**Department of Veterans Affairs**

**Checklist for Reviewing**

**Privacy, Confidentiality and Information Security in Research**

**Instructions for Use**



The Checklist for Reviewing Information Protection in Research is intended to be used collaboratively by principal investigators (PI), privacy officers (PO) and information security officers (ISO). When used as designed the checklist provides a forum for the PI to indicate how privacy and confidentiality of protected health information and security of VA data will be maintained. The PI may use the checklist as a guide to documenting the plan for privacy, confidentiality and security of data and information. Each item in the privacy and information security requirements sections is preceded by a subject that serves as an outline. The Checklist also provides the PO and ISO a forum to offer input on their respective reviews.

The Checklist may be completed electronically or manually based on the best practice for the facility. It is divided into sections that may be completed by the PI or a knowledgeable member of the PI’s staff.

Facilities are highly encouraged to utilize it in order to provide complete and consistent documentation. If a facility opts not to use the Checklist, PIs may want to utilize the outline properties of the checklist as privacy officers and information security officers will be expected to review studies against the requirements set forth in the Checklist and will be looking for documentation to support the review.

The completed checklist should become part of the IRB protocol file in accordance with VHA Handbook 1200.05, paragraph 38.

**Suggested Roles**:

The Research and Development Service should complete the Resource Contact Section and add any questions specific to the facility to the Comments Section.

The PI or study team member should complete the Study Information section and the Requirement column of questions 1 through 39. If additional space is needed for comments, the Comments Section on the last page may be used. The Principal Investigator should then sign the Signature Section. The signature should not be delegated by the PI.

The Privacy Officer should review the study documents and the checklist and complete the Met, Not Met and Comments columns of questions 1 through 22 and questions 40 through 42f. The Privacy Officer should indicate whether the study complies with policy or recommend changes by checking the appropriate box and signing in the Signature Section.

The Information Security Officer should review the study documents and the checklist and complete the Met, Not Met and Comments columns of questions 23 through 39. The Information Security Officer should indicate whether the study complies with the policy or recommend changes by checking the appropriate box and signing in the Signature Section.

**Resource Contacts**

The Resource Contacts section is intended to identify the facility’s Privacy Officer, Information Security Officer, Research Compliance Officer and Records Management Officer. It is informational for PIs and their study teams. The facility’s Research and Development Service should complete this section once and save it as a checklist template to be used by the PIs and their study teams.

**Study Information**

The Study Information section should be completed by the PI. It provides general information for POs and ISOs to be aware of when reviewing the study. Note that when a study is undergoing an amendment or annual review and the only change is adding study personnel, the individual completing the checklist should answer questions 1 and 23 then proceed to the Signature Section. Likewise, when the only change is removing study personnel from the study, the individual completing the checklist should complete the first two lines in the Study Information Section, answer question 38 and proceed to the Signature Section.

**Privacy Requirements and Information Security Requirements**

The Privacy and Confidentiality Requirements and Information Security Requirements sections should be completed by the PI or a study team member. The questions serve as guidance to the PI regarding the information that should be documented in the study in terms of privacy, confidentiality and information security policy. The PI may use the checklist as a guide to documenting the plan for information protection. Each item in the privacy, confidentiality and information security requirements sections is preceded by a subject that serves as an outline. Most of the questions are followed by a drop down list of source documents and a page number field. The PI should indicate 1) the specific source document where the requirement is discussed and 2) the page number of the source document. Also, after each requirement, a reference is cited for informational purposes.

PIs should document the plan for privacy, confidentiality and information security in a dedicated section of the protocol and address all appropriate requirements. It may not be necessary to document every item in the protocol. If an item does not apply to the study, it should be so stated on the Checklist.

PIs should not be expected to submit amendments to previously approved studies solely for the purpose of meeting the documentation requirements listed on the Checklist. PIs should consult with their IRB administrator regarding whether or not a change in data privacy, confidentiality or security requires an amendment to the protocol.

