

	Institutional Review Board	
Effective: July 16, 2008	Revised: January 21, 2019	Revision: 11
Responsibility: OIRB		Page 1 of 31

Informed Consent Policy and Procedure

Table of Contents

Policy

[General Policy on Informed Consent](#)
[Waiver of Informed Consent Process](#)

[Waiver of Informed Consent Documentation](#)
[Use of Short Form Documentation](#)

Procedures

[Informed Consent Process and Documentation](#)
[Use of the Short Form Consent Document](#)

Informed Consent Policy and Procedures for the South Texas Veterans Health Care

[System\(STVHCS\)](#)

[STVHCS Involving Decisionally Impaired](#)

[Illiterate Subjects](#)

[Assent](#)

[Minors](#)

[Obtaining Informed Consent outside the State of Texas](#)

[Non-English Speaking Subjects](#)

[Research that Requires Monitoring of Informed Consent/Assent Process and Procedures](#)

[Waiver of Informed Consent for Non-FDA Regulated Studies](#)

[Waiver of Informed Consent for Non-FDA Regulated Studies determined to be public benefit or service programs](#)

[Waiver of Informed Consent for non-FDA Regulated involving Planned Emergency Research](#)

[Exception from Informed Consent Requirement for Emergency use of an investigational drug or biologic product \(unapproved drug or biologic\) or an unapproved medical device](#)

[Waiver of Parental or Guardian Permission for Research Involving Children in Non-FDA Regulated Research](#)

[Waiver of Documentation of Informed Consent for FDA-Regulated Research](#)

[Waiver of Documentation of Informed Consent for Non-FDA Regulated Studies](#)

[Electronic Consent \(eConsent\)](#)

[Participant Withdrawal](#)

[References](#)

I. Policy

A. General Policy on Informed Consent

1. Obtaining legally effective informed consent, whether written or oral, of individuals or the legally authorized representative, before involving them in research is one of the central protections provided in the regulations governing research. Informed consent in research is founded on the Belmont Principle “respect for persons”.
2. Additional guidance related to legally effective informed consent under HHS, FDA, VA regulations and Texas state law are provided in Attachment 1 [“Legally Authorized Representatives Under Federal and Texas Law”](#).
3. The informed consent process involves three key features: (1) disclosing to potential research subjects or the legally authorized representative information needed to make an informed decision; (2) facilitating the understanding of what has been disclosed; and (3) promoting the voluntariness of the decision about whether or not to participate in the research. Informed consent is an ongoing communication process between the investigator and subject, beginning with the initial approach of an investigator to the potential subject (e.g., through a flyer, brochure, or any advertisement regarding the research study) and continuing until the completion of the research study.
4. In most cases, federal regulations require informed consent and documentation of the process. In certain circumstances, the federal regulations allow a waiver of informed consent documentation or of the process.
5. The consent document is not a substitute for discussion among investigators and research subjects or the legally authorized representative and must first begin with a concise and focused presentation of the key information most likely to assist in understanding the reasons why one might or might not want to participate in the research. To ensure an effective informed consent process, the Institutional Review Board (IRB) and investigators comply with all applicable federal regulations (e.g., 21 CFR 50.20, §50.25, §50.27; 45 CFR 46.116, §46.117; and 38 CFR 16.116, §16.117). These regulations mandate the inclusion of nine basic informed consent elements. Nine additional elements may be required, depending on the nature of the research. IRB policy also specifies the information to include in the consent process. The informed consent template included in the full and expedited IRB application forms outlines the required elements of informed consent. The investigator may use a short form if approved by the IRB in accord with applicable federal requirements.

6. For investigators conducting collaborative research, the UT Health San Antonio IRB may approve the use of a consent form approved for the study by another IRB if it conforms to the applicable federal regulations (e.g., 21 CFR 50.20, §50.25, §50.27; 45 CFR 46.116, §46.117; and 38 CFR 16.116, §16.117). Where appropriate, the consent form approved by the other IRB should also include the UT Health San Antonio IRB contact information.
7. Investigators conducting STVHCS research and the STVHCS are responsible for ensuring compliance with special VA requirements as outlined in the Veterans Health Administration Handbook 1200.5. The Principal Investigator is responsible for obtaining other institutional approvals for the research, as applicable, prior to obtaining consent.
8. This policy applies to research where HSC agrees to defer responsibility for IRB review to a non-HSC IRB (e.g., to act as the IRB of record).

B. Waiver of Informed Consent Process

1. The IRBs have the authority to approve a consent procedure that does not include or which alters some or all of the federally mandated elements of informed consent provided the approved procedure meets applicable federal regulations.
2. A summary of applicable waiver federal regulations and University requirements is as follows:
 - a) To waive informed consent requirements, the IRB must find and document that the requirements in 45 CFR 46.116(f) and 38 CFR 16.116(d) are met.
 - b) Studies determined to be public benefit or service programs: to waive informed consent requirements, the IRB must find and document that the requirements in 45 CFR 46.116(e) and 38 CFR 16.116(c) are met. Note: only public benefit or service program research activities that are under state or local authority meet this criterion.
 - c) Non-FDA regulated studies involving planned emergency research: exceptions from informed consent for planned emergency research for non-FDA regulated research, the IRB must find and document that the research meets the requirements of the HHS Secretarial waiver under (45 CFR 46.101(i) that permits a waiver of the general requirements for obtaining informed consent in a limited class of research in emergency settings [Federal Register: Oct 2, 1996 (Vol. 61, Num. 192)]. Note: this waiver is not applicable to research involving prisoners (subpart C of 45 CFR Part 46) or research involving fetuses, pregnant women, and human in vitro fertilization (subpart B of 45 CFR Part 46) or VA research.

