INFORMED CONSENT & HIPAA AUTHORIZATION

1. PURPOSE

This SOP contains the required elements of the informed consent document and HIPAA Authorization form, when a combined consent form/HIPAA Authorization form is permitted, documentation requirements when a participant is unable to sign these documents, and the disposition of signed documents.

2. DEFINITIONS

2018 Requirements: 45 CFR 46: Protection of Human Subjects, effective 2019 (replaced the Common Rule; also called the Revised Common Rule)
ACOS/R: Associate Chief of Staff for Research
AO/R: Administrative Officer for Research
CIRB: a Central IRB – an IRB external to MVAHCS
Common Rule: 45 CFR 46: Protection of Human Subjects, effective 1991
CVRE: Center for Veterans Research & Education
dACOS/R: Deputy Associate Chief of Staff for Research
FCOI: Financial Conflict of Interest
FDA: U.S. Food and Drug Administration
HRPP: Human Research Protection Program
ICF: Informed Consent Document/Informed Consent Form
IRB: Institutional Review Board
LAR: Legally Authorized Representative
LSI: Local Site Investigator
MCD: Medical Center Director
MVAHCS: Minneapolis VA Health Care System
NC: Non-compliance
NOK: Next of Kin
NPC: Non-profit corporation
PI: Principal Investigator
WOC: Without Compensation Employee
RDC: Research & Development Committee
RCO: Research Compliance Officer
SAE: Serious Adverse Event
SRS: Subcommittee on Research Safety
UP: Unanticipated Problem
UPR: Unanticipated Problem Report
VA CIRB: VA Central IRB

3. OVERVIEW

No investigator may involve a human being as a subject in research covered by this policy unless the investigator has obtained the legally effective informed consent of the subject or the subject's legally authorized representative (LAR), unless waived as described in VA policy.

This applies to human subjects research categorized as Non-Exempt for which the IRB of record has approved a use of a signed informed consent document and HIPAA Authorization form (or a combined document containing the required elements of both).

MVAHCS does not review projects involving use of Broad Consent.

4. REQUIREMENTS FOR INFORMED CONSENT DOCUMENT & HIPAA AUTHORIZATION

a) **CONSENT FORM:** Use of the informed consent document template (located in the IRBNet library) is recommended, but not required. The informed consent document must meet the following criteria for all studies, regardless of the regulations under which it is approved:

1) The information that is given to the subject or the representative must be in language understandable to the subject or the LAR.

2) No informed consent process, whether oral or written, may include any exculpatory language through which the subject or the 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.

b) For research subject to the 2018 Requirements:

1) 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;

2) 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 the research. This part of the informed consent must be organized and presented in a way that facilitates comprehension. *NOTE:* For some relatively simple research studies with limited risks or benefits, the entire informed consent document may be relatively brief and still satisfy the requirements below; and

3) 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's understanding of the reasons why one might or might not want to participate.

c) If a VA research study's informed consent approved by the IRB prior to January 21, 2019, requires modification, the general requirements described in this section are not applicable unless the research study has been transitioned to the 2018 Requirements. The IRB responsible for oversight of the study must determine and document whether all subjects previously consented must be provided the information through a re-consenting or other notification process.

d) **Basic Elements of Informed Consent.** Except when consent is not required (as under a Waiver of Informed Consent or Waiver of Documentation of Informed Consent), in seeking informed consent the following information must be provided to each subject or LAR:

1) A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures that are experimental;

2) A description of any reasonably foreseeable risks or discomforts to the subject;

3) A description of any benefits to the subject or to others that may reasonably be expected from the research;

4) A disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject;

5) A statement describing the extent, if any, to which confidentiality of records identifying the subject will be maintained;

6) For research involving more than minimal risk, an explanation as to whether any compensation is available, 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;

7) 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 research-related injury to the subject; and

8) A statement that participation is voluntary, refusal to participate involves no penalty or loss of benefits to which the subject is otherwise entitled, and that the subject may discontinue participation at any time without penalty or loss of benefits to which the subject is otherwise entitled.

9) For any research compliant with the 2018 Requirements, a statement about any research that involves the collection of identifiable private information or identifiable biospecimens:

   i. 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 investigator for future research studies without additional informed consent from the subject or the LAR, if this might be a possibility; *or*

   ii. 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.

10) A statement that VA will provide treatment for research related injury (per 38CFR17.85).

e) **Additional Elements of Informed Consent.** When appropriate, one or more of the following elements of information shall also be provided to each subject or LAR:

1) A statement that the particular treatment or procedure may involve risks to the subject (or to the embryo or fetus, if the subject is or becomes pregnant) that are currently unforeseeable;

2) Anticipated circumstances under which the subject's participation may be terminated by the investigator without regard to the subject's or the LAR’s consent;

3) Any additional costs to the subject that may result from participation in the research;

4) The consequences of a subject's decision to withdraw from the research and procedures for orderly and safe termination of participation by the subject;

5) A statement that any significant new findings developed during the course of the research that may relate to the subject’s willingness to continue participation will be provided to the subject;

6) The approximate number of subjects to be entered in the study;

7) For studies subject to the 2018 Requirements, 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;

