Privacy and Information Security Review of Research Protocol

1. Purpose: To delineate the process for obtaining Information Security Officer and Privacy Officer approval of research protocols as appropriate.

2. Policy: VA Directive and Handbook 6500, Information Security Program requires that sensitive and confidential information owned by the VA be protected from unauthorized disclosure to the public. The approving officials for information protection for human studies are the Privacy Officer and the Information Security Officer. The approval authority for animal protocols is the Information Security Officer (ISO).

3. Scope: The first part of this document addresses human research information protection. The second half of this document addresses animal research protection.

4. Procedures:

a. Human Subjects

(1) The Privacy Officer and the Information Security Officer have similar but not identical documentary needs. Only submit the documents that are pertinent to your particular study. It is best to submit documents at least 10 days before Institutional Review Board's deadline for submission of new protocols to ensure that any necessary changes are made prior to submission. See the table below for specifics

Document	Privacy	Information Security Officer
Checklist for Reviewing Privacy, Confidentiality and Information Security in Research	X	X
The Research Protocol(s)	X	X
VA Informed Consent Form	X	X
HIPAA Authorization for Release of Protected Health Information for Research Purposes	X	X
Request for Waiver or Alteration of Informed Consent and HIPAA Authorization for Research	X	X

Waiver of Documentation of Informed Consent	X	X
Other documents pertinent to a patient's privacy	X	

(2) Documents should be submitted to both Officers at the same time. Documents should be submitted electronically. Electronic signature using PKI soft certificates or the PIV card is acceptable. No other form of electronic signature is acceptable. If you wish to submit paper documents, you may. If you submit paper documents, they should first be provided to the Privacy Officer. Do not submit one set of paper documents to the Privacy Officer and a different set of paper documents to the Information Security Officer. The Primary Investigator should sign the checklist before it is provided to either Officer.

(3) When using the Checklist be sure to use a fillable form. If the form you have is not fillable, there is one available in the Research folder on the VA's S: drive.

(4) In the field next to Source, click on the drop down box and choose the document that fulfills the requirement. Be sure to enter the page number. If the requirement is not applicable mark it as such. You may enter comments in the "Comments" column.

Privacy and Confidentiality Requirements

Column To Be Completed by Principal Investigator or Study Team Member		These Columns To Be Completed by the PO Based on a Review of Source Documents			
	Requirement	Met	Not Met	N/A	Comments
1	**<u>Privacy Training:</u> All study staff are up-to-date with VHA Privacy Policy Training.** **(Ref: VHA Handbook 1200.05, ¶61a and VHA Handbook 1605.1, ¶3(4))** ☐ **Yes** ☐ **No**				
2	**<u>Privacy Interests</u>: Provisions have been made to protect the privacy interests of subjects and the protection of research data. (Ref: VHA Handbook 1200.05, ¶ 10j and VHA Handbook 1605.1, ¶ 14b)** **Source** Choose an item. **Page Number** **N/A** ☐ **Additional sources**				

3	**<u>Data Use</u>: There is a statement in the IRB submission package or protocol regarding how data will be used by each VA and non-VA entity that will have access.** **(Ref: VHA Handbook 1200.05, ¶10j and VHA Handbook 1605.1 ¶14b)** **Source** Choose an item. **Page Number** **N/A** ☐ **Additional sources**				

(5) Once all reviews are completed, you will be notified by email or telephone.

b. Animal Protocols

(1) The requirements for protection of animal research data are much simpler as there is no privacy component. Because of this the Checklist for Reviewing Privacy, Confidentiality and Information Security in Research is not appropriate. A new checklist has been developed just for animal protocols: ISO Animal Protocol Review Checklist (Animal Checklist). It was developed from the ISO Checklist by removal of items pertaining to human subjects protection.

(2) This Animal Checklist is located in the Research folder on the VA's S: drive.

(3) The Animal Checklist should be submitted to the IACUC. The IACUC will be responsible for sending the checklist to the ISO and insuring its return to Research Service.

5. Questions about this procedure can be addressed to the ISO at 919-286-6839.

Approved

Theresa G. Lynch

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Theresa G. Lynch
Information Security Officer

Emily C. Fuemmeler

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Emily C. Fuemmeler
Privacy Officer