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.

Privacy Board review includes, but is not limited to, applications for research in collections held by the following repositories:

Alan Mason Chesney Medical Archives of the Johns Hopkins Medical Institutions

Medical Records Division of the Johns Hopkins Hospital (for access to records that are more than 50 years old)

Department of Art as Applied to Medicine

Please refer to the policies of each individual repository for further limitations.

**Guidelines for Submission of Application**

1. 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 degree to which a waiver of individual authorization is necessary to your 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;
	* The degree of risk of unlawful, unauthorized, or unethical use or disclosure, reuse or redisclosure of the private information of individuals;
	* Your plan for disposing of the protected information at the conclusion of your research.
2. The application to the Privacy Board includes the attached form which includes a questionnaire and project abstract, along with 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 (see Part 3 in the application form).
* Curriculum Vitae
* A letter of reference. Letters of reference may be waived for faculty and staff of the Johns Hopkins Medical Institutions. Students must have their academic advisors sign their application form as an additional investigator, in addition to providing a letter of reference.
* Determination regarding human subject research. In cases that might involve living subjects, applicants should seek a determination from their home institution’s Institutional Review Board (IRB) or their institution’s equivalent. Applicants from Johns Hopkins conducting human subject research should apply to a Johns Hopkins IRB instead of the Privacy Board. Applicants from outside of Johns Hopkins conducting human subject research should apply to their home institution IRB and the Johns Hopkins Privacy Board when research involves PHI located at Johns Hopkins.
1. The Privacy Board will consider your application upon receipt of your completed questionnaire and all supporting documents. Contact the Privacy Board staff for dates of scheduled meetings.

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

\*Protected Health Information (PHI) includes the following types of identifiers:

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| * Names
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| * Geographic information smaller than a state
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| * Elements of dates (birthdates, admission dates, dates of death, ages greater than 89 years)
 |
| * Telephone numbers
 |
| * Fax numbers
 |
| * Electronic mail addresses
 |
| * Social security numbers
 |
| * Medical record numbers
 |
| * Account numbers
 |
| * Certificate or license numbers
 |
| * Vehicle identifiers and serial numbers including license plate
 |
| * Device identifiers and serial numbers
 |
| * URLs
 |
| * IP addresses
 |
| * Biometric identifiers
 |
| * Full face photographic images and comparable images
 |
| * Health plan beneficiary numbers
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| * Any other unique identifying number, characteristic or code that meets the following criteria:
	+ It is not derived from any other code (e.g., SSN, MRN) and is not used for any other purpose
	+ Persons using the data for research have not access to the code key and the key is held by a source that is not part of the research team. An investigator (or her study team member) may not create the code for de-identified data that she will use in her own research.
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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

*(Note that spaces will expand to fit.)*

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| --- | --- |
| Name of Applicant |        |
| Title of Project |       |
| Institution |       |
| Mailing address |       |
| Phone number |       | Email address |       |

