Avera

Institutional Review Board

Checklist: Children

NUMBER | HRP-416

IRB Number:	
Protocol Name:	
Investigator:	

1 The research meets all of the following: (all must be checked)

The research falls into ONE of the following categories of research involving children: (Check box that is true)

☐ Section 2 Criteria No greater than Minimal Risk	☐ Section 3 Criteria Greater than minimal risk, with direct benefit	☐ Section 4 Criteria Greater than minimal risk, NO direct benefit, but generalizable knowledge	☐ Section 5 Criteria Not otherwise approvable

☐	Adequate provisions are made for soliciting the permission of parents or guardians. (Everyone will COMPLETE Section 7)
☐	Adequate provisions are made for soliciting the assent of the children. (Everyone will COMPLETE Section 12)
☐	☐ The research at Avera does not knowingly involve Wards of the State. NOTE: Per Section 6 below: *Avera SOP 503 states, "Avera will not review research that knowingly involves Wards of the State."

Next, Complete One of these Sections: 2, 3, 4 OR 5, as selected above

Section 2 Minimal Risk research involving Children CATEGORY 1 **21 CFR §50.51 / 45 CFR §46.404**

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

Next, SKIP to Section 7

Section 3 Greater than minimal risk research involving Children with direct benefit CATEGORY 2 **21 CFR §50.52 / 45 CFR §46.405**

☐	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:*
☐	Risk versus benefit is as favorable as alternative approaches. *Provide protocol specific findings justifying this determination:*

Next, SKIP to Section 7

Section 4 Greater than minimal risk research involving children with no direct benefit, but will yield generalizable knowledge CATEGORY 3 **21 CFR §50.53 / 45 CFR §46.406**

☐	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.) *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:*
	Next, SKIP to Section 7

Section 5 Research not otherwise approvable involving children CATEGORY 4 **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:*
	Next, SKIP to Section 7

Section 6 Research involving wards of the state or any other agency, institution, or entity under 45 CFR §46.409

*Avera SOP 503 states, "Avera will not review research that knowingly involves Wards of the State."

Section 7 Adequate provisions for soliciting the permission of parents or guardians. (This section MUST be completed.)

☐	One of the following is true: (Check the 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, reasonable available, and shares legal responsibility for the care and custody of the child. (This one cannot be selected for the above Sections 4 or Section 5 criteria) ☐ Parental permission is waived under criteria in Section 8, 9, 10 or 11, and PI submitted a Waiver of Parental Permission. Next, proceed to the applicable section, which will be either 8, 9, 10 or 11 below.

Section 8 Waiver of Parental Permission under 45 CFR §46.408(c) (ONLY complete if appropriate, and a Waiver Application accompanied the submission. If so, 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:*

Section 9 Waiver of Parental Permission under 45 CFR §46.116(d) (ONLY complete if appropriate, and a Waiver Application accompanied the submission. If so, 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. (N/A if research does not use identifiable private information or biospecimens, or if the research is not subject to the 2018 Rule) ☐ N/A *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. ☐ N/A if waiving informed consent ☐ This does not apply because the research is not subject to the 2018 Rule.
	Section 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"[i] (ONLY complete if appropriate, and a Waiver Application accompanied the submission. If so, 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:*
	Section 11 Waiver of Parental Permission under 45 CFR §46.408 (c)/45 CFR §46.116(c) (ONLY complete if appropriate, and a Waiver Application accompanied the submission. If so, 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:*
	Section 12 Adequate provisions to solicit the assent of children. (Section 12 MUST be completed.)
☐	Assent will be obtained from : (Check box that is true) ☐ All children. (Next, SKIP to Section 14) ☐ None of the children. (Next, SKIP to Section 13) ☐ Some children. (Complete Section 13 and Section 14. The protocol needs to describe which children will not be asked for assent)

Section 13 Reason why assent is not necessary as under 45 CFR §46.408(a)/21 CFR §50.55(c) *Only complete this section if directed here from Section 12 above.*	
☐	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 or 16, and PI submitted a Waiver of Assent. Complete Section 15 or 16 below.
Section 14 Documentation of assent. *Only complete this section if directed here from Section 12 above*	
	☐ Investigator will document assent on an Assent Form. OR ☐ Other (NOTE: The protocol needs to describe the process of assent documentation)
Section 15 Waiver of child assent under 45 CFR §46.408(a) / 45 CFR §46.116(c) / 21 CFR §50.55(d) (ONLY complete if appropriate, and a Waiver of Assent accompanied the submission. If so, 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. ☐ This does not apply as the research does not use identifiable private information or biospecimens OR ☐ This does not apply because the research is not subject to the 2018 Rule. *Provide protocol specific findings justifying this determination:*
Section 16 Waiver of Child Assent Under 45 CFR §46.408(a) / 45 CFR §46.116(d) (ONLY complete if appropriate, and a Waiver of Assent accompanied the submission. If so, 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 of alteration.

Please turn this form into the IRB Office with your other completed checklists.

REVIEWER NAME: DATE: