Comparison of HIPAA Privacy Rule and The Common Rule for the Protection of Human Subjects in Research

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The chart below sets forth the primary differences between Health Insurance Portability and Accountability Act (HIPAA) and the Common Rule for the protection of human subjects in research. It contains references and hyperlinks for researchers that need detail information on determining whether a research project needs to comply with the statutory requirements or qualifies for an exemption from the rule. Depending on study specifics, research that involves interaction with individuals or private information about them such as private health information may be covered by both regulations. Both regulations cover data that are directly or indirectly identifiable. For covered identifiable data, data uses specified in the consent form (if applicable) determine how information can be collected, retained, used, and accessed by others.

While the primary purpose of both regulations is to protect the privacy and confidentiality of individuals that the data are related to, a major role of both regulations is enabling and enhancing public trust so that the public will continue to provide honest numbers, participate or permit their private information to be used to enable evidence-based policy and practice. The intent of this document is to provide an understanding of the main differences between these two rules and direct researchers to the appropriate resources for more detailed information.

	The Common Rule **For Protection of Human Subjects in Research**	**The HIPAA** **Privacy Rule**
Federal Regulation	45 CFR 46 subpart A is the US Department of Health and Human Services citation. The 18 Federal departments and agencies that have adopted it have various Code of Federal Regulations (CFR) citations. The Subpart A "Common Rule" applies to all 18. A listing by department is available at http://www.hhs.gov/ohrp/assurances/assurances/filasurt.html	45 CFR 160 and 165 applies to all private health information controlled by covered entities.
Primary Purpose	Protects individuals who are the subject of research from physical harms and informational harms. Factors to consider are whether aspects of the research--including privacy, confidentiality, data collection, data use, maintenance and record retention--may impact an individual's physical, emotional or financial condition or reputation.	Protects individuals from informational harms. Focuses on re-identification of the individual as a measure of harm. Its goal is to protect individuals against informational harm. Specific rules pertaining to the privacy and security of protected health information (PHI) are applied for accessing and using health information.
Application of Rule	Applies to systematic investigations designed to develop or contribute to generalizable knowledge-- if the research involves interacting with individuals or using identifiable private information about the study subjects. Human subjects research funded by any of the Common Rule agencies or departments is covered. Entities may opt in their Federal Wide Assurances (FWAs) to apply the	Only applies to HIPAA "covered entities" dealing with private health information (PHI). It does not apply to entities dealing with private information that are not covered by those regulations. The HIPAA Privacy Rule permits the use and disclosure of PHI for research where documentation is obtained approving an alteration to or waiver, in whole or in part, of the individual Authorization by either an IRB set up

	requirements to all human subject research, no matter the funding source. (Numerous entities apply the requirements at their own initiative, independently of the Federal Common Rule.) The Common Rule applies to identifiable data about living individuals. It does not apply if the study is not funded or conducted by a covered source. Not all quality assurance and improvement studies meet the definition of "human subjects research".	in accordance with the Projection of Human Subject regulations or a Privacy Board set up in accordance with the HIPAA regulations.
Required action for covered activities	Prior to initiating covered human subjects research, the study must be approved by an Institutional Review Board (IRB) and any entity "engaged" in the research must be covered by an FWA. (For guidance on the meaning of "engaged," see the Office for Human Research Protection (OHRP) at http://www.hhs.gov/ohrp/policy/engage08.html.) When the Institution becomes engaged in research to which the FWA applies, the Institution and IRB upon which it relies for review of such research will comply with the Common Rule. Informed consent of study participants is generally required unless waived by an IRB for minimal risk research. (The consent can include a statement on future research in the range of anticipated data uses in the initial informed consent.) The research plan must include adequate provision for monitoring the data collection to ensure the safety of subjects where appropriate.	When a researcher seeks access to health information that contains PHI from a covered entity, a HIPAA Authorization that includes all core elements including consent from the human subjects may be needed. Research is a permissible exception that allows use of PHI without a HIPAA authorization where it is impractical or impossible to obtain a HIPAA Authorization from every individual research participant and an IRB or HIPAA Privacy Board approves a waiver or alternation of an Authorization. To gain access for research purposes to PHI created or maintained by covered entities, the researcher may have to provide supporting documentation such as a signed Data Use Agreement and research protocol on which the covered entity may rely in meeting the requirements, conditions, and limitations of the Privacy Rule.
Enforcement	**The Offie for Human Research Protections (OHRP)** issues FWAs and Registers IRBs. FWA coverage and IRB approval is required to conduct any covered research. OHRP can suspend all human subjects research at an institution while it investigates, and can terminate an entity's FWA and/or IRB registration for serious violations. **The Federal agency funding the research** may terminate the grant or contract or take other corrective actions in instances of serious violations. If there are particularly serious violations, the agency can determine that the entity involved is ineligible for future funding by the agency. **IRBs** must approve nonexempt research before human subjects research is initiated. IRBs are responsible for monitoring for serious or continuing noncompliance or unanticipated risks, which must be reported to OHRP and the funding agency **The reviewing IRB, independently of any federal action**, may require corrective actions when violations are found. This can include termination of the research or other corrective actions such as removing the principal investigator or other key staff, requiring that information collected in violation cannot be used and that any publications based on it must be withdrawn.	**The Department of Health and Human Services, Office for Civil Rights (OCR)** is responsible for administering and enforcing the set of national standards for the use and disclosure of an individual's health information by covered entities, as well as standards for providing individuals with privacy rights to understand and control how their health information is used.**OCR** may conduct complaint investigations and compliance reviews and impose a Civil Monetary Penalty (CMP) on a covered entity for a failure to comply with a requirement of the Privacy Rule. CMPs can exceed several million dollars and will vary depending on factors such as the date of the violation, whether the covered entity knew or should have known of the failure to comply, or whether the covered entity's failure to comply was due to willful neglect. The CMP is based on the violation categories and increased penalty amounts authorized by Section 13410(d) of the Health Information Technology for Economic and Clinical Health (HITECH) Act.

	Many scientific publications require documentation of IRB approval or appropriate determination of exemption as a condition for publication of human subjects research. **Documentation of appropriate informed consent may be required** by data archives or repositories. Many scientific professional associations have related provisions in their professional codes of conduct.	
Exemptio nsand activities not covered	"**Covered source":** Many studies are not covered because they are not funded by a Federal agency and not conducted by an entity that has chosen to apply the regulation to all research conducted by the entity. **"Not research":** Much journalism, oral history, quality assurance, etc. does not meet the definition of "human subjects research". **Research that uses only de-identified data** is not covered as it does not involve interaction with individuals for research purposes or involve private information. **Exemptions:** The Common Rule provides six exemptions for studies that are usually minimal risk (§46.CFR 101(b)). Detailed information on these six exemptions is available at http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html#46.101%28b%29	None. All research projects seeking PHI from a HIPAA-covered entity must comply with the HIPAA privacy rule—even if the research is exempt from the Common Rule requirements. This website provides information on the Privacy Rule for the research community. https://privacyruleandresearch.nih.gov/ Detailed information on the conditions under which protected health information may be used or disclosed by covered entities for research purposes is available at **http://www.hhs.gov/ocr/privacy/hipaa/understanding/coveredentities/research.html** Information on the National Institute of Health's Genomic Data Sharing Policy is available at https://gds.nih.gov/03policy2.html

Additional information:

- The Common Rule regulation includes four subparts: subpart A, (also known as the Federal Policy or the "Common Rule"); subpart B, additional protections for pregnant women, human fetuses, and neonates; subpart C, additional protections for prisoners; and subpart D, additional protections for children (which modifies exemption 2).Some of the 18 participating Federal agencies and departments have adopted all of the subparts.

Additional information is available at:

  - The Common Rule regulation: http://www.hhs.gov/ohrp/humansubjects/guidance/45cfr46.html

- Summary of Privacy Rule: http://www.hhs.gov/ocr/privacy/hipaa/understanding/summary
- FAQs on Privacy Rule: http://privacyruleandresearch.nih.gov/faq.asp
- General Information about HIPAA available at http://www.hhs.gov/ocr/privacy