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1. POLICY:

Unless an exception applies, an Investigator may not enroll a human subject in a research study until informed consent has been obtained. Informed consent must be legally effective, prospectively obtained and in understandable language. Securing and maintaining consent is an ongoing process that begins with recruitment and continues through the end of the subject's involvement in the study.

These procedures apply to all non-exempt research protocols. At times, other institutional approvals may be required prior to enrolling a participant in research.

2. DEFINITIONS

- 2.1 *Assent.* An Individual's affirmative agreement to participate in research obtained in conjunction with permission of the individual's parents or legally authorized representative. Failure to object should not be construed as assent.
- 2.2 *Clinical Trial.* A research study in which one or more human subjects are prospectively assigned to one or more interventions (which may include placebo or other control) to evaluate the effects of the interventions on biomedical or behavioral health-related outcomes.
- 2.3 *Cognitively Impaired.* Having a condition that impairs the capacity for judgment and reason. This may include individuals under the influences of or dependent on drugs or alcohol, those suffering from degenerative diseases affecting the brain, terminally ill patients, and individuals with severely disabling mental handicaps, all of whom may be compromised in their ability to make decisions in their best interest.
- 2.4 *Consenter.* The Investigator or a designated member of the research team on the approved protocol who has the appropriate training and knowledge to conduct the informed consent process.
- 2.5 *Delegated Authority to Consent on Behalf of Incapable Party.* Per Indiana Code 16-36-1-6, an individual authorized to consent to health care for another who for a time will not be reasonably available to exercise the authority may delegate the authority to consent during that time to another individual. The delegation: (1) must be in writing; (2) must be signed by the delegate; (3) must be witnessed by an adult; and (4) may specify conditions on the authority delegated. Unless the writing expressly provides otherwise, the delegatee may not delegate the authority to another individual. It is the position of the Human Research Protection Program that this authorization to consent to health care extends to participation in research.
- 2.6 *Enroll.* To enter into a research study by means of signing an informed consent document.

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- 2.7 *Funding Source.* The source of funding may be through external (e.g., grants, contracts, gifts) or internal (University/department) sources. Projects which are internally funded should be acknowledged as funded by Purdue University.
- 2.8 *Identifiable Biospecimen.* A biospecimen for which the identity of the subject is or may readily be ascertained by the Investigator or associated with the biospecimen.
- 2.9 *Identifiable Private Information.* Private information for which the identity of the subject is or may readily be ascertained by the Investigator or associated with the information. Private information includes information about behavior that occurs in a context in which an individual can reasonably expect that no observation or recording is taking place, and information that has been provided for specific purposes by an individual and that the individual can reasonably expect will not be made public (e.g., a medical record).
- 2.10 *Informed Consent.* A person's affirmative agreement to participate in a research study after achieving an understanding of what is involved.
- 2.11 *Informed Consent Document.* A document that certifies a person's informed consent.
- 2.12 *Informed Consent Process.* The process of informing a potential subject or a potential subject's Legally Authorized Representative which includes, but is not limited to, explanation of the protocol, review of the consent document, and answering research-related questions.
- 2.13 *Legally Authorized Representative (LAR).* An individual or a judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. In Indiana, a health care representative (appointed in accordance with Indiana Code 16-36-1-7) is the equivalent of the federally defined LAR.
- 2.14 *Minimal Risk.* Level of risk in which the probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life of a normal healthy person living in a safe environment or during the performance of routine physical or psychological examinations or tests.
- 2.15 *Persons Authorized to Consent for Incapable Parties.* Per Indiana Code 16-36-1-5, if an individual incapable of consenting has not appointed a health care representative or the health care representative is not reasonably available or declines to act, consent to health care may be given by:
- 2.15.1 A judicially appointed guardian of the person or a representative appointed; or

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2.15.2 By a spouse, a parent, an adult child, or an adult sibling, if:

- (a) There is no guardian or other representative described in 2.14.1 above;
- (b) The guardian or other representative is not reasonably available or declines to act; or
- (c) The existence of the guardian or other representative is unknown to the health care provider.

