RUTGERS UNIVERSITY
Office for Research

WORKSHEET: Children

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7.205 (HRP-416)	5/1/2024	1 of 5

The purpose of this worksheet is to provide support for IRB members or the Designated Reviewer following the 4.202 (HRP-314) - WORKSHEET: Criteria for Approval when research involves children as subjects. This worksheet may be used for all reviews (initial, continuing, modification, review by the convened IRB, and review using the expedited procedure.)

- For initial review using the expedited procedure and modifications and continuing reviews where the determinations relevant to this worksheet made on the previous review have changed, the Designated Reviewer may utilize this worksheet to make determinations required by the regulations along with protocol-specific findings justifying those determinations. The Designated Reviewer documents their review in the electronic "Submit Designated Review" activity in eIRB+.

- For initial review using the convened IRB and for modifications and continuing reviews where the determinations relevant to this worksheet made on the previous review have changed, the convened IRB completes the corresponding section of the meeting minutes to document determinations required by the regulations along with protocol-specific findings justifying those determinations, in which case this worksheet does not need to be completed or retained.

- **NOTE**: Use a separate worksheet for each child determination for a study.

1 The research meets all of the following: (Check if **"Yes".** All must be checked)

☐ The research falls into one of the following categories of research involving children[i]: (Check box that is true)

☐ Section 2 Criteria ☐ Section 3 Criteria ☐ Section 4 Criteria ☐ Section 5 Criteria

☐ Adequate provisions are made for soliciting the permission of parents or guardians[ii]. **(Complete Section 7)**

☐ Adequate provisions are made for soliciting the assent of the children. **(Complete Section 12)**

☐ One of the following is true related to applicability of research involving wards: **(Check the one that is true)**

☐ The research falls into Section 2 or 3 **OR** does **NOT** involve wards of the state or any other agency, institution, or entity

☐ The research falls into Section 4 or 5 **AND** involves wards of the state or any other agency, institution, or entity **(Complete Section 6)**

2 Research involving children under 21 CFR §50.51/45 CFR §46.404 (Check if **"Yes".** All must be checked)

☐ No greater than Minimal Risk to children is presented.
Provide protocol-specific findings justifying this determination:

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3 Research involving children under 21 CFR §50.52/45 CFR §46.405 (Check if **"Yes".** All must be checked)

☐ The research involves greater than Minimal Risk to subjects.
Provide protocol-specific findings justifying this determination:

☐ The research presents the prospect of direct benefit to the individual subjects.
Provide protocol-specific findings justifying this determination:

☐ One of the following is true**. (Check box that is true**)

☐ The risk to children is presented by an intervention or procedure that holds out the prospect of direct benefit for the individual subject.

☐ The risk to children is presented by a monitoring procedure that is likely to contribute to the subject's well-being.

Provide protocol-specific findings justifying this determination:

☐ The risk is justified by the anticipated benefit to the subjects.
Provide protocol-specific findings justifying this determination:

☐ The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches.
Provide protocol-specific findings justifying this determination:

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4 Research involving children under 21 CFR §50.53/45 CFR §46.406 (Check if **"Yes".** All must be checked)

☐ The research involves greater than Minimal Risk to children presented by an intervention or procedure that does not hold out the prospect of direct benefit for the individual subject, or by a monitoring procedure which is not likely to contribute to the well-being of the subject.
Provide protocol-specific findings justifying this determination:

☐ The risk represents a minor increase over Minimal Risk. ("Minor increase over Minimal Risk" *means*, though the risks are greater than minimal, they do not exceed the socially acceptable risks for children with the condition or disorder under study.[iii])
Provide protocol-specific findings justifying this determination:

☐	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. *Provide protocol-specific findings justifying this determination:*
☐	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. *Provide protocol-specific findings justifying this determination:*

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5 Not otherwise approvable research involving children under 21 CFR §50.54/45 CFR §46.407 (Check if **"Yes".** All must be checked)

☐	The research does not meet the requirements of Sections 2, 3, or 4 *Provide protocol-specific findings justifying this determination:*
☐	The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children. *Provide protocol-specific findings justifying this determination:*

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6 Research involving wards of the state or any other agency, institution, or entity under 21 CFR §50.56/45 CFR §46.409 (Check if **"Yes".** All must be checked)

