



**VHA Handbook 1200.05: Requirements for the Protection of Human
Subjects in Research (Revised 11/12/14)
Full Disclosure: Informed Consent & HIPAA**

Soundia Duche, MA, MS
Program Analyst
Clinical Science Research and Development
VHA Office of Research and Development

4 February 2015



VHA Handbook 1200.05 Series Goals

- Discuss major topics as they pertain to changes in the revised VHA Handbook 1200.05, Requirements for the Protection of Human Subjects in Research
- Address questions received on the revised handbook by integrating responses into select topics

Revised VHA Handbook 1200.05

- Effective Date: November 12, 2014
- Implementation Date: March 12, 2015 (120 days post release date)
 - Facility Standard Operating Policies and Procedures (SOPs) cannot contradict requirements outlined in the revised handbook
 - Facility SOPs can include requirements that go beyond those outlined in the revised handbook
 - Facility SOPs should drive practices employed at the facility

Full Disclosure: Informed Consent & HIPAA

- Unless informed consent is waived by the IRB, the Common Rule requires that:
 - The investigator may not involve a human being as a subject in research unless informed consent is obtained and signed by the subject or the subject's legally authorized representative
 - Documentation of informed consent may be waived when informed consent is required if the IRB finds either of the two requirements described in 38 CFR 16.117(c) are met.
- The Privacy Rule (Health Insurance Portability and Accountability Act of 1996 - HIPAA) describes:
 - When written authorization is required before the use or disclosure of health care information that is not for a "permissible purpose" (i.e., treatment, payment, or healthcare operations).

Presentation Outline

- Informed Consent: Required and Additional Elements
- Documentation of Informed Consent in VA Research
- Documentation of Informed Consent in VA Research: Waiving the Signature of the Individual Obtaining Consent
- Electronic Informed Consent in VA Research: Issues for Implementation
- Documentation of Informed Consent for VA Research Studies and VHA Health Records
- Informing Subjects that Photos, Digital Images, Videos, and/or Audio Recordings Will be Taken or Obtained for Research Purposes
- Keeping or Removing the Requirement to use VA Form 10-3203 in VA Research
- ORD Requirement: Use of VA Form to Obtain Written HIPAA Authorization
- Available Optional Forms for Research: Waiver of HIPAA Authorization and Revocation of Authorization
- Available Resources

Informed Consent: Required and Additional Elements

- Common Rule:
 - Eight basic elements as described in 38 CFR 16.116(a)
 - Six additional elements as described in 38 CFR 16.116(b)
- VA -specific elements:
 - Basic elements as described in VHA Handbook 1200.05, Paragraph 15(c)
 - Any payments the subject is to receive for participating in the study;
 - Any real or apparent conflict of interest by investigators where the research will be performed; and
 - A statement that VA will provide treatment for research related injury in accordance with applicable federal regulations.
 - Additional element as described in VHA Handbook 1200.05, Paragraph 15(d)(7)
 - 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 (see para 15d(7)).

Documentation of Informed Consent in VA Research

- VA Investigators are no longer required to use VA Form 10-1086 (Research Consent Form) as the only acceptable template to document informed consent for VA studies involving human subjects.
- The written informed consent form must contain the elements of informed consent described in VHA Handbook 1200.05 as approved by the Institutional Review Board (IRB).
- The IRB approval date must be documented on the informed consent form.
- Informed consent document must be signed and dated by:
 - Subject or the subject's legally authorized representative (LAR) and
 - Person obtaining informed consent, unless waived by the IRB.

Documentation of Informed Consent in VA Research: Waiving the Signature of the Individual Obtaining Consent

- The IRB may waive obtaining the signature and date of the person obtaining informed consent where there is no physical contact with the subject.
 - The IRB cannot waive obtaining the signature and date of the person obtaining informed consent for any other reason in VA research.
 - Signature of the subject or the subject's legally authorized representative cannot be waived if documentation of informed consent is required by the IRB.

