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 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. The Checklist is designed to be adaptable to the operations of the various IRBs. For example, an IRB may decide the PI needs to identify the source and page number where each requirement is documented. Another IRB may require all documentation to be in one location, i.e. in the application or protocol, under a specified section, and therefore not ask the PI to complete the source and page number for each question.

Facilities are highly encouraged to utilize the Checklist in order to provide complete and consistent documentation, especially for new studies. For studies undergoing continuing review, where there have been no changes to how data is collected, used, stored or disclosed, it may be permissible to just state there are no changes. 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 Customizable Section and save it as a template.

The PI or study team member should obtain the template, complete the Study Information section and the Requirement column of questions 1 through 42. 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, N/A and Comments columns of questions 1 through 25e. The Privacy Officer should indicate whether the study complies with policy or recommend changes by checking the appropriate box and signing in the Privacy Officer's Signature Section.

The Information Security Officer should review the study documents and the checklist and complete the Met, Not Met, N/A and Comments columns of questions 26 through 42. 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 Information Security Officer's 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 continuing review and the only changes are to study personnel, or other changes *not* related to data collection, use, storage, disclosure, or security, the individual completing the checklist should answer questions 1, 26 and if applicable 41.

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 may be asked to 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 preferably in a dedicated section of the application or protocol and address all appropriate requirements. It may not be necessary to document every item in the application or 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 information 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 should **not** rely solely on the responses to the Checklist. The PO and ISO also have a space to offer comments to the Institutional Review Board (IRB) and Research and Development Committee (RDC).

For Privacy Officer Use Only – HIPAA Approval

The Privacy Officer Use Only – HIPAA Approval section should be completed by the PO. The Privacy Officer is the right person to approve the HIPAA authorization to ensure it meets the requirements of VHA Handbook 1605.1, Paragraph 14.

Privacy Officer's Signature Section

Local policy will dictate what is considered an acceptable signature, i.e. electronic signature or wet signature. The Privacy Officer should review the study and the PIs responses on the checklist and comment on whether there are any privacy issues. If the initial review is also the final review, i.e. there are no privacy issues and there is no request for waiver of HIPAA authorization, the PO may proceed directly to the final signature line. The PO should check the box indicating that the study complies with policy and provide a final signature.

If, however, there are privacy issues that must be resolved or there is a request for waiver of HIPAA authorization, the PO should check the appropriate box (or boxes) and provide an initial signature. When the issues are resolved or the waiver is approved and documented by the IRB, the PO should review it again, check the box indicating that the Study Complies with Policy and provide a final signature.

Information Security Officer's Signature Section

Local policy will dictate what is considered an acceptable signature, i.e. electronic signature or wet signature. The Information Security Officer should review the study and the PIs responses on the checklist and comment on whether there are any information security issues. If the initial review is also the final review, i.e. there are no information security issues to be addressed; the ISO may proceed directly to the final signature line. The ISO should check the box indicating that the study complies with policy and provide a final signature.

If, however, there are information security issues that must be resolved, the ISO should check the appropriate box (or boxes) and provide an initial signature. When the issues are resolved, the ISO should review it again, check the box indicating that the Study Complies with Policy and provide a final signature.

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.

Principal Investigator's Signature Section

Local policy will dictate what is considered an acceptable signature, i.e. electronic signature or wet signature. The PI should not delegate his/her signature, as the signature conveys accuracy of the form to the IRB.

Questions

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