☐	One of the following is true: **(Check box that is true**) ☐ The research is related to their status as wards. ☐ The research is conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards. *Provide protocol-specific findings justifying this determination:*
☐	An advocate will be 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 for research approved under §46.406 or §46.407. *Provide protocol-specific findings justifying this determination:*
☐	The advocate will have the background and experience to act in, and will agree to act in, the best interests of the child for the duration of the child's participation in the research. *Provide protocol-specific findings justifying this determination:*
☐	The advocate is not associated in any way (except in the role as advocate or member of the IRB) with the research, the investigator(s), or the guardian organization. *Provide protocol-specific findings justifying this determination:*

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7 Adequate provisions for soliciting the permission of parents or guardians (Check if **"Yes".**)

☐	One of the following is true: **(Check box that is true)** ☐ Permission is to be obtained from both parents 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. ☐ Permission of one parent is sufficient even if the other parent is alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child. **(Cannot be selected for Section 4 or 5 criteria)** ☐ Parental permission is waived under criteria in Section 8 ☐ Parental permission is waived under criteria in Section 9 ☐ Parental permission is waived under criteria in Section 10 ☐ Parental permission is waived under criteria in Section 11

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8 Waiver of Parental Permission under 45 CFR §46.408(c) (Check if **"Yes".** All must be checked)

☐	The research is not FDA-regulated.
☐	The research does not involve non-viable neonates.
☐	The research protocol is designed for conditions or for a subject population for which parental or guardian permission is not a reasonable requirement to protect the subjects. *Provide protocol-specific findings justifying this determination:*
☐	An appropriate mechanism for protecting the children who will participate as subjects in the research is substituted. *Provide protocol-specific findings justifying this determination:*

☐	The waiver is not inconsistent with Federal, State, or local law. *Provide protocol-specific findings justifying this determination:*

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9 Waiver of Parental Permission under 45 CFR §46.408(c)/45 CFR §46.116(d)/45 CFR §46.116(f) (Check if **"Yes".** All must be checked)

☐	The research is not FDA-regulated.
☐	The research does not involve non-viable neonates.
☐	The research involves no more than Minimal Risk to the subjects. *Provide protocol-specific findings justifying this determination:*
☐	The waiver or alteration will not adversely affect the rights and welfare of the subjects. *Provide protocol-specific findings justifying this determination:*
☐	The research could not practicably be carried out without the waiver or alteration *Provide protocol-specific findings justifying this determination:*
☐	Whenever appropriate, the subjects will be provided with additional pertinent information after participation. *Provide protocol-specific findings justifying this determination:*
☐	If the research involves using identifiable private information or identifiable biospecimens, the research could NOT practicably be carried out without using such information or biospecimens in an identifiable format. Provide protocol-specific findings justifying this determination:
☐	Alteration of the consent process can only omit or alter the basic and/or additional elements of consent. It cannot omit or alter any of the requirements described in 45 CFR 46.116(a). **(N/A if research is subject to Pre-2018 Requirements OR if waiving informed consent.)** ☐ **N/A**
☐	The waiver is not inconsistent with Federal, State or local law. [v]

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10 Waiver of Parental Permission under FDA Guidance "IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More Than Minimal Risk to Human Subjects"[iv] (Check if "**Yes**." All must be checked.)

☐	The research **IS** FDA-regulated.
☐	The clinical investigation involves no more than minimal risk (as defined in 21 CFR 50.3(k) or 56.102(i)) to the subjects. *Provide protocol-specific findings justifying this determination:*
☐	The waiver or alteration will not adversely affect the rights and welfare of the subjects. *Provide protocol-specific findings justifying this determination:*
☐	The clinical investigation could not practicably be carried out without the waiver or alteration. *Provide protocol-specific findings justifying this determination:*
☐	Whenever appropriate, the subjects will be provided with additional pertinent information after participation. *Provide protocol-specific findings justifying this determination:*

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11 Waiver of Parental Permission under 45 CFR §46.408(c)/45 CFR §46.116(c) (Check if "Yes". All must be checked)

