THE RESEARCH INFORMED CONSENT AND HIPAA AUTHORIZATION

PROCESS

1. OBJECTIVES:

   a) Outline the requirements for obtaining adequate and legal Informed Consent from subjects participating in research and development projects.
   
   b) Describe the policies and procedures for the review and documentation of VA Consent Form Documents to ensure that research subjects are consented properly.
   
   c) Comply with federal guidelines and the Atlanta VA Health Care System (AVAHCS) policies and procedures regarding the consenting process.

2. DEFINITION:

   a) The Informed Consent Process is the exchange of information that takes place between a subject and investigator (or designee) before, during, and sometimes after the study.

3. PRINCIPAL INVESTIGATOR’S RESPONSIBILITIES and GENERAL REQUIREMENTS:

   a) Obtaining and documenting legally effective informed consent of the subject or the subject's LAR (Legally Authorized Representative) prospectively that is in alignment with ethical principles that govern informed consent for research. The only exceptions are if the IRB overseeing the research determines the research is exempt, or approves a waiver of the informed consent process, or approves a waiver of documentation of consent. Please note – LAR’s may be qualified to sign the ICF (Informed Consent Form) but are not always qualified to sign a Health Insurance Portability and Accountability Act (HIPAA) authorization. See sections 6d and 8i.
   
   b) Obtains signed HIPAA authorization from subject or personal representative before initiation of any research activity unless waived by a Privacy Board.
   
   c) Obtains consent only under circumstances that provide the prospective subject or the LAR sufficient opportunity to discuss and consider whether or not to participate and that minimize the possibility of coercion or undue influence.
d) Ensures that when obtaining written informed consent for research, the most current IRB approved Informed Consent Form is used for all VA approved research. This includes, but is not limited to, studies in which VA investigators working on VA research enroll subjects at the affiliate hospital or other sites outside VA.

e) Includes all basic elements and additional elements (as required) in the consent document and/or consent process. See ICF templates located on the AVAHCS research website.

f) Ensures the information given to the subject is in a language understandable to the subject and LAR.

g) Discusses all relevant aspects of the study (e.g., study procedures, risks, and benefits, etc.) with potential subject and LAR (if applicable).

h) The informed consent process (written or oral) may not include any exculpatory language through which the subject or representative 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) For research subject to the 2018 Common Rule requirements:
   i. The prospective subject or LAR must be provided with the information that a reasonable person would want to have in order to make an informed decision about whether to participate, and an opportunity to discuss that information.
   ii. Informed consent must begin with a concise and focused presentation of the key information that is most likely to assist a prospective subject or LAR in understanding the reasons why one might or might not want to participate in research. This part of the informed consent must be organized and presented in a way that facilitates comprehension.
   iii. Informed consent as a whole must present information in sufficient detail relating to the research and must be organized and presented in a way that does not merely provide lists of isolated facts, but rather facilitates the prospective subject’s or LAR understanding or the reasons why one might or might not want to participate.

j) For research approved by the IRB prior to the 2018 Common Rule requirements, the 2018 requirements do not apply unless the research study has been transitioned to the 2018 Common Rule requirements.
k) If delegating the responsibility of obtaining consent, the Principal Investigator (PI) does so in writing.

l) Ensures the person(s) obtaining consent is knowledgeable, trained & qualified to do so.

m) Obtains a written “HIPAA (Health Insurance Portability and Accountability Act) Authorization” from each subject authorizing the use and/ or disclosure of Protected Health Information (PHI) prior to initiating any study activities, unless conducting the study under an approved waiver of HIPAA authorization or no VA HIPAA is required. See Section 8 on VA HIPAA Authorization.

n) Provides subject or LAR with either a physical or electronic copy of ICF and HIPAA document(s).

o) Ensures that all original and digitalized signed and dated ICFs are kept in investigator’s research files, readily available, retrievable, and secure.

p) Does not use “Broad Consent” because it is not currently permitted at the AVAHCS.

q) Either posts or verifies that a version of the ICF has been posted on https://clinicaltrials.gov within 60 days after the last study visit.

r) If obtaining photography, video and/or audio recordings for research purposes, the ICF must include information describing it, how they will be taken or obtained for research purposes, how they will be used in research, and whether they will be disclosed outside VA. This requirement may not be waived by the IRB. A HIPAA authorization is needed to make disclosures outside the VA.

s) Prior to contracting with a firm (i.e., a survey research firm), the Principal Investigator contacts the AVAHCS research office for guidance.

