

Johns Hopkins University	Johns Hopkins HIPAA Policies for Providers Research - Uses and Disclosures for Research Purposes	<i>Procedure Number</i>	A135
		<i>Effective Date</i>	04/17/2019
Johns Hopkins Medicine	<i>Subject</i> Providing PHI to Researchers	<i>Page</i>	1 of 5
		<i>Supersedes</i>	03/19/2019

This document applies to the following Participating Organizations:

All Children's Research Institute, Inc.	HCGH OB/GYN Associates	Howard County General Hospital	Johns Hopkins All Children's Foundation, Inc.
Johns Hopkins All Children's Health System	Johns Hopkins All Children's Home Care	Johns Hopkins All Children's Hospital	Johns Hopkins Bayview Medical Center
Johns Hopkins Community Physicians	Johns Hopkins Home Care Group	Johns Hopkins Imaging	Johns Hopkins Medicine International
Johns Hopkins Regional Physicians	Johns Hopkins School of Medicine	Johns Hopkins School of Nursing	Johns Hopkins Surgery Centers Series
Ophthalmology Associates	Pediatric Physician Services, Inc. (FL)	Potomac Home Health Care	Potomac Home Support
Sibley Memorial Hospital	Suburban Hospital	Suburban Outpatient Surgery Center	SurgiKid of Florida, Inc.
The Johns Hopkins Health System Corporation	The Johns Hopkins Hospital	The Johns Hopkins University	West Coast Neonatology, Inc.

Keywords: hipaa, research

Table of Contents	Page Number
I. DEFINITIONS	1
II. POLICY	2
III. PROCEDURES	3

I. DEFINITIONS

Disclosure/Disclose means the release, transfer, provision of access to, or the divulging in any manner of PHI to persons or entities outside of the Johns Hopkins Covered Entities and Related OHCA Participants.

HIPAA means the Health Insurance Portability and Accountability Act of 1996, and its implementing regulations, as amended.

Individual means the person who is the subject of the PHI.

Johns Hopkins Covered Entities and Related OHCA Participants -- see the Johns Hopkins Privacy Office website at http://intranet.insidehopkinsmedicine.org/privacy_office/about_hipaa/index.html.

Johns Hopkins means the Johns Hopkins covered entity that adopted this policy.

PHI means protected health information, i.e., individually identifiable health information.

Privacy Regulations means the regulations promulgated by the Secretary of the Department of Health and Human Services to implement portions of HIPAA that concerns the confidentiality of health information, as amended from time to time; these regulations currently include 45 CFR §§ 160 and 164, subparts A, D and E.

Research

For purposes of this policy, **Research** includes any systematic investigation (including research development, testing, and evaluation) that has as its **primary purpose** the development of or contribution to **generalizable knowledge**.

Johns Hopkins University	Johns Hopkins HIPAA Policies for Providers Research - Uses and Disclosures for Research Purposes	<i>Procedure Number</i>	A135
		<i>Effective Date</i>	04/17/2019
Johns Hopkins Medicine	<i>Subject</i> Providing PHI to Researchers	<i>Page</i>	2 of 5
		<i>Supersedes</i>	03/19/2019

- **Generalizable knowledge.** Knowledge may be generalizable even if a research study uses only PHI held within Johns Hopkins and the results are generalizable only to the population served by Johns Hopkins. Research is therefore not limited to clinical trials funded by government sponsors (such as the National Institutes of Health) or commercial sponsors. However, quality assurance and utilization management activities do not typically result in generalizable knowledge and thus would not be governed by this policy. Also, unplanned observations which may result in generalizable knowledge are not covered by this policy.
- **Primary purpose.** The development or contribution to generalizable knowledge must be the *primary purpose* of the investigation for this policy to be applicable. In some instances, the primary purpose of the activity may change as preliminary results are analyzed. An activity that was initiated as an internal Johns Hopkins outcomes evaluation, for example, may produce information that Johns Hopkins intends to generalize. *If the purpose of a study changes and the results will be generalized, the Principal Investigator (“PI”) must notify the IRB and the IRB must document the change in status of the activity.*

If an activity would be considered "Research" under other applicable Johns Hopkins policies, it should be considered Research for purposes of this policy.

Use means the sharing, employment, application, utilization, examination or analysis of PHI within the Johns Hopkins Covered Entities and Related OHCA Participants.

II. POLICY

It is the policy of Johns Hopkins to protect the privacy rights of all patients, health plan members, employees, students and donors; to maintain the confidentiality of patient information, health plan information, medical records, research information and business operations; and to comply with all applicable laws and regulations, including the Privacy Regulations under HIPAA.

