TITLE: VA Central IRB HIPAA Responsibilities

1.0 PURPOSE

This Standard Operating Procedure (SOP) sets forth the policies and procedures the VA Central IRB uses when reviewing human participant research projects that involve the use of Protected Health Information (PHI) as defined under the 45 CFR Parts 160 and 164, otherwise known as the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule.

2.0 REVISION HISTORY

<table>
<thead>
<tr>
<th>Date of Initial Approval</th>
<th>July 18, 2008</th>
</tr>
</thead>
<tbody>
<tr>
<td>Revision Dates</td>
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<td></td>
<td>November 2, 2009</td>
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<td>March 26, 2010</td>
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<td>February 14, 2011</td>
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<td>August 10, 2011</td>
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3.0 SCOPE

This standard operating procedure applies to all investigators involved with human participant research projects involving the use of PHI that are submitted to the VA Central IRB for review or are under the oversight of the VA Central IRB. It also applies to VA Central IRB members and the VA Central IRB administrative staff.

4.0 POLICY

4.1 It is the policy of the VA Central IRB to conduct all its research project reviews involving the use of PHI in accordance with the Privacy Rule and VHA Handbook 1605.1, Privacy and Release of Information.

4.1.1 A written HIPAA authorization signed by the individual to whom the information or record pertains is required when VA health care facilities need to utilize individual-identifiable health information for a purpose other than treatment, payment, or health care operations, e.g., research.

4.1.2 Authorization for use or disclosure of psychotherapy notes is not combined with any other authorization for a use or disclosure unless the other authorization is also for a use or disclosure of psychotherapy notes.

4.2 It is the policy of the VA Central IRB that the HIPAA authorization must not be part of the informed consent document but should be submitted separately. The VA Central IRB accepts local participating facility HIPAA authorization forms as part of local site investigator application packages, as long
as they contain all the elements required by VHA Handbook 1605.1, paragraph 14b. The local site investigator HIPAA authorizations must also be based on the model HIPAA authorization approved by the VA Central IRB as part of the PI/SC Application.

4.3 It is VA policy that investigators accessing patient records for recruitment of research participants receive prior approval by an IRB of the research project and IRB approval of both a waiver of informed consent and a waiver of the HIPAA authorization requirement if there is no prior authorization and/or consent. This includes investigators wanting to obtain information from their own patients' records.

5.0 DEFINITIONS

See VA Central IRB SOP 128, Definitions Used in VA Central IRB SOPs.

6.0 RESPONSIBILITIES

6.1 Investigators are responsible for obtaining the authority to use individually identifiable health information from non-employee research project participants prior to accessing and using the information.

6.1.1 If there is no prior written authorization, investigators are responsible for requesting a waiver of the required HIPAA authorization from the VA Central IRB in accordance with this SOP.

6.1.2 In addition, investigators are responsible for accessing, using, disclosing, handling, securing, and storing the data in accordance with the provision of VHA Handbook 1605.1 and other VA requirements, to include maintaining an accounting of disclosures.

6.2 The VA Central IRB is responsible for reviewing all research projects submitted involving the use of PHI in accordance with VHA Handbook 1605.1 and VHA Handbook 1200.5, Requirements for the Protection of Human Subjects in Research.

6.2.1 The VA Central IRB can grant waivers of the HIPAA authorization requirement if the project meets all required waiver criteria.

6.2.2 The VA Central IRB reviews all HIPAA authorizations submitted as part of the project. A HIPAA authorization may not be part of the informed consent document and must be submitted separately. The VA Central IRB does not approve the HIPAA document but does ensure that the HIPAA authorization is consistent with the informed consent, the protocol, and the PI/SC New Project Application.
6.3 The VA Central IRB Privacy Officer Representative is responsible for reviewing all new project applications to ensure they comply with all VA and other requirements for the protection of individually-identified health information and for completing the required assurance of compliance as required by VA Central IRB SOPs. The VA Central IRB Privacy Office Representative will also review all amendments that concern a change in the use of Protected Health Information (PHI).