- d) FDA regulated and Department of Health and Human Services (DHHS) funded planned emergency research: exceptions for informed consent requirements are approved if all of the requirements specified in 21 CFR 50.24 and 45 CFR 46.101(i) are met. Note: this waiver is not applicable to VA research.
- e) Emergency use of an investigational drug or biologic product (unapproved drug or biologic) or an unapproved medical device: exception from informed consent for emergency use is allowed if the investigator certifies the requirements in 21 CFR 50.23(a) are met. It is recommended that investigators consult with the IRB Chair or IRB Director/Associate Director before using an investigational drug/biologic in an emergency without informed consent to review the requirements listed in 21 CFR 50.23.
- f) For research involving children, a waiver of parental or guardian permission in non-FDA regulated studies may be granted:
- (1) In public benefit or service programs under 45 CFR 46.116(e) and 38 CFR 16.116(c), as described above.
 - (2) In general research under 45 CFR 46.116(d) and 38 CFR 16.116(d), as described above ("non-FDA regulated studies").
 - (3) When the IRB finds the research meets the requirements for HHS Secretarial waiver under 45 CFR 46.101(i) that permits a waiver of the general requirements for obtaining informed consent in a limited class of research in emergency settings as described above.
 - (4) When consent of parents or guardians is not a reasonable requirement because it poses additional risk to the potential subject or the parents' interest may not adequately reflect the child's interest (e.g., neglected or abuse children), in accord with 45 CFR 46.408(c) and 46.116(c).

- C. Waiver of Documentation of Informed Consent - Federal regulations permit an IRB to waive the documentation requirements for obtaining informed consent under special circumstances. Waiver of documentation of informed consent is not necessary when informed consent has been waived by the IRB.
1. FDA regulated studies: IRB may waive documentation for some or all of the subjects if the conditions listed in 21 CFR 56.109(c) are met.
 2. Non-FDA regulated studies: the IRB may waive the requirement to obtain a signed consent form for some or all of the subjects if requirements in 45 CFR 46.117(c) and 38 CFR 16.117(c) are met.

D. **Short Form** - Federal regulations permit oral presentation of informed consent information in conjunction with a short form written consent document (stating that the elements of consent have been presented orally) and a written summary of what is presented orally.

1. FDA regulated studies: IRB may permit informed consent in this manner for some or all of the subjects (21 CFR 50.27(b)(2))
2. Non-FDA regulated studies: the IRB may permit informed consent in this manner for some or all of the subjects (45 CFR 46.117(b)(2) and 38 CFR 16.117(b)(2))
3. This method of consent may be used if subjects do not speak English and a translated consent document is not available (obtaining informed consent from non-English speaking participants is covered in greater detail below).
4. A witness to the oral presentation is required, and the subject must be given copies of the short form document and the summary. At the time of consent, (i) the short form document must be signed by the subject (or the subject's legally authorized representative); (ii) the summary must be signed by the person obtaining consent as authorized under the protocol; and (iii) the short form document and the summary must be signed by the witness.
5. The IRB must approve the written summary, which may be the informed consent document.
6. Investigators will give the subject a copy of both the short form and the summary.
7. Short Form Requirements:
 - a) Potential subjects who do not speak English should be presented with a consent document written in a language understandable to them. The UT Health San Antonio IRB, however, recognizes that not every eventuality can be planned for ahead of time in every protocol.
 - b) In addition to the short form requirements explained above, the oral presentation must be in a language understandable to the subject. The short form should also be in a language understandable to the subject, however it may be in English if translation would represent an unreasonable delay that could be detrimental to the potential participant; researchers may not avoid translating the short form out of mere convenience or to reduce study expenses.

- c) If the short form is translated, the form must be submitted to the IRB for review and approval. If the researcher uses the English version but anticipates additional non-English speaking subjects, then the researcher should have the long or short consent forms translated and submit the form to the IRB for review and approval.
- d) The IRB-approved English language informed consent document may serve as the summary, and the translator and witness must both be conversant in both English and the language of the participant. When the person obtaining consent is assisted by a translator, the translator may serve as the witness.

II. Procedures

A. Informed Consent Process and Documentation

1. The PI submits a proposed informed consent procedure and written form with the IRB application prior to initiation of research, except in situations such as: research proposals that meet exempt criteria (although informed consent(s) may be used), and research that include a request for waiver of informed consent or waiver of documentation of informed consent. In addition to the description of the consent procedure, the IRB application lists the individuals who will be participating in the informed consent process from the research team or individuals who are authorized to obtain informed consent on behalf of the PI.
 2. The PI may request approval by the IRB to document the informed consent of the subject by receiving the signed and dated informed consent document from the subject by facsimile or other secure method.
 3. The UT Health San Antonio IRB provides consent form templates available for download on the IRB website. Investigators should use these templates as a guide to create study specific consent forms unless the IRB grants exceptions or a waiver. The consent templates contain the required elements, the additional elements of informed consent (where appropriate), and additional IRB requirements for UT Health San Antonio or STVHCS research involving human subjects. See section entitled *Additional Elements Where Appropriate* below.
- a) At a minimum, the proposed consent process and form include the name of the study, the name of the principal investigator and the following nine federally required elements and additional elements where appropriate:

