

Overview of HIPAA Requirements for Research Based Upon Existing Medical Records and for Clinical Research

Note: All terms highlighted in **red** are HIPAA terms that should be clearly understood (see [HIPAA Glossary](#), or the Glossary on page 21 of the [Primer](#)). All *italicized* words are links to web sites containing related information.

Whenever Research Planning Requires PHI

<p>Determining Feasibility and/or Preparatory to Research PHI record reviews by VCUHS "workforce" needs only a Medical Record Review Data Form to VCUHS Health Information Management Department</p> <ul style="list-style-type: none"> • Use of PHI is solely for planning or feasibility • PHI will not be removed • PHI is necessary for the research
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Whenever Research Requires PHI

RESEARCH USE WITH INDIVIDUAL PATIENT AUTHORIZATION	RESEARCH WITH LIMITED DATA SETS and WITH DE-IDENTIFIED DATA	RESEARCH WITHOUT AUTHORIZATION BY PATIENT	
<p>A Research Subject's Authorization for use/disclosure of PHI and research data requires no other authorization. Requires use of VCUHS Privacy Board Authorization Form for Research</p>	<p>De-identified data use does not require patient authorization nor a Waiver from the Privacy Board</p> <p>Limited data sets must meet specific criteria and require a Data Use Agreement from the VCU Sponsored Programs Offices briefly described below :</p>	<p>Requires VCUHS Privacy Board Authorization Waiver and, usually, an IRB Waiver of Informed Consent</p>	<p>The Covered Entity allowing the use of PHI without patient agreement must meet specific requirements as well.</p>
<p>Individual authorization must comply with CFR 164.508</p> <p>Authorization requires:</p> <ul style="list-style-type: none"> • The PHI information that may be used/disclosed • Who will use/disclose the PHI information • Who may receive the information • Purpose of use/disclosure • Expiration date or event, or • State that there is no expiration date or event • Individual's signature and date • Right to revoke the authorization • Right to refuse to sign the authorization • Re-disclosures not protected • Future treatment is not conditioned 	<p>Specified direct identifiers are excluded and Agreement must:</p> <ul style="list-style-type: none"> • Describe permitted uses and disclosures that would not violate the Privacy Rule • Limit who can receive the data • Disallow use or disclosure other than stated in the agreement or required by law • Safeguards to prevent use or disclosure other than in the agreement • Require reports to the Covered Entity of any disclosures not in the agreement • Ensure that other participants agree to Agreement restrictions • Not allow the recipient to identify the information or contact the patient. 	<p>VCUHS Privacy Board and IRB must:</p> <p>A. Assure only a minimal risk</p> <ul style="list-style-type: none"> • Protect identifiers from improper use or disclosure • Destroy identifiers ASAP • Have written assurance that PHI will not be re-used or disclosed except as permitted <p>B. Agree the research cannot be done without the waiver.</p> <p>C. Agree the research requires the PHI.</p>	<p>Covered Entity must document:</p> <ul style="list-style-type: none"> • Description of PHI for which access has been given • IRB/ Privacy Board approval of waiver, dated • Signatures of IRB and Privacy Board Chairs • Statement of satisfaction of VCU requirements