6.4 The VA Central IRB administrative staff is responsible for documenting the results of all VA Central IRB determinations in regards to requests for waivers of HIPAA authorization both in the meeting minutes and in the VA Central IRB determination letter to the PI/SC in accordance with this SOP and in accordance with VA Central IRB SOP 115, Recording and Distribution of VA Central IRB Meeting Minutes, and VA Central IRB SOP 111, VA Central IRB Communications with Investigators and Local Participating Sites. The VA Central IRB staff is also responsible for ensuring the final concurrence of the Privacy Officer Representative on the VA Central IRB is obtained if only an interim review was obtained at initial review.

7.0 PROCEDURES

7.1 Preparation by Investigators of HIPAA Authorization or Request for Waiver or Alteration of HIPAA Authorization.

7.1.1 PI/SCs are required to develop model HIPAA authorization forms as part of their PI/SC New Project Application packages if such authorization is required based on their project design. LSIs can use these models to complete their local HIPAA authorization forms and attach them to their application packages. All submitted HIPAA authorization forms must contain all the elements required by VHA Handbook 1605.1, paragraph 14b.

7.1.2 The PI/SC may also request a waiver or alteration of the requirement to obtain the HIPAA authorization by submitting a VA Central IRB Form 103, Request for Waiver of HIPAA Authorization Requirement (Attachment). If the PI/SC submits a VA Central IRB Form 103 for the entire project and it is approved, the LSIs do not need to submit any additional VA Central IRB Forms 103 with their local applications.

7.1.3 LSIs may request a waiver of HIPAA authorization for the purposes of participant recruitment only if they need access to PHI as part of their local participating site's recruitment methodology and strategy, and such a waiver was not requested as part of the PI/SC Application. If this is the case, LSIs can attach a copy of the VA Central IRB Form 103 to their application package.

7.2 Receipt of Application Packages and Review by the VA Central IRB Privacy Officer Representative
7.2.1 Upon receipt of the application packages, the VA Central IRB administrative staff performs an administrative review and prepares the applications for review in accordance with VA Central IRB SOP 108, VA Central IRB Convened Meeting Preparation. The staff ensures all required HIPAA authorization forms or waiver requests are included in the applications prior to sending them to the members for review.

7.2.2 The Privacy Officer Representative to the VA Central IRB must review all project applications involving the use of PHI to ensure that all VA and other requirements pertaining to safeguarding PHI are addressed and met by the investigators.

7.2.2.1 The Privacy Officer Representative performs this review in accordance with VA Central IRB SOP 108, completes the VA Central IRB Form 123, Privacy Officer Compliance Review, and returns the completed form to the VA Central IRB Administration Office within 10 working days of being notified that a project requires review. This form must be received by the VA Central IRB Administration Office prior to final approval of the project being granted by the VA Central IRB.

7.2.2.2 If the Privacy Officer has comments that need to be addressed by the study team or needs to review the IRB approval of a HIPAA waiver request, an interim certification can be provided. Once approval is granted by the VA Central IRB, the Privacy Officer will then provide a final certification within five working days. If the HIPAA Privacy Rule does not apply to a particular project, the VA Central IRB Privacy Officer Representative will state this on the certification form and provide these comments as a final certification within ten working days.

7.2.3 For amendment requests or requests for continuing review, a review by the Privacy Officer Representative is only required under the following circumstances:

7.2.3.1 The Primary Reviewer may request that the Privacy Officer Representative also review the submitted request and provide an updated VA Central IRB Form 123. If the Primary Reviewer determines this is necessary, the Reviewer informs the VA Central IRB Administrative Office. The VA Central IRB staff then sends a copy of the project package and a blank VA Central IRB Form 123 to the Privacy Officer for performance of the review or makes it available on the secure SharePoint site. The continuing review or amendment request may not then be approved until a completed VA Central IRB Form 123 is received from the Privacy Officer Representative with any comments.