2.15.3 The individual's religious superior, if the individual is a member of a religious order and:

- (a) There is no guardian or other representative described in 2.14.1 above;
- (b) The guardian or other representative is not reasonably available or declines to act; or
- (c) The existence of the guardian or other representative is unknown to the health care provider.

2.15.4 It is the position of the Human Research Protection Program that this authorization to consent to health care extends to participation in research.

2.16 *Risk.* The possibility of harm to a subject in a research study.

2.17 *Short Form.* Written consent document allowing use of an oral consent process.

2.18 *Witness.* A witness is a person who is physically present to observe the consent process and can attest to what actually occurred. Should the subject not speak English, the witness should be fluent in both English and the language of the subject.

3. PROCEDURES

3.1 General Requirements of Informed Consent

3.1.1 Except as described in SOP 321: Waiver or Alteration of Informed Consent, no Investigator may enroll a research subject into a research protocol unless s/he has obtained legally effective informed consent of the subject or the subject's LAR. Consent shall be sought only under circumstances that provide the prospective subject or the LAR sufficient opportunity to consider whether or not to participate and that minimize the possibility of coercion or undue influence. The information given to

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the subject or LAR must be in language understandable to the subject or the LAR and include all required elements of informed consent.

- 3.1.2 The prospective subject or LAR must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.
- 3.1.3 Except in the case of broad consent, informed consent must:
 - (a) Begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or LAR in understanding the reasons why one might or might not want to participate in the research; and
 - (b) Present information in sufficient detail relating to the research, and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the subject's or LAR's comprehension.
- 3.1.4 Informed consent may not contain any exculpatory language through which the subject is made to waive or appear to waive legal rights, or releases or appears to release the Investigator, the Sponsor, or Purdue University from liability for negligence.

3.2 Required Elements of Informed Consent

- 3.2.1 A statement that the study involves research, an explanation of the purposes of the research, the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental.
- 3.2.2 A description of any reasonably foreseeable risks or discomforts to the subject.
- 3.2.3 A description of any benefits to the subject or to others that may reasonably be expected from the research.
- 3.2.4 A disclosure of appropriate alternative procedures or courses of treatment, if any, which might be advantageous to the subject.
- 3.2.5 A statement describing the extent to which, if any, confidentiality of records identifying the subject will be maintained and, for research regulated by the Food and Drug Administration (FDA), a statement noting the possibility that the FDA may inspect the records.

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- 3.2.6 A statement noting the possibility that study records may be inspected by the IRB (or its designees) and the study sponsor, if the research is sponsored by a Funding Source.
- 3.2.7 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.
- 3.2.8 An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject.
- 3.2.9 A statement that participation is voluntary, that refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
- 3.2.10 For research that involves the collection of identifiable private information or identifiable biospecimens, one of the following must be included in the informed consent:
 - (a) A statement that identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the legally authorized representative, if this might be a possibility; or
 - (b) A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

3.3 Additional Elements

When appropriate, one or more of the following elements of information shall also be provided to each subject.

- 3.3.1 A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus if the subject is or may become pregnant), which are currently unforeseeable.
- 3.3.2 Anticipated circumstances under which the subject's participation may be terminated by the Investigator without regard to the subject's consent.

- 3.3.3 Any additional costs to the subject that may result from participation in the research.
- 3.3.4 The consequences of a subject's decision to withdraw from the research and procedures for orderly termination of participation by the subject.
- 3.3.5 A statement that significant new findings developed during the course of the research, which may relate to the subject's willingness to continue participation, will be provided to the subject.
- 3.3.6 The approximate number of subjects involved in the study.
- 3.3.7 A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.
- 3.3.8 A statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions.
- 3.3.9 For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).

3.4 Broad Consent

Broad consent for the storage, maintenance, and secondary research use of identifiable private information or identifiable biospecimens (collected for either research studies other than the proposed research or nonresearch purposes) is permitted as an alternative to the informed consent requirements in paragraphs 3.2 and 3.3 above. If the subject or LAR is asked to provide broad consent, the following shall be provided to each subject or LAR:

- 3.4.1 A description of any reasonably foreseeable risks or discomforts to the subject.
- 3.4.2 A description of any benefits to the subject or to others that may reasonably be expected from the research.
- 3.4.3 A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained.
- 3.4.4 A statement that participation is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, and the subject may discontinue participation at any time

without penalty or loss of benefits to which the subject is otherwise entitled.

