

REQUEST FOR PARTIAL WAIVER OF AUTHORIZATION

A partial waiver is used to allow prescreening of potentially eligible subjects.

a. Sponsor: _____	b. Protocol Number: _____
c. Study Title: _____	

The use / disclosure of the PHI must involve no more than minimal risk to the privacy of individuals.

PRINCIPAL INVESTIGATOR: _____

STUDY COORDINATOR / CONTACT PERSON: _____

Under the HIPAA Privacy Rule, use or disclosure of an individual's protected health information (PHI) by a covered entity for research purposes requires the individual's written authorization, unless a waiver or partial waiver of authorization is granted by an IRB / Privacy Board, in which case, such authorization may be given orally by the individual. A partial waiver does not eliminate the investigator's responsibility to obtain written informed consent and/or authorization from the individual prior to study enrollment. [45 CFR 164.512]

1. Describe the method(s) of recruitment for which are you requesting this partial waiver of authorization:

2. Federal regulations require that an IRB / Privacy Board determine that the researchers will use the minimum amount of PHI that is necessary for the method of recruitment as stated in #1. Please specify which PHI elements you propose to use or disclose and include a copy of the data collection tool or a description of how you will collect the data:

- | | | |
|--|---|---|
| <input type="checkbox"/> Name | <input type="checkbox"/> Health plan beneficiary number | <input type="checkbox"/> Any elements of dates (i.e., birth date, admission date, discharge date) |
| <input type="checkbox"/> Address | <input type="checkbox"/> Social Security number | <input type="checkbox"/> Biometric identifiers, including voice and finger prints |
| <input type="checkbox"/> Telephone number | <input type="checkbox"/> Medical record number | <input type="checkbox"/> Full facial photographic images |
| <input type="checkbox"/> Fax number | <input type="checkbox"/> Account number | <input type="checkbox"/> Any geographic subdivision smaller than a state |
| <input type="checkbox"/> Email address | <input type="checkbox"/> Medical history | <input type="checkbox"/> Certificate or license number |
| <input type="checkbox"/> Any other unique identifying number, characteristic or code:
<i>(please specify)</i> _____ | | |

3. Explain why each PHI element is necessary for using this/these method(s) of recruitment (*attach a separate sheet if necessary*).

4. List the individuals or groups who will receive and/or use the PHI (*attach a separate sheet if necessary*):

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5. Have these individuals or groups received training relating to the HIPAA Privacy Rule and the site's policies relating to privacy and confidentiality? Please describe relevant training and/or education (*attach separate sheet if necessary*).
6. Describe the plan to protect identifiers from improper use and disclosure. The plan should include information regarding where the PHI will be stored, and who will have access to the collected PHI (*attach separate sheet if necessary*).
7. Describe the plan to destroy identifiers at the earliest opportunity consistent with the PURPOSE, unless there is a health or research justification for retaining the identifiers or such retention is required by law. The plan should include a description of HOW the identifiers will be destroyed (*attach separate sheet if necessary*).
8. Provide an explanation as to why the PURPOSE cannot practicably be conducted without access to and use of the PHI (*attach separate sheet if necessary*).
9. Provide an explanation as to why the PURPOSE cannot be practicably carried out without the waiver (*attach separate sheet if necessary*).

Principal Investigator Assurances

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

- The PHI 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 PHI would be permitted by the HIPAA Privacy Rule.
- I certify that the information provided to Review Board in this Request for Waiver of Authorization Form is complete and accurate to the best of my knowledge.
- I agree to comply with the requirements of all federal, state and local laws regarding protected health information, including the HIPAA Privacy Rule [45 CFR 160 and 164].

Signature of Principal Investigator

Date