- (1) Research statement: a statement that the study involves research, an explanation of the purpose of the research, an explanation of the expected duration of participation, a description of the procedures involved, and identification of any procedures which will be experimental. UT Health San Antonio and STVHCS policies also require identification of any procedures which are done for research purposes.
- (2) Reasonably Foreseeable Risks or Discomforts: a statement that describes any reasonably foreseeable risks or discomforts associated with the research.
- (3) Reasonably Expected Benefits to Subjects or Others: a statement that describes any benefits to subjects or others that may be reasonably expected from the research or no benefit, if this is applicable. Payment for participation in a research project is not considered a benefit.
- (4) Appropriate Alternatives: a statement that describes with enough detail any alternative procedures or course of treatment that may be advantageous to the subject, if this is applicable.
- (5) Extent of Confidentiality: a statement that describes the extent to which confidentiality of records identifying the subject will be maintained or not maintained (e.g., law requires reporting child abuse, etc.), describes how the research team will protect subjects' private records during and after the conclusion of proposed research studies. Any research that is subject to audit or inspection must identify those entities that will have access to the subject's record (e.g., FDA, National Institutes of Health (NIH), UT Health San Antonio, STVHCS, sponsors, or contract research organizations).
 - a) Effective October 1, 2017, all NIH-funded and conducted research that was commenced or ongoing on or after December 13, 2016 and is within the scope of this Policy is deemed to be issued a Certificate through this Policy and is therefore required to protect the privacy of individuals who are subjects of such research in accordance with subsection 301(d) of the Public Health Service Act. This Policy will be included in the NIH Grants Policy statement as a standard term and condition of award effective October 1, 2017 for new and non-competing awards. Institutions and their investigators are responsible for determining whether research they conduct is subject to this Policy and therefore issued a Certificate. Certificates issued in this manner will not be issued as a separate document.
- (6) Compensation or Treatment for Injury: for studies with greater than minimal risk, a statement containing an explanation of: any compensation and an explanation of any

medical treatments available if injury occurs or where further information may be obtained. The IRB informed consent template contains standard statements in accordance with UT Health San Antonio and STVHCS policy.

- (7) Contact Information: a statement that describes contact information details, including telephone numbers, and whom to contact for the following situations: questions about the research study (e.g., investigator and other team members), concerns about the research study or questions about the subjects' rights, complaints, comments/suggestions, or concerns (e.g., the IRB Director or OIRB), and in the event of a research-related injury (depending on the nature of the research, the PI or a physician on the research team).
- (8) Voluntary Participation Statement: a clear statement that: participation in the research is voluntary, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled, the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.
- (9) One of the following statements about research that involves the collection of identifiable private information or identifiable biospecimens:
 - (a) A statement that identifiers must be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future research studies or distributed to another investigator for future research studies without additional informed consent from the subject or the subject' LAR, if this might be a possibility; or
 - (b) A statement that the subject's information or biospecimens collected as part of the research, even if identifiers are removed, will not be used or distributed for future research studies.

b)Additional Elements Where Appropriate: The IRB determines whether the additional elements are necessary (i.e., when the element(s) does not apply given the nature of the research or the proposed procedures (e.g., subjects will not be paid for participation):

- (1) Unforeseeable risks to subjects, embryos, or fetuses: a statement warning subjects that some risks are currently not known or foreseeable should be included when applicable (e.g., an early human study where very limited information related to risks);
- (2) Investigator-initiated termination of participation: a statement that describes the instances an investigator may terminate a subject's participation (e.g., subject non-compliance, subject not benefiting from research, etc);

- (3) Additional costs: a statement that describes any additional costs a subject may encounter such as: health costs, etc;
- (4) Early withdrawal/procedures for termination: a statement that describes a subject's right to withdraw from research and any procedures that may be necessary after an early withdrawal for subject's safety, and any possible harms that may result if the recommended withdrawal procedures are not followed (e.g., tapering a drug);
- (5) Significant new findings: a statement that subjects will be told of any new findings which may affect willingness to continue in the research;
- (6) Approximate number of subjects: a statement that explains the approximate number of subjects to be enrolled in the study;
- (7) Disposition of subject's biologic specimens: a statement of what will be done with any biologic specimens collected during the study (e.g., further DNA testing, cell lines, development of future commercially valuable products);
- (8) Payment: a statement which includes all information concerning the amount and schedule of payment for participation.
- (9) If the research involves vulnerable populations or sensitive issues, the investigator addresses additional regulatory and/or institutional requirements. The investigator may consult the Investigator Handbook or the OIRB staff for guidance. The vulnerable populations and sensitive issues include, but are not limited to:
 - (a) Research involving children;
 - (b) Research involving decisionally impaired subjects;
 - (c) Research involving screening for notifiable conditions, e.g. HIV screening and/or AIDS research;
 - (d) Research involving DNA Banking, Genetic Research or Gene Therapy;
 - (e) Research activities directed toward pregnant women;
 - (f) Research involving prisoners.

- (10) A statement that the subject's biospecimens (even if identifiers are removed) may be used for commercial profit and whether the subject will or will not share in this commercial profit.
- (11) A statement regarding whether clinically relevant research results, including individual results, will be disclosed to subjects, and if so, under what circumstances.
- (12) For research involving biospecimens, whether research will, if known, or might include whole genome sequencing.