Electronic Informed Consent in VA Research: Issues for Implementation

- Revised VHA Handbook 1200.05 permits informed consent to be obtained electronically, **HOWEVER:**
 - Electronic consent must meet all VHA requirements for documentation of consent, applicable VA requirements, and the identity of the subject and the date the form was signed must be able to be authenticated;
 - VHA Handbook 1004.05 (iMedConsent™) requires specific authorization from ORD before iMedConsent™ can be used in VA research;
 - ORD has not given specific authorization to utilize iMedConsent™ in VA research;
 - ORD and other VA and VHA Central Program Offices are working to coordinate issues related to implementing iMedConsent™ across VA Facilities for VA research;
 - Individual VA Facilities cannot contact iMedConsent™ vendor to implement use.

Documentation of Informed Consent for VA Research Studies and VHA Health Records

- ORD does not require a copy of the subjects' informed consent documents to be placed in their VHA Health Records.
- For VA studies with Certificates of Confidentiality involving a medical intervention, copies of VA subjects' informed consent forms and HIPAA authorizations cannot be included in the subjects' VHA Health Records.
- VHA Handbook 1108.04 (Investigational Drugs and Supplies) requires that
 - The initial order or prescription for each new subject on an investigational protocol must be accompanied by a signed informed consent or
 - Written assurance, by the provider, that the signed consent is available for viewing and printing in the electronic medical record.
 - VA Form 10-1086 must be completed in accordance with VHA Handbook 1200.05 and bear the appropriate signatures as required by the IRB and sponsor. This form is to be reviewed for each subject, by the Pharmacy Service or Investigational Drug Pharmacy designee, prior to dispensing to the subject for the first time.
 - Even though VHA Handbook 1108.04 specifically references VA Form 10-1086, it is acceptable to not utilize VA Form 10-1086.

Informing VA Subjects that Photos, Digital Images, or Audio/Video Recordings will be Taken or Obtained for Research Purposes

- The informed consent for research must include information describing how photographs, video, and/or audio recordings will 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.
- Informed Consent to take a photograph, video, and/or audio recording of a VA subject cannot be waived by the IRB.
- ORD no longer requires VA subjects to sign and date VA Form 10-3203 (Consent for Production and Use of Verbal and Written Statements, Photographs, Digital images, and/or Video and Audio recordings by VA) to document VA subjects' agreements to allow images or recordings of themselves to be taken for research purposes.
- Use of VA Form 10-3203 for non-research purposes is described in VHA Directive 1078(1) "Privacy of Persons Regarding Photographs, Digital images, and Video or Audio Recordings".

Keeping or Removing the Requirement to use VA Form 10-3203 in VA research

- Each VA facility can choose if it wishes to continue requiring the use of this form for research; this is a local decision.
- Revise Local Standard Operating Policies and Procedures (SOPs) if local policy changes regarding use of VA Form 10-3203 in VA Research.
- Regardless of whether or not a local VA Facility chooses to use VA Form 10-3203, the Common Rule requires as part of the basic elements of informed consent that subjects be provided:
 - A statement that the study involves research, an explanation of the purposes of the research and the expected duration of the subject's participation, a description of the procedures to be followed, and identification of any procedures which are experimental (38 CFR 16.116(a)(1)).

ORD Requirement: Use of VA Form 10-0493 to Obtain Written HIPAA Authorization for VA Research

- VA Form 10-0493, Authorization for Use & Release of Individually Identifiable Health Information for Veterans Health Administration (VHA) Research, must be used for HIPAA authorizations for **new VA studies**
- When a written authorization is required, the Privacy Rule requires that the authorization be signed and dated by the individual or their personal representative
- VA Form 10-0493 can be found at <http://vaww.va.gov/vaforms/medical/pdf/vha-10-0493-fill.pdf>

Available Optional Forms for Research: Waiver of HIPAA Authorization and Revocation of Authorization

- Two VA Forms are available which can be used to help resolve issues with documentation when the
 - IRB approves a waiver of HIPAA authorization for research, or the
 - Subject wishes to revoke authorization for use and release of individually identifiable health information for research.
- These two VA Forms are not currently required for use as per VA or VHA Handbooks or Directives.
- VA Form 10-0521: IRB Documentation of Waiver of HIPAA Authorization for Research is located at <http://vaww.va.gov/vaforms/medical/pdf/vha-10-0521-fill.pdf>
- VA Form 10-10116, Revocation of Authorization for Use & Release of Individually Identifiable Health Information for VHA Research is located at <http://vaww.va.gov/vaforms/medical/pdf/vha-10-10116-fill-4-11-2014.pdf>