A. PHI received or maintained by Johns Hopkins may *not* be Used internally or Disclosed to any persons or organizations outside Johns Hopkins for Research purposes except as follows:

1. Reviews preparatory to Research, based on representations of the researcher that:
 - a. Use is sought solely to review PHI as necessary to prepare a Research protocol or for similar purposes preparatory to Research,
 - b. no PHI is to be removed from Johns Hopkins by the researcher in the course of the review,

(Those granted access may record information only in a form that is “de-identified.” See HIPAA Policy A042 for a description of information that constitutes de-identified information.)

and

- c. the PHI being sought is necessary for the Research purposes.
2. Research on the PHI of decedents, based on representations of the researcher to a Johns Hopkins approved IRB or PB (as defined below) that:
 - a. the Use or Disclosure is solely for Research on the PHI of decedents, and
 - b. the PHI being sought is necessary for Research purposes.

The researcher must, at the request of Johns Hopkins, provide documentation of the death of the Individuals whose PHI is being sought.

Johns Hopkins University	Johns Hopkins HIPAA Policies for Providers Research - Uses and Disclosures for Research Purposes	<i>Procedure Number</i>	A135
		<i>Effective Date</i>	04/17/2019
Johns Hopkins Medicine	<i>Subject</i> Providing PHI to Researchers	<i>Page</i>	3 of 5
		<i>Supersedes</i>	03/19/2019

Information on Individuals who have been deceased for more than 50 years is not PHI, and is therefore not subject to this policy.

3. The researcher has obtained a valid, HIPAA compliant, privacy authorization (whether a separate form or a combined informed consent/authorization form) from the Individual.
 4. An Institutional Review Board (IRB) or Privacy Board (PB), acceptable to Johns Hopkins, has approved a waiver of the privacy authorization requirement.
 5. The information is partially de-identified into a “limited data set” and the researcher and Johns Hopkins sign a Data Use Agreement to protect the privacy of the information.
(See HIPAA Policy A091—HIPAA Related Agreements—for information about the identifiers that must be removed from an Individual’s PHI in order to create a *limited data set*-- and Form A.9.1.b.)
 6. The information is “de-identified” as defined by HIPAA.
(See HIPAA Policy A042 for a description of information that constitutes de-identified information as defined by HIPAA.)
- B. Special rules apply to the Use and/or Disclosure for Research purposes of psychotherapy notes.
1. When a Research protocol requires Use or Disclosure of psychotherapy notes, the principal investigator should complete a separate authorization form in addition to the privacy authorization form or combined authorization/informed consent form and have it signed by the Individual.
 2. The IRB or PB may not waive the requirement for HIPAA authorization for the Use or Disclosure of psychotherapy notes. The authorization for psychotherapy notes may not be combined with the informed consent form or with any other HIPAA authorization.
 3. If a person or organization is not included on the authorization for the Use or Disclosure of psychotherapy notes form, that person or organization may neither receive psychotherapy notes nor Use nor Disclose psychotherapy notes for Research purposes.

III. PROCEDURES

A. IRB Review

1. If the researcher is from a Johns Hopkins entity, before the researched can Use or Disclose PHI for purposes of Research, the researcher must provide documentation reflecting either (i) approval of his/her study protocol by a Johns Hopkins IRB, which includes the School of Medicine IRB (JHM IRB) or the Bloomberg School of Public Health IRB, or (ii) a local context review has been conducted by the JHM IRB or the Bloomberg School of Public Health IRB and the appropriate reliance documentation has been put in place to rely on an external IRB's approval.
The Johns Hopkins IRBs are responsible for implementing policies and procedures regarding compliance with HIPAA for human subjects research protocols that they review.
2. If the IRB documentation states only that the study is exempt from on-going IRB review/approval or that the study does not qualify as human subjects research (for example, because it involves only information on decedents), this documentation alone is NOT adequate on which to release PHI. A PB review and approval is still required.
 - a. If the researcher is from the Johns Hopkins University Bloomberg School of Public Health, before getting access to Johns Hopkins PHI, the researcher must follow the JHUSPH HIPAA Policies and Practices located at <https://www.jhsph.edu/offices-and-services/institutional-review-board/hipaa/index.html>.
3. If the researcher requesting PHI is from anywhere other than a Johns Hopkins entity and is requesting PHI on five (5) or less individuals, the Johns Hopkins Privacy Office should be consulted. If the request is for PHI on more than five (5) individuals, a collaboration agreement with a Johns Hopkins entity will be required before PHI can be shared.

