

CUNY Institutional Review Board

REQUEST FOR WAIVER OR ALTERATION OF HIPAA AUTHORIZATION FOR RESEARCH USE AND DISCLOSURE OF PROTECTED HEALTH INFORMATION

INSTRUCTIONS TO INVESTIGATOR

Effective April 14, 2003, there are new federal regulations issued under the Health Insurance Portability and Accountability Act (“HIPAA”) that deal with the privacy of health information, including mental health information.

This form must be completed if: (1) in order to conduct your research, you wish to use and/or disclose any individually identifiable protected health information (“PHI”) without obtaining the prior written authorization (a “HIPAA Authorization”) of all individuals who are the subjects of the information, and (2) the PHI is created or maintained by, or obtained from, a person or entity covered under HIPAA. Examples of entities covered under HIPAA are hospitals; physicians, and practices in psychology, psychotherapy, or social work; health insurers, HMOs, and health plans; and certain community clinics, and social service and mental health agencies.

CUNY is not an entity directly covered by HIPAA. CUNY investigators are therefore not covered under the HIPAA privacy regulations unless, in order to conduct research, they are using or disclosing patient or client information that they (a) create when acting as HIPAA-covered health care providers, (b) create as members of the workforce of a HIPAA-covered entity, or (c) obtain from a HIPAA-covered entity. For example, CUNY faculty or students who conduct or assist with research may also be employees or trainees in hospital or social service settings that are covered by HIPAA and may be using data obtained from those settings in research. CUNY investigators may also be collaborating with co-investigators who are covered by HIPAA.

The criteria required by the HIPAA privacy regulations for approving a waiver of HIPAA Authorization are set forth in Attachment 1 to this Request Form. These criteria are similar to the criteria that a CUNY IRB must use in considering whether to grant a waiver of informed consent to participate in a research study. If the subjects in your study will be required to give their written informed consent to participate, it is unlikely that a request for a waiver of HIPAA Authorization will be approved by a CUNY IRB.

You may, however, use this form to request that your IRB alter CUNY’s standard form of HIPAA Authorization. For example, if you plan to seek each subject’s authorization but the use of the standard authorization form would be impracticable, the IRB may approve the alteration of the standard form if it finds that the alteration would present no more than a minimal risk to privacy and that the other HIPAA waiver criteria, as applied to the alteration, are satisfied.

Under the HIPAA privacy regulations, a patient or client is entitled to an accounting of certain disclosures of his or her PHI. Even though a CUNY IRB approves a waiver of HIPAA Authorization, the HIPAA-covered entity that provides the PHI for your study will need to account for all disclosures that are made to persons other than the entity's own workforce if the patient or client asks for such an accounting. The accounting must include the name of the patient or client, the purpose of the disclosure, the date of the disclosure, the recipients of the PHI, and a description of the PHI that is disclosed. Some covered entities may have systems in place that will capture this information at the time of disclosure; others may expect the personnel conducting the study to maintain a log of all such disclosures and provide a copy to the respective data managers.

Please Complete the Following:

TO: Chair, _____ [College] IRB

FROM: _____
(Investigator Name)

(CUNY Institution/Department)

(Investigator's Telephone Number)

DATE: _____

PROJECT: _____

PURPOSE OF STUDY: [Give a brief description of the study and attach a copy of the full protocol to this Request Form.]

DESCRIPTION OF PROTECTED HEALTH INFORMATION¹ THAT IS NEEDED FOR THIS STUDY:

WHO ARE THE INDIVIDUALS OR ENTITIES COVERED UNDER HIPAA THAT WILL BE CREATING, MAINTAINING, USING OR PROVIDING THE PROTECTED HEALTH INFORMATION?:

WHO WILL HAVE ACCESS TO THE PROTECTED HEALTH INFORMATION?: [Describe each person and organization by name or category. Examples include the research sponsor, the investigator, the research staff, and all research monitors.]

¹ "Protected Health Information", as defined by the HIPAA privacy regulations, is, with certain exceptions, all individually identifiable health information that is created or maintained by a person or entity covered under HIPAA. "Health Information" is defined as any information created or received by a health care provider, health plan, public health authority, employer, life insurer, school or university, or health care clearinghouse that relates to the past, present, or future health or health care of an individual or payment for that care. Health Information is "individually identifiable" if it identifies an individual or if there is a reasonable basis to believe that the information can be used to identify an individual. The revised CUNY Investigator's Manual will include a discussion of information that is considered PHI. Until the revised CUNY Investigator's Manual is available, please consult your IRB Chair or IRB Administrator.

DESCRIBE THE RISKS TO PRIVACY INVOLVED IN THIS STUDY:

What identifiers will be observed, collected or stored? [Please indicate on Attachment 2 which identifiers will be observed, collected or stored, and which identifiers will not be needed.]

Who will have access to identified information?

How will access to study data be controlled?

Who will monitor access to study data?

Where will identified information be stored?

PLAN FOR DESTROYING IDENTIFIERS: [Describe how, by whom and when identifiers will be destroyed.]

