**Appendix NN**

**Checklist for Reviewing Privacy, Confidentiality**

**and Information Security in Research**

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| --- | --- | --- |
| **Privacy Officer (PO) Name**  **Karyn Stodden, RHIA**  **(alternate: Danielle Dobish)** | **E-Mail Address**  [**Karyn.Stodden@va.gov**](mailto:Karyn.Stodden@va.gov)  **(Danielle: Danielle.Dobish@va.gov)** | **Phone Number**  **402 995-3427**  **(Danielle: 308-382-3660 ext. 92420)** |
| **Information Security Officer (ISO) Name**  **Lawrence Green**  **(alternate: Bill Ramage)** | **E-Mail Address**  [**Lawrence.Green@va.gov**](mailto:Lawrence.Green@va.gov)  **(Bill: William.Ramage@va.gov)** | **Phone Number**  **402-995-3558/Cell 402-682-1794**  **(Bill: 402-995-3858/Cell 402-210-0315)** |
| **Research Compliance Officer (RCO) Name**  **Bonnie Farkas** | **E-Mail Address**  **Bonnie.Farkas@va.gov** | **Phone Number**  **402 995-3021** |

**Study Information**

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| --- | --- | --- | --- | --- | --- |
| Principal Investigator (PI) Name | E-Mail Address | | | Phone Number | |
| Study Title | | | | Protocol Number (if available) | |
| Study Contact Name | E-Mail Address | | | Phone Number | |
| Check all of the following that apply to this submission: | | | | | |
| **Purpose of Submission**: (check all that apply)  New Protocol  Amendment for change in data collection/use/storage/ transmission/disposition/Data Use Agreement | | **Type of Protocol**  Human  Animal  Bench/Science only | **Enrollment Status**  Open  Closed | | **Funding Source:**  None  VA/Coop Study  NIH or Other Government Agency  Private Funding. Specify: |
| **Data Use Information:** (check all that apply)  Affiliation Agreement exists (Check this if the external research partner is CU or UNMC; the VA has an affiliate agreement with both UNMC and CU.)  Business Associate Agreement exists (Not necessary if an affiliation agreement exists. Necessary when working with an entity that provides data collection, survey and clinical accessibility services and will have access to participant PHI and study team does not want to obtain individual Release of Information (ROI) forms from each patient)  Data Use Agreement or Data Transfer Agreement exists (Human Research only. Anytime VA data is given to a non-VA entity for use or storage, you must have a DUA/DTA. A DUA/DTA is still necessary even if working with limited data sets) If you are a dual appointment employee storing VA data in VA leased space at the University, technically you haven’t given it to a non-entity and therefore wouldn’t need a DUA.  Videos, pictures or audio recordings will be obtained  Study will require a contractor who will have access to VA sensitive data. Specify contractor and services: | | | | | |
| **Instructions for completing the following sections of the checklist, if applicable:**  **Human Research Protocols: You must answer all 39 questions.**  **Animal Protocols and/or Science ONLY Protocols: Follow the directions below.**  **All Protocols: This Checklist requires PIs to submit additional “Source Documentation” to the ISO and PO; the source documents required are identified in “red” type. Don’t forget to check the N/A box, when appropriate, to ensure all questions are answered. The ISO and PO will not review until all fields on the form are completed.** | | | | | |
| **Animal Protocols and/or Science ONLY protocols**: In general, animal research does not generate sensitive data, but a risk assessment of the animal study must be done to determine any potential for harm to the VA from unauthorized use or release of the data. For the purposes of this form, DNA and/or genetic information is considered sensitive if it can be used to specifically identify an individual. Critical to all protocols is the idea that all VA data is owned by the VA and must be protected.  If you answer “Yes” or “N/A” to the following two questions, you may just answer item #36 below, contact the ISO to discuss your protocol, and obtain all signatures on last page before including this document with your submission package. If you answer “No” to either question, you **must** answer question **#3 AND #36** prior to contacting the ISO/PO for signatures.  A. All research data for this VA protocol is used and stored within the VA.  Yes  No  N/A  B. All copies of VA research information/files are used and remain within the VA.  Yes  No  N/A | | | | | |

