Florida State University Policy 7-IRB-25

Title of Policy: Special Categories of Research: Children in Research

Responsible Executive: Gary K. Ostrander

Approving Official: Gary K. Ostrander

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Revised _____

I. INTRODUCTION

This policy explains the additional federal requirements that must be met to include children in human subject research. The policy also includes classification categories for research involving children.

II. POLICY

1. The special vulnerability of children makes consideration of involving children as research subjects particularly important. To safeguard their interests and to protect them from harm, special ethical and regulatory considerations apply for reviewing research involving children. The IRB may approve research involving children only if special provisions are met. The IRB must classify research involving children into one of four categories and document their discussions of the risks and benefits of the research study. The four categories of research that may be approved by the IRB are based on degree of risk and benefit to individual subjects, and are set out in the paragraphs below. Note: Under this policy, "children" includes all those who have not yet reached their 18th birthday.

2. Category One – Research Not Involving More than Minimal Risk. When the IRB finds that no greater than minimal risk to children is present, the IRB may approve the proposal 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, as set forth in this policy herein.

3. Category Two – Research Involving Greater than Minimal Risk but Presenting the Prospect of Direct Benefit to the Individual Subject. If the IRB finds that more than minimal risk to children is presented by an intervention or procedure but that the intervention or

procedure 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, the IRB may approve the research, provided the IRB finds that:

a) the risk is justified by the anticipated benefit to the subjects;
b) 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
c) adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in this policy herein.

4. Category Three – 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. If 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 which is not likely to contribute to the well-being of the subject, the IRB may approve the research provided the IRB finds that:

a) the risk represents a minor increase over minimal risk;
b) the intervention or procedure presents experiences to subjects that are reasonable commensurate with those inherent in their actual or expected medical, dental, psychological, social, or education situations;
c) the intervention or procedure is likely to yield generalizable knowledge about the subject's disorder or condition which is of vital important for the understanding or amelioration of the subject's disorder or condition; and
d) adequate provisions are made for soliciting assent of the children and permission of their parents or guardians, as set forth below.

5. Category Four – Research Not Otherwise Approvable Which Presents an Opportunity to Understand, Prevent, or Alleviate a Serious Problem Affecting the Health or Welfare of Children. If the IRB does not believe the research proposal meets any of the requirements set forth above, it may still approve the protocol provided:

a) 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 children; and
b) the Secretary of the DHHS, after consultation with a panel of experts in pertinent disciplines (i.e. science, medicine, education, ethics, law) and following opportunity for public review and comment, has determined either:

- that the research in fact satisfies one of the conditions set forth above, or
- that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children, the research will be conducted in accordance with sound ethical principals, and adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth below.

6. Requirements for Permission by Parents or Guardians and for Assent by Children.

a) Adequate Provisions for Child's Assent. The IRB must find that adequate provisions are made for soliciting the assent of child subjects when in the judgment of the IRB the children are capable of providing assent. In making this determination, the IRB shall take into account the ages, maturity, and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate. The child should be given an explanation of the proposed research procedures in a language that is appropriate to the child's age, experience, maturity, and condition.

b) Waiver of Assent. If the IRB determines either of the following two conditions are true, then the assent of the children is not a necessary condition for proceeding with the research.

- The capability of some or all of the children is so limited that they cannot reasonably be consulted; or
- 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 the research. Therefore, when the research offers the child the possibility of a direct benefit that is important to the health or well-being of the child and is available only in the context of research, the IRB may determine that the assent of the child is not necessary. Note: In the events of a child's dissent, which should normally be respected, such dissent may be overruled by the child's parents, at the IRB's discretion. When research involves the provision of experimental therapies for life-threatening diseases, however, the IRB should be sensitive to the fact that parents may wish to try anything, even when the likelihood of success is marginal and the probability of extreme discomfort is

high. Should the child not wish to undertake such experimental therapy, difficult decisions may have to be made. In general, if the child is a mature adolescent and death is imminent, the child's wishes should be respected.

c) "Assent" is defined, for purposes of this policy, to mean a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

d) Adequate Provisions for Parents' or Guardian's Permission. The IRB must find that adequate provisions are made for soliciting the permission of each child's parents or legally authorized representative.

- Research not involving greater than minimal risk. Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research not involving greater than minimal risk when the provisions of Paragraph 2 above are met.
- Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects. Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects when the provisions of Paragraph 3 above are met.
- 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. When the research is approved under Paragraph 4 above, and permission is to be obtained from parents, 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.
- Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children. When the research is approved under Paragraph 6 above, and permission is to be obtained from parents, 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.

e) Waiver of Parental or Guardian Permission. If the IRB determines that a research protocol is designed for conditions or for a subject population for which parental or legally authorized representative permission is not a reasonable requirement to protect the subjects (i.e. abused or neglected children), it may waive the consent requirements described above, provided both an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and the waiver is not inconsistent with federal, state, or local law. The choice of a mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

f) Documentation. Permission by parents or guardians shall be documented in the same manner as required for subjects under the Documentation of Consent Policy. When the IRB determines that assent of a child is required, it shall also determine whether and how assent must be documented.

g) Wards of the State or Other Agency. Children who are wards of the state or any other agency, institution, or entity can be included in research approved under Paragraph 4 or 5 of this policy only if the IRB finds and documents that such research is related to their status as wards, or conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

7. Pediatric Expertise on the IRB Committee. An IRB Committee considering a protocol involving children, should assess its need for pediatric expertise among the IRB voting membership to assure that it possesses the professional competence necessary to review the specific research activities and consider the inclusion of one or more individuals who are knowledgeable about and experienced in working with children. The IRB may invite nonvoting individuals to assist in the review of issues which require expertise beyond that available among voting IRB members.

III. LEGAL SUPPORT, JUSTIFICATION, AND REVIEW OF THIS POLICY

BOG 1.001(3)(m), 45 CFR 46.401-409, Subpart D