SOP: 701
CONSENT PROCESS AND DOCUMENTATION

1. POLICY

The IRB requires investigators to obtain legally effective informed consent.

Informed consent is the process by which the research study is explained to the potential participant and the participant then voluntarily agrees to participate in the research. Except as described in Section 1.3, informed consent to participate in a research study must be obtained from all participants (or their legally authorized representative) prior to their participation in the research.

The IRB requires that the research team must obtain legally effective informed consent, prior to conducting any study-related procedure or intervention, from each research participant or from his/her legally authorized representative. However, there are circumstances in which the IRB may grant a waiver of informed consent in accordance with Federal regulations.

Definition of legally effective informed consent: All of the required elements of the informed consent are contained in the consent form document. The consent of the participant is obtained prior to conducting any study-related procedure or intervention, and the person signing the consent form is the participant or the participant's legally authorized representative.

Specific Policies

1.1 Written Informed Consent

The IRB requires documentation of informed consent by use of a written informed consent form approved by the IRB and signed and dated by the participant or the participant's legally authorized representative, the person obtaining consent, the principal investigator if required by the sponsor, and a witness when appropriate.

The informed consent form must contain all federally required elements of informed consent plus additional federally required elements as indicated below.

A. Required Elements of Informed Consent

1. Consent is sought only under circumstances that provide the participant or the legally authorized representative sufficient opportunity to consider whether to participate and that minimize the possibility of coercion or undue influence.
2. Required Core Elements of Informed Consent:
    a. A statement that the study involves research.
    b. An explanation of the purposes of the research.
    c. The expected duration of the participant's participation.
    d. A description of the procedures to be followed
    e. Identification of any procedures that are experimental.
    f. A description of any reasonably foreseeable risks or discomforts to the participant.
    g. A description of any benefits to the participant or to others which may reasonably be expected from the research.

h. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the participant.

i. A statement describing the extent, if any,to which the confidentiality of records identifying the participant will be maintained and that notes the possibility that the IRB and Food and Drug Administration (if applicable) may inspect the records.

j. For research involving more than minimal risk, an explanation as to whether any compensation is provided and an explanation as to whether any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained.

k. An explanation of whom to contact for answers to pertinent questions about the research and research participants' rights and whom to contact in the event of a research-related injury to the participant.

l. A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the participant is otherwise entitled, and that the participant may discontinue participation at any time without penalty or loss of benefits to which the participant is otherwise entitled.

For DoD sponsored research, DoD components may have stricter requirements than Common Rule requirements for research-related injury.

3. Additional Elements of Informed Consent that May Be Required:

a. A statement that the particular treatment or procedure may involve risks to the participant (or to the embryo or fetus if the participant is or may become pregnant) which are currently unforeseeable. (Include when the research involves investigational test articles or involves procedures whose risk profile is not well known.)

b. A statement of anticipated circumstances under which the participant's participation may be terminated by the investigator or the sponsor without regard to the participant's consent. (Include when there are known circumstances under which the individual's participation may be terminated by the investigator or sponsor.)

c. A statement of any additional costs to the participant that may result from participation in the research (Include when there are additional costs to the participant that may result from participation in the research.)

d. A description of the consequences of a participant's decision to withdraw from the research and procedures for orderly termination of participation by the participant. (Include the consequences of a participant's decision to withdraw from the research when there are adverse consequences of a participant's decision to withdraw from the study.) (Include procedures for orderly termination of participation by the participant when such procedures are defined in the protocol.)

e. A statement that significant new findings developed during the course of the research that may relate to the participant's willingness to continue participation will be provided to the participant. (Include when such findings are likely to develop during the course of the research.)

f. The approximate number of participants involved in the study. (Include when such information might affect an individual's willingness to participate.)

g. The amount and schedule of payments.

B. Documentation of Informed Consent

1. Except as described below in Section 1.4, documentation of informed consent (usually written) is required to conduct research studies involving human participants. Documentation of informed consent is required for all studies that involve more than minimal risk.

