



## THE PRIVACY BOARD

40 Washington Street, Suite 130, Wellesley, MA 02481  
Tel (781) 431-7577 • Fax (781) 237-0330  
www.theprivacyboard.com

### Submitting a Request for Waiver of Authorization

1. If NEIRB has already reviewed the study, or is going to review the study, there is no need to submit another protocol/study plan and research CV to The Privacy Board.
2. Make sure your study plan includes all these elements:
  - The objective and background of the research project
  - Why the research could not practicably be conducted without the alteration or Waiver of Authorization
  - Why the research could not practicably be conducted without access to and use of the PHI
  - The rationale for the use of the selected subject population
  - The procedures that will be performed to generate research data
  - Each element of the data set to be used in the research and the rationale for its inclusion
  - The plan to protect the identifiers from improper use and disclosure
  - The security steps to protect health information so it will not be reused or disclosed
  - The plan to destroy the identifiers. (If there is no intent to destroy identifiers, discuss the health or research justification for retaining the identifiers, or such retention is otherwise required by law).
  - The anticipated beginning and end dates of the project (or length of data gathering activities)
  - Number of records involved in the project
3. The fee for review of your request for Waiver of Authorization must be included with your submission material.
4. Your submission will be reviewed for completeness and, if complete, will be reviewed for Waiver of Authorization as follows:

#### Turn-around

- Full Board review: Complete submissions received by the end of the day Friday will be reviewed on the following Thursday.
- If the project qualifies for Expedited Review, review will be completed within 72 hours.

**Don't leave anything out** – it will only delay the review of your request. If you cannot provide an element requested on the form, provide an explanation.



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## REQUEST FOR WAIVER OF AUTHORIZATION SUBMISSION FORM

### Project or protocol title:

Has this study been submitted to NEIRB? <input type="checkbox"/> No <input type="checkbox"/> yes	If yes, NEIRB # _____
Principal investigator/Researcher:	Phone:
Address:	
Contact person: ( <input type="checkbox"/> same as above)	Phone:
Address: ( <input type="checkbox"/> same as above)	Fax:
	E-mail:

### SPONSOR OR FUNDING ORGANIZATION:

Contact person:	Phone:
Address: ( <input type="checkbox"/> same as above)	Fax:
	E-mail:

### Where will the data be gathered?

	Include all locations for study related activities here or on separate sheet.

The following required materials have been included with this submission	<input type="checkbox"/> Protocol or plan for gathering and analyzing the data ( <input type="checkbox"/> See NEIRB submission)
	<input type="checkbox"/> Completed Privacy Board Submission Form
	<input type="checkbox"/> A copy of your data recording tool
	<input type="checkbox"/> CV/Resume of Principal Investigator / Researcher ( <input type="checkbox"/> See NEIRB submission)
	<input type="checkbox"/> Payment (or agreement from the sponsor to pay for services)

**Waiver is requested in order to use or disclose the following identifiers:**

<input type="checkbox"/>	Name;
<input type="checkbox"/>	All geographic subdivisions smaller than a state except for the initial three digits of a zip code if, according to the current publicly available data from the Bureau of the Census:
<input type="checkbox"/>	The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people: and
<input type="checkbox"/>	The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.
<input type="checkbox"/>	Dates directly related to an individual, i.e., birth date, admission date, discharge date, date of death (only the year may be included);
<input type="checkbox"/>	For individuals over 89, all elements of dates (including year) indicative of such age (except where aggregated into a single category of age 90 or older);
<input type="checkbox"/>	Telephone numbers;
<input type="checkbox"/>	Fax numbers;
<input type="checkbox"/>	Electronic mail addresses;
<input type="checkbox"/>	Social security numbers;
<input type="checkbox"/>	Medical record numbers;
<input type="checkbox"/>	Health plan beneficiary numbers;
<input type="checkbox"/>	Account numbers;
<input type="checkbox"/>	Certificate/license numbers;
<input type="checkbox"/>	Vehicle identifiers and serial numbers, including license plate numbers;
<input type="checkbox"/>	Device identifiers and serial numbers;
<input type="checkbox"/>	Web Universal Resource Locators (URLs);
<input type="checkbox"/>	Internet Protocol (IP) address numbers;
<input type="checkbox"/>	Biometric identifiers, including finger and voice prints;
<input type="checkbox"/>	Full face photographic images and any comparable images; and
<input type="checkbox"/>	Any other unique identifying number, characteristic, or code.

**Rationale for Waiver of Authorization**

The protocol or study plan must address each of the following. (Indicate the page # or section that addresses each item. If the item is not in the protocol, include the information below or on an additional sheet):

Section or pg. #	Required Element
	The objective of the research project
	Why the research could not practicably be conducted without the alteration or Waiver of Authorization
	Why the research could not practicably be conducted without access to and use of the protected health information
	The rationale for the use of the selected subject population
	The procedures that will be performed to generate research data
	Each element of the data set to be used in the research and the rationale for its inclusion in the data set
	The plan to protect the identifiers from improper use and disclosure
	Describe your security steps to protect health information so it will not be reused or disclosed to any other person or entity
	Describe the plan to destroy the identifiers. (If there is no intent to destroy identifiers, discuss the health or research justification for retaining the identifiers, or such retention is otherwise required by law)
	The anticipated beginning and end dates of the project (or approximate length of data gathering activities)
	Number of records involved in the project

**INVESTIGATOR'S ASSURANCE**

I certify that the information provided in this request for Waiver of Authorization is complete and correct.

- I understand that as the investigator, I have ultimate responsibility for the protection of confidential information and to ensure the privacy of research subjects and their protected health information.
- I agree to comply with all requirements of The Privacy Board as well as with all applicable federal, state, and local laws.
- I have read the regulations and understand my responsibilities and the requirements for using and disclosing protected health information.

\_\_\_\_\_  
Principal Investigator/Researcher

\_\_\_\_\_  
Date