

Privacy Board
The Johns Hopkins Medical Institutions
Health System/School of Medicine/School of Nursing/Bloomberg School of Public Health
5801 Smith Avenue, Suite 235, Baltimore MD 21209
410-735-6800, Fax 410-735-6770

**Application for a Waiver of Authorization for Research Use or
Disclosure of Protected Health Information (PHI) and
Other Personal Information that is Protected by Law**

The Policies of the Johns Hopkins Medical Institutions foster open intellectual inquiry within the context of the law and the ethics of the health professions. Research of records, data, and information held by the Medical Institutions may be conducted when it is legally possible to permit access to and use of these materials. The Privacy Board of the Johns Hopkins Medical Institutions reviews applications to conduct research of institutional records and data that contain information that is protected by law. It is the charge of the Privacy Board to allow research of these institutional materials whenever it is legally possible and ethically responsible to do so.

Guidelines for Submission of Application

1. The application to the Privacy Board includes the attached questionnaire and the following supporting documents:
 - A project abstract which includes a summary of the materials at the Johns Hopkins Medical Institutions that you wish to access
 - Curriculum Vitae
 - A letter of reference. Letters of reference may be waived for faculty and staff of the Johns Hopkins Medical Institutions.
2. Applications will be considered once a completed questionnaire and all supporting documents have been received. Contact the Privacy Board staff for dates of scheduled meetings.
3. In preparing your application, please clearly define the measures you intend to take to safeguard any personal information protected by law that you may encounter in your research. See the attached summary of laws protecting personal information. In reviewing applications, the Privacy board is required to evaluate the following factors:
 - Your intended use of the protected information, and the degree to which that information is necessary to your proposed research;
 - The specific legal terms of access that apply to the various types of protected information to which you seek access;
 - The degree to which your use or disclosure of the information may jeopardize the right to privacy of the subjects of that information;
 - Your plan for disposing of the protected information at the conclusion of your research;
 - The degree to which a waiver of individual authorization is necessary to your research;
 - The degree of risk of unlawful, unauthorized, or unethical use or disclosure, reuse or redisclosure of the private information of individuals.

Please contact the Privacy Board staff if you have questions or need assistance in the preparation of your application.

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Name of Applicant: _____

1. In order for the Privacy Board to grant a waiver of authorization, you must demonstrate that your research cannot practicably be conducted without access to the material and that your research cannot be practicably conducted without the waiver.

a) Indicate why the materials that you wish to access are necessary to your proposed research:

b) Indicate why the study cannot be conducted without the waiver of authorization. Check all that apply.

- It would be difficult or impossible to find the persons whose personal information may be included.
- Materials contain information of both living and deceased individuals.
- Until I review the information I will not know whose personal information may be included.
- Other reasons: _____

2. The materials you access may contain the confidential information of many individuals. Explain why your use of PHI/Confidential Information poses no more than a minimal risk to the subjects of that information: _____

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3. List those persons/entities with whom, for research purposes, you will need to share the PHI/Confidential Information: _____

4. Following are examples of elements included in a typical plan to protect confidential information. Please check all those that are included in your plan and add any other privacy protections that you intend to utilize.
- Only those persons indicated in this application will be granted access.
 - All paper files will be stored within a secured storage system to which only you and those persons indicated above will have access.
 - All electronic data will be password protected.
 - Passwords and system IDs will not be shared.
 - Passwords will be changed on a regular basis.
 - Additional protections: _____

5. Indicate how you will protect the PHI/Confidential Information you encounter if publications and/or oral presentations result from this research. Check all that apply.
- Omission of information from publication
 - Redaction of information
 - Modification of identifiers
 - Other methods: _____

6. Please indicate the procedures that you will follow to destroy your notes and data containing PHI/Confidential Information
- Physical and/or electronic data will be shredded or deleted.
 - Other methods: _____

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Summary of the Laws that Protect Personal Information

HIPAA – The Health Insurance Portability and Accountability Act of 1996.

HIPAA Privacy Rule – Under HIPAA, the Privacy Rule went into effect on April 14, 2003. The purpose of the Privacy Rule is to establish minimum Federal standards for safeguarding the privacy of individually identifiable health information. The Privacy Rule allows access to protected health information (**PHI**) for research purposes under limited circumstances, and only when that research corresponds to the Rule’s definition of research.

Research - Research means a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge.