- 3.4.5 When appropriate, a statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.
- 3.4.6 For research involving biospecimens, whether the research will (if known) or might include whole genome sequencing (i.e., sequencing of a human germline or somatic specimen with the intent to generate the genome or exome sequence of that specimen).
- 3.4.7 A general description of the types of research that may be conducted with the identifiable private information or identifiable biospecimens. This description must include sufficient information such that a reasonable person would expect that the broad consent would permit the types of research conducted.
- 3.4.8 A description of the identifiable private information or identifiable biospecimens that might be used in research, whether sharing of identifiable private information or identifiable biospecimens might occur, and the types of institutions or researchers that might conduct research with the identifiable private information or identifiable biospecimens.
- 3.4.9 A description of the period of time that the identifiable private information or identifiable biospecimens may be stored and maintained (which period of time could be indefinite), and a description of the period of time that the identifiable private information or identifiable biospecimens may be used for research purposes (which period of time could be indefinite).
- 3.4.10 Unless the subject or legally authorized representative will be provided details about specific research studies, a statement that they will not be informed of the details of any specific research studies that might be conducted using the subject's identifiable private information or identifiable biospecimens, including the purposes of the research, and that they might have chosen not to consent to some of those specific research studies.
- 3.4.11 Unless it is known that clinically relevant research results, including individual research results, will be disclosed to the subject in all circumstances, a statement that such results may not be disclosed to the subject.
- 3.4.12 An explanation of whom to contact for answers to questions about the subject's rights and about storage and use of the subject's identifiable

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private information or identifiable biospecimens, and whom to contact in the event of a research-related harm.

3.5 Documentation of Informed Consent

3.5.1 Unless waived as described in SOP 321: Waiver or Alteration of Informed Consent, the informed consent document must be either of the following:

- (a) A written consent document that embodies the elements of informed consent described in Sections 3.1, 3.2, and 3.3 above and complies with the IRB consent template. This form may be read to the subject or the subject's LAR, but, in any event, the Investigator shall give either the subject or the LAR adequate opportunity to read it before it is signed, or the Investigator shall read it to the subject of the LAR. The subject or the LAR must also be given a copy of the signed form. The IRB consent template requirement may be waived with appropriate justification.
- (b) A short form written consent document stating that the elements of informed consent as required above have been presented orally to the subject or the subject's LAR. The elements must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or LAR in understanding the reasons why one might or might not want to participate in the research. The IRB must approve a written summary of what is to be said to the subject or representative. When this method is used, there shall be a witness to the oral presentation. The subject or the LAR signs only the short form itself. However, the witness shall sign both the short form and a copy of the summary, and the person actually obtaining the consent shall sign a copy of the summary. A copy of the summary shall be given to the subject or the LAR in addition to a copy of the short form.

3.5.2 A subject or his/her LAR must sign and date a copy of the current IRB-approved consent form prior to enrollment into the study, including screening procedures conducted solely to determine eligibility, unless the requirement is waived by the IRB as described in SOP 321: Waiver or Alteration of Informed Consent. The subject and/or his or her LAR must also be given a copy of the signed document.

3.5.3 The written informed consent document should embody, in language understandable to the subject, all the elements necessary for legally effective informed consent as described in Sections 3.1, 3.2, and 3.3 of this SOP. The informed consent document should be written in simple language free of technical, scientific and/or scholarly jargon. Any

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complex terminology should be explained using common or lay terminology.

3.5.4 It is preferred that the informed consent document should be written in the second-person (e.g., “You will be asked to...”). This voice is intended to convey a dialogue between the researcher and the subject. However, the IRB will consider use of a different voice if appropriate given the subject population and the local context as well as any other relevant factors in the research.

3.5.5 Exculpatory language is not permitted in the consent document.

3.6 Informed Consent Documents for Subjects Who Do Not Speak English

3.6.1 When subjects in a research protocol do not speak English, the written informed consent document should be translated into a language understandable to the subject.

