IRB Policy 13: Informed Consent
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I. Summary Policy

It is the policy of both the East Tennessee State University Campus Institutional Review Board (ETSU IRB) and the East Tennessee State University/Veterans Affairs Institutional Review Board (ETSU/VA IRB) that the investigator must obtain legally effective written informed consent prior to enrolling a subject in a research project unless approval has been granted by the IRB to waive the requirement for informed consent or waive the requirement to obtain written documentation of informed consent. The IRB reviews all informed consent documents for adherence to local requirements and compliance with federal regulations regarding the required elements of informed consent and for assurance of the adequacy of the information contained in the informed consent. The IRB has the authority to observe or to have a third party observe the consent process and the research. The consent process should provide ample opportunity for the investigator and the participant to exchange information and ask questions. The possibility of coercion or undue influence must be minimized. The IRB evaluates such factors as who will obtain the informed consent, and the timing, including any waiting period, for obtaining consent. In addition, the IRB evaluates how and what information will be communicated during the consent process.

The ETSU IRB and ETSU/VA IRB require the use of a long form. Policies do not allow informed consent to be obtained using a short form written consent document. The IRB will affix the approval and, as applicable, expiration dates to all approved informed consent documents and stipulate in approval letters that copies of the approved document(s) must be used in obtaining consent. This helps ensure that only the current, approved ICDs are presented to participants and serves as a reminder to the investigators of the need for continuing review, as applicable.

As ETSU is choosing not to use exempt categories 7 and 8, broad consent associated with these categories is not permitted in this policy.

II. Definitions

Informed Consent is the knowing consent of an individual, or his/her legally authorized representative, which is obtained without undue inducement or element of

force, fraud, deceit, duress, or other forms of constraint or coercion**.** Informed consent is not just a form or signature, but a process of information exchange that includes:

- ✓ subject recruitment materials
- ✓ verbal instructions
- ✓ written materials
- ✓ questions/answer session
- ✓ agreement documented by signature

Legally authorized representative (LAR) means an individual, judicial, or other body authorized under applicable law to consent on behalf of a prospective participant to the participant's participation in the procedure(s) involved in the research. If there is no applicable law addressing this issue, LAR means an individual recognized by institutional policy as acceptable for providing consent in the nonresearch context on behalf of the prospective subject to the subject's participation in the procedure(s) involved in the research.

Children means persons who have not attained the legal age for consent to treatments or procedures involved in clinical investigations, under the applicable law of the jurisdiction in which the clinical investigation will be conducted.

Parent means a child's biological or adoptive parent.

Guardian means an individual who is authorized under applicable law to consent on behalf of a child to participate in research or to general medical care when general medical care includes participation in research.

Parental permission, or parental consent, means the agreement of parent(s) or guardian(s) to the participation of their child or ward in research or a clinical investigation.

Assent means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent.

Clinical trial means 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.

III. Informed Consent Process

No investigator may involve a human subject in research without obtaining the legally effective informed consent of the subject or their legally authorized representative, unless a waiver has been approved by the IRB in accordance with this policy. In general, the ETSU IRB considers individuals unable to consent for their own medical

care, as confirmed by the medical record, to be unable to consent for research participation. During the period of prospective enrollment, the investigator (or qualified designee) must ascertain the subject's ability to provide informed consent.

Investigators must obtain consent prior to entering a subject into a study and/or conducting any procedures required by the protocol, unless consent is waived by the IRB. Before participation in the research, the subject or their LAR must be given a copy of the signed and dated written informed consent form and any other written information provided to the subjects. During a subject's participation in the research, the subject or their LAR must be given a copy of the signed and dated consent form updates and a copy of any authorizations to PHI, or amendments to the written information originally provided.

The IRB will consider where the consent process will take place and the individual who will be obtaining consent (e.g. the investigator, collaborator, or qualified designee) in its determination regarding the appropriateness of the consent process. When the potential participant's understanding of the research may be impaired due to the timing, location, or individuals participating in the proposed consent process, the IRB will require an alternative process.

A. Legally authorized representative

When adult subjects cannot consent for themselves, the IRB may consider an appropriate alternative process where the subject's legally authorized representative provides consent on their behalf. Consent may only be obtained from a LAR if the IRB approves the enrollment of adult subjects with impaired capacity to consent with a defined LAR consent process in place. See IRB Policy 15: Vulnerable Populations.
NOTE: *Consent for research is required in addition to the consent that is obtained for a patient's non-research related treatments and procedures.*

In the case of an incompetent individual or an individual who lacks decision-making capacity, the individuals' LAR is designated in order of preference as one of the following:

1. Court-appointed Conservator or Guardian of the individual with authority to make health care decisions for the patient
2. Person named in the patient's Durable Power of Attorney for Health Care (DPAHC)
3. If the subject does not have a court-appointed guardian or conservator and does not have a person authorized to act under a DPAHC, then both of the following must be true for an alternative adult to serve as the LAR for this subject:
    a. The LAR must be an individual who:
        - Has exhibited special care and concern for the patient,
        - Is familiar with the patient's personal values, and
        - Is reasonably available to serve as a LAR.

b. It appears as though the individual can make research-related decisions in accordance with the subject's individual health care instructions, if any, and other wishes, if known. If the patient has not given individual health care instructions, and specific wishes are not known, the LAR can make a determination of the subject's desires or best interests in light of the subject's personal values and beliefs to the extent they are known. This person may include, in order of descending preference, the subject's spouse, adult child, parent, adult sibling, or other adult relative of the, or another adult who satisfies the requirements listed above.

