



**Request for a Waiver of Authorization**

To use or disclose protected health information without authorization by the research participant, a covered entity must obtain a Waiver of Authorization.

Section 1 Principal Investigator (PI) Information	
1.	PI Name:
2.	Sponsor:
3.	Study Title:
Section 2 Criteria For Waiving Requirement For Authorization	
	<b>Check One</b>
1. The use or disclosure of protected 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;	<b>Yes    No</b>
○ 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;	<b>Yes    No</b>
Identifiers will be destroyed: (check all that apply)	
❖ <input type="checkbox"/> Immediately	
❖ <input type="checkbox"/> Upon enrollment of the individual into the study	
❖ <input type="checkbox"/> Identifiers will be stored with the study records and destroyed with the records	
<i>When will the destruction occur?</i> _____	
○ adequate written assurances 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 project, or for other research for which the use or disclosure of protected health information would be permitted;	<b>Yes    No</b>
❖ This written assurance should be included in protocol or stated in this document.	
2. The research could not practicably be conducted without the waiver; and	<b>Yes    No</b>
3. The research could not practicably be conducted without access to and use of the protected health information.	<b>Yes    No</b>



**Section 3**

1. Will access to the PHI be limited to only those individuals who need to have access to the PHI for performance of the research?

\_\_\_\_\_ Yes \_\_\_\_\_ No

2. Are the persons who will have access to the information required to sign confidentiality agreements, business associates' agreements, or other obligation of confidentiality?

\_\_\_\_\_ Yes \_\_\_\_\_ No

3. What identifiers are included in the information you plan to use/disclose? **Check each that apply.**

\_\_\_\_\_ Name

\_\_\_\_\_ All geographic subdivisions smaller than a state, including street address, city, county, precinct, ZIP Code, and their equivalent geographical codes

\_\_\_\_\_ Dates (directly related to an individual **except** year)

\_\_\_\_\_ All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and all ages over 89 and all elements of dates (including year) indicative of such age, except that such ages and elements may be aggregated into a single category of age 90 or older.

\_\_\_\_\_ Telephone numbers.

\_\_\_\_\_ Fax numbers.

\_\_\_\_\_ E-mail addresses.

\_\_\_\_\_ Social security 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 URLs.

\_\_\_\_\_ Internet protocol (IP) address numbers.

\_\_\_\_\_ Biometric identifiers, including fingerprints and voiceprints.

\_\_\_\_\_ Full-face photographic images and any comparable images.

\_\_\_\_\_ Any other unique identifying number, characteristic, or code, unless otherwise permitted by the Privacy Rule for re-identification.

4. In what form will the information be maintained? \_\_\_\_\_ Paper \_\_\_\_\_ Electronic \_\_\_\_\_ Both



**Section 3 Continued**

5. Describe the precautions you are taking to protect the identifiers from improper use and disclosure.  
*You can reference page(s) in protocol if this has been explained.*

6. Why is the research unable to practicably be conducted without the waiver?  
*You can reference page(s) in protocol if this has been explained.*

**NAME OF PERSON COMPLETING THIS FORM:**

\_\_\_\_\_  
Printed or Typed Name of Person Completing This Form

\_\_\_\_\_  
Company & Title

\_\_\_\_\_  
Phone number

\_\_\_\_\_  
Fax number

\_\_\_\_\_  
E-mail address (optional)