UNIVERSITY AT BUFFALO
HUMAN RESEARCH PROTECTIONS PROGRAM

Request for *Waiver of the Authorization for Use of Individually Identifiable Health Information*

INSTRUCTIONS

In most situations Federal regulations require that an individual's signed HIPAA authorization be obtained before their Individually Identifiable Health Information can be acquired, used or disclosed for research purposes in situations where HIPAA applies. A waiver of this authorization requirement allows you to acquire, use or disclose health information without securing such an authorization.

You may apply to the IRB for a waiver of the authorization requirement if several regulatory criteria can be fulfilled. One criterion is key: the research could not practicably[1] be conducted without the waiver. If it will be difficult or impossible for you to secure a signed authorization from your research subjects, you pass an initial test for qualifying for a waiver of the authorization requirement.

Some instances where the request for a waiver of authorization may be appropriate include:

- research on existing health information, e.g., medical records research
- research where a waiver of informed consent is also being requested, e.g., survey research via phone

The criteria that must be satisfied for **full** waiver of authorization are:

- The research could not practicably be conducted without the waiver or alteration of authorization, i.e., there is no other mechanism available that would permit you to obtain the information needed for study recruitment under HIPAA.
- The research could not practicably be conducted without access to and use of the health information sought in the waiver.
- A brief description of the health information for which use or access has been determined to be necessary. The waiver will permit the researcher to access only this information
- The use or disclosure of health 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 and disclosure;
    - 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 is otherwise required by law; and
    - Adequate written assurances are provided that 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 study, or for other research for which the use or disclosure of protected health information would be permitted

A ***partial waiver***, or ***alteration***, of the HIPAA authorization may also may be granted by the IRB in cases where granting a full waiver of authorization is not warranted. These additional mechanisms allow the IRB to alter or eliminate one or more of the regulatory elements normally required in the HIPAA authorization. Consult with the IRB for more information on these options.

You can address all of the above criteria for a **full** waiver by completing and signing the Waiver of Authorization form and submitting it to the IRB for review.

[1] HIPAA does not define this term and leaves its meaning to the discretion of the IRB

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Investigator: _____

Project Title: _____

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1. Describe the specific types of Individually Identifiable health information (e.g., name, address, elements of medical record, entire medical record) to be used in this study and where this information will be accessed or obtained:

2. Explain why this research project cannot be carried out without use of individually identifiable health information (why is using de-identified data not practicable?).

3. Explain why obtaining a signed authorization from the research subjects is not practicable.

4. Describe the protections that will be put in place to protect the privacy of individually identifiable health information to be used in this study. What steps will be taken to help prevent accidental use or disclosure outside the scope of this project. This includes information maintained or communicated in electronic, written and oral form.

5. Describe your plan to assure that the individually identifiable health information will not be re-used or disclosed for other purposes.

6. Describe your plan to destroy the personal identifiers at the earliest opportunity or your justification for the need to retain personal identifiers.

I attest that the use or disclosure of individually identifiable health information will involve no more than a minimal risk to the privacy of the research subjects involved in this study and that the information will not be reused or disclosed to third parties unless required by law for authorized oversight of the research study.

Investigator Signature:_____ **Date:** _____