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SECTION: Human Research Protection Program	NUMBER: 118	
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1. PURPOSE

This policy describes the requirements for valid informed consent processes and additional elements of consent disclosure, and the criteria for waiver of or alteration to these requirements.

2. GENERAL REQUIREMENTS

Principal Investigators shall ensure that all investigators and study personnel comply with informed consent requirements.

2.1. Obtaining Informed Consent

- 2.1.1. Only IRB-certified investigators/study personnel (hereafter referred to as authorized personnel) who are listed on the informed consent form shall obtain informed consent from the subject or the subject's parent(s), guardian(s), or other authorized representative (see section 2.7 of this document) in accordance with 45 CFR 46.116, 21 CFR 50.20, and these policies. This responsibility shall not be delegated to personnel who are not IRB-certified or who are not listed on the informed consent document. Authorized personnel shall ensure that no human subject will be involved in any research project prior to obtaining informed consent from the subject or his/her authorized representative. Informed consent shall be obtained prior to initiating any clinical procedures performed solely for the purpose of determining eligibility for the research project, such as laboratory tests or withdrawal (washout) from medications. The Creighton University IRBs do not allow the use of the shortened form of the informed consent document.
- 2.1.2. Informed consent shall be obtained under circumstances that offer the subject and/or his or her authorized representative sufficient opportunity to consider whether the subject should participate. The informed consent shall not include exculpatory language through which the subject and/or his or her authorized representative is made to waive or appear to waive any of the subject's legal rights or releases, or that appears to release the investigator, the sponsor, the institution, or its agents from liability for negligence. Please see sections 2.7 and 8 of this policy for further

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information on legally authorized representatives, surrogate consenting, and parental/guardian permission.

- 2.1.3. The informed consent process must be conducted in a manner that minimizes the possibility of coercion or undue influence.
 - 2.1.3.1. Recruitment procedures shall be designed to assure that informed consent is freely given.
 - 2.1.3.2. Special safeguards are included to protect the rights and welfare of subjects who are likely to be vulnerable to coercion or undue influence (e.g., children, prisoners, pregnant women, persons with physical or mental illness, persons who are economically or educationally disadvantaged, students, patients from the investigator's medical practice, and employees).
 - 2.1.3.3. The nature of the disease or behavioral issue to be studied permits free consent.
 - 2.1.3.4. Incentives offered for participation shall not unduly influence a prospective subject's decision to participate.
 - 2.1.3.5. The IRB may require monitoring of the consent process.

2.2. In-Person Consent

The authorized personnel shall obtain informed consent in the presence of the human subject or his/her authorized representative, if applicable. The written informed consent document shall be signed by the human subject or his/her authorized representative, if applicable, before the human subject may participate in the research. The subject and/or representative shall be given a copy of the document (consent/permission/assent). If the investigator or sponsor chooses to have the subject's signature witnessed, the witness shall be an adult person not involved in the research study and may be an adult family member of the human subject. The witness' role is to witness the signature of the subject or representative only, except in cases in which the witnesses' role is to witness the entire consent process as required if the subject is illiterate or sight-impaired (see Section 2.6). This specific requirement shall be indicated in the consent form.

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2.3. Telephone Consent

The authorized personnel may obtain consent by telephone, as approved by the IRB. In such instances, the authorized personnel shall provide informed consent to the human subject and his/her authorized representative, if applicable, over the telephone. The authorized personnel shall document in the research record the informed consent process. The written informed consent document shall be sent by mail or facsimile or scanned via email to the human subject or his/her authorized representative for signature and returned before the human subject may participate in the research. The subject should be instructed to sign and date the document and return it to the authorized personnel. A facsimile or scanned email version of the signed informed consent document is as valid as the original. The subject and/or representative shall be given a copy of all the consent documents. When the authorized personnel receive the signed consent, the authorized personnel should call the subject to ensure that the subject understands the study and that all questions have been answered; at this time, the authorized personnel should sign and date the document.

2.4. Informed Consent Language

Informed consent shall be obtained in language understandable to the subject and/or the subject's authorized representative. The investigator should ensure that language used is likely to be understood by the average person. Technical and scientific terms should be adequately explained or common terms substituted. Informed consent should be written in second person (i.e., "you," "your," "yours") in reference to the subject because it helps communicate that there is a choice to be made by the prospective subject. In ALL cases, the writing style should be consistent throughout the written consent document (see "[Tips on Informed Consent](#)").