2. Format of written informed consent.

a. Unless otherwise authorized by the IRB, the consent form must use the format and template language provided in the sample on the IRB website.

b. The consent form must be in a question/answer format. OU Norman Campus IRB does not require a question format for the consent template.

c. The consent form must be written in the second person.

d. The consent form is written in language understandable to the participant. All necessary medical or technical terms must be explained in lay terms.

e. The consent form may not contain any exculpatory language through which the participant waives or appears to waive legal rights or releases or appears to release the investigator, the sponsor, or the University of Oklahoma from liability for negligence.

f. The consent form may not contain any language that disclaims or limits the warranty of drugs or devices used in the research.

g. The consent form must be signed and dated by the participant, the person obtaining consent, and the investigator (if required by the sponsor).

h. Informed Consent forms used for participants at the VAMC must include a witness to the participant's signature.

i. The participant must be given a copy of the signed consent form. The original signed informed consent is to be kept on-file at the investigator's site for auditing purposes.

j. The final approved consent form must be stamped by the IRB office with the date of approval and date of expiration. The expiration date will be no longer than 1 year after the last review by the convened Board or, if expedited review, by the Chair/Vice-Chair. All participants must sign the currently

approved IRB stamped form prior to participating in any study-related activity.

1.2 Verbal Consent and Obtaining Consent From Participants Who Do Not Speak English

Except as provided in Section 1.3 of this SOP, informed consent shall be documented by the use of a written consent form approved by the IRB and signed by the participant or the participant's legally authorized representative. A copy shall be given to the person signing the form. Except as provided in Section 1.4 of this policy, the consent form may be either of the following:

A. A written consent document that embodies the elements of the informed consent required in Section 1.1 of this SOP. This form may be read to the participant or the participant's legally authorized representative, but in any event, the investigator shall give either the participant or the representative adequate opportunity to read it before it is signed; or

B. A short form written consent document stating that the elements of informed consent required in Section 1.1 of this SOP have been presented orally to the participant or the participant's legally authorized representative. When this method is used, there shall be a witness to the oral presentation. Also, the IRB shall approve a written summary of what is to be said to the participant or the representative. Only the short form itself is to be signed by the participant or the representative. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining consent shall sign a copy of the summary. A copy of the summary shall be given to the participant or the representative, in addition to the copy of the short form.

The IRB shall consider the use of the short form written consent document in the following situations:

1. The participant is blind,
2. The participant is illiterate,
3. The participant does not speak English and cannot read the English version of the consent document.

Participants who do not speak English should be presented with a consent document written in a language understandable to them. The IRB strongly encourages the use of this procedure (presented with a consent document written in a language understandable to them) whenever possible.

For additional consent requirements for VA research, see Section 1.8 of this SOP.

1.3 Waiver of Informed Consent:

A. The requirement for informed consent may be waived partially or entirely by the IRB or the IRB Chair if the following conditions are met:

1. There is no more than minimal risk (including confidentiality risks) to the participants;
2. The waiver or alteration of consent will not adversely affect the rights and welfare of the participants;
3. The research could not practicably be carried out without the waiver or alteration; and
4. When appropriate, the participants will be provided with additional pertinent information after participation

   Note: The research must not be subject to FDA regulations, as the FDA has no provision for waiver or alteration of consent.

B. Examples of research that might qualify for a waiver of informed consent include but are not limited to:

1. Retrospective chart reviews
2. Observation of public behavior
3. Research or demonstration projects that are conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine:
   a. Public benefit or service programs
   b. Procedures for obtaining benefits or services under public or service programs
   c. Possible changes in or alternatives to public or service programs or procedures, or
   d. Possible changes in methods or levels of payment for benefits or services under public or service programs, and
4. In addition, the research could not practicably be carried out without the waiver or alteration.

   Note: The research must not be subject to FDA regulations, as the FDA has no provision for waiver or alteration of consent.

C. Emergency exemption from informed consent to participate in research that would normally require consent (i.e., research involving more than minimal risk) is not allowed under Oklahoma law.