**Privacy and Confidentiality Requirements**

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| --- | --- | --- | --- | --- |
| **Column To Be Completed by Principal Investigator or Study Team Member** | | **These Columns To Be Completed by Privacy Officer**  **Based on Review of Source Documents** | | |
|  | **Requirement** | **Met** | **Not Met** | **Comments** |
| **1** | **Privacy Training: 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** |  |  |  |
|  | **Human Research Protocol Worksheet (Appendix T)** |  |  |  |
| **2** | **Privacy Interests: 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: Human Research Protocol Worksheet (Appendix T item #9) N/A**  **Additional sources** |  |  |  |
| **3** | **Data Use: 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. Sharing with entities outside of VA will require a Data Use Agreement (consult your ISO).**  **ANIMAL AND SCIENCE ONLY PROTOCOLS: Explain in the comments section how data will be shared and what entities will have access to the data. Sharing with entities outside of VA will require a Data Use Agreement (consult your ISO).**  **(Ref: VHA Handbook 1200.05, ¶10j and VHA Handbook 1605.1 ¶14b)**  **Source: Human Research Protocol Worksheet (Appendix T item #10A) N/A**  **Additional sources** |  |  |  |
| **4** | **Consistency: The HIPAA authorization contains similar language as the application, protocol and informed consent with regard to the protected health information to be used or disclosed, entities to whom information will be disclosed, expiration of authorization, and purpose.**  **(Ref: VHA Handbook 1200.05, ¶9k.)**  **Source: Human Research Protocol Worksheet (Appendix T item #10b) and HIPAA Authorization (Appendix Z). N/A**  **Additional sources** |  |  |  |
| **5** | **De-Identification of Data: The research protocol indicates that data will be de-identified and the method described truly de-identifies the data according to VHA Handbook 1605.1, Appendix B, Paragraph 2a (document statistical determination) or Paragraph 2b (removal of all 18 individually-identifiable information). (Ref: VHA Handbook 1200.05, ¶37b)**  **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 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. statistician)**  **De-identified information will be disclosed to a non-VA party listed below:**    **Source: Human Research Protocol Worksheet (Appendix T items #8n-r) N/A  Additional sources** |  |  |  |
| **6** | **Specimens: The study states whether specimens will be labeled with identifiable or de-identified information. (Ref: VHA Handbook 1200.05, ¶53)**  **Source: Human Research Protocol Worksheet (Appendix T item #10c) N/A  Additional sources** |  |  |  |
|  | **HIPAA Authorization (Appendix Z)** |  |  |  |
| **7** | **Subject Identity: The HIPAA authorization has a place for the subject’s identity, i.e. name. (Ref: VHA Handbook 1605.1, ¶14b.)**  **Source: HIPAA Authorization (Appendix Z) N/A  Additional sources** |  |  |  |
| **8** | **Description of Information: The protected health information to be used or disclosed is specifically listed on the HIPAA authorization. Note: If HIV, sickle cell anemia, drug and/or alcohol abuse treatment information will be disclosed, it must be specifically stated in the HIPAA Authorization. (Ref: VHA Handbook 1605.1, ¶14b)**  **Source: HIPAA Authorization (Appendix Z) and Human Research Protocol Worksheet (Appendix T item #8m)**  **N/A  Additional sources** |  |  |  |
| **9** | **Authorization to Use or Disclose: The HIPAA authorization identifies the people and organizations authorized to make the requested use or disclosure. (Ref: VHA Handbook 1605.1, ¶14b)**  **Source: HIPAA Authorization (Appendix Z) N/A  Additional sources** |  |  |  |
| **10** | **Recipient Identification: The HIPAA authorization identifies to whom the information will be disclosed or released for use. (Ref: VHA Handbook 1605.1, ¶14b)**  **Source: HIPAA Authorization (Appendix Z) N/A  Additional sources** |  |  |  |
| **11** | **Description of Purpose: The HIPAA authorization includes a description of each purpose for which the information will be used or disclosed. A statement such as “for research purposes” is sufficient, though a more thorough description is preferred. If the study will eventually close, but the data will remain in a repository, the authorization should cover both events. (Ref: VHA Handbook 1605.1, ¶14b)**  **Source: HIPAA Authorization (Appendix Z) N/A  Additional sources** |  |  |  |
| **12** | **Expiration: The HIPAA authorization includes a date or event that explains when the authorization expires. “End of the research study” is sufficient for III in research. “None” is sufficient for III including for the creation and maintenance of a research database or research repository. (Ref:VHA Handbook 1605.1, ¶14b)**  **Source: HIPAA Authorization (Appendix Z) N/A  Additional sources** |  |  |  |
