UNIVERSITY OF SOUTHERN MAINE
Office of Research Integrity & Outreach

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Procedure Title:	HIPAA in Research

1.0 Objective

1.1. To describe Institutional Review Board (IRB) policy and procedures for conducting reviews of Health Insurance Portability and Accountability Act (HIPAA) research authorization forms, waiver of authorization requests, and coordination with the HIPAA Privacy Officer (PO) of each Collaborative IRB institution.

2.0 General Description

2.1. HIPAA requires that either an IRB or a Privacy Board reviews HIPAA research authorization and research waiver of authorization requests for the use of PHI in research (45 CFR 164.512(i)(1)(i)(A)).

2.1.1. At the University of Southern Maine (USM), the IRB(s) is responsible for this role.

2.1.2. There is no separate Privacy Board at USM.

2.2. The IRB reviews HIPAA research authorization and research waiver of authorization requests for any investigator obtaining protected health information (PHI) from a covered entity (CE).

2.1.1. All other HIPAA research issues, such as preparatory work, decedent research, limited data sets, public health activities, business associate agreements, privacy notices, and accounting of disclosures, fall under the jurisdiction of the POs.

2.2. Under HIPAA, in order for an IRB to review HIPAA research authorization and research waiver of authorization requests, an IRB must be established in accordance with the Common Rule (45 CFR 164.512(i)(1)(i)(A)).

2.2.1. The IRB is established in accordance with the Common Rule under HRPP-021 IRB Composition and Membership and is responsible for reviewing HIPAA research authorization and research waiver of authorization requests under HIPAA.

3.0 Responsibility

3.1. It is the responsibility of the Office of Research Integrity and Outreach (ORIO) staff, Research Compliance Administrator (RCA), IRB(s), POs, and investigators to execute this SOP.

4.0 Definitions

4.1. Business Associate Agreement means a contract in which a person or entity performs certain functions or activities that involve the use and/or disclosure of PHI.

4.2. Covered Entity means one of the following:

4.2.1. A health plan,

4.2.2. A health care clearinghouse, or

4.2.3. A health care provider who transmits any health information in electronic form in connection with a covered transaction.

4.3. Individually Identifiable Health Information means information that is a subset of health information, including demographic information collected from an individual, and:

4.3.1. Is created or received by a health care provider, health plan, employer, or health care clearinghouse; and

4.3.2. Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and

4.3.2.1. That identifies the individual; or
4.3.2.2. With respect to which there is a reasonable basis to believe the information can be used to identify the individual.

4.3.3. Health information that does not identify an individual and to which there is no reasonable basis to believe that the information can be used to identify an individual is not individually-identifiable health information.

4.4. Limited Data Set means protected health information that excludes the following direct identifiers of the individual or of relatives, employers, or household members of the individual:

4.4.1. Names;

4.4.2. Postal address information, other than town or city, state, and zip code;

4.4.3. Telephone numbers;

4.4.4. Fax numbers;

4.4.5. Electronic mail addresses;

4.4.6. Social Security numbers;

4.4.7. Medical record numbers;

4.4.8. Health plan beneficiary numbers;

4.4.9. Account numbers;

4.4.10. Certificate/license numbers;

4.4.11. Vehicle identifiers and serial numbers, including license plate numbers;

4.4.12. Device identifiers and serial numbers;

4.4.13. Web Universal Resource Locators (URLs);

4.4.14. Internet Protocol (IP) address numbers;

4.4.15. Biometric identifiers, including finger and voice prints; and

4.4.16. Full-face photographic images and any comparable images.

4.5. Protected Health Information (PHI) means individually identifiable health information:

4.5.1. That is, except as excluded below:

4.5.1.1. Transmitted by electronic media;
4.5.1.2. Maintained in any medium described in the definition of electronic media; or

