University of Southern Maine

CHILD ASSENT/PARENTAL PERMISSION: USM IRB GUIDANCE

When a research project proposes to involve ***children*** (in Maine persons who are under the age of 18, unless emancipated) as participants, provisions must be made to solicit the ***assent*** of the child and the ***permission*** of the ***parent***(s) or ***guardian***.

Respect for persons requires that subjects, to the degree that they are capable, be given the opportunity to choose what shall or shall not happen to them (consent). Children have not attained the legal age for consent therefore, it is critically important that investigators articulate (in the research protocol) a process for seeking the permission of the parent(s) or guardian AND the assent of the child. The parental permission and assent process must contain three elements: information, comprehension and voluntariness.

The process of obtaining parental permission and assent should be designed with a family-centered decision model in mind.

Investigators who propose to involve children who are *wards of the State* should contact the USM IRB (usmorio@maine.edu) to request specific guidance. Special protections for *wards* will apply and will require consideration when drafting the research protocol.

**Note: The intent of this document is to provide general guidance to investigators. Some projects include conditions that require additional protections for participants, are subject to specific regulations or laws, or require special consideration by the USM Institutional Review Board (IRB) or the Office of Human Research Protections (OHRP).

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 educational decisions, medical care, or research participation.

Parental Permission

Adequate provisions for soliciting the permission of the parent(s) or legal guardian(s) must be detailed in the research protocol submitted to the IRB.

Whether permission should be obtained from both parents before a child is enrolled in research is dependent on the actual research protocol. Relevant factors include: the risk level of participation and the specific aims of the study. In general, when one parent is deceased, unknown, incompetent, or not reasonably available, or when one parent has sole legal responsibility for the care and custody of the child permission from one parent is appropriate.

Parental or guardian permission should be sought before seeking the assent of a child unless the requirement for parental permission has been waived by the IRB. The permission of the parent(s) or guardian is required before a child can be enrolled in research, even in cases where the child assents to participate.

Requesting a waiver of parental/guardian permission:

Under certain circumstances an IRB may waive the requirements for obtaining parental or guardian permission. For example, a waiver may be requested if a research protocol is designed with conditions for which parental or guardian permission is not a reasonable requirement to protect the subjects (example, neglected or abused children). If, by law, a child is able to consent to treatment without parental permission, the minor may provide his or her own informed consent to participate in research related to that treatment.

If an investigator is requesting a waiver, a clear and sufficiently detailed explanation as to why a waiver is appropriate should be included in the research protocol. In addition, the investigator should also consider an alternative, appropriate mechanism (for example, appointing a child advocate or an assent monitor) to protect children.

Only the IRB can determine whether or not a waiver is appropriate. The waiver cannot be inconsistent with federal, state, or local law.

Documenting parental permission:

Parental permission should be documented by the use of a written parental permission form approved by the IRB and signed by the parent(s) or legal guardian of the child. The consent templates on the IRB website can be easily modified for use as parental permission forms.

Parental permission documents should be written in easily understandable language and include the basic elements of informed consent and additional elements when applicable. Voluntariness should be stressed and information must be presented in a manner that is understandable to the parent(s) or guardian providing permission. The parent(s) or guardian must be given a copy of the permission form.

Requesting a waiver of documentation of parental/guardian permission:
Under certain circumstances an IRB may determine that a waiver of documentation of parental/guardian permission may be appropriate. If an investigator is requesting a waiver, a clear and sufficiently detailed explanation as to why a waiver is appropriate should be included in the research protocol.

Only the IRB can determine whether or not a waiver of documentation is appropriate.

Assent
Children are unable to provide consent to participate in research given that they have not attained the legal age for consent, although they may be able to give their assent.

The child must actively show his or her willingness to participate in the research, rather than just complying with directions to participate and not resisting in any way.

Parental or guardian permission should be sought before seeking the assent of a child. If a child dissents from participating in research, even if his or her parent(s) or guardian has granted permission, the child's decision prevails.

