

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

Informed consent is legally effective if it is both obtained from the research participant or the research participant's legally authorized representative and documented in a manner that is consistent with the Health and Human Services (HHS) protection of human research participants regulations and with applicable laws of the jurisdiction in which the research is conducted. In general terms, the regulations stipulate that an investigator should seek consent only under circumstances that provide the prospective research participant or the legally authorized representative sufficient opportunity to consider whether to participate and that minimize the possibility of coercion or undue influence. The information provided should be in language that is understandable to the research participant or the representative. No informed consent, whether oral or written, may include any exculpatory language.

It is important to note that the informed consent requirements in the regulations are not intended to preempt any applicable federal, state, or local laws that require additional information to be disclosed for consent to be legally effective (45 CFR 46.116(e)).

The IRB requires that a research team member must obtain legally effective informed consent, prior to conducting any research project-related activities. However, there are circumstances in which the IRB may grant a waiver of informed consent in accordance with Federal regulations.

Neither "passive" nor "implied" consent is recognized by the IRB, per HHS regulations

Specific Policies

1.1 Written Informed Consent

The IRB requires documentation of informed consent by use of a written informed consent documents approved by the IRB and signed and dated by the participant or the participant's legally authorized representative, the person obtaining consent, the investigator if required by the sponsor, and a witness when appropriate. The participant or the representative must be given adequate opportunity to read it before it is signed.

The informed consent documents 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 research project 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 who may reasonably be expected to benefit 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 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. See SOP 603F: Department of Defense.

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 with a risk profile that is not well known.)
 - b. A statement of anticipated circumstances under which the participant's participation in the research project 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 research project.) (Include procedures for orderly termination of participation by the participant when such procedures are defined in the protocol.)
 - When a participant withdraws from a study, the data collected on the participant to the point of withdrawal remains part of the study database and may not be removed. The consent document cannot give the participant the option of having data removed.
 - A Researcher may ask a participant who is withdrawing whether the participant wishes to provide continued follow-up and further data collection subsequent to their withdrawal from the interventional portion of the study. Under this circumstance, the discussion with the participant distinguishes between study-related interventions and continued follow-up of associated clinical outcome information, such as medical course or laboratory results obtained through noninvasive chart review, and address the maintenance of privacy and confidentiality of the participant's information.
 - The Researcher must obtain the participant's consent for this limited participation in the study (assuming such a situation was not described in the original consent document). The IRB or EC must approve the consent document.
 - If a participant withdraws from the interventional portion of a study and does not consent to continued follow-up of associated clinical outcome information, the Researcher must not access for purposes related to the study the participant's medical record or other confidential records requiring the participant's consent. However, a Researcher may review study data related to the participant collected prior to the participant's withdrawal from the study, and may consult public records, such as those establishing survival status.
- 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 research project. (Include when such information might affect an individual's willingness to participate in the research project.)
- g. The amount and schedule of payments.
- h. The following exact statement must be included in the informed consent documents of "applicable clinical trials:" "A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."

B. Documentation of Informed Consent

- 1. Except as described below in Section 1.4, documentation of informed consent (usually written) is required according to legal and regulatory requirements 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 document must use the format and template language provided in the sample on the IRB website.
 - b. The consent document must be in a question/answer format. (OU Norman Campus IRB does not require a question format for the consent template.)
 - c. The consent document must be written in the second person.
 - d. The consent document is written in language understandable to the participant. All necessary medical or technical terms must be explained in lay terms.
 - e. The consent document 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 document may not contain any language that disclaims or limits the warranty of drugs or devices used in the research, except as to efficacy of the drug or device.
 - g. The consent document must be signed and dated by the participant, the person obtaining consent, and the investigator (if required by the sponsor).
 - h. 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 and is subject to audit.

- i. The final approved consent document 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 IRB Chair. All participants must sign the currently approved IRB stamped document prior to participating in any research project-related activity.
- j. Investigators shall use the consent form template available on the University's IRB websites for documenting consent. For VA research, VA Form 10-1086, VA Research Consent Form, shall be used for documenting consent. See SOP 603A: Veterans Affairs Medical Center.

1.2 Obtaining Consent From Participants Who Do Not Speak English

DHHS regulations require that informed consent information be presented in a language understandable to the subject and, in most situations, that informed consent be documented in writing. Participants who do not speak English should be presented with a consent document (a document that embodies all of the elements of the informed consent as required in Section 1.1 of this SOP) written in a language understandable to them. The IRB strongly encourages the use of this procedure whenever possible.

This document 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.

Alternatively, oral presentation of informed consent information in conjunction with a short form written consent document (stating that the elements of consent have been presented orally) and a written summary of what is presented orally is permitted.

When this method is used, follow the guidance below:

- 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) There shall be a third-party witness to the oral presentation.
- d) 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 in the investigator's files in accordance with the sponsor's requirements .
- e) 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.

The IRB shall also consider the use of the short form written consent document when the participant is blind or illiterate.

For written consent document (Short Form) requirements for VA research projects, see SOP 603A: Veterans Affairs Medical Center.