Open Q&A Session



Available Resources

Available Resources

- **Upcoming VHA Handbook 1200.05 Cyberseminar titled, “Local Site Responsibilities: VA Facility Director Approvals” (Tuesday, February 17th @ 2:30pm)**
- Recording of Cyberseminar series titled, “VHA Handbook 1200.05 rollout”:
<http://www.research.va.gov/pride/cyberseminars/pride-121114.cfm>

Available Resources (continued)

- Crosswalk between current version and 5/2/12 version of the handbook
- Summary of significant changes
- Recently released ORD guidance documents
 - Guidance on Advertisement of Non-VA Funded Research in VA Facilities (10/20/2014)
 - Guidance on Approval of International Research (10/20/2014)
 - Guidance on Conducting Research involving Children (10/20/2014)
 - Guidance on Conducting Research involving Pregnant Women (10/20/2014)
 - Guidance on Continuing Review (10/22/2014)
 - Guidance on Exempt Research Determination (10/20/2014)

See: <http://www.research.va.gov/PRIDE/120005.cfm>

See: <http://www.research.va.gov/resources/policies/default.cfm>

Questions & Contact Information

Questions can be submitted to vhacoordregulatory@va.gov

Presenter's contact information:

Soundia Duche, MA, MS

Program Analyst, CSR&D/ORD

E-mail: soundia.duche@va.gov

Waiver or Alteration of Informed Consent

(38 CFR 16.116(c) and VHA Handbook 1200.05 paragraph 15e)

An IRB may approve a consent procedure which does not include, or which alters, some or all of the elements of informed consent set forth above, or waive the requirement to obtain informed consent provided the IRB finds and documents that:

(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 (i) Public benefit of service programs; (ii) procedures for obtaining benefits or services under those programs; (iii) possible changes in or alternatives to those programs or procedures; or (iv) 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

OR

The IRB finds and documents that:

(1) The research involves no more than minimal risk to the subjects;
(2) The waiver or alteration will not adversely affect the rights and welfare of the subjects;
(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.

Waiver of Documentation of Consent

(38 CFR 16.117(c) and VHA Handbook 1200.05 paragraph 16c)

An IRB may waive the requirement for the investigator to obtain a signed consent form for some or all subjects if it finds either:

(1) That the only record linking the subject and the research would be the consent document and the principal risk would be potential harm resulting from a breach of confidentiality. Each subject will be asked whether the subject wants documentation linking the subject with the research, and the subject's wishes will govern; or
(2) That the research presents no more than minimal risk of harm to subjects and involves no procedures for which written consent is normally required outside of the research context. In cases in which the documentation requirement is waived, the IRB may require the investigator to provide subjects with a written statement regarding the research.

Waiver of HIPAA Authorization

(VHA Handbook 1200.05 Paragraph 23b)

An investigator requesting a waiver of HIPAA authorization must provide information sufficient to allow the IRB to make the requirement determination. In accordance with the HIPAA Privacy Rule at 45 CFR 164.512(i)(2), the IRB must document the following:

- (1) Identification of the IRB of Record
- (2) Date of IRB approval of waiver of HIPAA authorization
- (3) Statement that the waiver of HIPAA authorization satisfies the following criteria:
 - (a) The use or disclosure of the requested information involves no more than minimal risk to the privacy of individuals, based on, at least, the presence of the following elements:
 - (1) An adequate plan to protect the identifiers from improper use and disclosure;
 - (2) An adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law; and
 - (3) Adequate written assurances that the PHI will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research study, or for other research for which the use or disclosure of the requested information is permitted by the Privacy Rule;
 - (b) The research could not practicably be conducted without the waiver; and
 - (c) The research could not practicably be conducted without access to and use of the requested information
- (4) A brief description of the PHI for which the IRB has determined use or disclosure to be necessary
- (5) Identification of the IRB review procedure used to approve the waiver of HIPAA authorization (either convened IRB review procedures or expedited review procedures)
- (6) Signature of the Chair of the IRB, or a qualified voting member of the IRB designated by the Chair, on the HIPAA authorization waiver document