8) For studies subject to the 2018 Requirements, a statement regarding whether clinically relevant research results, including individual research results, will be disclosed to subjects, and if so, under what conditions;

9) For studies subject to the 2018 Requirements and involving biospecimens, 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); and

10) When appropriate, a statement that informs VA research subjects that they or their insurance will not be charged for any costs related to the research. ***NOTE:*** *Some Veterans are required to pay copayments for medical care and services specifically related to their medical care provided by VA. These co-payment requirements will continue to apply to medical care and services that are not part of the research procedures or interventions.*

f) **HIPAA AUTHORIZATION FORM.** Use of the *VA Form 10-0493 Authorization for Use & Release of Individually Identifiable Health Information for Veterans Health Administration (VHA) Research* is required when a standalone HIPAA Authorization form is used.

g) **COMBINED INFORMED CONSENT DOCUMENT & HIPAA AUTHORIZATION FORM.** A single document combining the required elements of the Informed Consent Document and the HIPAA Authorization may be used only if both of the following are true:

1) No optional banking of identifiable data or biospecimens is involved, *and*
2) The IRB does not approve the use of subject's legally authorized representatives (LARs) to consent for the subject.

5. REMOTE CONSENTING

In the event that a participant cannot be on site to be consented for a research study, remote consenting may be appropriate. Whether consent can be obtained remotely for a study is at the discretion of the IRB of record.

a) The research participant or LAR receives a copy of the informed consent document/HIPAA Authorization form in advance of the study discussion via email, fax or mail. If mailed, two copies must be sent so that the participant may retain a reference copy.

b) Investigator or designee discusses the study via telephone or video conference with the potential participant.

1) Discussion must be the same as investigator/designee would have had in person.
2) For FDA-regulated research, verification of identity must occur using personal questions and/or visualization of government issued ID (e.g., driver's license, VA identification, etc.).

c) If the participant or LAR agrees to participation in the study, they sign and return the consent form to the investigator via mail, fax or email. If postal mail is used, a self-addressed, stamped envelope should be provided to mail the consent form back to the investigator.

d) For studies on which the IRB of record requires the signature/date of the investigator/designee obtaining consent: Once the research team receives the consent form from the participant/LAR, the investigator/designee who conducted the consent process must add their signature/date on the document, using the current date. Below their signature, they must document the method by which the consent was conducted and on which date, the date the signed consent was received, as well as the reason for the remote consent, e.g., "Discussed with participant via telephone on ##/##/#### and signed consent received ##/##/####. Consent performed remotely due to COVID."

e) The date the investigator/designee signs the consent form is the official date of the informed consent for the trial, not the date the participant/LAR signed.

f) The final signed informed consent document must be filed in the appropriate regulatory location for the study (see Section 7 DISPOSITION OF SIGNED DOCUMENTS).

6. DOCUMENTATION WHEN A PARTICIPANT IS PHYSICALLY UNABLE TO SIGN

When a participant has the capacity to consent however is unable to provide their written signature/date, the following processes may be used. Note that the procedures differ between informed consent documents and HIPAA Authorization forms.

Informed Consent Document or Combined Informed Consent Document & HIPAA Authorization form

a) If a competent individual is unable to physically sign due to a physical limitation of disability but is able to make a mark:

   i. Briefly document the circumstances on the informed consent document

   ii. Include the signature of **1 adult witness** to authenticate the symbol or mark executed or adopted by the individual to indicate the individual's intention to consent to participation.

   iii. The witness should not be on the study team.

b) If no symbol or mark can be made by the individual:

   i. Briefly document the circumstances on the informed consent document.

   ii. Include the signature of **1 adult witness** which authenticates the individual's intent to provide consent.

   iii. The witness should not be on the study team.

HIPAA Authorization form

a) If a competent individual is unable to physically sign due to a physical limitation of disability but is able to make a mark:

i. Briefly document the circumstances on the authorization.

ii. Include the signature of **2 adult witnesses** to authenticate the symbol or mark executed or adopted by the individual to indicate the individual's intent to provide authorization.

iii. The witnesses should not be on the study team.

b) If no symbol or mark can be made by the individual:

i. Briefly document the circumstances on the authorization.

ii. Include the signature of **2 adult witnesses** which authenticates the individual's intent to provide authorization.

iii. The witnesses should not be on the study team.

7. DISPOSITION OF SIGNED DOCUMENTS

The original signed informed consent document, combined consent form/HIPAA Authorization form, and HIPAA Authorization forms are to be maintained by the Principal Investigator. These documents are also to be prepared for audit within 2 weeks of signature:

a) When a signed informed consent document/HIPAA Authorization form has been obtained, it is to be scanned, and placed in a subfolder of the study-specific, limited-access folder on R:\Data named *Signed Consents*.

b) Send an email which includes the IRBNet number of the project, and the number of consents to be audited, to VHAMINRCO@VA.GOV. CCDOR and RECOVER projects should include the link to the folder location.

c) Following audit of the documents, they are to be moved to a subfolder of *Signed Consents* named *Audited*.

8. REFERENCES

VHA Directive 1200.05 (01/14/2019)

VHA Directive 1605.01 (08/31/2016)

9. FOLLOW-UP RESPONSIBILITY

Human Research Protection Program