1 The research meets all of the following: (All must be "Yes")	
☐ Yes ☐ No	The research falls into one of the following categories of research involving children: (Check box that is true) ☐ CATEGORY 21 CFR §50.51/45 CFR §46.404 (Complete Section 2) ☐ CATEGORY 21 CFR §50.52/45 CFR §46.405 (Complete Section 3) ☐ CATEGORY 21 CFR §50.53/45 CFR §46.406 (Complete Section 4) ☐ CATEGORY 21 CFR §50.54/45 CFR §46.407 (Complete Section 5)
☐ Yes ☐ No	Adequate provisions are made for soliciting the permission of parents or guardians. (Complete Section 7)
☐ Yes ☐ No	Adequate provisions are made for soliciting the assent of the children. (Complete Section 12)
☐ Yes ☐ No	One of the following is true related to children who are wards of the state or any other agency, institution, or entity: (Check box that is true) ☐ The research does NOT involve children who are wards of the state or any other agency, institution, or entity OR The research falls into CATEGORY 21 CFR §50.51, 50.52/45 CFR §46.404, 46.405 ☐ The research involves children who are wards of the state or any other agency, institution, or entity and falls into CATEGORY 21 CFR §50.53, 50.54/45 CFR §46.406, 46.407 (Complete Section 6)

2 CATEGORY 21 CFR §50.51/45 CFR §46.404 (All must be "Yes")	
☐ Yes ☐ No	No greater than minimal risk to children is presented. *Provide protocol specific findings justifying this determination:*

3 CATEGORY 21 CFR §50.52/45 CFR §46.405 (All items in the left most columns must be "Yes")	
☐ Yes ☐ No	The research involves greater than minimal risk[1] to subjects. *Provide protocol specific findings justifying this determination:*
☐ Yes ☐ No	The research presents the prospect of direct benefit to the individual subjects. *Provide protocol specific findings justifying this determination:*
☐ Yes ☐ No	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 the checked determination:*
☐ Yes ☐ No	The risk is justified by the anticipated benefit to the subjects. *Provide protocol specific findings justifying this determination:*
☐ Yes ☐ No	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:*

[1] **Minimal risk** means that the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life of normal children or during the performance of routine physical or psychological examinations or tests in normal children.

4 CATEGORY 21 CFR §50.53/45 CFR §46.406 (All must be "Yes")	
☐ Yes ☐ No	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:*
☐ Yes ☐ No	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.[2]) *Provide protocol specific findings justifying this determination:*
☐ Yes ☐ No	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:*
☐ Yes ☐ No	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:*

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

5 CATEGORY 21 CFR §50.54/45 CFR §46.407[3] (All must be "Yes")	
☐ Yes ☐ No	The research does not meet the requirements of 21 CFR §50.51/45 CFR §46.404, 21 CFR §50.5/45 CFR §46.405, or 21 CFR §50.53/45 CFR §46.406. *Provide protocol specific findings justifying this determination:*
☐ Yes ☐ No	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:*

[3] For FDA-regulated research, the research may proceed only after FDA has reviewed and approved the research. For DHHS-regulated research, the research may proceed only after OHRP has reviewed and approved the research. For research conducted or funded by the Department of Defense (DOD) the research may proceed only after the Director, Defense, Research and Engineering has reviewed and approved the research.

6 Research Involving Children who are Wards of the State or Any Other Agency, Institution, or Entity for Research Approved under 21 CFR §50.53/45 CFR §46.406, or 21 CFR §50.54/45 CFR §46.407 (21 CFR 50.56/45 CFR §46.409) (All must be "Yes")	
☐ Yes ☐ No	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 the checked determination:*
☐ Yes ☐ No	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 for research approved under §46.406 or §46.407. *Provide protocol specific findings justifying this determination:*
☐ Yes ☐ No	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:*
☐ Yes ☐ No	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:*

7 Adequate provisions for Soliciting the Permission of Parents or Guardians (Must be "Yes")	
☐ Yes ☐ No	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 21 CFR §50.53, 50.54/45 CFR §46.406, 46.407) ☐ Parental permission is waived under 45 CFR §46.408(c). (Complete Section 8) ☐ Parental permission is waived under 45 CFR §46.408(c)/45 CFR §46.116(d). (Complete Section 9) ☐ Parental permission is waived under FDA Guidance "IRB Waiver or Alteration of Informed Consent for Clinical Investigations Involving No More Than Minimal Risk to Human Subjects" (Complete Section 10) ☐ Parental permission is waived under 45 CFR §46.408(c)/45 CFR §46.116(c). (Complete Section 11)

