



Department of Veterans Affairs

Checklist for Reviewing Privacy, Confidentiality and Information Security in Research

Resource Contacts

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Study Information

Principal Investigator (PI) Name	VA E-Mail Address	Phone Number
Study Title		Protocol Number (if available)
Study Contact Name	VA E-Mail Address	Phone Number

Check all of the following that apply to this submission:

Purpose of Submission:

- New Protocol
- Continuing Review **STOP HERE** answer questions 1 & 26 and proceed to PI Signature Section
- Amendment Only change is adding study personnel. If so, answer questions 1 & 26 & proceed to PI Signature Section
- Only change is study personnel have been removed from the study. If so, answer question 41 and proceed to PI Signature Section
- Change in data collection/use/storage/transmission/disposition Change in HIPAA Authorization Change in VA Informed Consent Change in Data Use Agreement
- NO** Change in data collection/use/storage/transmission/disposition. Proceed to PI Signature Section

Enrollment Status:

- Open Closed

Funding Source:

- None VA/Coop Study NIH or Other Government Agency Private Funding. Specify:

Data Use Information:

- Written Agreements Regarding Data Use Data Use Agreement exists Videos, pictures or audio recordings will be obtained
- Study will require a contractor who will have access to VA sensitive data. Specify contractor and services:

Check any of the following HIPAA identifiers that may be collected and recorded during the course of the study:		
<input type="checkbox"/> Names	<input type="checkbox"/> Social security numbers or scrambled SSNs	<input type="checkbox"/> Device identifiers and serial numbers
<input type="checkbox"/> E-mail addresses	<input type="checkbox"/> Medical record numbers	<input type="checkbox"/> URLs (Universal Resource Locator)
<input type="checkbox"/> All elements of dates (except year) associated with an individual & any age over 89. Specify:	<input type="checkbox"/> Health plan beneficiary numbers	<input type="checkbox"/> IP addresses (Internet Protocol)
<input type="checkbox"/> Telephone numbers	<input type="checkbox"/> Account numbers	<input type="checkbox"/> Biometric identifiers including finger and voice print
<input type="checkbox"/> Fax numbers	<input type="checkbox"/> Certificate or license numbers	<input type="checkbox"/> Full face photographic images and any comparable images
<input type="checkbox"/> All geographic subdivisions smaller than state. Specify:	<input type="checkbox"/> Vehicle IDs and serial numbers including license plate numbers	<input type="checkbox"/> Other unique identifying number, characteristic or code Specify:

Instructions for completing the following sections of the checklist, if applicable:

Each of the items listed must be discussed fully in the study application. Where requested, please select the applicable source document and enter the page number. The choices for source document are:

- A. Application
- B. HIPAA Authorization
- C. Request for HIPAA waiver of authorization
- D. VA Informed Consent
- E. Request for waiver of VA Informed Consent
- F. Attachment to Application. If applicable, please identify the specific attachment
- G. Data Use Agreement or Data Transfer Agreement
- H. Protocol
- I. Other Specify

If the answer is N/A (not applicable, no response will be expected in source code or page number fields. Additional sources may be indicated in the text field provided.

Privacy and Confidentiality Requirements

Column To Be Completed by Principal Investigator or Study Team Member		These Columns To Be Completed by the PO Based on a Review of Source Documents			
	Requirement	Met	Not Met	N/A	Comments
1	Privacy Training: All study staff are up-to-date with VHA Privacy Policy Training. (Ref: VHA Handbook 1200.05, ¶61a and VHA Handbook 1605.1, ¶3(4)) <input type="checkbox"/> Yes <input type="checkbox"/> No				
2	Privacy Interests: Provisions have been made to protect the privacy interests of subjects and the protection of research data. (Ref: VHA Handbook 1200.05, ¶ 10j and VHA Handbook 1605.1, ¶ 14b) Source Choose an item. Page Number N/A <input type="checkbox"/> Additional sources				