Determining a child's capacity to assent:
The ages, maturity, and psychological state of the children involved are considered by the IRB when determining whether children are capable of assent. Investigators should address these considerations, in sufficient detail in their research protocol, particularly if they are requesting a waiver of assent. Both the children's individual capacity and the capacity of all children are considered.

The design of the assent process should be informed by the capacity of the population and should ensure that information is presented in a way that the participant(s) can comprehend. Checks for comprehension should be incorporated into the assent process.

Requesting a waiver of child assent:
Under certain circumstances an IRB may waive the requirement for child assent. In general, child assent is required unless it can be appropriately waived, or if the child is not capable of providing assent.

Circumstances where the IRB may determine that a waiver of child assent is appropriate: 1) if the capability of some or all of the children is so limited that they cannot reasonably be consulted; 2) if the intervention or procedure involved in the research holds out the prospect of direct benefit to the health or well-being of the children and is available only in the context of the research; 3) if the research meets the same conditions as those for a waiver or alteration of consent in research involving adults.

Documentation of child assent:
When young children are participants in research and as of yet unable to read, it may not be necessary to document assent using an assent document. Rather it may be appropriate to document that the process took place by having the child or other witness record that assent took place. This could be done by initialing the parental permission form. In these cases it may also be determined that documentation of assent is not required. If an oral assent process is used, then a copy of the language that will be used must be included as part of the submission to the IRB.

If adolescents are involved in research then an assent document similar to the parental permission form may be an appropriate means to document the adolescent's assent. The assent form should be written in plain language and be easily understandable to the adolescent.

Assent documents should be written to include the basic elements of informed consent and additional elements when applicable. Voluntariness should be stressed and information must be presented in a manner that is understandable to the minor providing assent.

At a minimum, information presented during the assent process (whether oral, written or both) should include: what the experience will be; how long it will take; whether it might involve any pain or discomfort; the voluntary nature of the research. If minor assent if documented, the participant should be given a copy of the assent form.

Only the IRB can determine the appropriate manner, if any, of documenting child assent.

If you have questions about the parental permission or assent process for a study you will be submitting to the IRB you are encouraged to contact the IRB in advance of your submission to seek guidance.

In general, things to consider as you prepare your materials are

- Voluntariness, that the conditions are free of undue influence and coercion.
  - Who is the best person to obtain parental permission or assent (to avoid undue influence)?
- Ease of comprehension.
  - It is the investigator's responsibility to consider the literacy of the participant(s) and the parent(s) or guardian. An assent or parental permission procedure should address what provisions will be in place to ensure that information is presented orally or by other means to ensure comprehension of information. Further references below.
  - It is the investigators responsibility to present information to the minor participant and the parent(s) or guardian in a language that is easily understandable to each individual, keeping in mind, for example, that while the child may be proficient in English the parent(s) may not be. The investigator may need to make arrangements to have a translator available and/or translate study documents.
- The privacy of the potential participant, particularly for research studies that are sensitive in nature.
- If the research is being conducted in the child's school, that you have the support of the school

administration and that the school's obligations under FERPA or PPRA regulations have been considered in the design of your study. Further references below.

- The child and the parent(s) or guardian should be given sufficient time to consider participation and ask questions before agreeing to participate. The investigators assent and parental permission procedures should be reflective of this requirement.

Further References

Program for Readability In Science & Medicine (PRISM) is a Group Health Research Institute initiative to improve the readability of consent forms and other print materials used in communication with study participants. There is a free online training plain language tutorial created for researchers.
http://prism.grouphealthresearch.org/start.htm

Office of Human Research Protections, Research with Children Frequently Asked Questions-
http://www.hhs.gov/ohrp/policy/childrenfaqsmar2011.pdf

Family Educational Rights and Privacy Act (FERPA) -
http://www2.ed.gov/policy/gen/guid/fpco/ferpa/index.html

Protection of Pupil Amendment (PPRA) - http://www2.ed.gov/policy/gen/guid/fpco/ppra/index.html