In addition, if research involving adults who are unable to consent is being conducted outside of the state of Tennessee, the investigator must consult Legal Counsel about which individuals are "legally authorized representatives" when the research is conducted in that jurisdiction. Researchers must submit a copy of this legal opinion to the IRB.

Investigators must obtain a copy of the court order if a court appointed conservator or guardian gives consent. Investigators must obtain a copy of the DPAHC the subject's DPAHC gives consent. If an alternate individual is identified to serve as the LAR gives consent, the investigator must document additional information evidencing the individual's qualifications to serve as the LAR.

For VA studies, the following persons are authorized to consent on behalf of persons who lack decision-making capacity in the following order of priority in accordance with VA regulations at 38 CFR 17.32(e),(g)(3).

1. Health care agent (i.e., an individual named by the subject in a Durable Power of Attorney for Health Care);
2. Legal guardian or special guardian;
3. Next of kin: a close relative of the patient 18 years of age or older, in the following priority: spouse, child, parent, sibling, grandparent, or grandchild; or
4. Close friend.

NOTE: *The persons authorized to consent on behalf of persons who lack decision-making capacity for participation in the research may not necessarily be the same as the persons authorized to provide permission for the use and disclosure of information on a HIPAA authorization on behalf of persons who lack decision-making capacity (see VHA Handbook 1605.01).*

B. Parental Permission

For participants less than 18 years of age, their parents or legal guardian may grant permission for their participation in research. Grandparents and other relatives may not grant permission unless they have been granted formal custody of the child by a court. In such cases, the PI must obtain a copy of the court order as evidence of that person's authority. If research involving children is being conducted outside of the state of

Tennessee, the investigator must consult Legal Counsel to determine the definition of who is a “child” and who may provide “parental permission” when the research is conducted in that jurisdiction. Researchers must submit a copy of this legal opinion to the IRB.

According to the Tennessee Department of Children Services (DCS), applicable policies by virtue of the court order granting DCS legal custody of certain children (e.g., foster children) documents that DCS is authorized to grant permission for participation in research for children in their custody**.** The decision of whether to grant permission for research is made on a case-by-case basis by DCS. In such cases the PI must obtain a copy of the court order from DCS. The case manager (including the case manager’s supervisor(s) or Regional Administrators’ designee(s), the foster parent, and the contract agency caseworker are authorized by DCS to sign consent for routine medical care. DCS is authorized under Tennessee State law to consent to health care for the child, and therefore can serve as a guardian.

Refer to IRB Policy 15: Vulnerable Populations for other requirements when children are involved research.

C. Consent and Language Barriers

Informed consent must be obtained in a language that is understandable to the participant (or their LAR). Individuals should not be denied the opportunity to participate in research solely due to an inability to read, write, or understand English. Appropriate justification is required to exclude non-English speaking, or non-reading individuals, and will be considered during the protocol review. Without appropriate justification, studies must make provisions to obtain the legally effective informed consent of these individuals.

a) Non-reading subjects

Sometimes individuals may be able to understand English but cannot read or write, such as individuals who are legally blind or illiterate. Such subjects can understand the consent process but are unable to document their informed consent. Therefore, the consent process must include a witness to the process and documentation.

b) Non-English-speaking subjects

Validated translations of consent forms must be available for non-English speaking subjects. To address possible questions or concerns raised by the prospective subject, a qualified interpreter must be present and may act as a witness to the consent process. Credentials of the translator must be added to the research records and made available upon request. The IRB requires that the appropriately translated ICD be submitted to the IRB for review and approval prior to their use.

The IRB may use administrative review procedures in approving such documents if the English language ICD has already been approved, and the investigator attests in writing to the accuracy of the translation.

c) Requiring a Witness Signature on the Consent Form

The institution and the IRB reserve the right to require the signature of a witness on informed consent documents. Both the institution and the IRB have the authority to require protections for human subjects that exceed the minimum standards required under federal or state regulations. If the sponsor or the IRB require a witness to the consent process who also witnesses the signature, a note to that effect must be added to the consent document under the witness's signature line. Generally, witnesses should be independent of the research team. For VA studies, the witness cannot be the person who obtained consent from the participant, but may be a member of the study team or may be a family member.

IV. Required Elements of Informed Consent

Unless the IRB has waived the requirement for informed consent, the consent document must contain the elements of informed consent stated in this policy. The informed consent document must contain all the required elements of informed consent, as well as any pertinent additional elements.

A. Basic Required Elements

1. A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental
2. A description of any reasonably foreseeable risks or discomforts to the participant. In double-blinded studies, risks or possible reactions should be listed separately for each agent in each arm of the study
3. A description of any benefits to the subject or to others that may reasonably be expected from the research; if the individual will receive no benefit this must be stated
4. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject
5. A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained
6. 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. List point of contact by name and phone number to call to terminate participation
7. For research involving more than minimal risk, an explanation as to whether any compensation 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.