3	<p>Data Use: There is a statement in the IRB submission package or protocol regarding how data will be used by each VA and non-VA entity that will have access. (Ref: VHA Handbook 1200.05, ¶10j and VHA Handbook 1605.1 ¶14b) Source Choose an item. Page Number N/A <input type="checkbox"/> Additional sources</p>				
4	<p style="text-align: center;">HIPAA Authorization</p> <p>Consistency: The HIPAA authorization contains similar language as the application, protocol and informed consent with regard to the protected health information to be used or disclosed, entities to whom information will be disclosed, expiration of authorization, and purpose. (Ref: VHA Handbook 1200.05, ¶9k.) Source Choose an item. Page Number N/A <input type="checkbox"/> Additional sources</p>				
5	<p>Subject Identity: The HIPAA authorization has a place for the subject’s identity, i.e. name. (Ref: VHA Handbook 1605.1, ¶14b.) Source Choose an item. Page Number N/A <input type="checkbox"/> Additional sources</p>				
6	<p>Description of Information: The protected health information to be used or disclosed is specifically listed on the HIPAA authorization. Note: If HIV, sickle cell anemia, drug and/or alcohol abuse treatment information will be disclosed, it must be specifically stated in the HIPAA Authorization. (Ref: VHA Handbook 1605.1, ¶14b) Source Choose an item. Page Number N/A <input type="checkbox"/> Additional sources</p>				
7	<p>Authorization to Use or Disclose: The HIPAA authorization identifies the people and organizations authorized to make the requested use or disclosure. (Ref: VHA Handbook 1605.1, ¶14b) Source Choose an item. Page Number N/A <input type="checkbox"/> Additional sources</p>				
8	<p>Recipient Identification: The HIPAA authorization identifies to whom the information will be disclosed or released for use. (Ref: VHA Handbook 1605.1, ¶14b) Source Choose an item. Page Number N/A <input type="checkbox"/> Additional sources</p>				
9	<p>Description of Purpose: The HIPAA authorization includes a description of each purpose for which the information will be used or disclosed. A statement such as “for research purposes” is sufficient, though a more thorough description is preferred. If the study will eventually close, but the data will remain in a repository, the authorization should cover both events. (Ref: VHA Handbook 1605.1, ¶14b) Source Choose an item. Page Number N/A <input type="checkbox"/> Additional sources</p>				
10	<p>Expiration: The HIPAA authorization includes a date or event that explains when the authorization expires. “End of the research study” is sufficient for III in research. “None” is sufficient for III including for the creation and maintenance of a research database or research repository. (Ref: VHA Handbook 1605.1, ¶14b) Source Choose an item. Page Number N/A <input type="checkbox"/> Additional sources</p>				

11	<p>Signature and Date: The HIPAA authorization contains the signature line of the subject as well as the date signed. If subjects who are incompetent or lack decision making capacity will be included, a signature line for the person legally authorized in writing by the individual (or the individual's legal guardian) to act on behalf of the individual, (i.e. power of attorney) is listed. (Ref: VHA Handbook 1605.1, ¶15b and 14b)</p> <p>Source Choose an item. Page Number N/A <input type="checkbox"/> Additional sources</p>				
12	<p>Right to Revoke: The HIPAA authorization includes a statement that the subject has the right to revoke the authorization in writing, except to the extent that the entity has acted in reliance on it. (Ref : VHA Handbook 1605.1, ¶14b)</p> <p>Source Choose an item. Page Number N/A <input type="checkbox"/> Additional sources</p>				
13	<p>How to Revoke: The HIPAA revocation statement includes a description of how the subject may revoke the authorization, i.e. to whom it should be submitted. (Ref: VHA Handbook 1605.1, ¶14b)</p> <p>Source Choose an item. Page Number N/A <input type="checkbox"/> Additional sources</p>				
14	<p>Conditioning: The HIPAA authorization includes a statement that treatment, payment, enrollment, or eligibility for benefits cannot be conditioned on the subject completing the authorization, but participation in the study may be conditioned on the subject signing the authorization. (Ref VHA: Handbook 1605.1, ¶14b)</p> <p>Source Choose an item. Page Number N/A <input type="checkbox"/> Additional sources</p>				
15	<p>Data Protection and Re-disclosure: The HIPAA authorization includes a statement that individually identifiable health information disclosed pursuant to the authorization may no longer be protected by Federal laws or regulations and may be subject to re-disclosure by the recipient. (Ref: VHA Handbook 1605.1, ¶14b)</p> <p>Source Choose an item. Page Number N/A <input type="checkbox"/> Additional sources</p>				
16	Waiver of HIPAA Authorization				
	<p>Minimal Risk Justification: The waiver of HIPAA authorization is justified because the use of information includes no more than minimal risk to the privacy of the subjects. If so, the requirements in 16a, 16b and 16c below must be met. (Ref: VHA Handbook 1200.05, ¶37b)</p> <p>Source Choose an item. Page Number N/A <input type="checkbox"/> Additional sources</p>				
16a	<p>Written Assurance of Protection: The request for waiver of HIPAA authorization provides adequate written assurance that the requested information will be protected from improper use and disclosure and 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 would be permitted by the HIPAA Privacy Rule. (Ref: VHA Handbook 1200.05, ¶37b)</p> <p>Source Choose an item. Page Number N/A <input type="checkbox"/> Additional sources</p>				
16b	<p>Protection of Identifiers: The request for waiver of HIPAA authorization provides an adequate plan to protect the identifiers from improper use and disclosure. (Ref: VHA Handbook 1200.05, ¶37b)</p> <p>Source Choose an item. Page Number N/A <input type="checkbox"/> Additional sources</p>				

