

Lourdes University Institutional Review Board
Research On Children (Persons under the age of 18)

Background: Federal regulations require special protections for children (45 CFR 46 Subpart D, Additional Protections for Children Involved as Subjects in Research.) The majority of studies involving children require full IRB review. **Please complete this form and include it in your IRB Application.**

1. Screening for expedited review

The only research activities involving children that may fall under the exemption category are those involving educational tests or observation of public behavior where the investigators do not participate in the activity being observed. Further, the data that are recorded must be done so without personal identifiers.

Does the proposed study meet these two conditions?

YES (Submit application for IRB Confirmation)

NO (Submit application for full board review)

2. Determination of Risks and Benefits Federal regulations allow IRB's to approve research on children **only** under one of the following 3 conditions. Indicate which of the following 3 conditions is met by the proposed study.

 45 CFR 46.404 - Research not involving greater than minimal risk to the children. To approve this category of research, the IRB must make the following determinations:

- the research presents no greater than minimal risk to the children; **and**
- adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in HHS regulations at 45 CFR 46.408.

 45 CFR 46.405 - Research involving greater than minimal risk but presenting the prospect of direct benefit to the individual child subjects involved in the research. To approve research in this category, the IRB must make the following determinations:

- the risk is justified by the anticipated benefits to the subjects;
- the relation of the anticipated benefit to the risk presented by the study is at least as favorable to the subjects as that provided by available alternative approaches; **and**
- adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in HHS regulations at 45 CFR 46.408.

 45 CFR 46.406 –Research involving greater than minimal risk and no prospect of direct benefit to the individual child subjects involved in the research, but likely to yield generalizable knowledge about the subject's disorder or condition. In order to approve research in this category, the IRB must make the following determinations:

- the risk of the research represents a minor increase over minimal risk
- the intervention or procedure presents experiences to the child subjects that are reasonably commensurate with those inherent in their actual, or expected medical, dental, psychological, social, or educational situations;
- the intervention or procedure is likely to yield generalizable knowledge about the subject's disorder or condition which is of vital importance for the understanding or amelioration of the disorder or condition; **and**
- adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in HHS regulations at 45 CFR 46.408.