

Issues to consider in research with children

<input type="checkbox"/> Yes <input type="checkbox"/> No	Is the inclusion of children justified in the protocol?
<input type="checkbox"/> Yes <input type="checkbox"/> No	The level of risk is defined in the protocol
<input type="checkbox"/> 46.404	Not greater than minimal risk (probability of harm and magnitude of harm or discomfort not greater in and of themselves than those ordinarily encountered in daily life or during performance of routine physical/psychological examinations or tests
<input type="checkbox"/> 46.405	Greater than minimal risk but with prospect of direct benefit for the individual subject : <input type="checkbox"/> Potential for medical benefit justifies risks AND The relation of the anticipated benefit profile is at least as favorable as available alternative approaches.
<input type="checkbox"/> 46.406	Greater than minimal risk with no prospect of direct benefit for the individual subject : <input type="checkbox"/> The risk level is not greater than a minor increase over minimal risk AND The intervention or procedure present experiences reasonably commensurate with subject's medical, dental, psychological, social, or educational situations AND The intervention or procedure is likely to yield generalizable knowledge about the subject's disorder or condition and is of vital importance for the understanding or amelioration of the subjects' disorder or condition.
<input type="checkbox"/> 46.407	Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children <input type="checkbox"/> The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children AND The research has been reviewed by the Secretary, DHHS / OPRR in consultation with a panel of experts
<input type="checkbox"/> Yes <input type="checkbox"/> No If assent is to be obtained:	Adequate provisions are made for soliciting the assent of children Is assent required for all children or only those deemed capable? <input type="checkbox"/> all. <input type="checkbox"/> only some <input type="checkbox"/> Yes <input type="checkbox"/> No If some will not give consent, investigator states in the protocol how capacity to give assent will be determined. (Default age for assent is 7 years old) <input type="checkbox"/> Yes <input type="checkbox"/> No Information to be provided to children before they give assent is described (or assent form is provided) <input type="checkbox"/> Yes <input type="checkbox"/> No Protocol describes how assent is documented <input type="checkbox"/> Child signs assent form <input type="checkbox"/> Other approach: <input type="checkbox"/> Yes <input type="checkbox"/> No Can older children use the consent form as the assent?

<p>If assent will not be obtained:</p>	<p><input type="checkbox"/> No assent is required because of the age, maturity, or psychological state of the subjects OR <input type="checkbox"/> No assent is required because 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 research OR <input type="checkbox"/> The requirement for assent can be waived because the study meets the conditions for waiving consent (see 46.116 of 45-CFR-46)</p>
<p><input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A</p>	<p>If assent is waived for any subjects, protocol describes what investigators will do in the face of active dissent</p>
<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	<p>Adequate provisions are made for soliciting the permission (consent) of each child's parents or guardian.</p>
<p>If consent is to be obtained:</p>	<p><input type="checkbox"/> Not greater than minimal risk, one parent/guardian signature sufficient <input type="checkbox"/> Greater than minimal risk, with direct prospect of benefit: one parent/guardian signature sufficient <input type="checkbox"/> Minor increment over minimal risk, no prospect of benefit <u>or</u> Research not otherwise approvable: two parents/guardian must sign unless one parent not reasonably available or does not share custody</p>
<p>If consent will not be obtained:</p>	<p><input type="checkbox"/> Consent can be waived (see 46.116 of 45-CFR-46) OR <input type="checkbox"/> Consent can be waived because it is not a ‘reasonable requirement to protect the subjects (e.g. neglected or abused children)’ AND This waiver is not inconsistent with Federal, state or local law AND An “appropriate mechanism for protecting the children who will participate as subjects in the research is substituted.”</p>
<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	<p>Pediatric confidentiality issues are addressed in the protocol: <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A Will sensitive information obtained from child (e.g. HIV or pregnancy status, drug use history) be shared with parents? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A Will information from parent (family history) be shared with child?</p>
<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	<p>Will children be paid for participation? <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A How child will be paid is addressed in protocol <input type="checkbox"/> Yes <input type="checkbox"/> No <input type="checkbox"/> N/A Parents also receive money for participation</p>
<p><input type="checkbox"/> Yes <input type="checkbox"/> No</p>	<p>Blood withdrawals are described in the protocol, and compared to established pediatric research blood drawing limits (M95-9) <input type="checkbox"/> No blood is drawn <input type="checkbox"/> Total research blood to be drawn is less than 7 cc/kg per 6 weeks (and <450 cc) and is less than 3cc/kg per single blood withdrawal (note 7 cc/kg can be drawn during 1 day via multiple IV draws)</p>

