Criteria for IRB Approval of Children Involved in Research

Instructions - Mark the appropriate category.

- *Determine whether the research is approvable under one of the four categories listed below*
- *A subsequent checklist will be required based upon the following selection. Comments, revisions or clarifications can be identified in the area provided on the subsequent pages.*

Select one:

○ **Category #1:** Research not involving greater than minimal risk.	45 CFR 46.404 21 CFR 50.51
○ **Category #2:** Research involves greater than minimal risk but presents the prospect of direct benefit to the individual participants.	45 CFR 46.405 21 CFR 50.52
○ **Category #3:** Research involving greater than minimal risk and no prospect of direct benefit to the individual participants, but likely to yield generalizable knowledge about the participant's disorder or condition.	45 CFR 46.406 21 CFR 50.53
○ **Category #4:** Research not otherwise approvable, but which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children. **PLEASE NOTE:** Research in this category can ONLY be approved if the Secretary of DHHS and the Commissioner of the FDA also review and approve the research. Clear	45 CFR 46.407 21 CFR 50.54

Reviewer Checklist - Children Involved As Subjects in Research

Category #1 (45 CFR 46.404, 21 CFR 50.51)

Please determine whether the research is approvable under this particular category. Then complete the additional requirements regarding parental permission and assent, as applicable to the study population(s) involved. Please provide any comments, revisions or clarifications in the area provided below.

Finding: The research does not involve greater than minimal risk.

Determination of Parental Permission Method:
One option must be used to meet the requirement for making adequate provisions for soliciting the permission of the children's parents or guardians. Select the method the investigator will use to obtain parental permission.

- ○ The permission of each child's parents or guardian 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.
- ○ The permission of one parent is sufficient for this study.
- ○ The permission of a parent/guardian is waived.
  - *Waiver of Consent checklist must be completed.*
  - *Parental permission cannot be waived for studies subject to FDA regulation.*

Clear

Determination of Assent Process

Assent is a requirement of:

- ○ All Children.
  The assent checklist will be required.
- ○ None of the children.
- ○ Some of the children.
  The assent checklist will be required.

Clear

If "Some of the children," please specify which children are NOT required to assent:

If assent is NOT a requirement for some or all children, one or more of the following must be true.

- ☐ The children are not capable of providing assent based on the age maturity, or psychological state.
- ☐ The capability of the children is so limited that they cannot be reasonably consulted.
- ☐ 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 child and is available only in the context of the research.
- ☐ The assent process is entirely waived because all of the following are true:
  - The research involves no more than minimal risk to the subjects; **AND**
  - The waiver or alteration will not adversely affect the rights and welfare of the subjects; **AND**
  - The research could not practicably be carried out without the waiver or alteration; **AND**
  - Whenever appropriate, the subjects will be provided with additional pertinent information after participation

- Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

Specific Concerns:
If any, explain any concerns you may have and WHY they are of concern. You must be very specific. If you have none, please state "None."

Resolutions to Concerns:
Provide specific resolutions to concerns listed above. Your requested clarifications, suggestions, and revisions must be specific.

REMINDER: *If you need more information than is in the current application to resolve issues related to the approval criteria, the IRB encourages you to contact the PI before the Board meeting. Your IRB coordinator can contact the PI on your behalf (if you wish to remain anonymous).*

DETERMINATION: Is the proposed involvement of children approvable under category 1?

- ○ Yes.
- ○ Yes, if the above stipulation is met.
- ○ No.

Clear

Reviewer Checklist - Children Involved as Subjects in Research

Category #2 (45 CFR 46.405)

Please determine whether the research is approvable under this particular category. Then complete the additional requirements regarding parental permission and assent, as applicable to the study population(s) involved. Please provide any comments, revisions or clarifications in the area provided below.