7.2.3.2 If substantive changes are made in the HIPAA authorization or an amendment involves a change in the use of PHI, the VA Central IRB administrative staff will automatically prepare a certification form for
the VA Central IRB Privacy Officer Representative. This is sent, along with the amendment request or continuing review package for review by the VA Central IRB Privacy Officer Representative, whether the project is expedited or to be reviewed at a convened meeting.

7.3 VA Central IRB Review of HIPAA Authorizations and Requests for Waiver of the Required Authorization

7.3.1 The VA Central IRB reviews all HIPAA authorization requests and the associated project documentation received to ensure they meet the criteria for a HIPAA authorization as detailed in VHA Handbook 1605.1, paragraph 14b, and that they are consistent with the informed consent document, the protocol, and the PI/SC New Project Application. No project is approved by the VA Central IRB if the HIPAA authorization forms are not compliant with the Privacy Rule and VA requirements.

7.3.2 If a waiver has been requested, the VA Central IRB reviews the submitted VA Central IRB Form 123 and the associated project documentation to ensure the requirements for approval of a waiver are met. The investigator may request a waiver for only certain phases of a study or for the entire study. The VA Central IRB ensures all the following criteria are met prior to granting approval of a waiver request:

7.3.2.1 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:

- An adequate plan to protect the identifiers from improper use or disclosure,
- An adequate plan to destroy the identifiers at the earliest opportunity consistent with the 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
- Adequate written assurances have been provided 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

7.3.2.2 The research could not practicably be conducted without the waiver or alteration.

7.3.2.3 The research could not be practicably conducted without access to and use of the requested information.

7.3.2.4 The alteration or waiver will not adversely affect the privacy rights and welfare of the individuals.
7.3.2.5 The privacy risks to individuals whose PHI is to be used or disclosed are reasonable in relation to the anticipated benefits if any to the individuals, and the importance of the knowledge that may reasonably be expected to result from the research.

7.4 Documentation of VA Central IRB Review and Approval of a Waiver Request

7.4.1 The VA Central IRB minutes will contain specific documentation that the criteria indicated in paragraph 7.3.2 of this SOP were met.

7.4.1.1 The minutes will also contain a brief description of the PHI for which use or access had been determined to be necessary by the VA Central IRB or will reference VA Central IRB Form103 on which the PHI is listed. Additional documentation will be provided in the VA Central IRB minutes for those studies reviewed by the convened IRB that use real SSNs, scrambled SSNs, or the last four digits of the SSNs. This documentation will include a discussion of the security measures that are in place to protect the SSNs. This additional documentation is not required if the only use of the SSNs will be on the informed consent form and/or the HIPAA authorization as required by VHA Handbook 1907.01 for filing in the participant’s VA health record.

7.4.1.2 In addition, the minutes will include the identification of the VA Central IRB as the IRB making the waiver determination, the date of the action, and will be signed per VA Central IRB SOP 115, Recording and Distribution of VA Central IRB Meeting Minutes.

7.4.2 The VA Central IRB approval letter must contain the same information as was documented in the minutes. In addition, the approval letter will indicate whether the review took place by the convened VA Central IRB or whether the review was conducted under the expedited review process. Approval letters are prepared and distributed in accordance with VA Central IRB SOP 111, VA Central IRB Communications with Investigators and Local Sites.

7.5 Final Certification by the VA Central IRB Privacy Officer Representative. The VA Central IRB Privacy Officer Representative will provide a final certification that the study meets all the requirements of VHA Handbook 1605.1 as follows:

7.5.1 If during initial review, the VA Central IRB Privacy Officer Representative has no comments and there are no waiver requests, a final certification may be provided at that time.

