HIRB Waiver Request for HIPAA Authorization

Directions: This form is to be used in conjunction with the HIRB Initial Project Application

Project Title: _____

Researcher/program Evaluator Name: _____

The HIPAA Privacy Standard at 45 CFR 164.512(h)(i)(2)(ii) requires that certain criteria be met in order to grant a waiver of individual authorization for research uses of Protected Health Information, that is, individually identifiable health information held by a health care provider or health plan covered by HIPAA. In addition to these criteria, the federal Common Rule (45 CFR 46 section 116(d)) stipulates that "whenever appropriate, the subjects will be provided with additional pertinent information after participation."

If all of these criteria are met, HIRB may grant a waiver of authorization.
HIRB's action will be documented and communicated to the applying Researcher/Program Evaluator.

This request is for (select only one):

_____ Total Waiver
When you request a total waiver of the HIPAA Authorization, you are requesting permission to access, use or disclose a research subject's protected health information for your research study without seeking the subject specific authorization for that use or disclosure.

_____ Partial Waiver
When a partial waiver is requested, you may request that certain required elements of the HIPAA authorization be altered or that the HIPAA authorization be waived for a portion of the study. (For instance, you may request a waiver for subject identification or recruitment purposes but not for enrollment purposes. For example, you may request a waiver of the HIPAA authorization requirement so that a treating physician may obtain verbal permission from the patient so that the physician can notify the study coordinator of the patient's interest in the study. Once the study coordinator has discussed the study with the interested patient, they will consent the participant and obtain a full authorization.) Please specify what you are requesting the waiver for:
_____
_____
_____

Directions: Please respond to <u>every</u> question on this application.
Incomplete applications will be returned, and result in a delay of your study being reviewed.

1. Does the use or disclosure of protected health information involve no more than a minimal risk to the privacy of the individual based on at least the presence of the following:
    a. An adequate plan to protect the identifiers from improper use and disclosure.
    b. An adequate plan to destroy 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 as otherwise required by law.
    c. Adequate written assurances that the protected health information will not be reused or disclosed to another person or entity, except as required by law, for authorized oversight of the research study, or other research for which the use or disclosure of protected health information would be permitted.

    _____ Yes _____ No

2. Describe the plan to protect the identifiers (names, addresses, telephone numbers, social security numbers, medical record numbers, photos, and other identifying information etc.) from improper use and disclosure?

3. Describe the plan to destroy the identifiers at the earliest opportunity, or provide justification for retaining the identifiers?

4. Will a waiver adversely affect the privacy rights of the individual?

_____ Yes _____ No

5. Could the research be practicably done without the waiver?

_____ Yes _____ No

If "no" please justify below:

6. Could the research practicably be done without access to, use or disclosure of the identified below?

_____ Yes _____ No

Please identify below the protected health information that is necessary for this research study. (*Attach additional sheets if necessary)*

If applying for a partial waiver for subject identification, describe the method by which subjects will be identified and the protected health information necessary for subject identification.

7. Are the privacy risks to individuals whose protected health information will be used reasonable in relation to the anticipated benefit, if any, to the individuals? *(Please describe your risk/benefit analysis below.)*

   _____ Yes _____ No

8. By signing this form, I assure that the protected health information will not be reused or disclosed to another person or entity, except as required by law, for authorized oversight of the research study, or other research for which the use or disclosure of protected health information would be permitted.

Please name all of the individuals who will have access to the protected health information during the research study.

Name	Job Description/Role on Study

Researcher's/Program Evaluator's Agreement:
As researcher/program evaluator of this study, I assure Heartland IRB (HIRB) that the following statements are true:

1) The information that is provided in this form is true and accurate.
2) I will seek and obtain prior written approval from HIRB for any substantive modifications to the proposal, including but not limited to, changes in procedures and personnel.
3) I will report in writing any significant new findings that develop during the course of this study that may affect the risks and benefits to the individuals whose protected health information is being obtained.
4) I will not begin my research, including subject identification or recruitment, until I have received written notification of HIRB approval.
5) I will comply with all HIRB requests to report on the status of the study.
6) I will not reuse or disclose any protected health information to any other person or entity, except as required by law, for the authorized oversight of research or for other permitted research.
7) I will conduct the research in compliance with all applicable federal and state laws and regulations and the applicable hospital policies governing human subject research.

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Signature of Researcher/Program Evaluator Date