

# Privacy Rule and Common Rule

U.S. Department of Health and Human Services (DHHS)

OCR	Office of Civil Rights	Office of Human Research Protections	OHRP
HIPAA	Health Insurance Portability and Accountability Act (1996)	Common Rule for Protection of Human Subjects Regulations (1991)	Re: DHHS, CDC, FDA, etc.
Covered entity	Covered entities: any public or private health plan, provider, or clearinghouse that conducts covered health care transactions electronically.	Researchers/organizations receiving DHHS funds or covered by multiple-project or federal-wide assurances (MPA or FWA).	DHHS
	<b>Privacy Rule</b>	<b>Informed Consent</b>	
PHI	Applies to individually identifiable health information, i.e., protected health information (PHI) created or maintained in any medium.	Applies to informed consent for participation in research, including not only risks and benefits, but also respecting and safeguarding privacy and confidentiality of individually identifiable information.	
PB	Researchers who are members of the workforce of a covered entity who are <i>preparing for</i> a research study may access PHI after receiving oral or written approval from the Privacy Board (PB), must <i>not</i> remove PHI from the premises, and should use the “minimum necessary” PHI. Further <i>use or disclosure</i> of PHI requires individual <i>authorizations</i> or PB’s waiver or alteration of the <i>authorization</i> .	Researchers <i>contacting</i> participants or otherwise <i>conducting</i> a research study must seek approval by the Institutional Review Board (IRB); Researcher must obtain from each research participant: <i>authorization</i> to use PHI and <i>informed consent</i> for participation in research.	IRB
Waiver	Waivers and alterations of the <i>authorization</i> (consent) must be approved by the institution’s PB.	Waivers of <i>informed consent</i> must be authorized by the IRB.	Waiver
OCR	Unauthorized uses or disclosures of PHI subject to significant civil penalties by OCR.	Unauthorized solicitation or inclusions of participants without informed consent are subject to institutional or individual sanctions by the DHHS’s OHRP.	OHRP