Issues to consider in research with children

☐ Yes ☐ No	**Is the inclusion of children justified in the protocol?**
☐ Yes ☐ No	**The level of risk is defined in the protocol**
☐ 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
☐ 46.405	**Greater than minimal risk but with prospect of direct benefit for the individual subject :** ☐ Potential for medical benefit justifies risks **AND** The relation of the anticipated benefit profile is at least as favorable as available alternative approaches.
☐ 46.406	**Greater than minimal risk with no prospect of direct benefit for the individual subject :** ☐ 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.
☐ 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** ☐ 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
☐ Yes ☐ 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? ☐ all. ☐ only some ☐ Yes ☐ 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) ☐ Yes ☐ No Information to be provided to children before they give assent is described (or assent form is provided) ☐ Yes ☐ No Protocol describes how assent is documented ☐ Child signs assent form ☐ Other approach: ☐ Yes ☐ No Can older children use the consent form as the assent?

If assent will not be obtained:	☐ No assent is required because of the age, maturity, or psychological state of the subjects **OR** ☐ 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** ☐ The requirement for assent can be waived because the study meets the conditions for waiving consent (see 46.116 of 45-CFR-46)
☐ Yes ☐ No ☐ N/A	If assent is waived for **any** subjects, protocol describes what investigators will do in the face of active dissent
☐ Yes ☐ No	**Adequate provisions are made for soliciting the permission (consent) of each child's parents or guardian.**
If consent is to be obtained:	☐ **Not greater than minimal risk**, one parent/guardian signature sufficient ☐ **Greater than minimal risk, with direct prospect of benefit**: one parent/guardian signature sufficient ☐ **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
If consent will not be obtained:	☐ Consent can be waived (see 46.116 of 45-CFR-46) **OR** ☐ 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."
☐ Yes ☐ No	**Pediatric confidentiality issues are addressed in the protocol:** ☐ Yes ☐ No ☐ N/A Will sensitive information obtained from child (e.g. HIV or pregnancy status, drug use history) be shared with parents? ☐ Yes ☐ No ☐ N/A Will information from parent (family history) be shared with child?
☐ Yes ☐ No	**Will children be paid for participation?** ☐ Yes ☐ No ☐ N/A How child will be paid is addressed in protocol ☐ Yes ☐ No ☐ N/A Parents also receive money for participation
☐ Yes ☐ No	**Blood withdrawals are described in the protocol, and compared to established pediatric research blood drawing limits (M95-9)** ☐ No blood is drawn ☐ 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)

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