Boston Children's Hospital

Reviewer Worksheet New Protocols: Full Review

PI Last Name:	**Reviewer Name:**
Protocol Number:	**Meeting Date:**

Reviewer Criteria

☐	I do not have a conflicting interest[1]

NOTE: For research funded by or involving Department of Defense (DOD)[2], Department of Justice (DOJ)[3], or Department of Education/School Based Research[4], please also complete *"Reviewer Worksheet: DOD, DOJ, Dept .of Ed/School Based Research"*

Criteria for Approval

☐ YES ☐ NO	**1. Risks to participants are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose participants to risk.** **Points to Consider:** • Consider physical, psychological, social, legal, and economic risks. • Has the appropriate departmental scientific review occurred? • Are the aims and objectives clearly defined? • Are there adequate preliminary data and is there appropriate justification for the research? • Would alternative procedures or subject populations reduce the likelihood or magnitude of harm, but still answer the question? • Are there qualified staff and resources to conduct the research? • Is there appropriate monitoring of the subject during and after the research? • Are medical or psychological resources available that participants might require as a consequence of the research? • Are adequate references provided? **Comments:**
☐ YES ☐ NO	**2. Risks to participants are minimized whenever appropriate, by using procedures already being performed on the participants for diagnostic or treatment purposes.** **Points to Consider:** • Consider physical, psychological, social, legal, and economic risks. • Are procedures that will answer the scientific question being performed anyway? • If so, can the data from these procedures be used to reduce the likelihood or magnitude of harm? • Is there a clear differentiation between research and standard of care procedures? **Comments**:
☐ YES ☐ NO	**3. Risks to participants are reasonable in relation to anticipated benefits, if any, to participants, and the importance of the knowledge that may reasonably be expected to result.** **Points to Consider:** • Consider physical, psychological, social, legal, and economic risks. Are the risks and benefits adequately described? • Does the investigator have access to a population that will allow recruitment of the necessary number of participants? • Does the investigator have sufficient time to conduct and complete the research? • Is the research and timeline for completion feasible? • Does the knowledge expected to result have importance? • Are there adequate plans to notify the subjects about the research results (clinical issues, suicidal, referrals) **Comments:**

[1] See IRB Guidance 14.1: Institutional Review Board Conflict of Interest Policy
[2] See IRB Guidance 11.11: Research Involving Department of Defense Funding
[3] See IRB Guidance 11.16: Research Involving Department of Justice Funding
[4] See IRB Guidance 11.5: Guidelines for Research Funded by the Department of Education and School Based Research

☐ YES ☐ NO	**4. Selection of participants is equitable.** **Points to Consider:** • Consider the purpose of the research. • Are the inclusion and exclusion criteria adequately defined and equitable? • Are there populations vulnerable to coercion and undue influence and has this been addressed? • Are there acceptable procedures for screening subjects prior to recruitment? • If there is exclusion of women, minorities, and other vulnerable populations are they justified? **Comments**:
☐ YES ☐ NO	**5. Recruitment procedures are acceptable** **Points to Consider:** • Is the setting, location and timing of recruitment appropriate for the research being conducted? • Are recruitment methods well defined and appropriate for the population? • Are all recruitment materials non coercive, and easily understood? **Comments:**
☐ YES ☐ NO ☐ NA	**6. The research plan makes adequate provisions for monitoring the data collected to ensure the safety of participants. *(Not applicable if the research involves no more than minimal risk.)*** **Points to Consider:** • Does the protocol adequately specify: Who will monitor the data? What data will be monitored? How frequently will data be monitored? What analyses will be performed on the data? What decision rules (e.g., stopping rules) will be considered? • Is there a plan to promptly detect unexpected harms or an increase in frequency or severity of harms? • Is there an adequate plan to stop the protocol if benefits are proven to outweigh harms or harms are proven to outweigh benefits? **Comments:**
☐ YES ☐ NO	**7. There are adequate provisions to protect the privacy of participants**. **Points to Consider:** • Will participants have an expectation of privacy? • Will participants think that the information sought by the investigator is appropriate? • Will participants be comfortable in the research setting? • Are there adequate provisions to consider and assure the privacy of the subject? **Comments:**
☐ YES ☐ NO	**8. There are adequate provisions to maintain the confidentiality of the data.** **Points to Consider:** • Will confidentiality be pledged? • Are there adequate provisions to protect the confidentiality of the data? • Are there legal/ethical requirements to breach confidentiality and is this well described and addressed? • Will data release cause risk of harm? • Are appropriate techniques being used to protect confidentiality (storage, coding, use of identifiers)

