

UNIVERSITY AT BUFFALO  
HUMAN RESEARCH PROTECTIONS PROGRAM

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

**INSTRUCTIONS**

In most situations Federal regulations require that an individual's signed HIPAA authorization be obtained before their Individually Identifiable Health Information can be used or disclosed for research purposes in situations where HIPAA applies. A limited waiver of this authorization requirement can be sought for research subject recruitment that will allow you acquire, use or disclose such health information for the specific purpose of study recruitment. The requirement to determine whether additional HIPAA information release mechanisms are needed to obtain, use or disclose health information for any research purpose other than study recruitment remains in effect.

You may apply to the IRB for a limited waiver if several regulatory criteria can be fulfilled. One criterion is key: the research subject recruitment activity could not practicably<sup>1</sup> be conducted without the waiver. In other words the waiver addressed with this application is only appropriate if acquiring Individually Identifiable Health Information is prerequisite to identifying candidates who might participate in your study. An example of where a request to the IRB for a limited waiver of authorization for study recruitment is appropriate would be where you need information from preexisting health information, e.g., medical records, to identify a candidate pool based on specific criteria applied to those records.

The criteria that must be satisfied for such a waiver of authorization are:

- The research recruitment activity could not practicably be conducted without the waiver, i.e., there is no other mechanism available that would permit you to obtain the information needed for study recruitment under HIPAA.
- The research recruitment activity 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

NB when using a limited waiver of authorization for recruitment purposes, initial subject contact *must* occur through the subject's primary care provider unless the care provider has granted permission for an alternate contact route. This reflects generally policy requirements of primary care providers and is not a HIPAA requirement.

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

---

<sup>1</sup> HIPAA does not define this term and leaves its meaning to the discretion of the IRB

UNIVERSITY AT BUFFALO  
HUMAN RESEARCH PROTECTIONS PROGRAM

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

Investigator: \_\_\_\_\_

Project Title: \_\_\_\_\_

\_\_\_\_\_  
\_\_\_\_\_

**1. Describe the specific types of Individually Identifiable health information (e.g., name, address, elements of medical record) to be used for purposes of subject recruitment to this study and where this information will be accessed:**

**2. Explain why the recruitment phase of this research project cannot be carried out without use of individually identifiable health information (why is seeking a signed authorization prior to recruitment not practicable?).**

**3. Describe the protections that will be put in place to protect the privacy of individually identifiable health information acquired with a limited waiver. What steps will be taken to help prevent accidental use or disclosure of the information? This includes information maintained or communicated in electronic, written and oral form.**

**4. Describe your plan to assure that the individually identifiable health information acquired with a limited waiver will not be re-used or disclosed for any purpose other than subject recruitment in this study.**

**5. Describe your plan to destroy the personal identifiers acquired with a limited waiver at the earliest opportunity or your justification for the need to retain personal identifiers. Be sure to address this for subjects that decline to participate as well as for subjects that agree to participate in the study.**

**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 or for authorized oversight of the research study.**

PI Signature: \_\_\_\_\_ Date: \_\_\_\_\_