4. INFORMED CONSENT FORM TEMPLATES:

a) If you are utilizing NCI CIRB as the IRB of record for a human research study the current National Cancer Institute Central IRB Approved Letterhead for Informed Consents and Atlanta VAHCS Boilerplate Language must be used. Please contact the Research Office if you need access to the currently approved template.

b) The VA CIRB template must be used for VA CIRB studies, located here: https://www.research.va.gov/programs/orppe/vacentralirb/forms/investigator-forms.cfm
c) If you are utilizing the Emory University as the IRB of record for a human research study, you must use one of the following three versions of the ICF template, located on the AVAHCS research website: https://www.atlanta.va.gov/services/research/Conducting_Human_Research.asp

   i.  **Combined** VA Informed Consent Form with HIPAA template dated 1.21.19:
       1. Use this template for all new studies unless there is an optional tissue bank or data repository, or the study subject population is expected to include subjects with legal guardians and/or personal representatives.
       2. The “2018 Common Rule Consent Checklist” must be completed and uploaded in the ICF section of eIRB when using this consent template version.

   ii. **Standalone** VA Informed Consent Form template dated 1.21.2019:
       1. Use for new projects when there is an optional tissue bank and/or data repository.
       2. Use when the study subject population is expected to include subjects with legal guardians and/or personal representatives.
       3. Must be used with VA form 10-0483 standalone HIPAA.
       4. The “2018 Common Rule Consent Checklist” must be completed and uploaded in the ICF section of eIRB when using this consent template version.

   iii. Pre-2018 Common Rule VA Informed Consent Form template dated 7.19.18 (*old ICF template*).
       1. Use only for projects approved under pre-2018 Common Rule (before 1.21.2019).
       2. Continue to use this form if your existing project is not transitioning to the 2018 Common Rule.
       3. May continue to be used when changes are being made to the ICF.

d) Use of other templates must receive AVAHCS Research Office approval prior to being executed.

5. **PROCEDURES FOR OBTAINING VA WRITTEN INFORMED CONSENT:**

   a) The most current IRB approved ICF and HIPAA documents **MUST** be used.

   b) Subjects must be allowed sufficient time to read the ICF and consider whether or not they wish to take part in the study.
c) Conduct consent process in a private room.

d) Study staff should discuss all elements of the consent and ensure that all questions are answered before the subject decides whether to participate in the study.

e) The subject must read, sign, and date the ICF prior to starting any study activities (unless waived by the IRB of record).

f) Consent may be obtained electronically so long as the informed consent process meets all VA requirements related to obtaining consent and requirements for use of electronic signatures.

g) Study staff must ensure that the subject gives consent willingly, without coercion or undue influence.

h) Study staff should assess the subject’s ability to read and comprehend the consent document and the risks of the study (i.e., asking a few simple questions).

i) If required by the IRB, a witness whose role is to witness the subject’s signature will sign and date the VA ICF. A witness is an unbiased person and should not be part of the research team.

j) The study staff must keep all original or digitalized signed and dated informed consent documents with the investigator’s VA study files unless a waiver of documentation or a waiver of informed consent has been approved by the IRB. If so, then the appropriate method of documenting consent must be followed.

k) Study staff must provide a copy of the VA consent form and HIPAA authorization to the subject and/or LAR.

l) Investigators and research staff may be required to document the consent process either in CPRS or a paper research record within 72 hours. See the “Documentation Requirements” policy on the AVAHCS research website.

m) Study staff should reinforce the study information throughout the course of the study.

n) If the protocol is amended, the IRB may require that study subjects sign a revised consent form containing these changes. If the ICF is amended, it must be reviewed and approved by the IRB each time and before being used to consent any new subject(s). R&D Committee approval will also be required when the modification includes an increase in the risk/benefit ratio, a change in the PI, and/or creation of a data or tissue repository.
o) **Short Form:** An impartial person (not a member of the study staff) must witness* all oral presentations when a short form consent is used. An IRB approved summary of the short form consent must also be used. Please refer to the IRB of record’s policies and procedures for further details.

   i. Signatures and dates must be entered on the form(s) as follows:

      1. On the short form - by the witness and the subject or the subject’s LAR.
      2. On the copy of the summary - by the witness and the person obtaining consent.

      *NOTE: The IRB cannot waive the requirement for a witness or witness signature when the short form is used.

   ii. Signed copies of the short form and summary form should be provided to the subject or the subject’s LAR and the original should be filed in the investigator’s research file for that subject.