4.5.1.3. Transmitted or maintained in any other form or medium.

4.5.2. PHI excludes individually identifiable health information in:

4.5.2.1. Education records covered by FERPA (20 U.S.C. 1232g);
4.5.2.2. Records on a student who is eighteen years of age or older, or is attending an institution of postsecondary education, which are made or maintained by a physician, psychiatrist, psychologist, or other recognized professional or paraprofessional acting in their professional or paraprofessional capacity or assisting in that capacity, and which are made, maintained, or used only in connection with the provision of treatment to the student, and are not available to anyone other than persons providing such treatment, except that such records can be personally reviewed by a physician or other appropriate professional of the student's choice;
4.5.2.3. Employment records held by a Covered Entity in its role as employer; and
4.5.2.4. Regarding a person who has been deceased for more than fifty (50) years.

5.0 Requirements

5.1. Research Authorization Form

5.1.1 A valid authorization form must contain at least the following core elements:

5.1.1.1. A description of the information to be used or disclosed that identifies the information in a specific and meaningful fashion
5.1.1.2. The name or other specific identification of the person(s), or class of persons, authorized to make the requested use or disclosure
5.1.1.3. The name or other specific identification of the person(s), or class of persons, to whom the Covered Entity may make the requested use or disclosure
5.1.1.4. A description of each purpose of the requested use or disclosure
5.1.1.4.1. The statement "at the request of the individual" is a sufficient description of the purpose when an individual initiates the authorization and does not, or elects not to, provide a statement of the purpose.
5.1.1.5. An expiration date or an expiration event that relates to the individual or the purpose of the use or disclosure
5.1.1.5.1. The statement "end of the research study," "none," or similar language is sufficient if the authorization is for a use or disclosure of protected health information for research, including for the creation and maintenance of a research database or research repository.

5.1.1.6. Signature of the individual and date

5.1.1.6.1. If the authorization is signed by a personal representative of the individual, a description of such representative's authority to act for the individual must also be provided.

5.1.2. In addition to the core elements, the authorization must contain statements adequate to place the individual on notice of all of the following:

5.1.2.1. The individual's right to revoke the authorization in writing, and either:

5.1.2.1.1. The exceptions to the right to revoke and a description of how the individual may revoke the authorization; or

5.1.2.1.2.. To the extent that the information is included in the organization's notice of privacy practices.

5.1.2.4. The ability or inability to condition treatment, payment, enrollment or eligibility for benefits on the authorization, by stating either:

5.1.2.4.1. The covered entity may not condition treatment, payment, enrollment or eligibility for benefits on whether the individual signs the authorization; or

5.1.2.4.2. The consequences to the individual of a refusal to sign the authorization when the covered entity can condition treatment, enrollment in the health plan, or eligibility for benefits on failure to obtain such authorization.

5.1.2.5. The potential for information disclosed pursuant to the authorization to be subject to redisclosure by the recipient and no longer be protected by this subpart.

5.1.3. The authorization must be written in plain language.

5.1.4. If a covered entity seeks an authorization from an individual for a use or disclosure of protected health information, the covered entity must provide the individual with a copy of the signed authorization.

5.2. Compound Authorization

5.2.1. An authorization for use or disclosure of protected health information may not be combined with any other document to create a compound authorization, except as follows:

5.2.1.1. An authorization for the use or disclosure of protected health information for a research study may be combined with any other type of written permission for the same research study, including another authorization for the use or disclosure of protected health information for such research or a consent to participate in such research;

5.2.1.2. An authorization for a use or disclosure of psychotherapy notes may only be combined with another authorization for a use or disclosure of psychotherapy notes;

5.2.1.3. An authorization under this section, other than an authorization for a use or disclosure of psychotherapy notes, may be combined with any other such authorization, except when a covered entity has conditioned the provision of treatment, payment, enrollment in the health plan, or eligibility for benefits under 45 CFR 164.508(b)(4).