8. An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights; include contact information for the research team for questions and contact information for someone independent of the research team for problems, concerns, questions, information or input.
9. Contact information for the ETSU IRB to obtain answers about the research or their rights as research subjects. The ETSU IRB contact information may also meet the requirement for someone independent of the research.
10. For studies subject to the 2018 Common Rule, one of the following statements about any research that involves the collection of identifiable private information or identifiable biospecimens:
    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 researcher for future research studies without additional informed consent from the participant or legally authorized representative, if this might be possibility; or
    b. A statement that the participant's information or specimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

B. Additional Required Elements

Additionally, one or more of the following elements of information must also be provided to each subject if required as indicated below:

- The consent process must include a statement that the particular treatment or procedure may involve risks to the participant which are currently unforeseeable **unless** the risk profile of all research-related interventions is well known **and** the research involves no investigational drugs or devices.

- The consent process must disclose that the particular treatment or procedure may involve risks to the embryo or fetus, if the participant is or may become pregnant, which are currently unforeseeable **unless** the research excludes women of child bearing potential and pregnant women **or** the risk profile of all research interventions or interactions on embryos and fetuses is foreseeable and risks are described in the ICD **or** there is no reasonable expectation that this research causes risks to fetuses or embryos.

- The consent process must disclose anticipated circumstances under which the participant's participation may be terminated by the investigator without regard to the participant's consent **unless** there are no anticipated circumstances under which the participant's participation will be terminated by the investigator without regard to the participant's consent.

- The consent process must disclose any additional costs to the participant that may result from participation in the research **unless** there are no costs to the participant that may result from participation in the research.

- The consent process must disclose the consequences of a participant's decision to withdraw from the research **and** procedures for orderly termination of participation by the subject **unless** there are no adverse consequences (physical, social, economic, legal, or psychological) of a participant's decision to withdraw from the research.

- The consent process must disclose that significant new findings developed during the course of the research which may relate to the participant's willingness to continue participation will be provided to the participant **unless** significant new findings during the course of the research which may relate to the participant's willingness to continue participation are unlikely.

- The consent process must disclose the approximate number of participants involved in the study **unless** the approximate number of participants involved in the study is not important to a decision to take part in the research.

- The consent process must disclose the amount and schedule of all payments to research subjects **unless** there is no payment being made to subjects.

- If measures to prevent pregnancy should be taken while in the study, this should be explained in the consent process. If relevant animal data are available, the significance should be explained to potential participants.

- For FDA-regulated research determined to be an applicable clinical trial, the consent process must state: "A description of this clinical trial will be available on http://www.Clinical Trials.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."

- For FDA-regulated research, the consent process must disclose the possibility that the Food and Drug Administration may inspect the records.

- For studies subject to the 2018 Common Rule, the consent process must disclose that a subject's biospecimens, even if identifiers are removed, may be used for commercial profit and whether the participant will or will not share in this commercial profit **unless** the study does not involve the collection of biospecimens.

- For studies subject to the 2018 Common Rule, the consent process must disclose whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions **unless** there will be no clinically relevant research results.

- For studies subject to the 2018 Common Rule, the consent process must disclose a statement about 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) **unless** the study does not involve the collection of biospecimens or the study will not include any whole genome sequencing.

- All Public Health Service (PHS) studies require that when HIV testing is conducted or supported by PHS, individuals whose test results are associated with personal identifiers must be informed of their own test results and provided the opportunity to receive appropriate counseling unless exception criteria are met. This procedure must be described in the ICD.

When in the IRB's judgment, additional information would be meaningful to participants, the IRB will require that the additional information be given to participants and documented in the informed consent document as appropriate.

C. Concise Summary

For studies subject to the 2018 Common Rule, the consent document must begin with a concise and focused presentation of key information that is most likely to assist a prospective participant or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This beginning portion must be organized and presented in a way that facilitates comprehension. For some relatively simple research studies with limited risks or benefits, the entire informed consent document may be relatively brief (less than 3-4 pages) and still satisfy this requirement. In such circumstances, ETSU may determine that virtually all of the information required by § .116 would also satisfy this requirement.

The application of this requirement will depend on the nature of the specific study and the information presented in the consent. In general, if the information in the concise summary satisfies the consent disclosure requirements, then it does not have to be repeated later in the body of the consent. If, however, the concise summary just spotlights some aspects but does not disclose all necessary information, then more detail needs to be provided in the body of the consent.

In general, the expectation is that this initial presentation of the key pieces of information will be relatively short. The length will be associated with the complexity of the study itself and the information to be disclosed. For a shorter consent, a few paragraphs are expected for this concise summary. For longer consents (i.e., 20 pages), then the summary may be 3-4 pages long.

In general, the IRB expects the beginning of an informed consent would include a concise explanation of the following:

(1) the fact that consent is being sought for research and that participation is voluntary;
(2) the purposes of the research, the expected duration of the prospective subject's participation, and the procedures to be followed in the research;
(3) the reasonably foreseeable risks or discomforts to the prospective subject;
(4) the benefits to the prospective subject or to others that may reasonably be expected from the research; and
(5) appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the prospective subject

The IRB determination about the concise summary is dependent on the facts of the study; therefore, the IRB may require that additional information be included in the concise summary.