The following statements must be true to approve the research under this category:

◯ True ◯ False Clear	One or both of the following is true: ☐ More than minimal risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for each individual participant. ☐ More than minimal risk to children is presented by a monitoring procedure that is likely to contribute to the participant's well-being.
◯ True ◯ False Clear	The risk is justified by the anticipated benefit to the participants.
◯ True ◯ False Clear	The relation of the anticipated benefit to the risk is at least as favorable to the participants as that presented by available alternative approaches.

Determination of Parental Permission Method:
One option must be used to meet the requirement for making adequate provisions for soliciting the permission of the children's parents or guardians. Select the method the investigator will use to obtain parental permission.

◯ The permission of each child's parents or guardian 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.

◯ The permission of one parent is sufficient for this study.

Clear

Determination of Assent Process

Assent is a requirement of:

◯ All Children.
The assent checklist will be required.

◯ None of the children.

◯ Some of the children.
The assent checklist will be required.

Clear

If "Some of the children," please specify which children are NOT required to assent:

If assent is NOT a requirement for some or all children, one or more of the following must be true:

☐ The children are not capable of providing assent based on the age maturity, or psychological state.

☐ The capability of the children is so limited that they cannot be reasonably consulted.

☐ 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 child and is available only in the context of the research.

Specific Concerns:
If any, explain any concerns you may have and WHY they are of concern. You must be very specific. If you have none, please state "None."

Resolutions to Concerns:
Provide specific resolutions to concerns listed above. Your requested clarifications, suggestions, and revisions must be specific.

REMINDER: *If you need more information than is in the current application to resolve issues related to the approval criteria, the IRB encourages you to contact the PI before the Board meeting. Your IRB coordinator can contact the PI on your behalf (if you wish to remain anonymous).*

DETERMINATION: Is the proposed involvement of children approvable under category 2?

- ○ Yes.
- ○ Yes, if the above stipulation is met.
- ○ No.

Clear

Reviewer Checklist - Children Involved as Subjects in Research

Category #3 (45 CFR 46.406)

Please determine whether the research is approvable under this particular category. Then complete the additional requirements regarding parental permission and assent, as applicable to the study population(s) involved. Please provide any comments, revisions or clarifications in the area provided below.

The following statements must be true to approve the research under this category:

○ True ○ False Clear	More than minimal risk to children is presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual participant, or by a monitoring procedure, which is not likely to contribute to the well-being of the participant.
○ True ○ False Clear	The risk represents a minor increase over minimal risk.
○ True ○ False Clear	The intervention or procedure presents experiences to participants that are reasonably commensurate with those inherent in their actual or expected medical, dental, psychological, social, or educational situations.
○ True ○ False Clear	The participants have a disorder or condition.
○ True ○ False Clear	The intervention or procedure is likely to yield generalizable knowledge about the participants' disorder or condition which is of vital importance for the understanding or amelioration of the participants' disorder or condition.

Parental Permission: For research approved under category #3, the permission of each child's parents or guardian 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.

Determination of Assent Process

Assent is a requirement of:

- ○ All Children.
  The assent checklist will be required.
- ○ None of the children.
- ○ Some of the children.
  The assent checklist will be required.

Clear

If "Some of the children," please specify which children are NOT required to assent:

If assent is NOT a requirement for some or all children, one or more of the following must be true:

- ☐ The children are not capable of providing assent based on the age maturity, or psychological state.
- ☐ The capability of the children is so limited that they cannot be reasonably consulted.

Specific Concerns:
If any, explain any concerns you may have and WHY they are of concern. You must be very specific. If you have none, please state "None."

Resolutions to Concerns:
Provide specific resolutions to concerns listed above. Your requested clarifications, suggestions, and revisions must be specific.

REMINDER: *If you need more information than is in the current application to resolve issues related to the approval criteria, the IRB encourages you to contact the PI before the Board meeting. Your IRB coordinator can contact the PI on your behalf (if you wish to remain anonymous).*

DETERMINATION: Is the proposed involvement of children approvable under category 3?

- ○ Yes.
- ○ Yes, if the above stipulation is met.
- ○ No.

