UCI IRB REVIEWER'S CHECKLIST

A. Criteria for IRB Review and Approval: Please review the federal criteria for IRB approval and indicate whether the research meets each criterion by checking the appropriate box. List any concern that you would like communicated to the researcher in the corresponding comment box or in the open space below.

(Criteria for IRB approval of research in accordance with 45 CRF 46.111, 21 CFR 56.111 and UCI Policy)

CRITERIA FOR IRB REVIEW AND APPROVAL					COMMENTS
1	The IRB has the expertise needed to review this research.	YES ☐	NO ☐		*If no, contact IRB staff to arrange consultation with expert.*
2	I, the IRB reviewer, have a conflicting interest with this protocol.	YES ☐	NO ☐		*If yes, contact HRP staff ASAP to arrange for re-assignment of this protocol.*
3	The statement of purpose/hypothesis is adequate.	YES ☐	NO ☐		
4	Study personnel appear appropriate and qualified.	YES ☐	NO ☐		
Risk/Benefit Assessment – Risks include possible physical, psychological, economic, social and legal harms.					
5	Risks to subjects are minimized by using procedures which are consistent with sound research design and which do not unnecessarily expose subjects to risk.	YES ☐	NO ☐		
6	Risks to subjects are minimized, whenever appropriate, by using procedures already being performed on the subjects for diagnostic or treatment purposes.	YES ☐	NO ☐	N/A ☐	
7	Risks to subjects are reasonable in relation to both: • anticipated benefits, if any, to subjects; and • the importance of the knowledge that may reasonably be expected to result.	YES ☐	NO ☐		
Subject Selection					
8	Selection of subjects is equitable in relation to the purposes of the research and the setting in which the research will be conducted.	YES ☐	NO ☐		
9	Selection of subjects (i.e., inclusion/exclusion criteria) is appropriate based on the research and the setting in which the research will be conducted.	YES ☐	NO ☐		
10	The recruitment process minimizes the potential for undue influence or coercion.	YES ☐	NO ☐	N/A ☐	
11	Compensation - neither the amount of payment nor the proposed method and timing of disbursement is coercive or presents potential for undue influence.	YES ☐	NO ☐	N/A ☐	
12	Recruitment materials are appropriate.	YES ☐	NO ☐	N/A ☐	
Informed Consent					
13	Informed consent is sought from each prospective subject or the subject's legally authorized representative and appropriately documented in accordance with, and to the extent required by 45 CFR 46.116 and 45 CFR 46.117, and 21 CFR 50.25 and 21 CFR 50.27 as applicable.	YES ☐	NO ☐	N/A ☐	

Subject Protections					
14	The research plan makes adequate provision for monitoring the data collected to ensure the safety of subjects. *For > minimal risk studies, UCI requires investigators conducting clinical investigations to at a minimum, have a DSM plan.*	YES ☐	NO ☐	N/A ☐	
15	The research plan makes adequate provisions to protect the privacy of subjects.	YES ☐	NO ☐		
16	The research plan makes adequate provisions to maintain the confidentiality of data.	YES ☐	NO ☐		
17	The research **does** involve subjects likely to be vulnerable to coercion or undue influence, such as: children, prisoners, pregnant women, mentally disabled persons, or economically / educationally disadvantaged persons. If YES, the research plan **does** include additional safeguards to protect their rights and welfare.	YES ☐ YES ☐	NO ☐ NO ☐		

University of California, Irvine – Institutional Review Board
REVIEWER'S SUPPLEMENTAL CHECKLIST "B" – Pregnant Women, Fetuses and Neonates [Initial Review]

Protocol HS # : Lead Researcher:

Title:

REVIEWERS: Please review Appendix B and answer the applicable checklist questions based on the anticipated risks and benefits of the study.

SECTION 1: Research Involving Pregnant Women, or Human Fetuses § 46.204

A. [46.204 (a)] Has the researcher provided justification why the proposed research is scientifically appropriate; including descriptions of preclinical studies conducted on pregnant animals and any clinical studies conducted on non-pregnant women that provide useful data for assessing potential risks?

☐ YES ☐ NO

If No, provide comments back to researcher.

B. [46.204 (b)] Select the appropriate choice that to this research to describe the risks and anticipated benefits [If the research does not meet one of these two categories, it is not approvable.]:

☐ The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of a direct benefit to the pregnant woman or the fetus. Note: When the risk to the fetus (caused by interventions or procedures that hold out the prospect of a direct benefit to the pregnant woman or the fetus) is greater than minimal, the research study requires full Committee review.