3.6.2 In addition to the English version of the consent form, copies of the consent document translated into a language understandable by the participant should be submitted to the IRB. The consent form should contain the required elements in Sections 3.1, 3.2, and 3.3. The foreign language version must be congruent in substance and intent with the English version. The Investigator must be able to document that the content accurately reflects the English version of the consent form and that it is in a language appropriate to the local context for the target subject population.

(a) Investigators can certify the appropriateness of a translation by use of a translator who is on the approved list of translators offered by Purdue University’s Department of Languages and Cultures.

(b) Alternate procedures to certify a translation may include, but are not limited to, written verification either from a researcher or from a third party with demonstrated expertise in both that language and English. At the IRB’s discretion, a computer program may be used to certify a translation.

3.5.2.3 All translations are subject to verification by the HRPP/IRB and may require a confidentiality agreement for any translation services.

3.6.3 Oral Presentation with Short Form

Where informed consent is documented using a short form procedure for non-English speaking subjects, the written informed consent document

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should embody, in language understandable to the subject, all the elements necessary for legally effective informed consent. When this procedure is used with subjects who do not speak English,

- (a) The oral presentation and the short form written informed consent document should be in a language understandable to the subject;
- (b) The IRB-approved English language informed consent document may serve as the summary; and
- (c) The witness should be fluent in both English and the language of the subject.

Expedited review of these forms is acceptable if the protocol, the full English language informed consent document, and the English version of the short form document have already been approved by the convened IRB.

3.7 Use of Facsimile or Mail to Document Informed Consent

The IRB may approve a process that allows the informed consent document to be delivered and returned by mail, e-mail, or facsimile to the potential subject or the potential subject's LAR and to conduct the consent interview by telephone when the subject or the LAR can read the consent document as it is discussed. If the consent form is provided in an electronic format, it may be signed electronically by the subject or LAR. All other applicable conditions for documentation of informed consent must also be met when using this procedure.

3.8 Review of Informed Consent Processes and Documents

3.8.1 A Protocol Analyst will conduct administrative review of protocol applications and supporting documents to ensure that the informed consent procedures and consent document(s) are appropriate. If warranted, s/he will notify the Investigator of any omissions or necessary corrections prior to review by an IRB Chair, designee or the convened IRB. Otherwise, the Protocol Analyst will identify any existing issues and will forward the protocol application to the appropriate IRB Chair, designee, or the convened IRB, as appropriate.

3.8.2 If eligible for expedited review, the protocol application and supporting documents including the informed consent procedures and informed consent document(s) will be conducted by the IRB Chair or designated expedited reviewer. If the protocol application requires full IRB review, it will be reviewed by the convened IRB. The informed consent procedures and consent form document will be evaluated to ensure

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compliance with regulatory requirements and IRB guidelines and instructions.

- 3.8.3 Any required changes will be communicated to the Investigator in writing and noted in the protocol file.
- 3.8.4 After the application is approved, the Investigator must add the IRB Protocol Number and the Expiration Date to the header or footer of all approved informed consent document(s). Only approved consent forms can be used by Investigators to document subjects' informed consent.
- 3.8.5 When minor revisions occur in informed consent documents for approved protocols, a Protocol Analyst can review and approve the revision. In such cases the revisions to the consent form can only involve procedures that have been previously approved by the IRB. Any major changes or new procedures to the protocol must be submitted to the IRB for review and approval. See SOP 305: Amendment Requests. The revised consent documents will be forwarded to the IRB for filing in the protocol file.

3.9 Posting of Clinical Trial Informed Consent Materials

- 3.9.1 For each clinical trial supported by a Federal department or agency, one IRB-approved informed consent form used to enroll subjects must be posted by the Responsible Party on a publicly available Federal web site that will be established as a repository for such informed consent forms.
- 3.9.2 If the Federal department or agency supporting the clinical trial determines that certain information should not be made publicly available on a Federal web site (e.g. confidential commercial information), such Federal department or agency may permit or require redactions to the information posted.
- 3.9.3 The informed consent form must be posted on the Federal web site after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject, as required by the protocol.

3.10 Informed Consent Considerations for Special Populations

- 3.10.1 For additional considerations regarding informed consent of pregnant women, see SOP 501: Research Involving Pregnant Women, Fetuses, and Neonates
- 3.10.2 For additional considerations regarding informed consent of Children, see SOP 502: Research Involving Children.

