CARILION CLINIC INSTITUTIONAL REVIEW BOARD
Standard Operating Guidelines

Title: 2.14: Review of Research: HEALTH INSURANCE PORTABILITY AND ACCOUNTABILITY ACT (HIPAA)	
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Primary Sponsor: Human Research Protections Office	**Approved By:** Director of the Human Research Protections Office

Objective:

To provide a guideline that applies to anyone who conducts research, assists in the performance of research, or otherwise uses or discloses protected health information in connection with research activities at Carilion Clinic.

General Description:

HIPAA requirements are in addition to ethical and regulatory protections for human research subjects and do not supersede them. The HIPAA Privacy regulations are focused on health care consumer information protection. If a research study either uses or creates protected health information, HIPAA documentation requirements apply to those research uses of protected health information in addition to relevant privacy and confidentiality protections that are required by ethics and federal regulation for human research subject protection.

Definitions

Research: HIPAA defines research as a systematic investigation, including research development, testing, and evaluation, designed to develop or contribute to generalizable knowledge. Any project involving protected health information where one of the primary goals is generalizable knowledge, with or without publication or public presentation, is considered research. In contrast to research use of PHI, requests for access, use and disclosure of PHI for purposes of treatment, payment or healthcare operations are governed by a different set of rules.

Protected Health Information (PHI): HIPAA defines PHI as individually identifiable health condition, health care and health care payment information, including the demographic data that is a potential identifier of the individual, maintained in the records of health care providers, health plans and health care clearinghouses for treatment, payment and healthcare operations purposes. PHI does not include individually identifiable health information in personnel records or education records covered by the Family Education Right and Privacy Act.

Covered Entity: This is the term that the HIPAA regulations use to describe the businesses in the health care industry that are subject to HIPAA regulations. Specifically, covered entities are health plans, health care clearinghouses and health care providers who transmit any health information in electronic form in connection with the following transactions: health care claims or encounter information, health care payment and remittance advice, coordination of benefits, health care claim status, enrollment or disenrollment or eligibility information for health plans,

health plan premium payments, referral certification and authorization, first report of injury, or health claims attachments.

Different individuals or entities have different responsibilities with regard to HIPAA. For all research reviewed by Carilion Institutional Review Board (IRB), the responsibilities of those associated with the research are as follows:

- **Carilion IRB**: Carilion IRB will review and approve all authorization documents used by researchers in the informed consent process for protocols that are being reviewed by the Carilion IRB. It will also review and approve all Waivers of Authorization for protocols that it reviews. IRB review is required before any research can be conducted on Carilion patients or on Carilion-created medical records.
- **Principal Investigator/Study Team Member**: Any investigator whose research is reviewed by Carilion IRB or any member of the research staff will be responsible for:
  - Accurate and complete representation of the study's use and disclosure of PHI and data privacy practices to the IRB
  - Compliance with this policy in accessing and using PHI for research. Although an investigator or a research study team member may have access to PHI for her/his clinical roles, PHI may not be transferred from clinical or other health care provider records for research use except as described below.
    - Compliance with the PHI access procedures of any covered entity from whose records the investigator seeks PHI for research
    - Compliance in using and disclosing PHI only in accord with the terms and conditions of the permissions under which the PHI was received for research, which may include: informed consent, authorization, IRB waiver of informed consent, IRB waiver of authorization, limited waiver of authorization, data use agreement, sponsored research agreement or access for review preparatory to research or solely for decedents

Procedure:

Access to PHI

HIPAA permits the access, disclosure and use of PHI from a covered entity's treatment, payment or health care operations records for research purposes in the following ways:

- The signed authorization of the patient whose individually identifiable PHI is sought
- Waiver by the IRB, consistent with specified criteria, of the authorization requirement for use of individually identifiable PHI
- Review of PHI solely in preparation for research, without collecting the PHI for research use. Such information may not be documented or removed from the Carilion facility.
- Complete de-identification, by removal of the 18 HIPAA identifiers of the PHI
- Conversion of the PHI to a "limited data set" devoid of 16 specified identifiers together with execution of a data use agreement with specific provisions covering use and disclosure of the limited data set
- Use of PHI solely of decedents
- Transition provisions as described below

HIPAA Authorizations

As a general rule, a researcher must obtain an authorization from all research subjects prior to the internal use or external disclosure of PHI for any research related purpose, unless a waiver

of authorization is approved by the IRB. The researcher must submit an authorization, either by itself or as part of the informed consent, to the IRB for prior review and approval. An authorization must be written in plain language and contain all of the following elements:

