

Findings Regarding Additional Protections for Pregnant Women and Human Fetuses Involved in Research

Note: These requirements are in addition to those imposed under subparts A and D.

*Research Involving Pregnant Women or Fetuses Section 46.204*

Decision: Where scientifically appropriate, preclinical studies, including studies on pregnant animals, and clinical studies, including studies on nonpregnant women, have been conducted and provide data for assessing potential risks to pregnant women and fetuses;

yes                       no                       unclear

Explanation:

Decision: The risk to the fetus is caused solely by interventions or procedures that hold out the prospect of direct benefit for the woman or the fetus; or, if there is no such prospect of benefit, the risk to the fetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge which cannot be obtained by any other means;

yes                       no                       unclear

Explanation:

Decision: Any risk is the least possible for achieving the objectives of the research;

yes                       no                       unclear

Explanation:

Decision: If the research holds out the prospect of direct benefit to the pregnant woman, the prospect of a direct benefit both to the pregnant woman and the fetus, or no prospect of benefit for the woman nor the fetus when 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, her consent is obtained in accord with the informed consent provisions of subpart A of this part;

yes

no

unclear

Explanation:

Decision: 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.

yes

no

unclear

Explanation:

Decision: 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;

yes

no

unclear

Explanation:

Decision: For children as defined in Section 46.402 (a) who are pregnant, assent and permission are obtained in accord with the provisions of subpart D of this part;

yes

no

unclear

Explanation:

Decision: No inducements, monetary or otherwise, will be offered to terminate a pregnancy;

yes

no

unclear

Explanation:

Decision: Individuals engaged in the research will have no part in any decisions as to the timing, method, or procedures used to terminate a pregnancy; and

yes

no

unclear

Explanation:

Decision: Individuals engaged in the research will have no part in determining the viability of a neonate

yes

no

unclear

Explanation:

Pregnant women or fetuses may be involved in this research project because all of the preceding conditions have been met.

Vote:  in favor

opposed

abstain

Findings Regarding Additional Protections for Neonates Involved in Research

*Research Involving Neonates Section 46.205*

a. Neonates of uncertain viability and nonviable neonates

Decision: Where scientifically appropriate, preclinical and clinical studies have been conducted and provide data for assessing potential risks to neonates.

yes                       no                       unclear

Explanation:

Decision: Each individual providing consent under paragraph (b) (2) or (c) (5) of this section is fully informed regarding the reasonably foreseeable impact of the research on the neonate.

yes                       no                       unclear

Explanation:

Decision: Individuals engaged in the research will have no part in determining the viability of a neonate.

yes                       no                       unclear

Explanation:

Decision: The requirements of paragraph (b) or (c) of this section have been met as applicable.

yes                       no                       unclear

Explanation:

Vote:                       in favor                       opposed                       abstain

b. Neonates of uncertain viability.

For neonates of uncertain viability, the following additional conditions must be met:

Decision: 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 that objective, or

yes                       no                       unclear

Explanation:

Decision: The purpose of the research is the development of important biomedical knowledge which cannot be obtained by other means and there will be no added risk to the neonate resulting from the research; and

yes                       no                       unclear

Explanation:

Decision: The legally effective informed consent of either parent of the neonate or, if neither parent is able to consent because of unavailability, incompetence, or temporary incapacity, the legally effective informed consent of either parent’s legally authorized representative is obtained in accord with subpart A of this part, except that the consent of the father or his legally authorized representative need not be obtained if the pregnancy resulted from rape or incest.

yes                       no                       unclear

Explanation:

The preceding additional conditions have been met for neonates of uncertain viability.

Vote:                       in favor                       opposed                       abstain

c. Nonviable neonates

Decision: Vital functions of the neonate will not be artificially maintained;

yes                       no                       unclear

Explanation:

Decision: The research will not terminate the heartbeat or respiration of the neonate;

yes                       no                       unclear

Explanation:

Decision: There will be no added risk to the neonate resulting from the research;

yes                       no                       unclear

Explanation:

Decision: The purpose of the research is the development of important biomedical knowledge that cannot be obtained by other means;

yes                       no                       unclear

Explanation:

**AND**

Decision: The legally effective informed consent of both parents of the neonate is obtained in accord with subpart A of this part, except that the waiver and alteration provisions of Sec. 46.116 (c) and (d) do not apply. However, 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 to meet the requirements of this paragraph (c) (5), except that the consent of the father need not be obtained if the pregnancy resulted from rape or incest. The consent of a legally authorized representative of either or both of the parents of a nonviable neonate will not suffice to meet the requirements of this paragraph (c) (5).

yes                       no                       unclear

Explanation:

The preceding additional conditions have been met for nonviable neonates.