2.5. Non-English Speaking Population

In cases in which the study population includes non-English speaking subjects, the IRB shall require that the informed consent document be written in each subject's language. The IRB then shall send the consent form to a translator to back-translate the document (to compare the translated consent to the English approved consent). An independently qualified interpreter should be available during the consent process to assist the authorized personnel to ensure that the subject understands the study and that all questions have been answered. In those cases in which the investigator

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provides evidence that it is not possible to translate the written consent into a subject's native language, the IRB shall review on a case-by-case basis whether to allow alternative means to consent the subject.

2.6. Illiterate and/or Sight-Impaired or Hearing Impaired Population

If any member of the research subject population is illiterate and/or sight-impaired, the authorized personnel shall have the informed consent document read to the research subject in their native language by an individual fluent in that research subject's native language, and an impartial witness shall be present during the entire informed consent discussion and shall sign the consent form as a witness to the subject's signature. By signing the consent form, the witness attests that the information in the consent form and any other written information was accurately explained to, and apparently understood by, the subject or the subject's legally acceptable representative (i.e., legally authorized representative, surrogate, or parent/guardian), and that informed consent was freely given by the subject or the subject's legally acceptable representative. For hearing-impaired subjects, the authorized personnel shall provide a reasonable means of communication that may include providing sign language interpretation from an independently qualified interpreter.

2.7. Adults Who Have Diminished Decision-Making Capacity

2.7.1. Legally Authorized Representative

- 2.7.1.1. A legally authorized representative is defined as a person assigned by the courts to represent a person with diminished decision-making capacity.
- 2.7.1.2. The authorized personnel shall request legal documentation of representative status, and a copy shall be maintained in the source documents.

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2.7.2. Surrogate

2.7.2.1. A surrogate is defined as a person who represents another person with diminished decision-making capacity, in the following descending order of priority:

2.7.2.1.1. Spouse

2.7.2.1.2. Parent

2.7.2.1.3. Child (adult offspring, including adopted offspring)

2.7.2.1.4. Brother, sister, spouse of a brother or sister

2.7.2.1.5. Any individual related by blood or affinity whose close association with the subjects is the equivalent of a family relationship

2.7.2.2. With respect to an individual from whom an authorized personnel seeks to obtain surrogate consent and who claims to be a surrogate, and the authorized personnel is uncertain as to whether a legal relationship exists, the authorized personnel shall contact the Creighton University Office of the General Counsel to assist in the resolution of the matter. The authorized personnel shall clearly document the consent process in the source document.

2.7.3. The IRB shall review at a convened meeting and approve the consent process if a legally authorized representative or a surrogate is to give consent to participate in a research project. The decision to allow legally authorized representative or surrogate consenting will be approved for an individual project only.

2.7.4. The investigator shall provide to the IRB a plan to assess participants' capacity to provide consent. The IRB shall review this plan to ensure it is adequate.

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- 2.7.5. If the IRB approves legally authorized representative or surrogate consent, the authorized personnel shall conduct the consent process as defined in section 2.1 of this policy.
- 2.7.6. The IRB shall determine whether the participants must provide assent, and whether the plan for obtaining this assent is adequate.
- 2.7.7. Under this policy, individuals capable of providing legally authorized representative or surrogate consent are also considered capable of providing authorization for use and disclosure of the subject's Protected Health Information (PHI) under the Health Insurance Portability and Accountability Act of 1996 (HIPAA) and its implementing regulations.
- 2.7.8. If at any time after the subject is enrolled in a study through legally authorized representative or surrogate consent, he or she regains the capacity to provide informed consent, the authorized personnel shall obtain the legally effective informed consent of the subject for continued participation in the research.
- 2.7.9. Decision-making capacity of subjects may fluctuate. The consent process should be ongoing and involve the legally authorized representative or surrogate if at any time the authorized personnel believes that the subject is unable to provide informed consent for continuing in a research project for which the subject initially gave informed consent.