V. Informed Consent Document

The prospective subject or their 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. The consent process, including the information provided in an informed consent document must be presented 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 prospective subject's or their LAR's understanding of the reasons why one might or might not want to participate. Separate forms may be required for different participant groups (parents, children) as well as for release of particular types of information (photographs, audio recordings, video recordings). The form may be read or summarized to the participant or their LAR. The investigator is required to give the participant or their LAR adequate opportunity to read the consent document before it is signed. In addition to the basic and required elements of consent, the informed consent document and process must comply with the following:

A. Reading Level

The informed consent document must be written using language that can be understood by the participant or their LAR. Generally, a seventh-grade reading level is appropriate. Medical terminology should be avoided or defined using simple terms. The consent form is a document addressed to the participant and should read as such.

The signature and date of the participant or their LAR must be obtained on the informed consent document bearing the most recent IRB approval stamp. A copy of the informed consent document must be given to the person signing the form. These actions must be noted in the study records (e.g., participant given a copy of the signed

ICD on [date] by [name]). In certain types of research, it may also be useful to also include the time of signing the ICD along with the signature and date.

B. Version Date

All informed consent documents must bear a version date in the footer on each page of the consent. The version date must be updated whenever a revision is made to the informed consent document.

C. Payments to Participants

Payments to participants for their participation in a research study must be IRB approved. The amount must be commensurate with the expected contributions of the subject. The amount and terms of the payment (i.e., check, cash, gift card, etc.) as well as timing of receipt of compensation must be defined in the IRB submission. The informed consent document should provide information about the payment as appropriate. The informed consent document must note that that payments of any amount will be reported to the IRS and may be counted as income and should include language consistent with institutional policy for paying research subjects.

D. Payment of Investigators

It is recommended that notice be provided in the informed consent document if the investigator is to receive payment for enrollment of subjects. When a sponsor requires disclosure, the IRB will accept the statement if the provisions of 45 CFR 46.116(d)(1)-(4) exist and are documented in writing by the sponsor and/or investigator.

E. Research-related injury

ETSU has a required verbatim statement concerning compensation for research-related injury and/or the availability of medical treatment for the research-related injury that must be included in the informed consent document for studies sponsored by ETSU and determined by the IRB to be more than minimal risk or for studies that present a reasonable possibility for research-related injury (i.e., exercise protocols). Refer to the ETSU IRB informed consent template for the required statement.

For studies with an associated contract, the Vice Provost for Research is responsible for verifying consistency for provisions of medical care or other care or services for research-related injury between the informed consent document and contract terms. IRB approval will not be issued until verification is obtained. If revisions are subsequently made to the sections of the contract pertaining to provisions of medical care or other care or services for research-related injury, the PI is responsible for submitting the revisions to the IRB. The IRB Coordinator will obtain verification of consistency from the VPR prior to releasing IRB approval documentation.

F. Exculpatory language

Exculpatory language is prohibited. Informed consent, whether oral or written documents, may not contain any exculpatory language through which the subject is made to waive or appear to waive any of the subject's legal rights, or releases or appears to release the investigator, the sponsor, ETSU, VAMC, or its agents from liability for negligence.

G. HIPAA Authorizations

When the HIPAA Authorization is embedded in the body of the ICD the IRB shall be responsible for reviewing both the content of the Authorization and its appropriateness to the research. When the HIPAA Authorization is attached to the ICD as an addendum (preferred), the IRB Chair, designee of the Chair, or the IRB Coordinator shall be responsible for the review.

H. Applicable State Laws regarding Reporting Requirements

Each state may have laws regarding mandatory reporting when there is reasonable cause to believe that a child or elder was abused or neglected or when an individual may cause immediate harm to themselves or others. Because of these laws, the IRB must evaluate studies to determine whether disclosure of the implications of the laws is required for legally effective informed consent. When the ETSU IRB reviews research occurring in the state of Tennessee, the provisions noted below will be followed. For research occurring outside of Tennessee, the PI is responsible for providing an appropriate legal opinion or other documentation to ensure appropriate mandatory reporting laws are followed.

Because of these laws, investigators must ensure that the consent process provides participants with accurate information concerning required reporting. Investigators are also responsible for compliance with these regulations. In situations where conditions of abuse or neglect might be revealed, mandated reporters should make themselves known as such to parents of children under age 18, to subjects who are children, and to subjects who are potential victims of elder abuse or neglect.

1. Mandatory Reporting of Abuse. [T.C.A. § 37-1-403] Any person who has knowledge of or is called upon to render aid to any child who is suffering from or has sustained any wound, injury, disability, or physical or mental condition is required to report the harm immediately by telephone to the:
    - Judge having juvenile jurisdiction over the child;
    - County office of the department;
    - Sheriff of the county where the child resides; or

- Chief law enforcement official of the municipality where the child resides.
- The report will include (to the extent known) the name, address, and age of the child, the name address of the person responsible for the care of the child, and the facts requiring the report.