Clear

Reviewer Checklist - Children Involved as Subjects in Research

Category #4 (45 CFR 46.407)

Please determine whether the research is approvable under this particular category. Then complete the additional requirements regarding parental permission and assent, as applicable to the study population(s) involved. Please provide any comments, revisions or clarifications in the area provided below.

The following statements must be true to approve the research under this category:

True
False Clear

The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children

True
False Clear

For DHHS-regulated research, all of the following are true:

- The research is conducted, funded, or otherwise subject to regulation by DHHS; **AND**
- The Secretary of DHHS, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) and following opportunity for public review and comment, has determined that all of the following are true:
  - 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 will be conducted in accordance with sound ethical principles; **AND**
  - Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians.

For FDA-regulated research, all of the following are true:

- The research is subject to FDA regulation; **AND**
- The Commissioner of Food and Drugs, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) and following opportunity for public review and comment, has determined that all of the following is true:
  - 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 will be conducted in accordance with sound ethical principles; **AND**
  - Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians.

Parental Permission: For research approved under category #4, the permission of each child's parents or guardian 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.

Determination of Assent Process

Assent is a requirement of:

All Children.
The assent checklist will be required.

None of the children.

Some of the children.
The assent checklist will be required.
Clear

If "Some of the children," please specify which children are **NOT** required to assent:

If assent is NOT a requirement for some or all children, one or more of the following must be true:

The children are not capable of providing assent based on the age maturity, or psychological state.

The capability of the children is so limited that they cannot be reasonably consulted.

Specific Concerns:

Specific Concerns:
If any, explain any concerns you may have and WHY they are of concern. You must be very specific. If you have none, please state "None."

Resolution to Concerns:
Provide specific resolutions to concerns listed above. Your requested clarifications, suggestions, and revisions must be specific.

REMINDER: *If you need more information than is in the current application to resolve issues related to the approval criteria, the IRB encourages you to contact the PI before the Board meeting. Your IRB coordinator can contact the PI on your behalf (if you wish to remain anonymous).*

DETERMINATION: Is the proposed involvement of children approvable under category 4?

- ○ Yes.
- ○ Yes, if the above stipulation is met.
- ○ No.

Clear

Ward of State - (or any other agency, institution, or entity)

You have identified that children may be involved in research under category:

If you have selected Children category #1 or category #2, skip to the determination at the end of the page. *Wards of state may be included in minimal risk research or in research that offers the prospect of direct benefit without additional regulatory considerations.*

If you have selected Children category #3 or category #4, complete the additional questions on this page and then enter your determination at the end of the page. *Wards of state may only be included category #3 or #4 research if these additional stipulations are met.*

Complete only if you indicated Children Category 3 or 4:

- ○ The research is related to the children's status as wards.
- ○ The research will be conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as participants are not wards.

Clear

Complete only if you indicated Children Category 3 or 4
The following statements must be true to approve the research for Wards of State in Category 3 or 4:

○ True ○ False Clear	One or more individuals will be appointed as an advocate 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.
○ True ○ False Clear	The advocate(s) will have the background and experience to act in, and agree to act in, the best interests of the child for the duration of the child's participation in the research.
○ True ○ False Clear	The advocate(s) are not associated with any of the following: • The research • The investigator(s) • The guardian organization

Specific Concerns:
If any, explain any concerns you may have and WHY they are of concern. You must be very specific. If you have none, please state "None."

Resolutions to Concerns:
Provide specific resolutions to concerns listed above. Your requested clarifications, suggestions, and revisions must be specific.

REMINDER: *If you need more information than is in the current application to resolve issues related to the approval criteria, the IRB encourages you to contact the PI before the Board meeting. Your IRB coordinator can contact the PI on your behalf (if you wish to remain anonymous).*

DETERMINATION: Is the proposed involvement of wards of state approvable?

- ○ Yes.
- ○ Yes, if the above stipulation is met.
- ○ No.

Clear