| **13** | **Signature and Date: The HIPAA authorization contains the signature line of the subject as well as the date signed. If subjects who are incompetent or lack decision making capacity will be included, a signature line for the person legally authorized in writing by the individual (or the individual’s legal guardian) to act on behalf of the individual, (i.e. power of attorney) is listed. (Ref:VHA Handbook 1605.1, ¶5b and 14b)**  **Source: HIPAA Authorization (Appendix Z) N/A  Additional sources** |  |  |  |
| **14** | **Right to Revoke: The HIPAA authorization includes a statement that the subject has the right to revoke the authorization in writing, except to the extent that the entity has acted in reliance on it. (Ref : VHA Handbook 1605.1, ¶14b)**  **Source: HIPAA Authorization (Appendix Z) N/A  Additional sources** |  |  |  |
| **15** | **How to Revoke: The HIPAA revocation statement includes a description of how the subject may revoke the authorization, i.e. to whom it should be submitted. (Ref: VHA Handbook 1605.1, ¶14b)**  **Source: HIPAA Authorization (Appendix Z) N/A  Additional sources** |  |  |  |
| **16** | **Conditioning: The HIPAA authorization includes a statement that treatment, payment, enrollment, or eligibility for benefits cannot be conditioned on the subject completing the authorization, but participation in the study may be conditioned on the subject signing the authorization. (Ref VHA: Handbook 1605.1, ¶14b)**  **Source: HIPAA Authorization (Appendix Z) N/A  Additional sources** |  |  |  |
| **17** | **Data Protection and Re-disclosure: The HIPAA authorization includes 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. (Ref: VHA Handbook 1605.1, ¶14b)**  **Source: HIPAA Authorization (Appendix Z) N/A  Additional sources** |  |  |  |
| **18** | **Waiver of HIPAA Authorization**  **Minimal Risk Justification: The waiver of HIPAA authorization is justified because the use of information includes no more than minimal risk to the privacy of the subjects. If so, the requirements in 16a, 16b and 16c below must be met. (Ref: VHA Handbook 1200-05, ¶37b)**  **Source: HIPAA Waiver of Authorization (Appendix BB) N/A  Additional sources** |  |  |  |
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| **18a** | **Written Assurance of Protection: The request for waiver of HIPAA authorization provides adequate written assurance that the requested information will be protected from improper use and disclosure and 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 HIPAA Privacy Rule. (Ref: VHA Handbook 1200-05, ¶37b)**  **Source: HIPAA Waiver of Authorization (Appendix BB) N/A  Additional sources** |  |  |  |
| **18b** | **Protection of Identifiers: The request for waiver of HIPAA authorization provides an adequate plan to protect the identifiers from improper use and disclosure. (Ref: VHA Handbook 1200-05, ¶37b)**  **Source: HIPAA Waiver of Authorization (Appendix BB) N/A  Additional sources** |  |  |  |
| **18c** | **Destruction of Identifiers: The request for waiver of HIPAA authorization provides an adequate written 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. (Ref: VHA Handbook 1200-05, ¶37b)**  **Source: HIPAA Waiver of Authorization (Appendix BB) N/A  Additional sources** |  |  |  |
| **19** | **Need for Information: The request for waiver of HIPAA authorization explains why the research could not practicably be conducted without access to and use of the requested information. (Ref: VHA Handbook 1200-05, ¶37b)**  **Source: HIPAA Waiver of Authorization (Appendix BB) N/A  Additional sources** |  |  |  |
| **20** | **Need for Waiver: The request for waiver of HIPAA authorization explains why the research could not practicably be conducted without the waiver. (Ref: VHA Handbook 1200-05, ¶37b)**  **Source: HIPAA Waiver of Authorization (Appendix BB) N/A  Additional sources** |  |  |  |
| **21** | **Description of PHI: The request for waiver of HIPAA authorization includes a brief description of the protected health information. (Ref: VHA Handbook 1200-05, ¶37b)**  **Source: HIPAA Waiver of Authorization (Appendix BB) N/A  Additional sources** |  |  |  |
| **22** | **USC 7332 Information: If the waiver of HIPAA authorization is for the use of 38 USC 7332 information (applicable to drug abuse, alcohol abuse, HIV infection, and sickle cell anemia records), there is assurance in writing that the purpose of the data is to conduct scientific research and that no personnel involved 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. (Ref: 38 U.S.C. 7332(b)(2)(B))**  **Source: HIPAA Waiver of Authorization (Appendix BB) N/A  Additional sources** |  |  |  |