16c	<p>Destruction of Identifiers: The request for waiver of HIPAA authorization provides an adequate written 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. (Ref: VHA Handbook 1200.05, ¶137b)</p> <p>Source Choose an item. Page Number N/A <input type="checkbox"/> Additional sources</p>				
17	<p>Need for Information: The request for waiver of HIPAA authorization explains why the research could not practicably be conducted without access to and use of the requested information. (Ref: VHA Handbook 1200.05, ¶137b)</p> <p>Source Choose an item. Page Number N/A <input type="checkbox"/> Additional sources</p>				
18	<p>Need for Waiver: The request for waiver of HIPAA authorization explains why the research could not practicably be conducted without the waiver. (Ref: VHA Handbook 1200.05, ¶137b)</p> <p>Source Choose an item. Page Number N/A <input type="checkbox"/> Additional sources</p>				
19	<p>Description of PHI: The request for waiver of HIPAA authorization includes a brief description of the protected health information. (Ref: VHA Handbook 1200.05, ¶137b)</p> <p>Source Choose an item. Page Number N/A <input type="checkbox"/> Additional sources</p>				
20	<p>38 U.S.C. 7332 Information: If the waiver of HIPAA authorization is for the use of 38 USC 7332 information (applicable to drug abuse, alcohol abuse, HIV infection, and sickle cell anemia records), there is assurance in writing that the purpose of the data is to conduct scientific research and that no personnel involved may identify, directly or indirectly, any individual patient or subject in any report of such research or otherwise disclose patient or subject identities in any manner. (Ref: 38 U.S.C. 7332(b)(2)(B))</p> <p>Source Choose an item. Page Number N/A <input type="checkbox"/> Additional sources</p>				
	Other				
21	<p>Specimens: The study states whether specimens will be labeled with identifiable or de-identified information. (Ref: VHA Handbook 1200.05, ¶153)</p> <p>Source Choose an item. Page Number N/A <input type="checkbox"/> Additional sources</p>				
22	<p>De-Identification of Data: The research protocol indicates whether or not data will be de-identified and, if so, the method described truly de-identifies the data according to VHA Handbook 1605.1, Appendix B, Paragraph 2a (document statistical determination) <u>or</u> Paragraph 2b (removal of <u>all</u> 18 individually-identifiable information). (Ref: VHA Handbook 1200.05, ¶137b)</p> <p>Check all that apply:</p> <p><input type="checkbox"/> De-identified information is provided to PI by the research team who has access to IIHI per a HIPAA authorization or waiver of authorization</p> <p><input type="checkbox"/> De-identified information is provided by PI who has access to IIHI to his/her research team</p> <p><input type="checkbox"/> De-identified information is to be sent to non-VA research team member (i.e. statistician)</p> <p><input type="checkbox"/> De-identified information will be disclosed to a non-VA party listed below:</p> <p>Source Choose an item. Page Number N/A <input type="checkbox"/> Additional sources</p>				

NOTE TO PI: Please proceed to Information Security Requirements Section to complete questions specific to information security.

For Privacy Officer Use Only - HIPAA Validation

This section to be completed by the Privacy Officer		Met	Not Met	N/A	Comments
23	Has the IRB approved the study? If the PO review is conducted prior to the IRB meeting, IRB approval may not yet exist. IRB approval may be determined through personal knowledge (e.g. PO in attendance at IRB meeting when approved, IRB minutes, or an IRB approval letter.)				
24	If applicable, does the HIPAA authorization comply with content requirements?				
25	If applicable, has the IRB or Privacy Board approved, by signature, the waiver of HIPAA Authorization? (If yes, answer questions 25a-25e)				
25a	Does the IRB or Privacy Board memo or other documentation include the date of and approval of request for waiver of HIPAA authorization? Note: The documentation may also be found in the IRB minutes or in the IRB approval memo for the research study.				
25b	Is the IRB or Privacy Board identified in the memo/ letter/minutes?				
25c	Does the IRB or Privacy Board memo or other documentation state it has determined that the waiver of HIPAA authorization satisfies all criteria under Questions 16 through 19? Note: A simple statement as to compliance with criteria by the IRB is not sufficient. Each criterion must be addressed in the memo or other document. The IRB must state its determination for each criterion.				
25d	Does the IRB or Privacy Board memo or documentation state that alteration or waiver of authorization has been reviewed and approved under either normal (at a convened meeting) or expedited review procedures?				
25e	Has the memo or other documentation been signed by the IRB or Privacy Board Chair or other designated voting member?				