D. Department of Defense-Sponsored Research

If the research participant meets the definition of "Experimental Subject", as defined in SOP IV, Glossary, a waiver of consent is prohibited unless a waiver is obtained from the Secretary of Defense. If the research participant does not meet the definition of Experimental Subject, the IRB may waive consent. See SOP 603F, Department of Defense.

1.4 Waiver of Documentation of Informed Consent

A. Documentation of informed consent may be waived partially or entirely by the IRB or designee if it finds either:
   1. That all of the following are true:
      - The only record linking the participant and research would be the informed consent document, and

- The principal risk would be potential harm from a breach of confidentiality.
- Each participant will be asked whether the participant wants documentation linking the participant with the research, and the participant's wishes will govern,
- The research is not subject to FDA regulations**.**

2. Or that both of the following are true:
   - The research presents no more than minimal risk of harm to participants, and
   - The research involves no procedures for which written consent is normally required outside the research context.

An example of a type of study that would qualify for a waiver of documentation of informed consent is a survey.

If the IRB waives the requirement of documentation of informed consent, the IRB may require the investigator to provide a written statement of the research to the participant. The IRB shall review and approve the written statement prior to the investigator providing the statement to the participant. The informed consent form reviewed and approved by the IRB may also serve as the written statement.

1.5 Surrogate Consent by a Legally Authorized Representative

The IRB will not waive the requirement for informed consent for human research studies where informed consent is required. Under special circumstances, however, it may be appropriate to obtain surrogate consent to allow adult patients who, because of a medical condition, are incapable of giving informed consent for themselves, to be enrolled in research studies. Such consent must be obtained in accordance with Oklahoma Statutes, Title 63 §3102A, when the impairment is a cognitive one. The intent of this provision is to allow research of incapacitating conditions such as dementia, head trauma, coma, sepsis, and psychiatric disorders. Generally speaking, it is not intended to allow enrollment of incapacitated patients into protocols where competent patients are also to be enrolled (particularly randomized studies) unless the study involves access to treatments that may be of direct benefit to the participant, but which are not available outside of the research context.

A. The use of surrogate consent for incapacitated participants in a study must be approved by the convened IRB, whether a general permission or specific permission for an individual participant. In deciding whether it is appropriate to allow the use of surrogate consent, the IRB will consider:
   1. Will participating in the study directly benefit the participant?
   2. Are there alternative standard/approved treatments available for this participant?
   3. Could this study be done in a less vulnerable population?
   4. If there is no direct benefit to the individual participant, would the information gained result in a potential benefit for other patients with the same incapacitating condition?

5. If there is no direct benefit to the individual participant, is there more than a minimal risk to participation?

B. The participant must be treated by a licensed physician who holds a faculty appointment at an accredited medical or osteopathic school. If the treating physician and the investigator are not the same person, then the investigator must get the approval of the treating physician for the individual's participation.

C. No surrogate consent will be accepted if the experimental treatment is in contravention to the incapacitated person's expressed permission or authorization.

D. Surrogate informed consent may be obtained from a legal guardian, attorney-in-fact with health care decision authority, or a family member (in the following order: spouse, adult child, either parent, adult sibling, or a relative by blood or marriage) when the IRB approves this type of consent and if the participant is incapable of giving informed consent. When the legal guardian or attorney-in-fact with health care decision authority provides consent, the investigator must obtain a copy of the guardianship papers.

E. If the individual previously refused to participate in the research (at a time when he/she was competent to make that decision), his/her wishes cannot be subsequently overridden by the legal guardian, attorney-in-fact, or family member after the individual becomes incompetent.

F. Individuals who are incompetent to give informed consent may be able to assent to participation. (The IRB may require or waive participant assent, depending on the level of incapacity.)

G. If it is a long-term study and the participant for whom surrogate consent was obtained regains competency, the informed consent process should be repeated with the participant.

