceptives, treatment for venereal disease or drug abuse).
6. In an emergency situation, IRB Policy #0330-1010 "Emergency Use of Investigational Drugs, Biologics or Devices" must be followed.
7. Assent may be waived by the IRB if:
   a. Some or all of the children aren't capable of providing assent (i.e., the research may be complicated or the subject population may have limitations which make the likelihood that they can comprehend the research sufficiently to provide assent), or
   b. The research meets the criteria for a waiver of consent (see IRB Policy #0330-1002 "Informed Consent Process"), or
   c. The research (1) holds out the prospect for direct benefit to the child, (2) the benefit is important for the child's health and (3) the benefit is only available in the research. This usually means that the investigational agent(s) are only available in the context of the research.

G. Unmarried Minors who are pregnant or mothers, or babies of unmarried minor parents may participate in research.

1. For research when unmarried pregnant minors or minor mothers are research subjects, the subject's parents or guardians are required to consent for the minor's participation. The minor subject must also assent or agree to participate if required by the IRB.
2. Florida law allows unmarried pregnant minors, unmarried minor mothers, and emancipated minors to consent to "the performance of medical or surgical care or services" for themselves or their children.
3. In the case of research involving an unmarried pregnant minor, the minor may consent for research related to her pregnancy only.

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4. In the case of research involving a baby or child where the mother is an unmarried minor, the mother may have capacity of consent on behalf of her baby or child. The consent of the father of the baby/child may be requested as well.
5. In case of research involving an unmarried pregnant minor or minor mother where the minor has been declared emancipated, the minor may consent for research for herself.
6. Where one parent of a baby is a minor and the other is 18 or older, the consent of both parents is sufficient, if required.
7. There may be some cases where the IRB can waive or alter the requirement of informed consent as described in IRB Policy #0330-1002 "Informed Consent Process".

H. Married Minors (< 18 years of age) who are pregnant or mothers, or babies of married minor parents may participate in research.

1. A minor who is married has the same capacity as an adult to consent to medical treatment. The married minor must consent for all medical treatment and for all research.
2. If research study included enrollment of minors who are married, Subpart D (Additional Protections for Children Involved as Subjects in Research) does not apply to review of the study for these minors. However, the IRB may wish to apply Subpart D as a matter of policy. Also, if a research study includes enrollment of the children of minor parents, Subpart D would apply to enrollment of children.

I. Requirements for Child Wards

1. Children who are wards can be included in research only if:
    a. The research is related to their status as wards; or
    b. The research is conducted in schools, camps, hospital, institutions, or similar setting in which the majority of children involved as subjects are not wards.
2. If the research is approved under one of the above requirements, there must be a Guardian 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. The Guardian 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.
3. Under Florida State Law, Legal Guardians may only enroll their court appointed children in any experimental biomedical or behavioral research treatment if they have the appropriate documents stating the specific authority to do so.
4. A State of Florida court order is obtained permitting participation in research when the research is of direct benefit to the child, is intended to preserve the life of or prevent serious impairment to the mental or physical health of the ward, or it is intended to assist the ward to develop or regain his or her abilities.

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J. Children participating in Sexually Transmitted Disease studies should give informed consent rather than assent.

K. The IRB views obtaining consent as a duty that must be performed by an Investigator. Irrespective of what may be included on a standardized consent form, it is critical that the person obtaining consent have a discussion with the patient and then confirm in his/her own mind that the patient understands. Delegating tasks to those not qualified by training, experience, or professional licensure to perform them are grounds for disciplinary action.

V. REFERENCES:

A. Florida Statute §743.01, §744.102, §743.065(1) and (2), §744.361, §744.345, §743.015, §743.07, §1.01(13), §458.331(1)(w), §766.103, §744.3215 (4)(b)

B. Florida Administrative Code, Standards of Practice – 64B8-9.007(1)

C. HHS regulations (Subpart D): 45 CFR 46.404, 45 CFR 46.405, 45 CFR 46.406, 45 CFR 46.407

D. FDA regulations (Subpart D): 21 CFR 50.50, 21 CFR 50.51, 21 CFR 50.52, 21 CFR 50.53, 21 CFR 50.54, 21 CFR 50.55, 21 CFR 50.56

E. United States Department of Health & Human Services – https://www.hhs.gov/ohrp/regulations-and-policy/guidance/faq/children-research/index.html

F. HHS Regulatory Requirements for Research Involving Children - https://grants.nih.gov/policy/humansubjects/policies-and-regulations/vulnerable-populations.htm#Children

G. US Food & Drug Administration - Guidance for Industry: E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1) (fda.gov)