1.3 Waiver of Informed Consent:

A. The requirement for informed consent may be waived partially or entirely by the IRB or the IRB designee 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 are 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 addressed 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

The IRB or IRB designee may waive documentation of informed consent partially or entirely 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 research project 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 approve the written statement prior to the investigator providing the statement to the participant. The informed consent documents 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 research projects where competent patients are also to be enrolled (particularly randomized studies) unless the research project 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 research project 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 research project directly benefit the participant?
 2. Are there alternative standard/approved treatments available for this participant?
 3. Could this research project 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?
 6. If the plan for the assessment of the capacity is adequate.
 7. If the assent of the participant is a requirement, and, if so, whether the plan for assent is adequate.
- 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. 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.
- D. If the individual previously refused to participate in the research (at a time when he/she was competent to make that decision), the legal guardian, attorney-in-fact, or family member cannot subsequently override his/her wishes after the individual becomes incompetent.
- E. 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.)
- F. The research project is a long-term study and the participant for whom surrogate consent was obtained regains competency during the project, the informed consent process should be repeated with the participant, as described in SOP 501: Special Populations.
- G. Surrogate consent may be allowed in non-therapeutic research if the research entails no more than minimal risk to the participant.

- H. Surrogate consent cannot be used for participants who, in addition to being incapacitated, are pregnant or are prisoners.
- I. For surrogate consent involving VA patients, see SOP 603A: Veterans Affairs Medical Center.
- J. Legally Authorized Representative:

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

- 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 submission and provide to the IRB the definition of legally authorized representative for the applicable jurisdiction.

- K. 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 submission and provide to the IRB the definition of child for the jurisdiction.

- L. Guardian:

For research conducted in Oklahoma, where federal laws 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 submission 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 to participate in a research project.

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.

For LAR requirements specific to VA research projects, see SOP 603A Veterans Affairs Medical Center.

1.6 Informed Consent in Special 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 no more than minimal risk or more than minimal risk with or 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. The IRB may waive the requirement for parental permission under the same conditions that it may waive informed consent as noted in Section 1.3 above, if it determines:
 - the research project is designed to study conditions in children or a participant population for which parental or guardian permission is not a reasonable requirement to protect the participants (e.g., neglected or abused children),
 - there is an appropriate mechanism in place to protect the children, and
 - the waiver is not inconsistent with federal, state or local law.
5. 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 document is used, with a statement of assent added.

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 research project.

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 research project 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 document 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. See SOP 501: Special Populations.

E. Informed Consent in Research Involving Other Special Populations

Other special populations 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 applicable University 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 research project. 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 research project or risk that directly affects what the research participant is being asked to do. Examples include:
 - 1. The research project was originally going to last for 6 weeks but now the participants are going to be followed for 5 years.
 - 2. The research project 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. Research project required 5cc of blood but now requires 10cc of blood.
 - 2. Surveys are changed (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 research project.

- D. Participants who were enrolled in a research project by a legally authorized representative should be re-consented when they regain competency (if they are still actively participating in the research project).
- E. For Additional Consent Requirements for VA Research Projects see SOP 603A: Veterans Affairs Medical Center. Note: for VA Research, VA Form 10-1086 is required to be submitted to show documentation of consent.

2. Scope

This SOP applies to all research submitted to the IRB.

3. Responsibility

- 3.1 The IRB is responsible to verify that the consent documents allow for the signature of both parents where research meets the regulations of 45 CFR §46.406 and 45 CFR §46.407.
- 3.2 The IRB is responsible for determining which of the procedures at 45 CFR §46.117(b) is appropriate for documenting informed consent in research projects that it reviews.
- 3.3 The IRB Chair or IRB 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.
- 3.4 The IRB Chair or IRB designee is responsible for reviewing consent documents or changes to consent documents meeting expedited review criteria.
- 3.5 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 consent documents must be accompanied by a letter from the translator attesting to the accuracy of the translated consent.
- 3.6 The investigator is responsible to provide in the IRB submission a detailed description of the consent method, process, timing, and steps implemented 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

Oklahoma Statutes, Title 63 §3102A

5. References to Other Applicable SOPS

SOP 301: Research Submission Requirements

SOP 303C: Meeting Minutes
SOP 304: Documentation, Document and Data Management
SOP 501: Special Populations
SOP 603A: Veterans Affairs Medical Center
SOP 603F: Department of Defense

6. Attachments

701-A Informed Consent Template (HSC)
701-A-1 Informed Consent to Participate in a Research Study (NC)
701-A-2 Informed Consent Information Sheet (NC)
701-A-3 Assent to Participate in a Research Study (NC)
701-B Child Assent Template
701-C Tissue Consent Template
701-D Patient Information Sheet – Tissue Banking
701-E Template for Informed Consent Addendum
701-F Translator Statement (NC)
502-G-A Sample Consent Form for Emergency Use
203-A HSC Reviewer Checklist
203-A-1 NC Reviewer Checklist

7. Process Overview

- 7.1 Submitted items are processed by the IRB Administrator per SOP 301: Research Submission Requirements.
- 7.2 The IRB Administrator is responsible for reviewing the consent documents to ensure all required and additional elements are present, if applicable, prior to assigning the research project to the IRB reviewer.
- 7.3 For submissions that require a review of the consent process or of the consent documents, the IRB, the IRB Chair or IRB designee review the proposed consent process, the content of the consent document, the presence/absence of required/additional elements, presence/absence of exculpatory language, and/or any language that disclaims or limits the warranty of drugs or devices beyond the efficacy of the drug or devices. The IRB will either approve the consent process/document as is or make recommendations for changes.
- 7.4 When the revised submission materials are returned by the investigator, the IRB Administrator will confirm that all of the changes have been made and will assign the materials to the IRB Chair or IRB designee for review. If the IRB Chair or IRB designee 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 then 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 children, prisoners, pregnant women, and fetuses
 - Waiver of consent, alteration or deletion of consent elements, 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) per SOP 304: Documentation, Document and Data Management. The stamped version of the consent document is provided to the investigator. The IRB maintains a copy of the stamped consent document in the IRB's electronic information system.

APPROVED BY: _____ **DATE:** 09/09/2016

NEXT ESTABLISHED REVIEW DATE: AUGUST 2018