

Department of Veteran Affairs
Privacy, Confidentiality & Information Security Source Checklist for Research

NOTED: The source and Checklist documents have been combined into 1 document (1/7/2014)

Please Check: All information provided in this document must be found in one or more of the following supporting documents:

- Protocol VA Informed Consent VA HIPAA Authorization Request for HIPAA Waiver SSS Other as applicable

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Protocol Information:

PI Name:

Contact Name: Email: Ph#:

Protocol #:

Protocol Title:

Does this research involve:

Humans Animals Basic Science / Lab Facility

VA Research Required Training – (Ref: VHA Handbook 1200.05, ¶61a and VHA Handbook 1605.1, ¶3(4)) and (Ref: VA Directive 6500, 2a(5) and 3f(s) and VA Handbook 6500, Appendix D, AT-s)
Check all that apply below.

All individuals listed on the “VA R&DC Research Study Submission Form” have met required training.
 Except the following individuals:
 New research individuals have been added to the “VA R&DC Research Study Submission Form” and have taken required training

18 HIPAA Identifiers - 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"/> IP addresses (Internet Protocol)
<input type="checkbox"/> E-mail addresses	<input type="checkbox"/> Medical record numbers	<input type="checkbox"/> Certificate or license numbers
<input type="checkbox"/> Account numbers	<input type="checkbox"/> Health plan beneficiary numbers	<input type="checkbox"/> Full face photographic images and any comparable images
<input type="checkbox"/> Telephone numbers	<input type="checkbox"/> Device identifiers and serial numbers	<input type="checkbox"/> Biometric identifiers including finger and voice print
<input type="checkbox"/> Fax numbers	<input type="checkbox"/> URLs (Universal Resource Locator)	
<input type="checkbox"/> All geographic subdivisions smaller than state.	<input type="checkbox"/> Other unique identifying number, characteristic or code	<input type="checkbox"/> All elements of dates (except year) associated with an individual & any age over 89.

Specify: Specify: Specify:

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A. Use of the 18 HIPAA Identifiers – (Ref: VHA Handbook 1200.05, ¶ 10j and VHA Handbook 1605.1, ¶ 14b)

Indicate whether or not individually **identifiable information** is to be collected or used:

DATA collected:

Identifiable DATA

I am viewing/data mining without retaining any of the 18 HIPAA Identifiers for research. However, a Master List is used and includes identifiers.

Please check all 18 HIPAA Identifiers identified on the Master List.

De-identified Data.

De-Identification of Data -(Ref: VHA Handbook 1200.05, ¶37b)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) or Paragraph 2b (removal of all 18 individually-identifiable information). Check all that apply:

- De-identified information is provided to PI by the research team who has access to IIHI per a HIPAA authorization or waiver of authorization
- De-identified information is provided by PI who has access to IIHI to his/her research team
- De-identified information is to be sent to non-VA research team member (i.e. statistician)
- De-identified information will be disclosed to a non-VA party listed:

The process or assurance stated in the space above is consistent with other study documents

- Yes
- No, **Please correct all documents to match**
- Limited Data Set. (NOTE: A Data Use Agreement may be required)

SPECIMENS collected, will be labeled with:

- De-identified Data.
- Limited Data Set. (NOTE: A Data Use Agreement may be required)
- Identifiable Data** (Any of the 18 identifiers) as indicated on page 1
- Not Applicable

SPECIMENS: Are specimens Stored or Banked outside a VA facility?

- No
- Yes, Contact the VA R&D office & refer to: http://vaww.research.va.gov/programs/tissue_banking/

Has an application been submitted for Storing or Banking specimens off-site from the VA? Yes, No, If “No”, EXPLAIN:

Data Use Information:

Videos, pictures or audio recordings will be obtained

Written Agreements Regarding Data Use Data Use Agreement exists

Study will require a contractor who will have access to VA sensitive data. Specify contractor and services:

Data Use and Data Transfer Agreements (DUA &DTA) to be used for future protocols: refer to VHA Handbook 1200.12, Appendix C

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VASI - DEFINITION:

“VA Sensitive Information” (VASI) may include: (1) Individually-identifiable medical, benefits, and personnel information; (2) Financial, budgetary, research, quality assurance, confidential commercial, critical infrastructure, investigatory, and law enforcement information; (3) Information that is confidential and privileged in litigation, such as information protected by the deliberative process privilege, attorney work-product privilege, and the attorney-client privilege; and (4) Other information which, if released, could result in violation of law or harm or unfairness to any individual or group, or could adversely affect the national interest or the conduct of Federal programs.