4. Additional issues related to informed consent, if applicable:

- a) NIH-sponsored multicenter clinical trial must include a copy of the NIH-approved sample informed consent document in the IRB application. The investigator must justify in writing any deletion or substantive modification of information concerning risks or alternative procedures contained in the sample informed consent document, and the IRB must approve these deletions or modifications. For trials sponsored by the National Cancer Institute, investigators must forward copies of such IRB-approved changes, with their justifications to the appropriate Cooperative Group headquarters;
- b) Studies of investigational drugs, devices, or biologics inform the subject that the study includes evaluation of both safety and effectiveness of the test article and state the test article is investigational, and, if applicable, not approved by the FDA;
- c) The process of dose escalation;
- d) The possibility of risk for an unborn child, a man or woman's ability to procreate or a woman's ability to conceive or carry a child. Suggested wording in the consent form template may be revised to meet the needs of the study;

5. Additional requirements as specified in the IRB full and expedited review applications/informed consent template.

- a) If the research involves genetic testing or DNA banking, the PI must address, in the informed consent process and form, the applicable issues discussed in the Repository Consent template.
- b) If the research involves collecting materials for a specimen/tissue repository for future research use, the application must address the informed consent process and include the possible additional repository consent form.

- c) The IRB assesses the PI's description of the informed consent process to ensure that the process meets the general requirements of informed consent (i.e., consent be obtained from the subject or subject's legally authorized representative; the process protects privacy; be in language understandable to the subject; be obtained under circumstances that provide the subject with the opportunity to consider whether or not to participate, and that minimize coercive influences; does not include language through which the subject is made to waive his/her legal rights or releases the investigator, sponsor, or institution from liability for negligence). The IRB uses the Human Full Board Reviewer Checklist in conducting this assessment.
- d) The IRB determines whether disclosure of an investigator's conflict of interest is warranted in the informed consent process and document.
- e) The IRB is responsible for reviewing the proposed informed consent document to ensure that all applicable federal, STVHCS, and UT Health San Antonio requirements are met.
- f) Once the IRB approves the study, the OIRB staff affixes an approval stamp to the first page of the full consent document. OIRB staff forward the form to the investigator. Investigators may only enroll subjects using informed consent/assent forms which have a valid "IRB approval" stamp unless the IRB grants a waiver from the requirement for informed consent or documentation. The consent must also be the most current version.
- g) Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or legally authorized representative in understanding the reasons why one might or might not want to participate in the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension. The prospective subject or the legally authorized representative 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 investigator is responsible for ensuring that informed consent is obtained from each research subject or his/her legally authorized representative after the subject or the subject's legally authorized representative has had an adequate opportunity to read the form and before that subject participates in any part of the research study, using the process and form approved by the IRB. Informed consent as a whole must present information in sufficient detail relating to the research, and must be organized 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 reason why one might or might not want to participate.
- h) The subject or the subject's legally authorized representative and the person providing the information to the subject sign and date the informed consent document at the time of consent. Only individuals authorized (in the IRB approved application) to obtain informed consent should sign on the line entitled "Printed Name of person obtaining consent."

- i) The IRB assesses whether the informed consent process will require a witness to the subject's signature or the legally authorized representative's signature to sign and date the consent document.
- j) In cases where the sponsor or the IRB requires a witness to the consenting process in addition to the witness to the participant's signature and the same person serves both capacities, the informed consent form contains a note to that effect below the witness's signature line.
- k) The person authorized by the investigator to obtain the informed consent signs, dates and provides the time that consent was obtained, on the form and provides a copy of the informed consent form to the subject or the subject's legally authorized representative.
- l) The PI is responsible for keeping the original signed informed consent form and, in accord with the requirements specified in the UT Health San Antonio HOP on Record Retention and the study procedures as approved by the IRB.
- m) For each clinical trial conducted or supported by a Federal department or agency, one IRB-approved informed consent form used to enroll subjects must be posted by the awardee or the Federal department or agency supporting or conducting the trial on a publicly available Federal website that will be established as a repository for such informed consent forms (see [Institutional Review Policy and Procedure](#)).

B. Use of the Short Form Written Consent Document

1. The PI may request to use a short form written consent document stating that the elements of informed consent (as required by 45 CFR 46.116 and as required by VHA Handbook 1200.5 Appendix C and 38 CFR 16.116 for VA Research) have been presented orally to the subject or the subject's legally authorized representative.
2. The IRB reviews the request and may approve the short form option for documentation only if all of the requirements outlined in 45 CFR 46.117(b), and as applicable, 21 CFR 50.27(b) and/or 38 CFR 16.117(b) are met.
3. When the short form method is used:
 - a) The PI must ensure there will be a witness to the oral presentation. The PI must ensure the witness is conversant in both English and the language of the participant.
 - b) The IRB must approve a written summary (typically the long English consent is used as the summary) of what is to be said to the subject or the subject's legally authorized representative

(LAR) which embodies the basic and appropriate elements of disclosure and that the key information required by 46.116(a)(5)(i) was presented first to the subject, before other information, if any, was provided.

- c) Only the short form itself is to be signed *and* dated by the subject or the subject's LAR.
- d) The witness signs *and* dates both the short form and a copy of the summary.
- e) The person actually obtaining consent signs *and* dates a copy of the summary.
- f) A copy of the summary is given to the subject or the subject's LAR, in addition to a copy of the short form.
- g) The PI is responsible for keeping the original signed informed consent form and, in accord with the requirements specified in the UT Health San Antonio HOP on Record Retention and the study procedures as approved by the IRB.
- h) For VA Research only: A progress note documenting the informed consent process must be placed in the subject's medical record. The progress note, at a minimum, must include:
 - (1) The name of the study;
 - (2) The person obtaining the subject's consent;
 - (3) A statement that the subject or the subject's legally-authorized representative was capable of understanding the consent process;
 - (4) A statement that the study was explained to the subject; and
 - (5) A statement that the subject was given the opportunity to ask questions.
 - (6) An entry must also be placed in the progress note when the human subject is actually entered into the study and when the human subject's participation is terminated. (Consent and entry notes can be combined when both occur at the same visit.)
 - (7) The investigator is responsible for uploading an electronic copy of the signed consent form into the VA electronic medical record unless the IRB waives the requirement. The PI must also keep the original signed consent document in his/her research records in accord with the IRB-approved protocol.