<input type="checkbox"/> Yes <input type="checkbox"/> No	<p>Radiation exposure is described in the protocol and compared to NIH pediatric radiation exposure limits (NIH Protomechanics 2000, p. 74)</p> <input type="checkbox"/> No radiation exposure <input type="checkbox"/> Amount of radiation exposure is less than 300 mrem/ quarter and less than 500 mrem per year and is described in both consent & assent <input type="checkbox"/> Amount of radiation exposure exceeds usual limits but is justified by the information to be obtained
<input type="checkbox"/> Yes <input type="checkbox"/> No	<p>Use of medications (experimental or standard) are described in the protocol, with pediatric-specific issues addressed</p> <input type="checkbox"/> No medications to be given <input type="checkbox"/> Doses are adjusted for body size, effects of differing doses will be studied, or a justification why no adjustment is needed is made in the protocol <input type="checkbox"/> Yes <input type="checkbox"/> No If doses are size-adjusted, a <u>stable</u> pediatric formulation is available that will allow for precise dosing of patients based on body size <input type="checkbox"/> N/A <input type="checkbox"/> Pediatric-specific issues for experimental compounds, such as effects on growth and fertility are addressed in protocol
<input type="checkbox"/> Yes <input type="checkbox"/> No	<p>Protocol describes pediatric nursing units involved in study</p> <input type="checkbox"/> Units / nursing staff approved for pediatrics will care for patient. <input type="checkbox"/> A non-pediatric nursing unit will be involved but a plan assures that pediatric-specific staff training will be done
<input type="checkbox"/> Yes <input type="checkbox"/> No	<p>Ancillary services required are explained in protocol and involve AI's or staff that are readily available</p> <input type="checkbox"/> Pediatric medical consultants <input type="checkbox"/> Pediatric radiology <input type="checkbox"/> Pediatric nuclear medicine <input type="checkbox"/> Pediatric recreation therapy <input type="checkbox"/> Pediatric rehabilitation medicine <input type="checkbox"/> Pediatric nutrition services <input type="checkbox"/> Pediatric social work <input type="checkbox"/> School services <input type="checkbox"/> Pediatric special supplies, equipment, or services (list):
<input type="checkbox"/> Yes <input type="checkbox"/> No	<p>Pediatric medical coverage is elucidated in the protocol</p> <input type="checkbox"/> PI or AI who will be involved with patients is a pediatrician or PNP <input type="checkbox"/> Clinical Center pediatricians will provide coverage <input type="checkbox"/> Pediatric consultants needed for the research are identified <input type="checkbox"/> On-call coverage includes pediatric back-up <input type="checkbox"/> Other:
<input type="checkbox"/> Yes <input type="checkbox"/> No	<p>Pediatric sedation / pain management issues are addressed (M-92-9)</p> <input type="checkbox"/> N/A No sedation or painful procedures expected <input type="checkbox"/> PI or AI is approved for administration of pediatric sedation <input type="checkbox"/> Anesthesia or ICU physicians will provide sedation
<input type="checkbox"/> Yes <input type="checkbox"/> No	<p>Pediatric developmental and psychosocial issues are addressed in the protocol</p>
<input type="checkbox"/> Yes <input type="checkbox"/> No	<p>Sequence of testing is mapped out so that minimization of procedures can be accomplished (for example, drawing all blood on 1 day to avoid multiple sticks, or scheduling to avoid repeated sedation for procedures)</p>