- A specific and meaningful description of the information to be used or disclosed
- The name or identification of the persons or class of persons authorized to make disclosures of PHI and to use the PHI for research-related purposes
- The name or identification of the persons or class of persons authorized to receive disclosures of the PHI and to use the PHI for research-related purposes
- A description of each purpose of the use or disclosure (for example, a specific research study)
- An expiration date or event, or a statement "end of research study" or "none" when appropriate
- The individual's signature (or that of his/her authorized representative) and date. If the authorization is signed by an authorized representative, include a description of the representative's authority to act for the individual)
- A statement that the individual may revoke the authorization if done in writing to the principal investigator; however, the researcher may continue to use and disclose, for research integrity and reporting purposes, any PHI collected from the individual pursuant to such authorization before it was revoked
- A statement that an individual's clinical treatment may not be conditioned upon whether or not the individual signs the research authorization; however, participation in research may be conditioned on a signed authorization, including treatment protocols
- A statement that information disclosed for research use under the authorization could potentially be re-disclosed by the recipient and would no longer be protected under HIPAA
- For protocols involving treatment, disclosure that access to PHI may be delayed until the study is complete

Waiver of HIPAA Authorizations

In some circumstances, authorizations for research use of PHI may be waived by the IRB, provided the following criteria are satisfied and documented:

- The use or disclosure of PHI involves no more than minimal risk to the privacy of individuals, based on the presence of at least 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 the conduct of the research, unless there is a health or research justification for retaining the identifiers or such retention is otherwise required by law
  - 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 project, or for other research for which the use or disclosure of PHI would be permitted by this guideline
- The research could not practicably be conducted without the waiver
- The research could not practicably be conducted without access to and use of the PHI

The HIPAA section of the Research Submission Application, or a Waiver of Authorization to Disclose Private Health Information Application, must be completed by the investigator and submitted to the IRB with the research application. The IRB will review and either approve or deny the waiver. Additionally, in order to facilitate a process at Carilion for tracking disclosure of PHI for research purposes, the Carilion IRB will copy the Carilion Privacy Officer and the Carilion

Director of Health Information Management Operations on all research approval letters in which a waiver of HIPAA authorization is granted and/or in which a waiver of informed consent is permitted.

Under the "preparatory to research" provision of the Privacy Act, researchers who are members of Carilion's workforce may review PHI to aid in study recruitment, e.g. to identify potential research subjects who meet eligibility criteria. However, this access to PHI under the "preparatory to research" provision does not allow the researcher to contact potential subjects. In order to contact potential subjects, the researcher must follow procedures outlined in the Carilion IRB guideline entitled "Recruitment of Study Subjects." This guideline generally requires that a clinician with a treatment relationship to the prospective subject make the initial contact about recruitment for a research study. If the researcher has an existing treatment relationship with the subject, then the researcher or his/her staff is permitted to make contact.

If a researcher who does not have a treatment relationship with a patient wants to obtain and record PHI to aid in study recruitment, e.g. to determine if a patient meets eligibility criteria, then the researcher must obtain a partial waiver of authorization from the IRB in order to access the PHI. This partial waiver of authorization may be obtained at the same time the protocol is submitted for IRB review and could be granted on an expedited basis if the protocol is eligible for expedited review.

Whenever a researcher obtains and records PHI for the purposes of identifying potential human subjects to aid in study recruitment, this activity constitutes human subjects research. This is true whether or not the researcher has a treatment relationship with the prospective subjects. Therefore, the researcher would need to either 1) obtain informed consent from prospective subjects to have their PHI recorded or 2) ask the IRB to waive the requirement to obtain informed consent in accordance with 45 CFR 46.116 (c) or (d). This request for waiver to obtain consent may be obtained at the same time the protocol is submitted for IRB review and could be granted on an expedited basis if the protocol is eligible for expedited review.

Access to PHI without an Authorization or Waiver of Authorization

Researchers may access PHI with individual identifiers in the records of covered entities without an authorization or IRB waiver of authorization for the purposes of development of a research protocol or assessment of feasibility of a research protocol. Under the "preparatory to research" provision, the researcher must document all the following criteria are satisfied:

- The use or disclosure of PHI is solely to prepare or assess feasibility of a research protocol
- The researcher shall not record individually identifiable PHI or remove PHI from the records reviewed. (e.g., physically taken out of a facility, copied, or downloaded and retained on the researcher's device) The researcher may review identifiable PHI but may only record aggregate data or individual data that does not include any individual identifiers.
- The PHI sought is necessary for the purposes of the research
- "Preparatory to research" does not include patient contact or recruitment

Documented requests will be referred to the Carilion Privacy Officer or Information Systems (IS) Security Officer (or designee) for review.