Will all VA Sensitive Information (*VASI), as well as copies, be:

Stored within the VA and

Accessed by individuals with proper VA training who are VA employees, With Out Compensation (WOC) or on an IPA (Intergovernmental Personnel Act)?

Yes

No, Will study participants sign a **proper VA HIPAA Authorization Form** indicating that the VASI will be stored outside the VA? ***Or***, will the IRB submission include a request for **Waiver of HIPAA Authorization** where only de-identified data leaves the VA?

Yes

No, Explain

If No, Will a “VA Memo for Authorization to Transport VA Sensitive Information” be submitted?

Yes No

My study will obtain **VA HIPAA Authorization** and I verify that following areas are discussed:

- Subject identity
- Description of Information
- Authorization to Use or Disclose
- Recipient Identification
- Description of Purpose
- Expiration
- Signature and Date
- Right to revoke
- How to revoke
- Conditioning
- Data Protection and Re-disclosure

My study utilized full **WAIVER OF VA HIPAA Authorization** and I verify that following areas are covered in the VA HIPAA Recruitment Checklist:

- Minimal Risk Justification
- Need for Information
- Need for Waiver –
- Description of PHI
- USC 7332 Information - ***If*** a waiver of HIPAA authorization is utilized for records ***which include: drug abuse, alcohol abuse, HIV infection, or sickle cell anemia, then*** provide a written assurance on the HIPAA & Recruitment Checklist that:
 - A.** The purpose of the data is to conduct scientific research:
 - B.** 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 identifiers in any manner:

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<p>Data: Source, Collection</p> <p>How will the data be collected or acquired, including the source and method data is recorded, collected and destroyed?</p> <p>Data Source (Please check all that apply)</p> <ul style="list-style-type: none"> <input type="checkbox"/> Film <input type="checkbox"/> Treatment or Test Results, Medical and/or Dental Records, etc. <input type="checkbox"/> Electronic (e.g. CareWeb or Regenstrief Medical Record System, VA CPRS (VA medical record system), patient care database, etc.) <input type="checkbox"/> Interviews (Phone or Face-to-Face) <input type="checkbox"/> Survey or Questionnaire <input type="checkbox"/> Paper <input type="checkbox"/> Video <input type="checkbox"/> Audio <input type="checkbox"/> Photographs <input type="checkbox"/> Other 	<div style="border: 1px solid red; padding: 5px; display: inline-block;">Please describe in the box provided at the right</div>
<p>Data: Source, Collection</p> <p>Data Collection Method (Please check all that apply).</p> <p>Please note: Do not save any Research Records or Data on your desktop</p> <ul style="list-style-type: none"> <input type="checkbox"/> Laptop <input type="checkbox"/> Web-based <input type="checkbox"/> CDs, Flash Drive, External Hard drive, etc. <input type="checkbox"/> PDA (Personal Digital Assistant) <input type="checkbox"/> Paper (e.g. Notes, Case Report Form, etc.) <input type="checkbox"/> Local Network Shared Drive: <input type="checkbox"/> Video Audio <input type="checkbox"/> IU RedCap <input type="checkbox"/> Other 	<div style="border: 1px solid red; padding: 5px; display: inline-block;">Please describe in the box provided at the right</div>