	• Does the protocol and consent specify where the data and consent form will be stored? **Comments:**
☐ YES ☐ NO ☐ NA	**9. Additional safeguards have been included in the study to protect the rights and welfare of participants likely to be vulnerable to coercion or undue influence. (do not complete if these populations are not included, there is a separate section for children)** **Points to Consider**: • If the research involves pregnant women, fetuses, complete *Research Involving Pregnant Women and Fetuses* checklist. • If the research involves prisoners complete *Research Involving Prisoners* checklist. **Comments:**
☐ YES ☐ NO ☐ NA	**10. Other considerations** • If this is multi-site research, is the management of information that might be relevant to the protection of subjects adequate.

11. Subpart D. <u>Regulatory Determinations for Inclusion of Children</u> ☐ NA

A. Level of Risk: (please check category, for studies that involve more than one arm you may need to check multiple categories)

☐ No greater then minimal risk.

☐ Greater then minimal risk **<u>with</u>** prospect of direct benefit.
More than minimal risk to children is presented by **(check both or one):**

- ☐ an intervention or procedure that holds out the prospect of direct benefit for the individual subject
- ☐ a monitoring procedure which is likely to contribute to the well-being of the subject

In addition (both must be checked):

- ☐ **a.** the risk is justified by the anticipated benefit to the subjects

<u>AND</u>

- ☐ **b.** the relation of the anticipated benefit to the risk is at least as favorable to the subjects as that presented by available alternative approaches.

☐ Greater than minimal risk **<u>with no</u>** prospect of direct benefit but likely to yield generalizable knowledge about the subject's disorder or condition. More than minimal risk to children is presented by**(check both or one**):

- ☐ an intervention or procedure that does **<u>not</u>** hold out the prospect of direct benefit for the individual subject.
- ☐ a monitoring procedure which is **<u>not</u>** likely to contribute to the well-being of the subject

In addition (all must be checked):

- ☐ **a.** the risk represents a minor increase over minimal risk
- ☐ **b.** the intervention or procedure presents experiences to subjects that are reasonably commensurate with those expected in the daily life, medical, psychological, social educational situations:

<u>AND</u>

- ☐ **c.** the intervention or procedure is likely to yield generalizable knowledge about the subject's disorder or condition which is of vital importance for the understanding or amelioration of the subjects' disorder or condition.

Both parents must give their permission 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.

☐ None of the permissible categories apply to proposed research. → **STOP! Will need to Consult HHS/FDA. Subpart D NOT MET**.

Comments:

B. Parental permission – check as appropriate:

☐ Consent of one parent

☐ Consent of both parents required → If greater than minimal risk, without potential for benefit.

→ Other reason based on this protocol.

☐ Waiver of parental permission. **If waiver is requested, please check one of the following conditions,. There are two regulatory mechanisms to allow waiver of parental permission. Investigators have a choice which mechanism to choose. (Note this waiver cannot be applied to FDA regulated research).**

☐ Parental permission waived under Subpart D. Parental or guardian permission is not a reasonable requirement to protect the subjects (for example neglected or abused children), provided an appropriate mechanism for protecting the children who will participate as subjects in the research is substituted, and provided further that the waiver is not inconsistent with Federal, State or local law.

☐ Parental permission waived
The research involves no more than minimal risk to the subjects
The waiver/alternation will not adversely affect the rights and welfare of the subjects
The research could not practicably be carried out without the waiver or alteration, and
When appropriate, the subject will be provided with pertinent information after participation

Comments:

C. Assent of Children

In determining whether children are capable of assenting, take into account the ages, maturity and psychological state of the children involved. This judgment may be made for all children to be involved in research under a particular protocol, or for each child.

