AdventHealth Orlando

CHECKLIST: Children

Document No.:	Edition No.:	Effective Date:	Page:
HRP-310	002	05 APR 2019	1 of 3

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

Ⓟ

One or more of the categories in Section 1 must be met *For multi-armed studies that fit into multiple categories, describe in Notes section*

1. Categories of allowable research for children

Cat 1.1 Research involving no greater than <Minimal Risk> *45 CFR §46.404; 21 CFR §50.51*

1.1.1	☐	No greater than <Minimal Risk> to <Children> is presented
	ⓘ	
1.1.2	☐	There are adequate provisions for soliciting the permission of parents or guardian (see criteria in Section 2) and the assent of children (see criteria in Section 3)
Notes:		

Cat 1.2 Research involving greater than <Minimal Risk>, but with a prospect of direct benefit to the individual subjects *45 CFR §46.405; 21 CFR §50.52*

1.2.1	☐	The research involves procedures that present greater than <Minimal Risk> to <Children>
	ⓘ	
1.2.2	☐	The research procedures that present greater than <Minimal Risk> to <Children> hold out the prospect of direct benefit for the individual subject or are likely to contribute to the subject's well-being
	ⓘ	
1.2.3	☐	The risk is justified by the anticipated benefit to the individual subjects
1.2.4	☐	The relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches
	ⓘ	
1.2.5	☐	There are adequate provisions for soliciting the permission of parents or guardian (see criteria in Section 2) and the assent of children (see criteria in Section 3)
Notes:		

Cat 1.3 Research involving greater than minimal risk, no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition *45 CFR §46.406; 21 CFR §50.53*

1.3.1	☐	The research involves procedures that present greater than <Minimal Risk> to <Children>
	ⓘ	
1.3.2	☐	The risk represents a minor increase over <Minimal Risk>
	ⓘ	
1.3.3	☐	The research procedures that present greater than <Minimal Risk> to <Children> do not hold out the prospect of direct benefit for the individual subject or are not likely to contribute to the subject's well-being
	ⓘ	
1.3.4	☐	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
	ⓘ	
1.3.5	☐	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
	ⓘ	
1.3.6	☐	There are adequate provisions for soliciting the permission of parents or guardian (see criteria in Section 2) and the assent of children (see criteria in Section 3)
Notes:		

Cat 1.4 Research that is not otherwise approvable *45 CFR §46.407; 21 CFR §50.54*

1.4.1	☐	The research does not meet the requirements of Sections 1-3
	ⓘ	
1.4.2	☐	The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of <Children>
	ⓘ	
1.4.3	☐	An applicable official, after consultation with a panel of experts in pertinent disciplines and after opportunity for public review and comment, has determined either that the research meets the above conditions or (1) the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of <Children>; (2) the research will be conducted in accordance with sound ethical principles; and (3) adequate provisions are made for soliciting the assent of <Children> and the permission of their parents or <Guardians> (see Footnote 1)
1.4.4	☐	There are adequate provisions for soliciting the permission of parents or guardian (see criteria in Section 2) and the assent of children (see criteria in Section 3)
Notes:		

2. Adequate provisions for soliciting the permission of parents or guardian *45 CFR §46.408(b); 21 CFR §50.55(b)*

2.1	☐	Both parents must give their permission unless one parent is deceased, unknown, incompetent, or not reasonably available, or only one parent has legal responsibility for the care and custody of the child
2.2	☐	The permission of one parent is sufficient even if both parents are alive, known, competent, reasonably available, and shares legal responsibility for the care and custody of the child(Allowed only for criteria in Sections 1 and 2)
2.3	☐	Parental permission is waived per "CHECKLIST: Waiver of Consent HHS (HRP-300)" or by meeting all criteria in Section 4

3. Adequate provisions for soliciting the assent of the <Children> *45 CFR §46.408(a); 21 CFR §50.55(a)*

	☐	Assent is required of: ○ All <Children> ○ All <Children> except those determined by the investigator to have capability so limited that they cannot reasonably be consulted ○ None of the <Children> because their capability is so limited that they cannot reasonably be consulted ○ None of the <Children> because 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 ○ None of the <Children> because assent is waived by meeting all criteria in Section 5 or Section 6 ○ Other (specify): _____
3.2	☐	Written documentation of assent: ○ Will be by the child signing an assent form for children _____ years or older ○ Will be by a statement of the research team on the consent form ○ Will be by the child signing the consent form ○ Is not required ○ Other (specify): _____

4. Waiver of parental permission when permission is not a reasonable requirement *45 CFR §46.408(c)*

4.1	☐	The research is designed for conditions or a subject population for which parental or guardian permission is not a reasonable requirement to protect subjects
	ⓘ	
4.2	☐	An appropriate mechanism for protecting the <Children> who will participate as subjects in the research is substituted (see Footnote 2)
	ⓘ	
4.3	☐	The waiver is not inconsistent with Federal, State, or local law
	ⓘ	
4.4	☐	The research is not FDA-regulated

5. Waiver of assent for research involving no more than <Minimal Risk> to subjects *45 CFR §46.116(d)*

5.1	☐	The research involves no more than <Minimal Risk> to the subjects
	ⓘ	
5.2	☐	The waiver or alteration will not adversely affect the rights and welfare of the subjects
	ⓘ	
5.3	☐	The research could not practicably be carried out without the waiver or alteration
	ⓘ	
5.4	☐	Whenever appropriate, the subjects will be provided with additional pertinent information after participation
	ⓘ	

6. Waiver of assent for state or local government research *45 CFR §46.116(c)(1)*

6.1	☐	The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine one or more of the following: (1) Public benefit or service programs; (2) Procedures for obtaining benefits or services under those programs; (3) Possible changes in or alternatives to those programs or procedures; or (4) Possible changes in methods or levels of payment for benefits or services under those programs
	ⓘ	
6.2	☐	The research could not practicably be carried out without the waiver or alteration
	ⓘ	
6.3	☐	The research is not FDA-regulated

7. Notes

8.	Footnotes
8.1	For DHS, EPA, HHS, or VA research the applicable official is the Department Secretary. For DOD research, the applicable official is the Director, Defense, Research, and Engineering. For federal research, the meeting is announced in the Federal Register. For all other research , the applicable official is the <Organizational Official>.
8.2	The choice of an appropriate mechanism depends upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.