IRB Help Sheet
OHSU Guidance on Determining if Child Consent or Assent is Appropriate

The goal of any consent or assent process is to inform potential subjects of the research in a format that is understandable to the subjects, so that they may make informed decisions regarding voluntary enrollment in research.

With children, there are two questions that should be considered:
- **Are the child-subjects legally able to consent to the research?**
- **What format would be understandable to the children?**

I. What is Legal? What may this study population consent to legally?

Under Oregon law, minors may consent to participation in research without parental or guardian permission (i.e., as if adults) if legally emancipated and in certain treatment circumstances.

Any Type of Research: OHSU interprets laws regarding emancipated minors and married minors as authorizing a minor to consent to research as an adult does. This applies for any type of research.

- **Emancipates Minors:** Parental consent is not necessary if the minor is emancipated. ORS.419B.558. Proof of entry of Judgment of Emancipation is required.
- **Married Minors:** Per ORS 109.520, all persons shall be deemed to have arrived at the age of majority upon their being married and thus parental consent is not necessary when the minor is married. Proof of marriage is required.

Research Involving treatment: Oregon law does specify the age at which individuals under age 18 may seek medical care without parental consent. OHSU interprets these laws as authorizing certain partially-emancipated (for these services) minors to consent to research involving specific types of medical treatment. The allowances are as follows:

- People 15 years of age or older may give consent to hospital care, medical or surgical diagnosis or treatment by a physician dentist, or nurse practitioner without the consent of a parent or guardian. (ORS 109.640)
- People 14 years or older may consent for outpatient diagnosis or treatment of mental or emotional disorder or chemical dependency, excluding methadone maintenance, by physician, psychologist, nurse practitioner, social worker or community health worker. (ORS 109.675)
- People of any age may seek birth control information and services, or treatment for reportable venereal disease. A physician or nurse practitioner may provide birth control information and services to any person without regard to age (ORS 109.610 and 109.640)

II. Comprehension & Understanding – Determining what is appropriate for your study population.

Child Consent & Assent may range from a simple oral explanation for which a child's signature is not required to a consent document that contains all of the elements of informed consent. The form and content of the assent depends on the intellectual age of the child and his/her capacity to consent/assent. Assent will be obtained from children with an intellectual age of 7 years or more. Younger children cannot provide assent, but they should be appropriately informed of study procedures. The following guidelines generally apply:

1. **<u>Children younger than 7 years</u>:** A simple oral explanation should be offered to the child before study-related procedures are conducted. For example: "*We have to take a little bit of blood from your arm. That means that you will feel a little needle stick. It will only hurt for a minute. Your mom (or dad) will be with you the whole time and can hold your hand.*"

2. **<u>Children aged 7 to 11 years</u>:** Informed voluntary verbal assent should be obtained without pressure from parents or investigators. The IRB application should include an example of the explanation to be offered to the child. A sample child assent form is available. The child's assent should be solicited and recorded in the presence of a parent, and the signed parental permission form should include the following statement: "*This study has been explained to my child in my presence, in language he/she can understand. He/she has been encouraged to ask questions both now, and in the future, about the research study*."

3. **<u>Children aged 12 to 15 years</u>:** Investigators may choose to handle the consent/assent requirements for this group in one of two ways. They may either submit a combined child assent/parental permission form that is written at a level simple enough for both parent and child to read and understand, e.g. about a 6th grade reading level, or they may choose to submit a permission form for parents and a separate assent form for the child to read and sign. If a single form is designed for both parent(s) and child, it should be signed by each after the study has been explained. The form should be written as simply as possible and should cover the following points:
    - **a.** What the study is about
    - **b.** Why he/she was selected for the study
    - **c.** That taking part in the study is voluntary
    - **d.** The procedures that will be done
    - **e.** Potential benefits of the study
    - **f.** Potential risks of the study
    - **g.** Assurance that he/she will be treated the same whether or not he/she agrees to join the study
    - **h.** An invitation to ask questions about the study
    - **i.** Assurances that he/she may withdraw from the study after discussing it with his/her parents

4. **<u>Children aged 15 to 18 years</u>:** A combined child assent/parental permission form that includes all of the elements of informed consent, as appropriate, and is written in language that is easily understood by both the parents and the child (about an 8th grade reading level) is sufficient for this group. A separate child assent form need not be used. The parent(s) and the child must each sign the form.