Privacy Officer's Signature Section

I have reviewed this study for compliance with VA privacy and confidentiality policy. NOTE: If the PO recommended changes or there is a request for waiver of HIPAA authorization, the PO must conduct a second (final) review and provide sign-off after IRB approval of the waiver and/or the recommended changes are made or the issues resolved. If the PO has not recommended changes and there is no request for waiver of HIPAA authorization, the PO may proceed directly to the final signature and indicate that the study complies with policy.

Recommend Changes as Stated Above A waiver of HIPAA authorization is requested

Summary/Initial Signature or E-signature of Privacy Officer Date

Study Complies With Policy

Final Signature or E-signature of Privacy Officer Date

Information Security Requirements

Column To Be Completed by Principal Investigator or Study Team Member		These Columns To Be Completed by ISO Based on a Review of Source Documents			
	Requirement	Met	Not Met	N/A	Comments
26	Information Security Training: All study staff are up-to-date with VA Privacy and Information Security and Rules of Behavior training. (Ref: VA Directive 6500, ¶2a(5) and ¶3f(2) and VA Handbook 6500, Appendix D, ¶AT-2) <input type="checkbox"/> Yes <input type="checkbox"/> No				
27	Software: The study identifies specially obtained software that will be used, the source of the software, whether a license will be required, who will fund the license as well as any data that will be stored in temporary files on the computer's hard drive. (Ref: VA Handbook 6500, Appendix D, ¶¶SA-6 and SA-7) Source Choose an item. Page Number N/A <input type="checkbox"/> Additional sources				

28	<p>Web Applications: The study identifies any web application, as well as its security features, that will be used for such purposes as recruiting subjects, completing questionnaires or processing data. (Ref: VA Directive and Handbook 6102 and VA Directive and Handbook 6502.3)</p> <p>Source Choose an item. Page Number N/A <input type="checkbox"/> Additional sources</p>				
29	<p>Data Flow: The study includes a description of the data collection, data flow and/or data management process that will be used during the course of the study. (Ref: VHA Handbook 1200.05, ¶10j)</p> <p>Source Choose an item. Page Number N/A <input type="checkbox"/> Additional sources</p>				
30	<p>Data Security Plan: Study describes how electronic data as well as paper records will be secured. (Ref: VHA Handbook 1200.05, ¶10j)</p> <p>Source Choose an item. Page Number N/A <input type="checkbox"/> Additional sources</p>				
31	<p>Data on a Hard Drive: The study identifies whether VA research data will be stored on the hard drive of a PC. If so, it is considered VA best practice to encrypt the PC. (Ref: VHA Handbook 1200.05, ¶10j)</p> <p>Source Choose an item. Page Number N/A <input type="checkbox"/> Additional sources</p>				
32	<p>Mobile Devices: The study states that all mobile devices will be encrypted and that the encryption is FIPS 140-2 validated. Note: All mobile/portable devices and media and any information transmitted to and from a wireless device must be protected with VA approved encryption technology that is FIPS 140-2 validated. (Ref: VA Handbook 6500, Appendix D, ¶AC-19)</p> <p>Source Choose an item. Page Number N/A <input type="checkbox"/> Additional sources</p>				
33	<p>Storage Location: The study identifies precisely where data and specimens will be stored, i.e. physical site, network location/server name (e.g. vha-barsch), type of mobile storage device, building and room, etc. (Ref: VHA Handbook 1200.05, ¶10j and VA Handbook 6500, Appendix D, ¶Ac-19)</p> <p>Source Choose an item. Page Number N/A <input type="checkbox"/> Additional sources</p>				
34	<p>Removal of VA Sensitive Information from the VA Protected Environment: The study states whether or not research data is intended to be removed from the VA protected environment. (Ref: VHA Handbook 1200.05, ¶10j and VA Handbook 6500, Appendix D, ¶AC-19)</p> <p>Source Choose an item. Page Number N/A <input type="checkbox"/> Additional sources</p>				
35	<p>Protection of Media Stored at Alternate Site: If the study team plans to store VA sensitive information outside the VA protected environment, the study indicates by what method it will be protected. (Ref: VHA Handbook 1200.05, ¶10j and VA Handbook 6500, Appendix D, ¶PE-17)</p> <p>Source Choose an item. Page Number N/A <input type="checkbox"/> Additional sources</p>				
36	<p>Data Transmission: The study states how sensitive electronic information will be securely transmitted. Note: VA sensitive data or information may only be transmitted using VA-approved solutions such as FIPS 140-2 validated encryption. (Ref: VA Handbook 6500, Appendix D, ¶MP-1)</p> <p>Source Choose an item. Page Number N/A <input type="checkbox"/> Additional sources</p>				