Individual health information that conforms to the HIPAA definition of de-identified is exempt from HIPAA and may be used or disclosed for research purposes without an authorization or

waiver of authorization or data use agreement. Researchers must provide documentation to the IRB that the health information has been de-identified by one of the following two methods:

- Removal of all HIPAA identifiers concerning the individual and individual's employer, relatives and household members, which include: names; geographic subdivisions smaller than a state; zip codes; all elements of dates except year directly related to an individual, including birth or death or dates of health care service or health care claims; telephone numbers; fax numbers; electronic mail addresses; social security numbers; medical record numbers; health plan beneficiary identifiers; account numbers; certificate/license numbers; vehicle identifiers and serial numbers, including license plate numbers; device identifiers and serial numbers; web universal resource locators (URL); internet protocol (IP) address numbers; biometric identifiers, including finger and voice prints; full face photographic images; and any other number, characteristic or code that could be used to identify the individual. Note that although a de-identified data set cannot contain a birth date, it may contain the individual's age expressed in years, months, days, or hours, as appropriate, except for individuals who are aged 90 years or more. For persons aged 90 years and above, the age in a de-identified data set can only be stated as being within the category of age 90 or above.
- The IRB may determine that health information is de-identified if an independent, qualified statistician determines that the risk of re-identification of the data, alone or in combination with other data, is very small; and documents the methods and results by which the health information is de-identified and the expert makes his/her determination of risk. Note that the expert may not be the researcher or anyone directly involved in the research study. Also data configurations that meet these criteria are likely to also meet the criteria for an IRB waiver of authorization, which may be more practical to obtain than this expert certification.

A Limited Data Set may also be used to collect information about research subjects without authorization or a waiver of authorization. Although a Limited Data Set is nearly de-identified, the geographic data and dates that may be included make this data adequate for a broader array of research studies than completely de-identified data. A Limited Data Set contains PHI that may include: state, county, city, town, census track, precinct, zip code or any other geo-codes above the level that would identify an individual household; and/or all elements of dates directly related to an individual, including birth date, admission date, discharge date, dates of health care procedures or other services and date of death.

The Limited Data Set must exclude all other direct identifiers listed above, and may only be used or disclosed if there is a Data Use Agreement between the entity providing the data and the recipient of the limited data set.

The Data Use Agreement must:

- Establish the permitted uses and disclosures of such information by the limited data set recipient. The data use agreement may not authorize the limited data set recipient to use or further disclose the information in a manner that is in conflict with the Privacy Rule.
- Establish who is permitted to use or receive the limited data set
- Provide that the limited data set recipient will:
  - Not use or further disclose the information other than as permitted by the data use agreement or as otherwise required by law
  - Use appropriate safeguards to prevent use or disclosure of the information other than as provided for by the data use agreement
  - Report to the covered entity any use or disclosure of the information not provided for by its data use agreement of which it becomes aware
  - Ensure that any agents, including a subcontractor, to whom it provides the limited data

set agrees to the same restrictions and conditions that apply to the limited data set recipient with respect to such information.

- Not identify the information or contact the individuals

Limited Data Sets and Data Use Agreements will be referred to the Carilion Privacy Officer or Information Security Officer (or designee) before IRB approval can be given.

Transition Provisions for PHI Access and Use for Research in Progress

For research involving PHI and carried out according to a protocol reviewed and approved by Carilion IRB prior to April 14, 2003:

- A research study may continue to use or disclose the PHI created or received prior to April 14, 2003 without HIPAA documentation
- A research study operating under a waiver of informed consent approved by Carilion IRB prior to April 14, 2003, may continue to create, receive, use, and disclose PHI for the study after April 14, 2003, without an IRB Waiver of Authorization unless the research study subsequently seeks informed consent, in which case an authorization would be required together with the informed consent
- If the protocol approved by Carilion IRB before April 14, 2003, required the obtaining of an informed consent, then with respect to any individual who has executed informed consent before April 14, 2003, no additional authorization is required to create, receive, use and disclose that individual's PHI for the approved study
- For any research subject for which informed consent is required, any informed consent or re-consent obtained on or after April 14, 2003, must include an authorization for use or disclosure of the subject's PHI. If the research has been previously approved but will be enrolling subjects on or after April 14, 2003, the researcher must submit a protocol revision to the IRB in order to include an individual authorization with any informed consent obtained on or after April 14, 2003.