3. EXCEPTIONS TO INFORMED CONSENT REQUIREMENTS

- 3.1. For information about emergency use of unapproved drugs/devices/biologics, see IRB Policy 128, "[Emergency Use of Unapproved Drugs/Devices/Biologics.](#)"

4. ELEMENTS OF INFORMED CONSENT

- 4.1. The FDA and the DHHS both require that certain basic information be provided to subjects who will be participating in a research project (45 CFR 46.116(a) and 21 CFR 50.25(a)). For example, some of the basic elements required in an informed consent document include an explanation of the research, anticipated risks and benefits of participating in the research, alternative treatments available, and plans for maintaining confidentiality of patient information. When appropriate, additional information may need to be provided to subjects who will

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be participating in a research project (45 CFR 46.116(b) and 21 CFR 50.25(b)). For example, it may be necessary to inform patients of the possibility of unforeseeable risks associated with the treatment or procedures involved in the research.

- 4.2. The informed consent document should also include a statement regarding any compensation that will be provided to study participants. The provision of benefits to research subjects (e.g., money or medical services) is appropriate as a means of compensation for the subject's costs, time, and inconvenience. But benefits shall not be made as payment for assuming the risks of research or offered as inducements to volunteer for research. References to subject benefits shall link any such benefits to compensation for the "subject's cost, time, and inconvenience." Credit for payments should accrue as the study progresses and shall not be contingent upon the subject completing the entire study. Payments shall not be in the form of coupons to be used for discount purchase of the product tested after it has been marketed.
- 4.3. More detailed information on what must be included in the informed consent documents and examples of appropriate consent language are provided in the ["Model Consent Templates"](#) on the IRB web site.
- 4.4. A Subject's Bill of Rights shall be the last sheet of all Consents, Permissions, and Information Letters.

5. DOCUMENTATION OF INFORMED CONSENT

- 5.1. The informed consent document shall be prepared using either Times New Roman or Arial 12-point font or greater, with one-inch margins on the sides, top, and bottom.
- 5.2. Authorized personnel shall ensure that the informed consent is documented by the use of the written consent document most recently approved by the IRB, as indicated by the IRB date stamp at the bottom of each page of the informed consent document. Authorized personnel shall also ensure that the most recently approved consent document is used to enroll each research subject and is signed by the subject or the subject's legally authorized representative, unless this requirement is specifically waived by the IRB. The authorized personnel conducting the consent process shall also sign and date each consent form prior

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to initiating study procedures, unless this requirement is specifically waived by the IRB. Only copies of the stamped, dated consent shall be used when obtaining consent from subjects.

6. WAIVER OF DOCUMENTATION/CONSENT

In some instances, particularly with regard to online research, mail surveys, special populations, and international studies, the IRB should consider whether documented informed consent is appropriate. The responsible investigator shall inform and educate the IRB about special cultural situations. The IRB shall consider the information and make decisions appropriately. Investigators requesting a waiver of documentation shall submit the oral script or written information that will be provided to the subject or legally authorized representative.

6.1. Criteria for Waiver of Documentation

6.1.1. DHHS, 45 CFR 46.117

- 6.1.1.1. The IRB may waive the requirement to obtain a signed consent form for some or all subjects if it finds either:
 - 6.1.1.1.1. The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject shall be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
 - 6.1.1.1.2. That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context.
- 6.1.1.2. In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

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6.1.2. DHHS, 45 CFR 46.116

6.1.2.1. The IRB may approve a consent procedure that does not include, or that alters, some or all of the elements of informed consent set forth in this policy, or waive the requirements to obtain informed consent provided the IRB finds and documents that:

- 6.1.2.1.1. The research involves no more than minimal risk to the subjects;
- 6.1.2.1.2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
- 6.1.2.1.3. The research could not practicably be carried out without the waiver or alteration; and
- 6.1.2.1.4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

6.1.3. FDA, 21 CFR 56.109

6.1.3.1. An IRB shall require documentation of informed consent (FDA, 21 CFR 50.27), except as follows:

- 6.1.3.1.1. The IRB may, for some or all subjects, waive the requirement that the subject or the subject's legally authorized representative sign a written consent form if it finds that the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside the research context; or
 - 6.1.3.1.2. The IRB may, for some or all subjects, find that the requirements for an exception from informed consent for emergency research are met.
- 6.1.3.2. In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written

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study-specific document describing the risks and benefits and other elements of the informed consent.