2. Mandatory Reporting of Sexually Transmitted Disease. Every physician or other person who makes a diagnosis of, treats or prescribes for a case of sexually transmitted disease designated as reportable is required to report the case immediately to the Department of Health. Reports include the name, address, age, sex, race, stage of disease, treatment, and control of the disease.
   - Children 13 years of age or younger must be reported to the Department of Health.
   - Reporting is required for children where sexual abuse is suspected regardless of injury to the Department of Health and the Department of Health will notify the Department of Children's Services.

3. Mandatory Reporting of Cancer. All laboratories, hospitals, facilities and practitioners are required to report to the Department of Health within 6 months of diagnosis any cancer in an individual if making the initial diagnosis. The report includes the diagnosis, occupation, family history and personal habits of the person diagnosed with cancer.

4. Elder Abuse: [T.C.A. § 71-6-103] Any person, including, but not limited to, a physician, nurse, social worker, department personnel, coroner, medical examiner, alternate care facility employee, or caretaker, having reasonable cause to suspect that an adult has suffered abuse, neglect, or exploitation, shall report or cause reports to be made in accordance with this part. Death of the adult does not relieve one of the responsibilities for reporting the circumstances surrounding the death. However, unless the report indicates that there are other adults in the same or similar situation and that an investigation and provision of protective services are necessary to prevent their possible abuse, neglect or exploitation, it shall not be necessary for the department to make an investigation of the circumstances surrounding the death; provided, that the appropriate law-enforcement agency is notified. An oral or written report shall be made immediately to the department upon knowledge of the occurrence of suspected abuse, neglect, or exploitation of an adult. Any person making such a report shall provide the following information, if known: the name and address of the adult, or of any other person responsible for the adult's care; the age of the adult; the nature and extent of the abuse, neglect, or exploitation, including any evidence of previous abuse, neglect, or exploitation; the identity of the perpetrator, if known; the identity of the complainant, if possible; and any other information that the person believes might be helpful in establishing the cause of abuse, neglect, or exploitation. Each report of known or suspected abuse of an adult involving a sexual offense that is a violation of §§ 39-13-501 -- 39-13-506 that occurs in a facility licensed by the department of mental health and substance abuse services as defined in § 33-2-402, or any hospital shall also be

made to the local law enforcement agency in the jurisdiction where such offense occurred.

I. VA Consent Document

For VA studies, the VA Research Consent Form template must be used. The VA Research Consent Form must incorporate all the elements required by applicable regulations. In addition, the following statements are required to be included:

- ✓ This statement if the research involves an investigational drug with an IND or a medical device with an IDE) A verbatim statement: “I have been told because this study involves articles regulated by the FDA, the FDA may inspect research identifying me as a subject of this investigation.”

- ✓ A statement that a veteran subject will not be required to pay for care received as a subject in a VA research project except if they are in an eligibility category that requires they pay a co-pay for medical services that are not part of the study.

  Example 1: “You will not be charged for any treatments or procedures that are part of this study. However, if you are required to make co-payments for services provided by the VA or if you receive treatment that is part of your usual medical care, you or your third-party payer (e.g., insurance company) may be billed.”

- ✓ The confidentiality section must include a statement that the Government Accounting Office (GAO), the ETSU/VA IRB, R&D, FDA, OHRP, DHHS, ORO, and any other applicable institutions may have access to the records.

- ✓ This Injury/Complications paragraph must be included "According to VA Regulations [38CFR17.85(a)] the medical facility shall provide necessary medical care to a research subject injured as a result of participation in a research project. However, no additional compensation has been set aside. You have not waived any legal rights or released the VA or its agents from liability for negligence by signing this form."

- ✓ This statement is required for veteran subjects "If you are a veteran taking part in a research study at the James H. Quillen VAMC, a copy of your signed/dated consent form will be placed in your medical record."

- ✓ The form must contain an adequate description of any payment, which must include timing; method of payment; and if subject is being paid by VA check through Austin, the informed consent must note that the social security number will be required to process the check and that payments of any amount will be reported to the IRS and may be counted as income.

- ✓ If the researcher believes that bodily fluids, substances or tissues of a research subject could lead to the development of a commercially valuable product, the form must contain this statement "I authorize the use of my bodily fluids, substances or tissues for research purposes. The sample(s) (blood, tissue or fluids) that I am giving might be used in studies that lead to new products for research, diagnosis or treatment. These products may have some commercial value. By signing this consent form, I give up all rights to any commercial application related to information or samples that I have given during my participation in this research project."

- ✓ The form must contain signature and date lines for the following:
  - subject or the subject's legally-authorized representative,
  - person obtaining the informed consent, and
  - If required by the IRB, witness whose role is to witness the subject's or the subject's legally-authorized representative's signature.

- ✓ VA consents must include information about where and how a veteran could verify the validity of a study and authorized contacts.

- ✓ If the specimens are to be retained after the end of the study for future research, the consent must disclose where the specimens will be retained, who will have access to them, and how long they will be retained. All applicable policies, including organizations, VA, and other federal requirements must be met for handling, use and storage of biologic specimens and data.