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- 3.10.3 For additional considerations regarding informed consent of Prisoners, see SOP 503: Research Involving Prisoners.
- 3.10.4 Provisions of Assent for Adults Unable to Give Legally Effective Informed Consent
- (a) Should the IRB determine that adult subjects are cognitively impaired, whether temporary, progressive, or permanent, or are otherwise unable to give legally effective informed consent, the IRB will further determine if an assent process is required or it may waive assent when all of the waiver criteria are met as described in SOP 321: Waiver or Alteration of Informed Consent.
 - (b) If the IRB determines that an assent process is required, the IRB must determine whether that process occurs verbally or if that process should be documented by means of an assent form.
 - (c) When adults who are unable to give legally effective informed consent are subjects in research, the IRB determines the process for obtaining informed consent from LAR in accordance with this SOP, or the IRB may waive this consent when all of the waiver criteria are met as described in SOP 321: Waiver or Alteration of Informed Consent.

4. RESPONSIBILITY

4.1 Investigator Responsibilities Regarding Informed Consent

- 4.1.1 Unless informed consent is waived or altered, the Investigator must ensure that the subject or the subject's LAR sign a copy of the stamped IRB- approved informed consent document before any study related procedures are initiated.
- 4.1.2 The Investigator is responsible for assuring an appropriate informed consent process is approved and carried out. The Investigator may delegate the duty of obtaining informed consent to members of the research team listed on the approved protocol. The Investigator is responsible for assuring that any such designee is knowledgeable about the specific research study and the process of informed consent.
- 4.1.3 The Investigator or designee conducting the consent process must sign the informed consent document as the "Researcher," as well as obtain the signature of the subject or his/her LAR.
- 4.1.4 The Investigator or designee will file the original signed consent document with the project's research records. A copy of the consent

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document will be provided to the subject or the subject's LAR at the time of consent. Ideally, an original consent document should be provided to the subject or the subject's LAR signed by all parties.

4.1.5 The Investigator is responsible for assuring that the content of the written consent document, if required, is in compliance with IRB requirements.

4.1.6 Upon identification of a potential subject, the Investigator or designee is responsible for identifying who is legally authorized to consent for the subject, if consent is required. If the subject is physically or mentally unable to provide consent, then the LAR may be approached to give informed consent for the subject. The Investigator or designee should be sensitive to any potential impairment to informed consent.

4.1.7 Required Signatures on Consent Documents

(a) Written consent should be signed and personally dated by the subject or subject's LAR and by the Consenter. Other signatures must be provided as required by the IRB and/or the sponsor if specified on the IRB approved consent document. If the consent form is provided in an electronic format, it may be signed electronically by the subject or the subject's LAR. Physical signatures may be required for certain research protocols, at the discretion of the IRB.

(b) The Consenter's signature confirms that the informed consent process was conducted, not that the subject's signature was witnessed. The signature of the Investigator is not required on the consent document, unless s/he is the Consenter.

(c) The subject is not required to sign the consent document at the same time as the Consenter. The subject may take the consent form in order to review and/or consider it further before signing. The Consenter may sign the consent form documenting the consent process was completed prior to the subject taking it for further consideration. Hence the date of the Consenter's signature may precede that of the subject's signature.

4.1.8 Revisions to the Informed Consent Document

(a) The Investigator is responsible for assuring that the written consent document and any other written information to be provided to subjects is revised whenever important new information becomes available that may be relevant to the subject's willingness to participate (e.g., new procedures, new anticipated problems/adverse events, etc.). The Investigator may delegate to

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appropriate members of the research team the development and processing of the revised consent document or any other written information to be provided to subjects. Any such revisions must receive IRB approval prior to use. Immediate hazards should be communicated to the subject right away and reported to the IRB as soon as possible (see SOP 409: Unanticipated Problems and Adverse Event Reporting).