☐ This research involves no prospect of direct benefit to the woman or the fetus, but the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means.

Has the researcher provided an adequate justification for how the risk to the fetus is not greater than minimal?

☐ YES ☐ NO

If No, provide comments back to researcher.

Has the researcher provided an adequate justification for why the purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means?

☐ YES ☐ NO

If No, provide comments back to researcher.

C. [46.204 (c)] Has the researcher provided an adequate explanation that the risks are the least possible to the pregnant woman and fetus for achieving the objectives of the research?

☐ YES ☐ NO

If No, provide comments back to researcher.

D. [46.204 (d)] Acknowledge the following regulatory requirements for who will be required to consent to this research:

☐ The research holds out the prospect of direct benefit to the pregnant women only. The pregnant woman's consent is required.

☐ The research holds out the prospect of direct benefit to both the pregnant women and the fetus. The pregnant woman's consent is required.

☐ The research involves no prospect of direct benefit to the woman or the fetus, but the risk to the fetus is minimal and the purpose of the research is the development of important medical knowledge that cannot be obtained by other means. The pregnant woman's consent is required.

☐ The research holds out the prospect of direct benefit solely to the fetus. The pregnant woman and the father's consent are required. The father or his legally authorized representative's consent need not be obtained if he is unable to consent because of unavailability, incompetence, or temporary incapacity or if the pregnancy resulted from rape or incest [46.404 (e)].

E. [46.204 (f)] Has the researcher provided an adequate explanation for how each individual providing consent under D above will be fully informed regarding the reasonably foreseeable impact of the research on the fetus?

☐ YES ☐ NO

If No, provide comments back to researcher.

F. [46.204 (g)] Will the research involve pregnant females who meet the definition of "children" (Under the laws of the jurisdiction in which the research is to take place, the subject is under the age required to consent to the treatment or procedures involved in this research)?

☐ YES ☐ NO

If Yes, also complete the Supplemental Reviewer's Checklist for Children (Checklist "D").*

* EXCEPTION: "A minor may consent to medical care related to the prevention or treatment of pregnancy, except sterilization." If the IRB determines that the study involves the prevention or treatment of pregnancy and it is appropriate for the minor to consent to the treatment or procedures involved in the study, parental permission is not required (California Family Code 6925).

G. [46.204 (h)&(i)] Confirm that **all** of the following are true:

- ✓ No inducements, monetary or otherwise, will be offered to terminate a pregnancy for the purposes of the research activity.
- ✓ No individuals involved in the research will have any part in any decisions as to the timing, method, and

procedures used to terminate the pregnancy.
✓ No individuals involved in the research will have any part in determining the viability of the fetus.

☐ YES, ALL ARE TRUE ☐ NO, ALL ARE NOT TRUE

NOTE: All must be true; otherwise the research is not approvable.

SECTION 2: Research Involving Neonates § CFR 46.205
[IF NEONATES ARE NOT INVOLVED – SKIP THIS SECTION]

Neonates of uncertain viability AND nonviable neonates [46.205 (a)&(b)]

Neonates of uncertain viability may not be involved in research covered by Subpart B unless ALL of the conditions stated in this section and Section 3 are met.

After delivery, a nonviable neonate may not be involved in research covered by Subpart B unless ALL of the conditions stated in this section and Section 4 are met.

A. Has the researcher provided justification why the proposed research is scientifically appropriate; including information about preclinical studies and any clinical studies that provide useful data for assessing potential risks to neonates?

☐ YES ☐ NO

If No, provide comments back to researcher.

B. Has the researcher adequately explained that each individual providing consent will be fully informed regarding the reasonably foreseeable impact of the research on the neonate?

☐ YES ☐ NO

If No, provide comments back to researcher.

C. Confirm that the following is true:
No individuals involved in the research will have any part in determining the viability of the neonate.

☐ YES ☐ NO

NOTE: The statement must be true; otherwise the research is not approvable.

SECTION 3: Neonates of Uncertain Viability – Additional Requirements § CFR 46.205
[IF NEONATES ARE NOT INVOLVED – SKIP THIS SECTION]

A. Choose the one that best applies to the research:

☐ The research holds out the prospect of enhancing the probability of survival of the neonate to the point of viability, and any risk is the least possible for achieving the objective.

☐ The purpose of the research is the development of important biomedical knowledge which cannot be gained by any other means and there will be no added risk to the neonate resulting from the research.