**Information Security Requirements**

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| --- | --- | --- | --- | --- |
| **Column To Be Completed by Principal Investigator or Study Team Member** | | **These Columns To Be Completed by Information Security Officer Based on Review of Source Documents** | | |
|  | Requirement | Met | Not Met | Comments |
| **23** | **Information Security Training: All study staff are up-to-date with Information Security Awareness Training and Rules of Behavior.**  **(Ref: VA Directive 6500, ¶2a(5) and ¶3f(2) and VA Handbook 6500, Appendix D, ¶AT-2)**  **Yes  No** |  |  |  |
| **2** | **Software: The study identifies specially obtained software that will be used, the source of the software, whether a license will be required, who will fund the license as well as any data that will be stored in temporary files on the computer’s hard drive. (Ref: VA Handbook 6500, Appendix D, ¶SA-6 and SA-7)**  **Source: Human Research Protocol Worksheet (Appendix T item #8) N/A  Additional sources** |  |  |  |
| **25** | **Removal of VA Sensitive Information from the VA Protected Environment: The study states whether or not research data is intended to be removed from the VA protected environment.**  **(Ref: VHA Handbook 122.05, ¶10j and VA Handbook 6500, Appendix D, ¶AC-19)**  **Source: Human Research Protocol Worksheet (Appendix T item #8b) N/A  Additional sources** |  |  |  |
| **26** | **Protection of Media Stored at Alternate Site: If the study team plans to store VA sensitive information outside the VA protected environment, the study indicates by what method it will be protected. (Ref: VHA Handbook 1200.05, ¶10j and VA Handbook 6500, Appendix D, ¶PE-17)**  **Source: Human Research Protocol Worksheet (Appendix T item #8c) N/A  Additional sources** |  |  |  |
| **27** | **Data on a Hard Drive Data on Portable Electronic Devices and/or Removable Media: Will data be stored on a portable electronic device and/or removable media and if so, have the devices/media been properly encrypted?**  **(Ref: VHA Handbook 1200.05, ¶10j)**  **Source: Human Research Protocol Worksheet (Appendix T item #8e) N/A  Additional sources** |  |  |  |
| **28** | **Web Applications: The study identifies any web application, as well as its security features, that will be used for such purposes as recruiting subjects, completing questionnaires or processing data.**  **(Ref: VA Directive and Handbook 6102 and VA Directive and Handbook 6502.3)**  **Source: Human Research Protocol Worksheet (Appendix T item #8f) N/A  Additional sources** |  |  |  |
| **29** | **Data Transmission: The study states how sensitive electronic information will be securely transmitted. Note: VA sensitive data or information may only be transmitted using VA-approved solutions such as FIPS 140-2 validated encryption.**  **(Ref: VA Handbook 6500, Appendix D, ¶MP-1)**  **Source: Human Research Protocol Worksheet (Appendix T item #8g) N/A  Additional sources** |  |  |  |
| **30** | **Mobile Devices: The study states that all mobile devices will be encrypted and that the encryption is FIPS 140-2 validated. Note: All mobile/portable devices and media and any information transmitted to and from a wireless device must be protected with VA approved encryption technology that is FIPS 140-2 validated.**  **(Ref: VA Handbook 6500, Appendix D, ¶AC-19)**  **Source: Human Research Protocol Worksheet (Appendix T item #8h) N/A  Additional sources** |  |  |  |
| **31** | **Data Backup: The study indicates that mobile storage devices do not contain the only copy of research information. Original electronic VA research data stored on a mobile device or outside the VA protected environment will be backed up regularly and stored securely within VA’s protected environment. (Ref: VA Handbook, Appendix D, ¶AC-19)**  **Source: Human Research Protocol Worksheet (Appendix T item #8i) N/A  Additional sources** |  |  |  |
| **32** | **Shipping Data: Study indicates whether sensitive research data that must be sent via common carrier will be encrypted with FIPS 140-2 validated encryption if it is electronic and will be sent via delivery service with a chain of custody. (Ref: VA Handbook 6500, Appendix D, ¶AC-19 and VA Directive 6609)**  **Source: Human Research Protocol Worksheet (Appendix T item #8j) N/A  Additional sources** |  |  |  |
