

# Department of Veterans Affairs

# Memorandum

Date: February 1, 2011

From: Angela Pluff, Syracuse Privacy Officer 

Subj: Research Reviews by the Privacy Officer

To: Bernadette Kalman, ACOS, Research, Deborah Collins, AO, Research

A recent review was conducted of the Privacy Officer responsibilities as a non-voting member of the Institutional Review Board (IRB) and as a result some required changes in our current review process were identified. Specifically, per VHA Handbook 1200.05, section 38, item g, the ISO and PO are responsible for "providing their summary reports on each study to the IRB staff...within the time frame that does not prolong the study approval process. They must provide their summary reports prior to, or at, 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 the ACOS for R&D, and ensure the study is in compliance before the study is initiated". Additionally, per the VHA Privacy Office, in conjunction with the VHA Office of Research and Development, the primary role of the Privacy Officer is to perform the following:

- 1) A cursory privacy review of research documentation prior to submission to the IRB.
- 2) A retrospective privacy review of research documentation after approval of the research study by the IRB.
- 3) Ensure legal authority exists prior to the use of Protected Health Information (PHI) for research (this includes assessment for HIPAA waivers granted by the IRB, if required).
- 4) Ensure legal authority exists prior to the disclosure of PHI to outside entities for research.
- 5) Approval of HIPAA authorization
- 6) Ensure an accounting of disclosures is being maintained by research staff disclosing PHI/PII outside of VA.
- 7) Develop policies, in conjunction with the Research Department, for the privacy review of documentation for all facility research studies.

Currently, for the Privacy Officers serving on the Syracuse VA's IRB, one of our primary roles is to review and sign off on the Data Security Checklist for Principle Investigators form in conjunction with the Information Security Officer. The main intent of the checklist is to determine if VA sensitive information is being transmitted or stored outside of the VA. This is the primary role of the Information Security Officer (ISO) and only the ISO has the expertise to determine if the transmission or storing of VA sensitive information outside of VA meets VA security requirements. In addition, this is not a mandated form and there is no mandate that the Privacy Officer be directly involved with this process.

As such, in order to be in compliance with VA requirements for the role of the Privacy Officer on the IRB, effective March 1, 2011 the Privacy Officers will no longer be signing off on the Data Security Checklist and their review will include the following:

- 1) Preliminary review of all initial study reviews, notifications and amendments presented on the monthly IRB agendas to determine if any HIPAA issues need to be addressed. The summary of HIPAA issues will be presented to the IRB either prior to the scheduled IRB meeting where these studies will be reviewed or at the scheduled IRB meeting. (NOTE: The Privacy Officer for Syracuse will review studies pertaining to Syracuse, the Canandaigua Privacy Officer for Canandaigua studies, etc).
- 2) Post review of all studies where there is a change in HIPAA requirements or for new studies where the HIPAA authorization must be approved. (NOTE: This is a continuation of the current practice established with the IRB Coordinator who sends notifications to the Privacy Officer when HIPAA authorization approvals are required and all necessary documentation required for the approval is posted to the IRB Share Point). A checklist developed and issued to facility Privacy Officers by the VHA Privacy Office will be utilized to conduct this review. As such, the supporting documentation needed from the IRB, at a minimum, to allow for this is as follows:

- Research Study Protocol
- Research and Development (R&D) Committee Approval Letter, if VA Research
- Research Study Institutional Review Board (IRB) Approval Letter
- Sample Informed Consent and HIPAA Authorization, if applicable to the Research Study
- IRB Approval of Waiver of HIPAA-compliant Authorization, if applicable

Your attention and cooperation to this matter is appreciated and will greatly assist the Privacy Officers in mitigating potential concerns about proposed research studies as well as serve in an advisory capacity to the IRB.

## **Review of Research Documentation for Compliance with Privacy Requirements**

Purpose: Ensure all of the legal privacy requirements have been met in order to use or disclose protected health information for research purposes. In order to accomplish this, a review of all of the documentation for research studies should be conducted prior to providing the protected health information requested. *Though a preliminary review can (and in most cases should) be conducted prior to IRB approval, the final privacy review cannot be conducted until after the IRB approves the Research Study.*

1. Determine, based on VHA Research policy, if the Research Study is VA Research or not.
  - a. If the Researcher is a VA employee, WOC employee or under a contract or IPA, or is conducting the research at VA facilities, then the privacy requirements listed in the Privacy Fact Sheet on Privacy Requirements for Use of Data for Research should be met.
  - b. If the Researcher is not a VA employee, WOC employee or under a contract or IPA, or is not conducting the research at VA facilities, then the privacy requirements listed in the Privacy Fact Sheet on Privacy Requirements for Disclosure of Data for Research should be met.
2. In order to conduct the final privacy compliance review for the Research Study the following documentation needs to be pulled:
  - Research Study Protocol
  - Research and Development (R&D) Committee Approval Letter, if VA Research
  - Research Study Institutional Review Board (IRB) Approval Letter
  - Sample Informed Consent and HIPAA Authorization, if applicable to the Research Study
  - IRB Approval of Waiver of HIPAA-compliant Authorization, if applicable
3. The Privacy Officer will review the documentation provided to ensure that the privacy requirements have been satisfied and may document the findings of the review using Attachment A. The final review cannot be accomplished until after the IRB approves the research study, as some of the documents to review are from the IRB.
  - a. Review the Research Study Protocol to determine what health information is specifically being requested for the Research Study. This information is normally listed in the Research Study Protocol under Methodology or Data Analysis. By reading the Research Study Protocol you will also be able to determine if the Researcher will be obtaining Informed Consents and HIPAA authorizations or if a waiver of HIPAA-compliant authorization is required due to protected health information being used for recruitment of subjects into the research study or other reasons.