6.1.4. Family Educational Rights and Privacy Act (FERPA), 34 CFR 99.31

- 6.1.4.1. FERPA regulations apply only to identifiable data. Educational records may be released without consent under FERPA if all personally identifiable information has been removed, including:
- 6.1.4.1.1. Student's name and other direct personal identifiers, such as Social Security number or student number.
 - 6.1.4.1.2. Indirect identifiers, such as the name of the student's parent or other family members; the student's or family's address, and personal characteristics or other information that would make the student's identity easily traceable; date and place of birth; and mother's maiden name.
 - 6.1.4.1.3. Biometric records, including one or more measurable biological or behavioral characteristic that can be used for automated recognition of an individual, including fingerprints, retina and iris patterns, voiceprints, DNA sequence, facial characteristics, and handwriting.
 - 6.1.4.1.4. Other information that, alone or in combination, is linked or linkable to a specific student that would allow a reasonable person in the school community, who does not have personal knowledge of the relevant circumstances, to identify the student with reasonable certainty.
- 6.1.4.2. The Creighton University IRB follows the FERPA regulations on granting exceptions contained in [34 CFR 99.31](#). FERPA allows educational agencies or institutions to disclose personally identifiable information from an educational record of a student without consent if the disclosure is to organizations conducting studies for, or on behalf of, educational agencies or institutions to:
- 6.1.4.2.1. Develop, validate, or administer predictive tests.

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- 6.1.4.2.2. Administer student aid programs.
- 6.1.4.2.3. Improve instruction.
- 6.1.4.2.4. Investigators who wish to receive an exception to FERPA regulations shall contact the Creighton University Office of the Registrar

7. ORAL CONSENT

To approve oral consent, the IRB must find the criteria for a waiver of documentation are met. Though the informed consent document is usually written, informed consent occasionally may be obtained orally in situations in which written consent is deemed culturally disrespectful or inappropriate. In all cases, the IRB shall review in advance the language that will be used in obtaining oral informed consent. Investigators proposing to obtain informed consent orally shall include a script of the language and content of the oral consent with their IRB application. Oral informed consent shall include all the elements of informed consent and contact information, and should be given to subjects in writing. Investigators should keep a log documenting the oral consent process throughout the duration of the study.

8. ASSENT OF MINORS AND PERMISSION OF PARENT(S)/GUARDIAN(S)

8.1. Children's Assent

- 8.1.1. When a research study involves children as research subjects, both the FDA and the DHHS require that the investigator obtain and document the child's assent (when the children are capable of providing assent) prior to initiating the research project. In Nebraska, a person is considered a child until s/he turns 19 years old. For research done outside of Nebraska, the age of majority shall be determined by the governing laws of the state or country in which the research is to be conducted. For research studies involving children aged 7–18, the investigator shall prepare and submit an informed assent document for IRB approval that outlines the study in simplified language. A separate assent document outlining the key aspects of the research in very simple terms should be prepared for minors aged

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7–11. The assent document for minors aged 12–18 may be more comprehensive, but shall still use simplified, age-appropriate language.

8.1.1.1. If the IRB determines that assent is not required for some or all children, the authorized personnel shall document:

8.1.1.1.1. That children are not capable of providing assent based on age, maturity, or psychological state;

8.1.1.1.2. The capability of the children is so limited that they cannot reasonably be consulted;

8.1.1.1.3. The intervention or procedure involved in the research holds out a prospect of direct benefit that is important to the health or well-being of the child and is available only in the context of the research;

8.1.1.1.4. The assent can be waived under the criteria for waiver of the consent process (see section 6 of this policy).

8.1.2. Authorized personnel shall obtain each child's assent and ensure that assent is documented by use of the written assent document most recently approved by the IRB, as indicated by the date stamp at the bottom of each page of the assent document. The assent process shall follow the process for obtaining informed consent, as detailed in section 2.1 of this policy. The authorized personnel shall ensure that the child signs the most current age-appropriate assent document and that a copy of the assent is given to the child and his/her parent(s)/guardian(s). After a child turns 19 years of age, the authorized personnel shall re-consent the subject using the most recently approved adult consent document.