IF ALTERATION OF CUNY'S STANDARD HIPAA AUTHORIZATION FORM (INSTEAD OF A WAIVER) IS REQUESTED, EXPLAIN HOW THE FORM OF AUTHORIZATION WOULD BE ALTERED AND ATTACH THE FORM OF AUTHORIZATION THAT YOU WOULD PROPOSE TO USE:

EXPLAIN WHY THE STUDY PRESENTS NO MORE THAN A "MINIMAL RISK" TO PRIVACY²:

IMPRACTICABILITY OF OBTAINING AUTHORIZATION: [Describe why it would be impracticable to obtain each subject's authorization for use and/or disclosure of his or her data or to obtain authorization by using CUNY's standard HIPAA Authorization form.]

IMPRACTICABILITY OF THE RESEARCH WITHOUT PHI: [Describe why the research could not practicably be carried out without the use of PHI.]

² "Minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests. The IRB will determine whether a risk to privacy associated with a proposed study is "minimal" based on the investigator's plan (a) to protect the identifiers from improper use and disclosure, (b) to destroy the identifiers at the earliest opportunity consistent with the conduct of the research, and (c) to prevent the reuse or disclosure of protected health information beyond what is required for the proposed research.

INVESTIGATOR'S ASSURANCES:

I will not reuse the protected health information (“PHI”) for which I have requested this Waiver or Alteration of HIPAA Authorization other than as described in this application form, or disclose the PHI to any person or entity other than those listed above, except as required by law, for authorized oversight of this research study, or as specifically approved for use in another study by an IRB. I also assure the IRB that the PHI for which I have requested this waiver or alteration is the minimum amount of PHI necessary for the research purpose described in this application.

Signature of Investigator

Date

CUNY IRB Action:

- Waiver/Alteration Request Approved**
- Waiver/Alteration Request Denied**
- Approval Deferred Pending the Following Actions:**

(Signature of CUNY IRB Chair)

(Date)

ATTACHMENT 1

Criteria for IRB Approval of Waiver of Authorization for Use or Disclosure of Protected Health Information in Research - 45 CFR §164.512

Waiver criteria. A statement that the IRB or privacy board has determined that the alteration or waiver, in whole or in part, of authorization satisfies the following criteria:

- (A) 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:
 - (1) An adequate plan to protect the identifiers from improper use and disclosure;
 - (2) 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
 - (3) 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 study, or for other research for which the use or disclosure of protected health information would be permitted by this subpart;
- (B) The research could not practicably be conducted without the waiver or alteration; and
- (C) The research could not practicably be conducted without access to and use of the protected health information.

ATTACHMENT 2

IDENTIFIERS – 45 CFR §164.514(b)

<p align="center"><u>Identifier</u></p> <p><i>(For each of the following identifiers, indicate in the columns at the right whether or not the identifier will be part of the data observed, collected or stored.)</i></p>	<p align="center"><u>This identifier will be observed, collected or stored</u></p>	<p align="center"><u>This identifier will not be needed for research</u></p>
1. Names	<input type="checkbox"/>	<input type="checkbox"/>
2. All geographic subdivisions smaller than a State, including: <ul style="list-style-type: none"> - street address - city - county - precinct zip codes and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly-available data from the Bureau of the Census: (1) the geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people, and (2) 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"/>	<input type="checkbox"/>
3. Telephone numbers	<input type="checkbox"/>	<input type="checkbox"/>
4. Fax numbers	<input type="checkbox"/>	<input type="checkbox"/>
5. E-mail addresses	<input type="checkbox"/>	<input type="checkbox"/>
6. Social Security numbers	<input type="checkbox"/>	<input type="checkbox"/>
7. Medical record numbers	<input type="checkbox"/>	<input type="checkbox"/>
8. Health plan beneficiary numbers	<input type="checkbox"/>	<input type="checkbox"/>
9. Account numbers	<input type="checkbox"/>	<input type="checkbox"/>

<p style="text-align: center;"><u>Identifier</u></p> <p><i>(For each of the following identifiers, indicate in the columns at the right whether or not the identifier will be part of the data observed, collected or stored.)</i></p>	<p style="text-align: center;"><u>This identifier will be observed, collected or stored</u></p>	<p style="text-align: center;"><u>This identifier will not be needed for research</u></p>
<p>10. All elements of dates (except year) for dates related to an individual, including:</p> <ul style="list-style-type: none"> -birth date -admission date -discharge date -date of death -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 	<input type="checkbox"/>	<input type="checkbox"/>
<p>11. Certificate/license numbers</p>	<input type="checkbox"/>	<input type="checkbox"/>
<p>12. Vehicle identifiers and serial numbers, including license plate numbers</p>	<input type="checkbox"/>	<input type="checkbox"/>
<p>13. Device identifiers and serial numbers</p>	<input type="checkbox"/>	<input type="checkbox"/>
<p>14. Web Universal Resource Locators (URLs)</p>	<input type="checkbox"/>	<input type="checkbox"/>
<p>15. Internet Protocol (IP) address numbers</p>	<input type="checkbox"/>	<input type="checkbox"/>
<p>16. Biometric identifiers, including finger and voice prints</p>	<input type="checkbox"/>	<input type="checkbox"/>
<p>17. Full face photographic images and any comparable images</p>	<input type="checkbox"/>	<input type="checkbox"/>
<p>18. Any other unique identifying numbers, characteristics, or codes</p>	<input type="checkbox"/>	<input type="checkbox"/>