**NOTE:** The IRB determines if the privacy protections for the data being collected and used for the Research Study are adequate. However, if the Privacy Officer has concerns about the privacy protections of the data as outlined in the Research Study Protocol, these concerns should be raised to the R&D Committee or IRB.
  - b. Review the R&D Committee Approval letter for VA Research studies to ensure approval was given for this particular research study and that it is signed by the Chair of the R&D

Committee. You are only determining if the Research Study was approved by the R&D Committee. This is a requirement from VHA Handbook 1605.1 Para 13.

c. Review the IRB Approval letter to ensure that the Research Study Protocol was approved; that the Informed Consent and HIPAA authorization were approved; and that a waiver of HIPAA-complaint authorization was approved and appropriately documented, if a waiver was required (see Privacy Fact Sheets on Research).

**NOTE:** A Waiver of HIPAA-compliant authorization may be required for recruitment purposes ever if a HIPAA authorization is going to be signed at a later date by the study subject.

d. If the IRB approved the waiver of HIPAA-compliant authorization but did not appropriately document the approval as required by the HIPAA Privacy Rule in the approval letter, you will need to obtain and review supporting documents, such as the IRB minutes, in order to determine if the documentation requirements are met. If upon review of these supporting documents the IRB approval of the waiver is not appropriately documented, these deficiencies must be brought to the attention of the Principal Investigator and/or IRB.

**NOTE:** Until the IRB approval of the waiver of HIPAA-compliant authorization is appropriately document as required by the HIPAA Privacy Rule, the Researcher may not use or collect any information for the Research Study as the privacy requirements have not been met.

e. Review the HIPAA authorization to determine if it contains all of the content requirements for authorizations as outlined in VHA Handbook 1605.1 Para 14. Also, review the Informed Consent only to ensure that the HIPAA authorization is consistent with the Informed Consent. If the HIPAA authorization is inconsistent with the Informed Consent bring this issue forward to the Principal Investigator and/or IRB.

4. If the HIPAA authorization or waiver of HIPAA-compliant authorization does not adequately address privacy requirements, then the facility should not provide the protected health information to the Researcher and the Researcher should not be allowed to collect information related to the Research Study.

5. Facility Privacy Officers should work closely with their Research Department, IRB and R&D Committee to ensure appropriate policies and processes are implemented to allow for the adequate review and documentation of privacy requirements in the most efficient manner possible.

Note: You can conduct this same review retrospectively for Research Studies that you did not get to review previously to ensure privacy requirements were met. The results of the review should be discussed with the facility's ACOS for Research and Research Department to correct any deficiencies found.

# 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)  <b>NOTE:</b> 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)  <b>NOTE:</b> If HIPAA Authorization will be obtained from study subjects, also complete questions 8 – 17.		
5.	IRB Documentation of Approval of HIPAA-compliant Waiver (if applicable)  <b>NOTE:</b> If IRB approval of Waiver of HIPAA-compliant Authorization is required, also complete questions 18 – 29.		
6.	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)?  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.		
7.	The research study protocol discusses protection of the privacy interests of subjects and/or protection of the research data.		

	INDICATOR	N/A, ✓ or X	COMMENTS
	<b>HIPAA Authorization</b> (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:		
8.	The identity, i.e., name and social security number, of the individual to whom the information pertains. <b>Note:</b> <i>Social Security number added to template 3/9/07. This was not in the ORD template.</i>		
9.	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.		
10.	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.		
11.	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.		
12.	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.		
13.	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.		
	<b>Waiver of HIPAA Authorization (45 CFR 164.512(i)(2) Documentation must include ALL of the following:</b>		
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		

	by the Privacy Rule;		
24.	The research could not practicably be conducted without the waiver or alteration; and		
25.	The research could not practicably be conducted without access to and use of the requested information.		
26.	A brief description of the PHI for which the IRB has determined use or disclosure to be necessary		
27.	In accordance with 38 USC 7332 (Applicable to Drug Abuse, Alcohol Abuse, HIV Infection, and Sickle Cell Anemia Records). The PI provides assurance in writing that the purpose of the data is to conduct scientific research and that no personnel involved in the study 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.		
28.	Identification of the review procedure used to approve the waiver of authorization (either normal review procedures (Full Board) or expedited review procedures). (On IRB Approval Letter)		
29.	Signature of chair of the IRB or member designated by the chair to approve the waiver of authorization. (On IRB Approval Letter)		
	<b>NOTE:</b> When the IRB has a form for the Principal Investigator to fill out requesting a Waiver of HIPAA-compliant Authorization, this form may be used to satisfy the IRB document requirements if the form has been reviewed and approved by the IRB. One way you may determine this is by the presence of an IRB date stamp with initials or signature and date by the IRB reviewer or chairperson on the form.		

Additional Comments:
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Name of Privacy Officer	Date Review Completed