Department of Veterans Affairs

VHA RESEARCH PROTOCOL PRIVACY REVIEW CHECKLIST

STUDY INFORMATION

(To be completed by the Principal Investigator or other applicable research study personnel prior to sending to the Privacy Officer)

Study Title		Protocol Number *(if available)*
Principal Investigator (*PI*) Name	VA E-Mail Address	Phone Number
Co-Principal Investigator (*PI*) Name	VA E-Mail Address	Phone Number
Study Coordinator (*if applicable*)	VA E-Mail Address	Phone Number

Check all that apply to this submission:

Purpose of Submission:

☐ New Protocol *(Preliminary review must be completed prior to IRB approval/action or R&D if not reviewed by IRB and a Final Review after IRB/R&D approval.)*

☐ Continuing Review or Amendment: *(Review only required if changes made during Continuing Review or Study Amendment which have an impact on the safeguarding and protection of the privacy and confidentiality of human subjects and study data)*

Date of Initial IRB Approval: _____

Type of Review: ☐ Expedited Review ☐ Full Board ☐ Exempt Category: ____

Date of Initial R&D Approval: _____

☐ Change in data collection/use/storage/transmission/disposition ☐ Change in VA Informed Consent

☐ Change in Request for Waiver of HIPAA Authorization ☐ Change in Data Use Agreement (*DUA*)

☐ Change in HIPAA Authorization

Study Status:

☐ Open ☐ Closed for recruitment/data analysis only ☐ Closed: data analysis complete

Study Sponsor/Monitor:

☐ None ☐ VA/Cooperative Studies Program *(CSP)* ☐ NIH or Other Government Agency

☐ Private Funding/Monitor *(Specify)*: _____

Protected Health Information/Individually Identifiable Health Information *(PHI/IIHI)* Accessed, Collected or Disclosed:

☐ Yes ☐ No *(Privacy Review not Required. Notify Privacy Officer)*

Will the PI obtain written authorization from the human research subject or their representative before accessing or collecting PHI/IIHI?

☐ Yes ☐ No

Will the PI access or collect PHI/IIHI before obtaining or without needing written authorization from the human research subject or their representative?

☐ Yes ☐ No

Will a contractor or other non-VA personnel have access to the research data?

☐ Yes *(Specify who will have access)*: _____ ☐ No

Will the PI access or obtain Centers for Medicare and Medicaid (CMS) data on the human research subjects?

☐ Yes *(Requires DUA)* ☐ No

Storage of Research Data:

How is the research data stored?

☐ Paper ☐ Electronic ☐ Both

Location(s) where the data is or going to be stored *(bldg., room, office, cabinet, URL, etc., indicate if stored in non-VA location(s))*:

Will bio-specimens or a data repository be maintained for future/additional research studies not part of the current proposed study?

☐ Yes *(Specify type of specimens/repository)*: _____ ☐ No

PRELIMINARY REVIEW of Human Subject Research Study for Privacy and Confidentiality Requirements

1 General Privacy and Confidentiality Requirements

Privacy Officers are to conduct a review of proposed human subject research studies prior to submission to the IRB, or R&D if not reviewed by an IRB, to ensure that adequate safeguards to protect human subjects and the data from inappropriate access, use, disclosure and destruction are in place and are compliant with current policy and regulation. According to facility policy and practice, the Privacy Officer should work with the Principal Investigator and/or other members of the research team to address areas of non-compliance or concerns stemming from the privacy review.

VHA Directive 1200.01 Paragraph 5.h.(6), Paragraph 5.k., and Paragraph 12

	Requirement	Compliant *(Yes/No/N/A)*	Comments
1.1	**Privacy Interests:** Does the protocol outline the requirements for the protection of the privacy interests of research subjects and the research data?		
1.2	**Data Use:** Does the research protocol or other documentation contain a statement regarding how data will be used by each VA and non-VA entity that will have access to the research data?		
1.3	**Access, Use & Disclosure of PHI/IIHI with Authorization:** Is a signed, written Research HIPAA Authorization required? *(If yes, complete Section 2).* ***NOTE:*** *In-person research interactions with study subjects will require a Research HIPAA Authorization.*		
1.4	**Access, Use & Disclosure of PHI/IIHI without Authorization:** If PHI/IIHI is accessed, used or disclosed without written authorization from the subject, has a waiver of HIPAA authorization been requested from the IRB? *(If yes, complete Section 3).*		
1.5	**Disclosure of PHI/IIHI to non-VA entity**: If PHI/IIHI is disclosed to a non-VA entity, was legal authority for making the disclosure addressed in the protocol, Research HIPAA Authorization or Waiver of HIPAA Authorization?		
1.6	**De-Identification of Data:** If the study data will be de - identified, was the method described consistent with VHA Handbook 1605.1, Appendix A? **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 HIPAA 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. contracted statistician*) ☐ De-identified information will be disclosed to a non-VA party listed below: List parties to whom de-identified information will be disclosed:		
1.7	**Bio-specimens:** If bio-specimens are collected, do the study documents include whether the specimens will be labeled with identifiable, coded or de-identified information?		

