

PEDIATRIC RISK ASSESSMENT FORM

For all protocols involving subjects less than 18 years of age, this risk assessment form is required to be completed and signed by the individual who is designated by the investigator's department to review protocols for medical risk to pediatric populations. The individual so designated must be a physician with expertise in pediatric populations, or in the case of behavioral/social protocols that do not involve medical device or drug treatment, the department may designate a psychologist or other clinical professional with appropriate pediatric expertise.

Study Title: _____

Principal Investigator/Faculty Sponsor: _____

I have reviewed the attached protocol and have determined its level of risk to the pediatric population as follows:

- Minimal Risk:**
 - This protocol does not involve risk (physical or emotional) greater than that ordinarily encountered in daily life or during the performance of **routine** physical or psychological examinations or tests.
 - Only one parent need give consent.

- Greater than Minimal Risk (direct benefit):**
 - This protocol does involve greater than minimal risk but also presents the **prospect of direct benefit** to the individual subject.
 - Only one parent need give consent.

- Greater than Minimal Risk and no reasonable prospect of direct benefit:**
 - This protocol does involve greater than minimal risk and no reasonable prospect of direct benefit to the individual subject but is **likely to yield generalizable knowledge** about the subject's disorder or condition.
 - Both parents or legally appointed guardians must give consent unless one parent or guardian is deceased, unknown, incompetent, not reasonably available, or does not have legal responsibility for the custody of the minor.

- Research not otherwise approvable:**
 - This research is not otherwise approvable but presents an opportunity to understand, prevent, or alleviate serious problems affecting the health or welfare of children.
 - Requires approval by the Secretary of Health and Human Services
 - Requires consent of both parents or guardians.

Signature of Departmental Reviewer Date

Name of Reviewer Title
(please print)