5.3. Waiver of Authorization

5.3.1. The IRB has the authority to waive HIPAA Authorization. A request from an investigator for the IRB to waive the HIPAA authorization must be accompanied by sufficient information to allow the IRB to make the required determination.

5.3.2. For a use or disclosure to be permitted based on documentation of approval of an alteration or waiver, the documentation must include all of the following:

5.3.2.1. A statement identifying the IRB or privacy board and the date on which the alteration or waiver of authorization was approved;

5.3.2.2. 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:

5.3.2.2.1. 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;

5.3.2.2.1.1. An adequate plan to protect the identifiers from improper use and disclosure;

5.3.2.2.1.2. 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

5.3.2.2.1.3. 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;

5.3.2.2.2. The research could not practicably be conducted without the waiver or alteration; and

5.3.2.2.3. The research could not practicably be conducted without access to and use of the protected health information.

5.3.2.3. A brief description of the protected health information for which use or access has been determined to be necessary by the IRB or privacy board; and

5.3.2.4. A statement that the alteration or waiver of authorization has been reviewed and approved under either normal or expedited review procedures.

5.4. Data Use Agreement

5.4.1. A data use agreement between the covered entity and the limited data set recipient must:

5.4.1.1. Establish the permitted uses and disclosures of such information by the limited data set recipient.

5.4.1.1.1. The data use agreement may not authorize the limited data set recipient to use or further disclose the information in a manner that would violate the requirements of this subpart, if done by the Covered Entity;

5.4.1.2. Establish who is permitted to use or receive the limited data set; and

5.4.1.3. Provide that the limited data set recipient will:

5.4.1.3.1. Not use or further disclose the information other than as permitted by the data use agreement or as otherwise required by law;

5.4.1.3.2. Use appropriate safeguards to prevent use or disclosure of the information other than as provided for by the data use agreement;

5.4.1.3.3. 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;

5.4.1.3.4. 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; and

5.4.1.3.5. Not identify the information or contact the individuals.

5.5. Not Individually Identifiable Health Information

5.5.1. A Covered Entity may determine that health information is not individually identifiable health information only if:

5.5.1.1. A person with appropriate knowledge of and experience with generally accepted statistical and scientific principles and methods for rendering information not individually identifiable:

5.5.1.1.1. Applying such principles and methods, determines that the risk is very small that the information could be used, alone or in combination with other reasonably available information, by an anticipated recipient to identify an individual who is a subject of the information; and

5.5.1.1.2. Documents the methods and results of the analysis that justify such determination; or

5.5.1.2. The following identifiers of the individual or of relatives, employers, or household members of the individual, are removed:

5.5.1.2.1. Names;

5.5.1.2.2. All geographic subdivisions smaller than a state, including street address, city, county, precinct, zip code, 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:

5.5.1.2.2.1. The geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people; and

5.5.1.2.2.2. The initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to "000."

5.5.1.2.3. All elements of dates (except year) for dates directly related to an individual, including birth date, admission date, discharge date, date of death; and 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;

5.5.1.2.4. Telephone numbers;

5.5.1.2.5. Fax numbers;

5.5.1.2.6. Electronic mail addresses;

5.5.1.2.7. Social security numbers;

5.5.1.2.8. Medical record numbers;

5.5.1.2.9. Health plan beneficiary numbers;

5.5.1.2.10. Account numbers;

5.5.1.2.11. Certificate/license numbers;

5.5.1.2.12. Vehicle identifiers and serial numbers, including license plate numbers;

5.5.1.2.13. Device identifiers and serial numbers;

5.5.1.2.14. Web Universal Resource Locators (URLs);

5.5.1.2.15. Internet Protocol (IP) address numbers;

5.5.1.2.16. Biometric identifiers, including finger and voice prints;

5.5.1.2.17. Full-face photographic images and any comparable

images; and

5.5.1.2.18. Any other unique identifying number, characteristic, or code, except an assigned record identification code as permitted by 45 CFR 164.514(c); and

5.5.1.3. The covered entity does not have actual knowledge that the information could be used alone or in combination with other information to identify an individual who is a subject of the information.

