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RESEARCH UPDATE

A Call for Protection of Research Participants

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The Health Insurance Portability and Accountability Act (HIPAA) was originally established in 1996 (https://www.cdc.gov/phlp/php/resources/health-insurance-portability-and-accountability-act-of-1996-hipaa.html, 2026). It primarily established the *S*tandards for Privacy of Individually Identifiable Health Information (Privacy Rule) (https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html, 2026). This means it established what information could and could not be shared (Protected Health Information, PHI), who could or could not share it (Covered Entity), and when.

> "A major goal of the Privacy Rule is to assure that individuals' health information is properly protected while allowing the flow of health information needed to provide and promote high quality health care and to protect the public's health and well-being. The Rule strikes a balance that permits important uses of information, while protecting the privacy of people who seek care and healing. Given that the health care marketplace is diverse, the Rule is designed to be flexible and comprehensive to cover the variety of uses and disclosures that need to be addressed" (https://www.hhs.gov/hipaa/for-

professionals/privacy/laws-regulations/index.html, 2026).

Unfortunately balancing between the level of flexibility and comprehensiveness required has meant that HIPAA is a very complicated document that is still being changed and updated to meet current needs and technology. In fact, a level of complexity was removed when the detailed document on the OHRP.gov web site in 2024, which specified the regulations in detail was removed as part of the streamlining of the new administration. Instead of an improvement, this streamlining has resulted in significant reduction in clarity of the regulations and a lack of transparency. This has also placed both health care consumers and research study participants at risk.

For example: the current changes raise the question of whether health information taken in a research study setting which is not done under the umbrella of their "healthcare" organization or in a nonhealthcare setting is covered by HIPAA. This is primarily a question when it comes to human health research. HIPAA states it specifically relates to 'covered entities.' It further states, that these 'covered entities' are specifically "health plans, health care clearinghouses, and to any health care provider who transmits health information in electronic form in connection with transactions" (https://www.hhs.gov/hipaa/for-professionals/privacy/laws-regulations/index.html, 2026).

Fortunately the CDC has stated that some business associates, specifically those who perform functions for a covered entity, are also included (https://www.cdc.gov/phlp/php/resources/health-insurance-portability-and-accountability-act-of-1996-hipaa.html, 2026). Unfortunately the CDC also specifically states that HIPAA permits the disclosure of protected health information (PHI) in limited datasets for research (https://www.cdc.gov/phlp/php/resources/health-insurance-portability-and-accountability-act-of-1996-hipaa.html, 2026).

This means that not only is any research not conducted in a "covered entity" health care setting explicitly covered under HIPAA, but there is an argument that HIPAA never applies to any applied research. So, if you are a research participant and you decide to join a study developing a cancer drug, if that work is not being done under a "covered entity" none of your medical data and the records od same which have been taken in the study are private and confidential.

There is, currently, an ongoing debate about how this situation should be handled, especially since research participant confidentiality is specified in a number of other places. Unfortunately, most of these are not discussing health or medical information, but instead are discussing anything that makes the participant 'identifiable'. Whether health or medical information is included in that is extremely complicated, and depends on a number of factors, including the type of information and the size of the geographic area.

This is not enough protection for research participants. These individuals have put effort into helping the pursuit of knowledge. They should be protected by HIPAA. Their information should be protected, especially if there are legal questions about when samples for a secondary study can be rerun.

Bio:

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