

## **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. 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.

1. Determine 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, 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, 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 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 no Informed Consent required for the Research Study
3. The Privacy Board will review the documentation provided to ensure that the privacy requirements have been satisfied and document the findings of the review using Attachment A.
  - 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 protected health information being used for recruitment of subjects into the research study or other reasons.
  - 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.
  - c. Review the IRB Approval letter to ensure that the Research Study Protocol was approved and that a waiver of HIPAA-complaint authorization was approved and appropriately documented, if required, (see Privacy Fact Sheets on Research) or that informed consent and HIPAA authorization was approved.
  - 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 supporting documents, such as the IRB minutes in order to complete the review.
  - e. If informed consent and HIPAA authorization was approved by the IRB, review the informed consent form and HIPAA authorization to determine if it contains all of the content requirements for an authorization as outlined in VHA Handbook 1605.1 Para 14.

4. If any of the documentation does not adequately address privacy requirements, then the facility should not provide the protected health information to the Researcher.

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

Principal Investigator				
Number and title of study				
	Informed Consent Elements	N/A, ✓ or X		COMMENTS
		ENG	SPAN	
1.	Statement that the study involves research			
2.	Purpose of the research			
3.	Expected duration of subject's participation			
4.	Projected number of subjects to be recruited			
5.	Description of the procedures.			
6.	Identification of procedures that are experimental			
7.	Description of anticipated risks and discomforts			
8.	Statement that if the participant is or becomes pregnant, the particular treatment or procedure might involve risk to the embryo or fetus, which is currently unforeseeable.			
9.	If blood is drawn (venipuncture); indicate side effects			
10.	Identify blood samples disposition			
11.	Description of benefits to the subject and others			
12.	Disclosure of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject			
13.	How confidentiality of records will be protected confidentiality of records and identity will be maintained (who may examine records)			
14.	A statement that the FDA may inspect the records even if drugs/devices with an IND or IDE are not involved			
15.	A statement that in the event of a research-related injury, the VA will provide necessary medical treatment to a participant injured by participation			
16.	Additional cost that may result from participation			
17.	A statement that a veteran-participant would not be required to pay for care received as a participant in a VA research study except in accordance with federal law and that certain veterans were required to pay co-payment for medical care and services provided by VA.			
18.	Whom to contact regarding questions about the research or an injury that may result			
19.	Whom to contact regarding rights as a research subject. The Research Subjects Rights page must be included in VA Form 10-1086 (English /Spanish)			
20.	A statement indicating that the participant could discontinue participation at any time without penalty or loss of benefits to which the participant was otherwise entitled.			
21.	Circumstances under which the subject's participation may be terminated by the PI without the consent of subject			
22.	Amount and schedule of payment to subject for compensation			
23.	Consequences of subject's decision to withdraw from the research and procedures for orderly termination from the study by the participant			
24.	Statement that new significant findings developed during the course of the research will be provided to subject to determine willingness to continue participation			
25.	Statement indicating that project was approved by IRB – IRB approval letter and date stamped informed consent			
26.	A statement indicating whom to contact to voice concerns or complaints about the research			
27.	Statement that participation is voluntary			
28.	A statement that a copy of the signed and dated form will be provided to the subject			
29.	Language minimizes possibility of coercion or undue influence			
30.	Free of exculpatory language			

	<b>HIPAA Authorization (to be signed by subject).</b> When an authorization of the individual is required to release individually-identifiable information, the authorization must be in writing and include the following information:			
31.	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>			
32.	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.			
33.	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.			
34.	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.			
35.	Are research compliance monitors/research sponsors authorized by subject to receive III?			
36.	A description of each purpose of the requested use or disclosure. A statement “at the request of the individual” is sufficient when an individual initiates the authorization and does not, or elects not to, provide a statement of the purpose.			
37.	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:			*should say “has no expiration date”
	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.			
	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.			
38.	The signature of the individual, or someone with the legally authorized power of attorney signed and dated.			
39.	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).			
40.	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)).			
41.	If you properly execute this HIPAA authorization for disclosure of your protected health information (PHI) to an affiliate institution, transfer of the information to the affiliate sever constitutes a “disclosure” under HIPAA, after which VA no longer owns the transferred information.			
42.	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.			

	INDICATOR	N/A, ✓ or X	COMMENTS
	<b>Waiver of HIPAA Authorization (45 CFR 164.512(i)(2) Documentation must include ALL of the following:</b>		
43.	Identification of the IRB		
44.	Date of IRB approval of waiver of authorization (date stamp on authorization form)		
	Statement that alteration or waiver of authorization satisfies the following criteria:		
45.	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:		
46.	An adequate plan to protect the identifiers from improper use and disclosure		
47.	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		
48.	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;		
49.	The research could not practicably be conducted without the waiver or alteration; and		
50.	The research could not practicably be conducted without access to and use of the requested information.		
51.	A brief description of the PHI for which the IRB has determined use or disclosure to be necessary		
52.	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.		
53.	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)		
54.	Signature of chair of the IRB or member designated by the chair to approve the waiver of authorization. (On IRB Approval Letter)		

Additional Comments:	

Name of Privacy Officer or Information Sec. Officer	Date Review Completed
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**References:** VHA Handbook 1200.5, AAHRPP, HIPAA Privacy Rule, Common Rule

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