Vote:  in favor       opposed       abstain

d. Viable neonates.

Neonate, after delivery, that has been determined to be viable may be included in research only to the extent permitted by and in accord with the requirements of subparts A and D of this part.

yes       no       unclear

Explanation:

The preceding conditions a – d have been met and neonates may be involved in this research.

Vote:  in favor       opposed       abstain

Findings Regarding Additional Protections for Research Involving, After Delivery, the Placenta, the Dead Fetus or Fetal Material

*Research involving, after delivery, the placenta, the dead fetus or fetal material section 46.206*

Decision: Research involving, after delivery, the placenta; the dead fetus; macerated fetal material; or cells, tissue, or organs excised from a dead fetus, shall be conducted only in accord with any applicable Federal, State, or local laws and regulations regarding such activities.

Certification by chair:

yes

no

\_\_\_\_\_  
signature

Decision: If information associated with material described in paragraph (a) of this section is recorded for research purposes in a manner that living individuals can be identified, directly or through identifiers linked to those individuals, those individuals will be treated as research subjects and all pertinent subparts of this part are applicable.

Certification by chair:

yes

no

\_\_\_\_\_  
signature

Findings Regarding Additional Protections for Research Not Otherwise Approvable

*Research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates. 46.207*

Decision: The Secretary will conduct or fund research that the IRB does not believe meets the requirements of Section 46.204 or Section 46.205 only if:

- a) The IRB finds that the research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses or neonates; and

yes                       no                       unclear

Explanation:

- b) The Secretary, after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, ethics, law) and following opportunity for public review and comment, including a public meeting announces in the Federal Register, has determined either:

yes                       no                       unclear

Explanation:

- 1) That the research in fact satisfies the conditions of Section 46,204, as applicable; or

yes                       no                       pending decision

or

- 2) The following:

- (i) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of pregnant women, fetuses, or neonates;

yes                       no                       unclear

(ii) The research will be conducted in accord with sound ethical principles; and

yes

no

unclear

(iii) Informed consent will be obtained in accord with the informed consent provisions of subpart A and other applicable subparts of this part.

yes

no

unclear

Explanation:

Final Decision: Findings are in compliance with Section 46, subpart B.

Vote:  in favor

opposed

abstained

Investigator's name(s):

Title of Study:

Findings regarding conditions to be met to conduct research with children regarding the permission of parents for research under sections 46.404 and .405.

1. Decision: Adequate provisions have been made for soliciting the permission of each child's parent or guardian.

yes                       no                       unclear

Explanation:

2. Decision: Permission of one parent is sufficient for research to be conducted (46.404 or 46.405). The research either (a) does not involve greater than minimal risk or (b) does involve greater than minimal risk, but presents the prospect of direct benefit to the individual subjects.

yes (a)                       no (a)                       unclear (a)  
 yes (b)                       no (b)                       unclear (b)

If (b) complete below decision 3 as well.

Explanation:

3. Decision: Although the risk is greater than minimal, the intervention holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well being and the IRB has found all of the below:

(a) the risk is justified by the anticipated benefit to the subjects  yes  no  n/a

(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  yes  no  n/a

(c) Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians.  yes  no  n/a

4. Decision: Documentation of parental (or guardian's) permission is in accordance with and to the extent required in 46.117:

yes

no

unclear

Explanation:

Vote:  In favor

Opposed

Abstained

Final Decision:

yes

no

pending revisions

revisions approved

Vote:  In favor

Opposed

Abstained

Investigator's name (s):

Title of study:

Findings regarding condition to be met to conduct research with children relative to the assent of children.

1. Decision: There is no greater than minimal risk to children presented in the research study.

yes       no       unclear

Explanation:

Vote       in favor       opposed       abstained

If yes, then go to

2. Decision: Adequate provisions are made for soliciting the assent of children who are considered capable of providing assent and for the permission of their parents or guardians

yes       no       revisions needed

Explanation:

Vote:       in favor       opposed       abstained

3. Decision: The procedures for documentation of the required assent are appropriate and adequate

yes       no       pending revision  
 revision approved

or

4. Decision: Although assent is required, documentation of it is not required.

yes       no       unclear

Explanation:

Vote:       in favor       opposed       abstained

5. Decision: Factors such as age, maturity and psychological state of the children involved indicate that the capability of a given child or all children in the research is so limited that they cannot reasonably be consulted.