- ✓ If any of the data are to be retained after the end of the study for future research, the consent must disclose where the data will be retained, and who will have access to the data. All applicable policies, including organizations, VA and other federal requirements must be met regarding the use and storage of data.

- ✓ If the participant will be re-contacted for future research, whether within a VA facility or outside a VA facility, the consent must disclose this information.

- ✓ If the participant will receive a report of aggregate results or any results specific to the participant, the consent must disclose this information.

- ✓ If the research includes taking photographs or making video or phone recordings that will be used for research purposes, the consent document must include Information describing any photographs, video, and/or audio recordings to be taken or obtained for research purposes, how the photographs, video, and/or audio recordings will be used for the research, and whether the photographs, video, and/or audio recordings will disclosed outside VA. The consent for research does not give legal authority to disclose the photographs, video, and/or audio recordings outside VA. A HIPAA Authorization is needed to make such disclosures.

- ✓ Any real or apparent conflict of interest by investigators where the research will be performed must be disclosed.

For VA studies, in the event that someone other than the investigator will be conducting the consent interview or obtaining consent, the investigator must provide a formal and prospective delegation of the responsibility of obtaining informed consent (in the protocol or the IRB submission forms). The delegate must have received appropriate training (i.e., completed CITI requirements as well as protocol-specific training by the PI). The person, who must be a member of the study team, must be knowledgeable about the research to be conducted and the consenting process, and must be able to answer questions about the study. The informed consent document must be signed and dated by the subject or the subject's legally authorized representative, and the person obtaining the informed consent.

The original signed consent form must be maintained by the Principal Investigator in the study file and a copy is given to the subject, a copy of both the ICD and the HIPAA Authorization scanned into the electronic medical record of the subject, and an annotation is made in the progress notes indicating that the ICD had been scanned into the electronic record.

VI. Documentation of Informed Consent

The investigator must appropriately delegate and document the informed consent process with each subject consistent with the IRB-approved process for obtaining and/or documenting consent. A knowledgeable member of the IRB-approved study staff should facilitate the informed consent discussion, where appropriate.

The intention is that the IRB-approved consent process will be followed, usually involving in-person consenting; however, the IRB appreciates that there may be occasional exceptions to this process whereby an individual may need to provide consent over the phone or from long-distance. If the investigator anticipates substantial use of long-distance consenting, this should be specified in the consent process plan and approved by the IRB. When the informed consent discussion takes place over the phone, the investigator can email or fax a copy of the IRB-approved informed consent document to the participant for his or her review. The research team must receive a copy of the signed and dated consent document from the subject prior to beginning the research procedures.

In VA studies, during the recruitment process, researchers must make initial contacts with veterans in person and/or by letter prior to any telephone contact, unless there is written documentation that the participant is willing to be contacted by phone about the study in question or a specific kind of research (e.g. if the prospective participant has diabetes, the participant may indicate a desire to be notified of any diabetes-related

research studies.) The initial contact must provide a telephone number or other means that veterans can use to verify the study constitutes VA research.

If the subject providing informed consent is under medical treatment and a medical chart is maintained, a copy of the signed consent document must be included in both the patient's chart and the research records. Additionally, a copy of the consent form must be given to the participant. Signed consent forms should be stored so as to be available upon IRB request.

VII. Posting of Consents

For studies subject to the 2018 Common Rule, clinical trials supported by federal funding, one IRB-approved consent form used to enroll participants must be posted on a publicly available federal website. This provision only applies to consent forms from clinical trials conducted or supported by a Common Rule department or agency. If the federal department or agency supporting or conducting the clinical trial determines that certain information should not be made publicly available on a federal website (e.g. confidential commercial information), such federal department or agency may permit or require redactions to the information posted. If the study involves multiple sites, only one IRB-approved informed consent form for the entire clinical trial must be posted and not from separate participating sites.

The informed consent form must be posted after the clinical trial is closed to recruitment and no later than 60 days after the last study visit by any subject as described in the IRB-approved protocol. For multi-site studies, it applies when the entire study has closed to subject recruitment. Any proprietary or personal information (such as names and phone numbers) may be redacted prior to posting the informed consent form. Only one IRB-approved version of a consent form that has been used in the course of the study to enroll participants needs to be posted.

In addition, for VA Studies:
For any ORD-funded clinical trial, the applicable ORD funding service will be responsible for posting the informed consent form. For a clinical trial funded or supported by a federal agency or department other than VA, the awardee is responsible for posting the informed consent form. A clinical trial funded or supported by a non-federal agency or department (e.g., university, industry, nonprofit organization) or not funded, the VA Investigator conducting the clinical trial is responsible for ensuring that the informed consent form is posted. If the clinical trial includes multiple sites engaged in the clinical trial, an agreement must exist specifying who is responsible for posting the informed consent form.

VIII. Confidentiality/Anonymity

During the informed consent process, subjects are given assurances that the confidentiality of records identifying the subjects will be maintained. The informed

consent must include a description to which confidentiality of records identifying the subject will be maintained. Access to study records should be limited to the investigator and study team and others that have the legal right to inspect the records to ensure compliance with institutional or regulatory requirements. The informed consent document must inform subjects about who will or might have access to the study records.