5.6. Research on Decedent Information

5.6.1. Research on decedent information requires that the Covered Entity obtains from the researcher:

5.6.1.1. Representation that the use or disclosure sought is solely for research on the protected health information of decedents;

5.6.1.2. Documentation, at the request of the covered entity, of the death of such individuals; and

5.6.1.3. Representation that the protected health information for which use or disclosure is sought is necessary for the research purposes.

6.0 Procedure

6.1. Options for Obtaining Protected Health Information

6.1.1. An investigator has the following six (6) options for obtaining PHI for research purposes:

6.1.1.1. De-identified Information – health information that cannot be linked to an individual;

6.1.1.2. Authorization – a document signed by the subject that gives the researcher permission to use/disclose PHI collected during the research study for defined purposes;

6.1.1.3. Waiver of Authorization – a request to forgo the authorization requirement based on the fact that the disclosure of PHI is a minimal risk to the subject and the research cannot practically be done without access to/use of PHI;

6.1.1.4. Limited Data Set – a subset of identifiers that contain the following elements: city, state, zip code, date of birth, death, or date of service;

6.1.1.5. Preparatory Work – PHI reviewed for the purpose of designing a research study or identifying potential subjects. PHI cannot be removed from the CE during the review; or

6.1.1.6. Decedent Research – research where PHI is collected from a subject(s) that is deceased prior to the initiation of the study.

6.2. General Procedures

6.2.1. Investigators working with PHI must comply with their Collaborative IRB institution's HIPAA educational requirements.

6.2.2. IRB members do not review any research authorizations, waiver of authorization, or de-identification requests in which they have a conflict of interest.

6.3. Research Authorization Review Procedures

6.3.1. The investigator makes a preliminary assessment to determine whether their protocol requires an authorization form.

6.3.1.1. An investigator may call ORIO if they need assistance in determining if an authorization form is required.

6.3.2. The investigator submits their research protocol, with authorization-specific questions answered and any additional information included, to the IRB for review.

6.3.3. For submissions requiring full board review, the IRB reviews authorization forms at convened meetings of the IRB.

6.3.3.1. For submissions requiring expedited or exempt review, the IRB or ORIO reviewer reviews authorization forms.

6.3.4. The IRB or reviewer makes the final determination as to whether an authorization form is appropriate and whether the investigator must revise the submitted authorization form.

6.3.5. The IRB or reviewer reviews the authorization form or revisions and determines whether all the federally and institutionally mandated criteria for authorization forms are satisfied.

6.3.6. Once the IRB or reviewer determines the authorization form meets the federal regulations and institutional requirements, no further IRB review of the authorization form is necessary unless the investigator makes subsequent changes to the authorization form.

6.3.6.1. The investigator obtains IRB review prior to implementing changes in the authorization form.

6.3.7. Approval of the authorization form will be noted in the footer of the authorization form and it will be made available to the investigator upon approval of the IRB protocol.

6.3.8. The IRB does not review authorization forms under the following circumstances:

6.3.8.1. PHI that was created or received either before or after the compliance date (April 14, 2003) may continue to be used and disclosed for research purposes, if any one of the following was obtained prior to the compliance date:

6.3.8.1.1. An authorization or other express legal permission from the subject to use or disclose PHI for the research; or

6.3.8.1.2. The informed consent of the subject to participate in the research; or

6.3.8.1.3. A waiver of informed consent by the IRB in accordance with the federal regulations pertaining to human subject research protection commonly known as the Common Rule or in accordance with an exception under the FDA's human subject protection regulations.

6.3.8.2. If the investigator obtains a waiver of informed consent prior to the compliance date, but subsequently seeks informed consent after the compliance date, the investigator must obtain the subject's authorization at the time they obtain the new informed consent. It is the investigator's responsibility to submit a copy of the authorization form for IRB review.