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| List the persons/entities with whom, for research purposes, you will need to share PHI/confidential information |
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| PART 1. PROJECT ABSTRACT |
| Please describe the purpose of your research, summarize the materials at Johns Hopkins you wish to access, and describe the project you expect to result. If known, list the specific individuals or class of individuals whose PHI you wish to access as part of your research study. If these individuals have been deceased for more than 50 years and their information is excluded from the definition of PHI, do you anticipate disclosing their individually identifiable health information in publications or presentations? *Space will expand to fit.* |
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| PART 2. PROTECTIONS FOR PHI/CONFIDENTIAL INFORMATION |
| 1. In order for the Privacy Board to grant a waiver of authorization, you must demonstrate that your research, as described in your project abstract, cannot practicably be carried out without access to the material and that your research cannot be practicably conducted without the waiver.
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| * 1. State why the materials that you wish to access are necessary to your proposed research:
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| * 1. Indicate why the study cannot be conducted without the waiver of authorization. *Check all that apply.*
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|  | [ ]  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: |
|  |       |
| 1. Explain why your access to PHI and other Confidential Information poses no more than a minimal risk to the privacy of the subjects of that information. Since the materials you access may contain the confidential information of many individuals, your response should address whether your study poses a risk to specific individuals or groups, and the extent to which you will use confidential information about these individuals or groups in your research.
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| 1. If you anticipate needing to record any PHI, you must describe what type of PHI you plan to record and in what format you plan to record it. If there is valid justification for obtaining photocopies of medical records, electronic copies of electronic medical records or digital copies (e.g., PDF) of other archival materials containing PHI, you may be asked to sign a Data Use Agreement prepared by Johns Hopkins legal counsel.
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| * 1. Describe what type of PHI you may wish to record during the course of your proposed research and justify your need for recording PHI.
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| * 1. Indicate in what format you plan to record PHI. *Check all that apply. Be advised that the repository has limits on what materials may be reproduced.*
 |
|  | [ ]  Photocopies of any material used in research, excluding medical records |
|  | [ ]  Digital copies of any materials used in your research, excluding medical records |
|  | [ ]  Photocopies of medical records |
|  | [ ]  Electronic copies of electronic medical records |
|  | [ ]  Notes collected as electronic documents stored on a computer or other electronic device. |
|  | [ ]  Handwritten notes on paper |
|  | [ ]  Other: |
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| 1. Following are required 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 use. If approved you will also be required to sign a Data Security Acknowledgement for research use of PHI governed by the Privacy Board of the Johns Hopkins Medical Institutions.
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|  | [ ]  Data may be shared only with Privacy Board-approved and (if applicable) IRB-approved members of your study team. |
|  | [ ]  You are responsible for ensuring that all users meet these requirements. |
|  | [ ]  You will access only the records specified in your approved protocol. |
|  | [ ]  You will use reasonable efforts to record only the minimum necessary PHI. |
|  | [ ]  You will maintain only a single copy (plus one backup) in electronic form. |
|  | [ ]  You will put data only on portable media (e.g., laptops or thumbdrives) or desktop computers that have been encrypted by IT at Johns Hopkins or your local institution. |
|  | [ ]  All of your storage devices will be password-protected, and only authorized users will have access to the password. Passwords will be changed on a regular basis. |
|  | [ ]  Computers on which PHI is maintained will have anti-virus and anti-intrusion (anti-spy) software. |
|  | [ ]  All paper files will be stored within a secured storage system to which only you and those persons indicated above will have access.  |
|  | [ ]  You will extend these protections until you return or destroy any PHI that you remove from Johns Hopkins. |
|  | [ ]  You will consult with the Privacy Board staff before recording PHI as reproductions (paper or digital) or in electronic format to determine if a Data Use Agreement with Johns Hopkins is required. |
|  | [ ]  Additional protections: |
|  |  |       |
|  | If any of the required elements listed above is not included in your data security plan, please explain: |
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| 1. 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.*
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|  | [ ]  Omission of information from publication |
|  | [ ]  Redaction of information |
|  | [ ]  Modification of identifiers |
|  | [ ]  Other methods: |
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| 1. Please describe the procedures that you will follow to destroy your notes and data containing PHI/Confidential Information.
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|  | [ ]  Physical and/or electronic data will be shredded or deleted. |
|  | [ ]  Other methods: |
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| PART 3. HUMAN SUBJECTS RESEARCH DETERMINATION |
| Indicate whether your research constitutes human subjects research and what steps you have taken for review of your research. |
|  | [ ]  Research does not constitute human subjects research.  |
|  |  [ ]  Research involves exclusively PHI of deceased individuals and it not subject to IRB review. |
|  |  [ ]  Other reasons: |
|   |       |
|  | [ ]  If your research has been or will be reviewed by an IRB in your home institution or elsewhere, indicate the determination reached by the Board and attach documentation. |
|  |  [ ]  Approved as human subjects research |
|  |  [ ]  Approved as Exempt |
|  |  [ ]  Approved as “Not human subjects research” |
|  |  [ ]  Pending review |
|  |  [ ]  Other: |
|   |       |
|  | [ ]  If your research has not been reviewed by or is not pending with an IRB, please explain the steps you are taking to obtain review of your research and your data collection plan. |
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STATEMENT OF PRINCIPAL INVESTIGATOR

As applicant, I make the following assurances to the Privacy Board:

* The information that I have provided in this request for a Waiver of Authorization is complete and accurate.
* I will access only the minimum amount of PHI/Confidential Information necessary to accomplish the research described in this application.
* I will not reuse the PHI/Confidential Information or disclose it to any person or entity other than those indicated in this application, except:

 1. as required by law,

 2. for authorized oversight of research,

 3. In connection with other research for which the HIPAA Privacy Rule permits this PHI to be used or disclosed.

* If at any time I wish to reuse this information for other purposes or disclose the information to other individuals or entities, I will seek approval by the Privacy Board.
* I understand that I am ultimately responsible for protecting the private information of individuals.
* I assume responsibility to ensure that the additional investigators listed below use and disclose PHI only as permitted and protect its security and confidentiality as required by the Privacy Board.
* I acknowledge that it is not the intention of Johns Hopkins to disclose any confidential materials to me other than those described in this application. If I encounter such incidental confidential information, I agree not to review any such materials once I determine that such materials are or may be confidential.  When in doubt about the confidentiality of any materials, I agree to consult with Johns Hopkins personnel before conducting further review of the material in question and I agree to abide by any decision of Johns Hopkins personnel regarding confidentiality.

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Signature of Principal Investigator Please print or type name Date

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Signature of Additional Investigator Please print or type name Date

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Signature of Additional Investigator Please print or type name Date

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Signature of Additional Investigator Please print or type name Date

*Note to applicant:*

If the Privacy Board or its designee approves a waiver of authorization, it is your responsibility to keep an accounting of those to whom you disclose PHI at any time during the research activity. Under the Privacy Rule, an individual whose PHI you obtain may request an “accounting of disclosures” for the six year period prior to the request or since the applicable compliance date. An accounting for disclosures of identifiable health information is not required when PHI is shared with a researcher who is an employee or workforce member of a Johns Hopkins covered entity.