

CHECKLIST: Wards

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This checklist is used to determine and document whether non-exempt <Human Research> involving <Children> who are <Wards> can be approved.

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All criteria in 1 or 2 must be met

1. Research involving <Wards> as subjects involving the first two categories of research involving <Children> 45 CFR §46.409; 21 CFR §50.56

- 1.1 The research meets the criteria in Section 1 or 2 of "CHECKLIST: Children (HRP-310)"
- 1.2 Provisions for soliciting the assent of the <Children> and the permission of their parents or guardians meet the criteria in Sections 2 and 3 of "CHECKLIST: Children (HRP-310)"

2. Research involving <Wards> as subjects involving the last two categories of research involving <Children> 45 CFR §46.409; 21 CFR §50.56

- 2.1 One of the following is true:
- The research is related to the subject's 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>

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- 2.2 An advocate has been appointed for each child who is a <Wards> (see Footnote 1)

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- 2.3 Each advocate has the background and experience to act in, and agrees to act in, the best interests of the child for the duration of the child's participation in the research

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- 2.4 Each 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

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3. Notes

4. Footnotes

- 4.1 The advocate is in addition to any other individual acting on behalf of the child as guardian or in loco parentis. One individual may serve as advocate for more than one child.