yes

no

unclear

Explanation:

6. Decision: Despite the limited capability of the child or children to assent, the intervention or procedure 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.

yes

no

unclear

Explanation:

7. Decision: The assent of a child or the children in the study is not required for reasons stated in decision 3 or 4 above.

yes

no

pending revisions

revisions approved

Date:

Vote:  in favor

opposed

abstained

Investigators name (s):

Title of study:

Findings regarding conditions to be met to conduct research with children for which parental or guardian’s permission is not a reasonable requirement to protect subjects (46.408 (c))

1. Decision: This 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, e.g., neglect or abused children.

yes                       no                       unclear

Explanation:

Vote:                       in favor                       opposed                       abstained

2. Decision: Waiver of the consent requirement, in subpart A and subpart D 46.408 (d) are appropriate provided

(a) an appropriate mechanism for protecting the children who will serve as subjects in the research is substituted, and

(b) that the waiver is not inconsistent with federal, state or local law

yes                       no                       unclear

Note: The choice of an appropriate mechanism depends upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

Explanation:

Vote:                       in favor                       opposed                       abstained

Findings regarding conditions to be met to conduct research with children who are wards of the state or any other agency, institution, or entity:

1. Decision: Research is approvable under 46.404 or 46.405

yes                       no                       revisions needed

Explanation:

Vote:                       in favor                       opposed                       abstain

2. Decision: Research is approvable under 46.406 or 46.407

yes                       no                       revisions needed

Explanation:

Vote:                       in favor                       opposed                       abstain

3. Decision: Research is related to the children's status as wards

yes                       no                       revisions needed

Explanation:

Vote:                       in favor                       opposed                       abstain

4. Decision: Research is conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

yes                       no                       revisions needed

Explanation:

Vote:                       in favor                       opposed                       abstain

5. Decision: The IRB has appointed 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 and who 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 .

Certification by Chair:

yes

no

pending

\_\_\_\_\_  
Signature

re: 404, 405, 406, 407 & 409

Additional Findings Required:

For waiver of signature on Informed Consent Form

Decision: The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern.

yes                       no                       pending revision   
                      revision approved

Explanation: (protocol specific)

**OR**

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

yes                       no                       pending revision   
                      revision approved

Explanation (protocol specific):

For waiver of elements of informed consent or the waiver of the requirement to obtain informed consent.  
ALL FINDINGS MUST BE PRESENT.

1. Decision: The research involves no more than minimal risk to the subjects

yes                       no                       pending revision  
 revision approved

Explanation (protocol specific):

2. Decision: The waiver or alteration will not adversely affect the rights and welfare of the subjects.

yes                       no                       pending revision  
 revision approved

Explanation (protocol specific):

3. Decision: The research could not practicably be carried out without the waiver or alterations

yes                       no                       pending revision  
 revision approved

Explanation (protocol specific):

4. Decision: Whenever appropriate, the subjects will be provided with additional pertinent information after participation

yes                       no                       pending revision  
 revision approved

Explanation (protocol specific):

Investigator's name(s):

Title of Study:

Findings regarding conditions to be met to conduct research with children regarding the permission of parents for research under sections 46.404 and .405.

1. Decision: Adequate provisions have been made for soliciting the permission of each child's parent or guardian.

yes

no

unclear

Explanation:

2. Decision: Permission of one parent is sufficient for research to be conducted (46.404 or 46.405). The research either (a) does not involve greater than minimal risk or (b) does involve greater than minimal risk, but presents the prospect of direct benefit to the individual subjects.

yes (a)

no (a)

unclear (a)

yes (b)

no (b)

unclear (b)

If (b) complete below decision 3 as well.

Explanation:

3. Decision: Although the risk is greater than minimal, the intervention holds out the prospect of direct benefit for the individual subject, or by a monitoring procedure that is likely to contribute to the subject's well being and the IRB has found all of the below:

(a) the risk is justified by the anticipated benefit to the subjects                      yes                      no                      n/a

(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                      yes                      no                      n/a

(c) Adequate provisions are made for soliciting the assent of the children and permission of their parents or guardians.                      yes                      no                      n/a

4. Decision: Documentation of parental (or guardian's) permission is in accordance with and to the extent required in 46.117:

yes

no

unclear

Explanation:

Vote:  In favor

Opposed

Abstained

Final Decision:

yes

no

pending revisions

revisions approved

Vote:  In favor

Opposed

Abstained

Investigators name (s):

