

DHS – Public Health Division
CHILDREN PARTICIPATION IN RESEARCH

When a proposed research project includes children, the Public Health IRB will take into consideration federal regulatory requirements that provide additional protection for children who are involved in research. By regulatory definition, children are persons who have not attained the legal age for consent to treatment or procedures involved in the research, under applicable law of the jurisdiction in which the research will be conducted. Generally, the federal law considers any person under 18 years of age to be a child (although the age of consent for most medical procedures in Oregon is 15.)

When reviewing research involving children, the IRB will consider the benefits, risks and discomforts, and the probability of the risks and discomforts of the research to children and assess the justification for their inclusion in the research. In assessing the risks and potential benefits, the IRB shall consider the circumstances of the children to be enrolled in the study; for example, their health status, age, and ability to understand what is involved in the research, as well as potential benefits to participants, other children with the same disease or condition, or society as a whole.

The PH IRB will classify proposed research involving children in one of the following categories:

- 1) Research not involving greater than minimal risk (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);
- 2) Research involving greater than minimal risk but presenting the prospect of direct benefit to the minor. The PH IRB may approve such research if it finds:
 - a. The risk is justified by the anticipated benefit to the subject; and
 - b. The relationship of risk to benefit is at least as favorable as any available alternative approach;
- 3) Research involving greater than minimal risk and no prospect of direct benefit to the children who are participants. The PH IRB may approve such research if it finds:
 - a. The risk represents a minor increase over minimal risk;
 - b. 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 settings; and
 - c. The intervention or procedure is likely to yield generalizable knowledge about the participant's disorder or condition that is of vital importance for the understanding or amelioration of the participants' disorder or condition;

Research not otherwise approvable under 1), 2) or 3) above may be approved provided that the PH IRB and the Secretary of the U.S. Department of Health and Human Services (DHHS), after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a significant problem affecting the health and welfare of children. The panel of experts must also find that the research will be conducted with sound ethical principals.

Informed Consent Process

In pediatric research, the informed consent process includes two elements: parental (or guardian) permission and child assent, where “assent” means an affirmative agreement to participate and *not* mere failure to object. The PH IRB must determine in all cases that adequate provision have been made for soliciting the assent of children and the permission of their parents or guardians. As Oregon state law is silent on this issue, we extrapolate from state law regarding the age of consent for medical care without parental consent. The PH IRB may allow children at least 15 years of age to consent for themselves in the following circumstances:

- There is the potential of benefit to the child;
- Procedures involved in the research are not substantially different in their risks or benefits from existing treatment for which the minor would by state law be able to consent;
- Parental consent is not in the best interest of the child, is extremely difficult to obtain or would not be possible to obtain; and
- The research otherwise meets the federal requirements for research with children.

The PH IRB will require parental permission unless it determines that the research project is designed in such a manner that parental or guardian permission is not a reasonable requirement to protect the participants, and therefore may waive the requirement to obtain permission from parents or legal guardians. This requirement may be waived provided that both:

- An appropriate mechanism for protecting children who are research participants is substituted; and
- The waiver is not inconsistent with federal, state or local laws.

The choice of an appropriate mechanism would depend upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefits to the research participants, and their age, maturity, status and condition.

The PH IRB will determine whether the children to be enrolled in the study are capable of giving assent to participate in the study. Research participants’ age, maturity, condition, and psychological state should be considered; however, as a general rule, children seven years of age or older are considered capable of giving assent. The PH IRB will also determine how assent must be documented. The following guidelines are suggested:

- Age 7-9 > A simple oral description of the child’s involvement is given to the participant and verbal assent requested. The procedure may be documented on the informed consent form by the presence of the signature of a witness;
- Age 10-17 > A more complete oral description of the research is given to the participant, along with written assent using age-appropriate terminology.

Factors such as literacy and mental development should be considered when obtaining assent. As in any consent process, the primary concern is that the participant is able to understand the explanation that is presented. A minor’s dissent to participate in or withdraw from the research should be respected and honored unless the research provides access to a therapeutic intervention that is not otherwise available.

When parental permission is sought, the PH IRB will determine whether permission from both parents is necessary. If the research involves greater than minimal risk and no prospect of direct benefit to the children who are participants or is not otherwise approvable under categories 1) thru 3) above, 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.

Parental permission will not be considered necessary if the minor is married (ORS 109.520) or emancipated (ORS 419B.558).

Minors and Pregnancy

As state law sets age 15 years as the minimum necessary for a child to consent to general medical and dental treatment without the consent of a parent or guardian, including prenatal care, the Public Health Division will require that parents of people less than the age of 15 found to be pregnant must be informed of the pregnancy so that prenatal care can be sought. Research that may be conducted in minors where they will be tested for pregnancy must inform the participants who are younger than 15 that if they are found to be pregnant their parents will be told so that they can access prenatal care.

Wards

Wards of the state may participate in research if:

- the research involves no more than minimal risk; or
- the research presents greater than minimal risk but the prospect of direct benefit to the participant on the same basis as other minors.

If the research is greater than minimal risk and does not offer the prospect of direct benefit to the participant, wards may be research participants only if the 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 are not wards.

For research that is greater than minimal risk and does not offer the prospect of direct benefit to the child, the PH IRB will 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. The advocate shall be someone 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, or the guardian organization.

Minors as Prisoners

When a minor is also considered a prisoner per 45 CFR 46, Subpart C; the Public Health Division IRB policy on prisoners in research will also apply. Juvenile prisoners are an especially vulnerable population and must be afforded additional protections. Due to their confinement, juvenile prisoners may be exploited as research participants because of their ready availability, dependent status, and diminished capacity to consent. As such, the PH IRB will consider this type of research on a case-by-case basis. A clear rationale for conducting this type of research must be included in any application material sent to the PH IRB.

Applicable Regulations:
45 CFR 46, Subpart D
21 CFR 50, Subpart D