Has the researcher provided an adequate justification for the risks and benefits associated with the research study?

☐ YES ☐ NO

If No, provide comments back to researcher.

B. Legally effective informed consent of either parent of the neonate or the legally effective informed consent of either parent's legally authorized representative is required and will be obtained. *The father or his legally authorized representative's consent need not be obtained if the pregnancy resulted from rape or incest.*

☐ YES ☐ NO

SECTION 4: Nonviable Neonates – Additional Requirements § CFR 46.205
[IF NEONATES ARE NOT INVOLVED – SKIP THIS SECTION]

A. Confirm that **all** of the following are true:

- ✓ Vital functions of the neonate will not be artificially maintained.
- ✓ The research will not terminate the heartbeat or respiration of the neonate.
- ✓ There will be no added risk to the neonate resulting from the research.
- ✓ The main purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means.

☐ YES, ALL ARE TRUE ☐ NO, ALL ARE NOT TRUE

NOTE: All must be true; otherwise the research is not approvable.

If the researcher has not provided adequate explanation or justification for the four statements above, provide comments back to researcher.

B. The legally effective informed consent of both parents of the neonate is required and will be obtained.
If either parent is unable to consent because of unavailability, incompetence, or temporary incapacity, the informed consent of one parent of a nonviable neonate will suffice. Exception - the consent of the father need not be obtained if the pregnancy resulted from rape or incest. The consent of a legally authorized representative for either or both of the parents will not suffice.

☐ YES ☐ NO

SECTION 5: Research is not approvable based upon the above requirements; however the research presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, human fetuses, or neonates. § CFR 46.207
[IF NOT APPLICABLE– SKIP THIS SECTION]

Is the study Federally funded?

☐ YES, the study must also be submitted to the Secretary of HHS (through OHRP) for approval.

☐ NO, the IRB may approve the research only if it finds that the following conditions have been met:

1. Has the researcher provided sufficient explanation as to how the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a problem affecting children's health/welfare?

☐ YES ☐ NO

If NO, provide comments back to researcher or provide explanation.

2. Support the assumption that the research will be conducted in accordance with sound ethical principles.

NOTE: *The IRB must also determine whether informed consent will be obtained in accord with the informed consent provisions of subpart A and other applicable subparts of this part.*

Recommendation: [Choose One]

☐ Approve - all applicable criteria have been met for inclusion of this population

☐ Defer pending resubmission - all applicable criteria have NOT been met for inclusion of this population

☐ Defer pending certification from the Secretary (through OHRP)

☐ Disapprove the inclusion of this population.

(If Deferred or Disapproved, provide comments to researcher here)

Reviewer's Signature_____ Date_____

University of California, Irvine – Institutional Review Board
REVIEWER'S SUPPLEMENTAL CHECKLIST "C" – Prisoners [Initial Review]

Protocol HS#	Lead Researcher:
Title:	

REVIEWERS: Please review Appendix C and complete the checklist based on the anticipated risks and benefits of the study.

SECTION 1:	
	Minimal Risk: For research involving prisoners, the definition of minimal risk differs from the definition of minimal risk that UCI IRB has adopted. The definition for prisoners requires reference to physical or psychological harm, as opposed to harm or discomfort, to risks normally encountered in the daily lives of the general population, or routine medical, dental, or psychological examination of a healthy person. As used in this policy, "minimal risk" is defined as the probability and magnitude of physical or psychological harm that is normally encountered in the daily lives, or in the routine medical, dental, or psychological examinations of healthy persons.
1.	Is the research supported or conducted by DHHS? ☐ YES ☐ NO If YES, the UCI IRB must certify in writing to the Secretary (through OHRP) that the IRB has made the findings required under 45 CFR 46.305(a).
2.	Please indicate which one of the five categories listed below best represents the proposed research [45 CFR 46.306(a)(2)]. ☐ 46.306(a)(2)(i) - A study of the possible causes, effects, and processes of incarceration, and of criminal behavior, provided that the study presents no more than minimal risk and no more than inconvenience to the participants. ☐ 46.306(a)(2)(ii) - A study of prisons as institutional structures or of prisoners as incarcerated persons, provided that the study presents no more than minimal risk and no more than inconvenience to participants. ☐ 46.306(a)(2)(iii) - Research on conditions particularly affecting prisoners as a class (e.g., vaccine trials and other research on hepatitis which is much more prevalent in prisons than elsewhere; and research on social and psychological problems such as alcoholism, drug addictions, and sexual assaults). ☐ 46.306(a)(2)(iv) - Research on practices, both innovative and accepted, which have the intent and reasonable probability of improving the health or well-being of the participant. (If federally supported, must be submitted to the Secretary of HHS (through OHRP) for approval. ☐ The study is epidemiologic research to describe the prevalence or incidence of a disease by identifying all cases or to study potential risk factor associations for a disease, where prisoners are not a particular focus of the research [FR Doc. 03-15580 6-19-03]. Has the researcher sufficiently explained why the research meets the category chosen above? ☐ YES ☐ NO If NO, provide comments back to researcher.