Title of study:

Findings regarding conditions to be met to conduct research with children for which parental or guardian's permission is not a reasonable requirement to protect subjects (46.408 (c))

1. Decision: This 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, e.g., neglect or abused children.

yes

no

unclear

Explanation:

Vote:  in favor

opposed

abstained

2. Decision: Waiver of the consent requirement, in subpart A and subpart D 46.408 (d) are appropriate provided

(a) an appropriate mechanism for protecting the children who will serve as subjects in the research is substituted, and

(b) that the waiver is not inconsistent with federal, state or local law

yes

no

unclear

Note: The choice of an appropriate mechanism depends upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

Explanation:

Vote:  in favor

opposed

abstained

Investigator's name (s):

Title of study:

Findings regarding condition to be met to conduct research with children relative to the assent of children.

1. Decision: There is no greater than minimal risk to children presented in the research study.

yes                       no                       unclear

Explanation:

Vote  in favor                       opposed                       abstained

If yes, then go to \_\_\_\_\_\_\_\_\_\_

2. Decision: Adequate provisions are made for soliciting the assent of children who are considered capable of providing assent and for the permission of their parents or guardians

yes                       no                       revisions needed

Explanation:

Vote:  in favor                       opposed                       abstained

3. Decision: The procedures for documentation of the required assent are appropriate and adequate

yes                       no                       pending revision  
 revision approved

or

4. Decision: Although assent is required, documentation of it is not required.

yes                       no                       unclear

Explanation:

Vote:  in favor                       opposed                       abstained

5. Decision: Factors such as age, maturity and psychological state of the children involved indicate that the capability of a given child or all children in the research is so limited that they cannot reasonably be consulted.

yes

no

unclear

Explanation:

6. Decision: Despite the limited capability of the child or children to assent, the intervention or procedure 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.

yes

no

unclear

Explanation:

7. Decision: The assent of a child or the children in the study is not required for reasons stated in decision 3 or 4 above.

yes

no

pending revisions

revisions approved

Date:  \_\_\_\_\_

Vote:  in favor

opposed

abstained

Findings regarding conditions to be met to conduct research with children who are wards of the state or any other agency, institution, or entity:

1. Decision: Research is approvable under 46.404 or 46.405

yes                       no                       revisions needed

Explanation:

Vote:                       in favor                       opposed                       abstain

2. Decision: Research is approvable under 46.406 or 46.407

yes                       no                       revisions needed

Explanation:

Vote:                       in favor                       opposed                       abstain

3. Decision: Research is related to the children's status as wards

yes                       no                       revisions needed

Explanation:

Vote:                       in favor                       opposed                       abstain

4. Decision: Research is conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

yes                       no                       revisions needed

Explanation:

Vote:                       in favor                       opposed                       abstain

5. Decision: The IRB has appointed 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 and who 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 .

Certification by Chair:

yes

no

pending

\_\_\_\_\_  
Signature

re: 404, 405, 406, 407 & 409

Additional Findings Required:

For waiver of signature on Informed Consent Form

Decision: The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern.

yes                       no                       pending revision   
 revision approved

Explanation: (protocol specific)

**OR**

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

yes                       no                       pending revision   
 revision approved

Explanation (protocol specific):

For waiver of elements of informed consent or the waiver of the requirement to obtain informed consent.  
ALL FINDINGS MUST BE PRESENT.

1. Decision: The research involves no more than minimal risk to the subjects

yes                       no                       pending revision  
 revision approved

Explanation (protocol specific):

2. Decision: The waiver or alteration will not adversely affect the rights and welfare of the subjects.

yes                       no                       pending revision  
 revision approved

Explanation (protocol specific):

3. Decision: The research could not practicably be carried out without the waiver or alterations

yes                       no                       pending revision  
 revision approved

Explanation (protocol specific):

4. Decision: Whenever appropriate, the subjects will be provided with additional pertinent information after participation

yes                       no                       pending revision  
 revision approved

Explanation (protocol specific):

Investigator's name (s):

Title of study:

Findings for research involving greater than minimal risk and presenting no prospect of direct benefit to individual subjects, but likely to yield generalizable knowledge about the subject's disorder or condition

Decision: Although the risk is greater than minimal to children presented by this intervention or procedure which 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, the IRB finds all of the following:

- (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 inherent in their actual or expected medical, dental, psychological, social, or educational situations;
- (c) 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                       unclear

Explanation:

- (d) Adequate provisions are made for soliciting assent of the children and permission of their parents or guardians, as set forth in 46.408.

yes                       no                       unclear

Explanation:

Vote:                       in favor                       opposed                       abstained

re: Section 406, 407 & 408

Investigators name (s):

Title of study:

Findings regarding conditions to be met to conduct research with children regarding the permission of parents for research under section 46.406 and 407.