After the PI completes his/her part, the PO and ISO should then evaluate and validate the PI’s responses and indicate whether the study meets or does not meet the respective requirements. The PO and ISO also have a space to offer comments to the Institutional Review Board (IRB) and Research and Development Committee (RDC).

**Privacy Officer Approval**

The Privacy Officer Approval section should be completed by the PO after the IRB has approved the study. Here the PO should indicate whether the documents meet requirements for HIPAA compliance. There is also a space for comments.

**Customizable Section**

The Customizable Section is optional. It is available for facilities to use if needed. Questions for this section would need to be developed locally.

**Comments Section**

There is a comments section that may be used by the PI to provide additional information or further explain responses.

**Signature Section**

The Signature Section is for the signatures of the Principal Investigator, Privacy Officer and Information Security Officer. Local policy will dictate what is considered an acceptable signature, i.e. electronic signature or wet signature. This section is also where the PO and ISO should make a recommendation to the IRB or RDC for approval or changes to the study.

**Questions**

Questions regarding use of the Checklist should be referred to the IRB Administrator or R&D Committee Coordinator.

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Department of Veterans Affairs

Checklist for Reviewing

 Privacy, Confidentiality and Information Security in Research

**Resource Contacts**

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| --- | --- | --- |
| **Privacy Officer (PO) Name** | **E-Mail Address** | **Phone Number** |
| **Information Security Officer (ISO) Name** | **E-Mail Address** | **Phone Number** |
| **Research Compliance Officer (RCO) Name** | **E-Mail Address** | **Phone Number** |
| **Records Management Officer (RMO) Name** | **E-Mail Address** | **Phone Number** |

**Study Information**

|  |  |  |
| --- | --- | --- |
| Principal Investigator (PI) Name | E-Mail Address | Phone Number |
| Study Title | Protocol Number (if available) |
| Study Contact Name      | E-Mail Address      | Phone Number      |
| Check all of the following that apply to this submission: |
| **Purpose of Submission**:[ ]  New Protocol [ ]  Continuing Review [ ]  Amendment [ ]  Only change is adding study personnel. If so, answer questions 1 and 22 & proceed to Signature Section [ ]  Only change is study personnel have been removed from the study. If so, answer questions 37 and proceed to Signature Section[ ]  Change in data collection/use/storage/transmission/disposition [ ]  Change in HIPAA Authorization [ ]  Change in VA Informed Consent [ ]  Change in Data Use Agreement **Enrollment Status:** [ ]  Open [ ]  Closed **Funding Source:**  [ ]  None [ ]  VA/Coop Study [ ]  NIH or Other Government Agency [ ]  Private Funding. Specify:       **Data Use Information:**[ ]  Business Associate Agreement exists [ ]  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:         |

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| **Check any of the following HIPAA identifiers that may be collected and recorded during the course of the study:** |
| **[ ]  Names** | **[ ]  Social security numbers or scrambled SSNs** | **[ ]  Device identifiers and serial numbers** |
| **[ ]  E-mail addresses** | **[ ]  Medical record numbers** | **[ ]  URLs (Universal Resource Locator)** |
| **[ ]  All elements of dates (except year) associated with an individual & any age over 89. Specify:**  | **[ ]  Health plan beneficiary numbers** | **[ ]  IP addresses (Internet Protocol)** |
| **[ ]  Telephone numbers** | **[ ]  Account numbers** | **[ ]  Biometric identifiers including finger and voice print** |
| **[ ]  Fax numbers** | **[ ]  Certificate or license numbers** | **[ ]  Full face photographic images and any comparable images** |
| **[ ]  All geographic subdivisions smaller than state. Specify:**  | **[ ]  Vehicle IDs and serial numbers including license plate numbers** | **[ ] 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:** 1. **Application**
2. **HIPAA Authorization**
3. **Request for HIPAA waiver of authorization**
4. **VA Informed Consent**
5. **Request for waiver of VA Informed Consent**
6. **Attachment to Application. If applicable, please identify the specific attachment**
7. **Data Use Agreement or Data Transfer Agreement**
8. **Protocol**
9. **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**