C. Informed Consent Policy and Procedures for the South Texas Veterans Health Care System (STVHCS)

1. The informed consent form must contain elements required by the Veterans Health Administration Handbook 1200.5, Appendix C and 38 CFR 16.116., including the following disclosures:
 2. In the event of a research-related injury, the STVHCS must provide necessary medical treatment to the research subject injured by participation in a research project approved by the VA Research and Development Committee and conducted under the supervision of one or more VA employees in accordance with 38 CFR 17.85.
 - a) Except in limited circumstances, the necessary care must be provided in VA medical facilities. In cases of exceptions, the STVHCS Director may contract for such care. Exceptions include:
 - (1) Situations where VA facilities are not capable of furnishing economical care
 - (2) Situations where VA facility are not capable of furnishing the care or services required
 - (3) Situations involving a non-veteran research subject.
 - b) The requirement to provide medical treatment for a research-related injury does not apply in cases where injuries result from non-compliance by a research subject with study procedures.
3. The informed consent form also includes statements:
 - a) Explaining the VA's authority to provide medical treatment to research subjects injured by participation in a VA research project
 - b) Stating that a veteran-subject will not be required to pay for care received as a subject in a VA research project except as follows: in accordance with Title 38 United States Code (U.S.C.) 1710(f) and 1710(g) certain veterans are required to pay co-payments for medical care and services provided by VA. Veterans receiving medical care and services from VA that are not rendered as part of the VA-approved research study, must pay any applicable co-payment for such care and services.
 - c) All regulations pertaining to the participation of veterans as research subjects including requirements for indemnification in case of research-related injury pertain to non-veteran subjects enrolled in VA-approved research.

4. The IRB members may use the VA Research section of the Reviewer Checklist to ensure review and approval in accord with special VA informed consent requirements. The STVHCS Associate Chief of Staff (ACOS) for Research and Development or his designee also uses the checklist as a guide in conducting his/her administrative review of VA studies.
5. The STVHCS R&D Office may pre-review VA consents prior to IRB review. The IRB approves the wording of the consent. OIRB staff document the approval through the use of a stamp on the first page of the VA Form 10-1086 that indicates the date of the most recent IRB approval of the document.
6. If the investigator amends the consent form for STVHCS research, a modified consent form is provided, stamped with approval date of the amendment rather than the date of the approved protocol.
7. The investigator is responsible for ensuring that informed consent is obtained from each research subject or his/her legally authorized representative:
 - a) After the subject or the subject's legally authorized representative has had an adequate opportunity to read the form and before that subject participates in any part of the research study, using the process and form(s) approved by the IRB.
 - b) The subject or the subject's legally authorized representative signs and dates the informed consent document at the time of consent.

8. The person authorized by the investigator to obtain the informed consent from the subject signs and dates the informed consent document at the time of consent. Only individuals authorized (in the IRB approved protocol) to obtain informed consent should sign on the line entitled "Printed Name of person obtaining consent."
9. In cases where the sponsor or the IRB requires a witness to the consenting process the informed consent form contains a note to that effect below the witness's signature line.
10. The person authorized by the investigator to obtain the informed consent provides a copy of the signed informed consent form to the subject or the subject's legally authorized representative when the informed consent and HIPAA Authorization is combined.
11. A progress note documenting the informed consent process must be placed in the subject's medical record. The progress note, at a minimum, must include:
 - a)The name of the study;
 - b)The person obtaining the subject's consent;
 - c)A statement that the subject or the subject's legally-authorized representative was capable of understanding the consent process;
 - d)A statement that the study was explained to the subject; and
 - e)A statement that the subject was given the opportunity to ask questions.

12. An entry must also be placed in the progress note when the human subject is actually entered into the study and when the human subject's participation is terminated. (Consent and entry notes can be combined when both occur at the same visit.)
13. The investigator is responsible for uploading an electronic copy of the signed consent form into the VA electronic medical record unless the IRB waives the requirement. The PI must also keep the original signed consent document in his/her research records in accord with the IRB-approved protocol.

D. STVHCS Involving Decisionally Impaired

1. The PI may obtain consent by a legally authorized representative only in situations where the prospective subject is incompetent or has impaired decision-making capacity, as determined and documented in the person's medical record in a signed and dated progress note. The determination that a subject is incompetent or has an impaired decision-making capacity must be made by a legal determination or a determination by the practitioner (a psychiatrist or licensed psychologist must be consulted if based on mental illness diagnosis), in consultation with the chief of service or chief of staff after appropriate medical evaluation that the prospective subject lacks decision-making capacity and is unlikely to regain it within a reasonable period of time.
2. The investigator advises the LAR of his/her role and responsibilities in serving as the decision-maker for the subject. The investigator also advises the LAR that it is his/her obligation to try to determine what the subject would do if competent, or if the subject's wishes cannot be determined, what he/she thinks is in the incompetent person's best interest.
3. If feasible, the investigator explains the proposed research to the prospective subject even when the LAR gives consent. No one may, under any circumstances, force or coerce prospective subjects to participate in a VA research study.
4. For subjects whose decision-making capacity may fluctuate or those with decreasing capacity to give consent, a re-consenting process with surrogate consent may be necessary. [See: Veterans Health Administration Handbook 1200.5, Section 11 - Research Involving Human Subjects with Surrogate Consent]

E. Illiterate Subjects

1. The PI may obtain consent from an individual who is unable to read and/or write using the IRB approved consent document. A Short Form consent document is not necessary.
2. If the subject is unable to read but able to sign their name or “make their mark,” the investigator must read the entire consent document verbally to him or her while a witness follows along to ensure information is being presented accurately. If the subject agrees to participate in the study, he or she must sign their name or “make their mark”. The witness must write a note on the consent form that he or she was present during the entire consent process, that the entire consent form was read to the subject, and that the subject willingly agreed to participate in the study.
3. If the subject is unable to write or “make their mark,” a witness must be present during the entire consent process. The witness must write a note on the consent form that he or she was present during the entire consent process, the subject was unable to sign the consent form, the subject willingly agreed to participate in the study, and the method used to communicate their decision (e.g. nodding head, verbal agreement, etc.).

