



**Department of Veterans Affairs
Jesse Brown VA Medical Center
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R&D 537/151
August 24, 2009
Version 1.0
Revised April 11, 2011

**SOP: Review of Research
Documents for Compliance with
Privacy Requirements**

PURPOSE

To describe the responsibilities of the Privacy Officer regarding the review of research documents for compliance with all applicable local, VA, and Federal requirements regarding privacy and confidentiality and the access, use, and/or disclosure of protected health information (PHI), and to describe the procedures for conducting and documenting the review of the research documents.

POLICY

In accordance with VHA policy, the Privacy Officer serves as an Ex-Officio member of the IRB. In addition, the Privacy Officer is also an Ex-Officio member of the R&D Committee.

RESPONSIBILITIES

The Privacy Officer is responsible for:

- a) Ensuring the proposed research complies with all applicable local, VA and other Federal requirements for privacy and confidentiality, by identifying, addressing, and mitigating potential concerns about proposed research studies, and by serving in an advisory capacity to the IRB and R&D Committee as a nonvoting member.
- b) Reviewing the proposed study protocol and any other relevant materials submitted with the IRB application. [**NOTE:** *It is not sufficient for the Privacy Officer to review a checklist completed by the investigator, and not the study protocol and related materials themselves.*]
- c) Completing a review of the proposed research and informing IRB of all their findings related to privacy and confidentiality. [**NOTE:** *The Privacy Officer is not responsible for approving or disapproving a study, nor does the Privacy Officer have the authority to prevent or delay IRB approval of a study.*]
- d) Identifying specific deficiencies in their review of the proposed research, and making recommendations to the options available to correct the deficiencies.

- e) Ensuring the proposed research is in compliance with relevant privacy and confidentiality requirements before the investigator initiates the study.
- f) Providing summary reports of their review and assessment of each study. The summary report must clearly:
 - (1) Indicate either that all applicable local, VA and other Federal requirements for privacy and confidentiality have been met, or
 - (2) Identify specific deficiencies and suggest available options for correcting those deficiencies.
- g) Providing their summary reports on each study to the Collaborative IRB staff within a time frame that does not prolong the study approval process. They must provide their summary reports prior to the convened IRB meeting at which the study is to be reviewed or, in the case of expedited review, prior to, the IRB approval determination of the IRB Chair, or designee. For exempt studies, they must submit their summary reports to both the ACOS for R&D and the Collaborative IRB, and ensure the study is in compliance before the study is initiated.
- h) Providing their final reports on each study to the R&D Office and the Collaborative IRB staff in a timely manner.

PROCEDURE

1. Research submissions including but not limited to, initial review, continuing review, amendments, and final reports, will be submitted to the R&D Office for review by the Privacy Officer prior to submission to the IRB. All research submissions are submitted to the R&D Office prior to the submission to the IRB regardless of whether the submission will be reviewed by the Convened IRB, via Expedited Review, or as a Claim of Exemption.
2. The Privacy Officer will conduct a review of the proposed study protocol and any other relevant materials submitted with the IRB application.
3. The Privacy Officer will provide an initial summary report of their review. The initial summary report will either a) indicate that all applicable local, VA and other Federal requirements for privacy and confidentiality have been met, or b) identify specific deficiencies and suggest available options for correcting those deficiencies.
4. The Privacy Officer will provide a copy of their initial summary report for each research submission to the Human Subject Research Specialist or designee. The Human Subject Research Specialist or designee cannot sign and release the JBVAMC IRB Protocol Submission Checklist until both the ISO and the Privacy Officer have completed a review of the submission and have provided copies of their initial summary reports.
5. After the Human Subject Research Specialist or designee signs and releases the JBVAMC IRB Protocol Submission Checklist, including copies of the ISO's and Privacy Officer's initial summary reports, the investigator submits the research submission to the IRB. The IRB considers the ISO's and Privacy Officer's initial summary reports to be a part of the research submission.
6. The Privacy Officer attends the Convened IRB meetings as an Ex-Officio member of the IRB, and provides any additional comments regarding the research submissions.
7. Any issues raised by the Privacy Officer, whether on the initial summary report or during the Convened IRB meetings, are communicated to the investigators as part of

the IRB correspondence. The Privacy Officer receives a copy of all communications sent to the investigators by the IRB.

8. The Collaborative IRB staff will contact the Privacy Officer to request a review of all changes that affect privacy and confidentiality in any manner including, but not limited to responses received from investigators, complaints and serious and/or continuing non-compliance. Whether further review is required by the Privacy Officer is determined on a case-by-case basis by the Collaborative IRB staff with the assistance of the Collaborative IRB co-chairs as needed. If further review by the Privacy Officer is required, the Collaborative IRB staff will coordinate the review process with the Privacy Officer including making the protocol files available for review.
9. Once all of the items raised by the IRB and the Privacy Officer are satisfactorily addressed, the research receives IRB approval or Exemption determination. The Privacy Officer receives a copy of the IRB approval or Exemption determination that is sent to the investigator. Following IRB approval or Exemption determination, the Privacy Officer will provide a final summary report to the R&D Office in a timely manner. The R&D Office will ensure that a copy of the final report is sent to the UIC VA Liaison and/or Collaborative IRB staff.
10. After the R&D Office receives a copy of the IRB approval or Exemption determination letter, the ISO final report, and the Privacy Officer final report, the ACOS/R&D Committee performs a review of the research. Only after the ACOS/R&D Committee approval letter is sent to the investigator may the research be initiated at the JBVAMC.
11. The Privacy Officer is also an Ex-Officio member of the R&D Committee. Any issues raised to the IRB by the Privacy Officer and/or by the IRB to the Privacy Officer may be further discussed at the RDC meeting.