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| **Column To Be Completed by Principal Investigator or Study Team Member** | **These Columns To Be Completed by Privacy Officer** **Based on Review of Source Documents** |
|  | **Requirement** | **Met** | **Not Met** | **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))** **[ ]  Yes [ ]  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 [ ]  Additional sources** |  |  |  |
| **3** | **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 1606.1 ¶14b)****Source** Choose an item. **Page Number       N/A [ ]  Additional sources** |  |  |  |
|  | **HIPAA Authorization** |  |  |  |
| **4** | **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 100.05, ¶9k.)****Source** Choose an item. **Page Number       N/A [ ]  Additional sources** |  |  |  |
| **5** | **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 [ ]  Additional sources** |  |  |  |
| **6** | **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 [ ]  Additional sources** |  |  |  |
| **7** | **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 [ ]  Additional sources** |  |  |  |
| **8** | **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 [ ]  Additional sources** |  |  |  |
| **9** | **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 [ ]  Additional sources** |  |  |  |
| **10** | **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 [ ]  Additional sources** |  |  |  |
| **11** | **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, ¶¶5b and 14b)****Source** Choose an item. **Page Number       N/A [ ]  Additional sources** |  |  |  |
| **12** | **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)****Source** Choose an item. **Page Number       N/A [ ]  Additional sources** |  |  |  |
| **13** | **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)****Source** Choose an item. **Page Number       N/A [ ]  Additional sources** |  |  |  |
| **14** | **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)****Source** Choose an item. **Page Number       N/A [ ]  Additional sources** |  |  |  |
| **15** | **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)****Source** Choose an item. **Page Number       N/A [ ]  Additional sources** |  |  |  |
|  | **Waiver of HIPAA Authorization** |  |  |  |
| **16** | **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)****Source** Choose an item. **Page Number       N/A [ ]  Additional sources** |  |  |  |
| **16a** | **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)****Source** Choose an item. **Page Number       N/A [ ]  Additional sources** |  |  |  |
| **16b** | **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)****Source** Choose an item. **Page Number       N/A [ ]  Additional sources** |  |  |  |
| **16c** | **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, ¶37b)****Source** Choose an item. **Page Number       N/A [ ]  Additional sources** |  |  |  |
| **17** | **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, ¶37b)****Source** Choose an item. **Page Number       N/A [ ]  Additional sources** |  |  |  |
| **18** | **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, ¶37b)****Source** Choose an item. **Page Number       N/A [ ]  Additional sources** |  |  |  |
| **19** | **Description of PHI: The request for waiver of HIPAA authorization includes a brief description of the protected health information. (Ref: VHA Handbook 1200-05, ¶37b)****Source** Choose an item. **Page Number       N/A [ ]  Additional sources** |  |  |  |
| **20** | **USC 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))****Source** Choose an item. **Page Number       N/A [ ]  Additional sources** |  |  |  |
| **21** | **Specimens: The study states whether specimens will be labeled with identifiable or de-identified information. (Ref: VHA Handbook 1200.05, ¶53)****Source** Choose an item. **Page Number       N/A [ ]  Additional sources** |  |  |  |
| **22** | **De-Identification of Data: The research protocol indicates that data will be de-identified and 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). (Ref: VHA Handbook 1200.05, ¶37b)****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 below:****Source** Choose an item. **Page Number       N/A [ ]  Additional sources** |  |  |  |