<p>Data: Storage & Transportation</p> <p>A. Where (including Building & Room #) the identifiable data (original and all copies) is to be stored and corresponding security systems:</p> <ul style="list-style-type: none"> <input type="checkbox"/> On-Site at Indy VA <ul style="list-style-type: none"> <input type="checkbox"/> Paper, Location Address <input type="checkbox"/> Electronic, Network Location <input type="checkbox"/> Other/Location Address <input type="checkbox"/> Off-Site <ul style="list-style-type: none"> <input type="checkbox"/> Paper, Location Address <input type="checkbox"/> Electronic, Location Address <input type="checkbox"/> Network Location, (e.g. Research (Q):/PI Research Projects): <input type="checkbox"/> Encrypted Desktop Computer, VA <input type="checkbox"/> or Non VA <input type="checkbox"/> <input type="checkbox"/> Encrypted Laptop Computer, VA <input type="checkbox"/> or Non VA <input type="checkbox"/> <input type="checkbox"/> Encrypted Portable Data Assistant (PDA) , VA <input type="checkbox"/> or Non VA <input type="checkbox"/> 	<div style="border: 1px solid red; padding: 5px; display: inline-block;">Please describe in the box provided at the right</div>
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<input type="checkbox"/> Encrypted USB Thumb Drive, VA <input type="checkbox"/> or Non VA <input type="checkbox"/> <input type="checkbox"/> Encrypted External Hard Drive, VA <input type="checkbox"/> or Non VA <input type="checkbox"/> <input type="checkbox"/> Encrypted CDs or DVDs, VA <input type="checkbox"/> or Non VA <input type="checkbox"/> <input type="checkbox"/> Other/Location Address	
<p>B. How the VASI data is to be transported or transmitted from one location to another</p> <p>Indicate which secure method(s) of transmission will be used? Check all that apply:</p> <input type="checkbox"/> Secured web site <input type="checkbox"/> Encrypted email, PKI <input type="checkbox"/> US Postal Service or other trackable courier services (not campus mail) <input type="checkbox"/> Fax to a secured area <input type="checkbox"/> Shared drive with password protection <input type="checkbox"/> Personal delivery by authorized research personnel <input type="checkbox"/> Private telephone conversation to authorized personnel <input type="checkbox"/> Other:	<div style="border: 1px solid black; width: 100%; height: 100%;"></div> <div style="border: 1px solid black; width: 100%; height: 100%;"></div>

Please describe in the box provided at the right

<p>Data: Access & Security Measures</p> <p>C. Who is to have access to the data and how they are to access it (anyone who has access to the data is responsible for its security)</p> <input type="checkbox"/> Principal Investigator <input type="checkbox"/> Research Coordinator <input type="checkbox"/> Co-Investigators <input type="checkbox"/> Research Sponsor, Monitor, Other Research Organizations <input type="checkbox"/> ICRC <input type="checkbox"/> Governmental Agencies <input type="checkbox"/> IUPUI IRB or its designee <input type="checkbox"/> Other:	
<p style="text-align: center; font-size: small;">(e.g. BioStats, Collaborators, etc). These individuals and/or entities must also be listed on the VA R&DC Research Study Submission Form and VA HIPAA Authorization Form.</p> <p>How these individuals will access or receive the data, check all that apply:</p> <input type="checkbox"/> Use of the VA internal network <input type="checkbox"/> Secured web site <input type="checkbox"/> Encrypted email, PKI <input type="checkbox"/> US Postal Service or other trackable courier services (not campus mail) <input type="checkbox"/> Fax to a secured area <input type="checkbox"/> Shared drive with password protection <input type="checkbox"/> Personal delivery by authorized research personnel <input type="checkbox"/> Private telephone conversation to authorized personnel <input type="checkbox"/> Other:	<div style="border: 1px solid black; width: 100%; height: 100%;"></div> <div style="border: 1px solid black; width: 100%; height: 100%;"></div>
<p>D. All entities or individuals outside the VHA to whom the data is to be disclosed, and the justification for such disclosure and the authority (e.g., should match the HIPAA authorization)</p>	

Please describe in the box provided at the right

Please describe in the box provided at the right

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Is VASI removed physically from the VA, taken outside the VA electronic firewall, or shared with Non VA entities or individuals who are not VA employees or who do not have a WOC (Without Compensation) or IPA (Intergovernmental Personnel Act) appointment?

No

Yes, **please provide the rationale**

These individuals &/or entities (ie: Sponsoring Company, Cooperating University, etc.) **have been added to the HIPAA authorization form** before sharing or removing data from the VA Yes No

E. **Who is to have access and be responsible for the security** of the information?

A Coordinating Center

A statistician

The PI

Other, List:

Please describe in the box provided at the right

F. **Mechanisms used to account** for the information. Who is checking to make sure security measures are in place and how often is this being checked?

