Title: SARMC Institutional Review Board: Vulnerable Populations: Children

Policy Statement: In all human participant research, the agreement of the participant to take part is an essential protection of the rights and welfare of participants. Minors, by definition, cannot give legal “consent”. Therefore, a combination of “assent” (agreement) of the minor and “permission” of the parent or legal guardian is generally deemed an adequate substitute. If either the parent refuses permission or the minor participant refuses assent, the minor should not be enrolled.

If investigators plan to include children in their research, the IRB will take additional steps to meet the regulations, 45 CFR Part 46, Subpart D and FDA Regulations at 21 CFR Part 50 Subpart D – Additional Safeguards for Children Involved as Subjects in Research.

Procedure:

I. Definition of a Child
Children are persons who have not attained the legal age for consent to treatment or procedures involved in research under the applicable jurisdiction in which the research will be conducted. In Idaho the legal age for consent is 18 years of age unless the child has been emancipated.

In Idaho, a minor is automatically emancipated:
1) when validly married;
2) when reaching the age of 18 years;
3) during the period when the minor is on active duty with the armed forces; and
4) for the purposes of consenting to routine, non-surgical medical care or emergency medical treatment when the minor is in the custody of a law enforcement agency and the minor's parent or guardian cannot be promptly located. This last emancipation ends upon the termination of medical care or treatment or upon the minor's release from custody, whichever occurs first.

II. IRB Authority and Responsibility
The composition of the IRB membership is required to have representation that includes the professional competency necessary to consider specific kinds of research involving children. There are three main issues to consider when reviewing research involving children: (i) risk-benefit analysis; (ii) parental permission [informed consent obtained from the parent(s)]; and (iii) assent of the child.
A. Risk/Benefit Analysis
IRBs must make certain determinations when reviewing research involving children. IRB records must reflect the IRB’s understanding and justification for the risks and benefits posed by approved research involving children. Proposed research must fall within one of the following four categories:

1) Research not involving greater than minimal risk.
2) Research involving greater than minimal risk, but presenting the prospect of direct benefit to the individual subjects.
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.
4) Research not otherwise approvable, which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health and/or welfare of children.

Each of these four categories stipulates specific conditions for approval. The IRB must determine and document the Pediatric Risk Level for each proposal involving children. Categories of Research and Pediatric Risk Levels are summarized in Table I below. The categories and Pediatric Risk Level determinations will be documented in the meeting minutes and indicated in the initial approval letter to the principal investigator for the study being reviewed/approved. During the course of the study the IRB may determine that a pediatric risk level has changed to due unforeseen events, and this change will be documented at the time of review in the meeting minutes and communicated in a letter to the principal investigator.

B. Parental Permission and Assent
In addition to ensuring parental permission (consent), the IRB must determine that adequate provisions are made for soliciting the assent of the children who are being considered for participation in research. In determining when children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the child participants 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.

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 the research, the assent of the children is not a necessary condition for proceeding with the research. Even when the IRB determines that the subjects are capable of assenting, the IRB may still waive the assent requirement where (a) the research involves no more than minimal risk; (b) the waiver will not adversely affect subjects’ rights and welfare; (c) the research could not
practically be carried out without the waiver; and (d) when appropriate, the subjects will be provided with pertinent information after participation. (Please note that when the IRB waives the requirement for the child’s assent in a study that the parents’ permission is still required.)

IRBs should take great care in approving research where the child is suffering from a life-threatening illness with little real chance of therapeutic benefit from the research. IRBs should also take great care in allowing the parents to overrule the child’s dissent where experimental therapy has little or no reasonable expectation of benefit.

III. **Documentation and Written/Oral Assents**

If it is deemed appropriate that the child’s assent should be solicited, the assent form should be tailored for the child, with respect to his or her gender and level of understanding. The emphasis on obtaining assent should be on the interactive process in which information and values are shared and joint decisions are made. For young children, the assent form should be a relatively brief document, with simple, age-appropriate language, presented in a manner understandable to the child. Pictures may sometimes be used to help illustrate a procedure or a short video may be shown. Written assent is typically conducted for ages 7-17. The assents will differ in language and presentation of content to target specific age groups. The researcher should also describe the study at a level that is understandable to the child, and this oral presentation is supplemental to the previously approved written assent. The oral discussion should always be part of the assenting process. A template for children’s assent can be found here: [http://www.saintalphonsus.org/forms-and-resources](http://www.saintalphonsus.org/forms-and-resources)

Each research proposal is reviewed by the IRB with the mindset that the assent process should be one that considers not only age but also other characteristics of the target population as it relates to the risk/benefit of the objective to be studied. Most importantly, the assent process should provide ample opportunity for children to express and discuss their willingness or unwillingness to participate, regardless of whether written assent is conducted.

