

## **IRB Policy 13: Informed Consent**

**Revision date: October 6, 2008, revised July 10, 2009, revised July 27, 2010, revised January 27, 2011, revised 2/9/15, revised 10/15/15, revised November 18, 2015, revised April 29, 2016, revised 11/22/16, revised 4/2/18, revised January 24, 2019, revised Feb 7, 2019**

### **I. Definition**

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

Under the 1991 Common Rule and FDA regulations, ***Legally authorized representative*** 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. [21 CFR §50.3(l)] [45 CFR §46.102(c)] For studies subject to the 2018 Common Rule, legally authorized representative means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. If there is no applicable law addressing this issue, ***legally authorized representative*** 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. [45 CFR §46.402(d)] [21 CFR §50.3(o)]

***Guardian*** means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care when general medical care includes participation in research. [21 CFR §50.3(s)]

**A guardian** also means an individual who is authorized to consent on behalf of a child to participate in research. [21 CFR §50.3(s)]

**Guardian** means an individual who is authorized under applicable State or local law to consent on behalf of a child to general medical care. [45 CFR §46.402(e)]

**Permission** means the agreement of parent(s) or guardian to the participation of their child or ward in research. [45 CFR §46.402(c)] **Permission** means the agreement of parent(s) or guardian to the participation of their child or ward in a clinical investigation. [21 CFR§ 50.3(r)]

**Parent** means a child's biological or adoptive parent. [45 CFR §46.402(d)] [21 CFR§ 50.3(p)]

**Assent** means a child's affirmative agreement to participate in research. Mere failure to object should not, absent affirmative agreement, be construed as assent. [45 CFR §46.402(b)] [21 CFR§ 50.3(n)]

**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.

## **II. Summary Policy**

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 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. (refer to Section IX). 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 (see IRB web site for template). Policies do not allow informed consent to be obtained using a short form

written consent document. Every page of the approved informed consent must be date-stamped by the IRB Director or Coordinator. 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.

### **III. Documentation**

During the period of prospective enrollment, the investigator (or qualified designee) must ascertain, either during the preliminary telephone interview (interest query) (note: telephone inquiry prohibited by VA policy- see Policy 16), face-to-face encounter or by review of the medical history, the subject's ability to provide consent (HIPAA regulations regarding sharing/access to PHI apply). Before participation in the research, the subject or the subject's legally authorized representative 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 the subject's legally authorized representative 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.

### **IV. Informed Consent Document**

Unless the IRB has waived the requirement for informed consent (§46.116 (e) or (f)), or waived the requirement to obtain written documentation of informed consent as provided in §46.117(c)(1) or (2) or (3 for 2018 Common Rule), informed consent must be documented in writing. The consent document must contain the elements of informed consent required by the regulations. The investigator is required to give the participant or the participant's legally authorized representative adequate opportunity to read the consent document before it is signed. The form may be read to the participant or the participant's legally authorized representative. The signature of the participant or the participant's legally authorized representative must be obtained on the informed consent document bearing the most recent IRB approval stamp. Additionally, the participant or the participant's representative must date the informed consent document. 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 (ICD) along with the signatures and date.

### **A. Level**

The informed consent document must be written using language that can be understood by someone reading at the seventh grade level. Medical terminology should be avoided or defined. The consent form is a statement addressed to the participant and should read as such. The consent process, including the information provided in an informed consent form 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 legally authorized representative'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).

### **B. Version Date**

All Informed Consent Forms 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. (refer to modification policy).

### **C. Elements**

The prospective subject or the 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 informed consent document must contain all the required elements of Informed Consent, as well as any pertinent additional elements.

### **D. 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. This requirement applies to all informed consents, except for broad consents under exempt category 7. However, 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 § II.116 would also satisfy this requirement.

### Content and Length:

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, ETSU's 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 is expected for this concise summary. For longer consents, i.e., 20 pages, then the summary may be 3-4 pages long.

In general, ETSU expects that to satisfy this requirement, 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, and therefore the IRB may require that additional information be included in the concise summary.