**Information Security Requirements**

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| **Column To Be Completed by Principal Investigator or Study Team Member** | **These Columns To Be Completed by Information Security Officer Based on Review of Source Documents** |
|  | Requirement | Met | Not Met | Comments |
| **23** | **Information Security Training: All study staff are up-to-date with Information Security Awareness Training and Rules of Behavior.** **(Ref: VA Directive 6500, ¶2a(5) and ¶3f(2) and VA Handbook 6500, Appendix D, ¶AT-2)** **[ ]  Yes [ ]  No**  |  |  |  |
| **24** | **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 [ ]  Additional sources** |  |  |  |
| **25** | **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)**  **Source** Choose an item. **Page Number       N/A [ ]  Additional sources**  |  |  |  |
| **26** | **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)****Source** Choose an item. **Page Number       N/A [ ]  Additional sources** |  |  |  |
| **27** | **Data Security Plan: Study describes how electronic data as well as paper records will be secured. (Ref: VHA Handbook 1200.05, ¶10j)****Source** Choose an item. **Page Number       N/A [ ]  Additional sources** |  |  |  |
| **28** | **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)****Source** Choose an item. **Page Number       N/A [ ]  Additional sources** |  |  |  |
| **29** | **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)****Source** Choose an item. **Page Number       N/A [ ]  Additional sources** |  |  |  |
| **30** | **Storage Location: The study identifies precisely where data and specimens will be stored, i.e. physical site, network location/server name (e.g. vhacbarsch), type of mobile storage device, building and room, etc.** **(Ref: VHA Handbook 1200.05, ¶10j and VA Handbook 6500, Appendix D, ¶Ac-19)****Source** Choose an item. **Page Number       N/A [ ]  Additional sources** |  |  |  |
| **31** | **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 122.05, ¶10j and VA Handbook 6500, Appendix D, ¶AC-19)****Source** Choose an item. **Page Number       N/A [ ]  Additional sources** |  |  |  |
| **32** | **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)** **Source** Choose an item. **Page Number       N/A [ ]  Additional sources** |  |  |  |
| **33** | **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)****Source** Choose an item. **Page Number       N/A [ ]  Additional sources** |  |  |  |
| **34** | **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)****Source** Choose an item. **Page Number       N/A [ ]  Additional sources** |  |  |  |
| **35** | **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)** **Source** Choose an item. **Page Number       N/A [ ]  Additional sources** |  |  |  |
| **36** | **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)****Source** Choose an item. **Page Number       N/A [ ]  Additional sources** |  |  |  |
| **37** | **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 37. (Ref: VHA Handbook 1200.12, ¶¶9-10 and RCS 10-1)****Source Choose an item. Page Number       N/A [ ]  Additional sources** |  |  |  |
| **38** | **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)****Source Choose an item. Page Number       N/A [ ]  Additional sources** |  |  |  |
| **39** | **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 and VA Handbook 6500, Appendix D, ¶AC-19, ¶PL-4, ¶IR-1, ¶IR-6)****Source** Choose an item. **Page Number       N/A [ ]  Additional sources** |  |  |  |

**Privacy Officer Approval**

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| **This section to be completed by the Privacy Officer** | **Met or N/A** | **Not Met** | **Comments** |
| **40** | **Has the IRB approved the study?** |  |  |  |
| **41** | **If applicable, does the HIPAA authorization comply with content requirements?** |  |  |  |
| **42** | **If applicable, has the IRB or Privacy Board approved the waiver of HIPAA Authorization? (If yes, answer questions 42a-42f)** |  |  |  |
| **42a** | **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.** |  |  |  |
| **42b** | **Is the IRB or Privacy Board identified in the memo/ letter?** |  |  |  |
| **42c** | **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 question must be addressed in the memo or other documentation.** |  |  |  |
| **42d** | **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?** |  |  |  |
| **42e** | **Has the memo or other documentation been signed by the IRB or Privacy Board Chair or other designated voting member?** |  |  |  |

**Customizable Section**

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**Comments Section**

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| **Use this section for additional comments by the study team.** |

**Signature Section**

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| --- |
| **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**  |

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| --- |
| **I have reviewed this study for compliance with VA and VHA privacy and confidentiality policy and offer the following input.****Signature or E-signature of Privacy Officer Date** **[ ]  Study Complies With Policy** **[ ]  Recommend Changes as Stated Above** |

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| --- |
| **I have reviewed this study for compliance with VA information security policy and offer the following input.** **Signature or E-signature of Information Security Officer Date [ ]  Study Complies With Policy [ ]  Recommend Changes as Stated Above** |

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