F. Assent

1. The PI must develop processes and forms consistent with guidance provided in several IRB policies: [Research Involving Individuals with Impaired Decision-Making Ability Policy and Procedure](#) and application documents; also see the [IRB Approval of Research Policy and Procedure](#) and [Initial Review of Research Policy and Procedure](#) policies concerning review related to assent. The PI is responsible for including in the IRB application a description of the process/procedure for obtaining and documenting assent when research includes:

a)Children

- (1) The IRB reviews the proposed process and, if applicable, the assent process to ensure compliance with IRB guidance and federal requirements. In general in determining whether assent of children is required in all, some or none of the children in a study the IRB is guided by the following age ranges:
 - (a) Ages 0-6 – The capability of children of this age group is so limited that they cannot reasonably be consulted. Assent is not required.

- (b) Ages 7-12 – Children of this age group may be capable of providing assent depending on the maturity and psychological state of the children involved in the research. Assent may be required.
- (c) Ages 13 – 17 – Children of this age group are expected to be capable of providing assent. Assent is usually required unless waived by the IRB.
- (2) If assent is determined appropriate the investigator must obtain assent from minors he/she deems capable of understanding the nature and consequences of participation in the study regardless of the age, the child should be given an explanation, at a level appropriate to the child's age, maturity and condition, of the procedures to be used, their meaning to the child in terms of discomfort and inconvenience, and the general purpose of the research.
- (3) If assent is determined appropriate, documentation of assent is required. Generally, assent of the child is documented by having the child sign the consent form in the designated signature section.
- (4) The IRB may waive its requirements for obtaining or documenting assent if the IRB determines:
 - (a) Capability of the child is limited such that (s)he cannot be reasonably consulted, or
 - (b) The research intervention or procedure(s) involved hold out a prospect of direct benefit that is important to the health or well-being of the children, and is available only in the context of the investigation, or
 - (c) The research meets the following requirements:
 - (i) the research involves no more than minimal risk to the participants; and
 - (ii) the waiver will not adversely affect the rights and welfare of the participants; and
 - (iii) the research could not practicably be carried out if assent was required; and
 - (iv) when appropriate, pertinent information is provided after participation.

b) Decisionally impaired and/or incompetent adults

- (1) The IRB determines whether assent is required in research involving decisionally impaired adults, and/or incompetent adults based on their condition, the research procedures to be used, and the general purpose of the research.
- (2) If assent is determined appropriate in decisionally impaired adults, and/or incompetent adults, the individual should be given an explanation, at a level appropriate to the individual's condition, of the procedures to be used, their meaning in terms of discomfort and inconvenience, and the general purpose of the research.
- (3) If assent is determined appropriate in decisionally impaired adults, and/or incompetent adults, documentation of assent is required. Generally, assent is documented by having the individual sign the consent form in the designated signature section.
- (4) The IRB may waive its requirements for obtaining or documenting assent appropriate in decisionally impaired adults, and/or incompetent adults, if the IRB determines:
 - (a) Capability of the adult is limited such that (s)he cannot be reasonably consulted, or
 - (b) The research intervention or procedure(s) involved hold out a prospect of direct benefit that is important to the health or well-being of the adult, and is available only in the context of the investigation, or
 - (c) The research meets the following requirements:
 - (i) the research involves no more than minimal risk to the participants; and
 - (ii) the waiver will not adversely affect the rights and welfare of the participants; and
 - (iii) the research could not practicably be carried out if assent was required; and
 - (iv) when appropriate, pertinent information is provided after participation.

G. Minors

1. A minor is a person who is under the age of 18. A minor is only "emancipated" in Texas by a court order, though the proper legal terminology is that the person has had the

disabilities of minority removed (see Attachment 1 "[Legally Authorized Representatives Under Federal and Texas Law](#)"). If the person under age 18 has had the disabilities of minority removed (i.e., is "emancipated"), then the subject is treated as an adult and may provide informed consent. There are situations when a minor can give legally effective consent without resort to an LAR even if not "emancipated." For details, see Attachment 1.

2. When conducting the study, investigators may need to make decisions on a subject-by-subject basis regarding the applicable state statutory requirements. If there are questions relating to whether an individual meets the state statutory requirements to be emancipated or to give consent without an LAR, the investigator should consult the UT Health San Antonio legal counsel.

H. Obtaining Informed Consent of Children or persons with DADMC outside the State of Texas

1. If the PI is conducting the research outside the state of Texas and the research involves children or persons with diminished autonomous decision-making capacity (DADMC) the investigator must follow the requirements of the state/country in which he/she will conduct the research to determine which individuals meet the applicable legal or regulatory definitions for child/children, LAR, or guardian.
2. The PI should consult UT Health San Antonio legal counsel when preparing the IRB application

I. Non-English Speaking Subjects

1. Investigators must deliver all information regarding informed consent/assent to potential subjects or their legally authorized representatives in the subject's native language(s) or one that the subject understands. The investigator must provide the IRB and prospective subjects a translated version of the consent form.
2. The investigator submits to the IRB a translated document, a completed Form H-1 and a Translation Certificate, if a translation service was used to translate the consent form.
3. The OIRB reviews the completed Form H-1 and Translation Certificate, to ensure the most currently approved consent form was used to make the translated consent form.