Please check one:

☐ Some or all of the children involved in the research are capable of assenting.
If required:
☐ separate assent form required
☐ assent on parental permission form

☐ Assent is not required because the capability of some or all of the children is limited (age, psychological state, sedation)

☐ Assent is not required 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.

Comments:

D. Wards of State

Has the investigator indicated that is likely that wards will be recruited in the study? ☐ YES ☐ NO

↳ ***If YES:***

1. Has the investigator ensured that the appropriate person grants permission for each ward to participate in the research and provided a mechanism to determine whether there has been a change in guardianship status during the course of the research and permission should be obtained from the new guardian? ☐ YES ☐ NO

2. If the research is **Greater than Minimal Risk** and **No Potential for Direct Benefit,** have plans for an advocate been clarified? ☐ YES ☐ NO

   Please check one as it applies:

   ☐ The research relates to the participants' status as wards,

OR

☐ The research is conducted in schools, camps, institutions, or similar settings where the majority of children involved as participants are not wards.

Comments:

12. INFORMED CONSENT PROCESS: Informed consent will be sought from each prospective subject or subject's legally authorized representative Complete if informed consent will be obtained.	
☐ YES ☐ NO	**The investigator will obtain the legally effective informed consent of the participant or the participant's legally authorized representative.** **Points to Consider**: Has the investigator indicated whether consent will be obtained from the participant, from a legally authorized representative, or both? Are steps taken to help the participants or representatives understand the facts? Are adequate steps taken to help the participants or representatives understand the research and the associated ramifications? Does the investigator adequately address how he/she will determine that a subject understands the research prior to providing consent/assent? **Comments:**
☐ YES ☐ NO	**The circumstances of consent provide the prospective participant or the representative sufficient opportunity to consider whether or not to participate.** **Points to Consider:** Is adequate time devoted to the consent discussion and decision making process? Do the circumstances of consent minimize the possibility of coercion or undue influence? Have all issues regarding the capacity to make a decision been addressed? **Comments:**
☐ YES ☐ NO	**The circumstances of consent minimize the possibility of coercion or undue influence**. **Points to Consider:** Are consent procedures well defined? Are the timing, location and setting of obtaining consent acceptable? Are payment arrangements acceptable? Will parents and children be compensated and if so is the amount fair and distributed appropriately between parent and child? If study procedures are not complete or a subject withdraws is there any pro-rating of compensation? Are there plans so families avoid out of pocket expenses in order to participate? **Comments:**
☐ YES ☐ NO	**The information that will be given to the participant or the representative will be in language understandable to the participant or the representative**. **Points to Consider:** What language do the participants or representatives speak? Can the research team communicate in understandable language to the participants or representatives? Will written information be in the language understandable to the participants or representatives? **Comments:**
☐ YES ☐ NO	**No information will be provided to the participant or the representative that waives or appears to waive any of the participant's legal rights, or that releases or appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence**.

	Comments:

13. INFORMED CONSENT FORM: Informed consent will be appropriately documented in accordance with the regulations checklist			
A statement that the study involves research.	☐ YES	☐ NO	
An explanation of the purposes of the research.	☐ YES	☐ NO	
An explanation of the expected duration of the participant's participation.	☐ YES	☐ NO	
A description of the procedures to be followed.	☐ YES	☐ NO	
Identification of procedures that are experimental. (May be omitted if there are none.)	☐ YES	☐ NO	☐ NA
A description of any reasonably foreseeable risks or discomforts to the participant. (May be omitted if there are none.)	☐ YES	☐ NO	☐ NA
A description of any benefits to the participant or to others, which may reasonably be expected from the research. (May be omitted if there are none.)	☐ YES	☐ NO	☐ NA
A disclosure of appropriate alternative procedures or courses of treatment, if any, that may be advantageous to the participant. (May be omitted if there are none.)	☐ YES	☐ NO	☐ NA
A statement describing the extent, if any, to which confidentiality of records identifying the participant will be maintained. (May be omitted if confidentiality will not be maintained.)	☐ YES	☐ NO	☐ NA
A statement that notes the possibility that the Food and Drug Administration may inspect the records (May be omitted for research that is not FDA-regulated.)	☐ YES	☐ NO	☐ NA
An explanation as to whether compensation is available if injury occurs. (May be omitted if the research involves no more than minimal risk.)	☐ YES	☐ NO	☐ NA
If compensation is available when injury occurs, an explanation as to what it consists of or where further information may be obtained. (May be omitted if the research involves no more than minimal risk.)	☐ YES	☐ NO	☐ NA
An explanation as to whether any medical treatments are available if injury occurs. (May be omitted if the research involves no more than minimal risk.)	☐ YES	☐ NO	☐ NA
If medical treatments are available when injury occurs, an explanation as to what it consists of or where further information may be obtained. (May be omitted if the research involves no more than minimal risk.)	☐ YES	☐ NO	☐ NA
An explanation of whom to contact for answers to pertinent questions about the research.	☐ YES	☐ NO	
An explanation of whom to contact for answers to pertinent questions about the research participants' rights.	☐ YES	☐ NO	
An explanation of whom to contact in the event of a research-related injury to the participant. (Note: May not be omitted just because the research involves no more than minimal risk.)	☐ YES	☐ NO	
Contact information for the research team for questions, concerns, or complaints.	☐ YES	☐ NO	
Contact information for someone independent of the research team for problems, concerns,	☐ YES	☐ NO	
A statement that participation is voluntary.	☐ YES	☐ NO	
A statement that refusal to participate will involve no penalty or loss of benefits to which participant is otherwise entitled.	☐ YES	☐ NO	
A statement that the participant can discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.	☐ YES	☐ NO	
A statement that identifiers might be removed from the identifiable information/biospecimens and, the information/biospecimens could be used for future research studies without additional informed consent or the information/biospecimens will not be used or distributed for future research studies	☐ YES	☐ NO	

Additional

A statement that the particular treatment or procedure may involve risks to the participant, which are currently unforeseeable. (Look for when research involves investigational drugs/devices, novel procedures involving risk, or where a goal of the research is to define safety.)	☐ YES	☐ NO	☐ NA
A statement that if the participant is or becomes pregnant, the particular treatment or procedure may involve risks to the embryo or fetus, which are currently unforeseeable. (Look for when the research involves pregnant women or women of childbearing potential, and the effect of the procedures have not been evaluated in pregnancy or a goal of the research is to define safety in pregnancy.)	☐ YES	☐ NO	☐ NA
Anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the participant's consent. (Look for when the protocol mentions this as a possibility.)	☐ YES	☐ NO	☐ NA
Any additional costs to the participant that may result from participation in the research. (Look for when additional costs are expected.)	☐ YES	☐ NO	☐ NA
The consequences of a participant's decision to withdraw from the research. (Look for when withdrawal from the research will have adverse consequence.)	☐ YES	☐ NO	☐ NA
Procedures for orderly termination of participation by the participant. (Look for when such procedures are part of the protocol.)	☐ YES	☐ NO	☐ NA
A statement that significant new findings developed during the course of the research which may relate to the participant's willingness to continue participation will be provided to the participant. (Look for on long-term clinical trials.)	☐ YES	☐ NO	☐ NA
The approximate number of participants involved in the study.	☐ YES	☐ NO	☐ NA
The amount and schedule of all payments to the participant.	☐ YES	☐ NO	☐ NA
A statement that the subject's biospecimens may be used for commercial profit and whether the subject will or will not share in this commercial profit;	☐ YES	☐ NO	☐ NA
Whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions;	☐ YES	☐ NO	☐ NA
For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing	☐ YES	☐ NO	☐ NA
Comments:			

14. Informed consent will be documented.

Will Consent Be Waived? ☐ YES ☐ NO

If previous answer *is YES complete item 15*

Will the Long Form Of Consent Be Used? ☐ YES ☐ NO

Answer only if previous answer *is YES:*

The consent document embodies the basic and appropriate additional elements of disclosure. *(See Elements of Informed Consent Disclosure)* ☐ YES ☐ NO

