**Reviewer guide [**[**Subpart D**](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/common-rule-subpart-d/index.html)**]:**

**Protection for children as research participants**

This reviewer guide should be completed and retained in the study file.

*Note: If wards of the state are to be enrolled, refer to §46.409(a). Ancillary reviews may be needed.*

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| **PI Name** | Click or tap here to enter text. |
| **IRB #** | Click or tap here to enter text. |
| **Protocol Title** | Click or tap here to enter text. |
| **IRB Reviewer or DHR Pre-Reviewer** | Click or tap here to enter text. |
| **Date Completed** | Click or tap here to enter text. |

1. **DETERMINATION OF RISK AND PARENTAL PERMISSION:**

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|  | **Research NOT involving greater than minimal risk** (§46.404). Allowable only if the IRB finds adequate provisions are made for soliciting the assent of the children and the permission of their parents or guardians, as set forth in (§46.408):   |  |  | | --- | --- | |  | Signature of **one parent** is sufficient, **OR** | |  | Signature of **both parents** is required unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child, **OR** | |  | **Parental permission is waived;** study meets criteria for a waiver of consent in accordance with [45 CFR 46.116](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.116), **OR** | |  | **Parental permission is waived;** the study is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects *(for example, neglected or abused children)* provided an **appropriate mechanism is substituted** for protecting the children who will participate in the research. | |

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|  | **Research involving greater than minimal risk** butpresenting the prospect of **direct benefit** to the individual subjects and/or a **monitoring** procedure that is likely to contribute to the **subject's well-being** (§46.405)**. Allowable only if the IRB finds that:** | |
|  |  | The risk is justified by the anticipated benefit to the subjects, AND |
|  |  | The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches, AND |
|  |  | Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in (§46.408):   |  |  | | --- | --- | |  | Signature of **one parent** is sufficient, **OR** | |  | Signature of **both parents** is required unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child, **OR** | |  | **Parental permission is waived;** the study is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects *(for example, neglected or abused children)* provided an **appropriate mechanism is substituted** for protecting the children who will participate in the research. | |

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|  | **Research involving greater than minimal risk and NO prospect of direct benefit to individual subjects,** but likely to yield generalizable knowledge about the subject's disorder or condition (§46.406)**. Allowable only if the IRB finds that:**   |  |  |  | | --- | --- | --- | |  | | The risk represents a **minor increase** over minimal risk, AND | |  | | The intervention or procedure presents experiences to subjects that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations, AND | |  | | The intervention or procedure is likely to yield generalizable knowledge about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition, AND | |  | Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians, as set forth in (§46.408):   |  |  | | --- | --- | |  | Signature of **both parents** is required unless one parent is deceased, unknown, incompetent, or not reasonably available, or when only one parent has legal responsibility for the care and custody of the child, **OR** | |  | **Parental permission is waived;** the study is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects *(for example, neglected or abused children)* provided an **appropriate mechanism is substituted** for protecting the children who will participate in the research. | | | |

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|  | **Research is NOT approvable under any of the above categories** (see provisions at §46.407)**.** |

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1. **CHILD ASSENT:**

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|  | **Assent required.** *The IRB should also determine whether and how assent must be documented.* |
|  | **Assent not required;** the capability of some or all of the children is so limited that they cannot reasonably be consulted.  *In determining whether children are capable of assenting, the IRB shall take into account the ages, maturity, and psychological state of the children involved.*  *This judgment may be made for all children to be involved in research under a particular protocol, or for each child, as the IRB deems appropriate.* |
|  | **Assent not required;** the intervention or procedure involved in 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 the research** |
|  | **Assent is waived;** study meets criteria for a waiver of consent in accordance with [45 CFR 46.116](https://www.hhs.gov/ohrp/regulations-and-policy/regulations/45-cfr-46/revised-common-rule-regulatory-text/index.html#46.116) (Waiver or alteration of informed consent). |

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