## **Required Elements of Informed Consent**

In seeking informed consent the following information shall be provided to each subject (§46.116, 21CFR50, 21CFR56):

1. A statement (introduction) 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. Possible Risks/Discomforts -(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. Possible Benefits - 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. Financial Costs - list possible financial costs to participant
5. A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject (If there are alternatives, please describe them.)
5. Confidentiality - A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained. (include statement that notes the possibility that specific regulatory authorities may inspect the records (i.e., FDA, DHHS)
6. Voluntary Participation - note that participation is voluntary and subject may refuse to participate with no penalties. 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. Injury / Complications - An explanation of whom to contact for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject. Describe in detail how complications will be handled. ETSU requires that the consent include contact information for the research team for questions, concerns or complaints and contact information for someone independent of the research team for problems, concerns, questions, information or input.
9. 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.
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: This may be omitted if the research does not involve collection of identifiable information or identifiable biospecimens. If the research involves the collection of identifiable information or identifiable biospecimens, then the consent must contain whichever is the appropriate statement below:

- 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
- 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.

## **Additional Elements of Informed Consent**

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.
- ✓ For applicable clinical trials, the consent process must disclose "A description of this clinical trial will be available on <http://www.ClinicalTrials.gov>, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time."
- ✓ For FDA studies, the consent process must disclose the possibility that the Food and Drug Administration may inspect the records.
- ✓ The amount and schedule of all payments
- ✓ For studies subject to the 2018 Common Rule, the consent process must disclose a statement that 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 a statement regarding 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. This provision is intended to pertain to all clinically relevant research results, including general or aggregate research findings and individual 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

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.

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.

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.

#### **D. VA Consent Document**

The only informed consent document that the VA can recognize is the VA Form 10-1086. A VA Form 10-1086 must be used as the consent form for all VA research. The VA Form 10-1086 must incorporate all the elements required by regulations. In addition, the following statements are required to be inserted in VA 10-1086s.

- ✓ VA 10-1086 must contain 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."
- ✓ VA 10-1086 consents must contain 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."

- ✓ In the confidentiality section, the 10-1086 must include a statement that the Government Accounting Office (GAO), the ETSU/VAIRB, R&D, FDA, OHRP, DHHS, ORO, and any other applicable institutions may have access to the records.
- ✓ VA 10-1086 must contain this Injury/Complications paragraph "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"
- ✓ VA 10-1086 must contain this statement 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"
- ✓ VA 10-1086 must contain an adequate description of any payment. (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)
- ✓ VA 10-1086 must contain this statement if the researcher believes that bodily fluids, substances or tissues of a research subject could lead to the development of a commercially valuable product "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"
- ✓ VA 10-1086 must contain Signature and date lines for the following
  - subject or the subject's legally-authorized representative, and
  - person obtaining the informed consent
  - 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 be 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

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 (completed CITI IRB 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 form 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 10-1086 is maintained by the Principal Investigator in the study file, 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). “Refer to Section VIII.C for information about Certificates of Confidentiality

### **E. Payments**

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 (check or cash, etc, as well as timing of receipt of compensation) must be stated precisely. The Informed Consent form should reflect a fair and appropriate amount that does not place undue pressure (coercion) to the volunteer.

### **F. For non-English Speaking Subjects**

Regulations require that informed consent be obtained in a language that is understandable to the participant (or to the participant’s legally authorized representative). 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 translator must be present and may act as a witness. Documentation of the qualifications of the translator must be added to the research records and available for administrative or QI auditing upon request.

Unless a waiver is granted by the IRB, a consent written in a language understandable to the participant and embodying all the required elements is required by the IRB to document the consent process. The IRB requires that the appropriately translated ICD be submitted to the IRB for review and approval prior to their use in enrolling subjects.

The IRB may use expedited 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.

### **G. Legally authorized representative**

Under the 1991 Common Rule and FDA regulations, a legally authorized representative shall be an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research. Legally authorized representative is synonymous with legally acceptable representative. [21 CFR §50.3(l)] [45 CFR §46.102(c)]

For studies subject to the 2018 Common Rule, legally authorized representative means an individual or judicial or other body authorized under applicable law to consent on behalf of a prospective subject to the subject's participation in the procedure(s) involved in the research.