8.1.3. An assent process for children or young adults is *not* required if one or the other of the following situations exists (but parent or guardian consent is still required):

8.1.3.1. The child is found incapable of participating, or

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- 8.1.3.2. The study offers a treatment or procedure that “holds out a 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.” In other words, investigators are not required to ask for children's assent to participation if the study offers a treatment that is thought to be a better option than those currently available, or if it offers the only alternative. In life-threatening situations, such as that of a child with cancer, this situation may be especially relevant.
- 8.1.4. Although a legal requirement for assent is waived in these circumstances, the authorized personnel are still expected and encouraged to obtain a young person's assent.

8.2. Permission of Parent(s)/Guardian(s)

- 8.2.1. Authorized personnel shall obtain parental permission from the parents or guardians of each child subject enrolled in a research project. Under Nebraska law, *guardian* means a person who has qualified as a guardian of a minor or incapacitated person pursuant to testamentary or court appointment. When research is conducted outside of Nebraska, the determination of who may serve as a guardian shall be determined by the governing laws of the state or country in which the research is to be conducted. This will be determined by the Principal Investigator in consultation with the IRB and General Counsel. If a guardian is not a parent, the legal representative shall provide written documentation of their status as a guardian. The authorized personnel shall obtain a copy of the guardian's legal status and shall maintain it in the source file. Parental/guardian permission should be obtained using the permission document most recently approved by the IRB, as indicated by the date stamp at the bottom of each page of the consent document. The permission of only one parent or guardian is required for protocols involving either minimal risk, or greater than minimal risk but offering the prospect of direct benefit to the child. Permission of both parents or guardians is required if the project involves greater than minimal risk without prospect of direct benefit to the child. Permission of one parent/guardian is acceptable if one parent or guardian is deceased, unknown, incompetent, or not reasonably available, or when only one parent or guardian has legal

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responsibility. If the parents of a potential subject are children themselves (younger than 19 years of age in the state of Nebraska; if not in Nebraska governed by the laws of the state or country in which the research is conducted), they are not allowed to give permission for their child's participation as a research subject unless the IRB has granted a waiver to this requirement. The IRB shall only grant waivers for projects that include no invasive procedures and that present no more than minimal risk to the minor subjects or if no other treatment is available for the disease under study.

- 8.2.2. Parental informed permission documents should follow the same guidelines recommended for adult informed consent documentation. More detailed information on what must be included in informed consent documents and examples of appropriate consent language are provided in the "[Model Consent Documents](#)" on the IRB web site.

9. CHANGES AFTER SUBJECT CONSENTS TO PARTICIPATE IN RESEARCH

9.1. The authorized personnel shall inform enrolled subjects of any changes that may affect the subject's safety or willingness to continue with the research; the authorized personnel shall also inform subjects of any new findings in a study. Subjects should agree to continue participation after changes are made in a study in which they are actively engaged in the research and there have been major changes to any component of the consent form (e.g., drug dose(s), device, study procedures, risks and discomforts, benefits, and alternatives). This is paramount if knowledge of the new information might affect subjects' willingness to continue participation. Subjects should also be notified of a change of the Principal Investigator or contact information; however, in most cases this type of change can be adequately communicated in a letter. Please note that a change in authorized personnel (other than the Principal Investigator) is not considered a major change requiring subject notification and does not require the subject to re-sign the consent document. Subjects also will not require notification if changes are made to procedures that they will not be required to undergo, such as screening procedures.

