

Rev. 04/14

HIPAA COMPLIANCE

POLICY:

Whenever a research project involves obtaining protected health information (PHI) from a “Covered Entity,” as defined by HIPAA, proper authorization must be obtained from each subject.

PROCEDURES:

Responsibility for obtaining authorization rests with the Principal Investigator. Before the UM IRB approves a study involving collection of HIPAA protected health information, the Principal Investigator will supply a written assurance that all subjects will provide appropriate, signed authorization forms to the Covered Entity providing the information. The authorization (or Permission to Gather Health Information) form can be downloaded from: <http://www.umt.edu/research/compliance/IRB/Docs/permissiontogatherPHI.doc>.

Covered Entities at the University of Montana include:

- Curry Health Center Services Pharmacy
- MonTech - Montana Accessibility and Assistive Technology Center
- New Directions Program
- The Nora Staael Evert Physical Therapy Clinic
- RiteCare Clinic
- UMPT Sports and Orthopedics

HIPAA & Research

The Security Rule

The Security Rule, an important part of HIPAA, went into effect April 20, 2003. The rule's intention is to protect the confidentiality, integrity, and availability of electronic protected health information, which the University creates, accesses, transmits, or receives in both research and patient care settings. It sets forth specific requirements for the adoption of administrative, physical, and technical safeguards for the protection of electronic protected health information.

HIPAA's impact on research with human subjects and the IRB

Since April 14, 2003 all research that will enroll subjects (including existing studies) AND obtain subjects' PHI must comply with HIPAA regulations.

For new studies and those approved after April 14, 2003:

The standard IRB approval process applies.

- **For studies that plan to use PHI**, the [Permission to Gather Health Information](#) form should be submitted along with the IRB Checklist/Application.

- **For studies that plan to use de-identified data**, the approval for this use should be requested on the IRB Checklist/Application. The IRB may require that you enter into a [Data Use Agreement](#) with the provider.

For studies approved prior to April 14, 2003:

If enrolling or reenrolling subjects AND obtaining PHI, subjects are required to sign an IRB-approved authorization form. Use our [Permission to Gather Health Information template](#) and submit it to the IRB for review.

If using existing data (gathered before April 14, 2003), this data is acceptable for use as long as the research study met with IRB approval.

What is Protected Health Information (PHI)?

PHI is health information transmitted or maintained in any form or medium that:

1. identifies or could be used to identify an individual; and
2. is created or received by a healthcare provider, health plan, employer or healthcare clearinghouse; and
3. 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 healthcare to an individual.

Exempt Records

The following records ARE EXEMPTED from the definition of PHI even though they may contain health-related information:

1. student records maintained by an educational institution, and
2. employment records maintained by an employer related to employment status.

If your study uses these kinds of records, it is not subject to HIPAA. However, existing IRB rules on informed consent and confidentiality still apply.

Ways researchers can perform HIPAA-compliant research with PHI

1. Obtain Subject Authorization — use of an [authorization form](#) that includes required HIPAA authorization language. (It must be approved by the IRB prior to use - similar to a consent form.)
2. Obtain an IRB waiver of subject authorization—if the research is minimal risk to subjects and meets criteria for waiver or alteration (see below).
3. Obtain an IRB alteration of subject authorization—if the research is minimal risk to subjects and meets criteria for waiver or alteration (see below).
4. Use a [Limited Data Set](#) — PHI that excludes direct identifiers of the individual or of relatives, employers, or household members of the individual.

5. Use De-identified Data — health information that does not identify an individual and with respect to which there is no reasonable basis to believe that the information can be used to identify an individual. (see below, “Using data that is De-identified”)
6. Use or disclosure of decedents' PHI is acceptable without #1 or #2.

Using Authorization Forms

If a study using/disclosing PHI is going to use/disclose this PHI by means of a subject authorization (the most common and recommended means), investigators should be aware of the following:

- The authorization form needs to be submitted to the IRB along with the IRB checklist/application. Use our [Authorization Form Template](#) filled in with your study specifics.
- Two authorization forms require the subject's or authorized representative's signature:
 1. A copy for the subject to keep, and
 2. A copy for the investigator's records.
- It is the responsibility of the PI to keep this authorization form in their records for 6 years and assure that it is completed correctly.

Using Data that is De-Identified

Researchers may use or disclose health information that is de-identified without restriction under the Privacy Rule.

Covered entities seeking to release this health information must authorize that the information has been de-identified using either statistical verification of de-identification OR by removing the 19 identifiers from each record as specified in the Rule. These identifiers are:

1. Name
2. All geographic subdivisions smaller than a state (street address, city, county, precinct) Note: zip code or equivalents must be removed, but can retain first 3 digits if the geographic unit to which the zip code applies if the zip code area contains more than 20,000 people
3. For dates directly related to the individual, all elements of dates, except year. (date of birth, admission date, discharge date, date of death)
4. All ages over 89 or dates indicating such an age
5. Telephone number
6. Fax number
7. Email address
8. Social Security Number
9. Medical Record Number
10. Health Plan Number
11. Account Numbers
12. Certificate or license numbers
13. Vehicle identification/serial numbers, including license plate numbers
14. Device identification/serial numbers

15. Universal Resource Locators (URL's)
16. Internet Protocol addresses (IP's)
17. Biometric Identifiers
18. Full face photographs and comparable images
19. Any other unique identifying number, characteristic or code

Obtaining Authorization Form Waivers or Alterations

For research uses and disclosures of PHI, an IRB may approve a waiver or an alteration of the Authorization requirement in whole or in part. A complete waiver occurs when the IRB determines that no Authorization will be required for a covered entity to use and disclose PHI for a particular research project.

If a researcher has used or disclosed PHI for research with an IRB approval of waiver or alteration of Authorization, documentation of that approval must be retained by the researcher for 6 years from the date of the its creation or the date it was last in effect, whichever is later.

How do I qualify for a waiver of authorization?

(Approvals for waivers or alterations will be rare and in most cases researchers are advised to use an Authorization Form with their subjects to use/disclose PHI. IRB approval is required for this Authorization Form - similar to consent forms.)

The following criteria must be met to qualify for a waiver:

The use or disclosure of protected health information involves **no more than minimal risk** to the privacy of 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 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;
- The alteration or waiver will not adversely affect the privacy rights and the welfare of the individuals;
- The research could not practicably be conducted without the alteration or waiver or alteration; and
- The research could not practicably be conducted without access to and use of the protected health information.

The IRB maintains the authority to make the final decision if a study meets the aforementioned criteria.

Questions? Contact the IRB office at (406) 243-6672 or email irb@umontana.edu.