A signature line for legally authorized representatives may only be included on the consent document if the IRB approves the enrollment of participants based on the permission of a legally authorized representative.

**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). **NOTE:** *Consent for research is required in addition to the consent that is obtained for the patient's non-research related treatments and procedures.*

- (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 1605.1).*

**For non-VA studies**, in the case of an incompetent individual or an individual who lacks decision-making capacity, the individuals' health care decision maker (LAR) is designated in order of preference as one of the following:

- A. Court-appointed Conservator or Guardian of the individual with authority to make health care decisions for the patient
- B. Person named in the patient's Durable Power of Attorney for Health Care ( DPAHC)
- C. If the patient does not have a court-appointed guardian or conservator, AND does not have a person authorized to act under a Durable Power of Attorney for Health Care, then both of the following must be true for the individual identified to serve as the surrogate decision-maker for this patient:

1. The person identified above is:

- An adult
- Who has exhibited special care and concern for the patient
- Who is familiar with the patient's personal values AND
- Who is reasonably available to serve as a surrogate

2. It appears as though the person can make health care decisions for the patient in accordance with the patient's individual health care instructions, if any, and other wishes, if known to the health care decision maker. IF the patient has not given individual health care instructions, and the patient's specific wishes are not known, the health care decision maker can make a determination of the patient's desires or best interests in light of the patient's personal values and beliefs to the extent they are known.

This person may include, in order of descending preference, the patient's spouse, the patient's adult child, the patient's parent, the patient's adult sibling, any other adult relative of the patient or another adult who satisfies the requirements listed above.

The investigator must indicate in the application that he/she is requesting to utilize consent of a health care decision maker. The IRB must approve the use of an LAR. The IRB will review the rationale for this request, and ensure there are appropriate safeguards in place.

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 if Person named in the patient's Durable Power of Attorney for Health Care (DPAHC) gives consent. In addition, if an individual identified to serve as the surrogate decision-maker for this patient gives consent, the investigator must document additional information evidencing the person's qualifications to serve as a surrogate. That information must include how long this person has lived with the patients, how long this person has known the patient and how often this person sees the patient, and any other evidence of the appropriateness of the selected surrogate.

#### **H. 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. For studies subject to the 2018 Common Rule, no informed consent may include any exculpatory language through which the subject or the LAR 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, the institution, or its agents from liability for negligence.

### **I. Retention of ICDs**

If the subject is under treatment, and a medical chart is maintained, an original copy of the signed consent document must be included with BOTH the patient's chart and the research records (HIPAA regulations apply). Additionally, a copy of the consent form must be given to the participant. (If electronic medical charts are used, a hard copy informed consent must be generated and maintained as per the above guidelines. Annotation will be made in the electronic medical record that the patient is a subject in a research protocol.) Refer to Section D for VA requirements.

Signed consent forms should be stored so as to be available upon IRB request.

### **K. Deferred Consent or Ratification is Not Permitted (e.g., an investigator signs the ICD on behalf of a potential subject)**

Informed consent procedures which provide for other than legally effective, prospectively obtained consent fail to constitute informed consent under the Federal Regulations for the protection of human subjects. Therefore, waiving informed consent using a method other than those described herein and specified in the Federal Regulations is a violation of this policy.

### **L. Telephone Consenting is Not Recommended**

For non-VA Studies, an investigator may, however, conduct a preliminary telephone interview to query a participant's interest in possibly participating in the research. If initial contact with prospective study subjects is to be made by telephone, a script of the phone contact is to be reviewed and approved by the IRB prior to use. Similarly if initial contact is to be made by mail, the content of the mailing script and list must be reviewed and approved by the IRB prior to initiation.

Following the telephone interview, and under certain circumstances (to be determined by the IRB with evidence of need), the investigator can fax an IRB approved informed consent document to the participant for his or her review. Documentation of this process is critical. The signature page must be witnessed by an individual known to the IRB or notarized, and reflect both the date and time of each signature. Enrollment may begin once the Principal Investigator receives a copy of the signed and notarized consent document. The original document must be immediately (within 24 hours) forwarded to the study file or patient record as appropriate, to be placed in the patients medical record upon discharge. The date and time that the consent document (signed, notarized original copy) was entered into the patient chart must additionally be noted in the progress notes.

