The purpose of this checklist is to provide support for IRB members or the designated reviewer following the *OIA-314 WORKSHEET: Criteria for Approval and Additional Considerations*, or equivalent, when research involves children[1] as subjects. This checklist, or equivalent, should assist the reviewer/board in determining whether the IRB can approve the protocol (Levels 1-3) or if it needs to be referred to Department of Health and Human Services (DHHS) or Food and Drug Administration (FDA) for review and approval. This checklist, or equivalent, may be used for all initial reviews. This checklist, or equivalent, may also be used for continuing review and review of modifications when the previous determinations are changed. It does not need to be completed or retained.

IRB Number:	
Investigator:	
Applicability:	This research includes children as participants. ☐ Yes ☐ No (if "No," do not complete this checklist.) This research is subject to FDA or DHHS jurisdiction[2] ☐ Yes ☐ No

1	**Research involving children under 21 CFR 50.51/45 CFR 46.404** (Check if **"Yes."** All must be checked) **(Minimal Risk – Level 1)**
☐	No greater than minimal risk to children is presented. *Provide protocol specific findings justifying this determination:*
2	**Research involving children under 21 CFR 50.52/45 CFR 46.405** (Check if **"Yes."** All must be checked) **(Greater than Minimal Risk – Level 2)**
☐	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:*
3	**Research involving children under 21 CFR 50.53/45 CFR 46.406** (Check if **"Yes."** All must be checked)[3] **(Greater than Minimal Risk – Level 3)**
☐	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* no greater than risk in the daily lives of children with the condition or disorder under study, but still socially acceptable.)[4] *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:*
4	**Not otherwise approvable research involving children under 21 CFR 50.54/45 CFR 46.407** (Check if **"Yes."** All must be checked) **(Greater than Minimal Risk – Level 4 – DHHS Review & Approval Required)**
☐	The research does not meet the requirements of Sections 1, 2, or 3 *Provide protocol specific findings justifying this determination:*

[1] The definition of "children" is 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. Investigators must consult legal counsel if there is any question as to the ability of a minor to consent to procedures.

[2] If the research is not subject to FDA or DHHS jurisdiction, this checklist, or equivalent, must be used; however, the IRB may determine that alternative, equivalent provisions may be substituted for the provisions required in the checklist.

[3] If consent is to be obtained from the experimental subjects' legal representative as defined in Department of Defense Instruction 3216.02, the research must intend to benefit each participant enrolled in the study.

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

☐	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:*
DHHS or FDA Review and Approval are Required Prior to IRB Approval	
5	**Research involving wards of the state or any other agency, institution, or entity under 45 CFR 46.409**
☐	Wards of the state or any other agency, institution or entity under 45 CFR 46.409 will be enrolled. (Check if "Yes." If "Yes" all boxes in this section 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. *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:*
☐	If the research involves wards of the California Youth Authority, *OIA-415 Checklist: Prisoners*, or equivalent, also has been used and prior approval has been secured from the California Department of Corrections and Rehabilitation.
6	**Adequate provisions for soliciting the permission of parents or guardians** (Check if **"Yes."** All must be checked)
☐	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 3 or 4 criteria)** ☐ Parental permission is waived under criteria in Section 7 ☐ Parental permission is waived under criteria in Section 8 ☐ Parental permission is waived under criteria in Section 9
7	**Waiver of Parental Permission under 45 CFR 46.408(c)** (Check if **"Yes."** All must be checked)
☐	The research does NOT meet the State of California's definition of a medical experiment:[5] (a) The severance or penetration or damaging of tissues of a human subject or the use of a drug or device, electromagnetic radiation, heat or cold, or a biological substance or organism, in or upon a human subject in the practice or research of medicine in a manner not reasonably related to maintaining or improving the health of the subject or otherwise directly benefiting the subject; or (b) The investigational use of a drug or device; or (c) Withholding medical treatment from a human subject for any purpose other than maintenance or improvement of the health of the subject.
☐	The research is not FDA regulated.
☐	The research does not involve non-viable neonates.
☐	The research presents no greater than minimal risk. **(Cannot be selected for Section 2, 3, or 4 criteria)** *Provide protocol specific findings justifying this determination:*
☐	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:*
☐	No individuals were previously asked to provide broad consent for use of identifiable private information and/or identifiable biospecimens and refused to consent.

[5] California Code, Health and Safety Code - HSC 24174

8	**Waiver of Parental Permission under 45 CFR 46.408(c)/45 CFR 46.116(f)** (Check if **"Yes."** All must be checked)
☐	The research does NOT meet the State of California's definition of a medical experiment[6]: (a) The severance or penetration or damaging of tissues of a human subject or the use of a drug or device, electromagnetic radiation, heat or cold, or a biological substance or organism, in or upon a human subject in the practice or research of medicine in a manner not reasonably related to maintaining or improving the health of the subject or otherwise directly benefiting the subject; or (b) The investigational use of a drug or device; or (c) Withholding medical treatment from a human subject for any purpose other than maintenance or improvement of the health of the subject.
☐	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:*
☐	One must be checked: ☐ The research is being reviewed under the Pre-2018 Common Rule **and** is not FDA-regulated. ☐ The research uses only de-identified or anonymous private information or biospecimens; or ☐ The research cannot practicably be carried out without using identifiable private information or identifiable biospecimens because*:*
☐	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:*
☐	No individuals were previously asked to provide broad consent for use of identifiable private information and/or identifiable biospecimens and refused to consent.
9	**Waiver of Parental Permission under 45 CFR 46.408(c)/45 CFR 46.116(e)** (Check if **"Yes."** All must be checked)
☐	The research is not FDA regulated.
☐	The research does not involve non-viable neonates.
☐	The research presents no greater than minimal risk. **(Cannot be selected for Section 2, 3, or 4 criteria)** *Provide protocol specific findings justifying this determination:*
☐	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:*
☐	No individuals were previously asked to provide broad consent for use of identifiable private information and/or identifiable biospecimens and refused to consent.
10	**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 12)** ☐ None of the children. **(Complete Section 11)** ☐ Some children. **(Complete Section 11 and 12. The protocol needs to describe which children will not be asked for assent.)**
11	**Reason why assent is not necessary** (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 45 CFR 46.116(f) (See Section 8 above). ☐ Assent is waived under 45 CFR 46.116(e) (See Section 9 above).

[6] California Code, Health and Safety Code - HSC 24174

12 Documentation of assent (Check if **"Yes."** At least one must be checked)

☐ Assent will be documented. Specify the process for documentation:
- ☐ Investigator will document assent using an assent form.
- ☐ Other **(NOTE: The protocol needs to describe the process of assent documentation.)**

☐ Assent will not be documented.
Provide protocol specific findings justifying this determination:

13 Summary - 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: (Check box that is true)

☐ Section 1 Criteria	☐ Section 2 Criteria	☐ Section 3 Criteria	☐ Section 4 Criteria

☐ Adequate provisions are made for soliciting the permission of parents or guardians. **(Section 6)**

☐ Adequate provisions are made for soliciting and documenting the assent of the children. **(Section 10)**

☐ One of the following is true: **(Check the one that is true)**
- ☐ The research falls into Section 1 or 2. (permission from one parent or guardian allowable)
- ☐ The research falls into Section 3 or 4 **and does not** involve wards of the state or any other agency, institution, or entity. (permission from two parents or guardians required)
- ☐ The research falls into Section 3 or 4 **and** involves wards of the state or any other agency, institution, or entity. **(Section 5 is completed)** (permission from two parents or guardians required)