SECTION 2:

3.

In your opinion, are there are any possible advantages accruing to the prisoner through his or her participation in the research

☐ YES ☐ NO - skip to #4

If YES, has the researcher provided adequate explanation/justification that the possible advantages are NOT of such a magnitude that it would impair the prisoner's ability to weigh the risks of the research against the value of such advantages in the limited choice environment of the prison?

☐ YES ☐ NO

If NO adequate explanation/justification, provide comments back to researcher.

4.

Are the risks commensurate with risks that would be accepted by non-prisoner volunteers?

☐ YES ☐ NO

If NO, the research is not approvable.

Has the researcher provided an adequate explanation/justification?

☐ YES ☐ NO

If NO to *either question*, provide comments back to researcher.

5.

Is the selection of subjects in this research fair to all prisoners and immune from arbitrary intervention by prison authorities or prisoners?

☐ YES ☐ NO

If NO, the research is not approvable.

Has the researcher provided an adequate explanation/justification?

☐ YES ☐ NO

If NO to *either question*, provide comments back to researcher.

6.

Is the information presented during the informed consent process in a language understandable to the prison population?

☐ YES ☐ NO

If NO, the research is not approvable.

If NO, provide comments back to researcher.

7.

Has the researcher provided adequate assurances that parole boards will not take into account the prisoner's participation in the research in making decisions regarding parole, and that each prisoner is clearly informed in advance that participation in the research will have no effect on his or her parole?

☐ YES ☐ NO

	If NO, the research is not approvable. If NO, provide comments back to researcher.
8.	Is there need for follow-up examination or care of participants after the end of their participation? ☐ YES ☐ NO - skip to Recommendation If YES, has the researcher adequately described what provisions have been made for such examination or care, taking into account the varying lengths of individual prisoner's sentences, and for informing participants of this fact? ☐ YES ☐ NO If NO, provide comments back to researcher.

Recommendation:

☐ Approve - all applicable criteria have been met for inclusion of this population

☐ Defer recommendation - all applicable criteria have NOT been met for inclusion of this population

☐ Disapprove the inclusion of this population.

(If Deferred or Disapproved, provide comments to researcher here)

Reviewer's Signature_____ Date_____

University of California, Irvine – Institutional Review Board
REVIEWER'S SUPPLEMENTAL CHECKLIST "D" – Children [Initial Review]

Protocol HS#	Lead Researcher:
Title:	

REVIEWERS: Please review Appendix D. Indicate the appropriate regulatory category according to the anticipated risks and benefits of the study, indicate whether the researcher provided sufficient information to the applicable questions, and determine the parental permission and assent process. If this study involves a clinical investigation, 21 CFR 50 (Subpart D) also applies.

Section 1: Classify the research according to risk/benefit.

☐ 45 CFR 46.404 & 21 CFR 50.51

No greater than minimal risk to children is presented [*Expedited level research*].

Did the researcher adequately explain why the risk involved in the study is no greater than minimal risk?

☐ YES ☐ NO

If NO, provide comments back to researcher or provide explanation.

☐ 45 CFR 46.405 & 21 CFR 50.52

More than minimal risk is presented by an intervention or procedure that DOES hold out the prospect of a direct benefit for the individual child or by a monitoring procedure that is likely to contribute to the child's well-being.

The following must be justified:

1. Did the researcher adequately explain why the potential risks and discomforts are justified by the anticipated benefit to the subjects?

   ☐ YES ☐ NO

If NO, provide comments back to researcher or provide explanation.

2. Did the researcher sufficiently justify that the relation of the anticipated benefit to the risk is at least as favorable to the child as that presented by available alternative approaches?

   ☐ YES ☐ NO

If NO, provide comments back to researcher or provide justification.

☐ 45 CFR 46.406 & 21 CFR 50.53

More than minimal risk to the child is presented by an intervention or procedure that DOES NOT hold out the prospect of direct benefit for the individual child or by a monitoring procedure which is not likely to contribute to the well-being of the child.

