Application for IRB Waiver of Authorization or Altered Authorization under the HIPAA Privacy Rule

University of Wisconsin—Milwaukee

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.

Instructions

- **Waiver** 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.

- **Altered Authorization** If you are applying for approval of a new minimal risk initial review or exemption application, and you are seeking either a waiver of some of the required elements of informed consent or a waiver of documentation of informed consent from the IRB (such as for survey or interview research), you may request an altered authorization, which asks the IRB to waive some of the elements of a full HIPAA Authorization required under the Privacy Rule for research subject authorization to use/disclose PHI.

Please see HIPAA website at www.hipaa.uwm.edu 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)

[ ] Altered authorization. (Attach 2 copies of your altered authorization form proposed for use with subjects)

B. Required Information

The 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 answers to questions 1-5 below will help the IRB determine if the protocol presents minimal risk to the research subjects.

1. The Privacy Rule requires an IRB to determine that the researchers will use the minimum amount of PHI necessary to conduct the research (including, if practicable, a limited data set). Therefore, please list the specific health information that you propose to use in this study. State specifically whether sensitive information (e.g., illegal drug use, sexual practices, HIV status) will be collected. For most retrospective medical record research, a limited range of health information will normally be sufficient for the purposes of the research. A copy of the data collection sheet also should be submitted for medical record review or database research studies. For survey or interview research, the questions to be asked of research subjects should be attached to this application.

2. Specify which, if any, of the following identifiers will be associated with the health information you propose to collect.

	Names		Telephone Numbers
	Address		E-mail Addresses
	Fax Numbers		Medical Record Numbers
	Social Security Numbers		Account Numbers
	Health Plan Beneficiary Number		Vehicle Identifiers and Serial Numbers
	Certificate/License Numbers		Web Universal Resource Locators (URL)
	Device Identifiers and Serial Numbers		Biometric Identifiers (finger and voice prints)
	Internet Protocol (IP) Address Numbers		
	Any Geographic Subdivisions Smaller Than a State (specify which of the following identifiers you will use: county, city, parish, or zip code)		Any Elements of Dates (specify which of the following identifiers you will use: birth date, admission date, discharge date, date of death, age over 89)
	Full face photographic images and comparable images		Any other unique identifying number, characteristic, or code (please specify):

3. What is the source of the PHI? List all sources from which you plan to obtain PHI for the study *(e.g. clinic paper records, a departmental database, your own database).*

4a. List the individuals or groups within UWM's Covered Departments who will receive and/or use the PHI.

4b. List, if any, the individuals or groups outside UWM's Covered Departments to whom you will disclose the PHI (*e.g., research collaborators from other institutions or a research sponsor*). If PHI will NOT be released outside Covered Departments in 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 Covered Departments. This accounting must be made available upon request to the individual who is the subject of the PHI. 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.

5. Describe your plan to protect PHI from unauthorized use or disclosure. Specify the measures that will be implemented by your research group to safeguard the PHI from unauthorized use or disclosure for both paper and electronic forms of PHI. (Examples include locking up your research files while they are unsupervised, using screensavers, shredding excess copies of paper documents, protections for codes that link patients to their data, and security measures to protect storage and transmission of electronic data.) If PHI is to be disclosed outside the Covered Departments, describe the plans of any research collaborators to protect the PHI you will share with them.

6. Describe your plan for destroying the identifiers at or before the conclusion of the study or provide a justification for long term or permanent retention of the identifiers. Specify which identifiers and information will be destroyed. If long term retention is requested, such as maintenance of a database, specify the security measures you will use.

7. Explain why the study cannot be conducted without the waiver of or altered authorization. In order for an IRB to grant a waiver of authorization or altered authorization, the research cannot practicably be conducted without it. Criteria the IRB considers in determining whether a waiver of or altered authorization should be granted include: the number of research subjects proposed, difficulties of obtaining individual authorization, time constraints, time since last contact with the research subjects, and need to have historical controls. Other criteria may apply.

C. Researcher Assurances.

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

"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 other than those authorized to receive it, except: 1) as required by law, 2) for authorized oversight of the research, or 3) in connection with other research for which the HIPAA Privacy Rule permits the PHI to be used or disclosed."

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Signature of Principal Investigator Date

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Print Name of Principal Investigator

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Study Title

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IRB Protocol Number (if assigned)