| **33** | **Data Return: The study includes a statement regarding what VA information will be returned to the VA, how the information will be returned to the VA, or plans for its destruction. Note: VA research data and information must be retained in accordance with the applicable VA Records Control Schedule (RCS), which is a set of rules established by the Federal government that states when Federal agencies are allowed to dispose of records. Prior to destruction of research records, the PI should contact the Records Management Officer for current policy.**  **(Ref: RCS 10-1, VHA Handbook 1200.12, ¶9-10)**  **Source: Human Research Protocol Worksheet (Appendix T item #8k) N/A  Additional sources** |  |  |  |
| **34** | **Data Flow: The study includes a description of the data collection, data flow and/or data management process that will be used during the course of the study.**  **(Ref: VHA Handbook 1200.05, ¶10j)**  **Source: Human Research Protocol Worksheet (Appendix T item #13) N/A  Additional sources** |  |  |  |
| **35** | **Data Security Plan: Study describes how electronic data as well as paper records will be secured. (Ref: VHA Handbook 1200.05, ¶10j)**  **Source: Human Research Protocol Worksheet (Appendix T item #13) N/A  Additional sources** |  |  |  |
| **36** | **Storage Location: The study identifies precisely where data and specimens will be stored, i.e. physical site, network location/server name (e.g. vhacbarsch), type of mobile storage device, building and room, etc. (Ref: VHA Handbook 1200.05, ¶10j and VA Handbook 6500, Appendix D, ¶Ac-19)**  **Source: Human Research Protocol Worksheet (Appendix T item #13) N/A  Additional sources**  **ANIMAL AND SCIENCE ONLY PROTOCOLS: Provide explanation in comments section regarding storage of VA research data per above:** |  |  |  |
| **37** | **Data Destruction: The study includes a description of the methods that will be used to destroy data at the end of its life cycle. Note: If the protocol states information will not be returned to the VA, the protocol must state how and when the information will be destroyed. See note above in Question 36. (Ref: VHA Handbook 1200.12, ¶9-10 and RCS 10-1)**  **Source: Human Research Protocol Worksheet (Appendix T item #13) N/A  Additional sources** |  |  |  |
| **38** | **Termination of Data Access: The study states that removal of access to research study data will be accomplished for study personnel when they are no longer part of the research team. (Ref: VA Handbook 6500, Appendix D, ¶AC-2)**  **Source: Human Research Protocol Worksheet (Appendix T item #13) N/A  Additional sources** |  |  |  |
| **39** | **Incident Reporting: In accordance with VA policy, procedures are in place for reporting incidents, i.e. theft or loss of data or storage media, unauthorized access of sensitive data or storage devices or non-compliance with security controls. (Ref: VHA Handbook 1200.05, ¶10j and VA Handbook 6500, Appendix D, ¶AC-19, ¶PL-4, ¶IR-1, ¶IR-6)**  **Source: Human Research Protocol Worksheet (Appendix T item #13) N/A  Additional sources** |  |  |  |

**For Privacy Officer Use Only – HIPAA Validation**

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| --- | --- | --- | --- | --- |
| **This section to be completed by the Privacy Officer** | | **Met or N/A** | **Not Met** | **Comments** |
| **40** | **If applicable, does the HIPAA authorization comply with content requirements?** |  |  |  |

**Signature Section**

**Principal Investigator’s Signature Section**

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| **As the Principal Investigator on this study, I have read the above document and agree the information contained herein is correct.**  **Signature or E-signature of Principal Investigator Date:** |

**Information Security Officer’s Signature Section**

**Comments and/or recommendations needing attention prior to signature:**

**⬜ This study has been reviewed and is in compliance with data security regulations and policies.**

**Signature or E-signature of Information Security Officer Date:**

**Privacy Officer’s Signature Section**

**Privacy Officer’s Signature Section**

**Comments and/or recommendations needing attention prior to signature:**

**⬜ This study has been reviewed and is in compliance with VA Privacy and confidentiality policies.**

**Signature or E-signature of Privacy Officer Date:**