H. Surrogate consent may be allowed in non-therapeutic research if the research entails no more than minimal risk to the participant.

I. Surrogate consent cannot be used for participants who, in addition to being incapacitated, are pregnant or prisoners.

J. For surrogate consent involving VA patients, the approval of the VA Chief of Staff is required. For VA research, the definition of a legally authorized representative is located in section 1.9 of this SOP. The VA order of priority for next-of-kin differs from the order of priority under Oklahoma law.

K. Legally Authorized Representative:

For research involving health care treatments or procedures conducted in Oklahoma, under which federal regulation and Oklahoma law both apply, the following individuals in the following order can serve as a legally authorized representative and provide surrogate consent:

- a legal guardian
- attorney-in-fact with health care decision authority

- a family member (in the following order: spouse, adult child, either parent, adult sibling, or a relative by blood or marriage).

For research involving procedures that are **not** health care related conducted in Oklahoma, where federal regulation and Oklahoma law both apply, the following individuals in the following order can serve as a legally authorized representative and provide surrogate consent:

- A legal guardian
- attorney-in-fact with health care decision authority

For research conducted outside of Oklahoma, individuals who meet the definition of a legally authorized representative are those individuals as described under the applicable law of the jurisdiction in which the research will be conducted. If recruiting a participant through a legally authorized representative, the investigator must report this category of participant on the IRB application and provide to the IRB the definition of legally authorized representative for the applicable jurisdiction.

Children:

For research conducted in Oklahoma, where federal regulations and Oklahoma law both apply, individuals under the age of 18 are considered to meet the DHHS and FDA definition of "children."

For research conducted outside of Oklahoma, individuals who meet the definition of a child are those individuals as described under the applicable law of the jurisdiction in which the research will be conducted. If recruiting children outside of Oklahoma, the investigator must report this category of participant on the IRB application and provide to the IRB the definition of child for the jurisdiction.

Guardian:

For research conducted in Oklahoma, where federal regulations and Oklahoma law both apply, a guardian is an individual who is authorized to consent to the general medical care of a child and therefore meet the DHHS and FDA definition of "guardian."

For research conducted outside of Oklahoma, investigators must provide on the IRB application the definition of a guardian in the jurisdiction in which enrollment will take place. Only those individuals will be able to provide consent for children.

For additional consent requirements for VA research, see Section 1.9 of this SOP.

Legal Counsel may be consulted by the HRPP Director and IRB Chair for assistance in applying laws to research involving human participants.

1.6 Informed Consent in Vulnerable Populations

A. Informed Consent in Children

"**Assent**" in research involving children means a child's affirmative agreement to participate in research. Mere failure to object should not be

construed as assent. "**Permission**" in research involving children means the agreement of the parent(s) or guardian to the participation of their child or ward in research. Informed legal consent for children must meet the following:

Children are defined as being less than 18 years old. Oklahoma law does not recognize the concept of an “emancipated minor” for the purposes of research.

1. In children, informed consent is obtained from the parent (s) or legal guardian.
2. Research involving more than minimal risk without the prospect of direct benefit requires both parents’ signatures when both are available. 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.
3. For some types of research where documentation of informed consent would normally be waived (such as surveys), documentation may be required for children.
4. Assent from the child is usually required unless:
    a. The minor participant is too immature or incapacitated to be consulted.
    b. The intervention/procedure involved in the research holds out the prospect of direct benefit that is important to the health or well-being of the child and is available only in the context of the research.
    c. The assent document would be the only link between the participant and the research and would pose a confidentiality risk.

    Assent is documented depending on the age, maturity, and psychological state of the child:
        iii. Age < 7 years old, assent is waived or verbal assent is obtained, as determined by the IRB.
        iv. Age 7-12 years old, a simple assent statement is obtained.
        v. Age 13-17, the IRB approved informed consent form is used, with a statement of assent added.

    5. Assent may be obtained verbally or as a written document or a combination of both as appropriate to the age, maturity, and psychological state of the child as well as the nature of the study.