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. (One source of information about clinical trials is <http://www.clinicaltrials.gov>).

#### **M. 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, as a matter of policy, under certain situations. 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.

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.

#### **O. 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.



## **P. Payment of Investigators**

It is recommended that notice be provided in the Informed Consent Document that is signed and given to the subject 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.

## **Q. Injury**

ETSU has a required verbatim paragraph concerning compensation for injury that must be included in the informed consents of studies determined to be more than minimal risk. Refer to the informed consent template on the ETSU IRB web site, [www.etsu.edu](http://www.etsu.edu) for the required statement.

## **R. Children**

For participants < than 18 years of age, their parents or legal guardian are the legally authorized representative who may grant permission for their participation in research. When research is conducted in the state of Tennessee, children are all individuals under under the age of 18 without exception.

In addition, 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” 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) that department is the agency that is authorized to grant permission for participation in research 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 as defined in Subpart D.

In addition, 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 “guardian” when the research is conducted in that jurisdiction. Researchers must submit a copy of this legal opinion to the IRB.

## **S. Applicable State Laws regarding Reporting Requirements**

**I. Mandatory Reporting of Abuse.** 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:

- A. Judge having juvenile jurisdiction over the child;
- B. County office of the department;
- C. Sheriff of the county where the child resides; or
- D. Chief law enforcement official of the municipality where the child resides.
- E. 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.

Reference: T.C.A. § 37-1-403

**II. 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.

- A. Children 13 years of age or younger must be reported to the Department of Health.
- B. 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.

**III. 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.

**IV. Elder Abuse:** T.C.A. § 71-6-103 states: “**(b) (1)** 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 responsibility 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.” (c) 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.”

T.C.A. § 71-6-102 states: Adult means a person eighteen (18) years of age or older who because of mental or physical dysfunctioning or advanced age is unable to manage such person's own resources, carry out the activities of daily living, or protect such person from neglect, hazardous or abusive situations without assistance from others and who has no available, willing, and responsibly able person for assistance and who may be in need of protective services; provided, however, that a person eighteen (18) years of age or older who is mentally impaired but still competent shall be deemed to be a person with mental dysfunction for the purposes of this chapter. Advanced age means sixty (60) years of age or older.

Because of these laws, IRB members must evaluate studies to determine whether disclosure of the implications of the laws is required for legally effective informed consent. 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.

#### **T. Consistency of consent with contract**

For initial studies with an associated contract, ETSU's VPR is responsible for verifying that there is consistency for provisions of medical care or other care or services for research-related injury between the consent document and contract.

If verification of consistency between the consent document and the contractual language regarding provisions of medical care or other care or services for research-related injury is not available at the time of initial review, a final IRB approval will not be issued until this verification by Sponsored programs is obtained.

Principal Investigators are responsible for verifying consistency of language between the contract and the consent document before submission to the IRB. 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 forward to Sponsored Programs contract staff for verification of consistency.

This policy applies to all studies with an associated contract.

#### **U. Broad Consent**

As ETSU is choosing not to use exempt categories 7 and 8, the required elements of broad consent associated with these categories is not written in this policy.

#### **V. 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.

For VA studies subject to the 2018 Requirements, if a research study is a federally – funded clinical trial, one IRB-approved informed consent form used to enroll subjects, unless the IRB waived documentation of informed consent, must be posted by either the investigator or the Federal department or agency conducting or supporting the study. Multiple versions of the IRB-approved informed consent form are not required to be 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.

(1) 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. Consent forms must be posted on either <https://clinicaltrials.gov> or a docket folder on <http://Regulations.gov> (Docket ID: HHSOPHS-2018-0021).

(2) For any ORD-funded clinical trial, the applicable ORD funding service will be responsible for posting the informed consent form.

(3) 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.

(4) For VA studies, 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.

5) Any proprietary or personal information (such as names and phone numbers) must be redacted prior to posting the informed consent form

(6) The informed consent form must be posted on <https://clinicaltrials.gov> or a docket folder on <http://Regulations.gov> (Docket ID: HHS-OPHS-2018-0021).

