

UC San Diego INSTITUTIONAL REVIEW BOARD ADMINISTRATION	OIA-416 CHECKLIST: Children		
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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 children¹ 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 <u>research</u> includes <u>children</u> as participants. <input type="checkbox"/> Yes <input type="checkbox"/> No (if "No," do not complete this checklist.) This <u>research</u> is subject to FDA or DHHS jurisdiction ² <input type="checkbox"/> Yes <input type="checkbox"/> 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)	
<input type="checkbox"/>	No greater than <u>minimal risk</u> to <u>children</u> is presented. <i>Provide protocol specific findings justifying this determination:</i>
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)	
<input type="checkbox"/>	The <u>research</u> involves greater than <u>minimal risk</u> to subjects. <i>Provide protocol specific findings justifying this determination:</i>
<input type="checkbox"/>	The <u>research</u> presents the prospect of direct benefit to the individual subjects. <i>Provide protocol specific findings justifying this determination:</i>
<input type="checkbox"/>	One of the following is true. (Check box that is true) <input type="checkbox"/> The risk to <u>children</u> is presented by an <u>intervention</u> or procedure that holds out the prospect of direct benefit for the individual subject. <input type="checkbox"/> The risk to <u>children</u> is presented by a monitoring procedure that is likely to contribute to the subject's well-being. <i>Provide protocol specific findings justifying this determination:</i>
<input type="checkbox"/>	The risk is justified by the anticipated benefit to the subjects. <i>Provide protocol specific findings justifying this determination:</i>
<input type="checkbox"/>	The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches. <i>Provide protocol specific findings justifying this determination:</i>
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)	
<input type="checkbox"/>	The <u>research</u> involves greater than <u>minimal risk</u> to <u>children</u> presented by an <u>intervention</u> 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. <i>Provide protocol specific findings justifying this determination:</i>
<input type="checkbox"/>	The risk represents a minor increase over <u>minimal risk</u> . ("Minor increase over <u>minimal risk</u> " means no greater than risk in the daily lives of <u>children</u> with the condition or disorder under study, but still socially acceptable.) ⁴ <i>Provide protocol specific findings justifying this determination:</i>
<input type="checkbox"/>	The <u>intervention</u> 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. <i>Provide protocol specific findings justifying this determination:</i>
<input type="checkbox"/>	The <u>intervention</u> or procedure is likely to yield <u>generalizable knowledge</u> about the subjects' disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition. <i>Provide protocol specific findings justifying this determination:</i>
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)	
<input type="checkbox"/>	The <u>research</u> does not meet the requirements of Sections 1, 2, or 3 <i>Provide protocol specific findings justifying this determination:</i>

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.](#)

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<input type="checkbox"/>	The <u>research</u> presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of <u>children</u> . <i>Provide protocol specific findings justifying this determination:</i>
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	
<input type="checkbox"/>	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)
<input type="checkbox"/>	One of the following is true: (Check box that is true) <input type="checkbox"/> The <u>research</u> is related to their status as wards. <input type="checkbox"/> The <u>research</u> is conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of <u>children</u> involved as subjects are not wards. <i>Provide protocol specific findings justifying this determination:</i>
<input type="checkbox"/>	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. <i>Provide protocol specific findings justifying this determination:</i>
<input type="checkbox"/>	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 <u>research</u> . <i>Provide protocol specific findings justifying this determination:</i>
<input type="checkbox"/>	The advocate is not associated in any way (except in the role as advocate or member of the IRB) with the <u>research</u> , the investigator(s), or the guardian organization. <i>Provide protocol specific findings justifying this determination:</i>
<input type="checkbox"/>	If the <u>research</u> involves wards of the California Youth Authority, <i>OIA-415 Checklist: Prisoners</i> , 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)	
<input type="checkbox"/>	One of the following is true: (Check box that is true) <input type="checkbox"/> 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. <input type="checkbox"/> 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) <input type="checkbox"/> Parental permission is waived under criteria in Section 7 <input type="checkbox"/> Parental permission is waived under criteria in Section 8 <input type="checkbox"/> 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)	
<input type="checkbox"/>	The <u>research</u> 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 <u>human subject</u> or the use of a drug or device, electromagnetic radiation, heat or cold, or a biological substance or organism, in or upon a <u>human subject</u> in the practice or <u>research</u> 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 <u>human subject</u> for any purpose other than maintenance or improvement of the health of the subject.
<input type="checkbox"/>	One of the following is true: (Check box that is true) <input type="checkbox"/> The <u>research</u> is not FDA-regulated. <input type="checkbox"/> The <u>research</u> presents no greater than <u>minimal risk</u> . (Cannot be selected for Section 2, 3, or 4 criteria)
<input type="checkbox"/>	The <u>research</u> does not involve non-viable neonates.
<input type="checkbox"/>	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. <i>Provide protocol specific findings justifying this determination:</i>
<input type="checkbox"/>	An appropriate mechanism for protecting the <u>children</u> who will participate as subjects in the <u>research</u> is substituted. <i>Provide protocol specific findings justifying this determination:</i>
<input type="checkbox"/>	The waiver is not inconsistent with federal, state, or local law. <i>Provide protocol specific findings justifying this determination:</i>