B. Informed Consent in Research Involving Pregnant Women

For research involving pregnant women and/or fetuses, consent must be obtained from both the pregnant woman and father unless:

1. The purpose of the research is to meet the health needs of the mother.

2. The identity or whereabouts of the father cannot reasonably be ascertained or he is otherwise unavailable.

3. The pregnancy resulted from rape or incest.

C. Informed Consent in Research Involving Native Americans

1. Informed consent from the individual participant is sufficient if the study is not directed at or about Native Americans as a group.

2. For studies involving Native Americans as a group, informed consent is required from the individual participant and the appropriate tribal authority.

D. Informed Consent in Research Involving Prisoner Populations

1. The informed consent will be presented in language that is understandable to the prisoner population.

2. The informed consent form shall include language to clearly inform participants in advance that parole boards will not take into account a prisoner's participation in research in making decisions regarding parole.

E. Informed Consent in Research Involving Other Vulnerable Groups

Other vulnerable groups may include mentally impaired persons, HIV+ participants, employees of the sponsor or investigator, terminally ill patients, and the elderly, 65 years of age and older. The IRB will determine special protections for these groups on a case-by-case basis, taking into account the risks and benefits and other protections afforded by institutional policies and state and federal law.

1.7 Re-consenting Participants

The investigator has a responsibility to inform research participants of any new information that might affect a participant's willingness to continue participating in the research. Often, re-consent can be obtained verbally with the investigator documenting in the research file that he/she has done so. However, under certain circumstances, the investigator must obtain written documentation that the new information was conveyed to the participant and the participant agreed to continue in the study. Written documentation of re-consent must be obtained by having the participant sign an updated version of the informed consent document or an addendum to the original consent form.

A. Written documentation of the participant's willingness to continue to participate must be obtained if there is a significant change to the protocol or risk that directly affects what the research participant is being asked to do. Examples include:

1. The study was originally going to last for 6 weeks but now the participants are going to be followed for 5 years.
2. The study drug was originally to be given in randomized, double-blind fashion but now is going to be open label.

3. The drug was recently reported to cause liver failure.
4. The drug was originally intended to be given by peripheral IV but now requires a central line.
5. Blood originally stored for future analysis of unknown biomarkers will now be used for genetic testing.

B. Minor changes that require notification but not written informed consent include:

1. Study required 5cc of blood but now requires 10cc of blood.
2. Changes to surveys (unless the new questions pose new risks; i.e., questions about illegal activity).
3. Final follow-up visit was originally scheduled in-office but now will occur via telephone.

C. Participants who were enrolled in research studies at a time when they were minors must be re-consented when they turn 18 years old if they are still actively participating in the study.

D. Participants who were enrolled in a research study by a legally authorized representative should be re-consented when they regain competency (if they are still actively participating in the study).

1.8 VA Research

A. Additional Consent Requirements for VA Research

1. For VA research, consent is documented through the use of VA Form 10-1086. It includes the VA required language and the requirements for the signature and date of the witness and the person obtaining consent.
2. If someone other than the investigator will be conducting the interview and obtaining consent, the investigator must formally delegate the responsibility to an individual who has received appropriate training to perform this activity.
3. A witness to the participant's signature or the participant's legally authorized representative's signature is required to sign and date the consent document. A signed and dated copy of the informed consent document is given to the person signing the form. If the sponsor requires a witness to the consenting process in addition to the participant's signature and if the same person needs to serve both capacities, then a note to that effect is placed under the witness signature line.
4. IRB approval of the VA informed consent document is documented through the use of a stamp on each page of the VA Form 10-1086 that indicates the date of the most recent IRB approval.
5. If the informed consent document for VA research is amended during the protocol approval period, the document will bear the approval date of the amendment rather than the date of the approved protocol.
6. In the event of a research-related injury the VA has to provide necessary medical treatment to a participant injured by participation.

7. A veteran-participant will not be required to pay for care received as a participant in a VA research project except in accordance with federal law and that certain veterans are required to pay co-payments for medical care and services provided by VA.