For non-VA studies subject to the 2018 Common Rule, researchers conducting clinical trials are required to post trial consent forms on a federal website, “after the clinical trial is closed to recruitment, and no later than 60 days after the last study visit by any subject, as required by the protocol.” For a multi-site study, only a single consent form from the entire study is required to satisfy the posting requirement – not a consent form from each participating site. 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.

This provision only applies to consent forms from clinical trials conducted or supported by a Common Rule department or agency. See Policy 5 for the DHHS definition of clinical trial.

The Office for Human Research Protections (OHRP) has identified two publicly available federal websites that will satisfy this consent form posting requirement- <https://clinicaltrials.gov> and a docket folder (HHS-OPHS-2018-0021) on <http://Regulations.gov>. 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 Web site (e.g. confidential commercial information), such Federal department or agency may permit or require redactions to the information posted.

## **Waiver of Informed Consent**

DHHS provides for waiving or altering elements of informed consent under certain conditions [§.116(c)-(f)].

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:

45 CFR 46.116(c) (Must meet one of the following criteria from section 1 as well as criteria number 2) **(not applicable to research subject to FDA regulation)**

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.

45 CFR 46.116(d) (Must meet all four criteria detailed below)

1. The research 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 could not practicably be carried out without the waiver or alteration and,
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation.
5. For studies subject to the 2018 Common Rule, an additional criteria is added: "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"

For FDA research, 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 21 CFR 50.25, or waive the requirements to obtain informed consent when the IRB finds and documents that:

1. The clinical investigation involves no more than minimal risk (as defined in 21 CFR 50.3(k) or 56.102(i)) to the subjects;
2. The waiver or alteration will not adversely affect the rights and welfare of the subjects;
3. The clinical investigation could not practicably be carried out without the waiver or alteration; and
4. Whenever appropriate, the subjects will be provided with additional pertinent information after participation

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 IRB cannot approve a consent procedure that omits/alters any of the general requirements of informed consent . Specifically, the consent process must ensure the following:

Legally effective informed consent is obtained under circumstances that

- provide the subject/LAR sufficient opportunity to decide whether to participate;
- minimize coercion/undue influence and
- does not include any exculpatory language through which the subject/LAR is made to waive/appear to waive their rights or releases/appears to release the investigator, sponsor, institution or its agents from liability for negligence
- Information is provided to subjects/LARs in a language they can understand
  - Sufficient information is provided to allow them to make an informed decision
- A short summary of key information related to participation in the study is provided upfront as part of the consent process

The appropriate checklist (xForm 137 for Waiver or Alteration of Requirement to Obtain Informed Consent) will be completed by the IRB Chair or Primary Reviewer. In addition, the IRB minutes will document required determinations regarding waiver or alteration of requirement to obtain informed consent. The 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.

For studies subject to the 2018 Common Rule, the revised Common Rule adds an “exception” to the consent requirement to determine eligibility

1. Allows for the collection of identifiable information or identifiable biospecimens for purposes of screening, recruiting, or determining eligibility of prospective subjects if:

- the investigator will obtain information through oral or written communication with prospective subject or LAR, OR
- the investigator will obtain identifiable private information or biospecimens by accessing records or stored identifiable biospecimens
  - The IRB will be reviewing and approving the entire research proposal, and the preparatory to research activities are a part of it.
  - The IRB must determine that there are adequate privacy and confidentiality safeguards in place for the preparatory-to-research activities as part of the review and approval process.

If subjects identified during the screening process are then successfully recruited to participate, all other requirements must be met.

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.

## **V. VA Studies**

For VA studies, if someone other than the investigator will conduct the interview and obtain consent, the PI must formally delegate this responsibility and the delegate must have received appropriate training (CITI IRB training as well as protocol-specific training by the PI).

## **VI. 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 (46 CFR 117(c):

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. **(not applicable to research subject to FDA regulation)**



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.

For studies subject to the 2018 Common Rule, a third category is added:

- 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 alternative documentation mechanism is used.