All and any assent documents, story boards, videos, etc. will be reviewed and approved by the IRB before they can be utilized in approved research endeavors.

IV. **Children who are Wards**

Children who are wards of the state or any other agency, institution, or entity can be included in research approved under §46.406 or §46.407 only if such research is:

1. Related to their status as wards; or
2. Conducted in schools, camps, hospitals, institutions, or similar
settings in which the majority of children involved as subjects are not wards.

If the research is approved 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. 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) with the research, the investigator(s), or the guardian organization.

V. Dissent (Refusal)

A patient’s refusal, whether that of child or parent, should be respected especially when the proposed intervention is not essential to his or her welfare and/or can be deferred without substantial risk. Coercion in diagnosis or treatment is not permissible.

VI. Definitions

- **Children (Minors)** – persons who are less than 18 years of age.
- **Assent** – the child’s affirmative agreement to participate in the research. Mere absence of an objection should not be construed as assent.
- **Parental Permission** – the agreement of parent(s) or guardian to the participation of the child or ward in the research. Investigators need to obtain permission for the child to be enrolled in the research project by way of a parental consent document.
- **Guardian** – an individual who is authorized under state or local law to give permission on behalf of a child to general medical care. Although other relatives (i.e. grandparents, siblings) may give consent for clinical care when they have custody of a child without legal authority, they may not give permission for research studies. If the researcher wishes to enroll a child in a research project, the researcher must seek permission from the parents, legally appointed guardian, or have the court appoint another relative as the legal guardian.
- **Parent** – a child’s biological or adoptive parent. If a foster parent provides documentation that establishes guardianship then the foster parent may be considered a legal guardian.
- **Minimal Risk** – means that the research participant will not experience any harm or discomfort more than ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.
- **Emancipated** – a legal status where upon persons have reached the age of 18 or by virtue of assuming adult responsibility; such as marriage or serving on active duty in the military, or by virtue of a court order.
- **Ward** – a minor who by reason of incapacity (as a minor) is under the protection of a court either directly or through a guardian appointed by the court—called also a ward of the court.
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<th>Risk of Harm Category</th>
<th>Requirements</th>
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<td><strong>Level I</strong> <em>(45 CFR 46.404 &amp; 21 CFR 50.51)</em> &lt;br&gt;No greater than minimal risk, with or without potential for direct benefit to the child.</td>
<td>Assent* of child and permission** of at least one parent/guardian</td>
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<td><strong>Level II</strong> <em>(45 CFR 46.405 &amp; 21 CFR 50.52)</em> &lt;br&gt;Greater than minimal risk and prospect of direct benefit to the child</td>
<td>Assent* of child and permission** of at least one parent/guardian &lt;br&gt;Anticipated benefit justifies the risk &lt;br&gt;Anticipated benefit is at least as favorable as that of alternative approaches</td>
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<td><strong>Level III</strong> <em>(45 CFR 46.406 &amp; 21 CFR 50.53)</em> &lt;br&gt;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.</td>
<td>Assent* of child and permission** of both parents/guardians (regardless of marital status) &lt;br&gt;Only a minor increase over minimal risk &lt;br&gt;Likely to yield generalizable knowledge about the child’s disorder or condition that is of vital importance for the understanding or amelioration of the disorder or condition &lt;br&gt;The intervention or procedure presents experiences to the child that are reasonably commensurate with those in the child’s actual or expected medical, dental, psychological, social, or educational situations</td>
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<td><strong>Level IV</strong> <em>(45 CFR 46.407 &amp; 21 CFR 50.54)</em> &lt;br&gt;Research not otherwise approvable (does not meet the requirements of Level I, II, or III).</td>
<td>Assent* of child and permission** of both parents/guardians. (regardless of marital status) &lt;br&gt;IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health and/or welfare of children &lt;br&gt;The HHS Secretary or the FDA Commissioner approves, after consultation with a panel of experts in pertinent disciplines (e.g., science, medicine, education, ethics, law) and following publication in the Federal Register and public comment</td>
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**NOTE:** * Assent can be waived by the IRB <br>** Parental/Guardian Permission = Parental Informed Consent

**Related Policies:** Vulnerable Populations.

**Related Forms:** Children's Assent Template; Parental Consent Template. <br>[http://www.saintalphonsus.org/forms-and-resources](http://www.saintalphonsus.org/forms-and-resources)

**References:**