1. Decision: Adequate provisions have been made for soliciting the permission of each child's parents (both) or guardian(s).

yes

no

unclear

Explanation:

Vote:  in favor

opposed

abstained

2. Decision: Both parents cannot give permission because 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.

yes

no

unclear

Explanation:

Vote:  in favor

opposed

abstain

3. Decision: Documentation of parental or guardian's permission is in accordance with and to the extent required in Section 46.117.

yes

no

unclear

Explanation:

Vote:  in favor

opposed

abstain

Investigator's name (s):

Title of study:

Findings regarding condition to be met to conduct research with children relative to the assent of children.

1. Decision: There is no greater than minimal risk to children presented in the research study.

yes                       no                       unclear

Explanation:

Vote  in favor                       opposed                       abstained

If yes, then go to

2. Decision: Adequate provisions are made for soliciting the assent of children who are considered capable of providing assent and for the permission of their parents or guardians

yes                       no                       revisions needed

Explanation:

Vote:  in favor                       opposed                       abstained

3. Decision: The procedures for documentation of the required assent are appropriate and adequate

yes                       no                       pending revision  
 revision approved

or

4. Decision: Although assent is required, documentation of it is not required.

yes                       no                       unclear

Explanation:

Vote:  in favor                       opposed                       abstained

5. Decision: Factors such as age, maturity and psychological state of the children involved indicate that the capability of a given child or all children in the research is so limited that they cannot reasonably be consulted.

yes

no

unclear

Explanation:

6. Decision: Despite the limited capability of the child or children to assent, the intervention or procedure 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.

yes

no

unclear

Explanation:

7. Decision: The assent of a child or the children in the study is not required for reasons stated in decision 3 or 4 above.

yes

no

pending revisions

revisions approved

Date: \_\_\_\_\_  \_\_\_\_\_

Vote:  in favor

opposed

abstained

Findings regarding conditions to be met to conduct research with children who are wards of the state or any other agency, institution, or entity:

1. Decision: Research is approvable under 46.404 or 46.405

yes  no  revisions needed

Explanation:

Vote:  in favor  opposed  abstain

2. Decision: Research is approvable under 46.406 or 46.407

yes  no  revisions needed

Explanation:

Vote:  in favor  opposed  abstain

3. Decision: Research is related to the children's status as wards

yes  no  revisions needed

Explanation:

Vote:  in favor  opposed  abstain

4. Decision: Research is conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

yes  no  revisions needed

Explanation:

Vote:  in favor  opposed  abstain

5. Decision: The IRB has appointed 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 and who 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 .

Certification by Chair:

yes

no

pending

\_\_\_\_\_  
Signature

re: 404, 405, 406, 407 & 409

Additional Findings Required:

For waiver of signature on Informed Consent Form

Decision: The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern.

yes  no  pending revision

revision approved

Explanation: (protocol specific)

**OR**

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

yes  no  pending revision

revision approved

Explanation (protocol specific):

For waiver of elements of informed consent or the waiver of the requirement to obtain informed consent.  
ALL FINDINGS MUST BE PRESENT.

1. Decision: The research involves no more than minimal risk to the subjects

yes                       no                       pending revision  
 revision approved

Explanation (protocol specific):

2. Decision: The waiver or alteration will not adversely affect the rights and welfare of the subjects.

yes                       no                       pending revision  
 revision approved

Explanation (protocol specific):

3. Decision: The research could not practicably be carried out without the waiver or alterations

yes                       no                       pending revision  
 revision approved

Explanation (protocol specific):

4. Decision: Whenever appropriate, the subjects will be provided with additional pertinent information after participation

yes                       no                       pending revision  
 revision approved

Explanation (protocol specific):

Investigator's name (s):

Title of study:

Findings for research not otherwise approvable which presents an opportunity to understand, prevent, or alleviate a serious problem affecting the health or welfare of children.