In most circumstances, the researcher must obtain authorization from the individual whose **PHI** he wishes to use or disclose. However, a Privacy Board or Institutional Review Board may grant a waiver of the required individual authorization to use or disclose **PHI**. In order to be considered for this waiver, the researcher must demonstrate to the Privacy Board or IRB that his plan of research meets, in whole or in part, the following criteria:

- The use or disclosure of **PHI** 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 **PHI** from improper use and disclosure.
 2. An adequate plan to destroy the **PHI** at the earliest opportunity consistent with conduct of the research, unless there is a health or research justification for retaining the protected health information or such retention is otherwise required by law.
 3. Adequate written assurances that 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 HIPAA.
- The research could not practicably be conducted without the waiver or alteration; and
- The research could not practicably be conducted without access to the materials that may contain **PHI**.

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Minimal Risk – The Privacy Rule adopts the definition of “minimal risk” that was established under the Common Rule. By this definition, “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.”

PHI (Protected Health Information) is defined as “individually identifiable health information, held or maintained by a covered entity or its business associates acting for the covered entity, that is transmitted or maintained in any form or medium [...]. This includes identifiable demographic and other information relating to the past, present, or future physical or mental health or condition of an individual, or the provision or payment of health care to an individual that is created or received by a health care provider, health plan, employer, or health care clearinghouse”. This definition applies to living and deceased individuals.

Thus in protecting the privacy of individuals, the following **18 identifiers** may not be revealed: names; geographic subdivisions smaller than a state; all elements of dates (except year); telephone numbers; facsimile numbers; electronic mail addresses; social security numbers; medical record numbers; health plan beneficiary numbers; account numbers; certificate/license numbers; vehicle identifiers and serial numbers; device identifiers and serial numbers; web universal resource locators (URLs); internet protocol (IP) address numbers; biometric identifiers; full-face photographic images; Any other unique identifying number, characteristic, or code, unless otherwise permitted by the Privacy Rule for re-identification.

For more information on the **HIPAA Privacy Rule** (45 CFR 160, 164), and the **Common Rule** (45 CFR 46 Subpart A) visit the following websites:

U.S. Department of Health and Human Services, National Institutes of Health; HIPAA Privacy Rule Information for Researchers:

<http://privacyruleandresearch.nih.gov/>

Details on the **18 identifiers** may be found at:

http://privacyruleandresearch.nih.gov/pr_08.asp#8a

National Institute of Health, Office of Human Subjects Research; Code of Federal Regulations:

<http://ohsr.od.nih.gov/guidelines/45cfr46.html>

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FERPA - The Family Educational Rights and Privacy Act (commonly referred to as the *Buckley/Pell Amendment*, 20 U.S.C. § 1232g; 34 CFR Part 99) is a Federal law that protects the privacy of the education records of living individuals.

Confidential Education Records - As defined in FERPA, Confidential Education Records are “those records that are

- 1) directly related to a student; and
- 2) maintained by an educational agency or institution or by a party acting for the agency or institution.”

The law applies to all schools that receive funds under an applicable program of the U.S. Department of Education. Under this Act, confidential education information may be disclosed without the authorization of the subject of that information under only a very limited number of circumstances. Disclosure is allowed for limited research uses:

- To develop, validate, or administer predictive tests;
- To administer student aid programs; or
- To improve instruction

This disclosure is only allowed, however, under the following conditions:

- Personally identifiable information is not shared;
- Personally identifiable information is not redisclosed;
- The information is used only for the reason for which it was disclosed;
- The information is destroyed when no longer needed for research.

While FERPA only restricts disclosure of the educational records of living individuals, it is the policy of the Johns Hopkins Medical Institutions to not disclose grades or any evaluative information of all individuals, living or deceased.

For information on **FERPA**, visit the following websites:

United States Code, Title 20:

<http://frwebgate3.access.gpo.gov/cgi-bin/waisgate.cgi?WAISdocID=90598411836+1+0+0&WAIAction=retrieve>

Code of Federal Regulations:

http://www.access.gpo.gov/nara/cfr/waisidx_03/34cfr99_03.html

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Common law and institutional policy - While HIPAA protects health information and FERPA protects student information, common law protects other types of private information when that information is of a kind that

- 1) would be highly offensive to a reasonable person, and
- 2) is not of legitimate concern to the public

(See Second Restatement of Torts at §§ 652A – 652I).

Finally, it should be noted that the privacy policies of the Johns Hopkins Medical Institutions supplement all of the above-noted federal laws and regulations and that the policies of The Johns Hopkins Medical Institutions may be stricter, concerning certain aspects of privacy protection, than federal or state laws or regulations. The Privacy Board of The Johns Hopkins Medical Institutions reserves the right to refuse access to any information in all cases where it finds that such access may jeopardize the privacy of any individual.