8. All regulations pertaining to the participation of veterans as participants including requirements for indemnification in case of research-related injury pertain to non-veteran participants enrolled in VA-approved research.

B. Written Consent Document (Short Form)

1. A shortened written consent document stating that the elements of informed consent required in 38 CFR 16.116 have been presented orally to the participant or the participant's legally authorized representative may be used. When this method is used, there must be a witness to the oral presentation. This process includes the following:

   a. The IRB must approve a written summary of what is to be said to the participant or the participant's legally authorized representative.

   b. The participant or the participant's legally authorized representative must sign and date only the short form of the consent documentation.

   c. The witness must sign and date **both** the short form and a copy of the IRB-approved summary. The person actually obtaining the consent must sign and date a copy of the summary. The original short form and summary must be filed as required.

   d. A copy of the signed and dated short form must be given to the participant or the participant's legally-authorized representative, along with a copy of the signed and dated summary.

C. Progress Note Documenting the Consent Process

1. For VA research, a progress note documenting the consent process is placed in the participant's medical record that records:

   - The name of the study.
   - The person obtaining the participant's consent.
   - A statement that the participant or the participant's legally authorized representative is capable of understanding the consent process.
   - A statement that the study is explained to the participant.
   - A statement that the participant is given the opportunity to ask questions.

The progress note also documents when a participant is entered into the research study and when a participant's participation is terminated.

D. VA Research Involving Adults Who Lack the Ability to Consent

1. For VA research, the IRB limits consent by a legally authorized representative to situations where the prospective participant is incompetent or has impaired decision-making capacity, as determined and documented in the person's medical record in a signed and dated progress note.
2. The IRB requires that the determination that a participant is incompetent or has an impaired decision-making capacity to be made by a legal determination or a determination by a practitioner, in consultation with the chief of service, after appropriate medical evaluation that the prospective participant lacks decision-making capacity and is unlikely to regain it within a reasonable period of time.
3. The IRB requires consultation with a psychiatrist or licensed psychologist to be obtained if the determination that the prospective participant lacks decision-making capacity is based on a diagnosis of mental illness.
4. The IRB requires that, when feasible, the practitioner explains the proposed research to the prospective participant even when the surrogate gave consent.
5. The IRB prohibits participants from being forced or coerced to participate in a research study.
6. For VA research, the legally authorized representative is defined as the following persons in the following order of priority:
    - Health-care agent.
    - Legal guardian or special guardian.
    - Next-of-kin: a close relative of the patient eighteen years of age or older, in the following priority: Spouse, adult child (18 years or older), parent, sibling (18 years or older), grandparent, adult grandchild (18 years or older), close friend (18 years or older).

2. Scope

These policies and procedures apply to all research submitted to the IRB.

3. Responsibility

The IRB is responsible to verify that the consent form allows for the signature of both parents where research meets the regulations of 45 CFR §46.406 and 45 CFR §46.407.

The IRB is responsible for determining which of the procedures at 45 CFR §46.117(b) is appropriate for documenting informed consent in protocols that it reviews.

The IRB Chair or designee is responsible for determining whether informed consent exemptions or waivers of documentation of informed consent are applicable and appropriate with regard to research meeting expedited criteria.

The IRB Chair or designee is responsible for reviewing consent forms or changes to consent forms meeting expedited review criteria.

The investigator is responsible for providing appropriately translated consent documents if there is the potential for or actual inclusion of non-English speaking participants. Translated consents must be accompanied by a letter from the translator attesting to the accuracy of the translated consent.

The investigator is responsible to provide a detailed description of the consent method, process, timing, and methods to reduce undue influence.

4. Applicable Regulations and Guidelines

21 CFR 50.23, 50.24

21 CFR 56.109 (c), 56.109 (d)

38 CFR 16

45 CFR 46.116

45 CFR 46 Subpart A

45 CFR 46 Subpart B

45 CFR 46 Subpart D

OHRP Guidance: 11/09/95 Obtaining and Documenting Informed Consent of Subjects Who Do Not Speak English

5. References to Other Applicable SOPS

This SOP affects all other SOPs that include references to informed consent.