9.2. Changes and new information may be disseminated to subjects by various means at the discretion of the investigator and with the approval of the IRB. Examples

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include the following:

- 9.2.1. Changes may be added to the consent /permission/assent, and the subject/parent/guardian will be asked to review and re-sign the document if they are willing to continue their participation.
 - 9.2.2. Changes may be documented in a letter or memo form that can be given to subjects; the subject should be asked to sign receipt of letter/memo if willing to continue his/her participation.
 - 9.2.3. The authorized personnel should document in the source document that the new information was given to enrolled subjects and document the subject's willingness to continue in the project.
- 9.3. Subjects should be given any new information in a timely manner so that they can make a fully informed decision about whether they wish to continue their participation. The greater the import of the new information, the more quickly subjects should be made aware of it. Examples of when a subject should be asked for new consent (either signature of revised consent, addendum consent, or patient letter) with signature include the following:
- 9.3.1. The "Procedures" section of the consent form has been revised to include a new procedure that the subject will be asked to undergo (e.g., genetic testing, cardiac catheterization, biopsy, colonoscopy, mammogram, ultrasound, etc). An investigator shall not perform a procedure on a subject without new consent if the procedure was not mentioned in the original consent process and form.
 - 9.3.2. The "Risks and Discomforts" section of the consent form has been revised to include a newly identified serious adverse event.
 - 9.3.3. The "Risks and Discomforts" section of the consent form has been revised to include a change in the severity or frequency of a serious expected event.
 - 9.3.4. The "Alternatives" section has been revised to include newly identified alternative therapies or diagnostic tests.

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- 9.3.5. The “Procedures and Alternatives” section has been revised to include a change in FDA approval status of the drug or device being studied.
- 9.4. Examples of when the Creighton University IRB may approve a letter being sent to notify the subject of the change (that does not require a proof of receipt signature) include the following:
- 9.4.1. The Principal Investigator has been changed
- 9.4.2. The study contacts and/or the contact telephone numbers have been changed
- 9.4.3. The subject has completed the study interventions and is in the follow-up phase of the study or, in some cases, has completed the study, and the information is such that learning it would not materially affect the subject’s decision to continue participation in follow-up

10. CONSENT/PERMISSION/ASSENT STAMP DATING

- 10.1. All approved consent, permission, and assent documents shall be stamped with a date of approval. These documents shall be stamped at the time of approval, at the time of modification, and at the time of renewal. The validated stamp date shall state “APPROVAL” at time of approval for a new consent or a modified consent (including at renewal).
- 10.2. It is recognized that there is a span of time between approval of a consent and the time that the investigator receives the updated copy. The time that the new consent, permission, and assent documents should be used is as follows:
- 10.2.1. Document stamping post-approval of a minor modification to a project: the investigator may use previous copies of the consent for up to 10 working days after the approval date of the modified consent form.
- 10.2.2. If a modification is made that increases risks or adds procedures, new subject enrollment shall be delayed until the updated information is approved. The existing subjects shall sign the updated consent at the next study visit as soon as investigator receives approval (if added risks are serious, subjects shall be notified as soon as possible and this shall be

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CHAPTER: Institutional Review Board	ISSUED: 2/2000	REVISED/REVIEWED: 9/2004; 6/2006; 10/2009; 11/2010; 11/2013
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documented on the source document).

11. PARTICIPANT WITHDRAWAL FROM A CLINICAL TRIAL WITH FDA OVERSIGHT

- 11.1. According to FDA regulations, when a subject withdraws from a study, the data collected on the subject to the point of withdrawal remains part of the study database and may not be removed.
- 11.2. Authorized personnel may ask a subject who is withdrawing whether the subject 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 subject would distinguish between study-related interventions and continued follow-up of associated clinical outcome information, such as medical course or laboratory results obtained through non-invasive chart review, and address the maintenance of privacy and confidentiality of the subject's information.
- 11.3. If a subject withdraws from the interventional portion of the study, but agrees to continued follow-up of associated clinical outcome information as described in the previous bullet, the authorized personnel must obtain the subject's informed consent for this limited participation in the study (assuming such a situation was not described in the original informed consent form). In accordance with FDA regulations, IRB approval of informed consent documents would be required (21 CFR 50.25, 56.109(b), 312.60, 312.66, 812.100).
- 11.4. If a subject withdraws from the interventional portion of a study and does not consent to continued follow-up of associated clinical outcome information, the investigator shall not access for purposes related to the study the subject's medical record or other confidential records requiring the subject's consent. However, an investigator may review study data related to the subject collected prior to the subject's withdrawal from the study, and may consult public records, such as those establishing survival status.

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12. RETENTION OF SIGNED CONSENT DOCUMENTS

See separate Creighton University Policy on “[Retention of University Research and Compliance Records](#).”