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

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8	Waiver of Parental Permission under 45 CFR 46.408(c)/45 CFR 46.116(f) (Check if "Yes." All must be checked)
<input type="checkbox"/>	The <u>research</u> 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 <u>human subject</u> or the use of a drug or device, electromagnetic radiation, heat or cold, or a biological substance or organism, in or upon a <u>human subject</u> in the practice or <u>research</u> 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 <u>human subject</u> for any purpose other than maintenance or improvement of the health of the subject.
<input type="checkbox"/>	The <u>research</u> does not involve non-viable neonates.
<input type="checkbox"/>	The <u>research</u> involves no more than <u>minimal risk</u> to the subjects. <i>Provide protocol specific findings justifying this determination:</i>
<input type="checkbox"/>	The waiver or alteration will not adversely affect the rights and welfare of the subjects. <i>Provide protocol specific findings justifying this determination:</i>
<input type="checkbox"/>	One must be checked: <input type="checkbox"/> The <u>research</u> is being reviewed under the Pre-2018 Common Rule. <input type="checkbox"/> The <u>research</u> uses only de-identified or anonymous <u>private information</u> or biospecimens; or <input type="checkbox"/> The <u>research</u> cannot practicably be carried out without using <u>identifiable private information</u> or <u>identifiable biospecimens</u> because:
<input type="checkbox"/>	The <u>research</u> could not practicably be carried out without the waiver or alteration. <i>Provide protocol specific findings justifying this determination:</i>
<input type="checkbox"/>	Whenever appropriate, the subjects will be provided with additional pertinent information after participation. <i>Provide protocol specific findings justifying this determination:</i>
9	Waiver of Parental Permission under 45 CFR 46.408(c)/45 CFR 46.116(e) (Check if "Yes." All must be checked)
<input type="checkbox"/>	One of the following is true: (Check box that is true) <input type="checkbox"/> The <u>research</u> is not FDA-regulated. <input type="checkbox"/> The <u>research</u> presents no greater than <u>minimal risk</u> . (Cannot be selected for Section 2, 3, or 4 criteria)
<input type="checkbox"/>	The <u>research</u> does not involve non-viable neonates.
<input type="checkbox"/>	The <u>research</u> or demonstration project is to be conducted by or subject to the approval of state or local government officials. <i>Provide protocol specific findings justifying this determination:</i>
<input type="checkbox"/>	The <u>research</u> or demonstration project is designed to study, evaluate, or otherwise examine one or more of the following: (Check boxes that are true) <input type="checkbox"/> Public benefit or service programs. <input type="checkbox"/> Procedures for obtaining benefits or services under those programs. <input type="checkbox"/> Possible changes in or alternatives to those programs or procedures. <input type="checkbox"/> Possible changes in methods or levels of payment for benefits or services under those programs. <i>Provide protocol specific findings justifying this determination:</i>
<input type="checkbox"/>	The <u>research</u> could not practicably be carried out without the waiver or alteration. <i>Provide protocol specific findings justifying this determination:</i>
10	Adequate provisions to solicit the assent of <u>children</u> (Check if "Yes." All must be checked)
<input type="checkbox"/>	Assent will be obtained from: (Check box that is true) <input type="checkbox"/> All <u>children</u> . (Complete Section 12) <input type="checkbox"/> None of the <u>children</u> . (Complete Section 11) <input type="checkbox"/> Some <u>children</u> . (Complete Section 11 and 12. The protocol needs to describe which <u>children</u> will not be asked for assent.)
11	Reason why assent is not necessary (Check if "Yes." All must be checked)
<input type="checkbox"/>	One or more of the following are true. (Check all boxes that are true.) <input type="checkbox"/> The capability of these <u>children</u> (taking into account the ages, maturity, and psychological state of the <u>children</u> involved) is so limited that they cannot reasonably be consulted. <input type="checkbox"/> The <u>intervention</u> or procedure involved in the <u>research</u> holds out a prospect of direct benefit that is important to the health or well-being of the <u>children</u> and is available only in the context of the <u>research</u> . <input type="checkbox"/> Assent is waived under 45 CFR 46.116(f) (See Section 8 above). <input type="checkbox"/> Assent is waived under 45 CFR 46.116(e) (See Section 9 above).
12	Documentation of assent (Check if "Yes." At least one must be checked)
<input type="checkbox"/>	Assent will be documented. Specify the process for documentation: <input type="checkbox"/> Investigator will document assent using an assent form. <input type="checkbox"/> Other (NOTE: The protocol needs to describe the process of assent documentation.)

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

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<input type="checkbox"/>	Assent will not be documented. <i>Provide protocol specific findings justifying this determination:</i>
13 Summary - The research meets all of the following: (Check if "Yes." All must be checked)	
<input type="checkbox"/>	The <u>research</u> falls into one of the following categories of <u>research</u> involving <u>children</u> : (Check box that is true)
<input type="checkbox"/>	Section 1 Criteria
<input type="checkbox"/>	Section 2 Criteria
<input type="checkbox"/>	Section 3 Criteria
<input type="checkbox"/>	Section 4 Criteria
<input type="checkbox"/>	Adequate provisions are made for soliciting the permission of parents or guardians. (Section 6)
<input type="checkbox"/>	Adequate provisions are made for soliciting and documenting the assent of the <u>children</u> . (Section 10)
<input type="checkbox"/>	One of the following is true: (Check the one that is true)
<input type="checkbox"/>	The <u>research</u> falls into Section 1 or 2. (permission from one parent or guardian allowable)
<input type="checkbox"/>	The <u>research</u> 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)
<input type="checkbox"/>	The <u>research</u> 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)