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MYTH: HIPAA and the Common Rule regulate research in the same way.
FACT: HIPAA and the Common Rule differ in their scope and application.

Both the HIPAA Privacy Rule and the Common Rule define research as a systematic investigation designed to develop or contribute to generalizable knowledge.[1] However, the two regulations differ in their scope and the individuals or entities to which they apply. The key distinction is that the HIPAA Privacy Rule regulates the use of individuals' health information for research while the Common Rule regulates the ethical performance of research involving human subjects. Another distinction is that the Common Rule applies only to specific federal departments and agencies and the research supported by those agencies, while the HIPAA Privacy Rule applies to all health care providers (who transmit information electronically for certain transactions), health plans, and health care clearinghouses.

The Common Rule regulates human subject research conducted or supported by one of the federal departments or agencies that have codified the Common Rule in regulation or agreed to comply with all parts of the Rule. Under the Common Rule, any human subject research project conducted or supported by these departments and agencies must obtain informed consent from all research subjects, receive approval from an Institutional Review Board (IRB), and certify compliance with the Common Rule before beginning research. The Common Rule provides basic protections for all human subjects and additional protections for certain vulnerable populations (pregnant women, children, human fetuses and newborns, and prisoners). The Rule also sets requirements for the department or agency supporting the research, the institution conducting the research, the IRB reviewing the research, and the investigating researchers themselves.

With respect to informed consent, the Common Rule requires legally effective consent (after the subject receives sufficient information to make a voluntary decision) through a written consent form approved by an IRB (unless the IRB waives the consent requirement). The consent form must identify procedures to be followed, risks to the subject and a statement regarding the extent to which confidentiality of records will be maintained.

The HIPAA Privacy Rule, on the other hand, applies to all covered entities (providers, health plans, or clearinghouses) and sets terms for the disclosure and use of protected health information (PHI) for research purposes and the authorization for such disclosure and use. Researchers who are covered entities and their business associates must comply with the HIPAA Privacy Rule regardless of the source of their funding. The HIPAA Privacy Rule has specific requirements for notice of the proposed disclosure and for obtaining authorization to use PHI for research. The HIPAA Privacy Rule identifies core elements and statements that must be included in the authorization (i.e., consent to use the individual's information for research), such as

[1] 42 CFR § 46.102(d); 45 CFR § 164.501.

the purpose of the requested use or disclosure, the time frame the authorization will be valid, notice of the individual's right to revoke authorization, etc. A valid authorization under the HIPAA Privacy Rule will not constitute informed consent for the research itself, only for the disclosure and use of information about the individual who is the subject of the research for the specific research purpose.

The standards for waiving consent under the Common Rule are not the same as the standards for waiving authorization under the HIPAA Privacy Rule, although both regulations establish procedures for IRBs to waive the consent or authorization requirement under certain circumstances (e.g., where the research cannot reasonably be carried out with consent and involves no more than minimal risk to the subject).

Finally, note that the HIPAA Privacy Rule and the Common Rule exist side-by-side, with neither rule preempting the other. A researcher who is a covered entity and receives federal funding from a federal agency that has adopted the Common Rule must comply with both regulations to ensure proper protections for the individuals who are the subject of the research as well as any information about those individuals used in the research.

For More Information:

- See our resources on research, including a summary of the Common Rule
- Learn how HIPAA applies to research.
- Explore about state and federal laws related to health information privacy and confidentiality.

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