



# Pennsylvania Department of Education Institutional Review Board (PDE IRB) Application for PDE IRB Review

## Attachment E-3: Research Involving Children as Subjects

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### **Risks and Benefits**

Check which category applies to this research and complete the appropriate sections.

1. This research does not involve greater than minimal risk (45 CFR 46.404).

Explain why this research does not involve greater than minimal risk.

2. This research involves greater than minimal risk but presents the prospect of direct benefit to the individual subjects

[\(45 CFR 46.405\)](#).

Explain how the risk is justified by anticipated benefits to the subjects.

Explain how the relation of the anticipated benefits to the risk is at least as favorable to the subjects as that presented by available alternative approaches.

3. This research involves greater than minimal risk and presents no prospect of direct benefit to the individual subjects, but the research is likely to yield generalizable knowledge about the subject's disorder or condition ([45 CFR 46.406](#)).

Explain why the risk represents a minor increase over minimal risk.

Explain why the interventions or procedures present experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations.

Explain why the interventions or procedures are likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subject's disorder or condition.

4. This research is not otherwise approvable but presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children ([45 CFR 46.407](#)).

*Research falling into this category can be approved only after the Secretary of Health and Human Services (HHS), in consultation with a panel of experts and following opportunity for public review and comment, determines that the research satisfies applicable conditions under §46.407.*

## **Wards as Subjects**

Complete this section only if Item 3 or 4 above is checked.

5. Will this research include children who are wards of the State or another agency, institution, or entity?

No Yes

Is the research related to their status as wards?

Yes No

**OR**

Is the research conducted in schools, camps, hospitals, institutions or similar setting in which the majority of children involved are not wards?

Yes No

*Research involving wards as subjects may only be approved under categories 45 CFR 46.406 and 407 if either condition above it satisfied.*

6. Has an advocate been appointed for each child who is a ward, in addition to any other individual acting on behalf of the child as guardian or in *loco parentis*?

Yes No