Decision: This research does not meet the requirements of section 46.404, section 46.405, or section 46.406. For this funded research, the IRB finds the following:

(a) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health or welfare of children.

yes  no  unclear

Explanation:

(b) The Secretary after consultation with a panel of experts in pertinent disciplines (for example: science, medicine, education, ethics, law) and following opportunity for public review and comment has determined either:

(1) That the research in fact satisfies the conditions of Section 46.404, Section 46.405 or Section 46.406, as applicable, or

yes  no  pending decision

Explanation:

or

(2) The following:

(i) The research presents a reasonable opportunity to further the understanding, prevention, or alleviation of a serious problem affecting the health and welfare of children.

yes  no  unclear

Explanation:

( ii ) The research will be conducted in accordance with sound ethical principals

yes       no       unclear

Explanation:

(iii) Adequate provisions are made for soliciting the assent of children and the permission of their parents or guardians, as set forth in Section 46.408.

yes       no       unclear

Explanation:

Final Decision: Findings are in compliance with Section 46 subpart D.

Vote:  in favor       opposed       abstained

Investigators name (s):

Title of study:

Findings regarding conditions to be met to conduct research with children regarding the permission of parents for research under section 46.406 and 407.

1. Decision: Adequate provisions have been made for soliciting the permission of each child's parents (both) or guardian(s).

yes                       no                       unclear

Explanation:

Vote:  in favor                       opposed                       abstained

2. Decision: Both parents cannot give permission because 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.

yes                       no                       unclear

Explanation:

Vote:  in favor                       opposed                       abstain

3. Decision: Documentation of parental or guardian's permission is in accordance with and to the extent required in Section 46.117.

yes                       no                       unclear

Explanation:

Vote:  in favor                       opposed                       abstain

Investigators name (s):

Title of study:

Findings regarding conditions to be met to conduct research with children for which parental or guardian's permission is not a reasonable requirement to protect subjects (46.408 (c))

1. Decision: This 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, e.g., neglect or abused children.

yes                       no                       unclear

Explanation:

Vote:  in favor                       opposed                       abstained

2. Decision: Waiver of the consent requirement, in subpart A and subpart D 46.408 (d) are appropriate provided

(a) an appropriate mechanism for protecting the children who will serve as subjects in the research is substituted, and

(b) that the waiver is not inconsistent with federal, state or local law

yes                       no                       unclear

Note: The choice of an appropriate mechanism depends upon the nature and purpose of the activities described in the protocol, the risk and anticipated benefit to the research subjects, and their age, maturity, status, and condition.

Explanation:

Vote:  in favor                       opposed                       abstained

Investigator's name (s):

Title of study:

Findings regarding condition to be met to conduct research with children relative to the assent of children.

1. Decision: There is no greater than minimal risk to children presented in the research study.

yes                       no                       unclear

Explanation:

Vote  in favor                       opposed                       abstained

If yes, then go to  \_\_\_\_\_

2. Decision: Adequate provisions are made for soliciting the assent of children who are considered capable of providing assent and for the permission of their parents or guardians

yes                       no                       revisions needed

Explanation:

Vote:  in favor                       opposed                       abstained

3. Decision: The procedures for documentation of the required assent are appropriate and adequate

yes                       no                       pending revision  
 revision approved

or

4. Decision: Although assent is required, documentation of it is not required.

yes                       no                       unclear

Explanation:

Vote:  in favor                       opposed                       abstained

5. Decision: Factors such as age, maturity and psychological state of the children involved indicate that the capability of a given child or all children in the research is so limited that they cannot reasonably be consulted.

yes

no

unclear

Explanation:

6. Decision: Despite the limited capability of the child or children to assent, the intervention or procedure 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.

yes

no

unclear

Explanation:

7. Decision: The assent of a child or the children in the study is not required for reasons stated in decision 3 or 4 above.

yes

no

pending revisions

revisions approved

Date:

Vote:  in favor

opposed

abstained

Additional Findings required for Wards:

Decision: The research is related to the subjects status as wards.

Yes  No  Pending revision   
Revision approved

Explanation:

Vote:  In favor  Opposed  Abstaining

If yes, continue below:

Decision: The IRB has required 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. (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 and who 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.

Yes  No

Vote:  In favor  Opposed  Abstaining

**OR**

Decision: The research will be conducted in schools, camps, hospitals, institutions, or similar settings in which the majority of children involved as subjects are not wards.

Yes  No  Pending Revision  Revision Approved

Explanation:

re: 404, 405, 406, 407 & 409

Additional Findings Required:

For waiver of signature on Informed Consent Form

Decision: The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern.

yes                       no                       pending revision   
 revision approved

Explanation: (protocol specific)

**OR**

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

yes                       no                       pending revision   
 revision approved

Explanation (protocol specific):