7.5.2 If during initial review, the VA Central IRB Privacy Officer Representative had comments, the investigator’s response is forwarded to the VA Central IRB Privacy Officer Representative for review upon receipt. If there
are no further comments and there were no HIPAA waiver requests, a final certification may be provided at that time.

7.5.3 If there were waiver requests, the VA Central IRB Privacy Officer Representative will not provide the final certification until the VA Central IRB has formally granted the waiver and documented such approval in the meeting minutes or in the approval letter to the PI/SC.

7.5.3.1 The VA Central IRB staff forwards the appropriate documentation to the VA Central IRB Privacy Officer Representative who then completes the final certification and returns it to the applicable VA Central IRB Coordinator.

7.5.3.2 The VA Central IRB Coordinator documents in the project master log the date the Privacy Officer Certification was completed and received.

7.5.3.4 Copies of the interim certification, if applicable, and the final certification, are filed in the VA Central IRB Project File.

8.0 REFERENCES

8.1 38 CFR 16, Department of Veterans Affairs, Protection of Human Subjects

8.2 VHA Handbook 1200.5, Requirements for the Protection of Human Subjects in Research

8.3 VHA Handbook 1605.1, Privacy and Release of Information

8.4 45 CFR 160, General Administrative Requirements

8.5 45 CFR 164, Security and Privacy

Attachment
VA Central IRB Form 103, Request for Waiver or Alteration of HIPAA Authorization

I have reviewed and approved the content of this SOP.

K. Lynn Cates, MD
Director, PRIDE

Date: 8/10/11
Request for Waiver of HIPAA Authorization

This form must be included with the PI project application when requesting a waiver of the HIPAA authorization requirement for the project as a whole or a particular portion of the project. It may also be included as part of the Local Site Investigator Application if a waiver or alteration is needed for a particular participating site, such as for recruitment purposes only.

I. Project Identification

<table>
<thead>
<tr>
<th>Title of Project</th>
<th></th>
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<tbody>
<tr>
<td>Principal Investigator</td>
<td></td>
</tr>
<tr>
<td>Local Site Investigator (If applicable)</td>
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<tr>
<td>Name of Local Site (If applicable)</td>
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</tbody>
</table>

II. Type of Request

- [ ] Waiver of the HIPAA authorization requirement is required for recruitment purposes only. HIPAA authorization will be sought from participants prior to enrollment.
- [ ] Waiver HIPAA authorization requirement in its entirety.
- [ ] Alteration of a particular element(s) of the HIPAA authorization requirement for use or disclosure of information. (See VHA Handbook 1605.1 for required elements)

III. Criteria to be Eligible to Submit a Waiver Request

The principal investigator must check that the proposed research meets all of the following criteria in order to be eligible to submit a request.

<table>
<thead>
<tr>
<th>Criteria</th>
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<tbody>
<tr>
<td>The use or disclosure of protected health information involves no more than minimal risk to the privacy of individuals based on the following:</td>
</tr>
<tr>
<td>[ ] There is an adequate plan to protect the participant identifiers from improper use and disclosure.</td>
</tr>
<tr>
<td>[ ] There is an adequate plan to destroy the identifiers at the earliest opportunity consistent with the conduct of the research, unless there is a health or research justification for retaining the identifiers, or such retention is otherwise required by law.</td>
</tr>
<tr>
<td>[ ] The research cannot be practicably conducted without the waiver.</td>
</tr>
<tr>
<td>The research cannot be practicably conducted without access to and use of the protected health information.</td>
</tr>
<tr>
<td>The protected health information will not be reused or disclosed to any other person or entity, except as required by law, for authorized oversight of the research project, or for other research for which the use or disclosure of the requested information would be permitted under the HIPAA Privacy Rule.</td>
</tr>
</tbody>
</table>
IV. Justification for Waiver or Alteration

**The principal investigator must provide a response for each of the items listed below if applicable.**

1. Describe why the research could not be practicably conducted without the waiver.

2. Describe why the research could not practicably be conducted without access to and use of the protected health information.