A. Legal Challenges and Confidentiality

Loss of confidentiality may occur when a court orders that research files or information be submitted as evidence in a legal matter. The court decides who has access to the files and what information may be required to be provided. Unless there are no identifiers in the dataset and subject lists are not maintained, complete confidentiality may be assured only to the extent that disclosure is not compelled by court order.

B. Inadvertent Disclosure

Security in storage, limitation of access, and coding constitute the best means to minimize risk of inadvertent disclosure to unauthorized parties. Measures to prevent inadvertent disclosure should be described in applications for studies in which the data collected is sensitive.

C. Certificate of Confidentiality

Certificates of Confidentiality (CoC) are issued by the National Institutes of Health (NIH) and other HHS agencies to protect personally identifiable, sensitive information collected in research from forced or compelled disclosure. For the purposes of a CoC, sensitive information may include, but is not limited to:

a) Information relating to sexual attitudes, preferences, or practices;
b) Information relating to the use of alcohol, drugs, or other addictive products
c) Information pertaining to illegal conduct;
d) Information that if released might be damaging to an individual's financial standing, employability, or reputation within the community, or might lead to social stigmatization or discrimination;
e) Information pertaining to an individual's psychological well-being or mental health; or
f) Genetic information or tissue samples.

Certificates of Confidentiality protect researchers and institutions from being compelled by legal demands to disclose information that would identify research subjects, add another level of protection, and are a tool to help minimize the risks to subjects by further protecting the confidentiality of private information. Certificates of Confidentiality are authorized by Public Health Service Act subsection 301(d). Effective October 1, 2017, NIH policy requires the HHS Secretary to automatically grant a CoC to investigators or institutions who are engaged in federally funded biomedical, behavioral, clinical, or other research in which identifiable, sensitive information is

collected. Investigators and institutions are responsible for determining when a NIH-funded activity falls within the scope of the policy.

The term “identifiable, sensitive information” means information that is about an individual and that is gathered or used during the course of biomedical, behavioral, clinical, or other research and—

(A) through which an individual is identified; or

(B) for which there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual.

Examples of research automatically covered by a CoC include:

- Biomedical, behavioral, clinical or other research, including exempt research, except where the information obtained is recorded in such a manner that human participants cannot be identified or the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects.
- The collection or use of biospecimens that are identifiable to an individual or for which there is at least a very small risk that some combination of the biospecimen, a request for the biospecimen, and other available data sources could be used to deduce the identity of an individual.
- The generation of individual level, human genomic data from biospecimens, or the use of such data, regardless of whether the data is recorded in such a manner that human subjects can be identified or the identity of the human subjects can readily be ascertained.
- Any other research that involves information about an individual for which there is at least a very small risk, as determined by current scientific practices or statistical methods, that some combination of the information, a request for the information, and other available data sources could be used to deduce the identity of an individual.

A CoC may also be issued if the research is not federally funded and can be requested by applying to the NIH, FDA, or other authorized federal agencies or departments.

When research is covered by a certificate of confidentiality, researchers may not:

- Disclose or provide, in any federal, state, or local civil, criminal, administrative, legislative, or other proceeding, the name of such individual or any such information, document, or biospecimen that contains identifiable, sensitive information about the individual and that was created or compiled for purposes of the research, unless such disclosure or use is made with the consent of the individual to whom the information, document, or biospecimen pertains; or
- Disclose or provide to any other person not connected with the research the name of such an individual or any information, document, or biospecimen that contains identifiable, sensitive information about such an individual and that was created or compiled for purposes of the research.

Researchers may disclose information only when:

- Required by federal, state, or local laws (e.g., as required by the U.S. Food, Drug, and Cosmetic Act, or state laws requiring the reporting of communicable diseases to state and local health departments), excluding instances of disclosure in any federal, state, or local civil, criminal, administrative, legislative, or other proceeding.
- Necessary for the medical treatment of the individual to whom the information, document, or biospecimen pertains and made with the consent of such individual;
- Made with the consent of the individual to whom the information, document, or biospecimen pertains; or
- Made for the purposes of other scientific research that is in compliance with applicable federal regulations governing the protection of human subjects in research.

When research is covered by a CoC, researchers must inform participants of the protections and limitations of the CoC. Researchers conducting NIH-supported research or FDA-regulated research covered by a CoC must ensure that if identifiable, sensitive information is provided to other researchers or organizations (i.e., sponsor, CRO), regardless of whether or not the research is federally funded, the other researcher or organization must comply with the CoC.

For VA studies that are protected by a CoC, the following requirements apply:

(1) For studies in which information about the subject's participation will be included in the subject's VHA medical record, information must be given to the prospective subjects as part of the informed consent process that information regarding study participation will be included in the medical record; and

(2) For studies in which the IRB requires a written informed consent, the informed consent document approved by the IRB must include a statement that the study has a Certificate of Confidentiality. NOTE: The HHS agencies that issue Certificates of Confidentiality usually have guidance specific to the issuing agency on statements that must be included.