4. If necessary, the OIRB staff identifies a cultural consultant to review the study and informed consent/assent document for accuracy and cultural appropriateness. If the OIRB staff is unable to identify an individual to serve as a cultural consultant, the investigator provides a cultural consultant for review of accuracy of the informed consent form and cultural appropriateness. The cultural consultant must not have any affiliation with or investment in the research.
 - a)The OIRB staff ensures that the consultant does not have a conflict of interest. (See [IRB Member and Consultant Conflict of Interest Policy and Procedure](#))
 - 5.
 6. The IRB may utilize administrative review procedures in approving such documents if the English language consent/assent document has already been approved by the IRB
- J. Research that Requires Monitoring of Informed Consent/Assent Process and Procedures - The IRB may determine that monitoring of the informed consent process is necessary in accordance with the Continuation Review Policy and Procedure.
- K. Waiver of Informed Consent /Alteration of Informed Consent for human research studies.
1. The PI may request a waiver of informed consent/alteration of informed consent and submit a justification for the request in the IRB application.
 2. The IRB may waive the requirements or alter elements if it finds and documents:
 - a)The research involves no more than minimal risk to the subjects,
 - b)The rights and welfare of subjects will not be adversely affected,
 - c)The research could not practicably be carried out without the requested waiver or alteration,
 - d)Whenever appropriate, the subjects or legally authorized representatives are provided additional pertinent information after participation,
 - e)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.

3. If the IRB reviews the protocol at a convened meeting, OIRB staff document the waiver of informed consent approval in the IRB meeting minutes.
4. If the protocol is eligible for expedited review, the expedited reviewer documents on the expedited review documentation form whether each of the criterion has been met.

L. Waiver of Informed Consent for human research studies to be public benefit or service programs

1. The IRB may also waive the requirement to obtain informed consent or alter some of the elements if the IRB finds and documents that the research or demonstration project is to be conducted by or is subject to approval of state or local government officials and is designed to study, evaluate or examine
 - a)public benefit or service programs;
 - b)procedures for obtaining benefits or services under those 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

 - e)The research could not practicably be carried out without the waiver or alteration.

2. If the IRB reviews the protocol at a convened meeting, OIRB staff document the waiver of informed consent approval in the IRB meeting minutes.
3. If the protocol is eligible for expedited review, the expedited reviewer documents on the expedited review approval signature page whether each of the criterion has been met.

M. Waiver of Informed Consent for non-FDA Regulated studies involving Planned Emergency Research

1. The PI submits an IRB application for review by the convened IRB. The OIRB staff screen the application using procedures outlined in the [Initial Review Policy of Research Policy and Procedure](#) and Procedure. The guidance document entitled Harmonization Rule on Waiver of Consent For Emergency Research is used by the PI, OIRB staff and IRB members to ensure the regulatory requirements are met. The PI must address any additional issues not included in the standard IRB application, such as plans for public disclosure in communities prior to initiation.
2. At a convened meeting, the IRB must find and document that the research meets the requirements of the HHS Secretarial waiver under (45 CFR 46.101(i) that permits a waiver of the general requirements for obtaining informed consent in a limited class of research in emergency settings [Federal Register: Oct 2, 1996 (Vol. 61, Num. 192)]. Note: this waiver is not applicable to research involving prisoners (subpart C of 45CFR46) or research involving fetuses, pregnant women, and human in vitro fertilization (subpart B of 45CFR46).
3. The individual chairing the meeting goes through each regulatory requirement. The IRB discusses whether the research meets each requirement and raises any applicable controverted issues. The outcomes of the review are the same as those listed in the [IRB Approval of Research Policy and Procedure](#). OIRB staff record the discussion in the minutes, following the procedures in the [IRB Minutes Policy and Procedure](#).

N. Waiver of Informed Consent for FDA Regulated and DHHS Funded Planned Emergency Research

1. The PI submits an IRB application for review by the convened IRB. The OIRB staff screen the application using procedures outlined in the Initial Full Review Policy and Procedure. 21 CFR 50.24 and other guidance documents such as “Harmonization Rule on Waiver of Consent For Emergency Research” are used by the PI, OIRB staff and IRB members to ensure the regulatory requirements are met. The PI must address any

additional issues not included in the standard IRB application, such as plans for public disclosure in communities prior to initiation.

2. At the convened meeting, the OIRB staff provide the IRB Chair or designee with a copy of 21 CFR 50.24 and/or the HHS Secretarial waiver under 45 CFR 46.101(i). The individual chairing the meeting goes through each regulatory requirement. The IRB discusses whether the research meets each requirement and raises any applicable controverted issues. The outcomes of the review are the same as those listed in the [IRB Approval of Research Policy and Procedure](#). OIRB staff record the discussion in the minutes, following the procedures in the IRB Minutes Policy and Procedure.
- O. Exception from Informed Consent Requirement for Emergency use of an investigational drug or biologic product (unapproved drug or biologic) or an unapproved medical device
1. The PI must obtain informed consent, even in an emergency use situation, unless certain conditions are met. (See [Emergency Use of an Investigational Drug or Device Article Policy and Procedure](#))
- P. Waiver of Parental or Guardian Permission for Research Involving Children in Non-FDA Regulated Research
1. The PI makes a preliminary decision to seek waiver of parental or guardian permission for participation of children in accord with 45 CFR Subpart D 46.408 (c) or 45 CFR 46.116(c)(d). The PI includes justification for the waiver and a description of a substituted appropriate mechanism for protecting the children who will participate in the research.
 2. The IRB may approve the request provided the conditions as outlined in section L (bullet 1) are satisfied in addition to the following:
 - a)The research is designed for conditions or for a participant population for which parental or guardian permission is not a reasonable requirement to protect the participants.
 - b)An appropriate mechanism for protecting the children who would participate as participants in the research was substituted.
 - c)The research was not FDA-regulated.