3. Indicate below the specific individual identifiers required as part of the research effort. **Check all the identifiers that will be collected, used and/or disclosed.**

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<table>
<thead>
<tr>
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<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>Names</td>
<td>Social security numbers or scrambled SSNS</td>
<td>Device identifiers and serial numbers</td>
</tr>
<tr>
<td>E-mail addresses</td>
<td>Medical record numbers</td>
<td>URLs (Universal Resource Locator)</td>
</tr>
<tr>
<td>All elements of dates (except year) and any age over 89 Specify:</td>
<td>Health plan beneficiary numbers</td>
<td>IP Addresses (Internet Protocol)</td>
</tr>
<tr>
<td>Telephone numbers</td>
<td>Account numbers</td>
<td>Biometric Identifiers including finger and voice print</td>
</tr>
<tr>
<td>Fax numbers</td>
<td>Certificate or license numbers</td>
<td>Full face photographic images and any comparable images</td>
</tr>
<tr>
<td>All geographic subdivisions' smaller than a state Specify:</td>
<td>Vehicle ID and serial numbers including license plate numbers</td>
<td>Other unique identifying number, characteristic, or code Specify:</td>
</tr>
</tbody>
</table>

- a. If SSNS are going to be used, describe the specific use, the type of SSN to be used (real, scrambled, last 4 digits) and the security measures in place for protecting them.  
  - N/A

- b. Indicate what other "specific" health information (past, present, or future physical or mental health or condition of the individual) is required to be used and collected:

- c. Indicate the number of subjects for which the requested information will be obtained:

4. Indicate by name, and location if applicable, the databases from which the information will be obtained.

6. Describe the overall plan to protect the identifiers from improper use or disclosure.

7. Describe the plan to destroy the identifiers at the earliest opportunity. If there is a health, research, or other justification for retaining the identifiers, please provide such justification below.
8. If requesting the waiver for only a certain portion or phase of the study (recruitment or alteration under Paragraph II), please provide a specific description of what aspects of your study you wish to waive.

V. Investigator Certification

By signature below, the principal investigator acknowledges the following:

1. The information listed in this waiver application is accurate and all the research project staff will comply with HIPAA regulations and the criteria set forth in this request.

2. The protected health information described above is the minimum necessary in order to conduct the research.

3. 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.

_________________________________________  ____________________________
Signature                                      Date
VI. Review by VA Central IRB

This section is to be completed by the VA Central IRB Co-Chair based upon the actions taken at a convened meeting of the VA Central IRB or during the expedited review process.

Check how the review was conducted:  □ Convened IRB  □ Expedited Review

This waiver request meets the below checked criteria for approval: (All boxes must be checked)

- The use or disclosure of the requested information involves no more than minimal risk to the privacy of individuals based on the following:
  - There is an adequate plan to protect the identifiers from improper use or disclosure.
  - There is 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 required by law.
  - The investigator has provided adequate written assurance 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 project, or for other research for which the use or disclosure of the requested information would be permitted by the HIPAA Privacy Rule.

- □ The research could not practicably be conducted without the waiver.

- □ The research could not practicably be conducted without access to and use of the requested information.

Specific findings for basis of approval decision:

1. Comments on plan for protecting identifiers and destroying identifiers at the earliest opportunity:

2. Comments on the protections regarding the use of SSNs:

3. Other comments to include any restrictions or limitations placed on the request:

The action taken regarding this waiver request is indicated by the box checked below:

- □ The request for waiver of HIPAA Authorization is approved for recruitment only.
- □ The request for waiver of HIPAA Authorization is approved for this study as requested.
- □ The request for waiver of HIPAA Authorization is approved only as indicated in the below remarks.
- □ The request for waiver of HIPAA Authorization is not approved. The reasons for the disapproval are indicated in the remarks below.

Remarks:

Signature of VA Central IRB Co-Chair  Date:_________