**APPLICATION FOR IRB WAIVER OF AUTHORIZATION OR ALTERED AUTHORIZATION**

**UNDER THE HIPAA PRIVACY RULE**

FOR PROTOCOLS CONDUCTED BY VA RESEARCHERS

**Study Name**:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Principal Investigator**:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Date:**\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**Purpose of this form**

This form was created to facilitate the submission and review of a request to use/disclose protected health information (PHI) under an IRB approved waiver of or altered authorization. This form must be included with the research study application when requesting a waiver of the HIPAA authorization.

If you are applying for approval of a new minimal risk initial review or exemption application (such as retrospective medical record review), and you believe it would be impracticable to obtain a signed authorization from some or all of the research subjects, you may apply to the IRB for a waiver of authorization to use/disclose their PHI. This application may be to use/disclose PHI located in either a medical record or in a database.

Please see VHA Handbook 1200.05 *Requirements for the Protection of Human Subjects in Research* for further guidance.

**APPLICATION**:

**A.** **This application is to request the following (check all that apply)**:

[ ] Waiver of authorization (for all uses of PHI)

[ ] Partial waiver of authorization (for some uses of PHI- describe the parts of the protocol for which you are requesting a waiver)

**B.**  **Criteria for Eligibility**

Regulations require that the protocol present minimal risks to research subjects in order to qualify for a waiver of or altered authorization. Note that risks to research subjects can be physical or psychosocial. The principal investigator must check that the proposed research meets all of the following criteria in order to be eligible to submit a request.

* The use or disclosure of protected health information 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 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 protected health information.
* 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.

**C: Justification for Waiver or Alteration**

1. Describe why the research could not be practicably conducted without the waiver.
2. Describe why the research could not be practicably conducted without access to and use of the specific protected health information.
3. List the name and location of databases from which information will be obtained.
4. Indicate which, if any, of the following individual identifiers will be required as part of the study. Check all identifiers that will be collected, used, and/or disclosed.

|  |  |  |  |
| --- | --- | --- | --- |
|  | Names |  | Social Security Number (including partial or scrambled) |
|  | Fax numbers |  | E-mail addresses |
|  | Telephone numbers |  | Medical Record Numbers |
|  | Health plan beneficiary numbers |  | Account numbers |
|  | Certificate/License numbers |  | Vehicle identifiers and serial numbers including license plate numbers |
|  | Device identifiers and serial numbers |  | Web Universal Resource Locators (URL) |
|  | Internet Protocol (IP) Address numbers |  | Biometric identifiers ( including finger and voice prints) |
|  | Any Geographic Subdivisions Smaller Than a State (specify which of the following identifiers you will use: address or only county, city, parish, or zip code) |  | All elements of dates (except year only) and any age over 89  Specify which of the following you will use: birth date, admission date, discharge date, date of death, age over 89) |
|  | Full face photographic images or any comparable images |  | Any other unique identifying number, characteristic, or code (please specify): |
|  |  |  |

1. List specific health information that will be used or collected. State specifically whether 7332 information (drug abuse, alcohol abuse, HIV, or sickle cell anemia) will be collected. A copy of the data collection sheet also should be submitted for medical record review or database research studies.
2. Indicate the number of subjects for which the requested information will be collected.
3. Identifiable information will be used or disclosed only by members of the research team and the following individuals (specify their role and agency, including internal VA employees). If PHI will NOT be released outside the William S. Middleton VA Hospital for this study, please make a statement to that effect.

**Note**: The Privacy Rule requires researchers to keep a detailed accounting of releases of PHI outside the William S. Middleton VA Hospital. This accounting must be made available to the Release of Information Office for disclosure to requesting individuals. If you can share health information that is de-identified, or that is a limited data set under a data use agreement with the collaborators or sponsor, you will not need to keep an accounting.

1. Describe the overall plan to protect identifiers from improper use or disclosure. If PHI is disclosed outside the William S. Middleton Memorial Veterans Hospital, describe the plans of any research collaborators to protect the PHI they receive.
2. ALL records including identifiers must be retained until disposition instructions are approved by the National Archives and Records Administration (NARA) and are published in VHA’s Records Control Schedule (RCS 10-1). Specify where and how records will be maintained.
3. If requesting the waiver for only a certain portion or phase of the study, provide a specific description of which aspects of the study apply.

**C. Investigator Certification.**

As Principal Investigator of the research described above, I make the following assurances to the IRB regarding the use and disclosure of PHI:

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 investigators and research staff who use and disclose PHI in connection with this research will not reuse the PHI or disclose it to any person or entity except as required by law, for authorized oversight of the research study, or in connection with other research for which the HIPAA Privacy Rule permits the PHI to be used or disclosed.

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Signature Date