All of the following conditions must be met:

1. Did the researcher adequately explain how the risk represents only a minor increase over minimal risk?

   ☐ YES ☐ NO

If NO, provide comments back to researcher or provide explanation.

2. Did the researcher sufficiently explain why 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?

☐ YES ☐ NO

If NO, provide comments back to researcher or provide explanation.

3. Did the investigator identify the subjects' disorder or condition?

☐ YES ☐ NO

If NO, provide comments back to researcher or indicate disorder/condition.

4. Did the researcher sufficiently explain why 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?

☐ YES ☐ NO

If NO, provide comments back to researcher or provide explanation.

☐ 45 CFR 46.407 & 21 CFR 50.54

Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children. The IRB does not believe the research meets the requirements of (as applicable) §46.404 /§50.51, §46.405 / §50.52, or §46.406 / §50.53.

1. Is the study Federally funded?

☐ YES, the study must be submitted to the Secretary of HHS (through OHRP) for approval. Also complete # 1 below.

☐ NO, the IRB may approve the research only if it finds that the following conditions have been met:

2. Does this study involve a clinical investigation?

☐ YES, the study must be submitted to the Commissioner of Food and Drugs for approval. Also complete # 1 below.

☐ NO, the IRB may approve the research only if it finds that the following conditions have been met:

3. Has the researcher provided sufficient explanation as to how the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a problem affecting children's health/welfare?

☐ YES ☐ NO

If NO, provide comments back to researcher or provide explanation.

4. Support the assumption that the research will be conducted in accordance with sound ethical principles.

Section 2: Determine the parental permission and child assent process.

Parental Permission:

1. Indicate whether parental permission should be obtained.

☐ Yes, Parents/Legal guardians permission must be obtained (§46.408(b) and §50.55).

(check one)

☐ *Permission by one parent is sufficient (optional for §46.404 / §50.51 and §46.405 / §50.52).*

☐ *Permission must be sought from both parents. 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 if consistent with State law (required for §46.406 / §50.53 and §46.407 / §50.54).*

☐ No, a waiver of permission from Parents or Legal guardians should be granted

If you are granting a waiver, justify your determination by choosing from one of the three options below (A-C) and answering the corresponding questions: *NOTE: Appendix O or P should be provided by the researcher if requesting a waiver of informed consent or a waiver of written (signed) consent, respectively.*

A. ☐ It is appropriate to grant a waiver of Parents/Legal guardians permission because all of the following are true:

- ✓ 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 parents will be provided with additional pertinent information after participation.
- ✓ The research involves no drugs or medical devices other than the use of FDA drugs or medical devices approved for marketing.
- ✓ The research will not be submitted to or held for inspection by FDA.

SEE APPENDIX O FOR RESEARCHER'S SPECIFIC JUSTIFICATIONS

☐ YES, ALL ARE TRUE ☐ NO, ALL ARE NOT TRUE

NOTE: All must be true; otherwise the waiver cannot be granted.

Did the researcher provide adequate explanation/justification for the above requirements in Appendix O?

☐ YES ☐ NO

If NO, provide comments back to the researcher:

B. ☐ It is appropriate to grant a waiver of Parents/Legal guardians permission because all of the following are true:

- ✓ The research protocol is designed for conditions or for a subject population (for example, neglected or abused children) for which parental or guardian permission is not a reasonable requirement to protect the subjects.
- ✓ An appropriate mechanism for protecting the children who participate as subjects will be substituted in place of parental/guardian permission.
- ✓ The research involves no drugs or medical devices other than the use of FDA drugs or medical devices approved for marketing.
- ✓ The research will not be submitted to or held for inspection by FDA.
- ✓ The waiver is not inconsistent with Federal, State or local law.

☐ YES, ALL ARE TRUE ☐ NO, ALL ARE NOT TRUE

NOTE: All must be true; otherwise the waiver cannot be granted.

Did the researcher provide adequate explanation/justification for the above requirements in Appendix O?

☐ YES ☐ NO

If NO, provide comments back to the researcher:

C. ☐ It is appropriate to grant a waiver of Parents/Legal guardians permission because all of the following are true:

- ✓ 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: *(check one)*
  - ☐ Public benefit or service
  - ☐ Procedures for obtaining benefits or services under those programs;
  - ☐ Possible changes in or alternatives to those programs or procedures; or
  - ☐ 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 or alteration.
- ✓ The research involves no drugs or medical devices other than the use of FDA drugs or medical devices approved for marketing
- ✓ The research will not be submitted to or held for inspection by FDA

☐ YES, ALL ARE TRUE ☐ NO, ALL ARE NOT TRUE

NOTE: All must be true; otherwise the waiver cannot be granted.

Did the researcher provide adequate explanation/justification for the above requirements in Appendix O?

☐ YES ☐ NO

If NO, provide comments back to the researcher:

Child Assent:

1. Assent should be obtained from: (check one)

☐ All children

☐ Some children. Did the investigator explain which children would not be asked for assent? ☐ YES ☐ NO

☐ None of the children

If assent will not be obtained from some or all children, provide a rationale: (check one of four options)

☐ A - The capability of these children is so limited that they cannot reasonably be consulted.

☐ B - 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.

☐ C - Assent will be waived

- ✓ 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 children will be provided with additional pertinent information after participation.

☐ D - Assent will be waived because all of the following are true:

- ✓ 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: *(check one)*
  - ☐ Public benefit or service programs;
  - ☐ Procedures for obtaining benefits or services under those programs;
  - ☐ Possible changes in or alternatives to those programs or procedures; or
  - ☐ 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 or alteration.

- ✓ The research involves no drugs or medical devices other than the use of FDA drugs or medical devices approved for marketing.
- ✓ The research will not be submitted to or held for inspection by FDA.

2. Did the researcher provide adequate explanation/justification for the assent process outlined in Appendix D?

☐ YES ☐ NO

If NO, provide comments back to the researcher:

3. Is documentation (i.e., written assent form) of child assent required (§46.409(e) and §50.55)?

☐ YES, signature of child is always required for assent.

☐ The Investigator may consider appropriateness of obtaining a signature on a case-by-case basis taking into consideration the age, maturity, and psychological state of the child; however an assent process is always required.

☐ NO, verbal assent is sufficient.

☐ N/A, no assent required.

4. If documentation of assent is required, is the language in the assent form appropriate for the age, maturity, and psychological state of the child?

☐ YES ☐ NO

If NO, provide comments back to the researcher:

Section 3: When Parental Permission is not needed

In California, certain people under 18 years of age are legally able to consent for certain treatments or procedures. For those procedures, these minors do not fit the federal definition of "children" under 45 CFR 46 and 21 CFR 50, nor do the special protections of Subpart D apply. These individuals who do not fit the federal definition of "children" for certain treatments or procedures may consent for themselves to participate in research involving those treatments or procedures.

1. Does this study involve people under 18 years of age are legally able to consent for certain treatments or procedures?

☐ YES ☐ NO [If NO, skip this section]

2. Is it appropriate for the researcher to enroll people under the age of 18 who per California law are able to consent for themselves? NOTE: Researchers enrolling research participants in other states or countries must comply with local laws.

☐ YES ☐ NO

If NO, provide comments back to the researcher:

Section 4: Children who are Wards of the State

There are no special requirements for the enrollment of wards in research approved under §46.404 or §47.405 (FDA §50.51 or §50.52) [see categories in Section 1 above].

Children who are wards of the state or any other agency, institution, or entity can be included in research approved under §46.406 or §46.407 (FDA §50.53 or §50.54) only if such research is:

- Related to their status as wards; *OR*
- Conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

The inclusion of children who are wards requires that the following conditions are met:

- ✓ Appointment of an advocate 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 NOTE: One individual may serve as advocate for more than one child
- ✓ The advocate shall be an individual who 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
- ✓ The advocate must not be 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.

1. Does this study involve wards of the state or any other agency, institution, or entity?
   ☐ YES ☐ NO [If NO, skip this section]
2. Is it appropriate to enroll wards in this study?
   ☐ YES ☐ NO
   If NO, provide comments back to the researcher:

3. Does the study fall under §46.406 or §46.407 (FDA §50.53 or §50.54) and will wards be enrolled?
   ☐ YES ☐ NO [If NO, skip this section]
4. Did the researcher provide adequate plans for appointing advocates and an adequate description of the advocates' responsibilities?
   ☐ YES ☐ NO
   If NO, provide comments back to the researcher:

Recommendation:

☐ Approve - all applicable criteria have been met for inclusion of this population

☐ Defer recommendation - all applicable criteria have NOT been met for inclusion of this population

☐ Defer pending certification from the Secretary (through OHRP)

☐ Disapprove the inclusion of this population.

(If Deferred or Disapproved , provide comments to researcher here)

Reviewer's Signature_____ Date_____