6. **OBTAINING VA INFORMED CONSENT FROM A LEGALLY AUTHORIZED REPRESENTATIVE (LAR):**

   a) When planning to enroll a research subject who is incompetent or has impaired decision-making capacity, investigators must address in the protocol how they will determine when surrogate consent will be required.

   b) A Legally Authorized Representative (LAR) is an individual(s) authorized under applicable law to provide permission on behalf of a prospective subject for a subject’s participation in the procedure(s) involved in a research study.

   c) A Legally Authorized Representative can be (in this order):

      i. Healthcare Power of Attorney (POA)
      ii. Court Appointed Legal guardians
      iii. Spouse
      iv. Adult children
      v. Parents of adult children
      vi. Siblings
      vii. Grandparents
      viii. Grandchildren
      ix. Close Friend: A close friend is defined is any person 18 years or older who has shown care and concern for the subject’s welfare, who is familiar with the subject’s activities, health, religious beliefs and values, and who has presented a signed written statement for the record that describes that person’s relationship to and familiarity with the subject.
d) The two types of LAR’s that are approved to sign both the ICF and the HIPAA document are:
   i. The subject’s Health Care Power of Attorney (POA)
   ii. The subject’s Court Appointed Legal Guardian

e) If possible, study staff should explain the proposed research to the prospective subject even when the LAR gives consent.

f) Under no circumstances may a subject be forced or coerced to participate in a research study.

g) The same consenting process and requirements followed for subjects, applies to the subject’s LAR.

7. ALTERNATIVES TO VA WRITTEN INFORMED CONSENT:

a) The PI may request, and the IRB can determine, in which circumstances written informed consent may be obtained in an alternative manner.

b) Only the IRB may grant either (1) a waiver of the documentation of informed consent or (2) a waiver of informed consent (or elements of consent).

c) The PI can find the documentation of the IRB’s determination regarding these types of waivers in the protocol file and/or the approval letter.

d) When a waiver of documentation of informed consent is granted, the IRB may require that the PI provide a written statement regarding the research to the study subjects.

e) If a standard written ICF cannot be obtained, the IRB may require that the PI submit a written summary or script that embodies the elements of the ICF for approval.

f) The IRB may waive the requirement that the person obtaining consent sign and date the ICF where there is no physical contact with the subject (e.g. where the only contact with the subject is by telephone or mail.).

8. VA HIPAA AUTHORIZATION:

a) PIs are required to obtain a signed HIPAA Authorization form when needing to access, collect, develop, use, or disclose individually identifiable health information for research unless the research qualifies for a waiver of HIPAA authorization or Data Use Agreement.
b) The HIPAA authorization must be signed by the subject or personal representative before initiation of any research activity unless waived by the IRB of record.

c) The written VA HIPAA Authorization may either be a standalone document or in some cases combined with the research informed consent approved by the IRB.

d) VA Form 10-0493 must be used when using a standalone HIPAA Authorization for any AVAHCS human subject research
   i. Staff may complete the header on each page of VA Form 10-0493.
   ii. All subjects or personal representative must sign and date page 4
   iii. Page 5 is signed only if the project involves optional use of data or specimens for banking or further analysis (future use projects)
   iv. Remove page 5 if not applicable. Do not complete page 5 if it does not apply.

e) The written VA HIPAA Authorization may not be combined with the informed consent form when the project involves:
   i. Optional use of data or specimens for banking or further analysis (future use projects).
   ii. The study subject population is expected to include subjects with legal guardians and/or personal representatives.

f) All potential disclosures to a non-VHA entity must be listed within the written authorization.

g) The AVAHCS Privacy Officer (PO) must review and approve the HIPAA authorization to ensure it contains all required elements and is consistent with all privacy requirements before the PI can begin to use or collect the individual’s information.

h) Data disclosed must be securely transferred according to VA information security requirements.

i) VA HIPAA Authorization is valid when signed by either:
   i. The research study subject
   ii. The subject’s personal representative who can be either:
       1. Healthcare Power of Attorney (POA)
       2. Court appointed Legal Guardian

j) A paper or electronic copy of the VA HIPAA Authorization must be provided to the study subject

k) Waiver of VA HIPAA Authorization- A request from a PI for the Privacy Board to waive VA HIPAA Authorization must have sufficient information
with it to make a determination. The Privacy Board must document its findings.