Research HIPAA Authorization VHA Directive 1605.01 Paragraph 14, Authorization Requirements VA Form 10-0493, Authorization for Use & Release of Individually Identifiable Health Information for VHA Research		
	Requirement	Compliant *(Yes/No/N/A)*
2	Is a signed, written Research HIPAA Authorization being combined with the Research Informed Consent Form *(ICF)*?	
	Does the study include tissue or data banking for future use? *(If yes, a combined Research Informed Consent with Research HIPAA Authorization is not permitted. VA Form 10-0493 MUST be used).*	
	Does the study include any voluntary or optional component of the study requiring separate Research Informed Consent? *(If yes, then a combined Research Informed Consent with Research HIPAA Authorization is not permitted. NOTE: VA Form 10-0493 MUST be used).*	
	Is the Research HIPAA Authorization Form template *(or elements if combined with the Informed Consent Form)* required for disclosing protected health information compliant with VHA Directive 1605.01 Para. 14?	
	Response Criteria: *A compliant authorization contains the following elements: Place for individual subject's full name; clear and specific description of the information to be used/disclosed; List of people and organizations authorized to use AND disclose; Purpose for each use AND disclosure; Expiration Date or specific event when authorization expires; Signature lines for research subject signature; Right to revoke statement and conditions of revocation; Statement regarding not conditioning care, treatment or eligibility based on not signing authorization; Separation of Conditional v. Unconditional activities. *Place for signature of subject or personal representative and date is included as part of the template.*	Comments:
Request for Waiver of HIPAA Authorization VHA Directive 1200.05 Paragraph 23a.b. Waiver of HIPAA Authorization; VHA Directive 1605.01 Paragraph 13a. (6)		
	Requirement	Compliant *(Yes/No/N/A)*
3	Was a request to access protected health information without a HIPAA Authorization *(i.e., waiver of HIPAA Authorization)* submitted to the IRB or R&D Committee acting as a Privacy Board?	
	Does the waiver of HIPAA Authorization contain all required elements to permit approval in accordance with VHA Directive 1605.01 and VHA Directive 1200.05?	
	Response Criteria: *Response is based on the review of the Principal Investigator's (PI) request to the IRB for waiving the requirements to obtain written authorization from human subject(s) for obtaining PHI/IIHI. The request must contain a statement: 1) indicating the use of PHI poses no more than minimal risk to the privacy of the research subjects; 2) explaining how the research could not practicably be conducted without the waiver; 3) explaining how the research could not practicably be conducted without access to PHI; and 4) briefly describing the PHI sought (e.g., demographics, progress notes, medical Hx, diagnoses, labs, etc.). The PO review is only to determine that this information is in the request not that it is adequate.*	Comments:
	Requirement	Compliant *(Yes/No/N/A)*
	Does the waiver of HIPAA Authorization indicate what PHI and databases will be accessed and for what specified study activities *(e.g., recruitment, entire study)* as outlined in the Protocol?	
	Response Criteria: *The waiver of HIPAA Authorization must state what PHI is going to be accessed (not just the identifiers) and it should match what is stated in the protocol. While not required in the wavier, if the waiver indicates what databases (e.g., CPRS, VINCI, CDW) will be used to access the PHI, this information must match the protocol.*	

	Requirement	Compliant *(Yes/No/N/A)*
	Does the waiver of HIPAA Authorization cover disclosures of PHI/IIHI, including 38 USC 7332-protected information, outside of VA?	
	Response Criteria: *Either the request or protocol must provide assurance in writing that the purpose of the data containing 38 USC 7332 information was for scientific research only and there will be no attempt to identify directly or indirectly any subjects in the research data. In addition, Privacy Act authority will be required.*	Comments:

VHA Notice of Privacy Practices (Non-Veteran Subjects)

VHA Handbook 1605.04; VHA Directive 1200.01 Paragraph 13f

	Requirement	Compliant *(Yes/No/N/A)*
4	If the study includes non-Veterans in clinical trials, is there a process to provide the subjects with a copy of the VHA Notice of Privacy Practices?	
	Response Criteria: *Response is based on the review of the research study documents and the recruitment of non-Veterans in clinical trials. The process must include providing the non-Veteran with a copy of the VHA Notice of Privacy Practices and obtaining the signed (VA) Form 10-0483, Acknowledgement of the Notice of Privacy Practices.*	Comments:

Records Management

VHA Directive 1200.01 Paragraph 10b; VHA Directive 1200.05 Paragraph 5g. (15); VHA Directive 1200.01 Paragraph 10.b.(1)

	Requirement	Compliant *(Yes/No/N/A)*
5	Do the research protocols ensure custody and disposition of VA Federal Records are maintained in accordance with RCS 10-1?	
	Response Criteria: *Response is based on the review of the research study documents outlining the requirements for maintaining Federal records according to the VHA Records Control Schedule (RCS) 10-1.*	Comments:

Privacy Officer's Signature Section

A **PRELIMINARY REVIEW** of this study for compliance with VA privacy and confidentiality policy was completed on *(Date):* _____

_____
Signature or E-signature of Privacy Officer

***NOTE**: Recommended changes or concerns must be addressed or corrected prior to approval by IRB, or R&D (if not reviewed by an IRB). A final review must be completed after IRB approval to ensure any changes made to the privacy and confidentiality safe guards of human subjects and the data are in compliance with current policy and regulation and proper legal authority exists to access PHI/IIHI in accordance with VHA Directive 1605.01 (e.g., properly documented approval of a request for a waiver of HIPAA authorization).*

FINAL REVIEW of Human Subject Research Study for Privacy and Confidentiality Requirements

General Privacy Requirements

The Privacy Officer must conduct a review of the human subject research study documents after IRB approval or R&D Committee approval, even if study is IRB Exempt, to ensure any changes made to the privacy and confidentiality safeguards of human subjects and the data are in compliance with current policy and regulation and proper legal authority exists to access PHI/IIHI in with VHA Directive 1605.01 *(e.g., properly documented approval of a request for a waiver of HIPAA authorization).*

VHA Directive 1200.01 Paragraph 5.h.(6)

	Requirement	Compliant *(Yes/No/N/A)*
6	If deficiencies or concerns were identified with the Research HIPAA Authorization or waiver of HIPAA Authorization during the preliminary review of the research study, were they corrected?	
	Response Criteria: *The PI must correct any issues with the Research HIPAA Authorization template prior to final approval by the PO. The PO approves the authorization not the IRB. If the Research HIPAA Authorization is combined with the Research Informed Consent, the PO's issues with the authorization language must be addressed prior to the start of the study.*	Comments
	Additional Comments:	

Documented Approval of a Request for Waiver of HIPAA Authorization

VHA Directive 1200.05 Paragraph 23b. Waiver of HIPAA Authorization VHA Directive 1605.01 Paragraph 13a. (6)

	Requirement	Compliant *(Yes/No/N/A)*
7	Does the documented approval of a request for waiver of HIPAA Authorization contain all elements in accordance with VHA Directive 1605.01 and VHA Directive 1200.05?	
	Response Criteria: *Response based on the review of the documented approval of a request to waive HIPAA Authorization was made to the IRB or R&D Committee acting as a Privacy Board.* *An IRB or Privacy Board approval must include: 1) date request was approved; 2) statement that the use or disclosure of PHI involves no more than a minimal risk to the privacy of individuals based on: 2a) "An adequate plan to protect the identifiers from improper use and disclosure"; 2b) "an adequate plan to destroy the identifiers at the earliest opportunity consistent with conduct of research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law" ; and 2c) "adequate written assurances that the PHI will not be reused or disclosed except as required by law, for authorized oversight of the research for which the use or disclosure of PHI would be permitted by the Privacy Rule"; 3) a statement that the research could not practicably be conducted without a waiver; 4) a statement that the research could not practicably be conducted without access to and use of the requested information; 5) brief description of the PHI for which the IRB has determined use or disclosure to be necessary; 6) the review procedure used to approve the waiver of HIPAA authorization (e.g., Expedited); 7) signature of the Chair or a qualified voting member designated by the Chair or the IRB or Privacy Board.*	Comments

Privacy Officer's Signature Section

A **FINAL REVIEW** of this study for compliance with VA privacy and confidentiality policy was completed on *(Date)*: _____

_____
Signature or E-signature of Privacy Officer

Note: *This checklist should become part of the IRB protocol file in accordance with VHA Directive 1200.05, paragraph 13 and part of the R&D protocol file (if not reviewed by the IRB) in accordance with VHA Directive 1200.01, paragraph 11 & 12.*