- (b) The informed consent process must be revised any time the risk-benefit ratio changes or when new information becomes available that alters information previously reported to subjects (e.g., new procedures, new anticipated problems/adverse events, etc.). If a written consent document is revised during the course of a subject's participation in the research, then the subject may need to be re-consented with the revised IRB-approved consent document. The original newly obtained revised signed consent document should be filed with the subject's research records. A copy of the newly obtained revised signed consent document should also be provided to the subject or subject's LAR at the time of consent. The initial previously signed consent should be retained by the Investigator.
- (c) In situations where consent documents have been revised and approved by the IRB, the newly approved revised consent document will be authorized with the same expiration date. It is important for the Investigator or designee to assure that newly enrolled subjects sign the current IRB-approved version of the consent document.
- (d) While some changes to the consent document may require re-consenting of all subjects currently enrolled in the research study (e.g., discovery of serious unanticipated problems), not all changes to the consent document require re-consenting of currently enrolled subjects. Some examples might include grammatical error corrections or any revisions that do not change the risk-benefit ratio.
- (e) In cases where subjects have completed active study or follow-up procedures and new safety information is discovered that may affect a subject's participation or long-term risks from the research, the subject must be informed of this new information. This may be accomplished through re-consenting subjects with a revised consent document which explains this new information or by other methods of notification approved by the IRB. The timeliness of

informing subjects and re-consenting them will depend on the degree of risk associated with the new information.

4.1.9 When the Subject or the Subject's LAR is Unable to Read or Understand the Consent Document

- (a) If written consent is required and the subject or the subject's LAR is unable to read, then the IRB-approved consent document must be read in its entirety in the presence of a witness. This should be documented directly onto the consent document and signed by the subject or the subject's LAR, as well as the witness.
- (b) If the subject or the subjects' LAR or witness, if involved, is unable to speak or understand the written informed consent document because of the language in which it is written, the IRB-approved process and written consent document, if required, must be conducted in a language the subject understands and documented in the subject's record and reported to the IRB at each occurrence. If these situations can be anticipated, prior IRB approval of a translated consent form should be obtained. Translators or sign language interpreters should be part of the ongoing communication throughout the research study and may be used to assist with verbal and written translation. See Section 3.6.

4.1.10 Obtaining Informed Consent Remotely

- (a) Informed consent may only be obtained via telephone when written documentation of informed consent has been waived by the IRB. In these situations, the consentor must document the informed consent process took place by making appropriate notation regarding the process in the research records.
- (b) There may be situations when obtaining signed informed consent documentation from subjects via fax, mail, or email is appropriate. This is acceptable in situations where the informed consent process has already been appropriately conducted in person or when it is conducted over the phone. The consentor should sign and date the consent document prior to faxing, mailing, or emailing it to the subject, or giving it to the subject should the consent process take place in person. If the consent process occurs over the phone, the consentor should note in the subject's records that it took place. The subject should return the original signed consent document to the researcher either at the next scheduled research session, provide a copy of the signed consent document via fax, mail, or email. The research team member receiving the signed original document should note the received date on the document and file it

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with the research records and make appropriate notes to the research records explaining how the consent process occurred.

4.2 IRB Responsibilities Regarding Informed Consent

- 4.2.1 A Protocol Analyst is responsible for conducting administrative review of informed consent procedures and informed consent documents, communicating required changes to Investigators and advising Investigators on appropriate procedures and requirements. A Protocol Analyst is responsible for reviewing and approving minor revisions in informed consent documents for previously approved procedures and forwarding the newly approved revised consent documents to the IRB.
- 4.2.2 The IRB Administrator is responsible for advising Investigators on appropriate procedures and requirements. Additionally, s/he is responsible for assisting Protocol Analysts with administrative reviews.
- 4.2.3 IRB Members are responsible for reviewing informed consent procedures and documents as well as communicating required changes to Investigators.

5. APPLICABLE REGULATIONS AND GUIDELINES

21 CFR 50.25; 21 CFR 50.27

45 CFR 46.116; 45 CFR 46.117

[OHRP, Frequently Asked Questions on Informed Consent](#)

6. REFERENCES TO OTHER APPLICABLE SOPs

321 Waiver or Alteration of Informed Consent

409 Unanticipated Problems and Adverse Event Reporting

501 Research Involving Pregnant Women, Fetuses, and Neonates

502 Research Involving Children

503 Research Involving Prisoners