Guidance -
Parental Permission

Since children cannot legally give consent, informed consent must be obtained from parents ("parental permission"), or the legally appointed guardian. The IRB requires the investigator to obtain the permission of a child's parent(s) or guardian before enrolling the child in a study.

The procedures used in obtaining informed consent and parental permission should be designed to inform the subject population or the parents of the subject population about the research in terms that they can understand. Therefore, informed consent and parental permission language and its documentation in the accompanying forms (especially explanation of the study's purpose, duration, experimental procedures, alternatives, risks, and benefits) should be provided in language that is understandable and culturally sensitive to those being asked to participate or provide permission for their child's participation.

In accordance with Pennsylvania law, there are certain situations in which the IRBs permit minors to consent to participation in research as adults without parental permission. If the PI is not familiar with such laws, he or she may need to consult with IRB staff prior to enrolling a minor in a research study without parental permission, to ensure that the applicable legal requirements are met.

Definitions:

Children are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

Assent means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

Permission means the agreement of parent(s) or guardian to the participation of their child or ward in research.

Parent means a child's biological or adoptive parent.

Guardian means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

IRB's must review and approve only research which satisfies the conditions of all applicable sections listed below:

45 CFR 46.408(b) (OHRP) and 21 CFR 50.55(e)(2) (FDA)
…the IRB will determine, in accordance with and to the extent that consent is required, that adequate provisions are made for soliciting the permission of each child's parents or guardian. Where parental permission is to be obtained, the IRB may find that the permission of one parent is sufficient for research to be conducted under §46.404/§50.51 or §46.405/§50.52. Where research is covered by §46.406/§50.53 and §46.407/§50.54 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.

45 CFR 46.404 and 45 CFR 46.405 *(OHRP)* 21 CFR 50.51 and 21 CFR 50.52 *(FDA)*	45 CFR 46.406 and 45 CFR 46.407 *(OHRP)* 21 CFR 50.53 and 21 CFR 50.54 *(FDA)*
The IRB may determine that the permission of one parent is sufficient. If the IRB determines that permission of two parents is required, then the investigator must obtain both parents' permission unless one parent is deceased, unknown, incompetent, not reasonably available* or only one parent has legal responsibility for the care and custody of the child.	Permission of both parents is required unless one parent is deceased, unknown, incompetent, not reasonably available, or only one parent has legal responsibility for the care and custody of the child.
The consent form includes signature lines for ***both*** *parents:* _____ _____ Signature of LAR Date *(parent, guardian, or conservator)* _____ Authority to Act for participant _____ _____ (If available) Signature of other parent or guardian Date ***Not reasonably available** ***Means*** the other parent is not present during the consenting process, or will not be available prior to start of research procedures. *Examples of not reasonably available:* The other parent is at work, caring for other children, or traveling. **45 CFR 46.404 and 21 CFR 50.51** **Research not involving greater than minimal risk.** …the IRB find that no greater than minimal risk to children is presented…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 §46.408 or §50.55. **45 CFR 46.405** and **21 CFR 50.52** **Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual subjects.** …the IRB find that more than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject, or by monitoring procedure that is likely to contribute to the well-being of the subject … 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	The consent form ***must include*** signature lines for both parents ***and*** if permission is only obtained from one parent, the reason for not obtaining the permission of the other parent must be documented on the consent as follows: ☐ the other parent is deceased ☐ the other parent is unknown ☐ the other parent is incompetent ☐ the other parent is not reasonably available*; ☐ only one parent has legal responsibility for the care and custody of the child ***Not reasonably available** ***Means*** the other parent is not contactable by phone, mail, email or fax or the other parent's whereabouts are unknown. ***Does not mean*** the other parent is at work, at home, lives in another city, state or country, but is contactable by phone, mail, email or fax *Examples of not reasonably available:* • The other parent is on active military duty and is not contactable by phone, mail, email or fax. • The other parent is incarcerated and is not contactable by phone, mail, email or fax. • The whereabouts of the other parent are unknown **45 CFR 46.406 and 21 CFR 50.53** **Research involving greater than minimal risk and no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subjects' disorder or condition.** …the IRB find 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…the IRB finds: (a) The risk represents a minor increase over

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 §46.408 or §50.55.

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 situations;

(c) The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' 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 in §46.408 or §50.55.

45 CFR 46.407 and 21 CFR 50.54

Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

…the IRB does not believe [the research] meets the requirements of 46.404, 46.405 or 46.406…

(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;

(b) The Secretary, after consultation with a panel of experts ..and following opportunity for public review and comment has determined either:

The research will be conducted in accordance with sound ethical principles;

(1) The research…satisfies §46.404, §46.505, §46.406 or §50.51, §50.52 or §50.53 or;

(2) The following:

(i) The research presents a reasonable opportunity to further understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children;

(ii) The research will be conducted in accordance with sound ethical principles;

(c) Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians, as set forth in §46.408 or §50.55.