IX. Observation of Consent Process

The ETSU IRB has the authority to observe, or have a third party observe, the consent process. Situations where observation of informed consent may be requested include:

- Studies where the capacity of the participant to provide informed consent may be questionable
- High-risk studies, such as Phase I clinical trials
- Investigators have a suspected or confirmed history of problems relating to the consent process
- Complaint(s) regarding the consent process
- Others as determined necessary by the IRB

X. Waiver of Informed Consent

The IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent, or waive the requirement to obtain informed consent provided one of the following sets of conditions exists and is documented:

1) The research or clinical investigation involves no more than minimal risk to the subjects; and
2) The waiver or alteration will not adversely affect the rights and welfare of the subjects; and
3) The research or clinical investigation could not practicably be carried out without the waiver or alteration; and
4) For studies subject to the 2018 Common Rule, if the research involves using identifiable private information or identifiable biospecimens, the research could not practicably be carried out without using such information or biospecimens in an identifiable format; and
5) Whenever appropriate, the subjects will be provided with additional pertinent information after participation.

OR

1) The research or demonstration project is to be conducted by or subject to the approval of state or local government officials and is designed to study, evaluate, or otherwise examine at least one of the following (a) public benefit or service programs; (b) procedures for obtaining benefits or services under these programs; (c) possible changes in or alternatives to those programs or procedures; or (d) possible changes in methods or levels of payment for benefits or services under those programs; AND
2) The research could not practicably be carried out without the waiver or alteration.

Note: For research regulated by the FDA, informed consent may also be waived for emergency situations (21 CFR 50.23) or for emergency research (21 CFR 50.24).

A waiver of parental permission (or student consent if the student is an adult) may not be granted if the study involves funding from the Department of Education and the study involves a survey, analysis, or evaluation that reveals information concerning the following categories:

(1) political affiliations or beliefs of the student or the student's parent;
(2) mental or psychological problems of the student or the student's family;
(3) sex behavior or attitudes;
(4) illegal, anti-social, self-incriminating, or demeaning behavior;
(5) critical appraisals of other individuals with whom respondents have close family relationships;

(6) legally recognized privileged or analogous relationships, such as those of lawyers, physicians, and ministers;
(7) religious practices, affiliations, or beliefs of the student or student's parent; or
(8) income (other than that required by law to determine eligibility for participation in a program or for receiving financial assistance under such program).

In addition, all instructional materials, including teacher's manuals, films, tapes, or other supplementary material which will be used in connection with any survey, analysis, or evaluation as part of any applicable program shall be available for inspection by the parents or guardians of the children.

The appropriate reviewer checklist xform will be completed by the IRB Chair or Primary Reviewer to document and determine if a waiver of informed consent is appropriate. In addition, the IRB minutes will document required determinations regarding waiver or alteration of requirement to obtain informed consent for studies review by the convened IRB. The xform and minutes will also document the protocol specific findings justifying the determinations.

For VA studies, an informed consent to take a photograph, video, and/or audio recording cannot be waived by the IRB.

A waiver of HIPAA authorization must be approved by the IRB or Privacy Board prior to accessing any PHI for screening, recruiting, or determining eligibility. Informed consent, or an IRB-approved waiver thereof is required before any research interventions occur after eligibility is determined.

XI. Waiver of Documentation of Informed Consent

Under certain conditions, the IRB can waive the requirement that the participant sign the consent form. However, waiver of documentation of informed consent does not constitute waiver of informed consent. The IRB reviews the written description of the information that will be provided to participants. The IRB may waive the requirement for the investigator to obtain a signed consent form for some or all participants if it finds either:

1) That 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 participant will be asked whether the subject wants documentation linking the subject with the research, and the participant's wishes will govern.

   OR

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.

   OR

3) It is not the cultural norm for subjects to sign such documents, as long as the research is no more than minimal risk and an appropriate alternative documentation mechanism is used. Note: not applicable to FDA-regulated research.

The oral or written information provided to participants must include all required and appropriate elements of consent disclosure. In cases where the documentation requirement for informed consent is waived, the IRB may require the investigator to provide participants with a written statement regarding the research.

The appropriate reviewer checklist xform will be completed by the IRB Chair or Primary Reviewer to determine and document the appropriate waiver of documentation. In addition, the IRB minutes will document required determinations regarding waiver of requirement for written documentation of informed consent for studies reviewed by the convened IRB. The xform and minutes will also document the protocol specific findings justifying the determinations.

References:
45 CFR 46.116
45 CFR 46.117(a)
OHRP Guidance
45 CFR 46.109
21 CFR 50.20
21 CFR 56.109
OHRP Guidance
FDA Information Sheets
TCS Administrative Policy and Procedure 6.1 and Research Proposals: DCS Administrative Policy and Procedure 20.24
VHA Directive 1200.05
TCA 68-1-1-003
TCA 37-1-403
TCA 68-10-101
TCA 68-1-2101
Memo, Department of Veterans Affairs, Subject: Researcher Contacts with Veterans, July 10, 2006
Protection of Public Rights Amendment (PPRA)
IRB Waiver or Alteration of Informed Consent for Clinical Investigation Involving No More than Minimal Risk to Human Subjects, FDA Guidance for Sponsors, Investigators and IRBs, July 2017