The participant or the participant's legally authorized representative will sign (and date for FDA-regulated research) the consent document. ☐ YES ☐ NO

A copy of the consent document will be given to the person signing the consent document. ☐ YES ☐ NO

The investigator will give either the participant or the representative adequate opportunity to read the consent document before it is signed. ☐ YES ☐ NO

Short Form Used? ☐ YES ☐ NO

(There is a provision in the regulations to allow verbal explanation of the research followed by the subject signing a brief statement that the research was explained. This is used most frequently when an interpreter is used for a non-English speaking subject. Since CH has funds to translate consents we generally do not use this method, however if an investigator requests this, please review and complete the separate "short form" checklist and attach to this form. It may be found on the web. The checklist all of the associated requirements

Comments:

15. Complete if there is a request for WAIVERS OR MODIFICATIONS of REQUIRED ELEMENTS IN INFORMED CONSENT ☐ NA

- **Complete if there is a complete waiver of informed consent (no consent obtained by any method)**
- **Complete if there is a request to not include one of the required elements**
- **Note this cannot apply to FDA regulated research**

If waiver or modification of required consent elements is proposed, have all the criteria been met? ☐ YES ☐ NO

1. The research involves no more than minimal risk to the subjects
2. The waiver/alternation will not adversely affect the rights and welfare of the subjects
3. The research could not practicably be carried out without the waiver or alteration
4. The research could not practicably be carried out without using the information/biospecimens in an identifiable form
5. As appropriate, the subject will be provided with pertinent information after participation

Comments:

16. Complete if there is a request WAIVER OF INFORMED CONSENT DOCUMENT. ☐ NA

- **Complete if there is another method of consent (verbal, information sheet)**

One of the criteria must be checked:

☐ The consent form would be the only record linking the subject with the research, and a potential risk would be a breach in confidentiality. In such case, each subject should be asked if they want documentation. And their wishes would govern (**cannot apply to FDA regulated research**)

or

☐ Study is no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context.

And the following apply to both sets of waiver criteria

If informed consent documentation is waived, should the investigator be required to provide subjects with a written statement regarding the research? ☐ YES ☐ NO

↳ **Answer only if previous answer *is YES:***

↳ If written statement is required, is the statement appropriate and can it be approved? ☐ YES ☐ NO

Comments:

17. Drugs, Biologics, Devices ☐ NA

WILL THIS PROTOCOL INVOLVE THE TESTING OF DRUGS & BIOLOGICS: ☐ YES ☐ NO

↳ **Answer only if previous answer *is YES:***

↳ Select category as appropriate:

a. ☐ Drug is marketed / FDA-approved & will be used as marketed/approved.
b. ☐ Drug is investigational and research is conducted under IND. IND information included and investigational drug brochure is attached.

c. ☐ Drug is marketed but being studied in an off label indication. IND information included
d. ☐ Drug is marketed but being studied in an off label indication. PI claims no IND is required. In order for no IND to be required all of the following must be true

Complete only if (d) is checked. All of the answers must be 'Yes'

Do you agree that the following are true? ☐ YES ☐ NO

- The results will not be reported to the FDA as a well-controlled study in support a new drug indication for use will it be reported or to support any significant change in the labeling of the drug?
- The study is not intended to be reported to the FDA in support of a new indication for use or to support any other significant change in labeling.
- The study is not intended to support a significant change in the advertisement for the product.
- The study does not involve a route of administration or dosage level, use in a subject population, or other factor that significantly increases the risks (or decreases the acceptability of the risks) associated with the use of the product.
- The study is conducted in compliance with the requirements for IRB review and informed consent.
- The study is conducted in compliance with the requirements for the promotion and sale of drugs.
- The study does not intend to invoke the (exceptions from informed consent for emergency research

Comments:

WILL THIS PROTOCOL INVOLVE THE TESTING OF DEVICES? ☐ YES ☐ NO

↳ **Answer only if previous answer *is YES:***

↳ Complete and select appropriate category if device is being studied:

a. ☐ Sponsor categorizes investigational device as significant risk (SR) and IDE is provided. SR documentation has been included as well as an investigational brochure about device.

b. ☐ Sponsor categorizes investigational device as non-significant risk (NSR)

Please complete if you checked **(b)**.