37	<p>Data Backup: The study indicates that mobile storage devices do not contain the only copy of research information. Original electronic VA research data stored on a mobile device or outside the VA protected environment will be backed up regularly and stored securely within VA’s protected environment. (Ref: VA Handbook, Appendix D, ¶AC-19)</p> <p>Source Choose an item. Page Number N/A <input type="checkbox"/> Additional sources</p>				
38	<p>Shipping Data: Study indicates whether sensitive research data that must be sent via common carrier will be encrypted with FIPS 140-2 validated encryption if it is electronic and will be sent via delivery service with a chain of custody. (Ref: VA Handbook 6500, Appendix D, ¶AC-19 and VA Directive 6609)</p> <p>Source Choose an item. Page Number N/A <input type="checkbox"/> Additional sources</p>				
39	<p>Data Return: The study includes a statement regarding what VA information will be returned to the VA, how the information will be returned to the VA, or plans for its destruction. Note: VA research data and information must be retained in accordance with the applicable VA Records Control Schedule (RCS), which is a set of rules established by the Federal government that states when Federal agencies are allowed to dispose of records. Prior to destruction of research records, the PI should contact the Records Management Officer for current policy. (Ref: RCS 10-1, VHA Handbook 1200.12, ¶¶9-10)</p> <p>Source Choose an item. Page Number N/A <input type="checkbox"/> Additional sources</p>				
40	<p>Data Destruction: The study includes a description of the methods that will be used to destroy data at the end of its life cycle. Note: If the protocol states information will not be returned to the VA, the protocol must state how and when the information will be destroyed. See note above in Question 39. (Ref: VA Handbook 6500.1, VHA Handbook 1200.12, ¶¶9-10, and RCS 10-1)</p> <p>Source Choose an item. Page Number N/A <input type="checkbox"/> Additional sources</p>				
41	<p>Termination of Data Access: The study states that removal of access to research study data will be accomplished for study personnel when they are no longer part of the research team. (Ref: VA Handbook 6500, Appendix D, ¶AC-2)</p> <p>Source Choose an item. Page Number N/A <input type="checkbox"/> Additional sources</p>				
42	<p>Incident Reporting: In accordance with VA policy, procedures are in place for reporting incidents, i.e. theft or loss of data or storage media, unauthorized access of sensitive data or storage devices or non-compliance with security controls. (Ref: VHA Handbook 1200.05, ¶10j; VHA Handbook 1058.01, ¶11.a; VA Handbook 6500, Appendix D, ¶AC-19, ¶PL-4, ¶IR-1, ¶IR-6 and VHA Handbook 6500.2))</p> <p>Source Choose an item. Page Number N/A <input type="checkbox"/> Additional sources</p>				

Information Security Officer's Signature Section

I have reviewed this study for compliance with VA information security policy. NOTE: If the ISO has not recommended changes, the ISO may proceed directly to the final signature.

Recommend Changes Without Further Review Recommend Changes With Second Review Requested

Summary/Initial Signature or E-signature of Information Security Officer Date

Study Complies With Policy

Final Signature or E-signature of Information Security Officer Date

Customizable Section

PI	NOTICE OF PRIVACY PRACTICES: A copy of the VHA Notice of Privacy Practices (NOPP) will be given to all Non-Veteran participants. The signed Acknowledgement (10-0483) form is maintained with the protocol package.			
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Comments Section

Use this section for additional comments by the study team.

Principal Investigator's Signature Section

As the Principal Investigator on this study, I have read the above document and agree the information contained herein is correct.

Signature or E-signature of Principal Investigator

Date

Note: This checklist should become part of the IRB protocol file in accordance with VHA Handbook 1200.05, paragraph 38.