8 Waiver of Parental Permission (45 CFR §46.408(c)) (All must be "Yes")	
☐ Yes ☐ No	The research is not FDA-regulated.
☐ Yes ☐ No	The research does not involve non-viable neonates.
☐ Yes ☐ No	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:*
☐ Yes ☐ No	An appropriate mechanism for protecting the children who will participate as subjects in the research is substituted. *Provide protocol specific findings justifying this determination:*
☐ Yes ☐ No	The waiver is not inconsistent with Federal, State, or local law. *Provide protocol specific findings justifying this determination:*

9 Waiver of Parental Permission (45 CFR §46.408(c)) (All must be "Yes" or "Not Applicable")	
☐ Yes ☐ No	The research is not FDA-regulated.
☐ Yes ☐ No	The research does not involve non-viable neonates.
☐ Yes ☐ No	The research involves no more than minimal risk to the subjects. *Provide protocol specific findings justifying this determination:*
☐ Yes ☐ No	The waiver or alteration will not adversely affect the rights and welfare of the subjects. *Provide protocol specific findings justifying this determination:*
☐ Yes ☐ No	The research could not practicably be carried out without the waiver or alteration *Provide protocol specific findings justifying this determination:*
☐ Yes ☐ No ☐ Not Applicable	Whenever appropriate, the subjects will be provided with additional pertinent information after participation. *Provide protocol specific findings justifying this determination:*

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] (All must be "Yes" or "Not Applicable")	
☐ Yes ☐ No	The research IS FDA-regulated.
☐ Yes ☐ No	The research involves no more than minimal risk to the subjects. *Provide protocol specific findings justifying this determination:*
☐ Yes ☐ No	The waiver or alteration will not adversely affect the rights and welfare of the subjects. *Provide protocol specific findings justifying this determination:*
☐ Yes ☐ No	The research could not practicably be carried out without the waiver or alteration *Provide protocol specific findings justifying this determination:*
☐ Yes ☐ No ☐ Not Applicable	Whenever appropriate, the subjects will be provided with additional pertinent information after participation. *Provide protocol specific findings justifying this determination:*

11 Waiver of Parental Permission (45 CFR §46.408(c)) (All must be "Yes" or "Not Applicable")	
☐ Yes ☐ No	The research is not FDA-regulated.
☐ Yes ☐ No	The research does not involve non-viable neonates.
☐ Yes ☐ No	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:*
☐ Yes ☐ No	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:*
☐ Yes ☐ No	The research could not practicably be carried out without the waiver or alteration. *Provide protocol specific findings justifying this determination:*

12 Adequate Provisions to Solicit the Assent of Children (Must be "Yes")	
☐ Yes ☐ No	Assent is required from: (Check box that is true) ☐ All children. (Complete Section 14) ☐ None of the children. (Complete Section 13) ☐ Some children. (Indicate which children below and Complete Section 14) ☐ Assent is required from children who have the maturity and cognitive ability to be consulted. ☐ Assent is required from children meeting these criteria:

13 Reason Why Assent is Not Necessary (Must be "Yes")	
☐ Yes ☐ No	One or more of the following are true. (Check all boxes that are true.) ☐ The capability of the children being studied is so limited that they cannot reasonably be consulted (45 CFR §46.408(a)/21 CFR §50.55(c)). ☐ 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 being studied and is available only in the context of the research (45 CFR §46.408(a)/21 CFR §50.55(c)). ☐ Assent is waived under 45 CFR §46.116(d)/21 CFR §50.55(d). (Complete Section 15) ☐ Assent is waived under 45 CFR §46.116(c). (Complete Section 16)

14 Documentation of Assent (May be "Yes" or "No")	
☐ Yes ☐ No	If "Yes", specify the process for documentation: ☐ Investigator will document assent in the consent signature block. ☐ Assent will be documented on the assent form. ☐ Other:

15 Waiver of Child Assent (45 CFR §46.408(c)/21 CFR §50.55(c)) (All must be "Yes" or "Not Applicable")	
☐ Yes ☐ No	The research involves no more than minimal risk to the subjects.
☐ Yes ☐ No	The waiver or alteration will not adversely affect the rights and welfare of the subjects.
☐ Yes ☐ No	The research could not practicably be carried out without the waiver or alteration.
☐ Yes ☐ No ☐ Not Applicable	Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

16 Waiver of Child Assent (45 CFR §46.408(a)) (All must be "Yes")	
☐ Yes ☐ No	The research is not FDA-regulated.
☐ Yes ☐ No	The research or demonstration project is to be conducted by or subject to the approval of state or local government officials
☐ Yes ☐ No	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.) ☐ 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.
☐ Yes ☐ No	The research could not practicably be carried out without the waiver or alteration.

[i] https://www.fda.gov/downloads/RegulatoryInformation/Guidances/UCM566948.pdf.