6. Attachments

701-A	Informed Consent Template
701-A-1	Informed Consent to Participate in a Research Study
701-A-2	ICF Template Information Sheet – Norman Campus
701-A-3	Assent to Participate in a Research Study
701-B	Child Assent Template
701-C	Tissue Consent Template
701-D	Patient Information Sheet – Tissue Banking
701-E	Template for Informed Consent Addendum
502-G-A	Sample Consent Form for Emergency Use
203-A	New Study Reviewer Checklist – Full Board (HSC)
203-A-1	New Study Reviewer Checklist – Full Board (NC)
203-B	New Study Reviewer Checklist – Expedited (HSC)
203-B-1	New Study Reviewer Checklist – Expedited (NC)
203-D	VA Research Reviewer Checklist
203-E	Reviewer Checklist for Research Involving Pregnant Women, Fetuses & Neonates (HSC)
203-E-1	Reviewer Checklist for Research Involving Pregnant Women, Fetuses & Neonates (NC)
203-F	Reviewer Checklist for Research Involving Prisoners (HSC)
203-F-1	Reviewer Checklist for Research Involving Prisoners (NC)
203-G	Reviewer Checklist for Research Involving Children (HSC)
203-G-1	Reviewer Checklist for Research Involving Children (NC)

203-H Continuing Review Reviewer Checklist (HSC)
203-H-1 Continuing Review Reviewer Checklist (NC)
203-I Modification Reviewer Checklist (HSC)
203-I-1 Modification Reviewer Checklist (NC)
203-J Waiver of Consent Checklist (HSC)
203-J-1 Waiver of Consent Checklist (NC)

7. Process Overview

7.1 Submitted items are processed per SOP 301, Research Submission Requirements.

7.2 The IRB Administrator is responsible for reviewing the consent form to ensure all required elements and the additional elements of the consent form are present, if applicable, by completing the consent form section of the reviewer checklist prior to forwarding to the IRB Chair. The IRB Administrator provides the reviewers with the appropriate reviewer checklists per SOP 203, Duties of IRB Members.

7.3 At the convened IRB meeting, the IRB members review the consent process as described on the application (or request for waiver of consent), the content of the consent document, the required/additional elements, presence/absence of exculpatory language, any language that disclaims or limits the warranty of drugs or devices, and/or requested changes. The IRB will either approve the consent as is or recommend revisions to the content. In the case of expedited review, the IRB Chair reviews the consent for content and either approves or recommends revisions.

7.4 When the revised consent document is returned from the investigator, the IRB Administrator will confirm that all of the changes have been made and will present them to the IRB Chair or designee for review. If the IRB Chair determines that convened Board review is necessary, the IRB Administrator will post the item to the next appropriate meeting agenda.

7.5 In the event the consent process or consent document is in a language other than English, the IRB must receive appropriately translated documents and a signed attestation from the translator and assess the consent process.

7.6 The IRB Administrator documents in the minutes per SOP 303C, Meeting Minutes, the outcome of any IRB discussion related to the consent process or the consent document including, but not limited to:

- Use of non-English documents and use of translator
- Use of surrogate consent from a legally-authorized representative
- Consent requirements related to minors, pregnant women, and fetuses
- Waiver of consent or waiver of documentation of consent
- Letters of tribal support when research involves Native Americans/American Indians as a group

7.7 Once consent documents are approved, the IRB Administrator will stamp each page of the consent document, assent document (if applicable), or short form (if applicable) with a red approval and expiration stamp and process all documents per SOP 304, Documentation, Document and Data Management. The red-stamped version of the consent document is forwarded to the investigator. The IRB keeps a copy of the stamped consent document in the IRB study file.

APPROVED BY:_____ **DATE: 01/15/2010**

NEXT ESTABLISHED REVIEW DATE: MAY 2012