3. If the IRB reviews the research at a convened meeting, OIRB staff record the discussion on each criterion in the minutes.
4. If the IRB reviews the study using expedited procedures, the expedited reviewer documents on the expedited review signature page whether the research meets each of the criteria.

Q. Waiver of Documentation of Informed Consent for FDA-Regulated Research

1. The PI makes an initial request to waive the documentation requirements for obtaining informed consent, as specified in the IRB application.
2. The IRB may waive the documentation requirement to obtain a signed consent if the research procedures for which the waiver is requested presents no more than minimal risk and involves no procedures which normally require written consent.
3. When the IRB waives the requirement to obtain written documentation of informed consent, the IRB reviews a written description of the information that the PI will provide to the subjects.
4. In cases in which the IRB waives the documentation requirement, the IRB has the authority to require the investigator to provide subjects with a written statement regarding the research.
5. If the IRB reviews the request at a convened meeting, the meeting minutes include the discussion on each of the criteria.
6. If the IRB reviews the study using expedited procedures, the expedited reviewer documents on the expedited review documentation form whether the research meets each of the criteria.

R. Waiver of Documentation of Informed Consent for Non-FDA Regulated Studies

1. The PI makes an initial request to waive the documentation requirements for obtaining informed consent, as specified in the IRB application.
2. The IRB may waive the documentation requirements to obtain a signed consent if:

- a) The only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject must be asked whether the subject wants documentation regarding the research; or
- b) The research procedures for which the waiver is requested presents no more than minimal risk to subjects and involves no procedures for which written consent is normally required (i.e., a cover letter or a phone script).
- c) If the subjects or legally authorized representatives are members of a distinct cultural group or community in which signing forms is not the norm, and that the research presents no more than minimal risk of harm to subjects, and providing an appropriate alternative mechanism for documenting that informed consent was obtained.

3. When the IRB waives the requirement to obtain written documentation of informed consent, the IRB reviews a written description of the information that the PI will provide to the subjects (i.e., a cover letter or a phone script).
4. In cases in which the IRB waives the documentation requirement, the IRB has the authority to require the investigator to provide subjects with a written statement regarding the research.
5. If the IRB reviews the request at a convened meeting, OIRB staff include the discussion on each of the criteria in the meeting minutes.
6. If the IRB reviews the protocol using expedited procedures, the expedited reviewer documents on the expedited review documentation that 45 CFR 46.111(4) has been appropriately satisfied.

S. Electronic Consent (eConsent)

1. Unless the IRB waives the requirement for the investigator to obtain a signed consent or grants a waiver of documentation of consent as described above, the standard expectation is that a signature will be handwritten using a permanent medium (i.e. ink pen) by the subject or subject's LAR. However, agreement to participate in the research study can be documented electronically.
2. The IRB makes the following considerations regarding the electronic documentation of informed consent.
3. The mechanism used to obtain consent should:
 - a) Ensure safeguards of the protection of privacy and confidentiality;
 - b) Have the ability to display or use most current version of the IRB approved consent form;
 - c) Have the ability to re-consent subjects who are already enrolled in the research study (if applicable);
 - d) Have a mechanism for the subjects or subjects LAR to document willingness to participate in the research study, if applicable (i.e. checkbox, capture of signature by mouse or finger pad);

e) Allow the subject to print or download and save a copy of the consent form or updated consent form.

f) Provide a method to ensure that the person signing the informed consent is the subject (or the subject's legally authorized representative) who will be participating in the research study, if applicable based on the risk level of the study

T. Participant Withdrawal

1. When a participant withdraws from a study, the data collected on the participant to the point of withdrawal remains part of the study database and may not be removed. The consent document cannot give the participant the option of having data removed.
2. A researcher may ask a participant who is withdrawing whether the participant wishes to provide continued follow-up and further data collection subsequent to their withdrawal from the interventional portion of the study. Under this circumstance, the discussion with the participant distinguishes between study-related interventions and continued follow-up of associated clinical outcome information, such as medical course or laboratory results obtained through non-invasive chart review, and address the maintenance of privacy and confidentiality of the participant's information.
3. The researcher must obtain the participant's consent for this limited participation in the study (assuming such a situation was not described in the original consent document). The PI may submit:
 - a) Exception Request Form and consent document for a single subject exception
 - b) Amendment Form and Addendum consent document
 - c) Amendment Form and revised informed consent.
 - d) The IRB must approve the single subject exception or Amendment before the activity commences. (See the [Modifications and Amendments Policy and Procedure](#).)
4. If a participant withdraws from the interventional portion of a study and does not consent to continued follow-up of associated clinical outcome information, the researcher must

not access for purposes related to the study the participant's medical record or other confidential records requiring the participant's consent. However, a researcher may review study data related to the participant collected prior to the participant's withdrawal from the study, and may consult public records, such as those establishing survival status.

III. References

- A. Definitions (see [Glossary](#))
- B. Regulatory (see [Policy on Policies Policy and Procedure](#))
- C. Attachment: [Legally Authorized Representatives Under Federal and Texas Law](#)