☐	The research is not FDA-regulated.
☐	The research does not involve non-viable neonates.
☐	The research or demonstration project is to be conducted by or subject to the approval of state or local government officials. *Provide protocol-specific findings justifying this determination:*
☐	The research or demonstration project is designed to study, evaluate, or otherwise examine one or more of the following: **(Check boxes that are true)** ☐ Public benefit or service programs. ☐ Procedures for obtaining benefits or services under those programs. ☐ Possible changes in or alternatives to those programs or procedures. ☐ Possible changes in methods or levels of payment for benefits or services under those programs. *Provide protocol-specific findings justifying this determination:*
☐	The research could not practicably be carried out without the waiver or alteration. *Provide protocol-specific findings justifying this determination:*

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12 Adequate provisions to solicit the assent of children (Check if **"Yes".** All must be checked)

☐ Assent will be obtained from: **(Check box that is true)**
- ☐ All children. **(Complete Section 14)**
- ☐ None of the children. **(Complete Section 13)**
- ☐ Some children. **(Complete Section 13 and Section 14. The protocol needs to describe which children will not be asked for assent)**

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13 Reason why assent is not necessary 45 CFR §46.408(a)/21 CFR §50.55(c) (Check if **"Yes".** All must be checked)

☐ One or more of the following are true. **(Check all boxes that are true.)**
- ☐ The capability of these children (taking into account the ages, maturity, and psychological state of the children involved) is so limited that they cannot reasonably be 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 children and is available only in the context of the research
- ☐ Assent is waived under Section 15 criteria
- ☐ Assent is waived under Section 16 criteria

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14 Documentation of assent (Check if **"Yes".** All must be checked)

☐ If **"Yes"**, specify the process for documentation:
- ☐ Investigator will document assent in the consent signature block.
- ☐ Other **(NOTE: The protocol needs to describe the process of assent documentation)**

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15 Waiver of child assent under 45 CFR §46.408(a)/45 CFR §46.116(c)/21 CFR §50.55(d) (Check if **"Yes".** All must be checked)

- ☐ The research involves no more than Minimal Risk to the subjects.
- ☐ The waiver or alteration will not adversely affect the rights and welfare of the subjects.
- ☐ The research could not practicably be carried out without the waiver or alteration
- ☐ Whenever appropriate, the subjects will be provided with additional pertinent information after participation.
- ☐ If the research involves using identifiable private information or identifiable biospecimens, the research could NOT practicably be carried out without using such information or biospecimens in an identifiable format. **(N/A if research is FDA regulated, is subject to Pre-2018 Requirements OR if does not use identifiable private information or biospecimens) ☐ N/A**

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16 Waiver of Child Assent under 45 CFR §46.408(a)/45 CFR §46.116(d) (Check if **"Yes".** All must be checked)

- ☐ The research is not FDA-regulated.
- ☐ The research or demonstration project is to be conducted by or subject to the approval of state or local government officials
- ☐ The research or demonstration project is designed to study, evaluate, or otherwise examine one or more of the following: **(Check all boxes that are true. At least one must be checked.)**
  - ☐ Public benefit or service programs.
  - ☐ Procedures for obtaining benefits or services under those programs.
  - ☐ Possible changes in or alternatives to those programs or procedures.
  - ☐ Possible changes in methods or levels of payment for benefits or services under those programs.
- ☐ The research could not practicably be carried out without the waiver or alteration.

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[i] "Children" are persons who have not attained the legal age for consent to treatments or procedures involved in the research, under the applicable law of the jurisdiction in which the research will be conducted.

[ii] "Guardian" means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care.

[iii] Wendler D. "What is a "minor" increase over minimal risk?" *J Pediatr;* 01-Nov-2005; 147(5): 575-8.

[iv] Institutional Review Board Waiver or Alteration of Informed Consent for Minimal Risk Clinical Investigations | FDA.

[V] NJ State Statute Chapter 36 of Title 18A School Surveys: Parental or legal guardian permission may not be waived if the research proposes school research that includes any academic or nonacademic survey, assessment, analysis or evaluation which reveals information concerning: political affiliations; mental and psychological problems potentially embarrassing to the student or the student's family; sexual behavior and attitudes;

illegal, anti-social, self-incriminating and demeaning behavior; critical appraisals of other individuals with whom a respondent has a close family relationship; legally recognized privileged or analogous relationships, such as those of lawyers, physicians, and ministers; income, other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under a program; or social security number.