A Coordinating Center, frequency per their policy

A statistician, frequency per their policy

The PI, frequency (list):

Other, List: frequency (list):

Please describe in the box provided at the right

G. **Security measures** that must be in place to protect individually identifiable information if collected or used

Locking cabinets and doors

Information is located in an area with limited public access

Computers and/or files will be password-protected

PDAs and removable media (such as CDs, diskettes, etc.) will be FIPS 140-2 encryption compliant and kept in a secure location

Regular back-ups of electronic data.

NOTE: All electronic data should be backed up on a regular basis and stored in a secure location.

Describe any other measures you are using to safeguard the data:

Data: Access & Security Measures

Secure Transcription Service

Performed by local research staff

Vendor (e.g. PSI) Please list

Please describe in the box provided at the right

H. How and to whom a suspected or confirmed ***incidents, if it occurs, will be reported.**

PI

IRB, and subjects as directed by the IRB

VA ISO/PO (listed on the front of the checklist)

VA R&D office

Study Sponsor

***NOTED - Incidents include:** Theft or loss of data or storage media; unauthorized access of sensitive data or storage devices; or non-compliance with security controls.

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<p>Data: Specialized Electronic Research Tools</p> <p>A. Software – (Ref: VA Handbook 6500, Appendix D, ¶¶SA-6 and SA-7) Study specific software: <input type="checkbox"/> Yes, List where will it be purchased or obtained from: <input type="checkbox"/> No</p> <p>License required: <input type="checkbox"/> Yes, List who will fund the license: <input type="checkbox"/> No</p> <p>Will any of the Data generated using this software be stored in Temporary files on the computer’s hard drive: NOTE: This is not allowed as all data should be stored on a secure server <input type="checkbox"/> Yes <input type="checkbox"/> No</p> <p>B. Web Applications - (Ref: VA Directive and Handbook 6102 and VA Directive and Handbook 6502.3) Study specific Web Applications: <input type="checkbox"/> Internet Data Collection – must use VA’s http://va.wv1.va.gov/surveylicracker/: Contact VA ISO & RD for questions. <input type="checkbox"/> No <input type="checkbox"/> Yes, list the Security Features, for such purposes as recruiting subjects, completing questionnaires or processing data: List:</p>	<div style="border: 1px solid black; height: 40px; margin-bottom: 10px;"></div> <div style="border: 1px solid black; height: 40px; margin-bottom: 10px;"></div> <div style="border: 1px solid black; height: 100px;"></div>
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Please describe in the box provided at the right

<p>Closeout of VA Research – Requirements</p> <p>A. Will the data remain in a repository after this protocol closes?</p> <ol style="list-style-type: none"> i. <input type="checkbox"/> Yes ii. <input type="checkbox"/> I have contacted the IRB for requirements related to the protocol, consent & authorization forms related to this specific study and related to a separate repository protocol. iii. <input type="checkbox"/> I have contacted the R&DC office for guidance on the VA requirements for a data repository, per VHA Handbook 1200.12 iv. <input type="checkbox"/> No <p>B. Data Return & Data Secure Disposal</p> <ol style="list-style-type: none"> a. Will VA information (Electronic or Paper) be returned to the VA? <ol style="list-style-type: none"> i. <input type="checkbox"/> Yes, please contact the VA Research Service for sever location and paper long-term storage process ii. <input type="checkbox"/> No, explain why data will not be returned: iii. <input type="checkbox"/> N/A b. How long will you retain the identifiable data before discarding? <ol style="list-style-type: none"> i. <input type="checkbox"/> Minimum required by the VA policy, currently indefinitely or until redefined by National Archives & Records Administration (NARA) ii. <input type="checkbox"/> Per sponsor requirements, <i>if longer than VA policy</i> iii. <input type="checkbox"/> Other, Explain 	<div style="border: 1px solid red; padding: 10px; margin-bottom: 10px; text-align: center;">Please describe in the box provided below</div> <div style="border: 1px solid black; height: 100px; margin-bottom: 10px;"></div> <div style="border: 1px solid black; height: 100px;"></div>
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