VAIRRS	Request for Waiver of HIPAA Authorization

INSTRUCTIONS

This form must be included with the Principal Investigator (PI) project application when requesting a waiver of the HIPAA authorization requirement. The form can be submitted to cover the entire project or for only a specific portion of the project. Note: For multi-site studies it may also be submitted as part of a Local Site Investigator (LSI) Application if the collection and use of PHI at the site will not be covered by the waiver granted when the PI Application was approved, such as accessing a local database for recruitment purposes only.

I. Project Identification

Project Title	
Principal Investigator (PI)	

II. Type of Request (Check applicable boxes)

☐	Waiver of the HIPAA authorization is required for recruitment purposes only. HIPAA authorization will be sought from participants prior to enrollment for all other research project activities involving the collection and use of protected health information (PHI).
☐	Waiver of the HIPAA authorization for all research project procedures involving the collection and use of PHI.
☐	Waiver of the HIPAA authorization for the specific portions of the research project as detailed below in Section IV, Item 1, excluding recruitment purposes.

III. Waiver Eligibility Criteria

The PI must select all of the following criteria to ensure eligibility with the federal regulations.

The use or disclosure of the PHI involves no more than minimal risk to the privacy of individuals based on the following:	
☐	There is an adequate plan to protect the participant identifiers from improper use and disclosure.
☐	There is an adequate plan to destroy the participant 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.
☐	The research cannot be practicably conducted without the waiver.
☐	The research cannot be practicably conducted without access to and use of the PHI.
☐	The PHI 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.

If unable to check all boxes, STOP HERE.
A waiver of HIPAA Authorization cannot be granted.

IV. Justification for Waiver

The PI must provide a response for each of the items listed below. Separate the plans for PHI as described in the protocol if the submitted project has multiple phases (e.g., Phase I, Phase II, or Aim 1, Aim 2, etc.), if applicable.

1. Provide a specific description for each aspect of the research project for which the waiver is being sought:
   ☐ N/A

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

3. Describe why the research could not practicably be conducted without access to, and use of, the PHI.

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

☐ Names	☐ Social security numbers or scrambled SSNs	☐ Device identifiers and serial numbers
☐ E-mail addresses	☐ Medical record numbers	☐ URLs (Universal Resource Locator)
☐ All elements of dates (except year) and any age over 89 Dates may include dates of birth, dates of treatment, procedures, death, etc. *Specify:*	☐ Health plan beneficiary numbers	☐ IP Addresses (Internet Protocol)
☐ Telephone numbers	☐ Account numbers	☐ Biometric Identifiers including finger and voice print
☐ Fax numbers	☐ Certificate or license numbers	☐ Full face photographic images and any comparable images
☐ All geographic subdivisions' smaller than a state This may include mailing addresses, etc. *Specify:*	☐ Vehicle ID and serial numbers including license plate numbers	☐ Other unique identifying number, characteristic, or code *Specify:*

a. If SSNs will be used, describe all of the following: ☐ N/A

1. Type of SSN to be used: ☐ Real ☐ Scrambled ☐ Last 4 digits
2. Specific use: for each type of SSN to be used:
3. Security measures in place for protecting the SSNs:

b. Indicate the "specific" health information (past, present, or future physical or mental health or condition of the individual) that will be accessed, collected, and/or used in addition to the above identifiers:

5. Indicate by name, and location if applicable, the database(s) from which information will be obtained.

☐ VistA/CPRS (Research project Sites)	☐ VINCI/CDW	☐ CMS
☐ Other data source(s)/database(s) *Specify:*		

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 in accordance with the VHA's Records Control Schedule (RCS 10-1). If there is a health, research, or other justification for retaining the identifiers, please provide such justification below.

8. Indicate any non-VA collaborators or service providers such as a transcription company, academic collaborators, etc. who are covered under this waiver.

V. Investigator Certification

The PI acknowledges the following:

1. The information contained in this waiver application is accurate and all 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 project, or for other research for which the use or disclosure of the requested information would be permitted by the Privacy Rule.

The PI's permission for submission of this form is attestation of their acknowledgment, no PI signature is required.

VI. Review by IRB/Privacy Board

This section is to be completed by IRB/Privacy Board reviewer.

If the assigned reviewer has a Conflict of Interest (COI), check the box below and return without completing the form.

☐ **I have a Conflict of Interest**

Review Type: ☐ Convened ☐ Expedited

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.
☐	The health information including identifiers listed in Section IV, Item 4 is approved to be accessed, collected, and/or used unless otherwise noted or stated:

Reviewer Comments (optional):

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 research project as requested. .
☐	The request for waiver of HIPAA Authorization is not approved. The reasons for the disapproval are indicated in the remarks above.

IRB/Privacy Board Reviewer Signature

Date

IRB of Record or Privacy Board Name: