



Office of Research Administration

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HIPAA Summary

HIPAA, the Health Insurance Portability and Accountability Act, governs the use and disclosure of health information that is created or received by a covered entity (such as a university, healthcare provider, or insurer). Health information that relates to the physical or mental health of an individual, to the provision of health care to an individual, or to the payment for the provision of health care to an individual **and identifies the individual or reasonably may be used to identify the individual** is considered *Individually Identifiable Health Information (IIHI)*. HIPAA governs the use and disclosure of IIHI by covered entities that is:

- Transmitted electronically, or
- Maintained in electronic media, or
- **Transmitted or maintained in any other form or medium**

Because your research may involve storing and transmitting Individually Identifiable Health Information, you need to be aware of the HIPAA regulations. Failure to comply with HIPAA has the potential to cause agencies to deny you funding and/or cause the University to terminate your research.

How do I know if HIPAA regulations apply to my research?

Do you use medical records of any kind to identify potential participants in your studies?

-or-

Do medical records obtained from a healthcare provider or insurer (anything from a simple diagnosis to full medical records) form a part of your research documentation?

If you answered “Yes” to either of the above questions, below are procedures you must consider:

- You cannot use records provided to you by a healthcare provider or insurer to contact potential participants. You must ask the provider to contact individuals on your behalf. Make this task easier by preparing the letters or writing a phone script for the provider’s office to use.
- You should obtain copies of any release forms or authorization forms the healthcare provider obtains from patients. You should contact the UM-St. Louis HIPAA Compliance Officer (Gloria Leonard, Director, Business Services, 314-516-5362 or Gloria.leonard@umsl.edu) to have the forms reviewed by university legal representatives.

Do you ask individuals who self-report health information if you may, at a later date, have access to their health records?

-or-

Do you provide any type of healthcare to participants in your research project?

If you answered “Yes” to either of the above questions, below are procedures you must consider:

- You should require each participant to sign an “Authorization” form granting you permission to access or maintain health records. The HIPAA Compliance Officer can help you make sure necessary information and provisions appear in the form you create. ***Your form must pass review before you may proceed with your research.***
- You may need to provide each participant with a “Notice of Privacy Practices” that explains how you will handle private information. Please consult with the HIPAA Compliance Officer about whether this requirement applies to your research.

Do you serve as a sub-contractor, contracted researcher, or consultant for a healthcare provider or other entity that provides you with IHI for your work?

If so, you should obtain a “Business Associate Agreement” regarding the handling of that information. This document is in addition to your contract with the entity. Please provide a copy of the agreement (provided by the entity) to our office for review.

Do you use the health records of deceased persons in your research?

HIPAA regulations still apply to these records, so be sure that your information storage and transmission procedures are compliant. In these cases, the healthcare provider or insurer will provide the information upon written justification from the researcher, and authorization forms are not needed.

Important Information

All authorization forms and other compliance issues should be addressed **before** a research protocol is presented to the Internal Review Board for approval.

HIPAA also specifies the type of security you must maintain to protect electronically stored IHI. Contact Information Technology Services for help in evaluating the security of your computer systems.

If you have questions regarding HIPAA compliance in research, contact John Hancock, 341 Woods Hall, 314-516-5894 or hancockjc@umsl.edu.

UM System “HIPAA and Research” information: <http://irb.missouri.edu/hipaa/index.html>