6.3.9. The ORIO maintains copies of all approved authorization forms for a period of no less than six (6) years after the study closure.

6.4. Research Waiver of Authorization Request Review Procedures

6.4.1. The investigator makes a preliminary assessment to determine whether their protocol requires a waiver of authorization.

6.4.1.1. An investigator may call ORIO if they need assistance in determining if a waiver of authorization is required.

6.4.2. The investigator submits their research protocol, with authorization-specific questions answered and any additional information included, to the IRB for review.

6.4.3. For submissions requiring full board review, the IRB reviews requests for a waiver of authorization at convened meetings of the IRB.

6.4.3.1. For submissions requiring expedited or exempt review, the IRB or ORIO reviewer reviews requests for a waiver of authorization.

6.4.4. The IRB or reviewer makes the final determination as to whether a waiver of authorization is appropriate and whether the investigator must revise the request for a waiver of authorization.

6.4.5. The IRB or reviewer reviews the request for waiver of authorization or revisions and determines whether all the federally and institutionally mandated criteria for waiver of authorization are satisfied.

6.4.6. Once the IRB or reviewer determines the request for waiver of authorization meets the federal regulations and institutional requirements, no further IRB review of request for waiver of authorization is necessary unless the investigator makes subsequent changes to the authorization form.

6.4.6.1. The investigator obtains IRB review prior to implementing changes in the authorization form use.

6.4.7. Approval of the request for waiver of authorization will be noted in the IRB approval letter and sent to the investigator upon IRB approval of the research protocol.

6.4.8. The IRB does not require a research waiver of authorizations under the following circumstances:

6.4.8.1. An investigator may use and disclose for research purposes PHI that was created or received either before or after the compliance date (April 14, 2003) if a waiver of informed consent was reviewed by the IRB in accordance with the federal regulations and obtained prior to the compliance date.

6.4.8.2. If the investigator obtains a waiver of informed consent prior to the compliance date, but subsequently seeks informed consent after the compliance date, they must obtain the subject's authorization at the time they obtain the new informed consent.

6.4.9. ORIO maintains copies of all versions of the investigator's request for waiver of authorization for a period of no less than six (6) years after the study is closed.

6.5. HIPAA Compliance Procedures for Investigators

6.5.1. Any significant noncompliance HIPAA issue, such as a breach or complaint involving research, will be reviewed in conjunction with the appropriate Collaborative IRB Institution’s PO.

6.5.2. If ORIO receives a HIPAA research complaint or report of an alleged HIPAA research noncompliance issue, the USM RCA or designee will immediately (i.e., within approximately two (2) working days) notify the appropriate PO.

6.5.2.1. The RCA may confer with the PO to assess whether the complaint/alleged noncompliance issue falls under the purview of the IRB.

6.5.3. If the complaint/alleged noncompliance issue falls under IRB purview, the RCA will initiate an inquiry in compliance with HRPP-004 Noncompliance.

6.5.4. The IRB determines whether the incident meets requirements for reporting to the federal regulatory agencies. In making the determination, the IRB follows procedures in accordance with HRPP-034 Mandated Reporting to External Agencies.

6.5.5. After the IRB has completed its review of the complaint/alleged noncompliance issue, the RCA provides the appropriate PO with a copy of the final deliberations if the allegation involves both research and a violation of the HIPAA regulations.

6.5.5.1. If the IRB determines the incident to be reportable to a federal regulatory agency, the RCA sends a copy of the federal report to the appropriate PO.

7.0 References:

7.1. 45 CFR 164.512;

7.2. 45 CFR 164.532;

7.3. 45 CFR 164.530;

7.4. 45 CFR 164.508;

7.5. 45 CFR 164.514;

7.6. NIH Institutional Review Boards and the HIPAA Privacy Rule

7.7. HHS Institutional Review Boards