REFERENCES

VHA Handbook 1605.1

VHA Directive 2007-040

VA Handbook 6500

VHA Handbook 1200.05

VHA Handbook 1200.01

APPENDIX A

Research **PRIVACY Review Checklist**

February 2009

Principal Investigator			
Title of study			
	INDICATOR	N/A, ✓ or X	COMMENTS
1.	Signed Research and Development Committee Letter, if VA Research		
2.	Signed IRB Approval Letter		
	a. IRB Approval Letter indicates the following was approved: Informed Consent Form and HIPAA authorization, or HIPAA waiver (as applicable)		
3.	IRB Stamped or Signed-Off Informed Consent Form (if applicable) NOTE: Even if the Informed Consent and HIPAA Authorization are one document, you must still complete the HIPAA Authorization review.		
4.	IRB recognition that HIPAA Authorization will be obtained (if applicable) NOTE: If HIPAA Authorization will be obtained from study subjects, also complete questions 8 — 17.		

5.	<p>IRB Documentation of Approval of HIPAA-compliant Waiver (if applicable)</p> <p>NOTE: If IRB approval of Waiver of HIPAA-compliant Authorization is required, also complete questions 18 — 29.</p>		
6.	<p>Will Protected Health Information be used for Recruitment of study subjects (e.g., names and addresses provided to Research prior to HIPAA Authorization being signed by study subject)?</p> <p>If so, then IRB approval of Waiver of HIPAA-compliant Authorization is required in addition to a HIPAA Authorization. Therefore, complete questions 8 — 17 and 18 — 29.</p>		
7.	<p>The research study protocol discusses protection of the privacy interests of subjects and/or protection of the research data.</p>		
	<p>INDICATOR HIPAA Authorization (to be signed by subject). When an authorization of the individual is required to release individually-identifiable information, the authorization must be in writing and include the following information: The identity, i.e., name and social security number, of</p>	<p>N/A, ✓ or X</p>	<p>COMMENTS</p>
8.	<p>A description of the information to be used or disclosed that identifies the information in a specific and meaningful fashion. If HIV, sickle cell anemia, drug and /or alcohol abuse treatment information is to be disclosed, this information must be specifically identified in the description.</p>		

9.	The name, or other specific identification, of the person(s), class of persons, or office designation(s) authorized to make the requested use or disclosure.		
10.	The name or other specific identification of the person(s), class of persons, or office designation(s) to which the agency may make the requested use or disclosure.		
	a. If research compliance monitors/research sponsors are going to obtain or receive PHI or case abstract forms, the authorization form must list these research compliance monitor/ sponsor under this section.		
11.	A description of each purpose of the requested use or disclosure. A statement such as "For research purpose" is sufficient, though a more detailed purpose is preferential.		
12.	An expiration date or event that relates to the individual or the purpose of the use or disclosure. Examples of appropriate expiration date language are as follows:		
	a. The statement "end of the research study" or similar language is sufficient if the authorization is for use or disclosure of individually-identifiable health information for research.		
	b. The statement "none" or similar language is sufficient if the authorization is for the agency to use or disclose individually-identifiable health information, including for the creation and maintenance of a research database or research repository.		

	INDICATOR	N/A, ✓ or X	COMMENTS
14.	The signature of the individual, or someone with the authority to act on their behalf, and date signed.		
15.	A statement that the individual has the right to revoke the authorization in writing except to the extent that the entity has already acted in reliance on it, and a description of how the individual may revoke the authorization (e.g., to whom the revocation is provided).		
16.	A statement that treatment, payment, enrollment, or eligibility for benefits cannot be conditioned on the individual completing an authorization. Participation in a research study may be conditioned on the individual signing the authorization (see 45 CFR 164.508 (b)(4(i)).		
17.	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. Waiver of HIPAA Authorization (45 CFR 164.512(i)(2) Documentation must include ALL of the following: 18. Identification of the IRB		
19.	Date of IRB approval of Waiver of HIPAA-compliant Authorization		

	Statement that alteration or waiver of authorization satisfies the following criteria:		
20.	The use or disclosure of the requested information involves no more than a minimal risk to the privacy of individuals based on, at least, the presence of the following elements:		
21.	An adequate plan to protect the identifiers from improper use and disclosure		
22.	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		
23.	Adequate written assurances that the requested information 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		