In order for the device to be considered a NSR, all the following must true:

Do you agree that the following are true? ☐ YES ☐ NO

- is not intended as an implant to remain more than 30 days in the human body and does not present a potential for serious risk to the health, safety, or welfare of a subject;
- is not purported or represented to be for a use in supporting or sustaining human life and does not present a potential for serious risk to the health, safety, or welfare of a subject;
- is not for a use of substantial importance in diagnosing, curing, mitigating, treating, or otherwise preventing impairment of human health and does not presents a potential for serious risk to the health, safety, or welfare of a subject;
- the device does not present a potential for serious risk to the health, safety and welfare of the subject.

d. ☐ Device is marketed / FDA-approved & will be used as marketed/approved

e. ☐ 501(k) is marketed / FDA-approved & will be used as marketed/approved

☐ documentaton attached

f. ☐Other:

Does the protocol describe acceptable accountability, storage, access, and control of the devices? ☐ YES ☐ NO

Comments:

18. Does the investigator disclose a conflict of interest? ☐ YES ☐ NO

↳ Check "YES" if any section in the Financial Disclosure section of SmartForm is checked "YES".

If Yes, please answer the following:

a. Does the protocol-specific interest have the potential to adversely affect the protection of participants in terms of the criteria for IRB approval (e.g., whether, due to the conflict, risks to subjects are made greater, rather than minimized)?	
☐ **Yes** ► please specify concerns	**Concerns/Comments:**
☐ **No**	
b. Do the risks associated with the interest compared to benefits remain reasonable?	
☐ **Yes**	**Concerns/Comments:**
☐ **No** ► please comment	
c. Does the interest permit subject selection to remain equitable and unbiased?	
☐ **Yes**	**Concerns/Comments:**
☐ **No** ► please comment	
d. Will the interest and the current protocol design have the potential to adversely affect the integrity of the research?	
☐ **Yes** ► please specify concerns	**Concerns/Comments:**
☐ **No**	

e. Please review comments and recommendations from COI officers (in CHERP HISTORY LOG) and check one:

☐ **Accept recommendation from COI officer; no additional actions required,** *or*

☐ **Requests actions or information in addition to recommendation(s) from COI officer**

► Please check all that apply:

- ☐ Limit the researcher's role in the study. Consider, for example, prohibiting recruitment of or obtaining consent from potential research volunteers.
  Provide details:
- ☐ Restrict data collection or analysis activities.
  Provide details:
- ☐ Require a monitor for the initial consent process with potential research volunteers.
  Provide details:
- ☐ Require an independent Data and Safety Monitoring Board, or someone external to oversee the conduct of a study, or evaluate study outcomes or adverse events
  Provide details:
- ☐ Eliminate the conflict either by removing the individual with the conflict from the study or requiring the individual to reduce the interest to a permissible level:
  Provide details:
- ☐ Include interest in informed consent form
  Provide details:
- ☐ Other actions

Provide details:

19. Are Pregnant Women or Fetuses Involved ☐ YES ☐ NO

If Yes please answer these questions: If no skip to 19

(a) Pre-clinical data available: Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on non-pregnant women, have been conducted **AND** provide data for assessing potential risks to pregnant women and fetuses [Data is available to assess risks to pregnant women & fetuses] [§46.204(a)]

☐ **No** ▶ STOP! §46.204 **NOT** met.	**Comments**
☐ **Yes**	
☐ **N/A** [i.e. not scientifically appropriate]	

(b) Risk/Benefit ratio: Does the research hold out the prospect of direct benefit for the woman OR fetus? [§46.204(b)]