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 checklist (xForm 138 Waiver of Requirement for Written Documentation of Informed Consent) will be completed by the IRB Chair or Primary Reviewer. In addition, the IRB minutes will document required determinations regarding waiver of requirement for written documentation of informed consent. The minutes will also document the protocol specific findings justifying the determinations.

## **VIII. Confidentiality/ Anonymity**

### **A. Legal Challenges and Confidentiality**

In the informed consent procedure, subjects are often given assurances that the confidentiality of records identifying the subjects will be maintained.

Loss of confidentiality may occur however, 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 on project materials and subject lists are not maintained, complete confidentiality or records identifying the subjects may be assured only to the extent that disclosure is not compelled by court order. When FDA regulated products are being studied, the informed consent document should state that the FDA may review and copy the subject's medical records and, if necessary, obtain the identity of the subject.

### **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 this problem should be described in applications for studies in which the data collected is sensitive.

### **C. Certificate of Confidentiality**

Certificates of Confidentiality 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 Certificate of Confidentiality, 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
- (f) Information pertaining to an individual's psychological well-being or mental health.
- (g) 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. Certificates of Confidentiality 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 the following subsection [301(d)] of the Public Health Service Act:

The Secretary may authorize persons engaged in biomedical, behavioral, clinical, or other research (including research on mental health, including research on the use and effect of alcohol and other psychoactive drugs) to protect the privacy of individuals who are the subject of such research by withholding from all persons not connected with the conduct of such research the names or other identifying characteristics of such individuals. Persons so authorized to protect the privacy of such individuals may not be compelled in any Federal, State, or local civil, criminal, administrative, legislative, or other proceedings to identify such individuals. [(Public Health Service Act, S 301(d), 42 U.S.C. §241(d), as added by Pub. L. No. 100-607, S 163 (November 4, 1988)].

NIH updated its policy for issuing CoCs, effective October 1, 2017. This update is a result of NIH's need to implement Section 2012 of the 21st Century Cures Act, P.L. 114-255, enacted December 31, 2016. This law requires the Secretary of HHS to issue 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. CoCs are automatically granted, and the requirements of such must be complied with, whenever a NIH-funded activity falls within the scope of the policy. 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 certificate of confidentiality 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

Certificates may also be issued if the research is not federally funded.

*Certificates of Confidentiality* can be requested by applying to the NIH 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

- May not 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 Federal 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.

Written materials require that when research is covered by a certificate of confidentiality, researchers must inform participants (for example, in the consent document) of the protections and limitations of certificates of confidentiality.

This requirement also applies to existing studies active on after December 13, 2016 whenever the study is funded in whole or in part by the NIH and involves identifiable, sensitive information. For existing studies, researchers must notify participants that the research is now covered by a certificate of confidentiality. However, because a certificate of confidentiality reduces risks, the IRB does not need to require the researcher to obtain consent again based on this information, and can simply notify participants of this change.

- Written materials require that researchers conducting NIH-supported research covered by a certificate of confidentiality must ensure that if identifiable, sensitive information is provided to other researchers or organizations, regardless of whether or not the research is federally funded, the other researcher or organization must comply with applicable requirements when research is covered by a certificate of confidentiality

For VA studies that are protected by a Certificate of Confidentiality, the following requirements apply:

When VA conducts a study that is protected by a Certificate of Confidentiality, 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

Per 45 CFR 46, the 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:

- a. Studies where the capacity of the participant to provide informed consent may be questionable
- b. High risk studies, such as Phase I trials
- c. PI has a history of previous studies with problems relating to the consent process for participants
- d. Complaint(s) regarding the consent process
- e. Any others as determined necessary by the IRB

Regulations

45 CFR 46 116

45 CFR 46 117 (a)

OHRP Guidance

45 CFR 46 (109)

21 CFR 50.20

FDA Information Sheets

21 CFR 56.109

TCS Administrative Policy and Procedure 6.1 and Research Proposals: DCS

Administrative Policy and Procedure 20.24

VHA Directive 1200.5

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 of Alternation of Informed Consent for Clinical Investigation Involving No More than Minimal Risk to Human Subjects, Guidance for Sponsors, Investigators and IRBs, July 2017