Johns Hopkins University	Johns Hopkins HIPAA Policies for Providers Research - Uses and Disclosures for Research Purposes	<i>Procedure Number</i>	A135
		<i>Effective Date</i>	04/17/2019
Johns Hopkins Medicine	<i>Subject</i> Providing PHI to Researchers	<i>Page</i>	4 of 5
		<i>Supersedes</i>	03/19/2019

B. Privacy Board Review

1. PHI may be provided to either an internal or external researcher after documentation is presented reflecting a waiver or alteration of authorization has been granted from a PB approved by Johns Hopkins.
2. Required Composition of a Johns Hopkins approved PB
 - a. Any PB that has the authority under HIPAA to approve a waiver request must:
 1. Include members of varying backgrounds and appropriate professional competency as necessary to review the effect of the Research protocol on the individual's privacy rights and related interests;
 2. Include at least one member who is not affiliated with Johns Hopkins, not affiliated with any entity conducting or sponsoring the Research, and not related to any person who is affiliated with any of such entities; and
 3. Does not have any member participating in a review of any project in which the member has a conflict of interest.
3. Authority of the PB
 - a. The JHM IRB, the Bloomberg School of Public Health IRB, and The Alan Mason Chesney Medical Archives of The Johns Hopkins Medical Institutions PB meet the requirements of a PB under HIPAA and are considered approved PBs authorized to act as PBs on behalf of Johns Hopkins.
4. Johns Hopkins PB Review Process
 - a. In the event a researcher requests PHI for Research purposes, but the Research is exempt from on-going IRB review/approval or the study does not qualify as human subjects research, PHI can be provided to the researcher after documentation is obtained reflecting that one of the PBs authorized by this policy to act on behalf of Johns Hopkins has either waived or altered the HIPAA authorization requirement, and the researcher has complied with such approval or (ii) a local context review has been conducted by one of the PBs authorized by this policy to act on behalf of Johns Hopkins and the appropriate reliance documentation has been put in place to rely on an external PB's approval.
 - b. In considering a request to waive or alter the authorization requirement under HIPAA, the PB shall consider the following criteria:
 1. The Use or Disclosure involves no more than minimal risk to the privacy of the individuals, based on, at least, the presence of the following elements:
 - An adequate plan to protect the identifiers from improper Use and Disclosure;
 - 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
 - Adequate written assurances that the PHI will not be re-Used 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.
 2. The Research could not practicably be conducted without the waiver or alteration; and
 3. The Research could not practicably be conducted without access to and use of the PHI.
 - c. If a researcher applies to a Privacy Board to approve a waiver or alteration of authorization, the PB shall:
 1. Review the proposed Research at a convened meeting at which a majority of the PB members are present, including at least one member who meets the criteria set forth in III.B.2.a.(2) above, and the waiver or alteration of authorization is approved by a majority of the PB members present at the meeting; or
 2. Approve the waiver or alteration of authorization pursuant to an expedited review procedure, if the Research involves no more than minimal risk to the privacy of the individuals who are the subject of the PHI for which Use or Disclosure is being sought. In such event, the approval of the waiver or alteration

Johns Hopkins University	Johns Hopkins HIPAA Policies for Providers Research - Uses and Disclosures for Research Purposes	<i>Procedure Number</i>	A135
		<i>Effective Date</i>	04/17/2019
Johns Hopkins Medicine	<i>Subject</i> Providing PHI to Researchers	<i>Page</i>	5 of 5
		<i>Supersedes</i>	03/19/2019

of authorization may be carried out by the chair of the PB, or by one or more members of the PB as designated by the chair.

- d. Any approval of a waiver or alteration of the authorization requirement must be documented and signed by the chair of the PB or other member, as designated by the chair. Such documentation and signature requirement is met if approval is documented by a PB approval stamp or PB determination is reflected in an electronic system.
 5. In the event a researcher requesting PHI is from anywhere other than a Johns Hopkins entity and is requesting PHI on five (5) or less individuals, the Johns Hopkins Privacy Office should be consulted. If the request is for PHI on more than five (5) individuals, a collaboration agreement with a Johns Hopkins entity will be required before PHI can be shared.
- C. Tracking
1. It is not necessary for Johns Hopkins holders of health information to track release of PHI to researchers from the Johns Hopkins University Schools of Medicine, School of Nursing or Bloomberg School of Public Health; tracking is addressed at the School or IRB level.
 2. If the Disclosure of PHI to a researcher from anywhere other than the Johns Hopkins University Schools identified in C.1 above occurs and is based on anything other than
 - a. the authorization of the Individual whose information is being sought, or
 - b. de-identified information, or
 - c. a limited data set,
 then the Disclosure must be “tracked” in a manner that permits linking the Disclosure to each Individual’s record. (See HIPAA Policy A064 - Tracking, and Right for an Accounting of, Disclosures From Clinical Records.)

HIPAA Regulation Cross-walk

§ 164.512(i) – Uses and disclosures for research purposes