☐ **No** ▶	Is the risk to fetus greater than minimal?	☐ **No** ▶	Is the purpose of the research for the development of important biomedical knowledge which cannot be obtained by any other means?	☐ **No** ▶ STOP! §46.204 **NOT** met.
				☐ **Yes**
		☐ **Yes**▶ STOP! §46.204 **NOT** met.		
☐ **Yes**▶	Is the risk to the fetus caused *solely* by interventions or procedures that hold out the prospect of direct benefit for woman OR fetus?			☐ **No** ▶ STOP! §46.204 **NOT** met.
				☐ **Yes**

Comments

(c) Least possible risk: Any risk is the least possible for achieving the objectives of the research. [§46.204(c)]

☐ **No** ▶ STOP! §46.204 **NOT** met.	**Comments**
☐ **Yes**	

(d) Consent of woman: Consent of pregnant woman is obtained in accord with the informed consent provisions of subpart A. [§46.204(d)]

☐ **No** ▶ STOP! §46.204 **NOT** met.	**Comments**
☐ **Yes**	

(e) Consent of father: If the research holds out the prospect of direct benefit solely to the fetus then the consent of the pregnant woman and the father is obtained in accord with the informed consent provisions of subpart A of this part, except that the father's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or the pregnancy resulted from rape or incest. [§46.204(e)]

☐ **No** ▶ STOP! §46.204 **NOT** met.	**Comments**
☐ **Yes**	
☐ **N/A** [i.e. research benefits woman or direct benefit solely to fetus does not apply]	

(f) Consent includes impact on fetus/neonate: Each individual providing consent under paragraph (d) or (e) of this section is fully informed regarding the reasonably foreseeable impact of the research on the fetus or neonate. [§46.204(f)]

☐ **No** ▶ STOP! §46.204 **NOT** met.	**Comments**
☐ **Yes**	

(g) Pregnant children: For children as defined in Sec. 46.402(a) who are pregnant, assent and permission are obtained in accord with the provisions of subpart D of this part. [§46.204(g)]

☐ **No** ▶ STOP! §46.204 **NOT** met.	**Comments**
☐ **Yes**	
☐ **N/A** [i.e. children not enrolled]	

(h) Inducements: No inducements, monetary or otherwise, will be offered to terminate a pregnancy [§46.204(h)]	
☐ **No** ► STOP! §46.204 **NOT** met.	**Comments**
☐ **Yes** (Statement is true)	

(i) Pregnancy termination: Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy. [§46.204(i)]	
☐ **No** ► STOP! §46.204 **NOT** met.	**Comments**
☐ **Yes** (Statement is true)	

(j) Neonate viability: Individuals engaged in the research will have no part in determining the viability of a neonate. [§46.204(j)]	
☐ **No** ► STOP! §46.204 **NOT** met.	**Comments**
☐ **Yes** (Statement is true) ►Subpart B: §46.204 [for pregnant women or fetuses] met.	

20. Does the research meet FDAA or ICMJE criteria[5] for registration as an applicable clinical trial?

If Yes please answer these questions: If no skip to 23

Has the investigator indicated (on the "Recruitment and remuneration" page of the Protocol SmartForm) that the FDA requires this study to be registered at **ClinicalTrials.gov**?	☐ YES	☐ NO	
If YES to the above, has the FDA-required language been included in the consent form? *A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. law. This web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this web site at any time.*	☐ YES	☐ NO	☐ NA

21. Reviewer's Final Assessment/Opinion	
☐ **YES** ☐ **NO**	**Should review occur more frequently than once a year?** ↳ ***If YES,*** please specify how often:
☐ **YES** ☐ **NO**	If this protocol is minimal risk and there are no changes in risk during the next year, can continuing review be conducted by expedited review procedures?

You may attach a marked up copy of the consent/assent forms and/or other study materials with any edits, changes, typos or suggested wording. Circle word/phrases that need to be rewritten in lay language or clarified. Please make clear which comments are suggestions and which are required.

22. Is there any additional information or question you have that you would like to try and get answered before the meeting to try and avoid a deferral?	
☐ **Yes** ► please comment	**Concerns/Comments:**
☐ **No**	

Additional Comments/Questions you would like the Principal Investigator to address: