This guidance provides information about the Health Insurance Portability and Accountability Act and how it applies to human subjects research projects conducted through the University of Denver.

The Health Insurance Portability and Accountability Act (HIPAA) of 1996 is a Federal law issued by the U.S. Department of Health and Human Services (HHS). HHS issued the “Privacy Rule” in 2000 to carry out HIPAA’s mandate that HHS establish Federal standards for safeguarding the privacy of individually identifiable health information. The Privacy Rule was issued to protect the privacy of health information that identifies individuals who are living or deceased.

Covered entities are defined in the HIPAA rule as (1) health plans, (2) health care clearinghouses, and (3) health care providers who electronically transmit any health information in connection with transactions for which HHS has adopted standards.

The University of Denver is not defined as a covered entity per the HIPAA rule.

**Federal Laws and Regulations**

The biomedical and behavioral research conducted in the United States is governed either by the rule entitled “Federal Policy for the Protection of Human Subjects” (also known as the “Common Rule”) – Title 45 CFR Part 46, and/or the Food and Drug Administration’s Protection for Human Subjects Regulations – Title 21 CFR Parts 50 & 56. Although these human subject regulatory requirements, which apply to most Federally-funded research, include protections to help ensure the privacy of subjects and the confidentiality of information, the intent of the Privacy Rule, is to supplement these protections by requiring covered entities to implement specific measures to safeguard the privacy of individually identifiable health information.

**DU IRB Requirements**

University of Denver Institutional Review Board (IRB) does not mandate the HIPAA Privacy Rule requirements to the any research submitted by the university community for IRB review and approval. The Privacy Rule applies only to covered entities and does not apply to research. Currently, the University of Denver is not a covered entity.

Reference: Department of Health and Human Services, “Protecting Personal Health Information in Research: Understanding the HIPAA Privacy Rule”, NIH Publication Number 03-5388
For additional guidance and information, contact University of Denver Office of Research Compliance at (303)871-4050 or at: IRBAdmin@du.edu