

HIPAA Privacy Rule, Research and the IRB -- A Quick Reference

Research Activity	HIPAA Prerequisites	HIPAA Responsibilities	IRB Interface
<p>1. Entity Responsibilities.</p>	<p>Designate privacy official and contact person, develop and implement policies and procedures regarding protected health information (PHI).</p>	<p>Train personnel handling PHI in policies and procedures (administrative, procedural & technical) regarding identifiable health information.</p>	<p>Verify that all staff have been trained in HIPAA privacy protections.</p>
<p>Research Site Activity:</p>			
<p>2. Perform Prospective Research</p>		<p>Specific authorization (Authorization) from subject is required to use PHI to conduct the research.</p>	<p>IRB-approved protocol and informed consent is necessary for patient to participate in the study.</p>
<p>A. Place information into a database for future research or for identification of potential research subjects.</p>			
<p>1. Maintain treatment PHI in a database within the covered entity.</p>	<p>This practice must be described in the covered entity's notice of privacy practices (Privacy Notice).</p>	<p><i>No additional HIPAA requirement</i></p>	<p><i>No additional IRB requirement</i></p>
<p>2. Create (collect or manipulate) PHI to create a research database or bank tissue.</p>	<p>This practice must be described in the covered entity's Privacy Notice.</p>	<p>A covered entity must obtain subjects' Authorization or a waiver of Authorization (Waiver) from an IRB/Privacy Board. Scope of Authorization or Waiver must be limited to the creation of the database/tissue bank.</p>	<p><i>No additional IRB requirement to create a database.</i></p> <p>The IRB must determine whether informed consent is required for collection, banking and distribution of identifiable (including coded) tissue.</p>
<p>3. Disclose information for placement into a database that exists outside of the covered entity.</p>	<p>This practice must be described in the covered entity's Privacy Notice.</p>	<p>The covered entity must obtain subjects' Authorization or a Waiver from an IRB/Privacy Board; or obtain a data use agreement from recipient if disclosing a limited data set.</p>	<p><i>No additional IRB requirement</i></p>
<p>B. Identify/Contact Eligible Research Subjects</p>			<p>The investigator's IRB must review and approve the investigator's plan for how subjects will be identified and recruited, AND ...</p>
<p>1. As they present during a scheduled appointment.</p>	<p><i>No HIPAA prerequisite</i></p>	<p><i>No HIPAA requirement</i></p>	<p><i>No additional IRB requirement</i></p>

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2. Review records within the investigator's covered entity.	This practice must be described in the investigator's covered entity's Privacy Notice. AND Investigator must represent (to his/her covered entity) that the review is necessary to the research and that PHI will not be removed from the covered entity.	<i>No additional HIPAA requirement</i>	<i>No additional IRB requirement</i>
3. Review investigator's database	Ditto	<i>No additional HIPAA requirement</i>	<i>No additional IRB requirement</i>
a. Review database(s) within the investigator's covered entity.	Ditto	A "data use agreement" must be in place with the recipient.	<i>No additional IRB requirement</i>
b. Delegate prescreening of database records to a third party (even to the sponsor) outside the investigator's covered entity by providing a "limited data set" ^b [Also see below: 3.D.b. <i>Limited Data Set, Sharing</i>].	This practice must be described in the treating physician's (source of the records) Privacy Notice.	The treating physician must obtain patient Authorization or Waiver ^a from an IRB / Privacy Board to allow investigator access to PHI. AND The investigator must also verify that Authorization or Waiver ^a was obtained.	<i>No additional IRB requirement</i>
4. Review records/database outside of the investigator's covered entity.	<i>No HIPAA prerequisite</i>	<i>No HIPAA prerequisite</i>	The investigator's IRB must review and approve all advertisements and screening scripts prior to use.
5. Advertise	<i>No HIPAA prerequisite</i>	An Authorization or Waiver is required to <i>record</i> information from this activity.	When a screening script is submitted, it must be reviewed and approved by the investigator's IRB prior to use. If no Authorization exists and PHI will be recorded, it makes sense for the IRB to
a. Result in the subject initiating contact with the investigator (self-referral).	<i>No HIPAA prerequisite</i>	An Authorization or Waiver is required to <i>record</i> information from this activity.	When a screening script is submitted, it must be reviewed and approved by the investigator's IRB prior to use. If no Authorization exists and PHI will be recorded, it makes sense for the IRB to
b. Result in research investigator/study staff (covered entity) administering a screening interview.	<i>No HIPAA prerequisite</i>	An Authorization or Waiver is required to <i>record</i> information from this activity.	When a screening script is submitted, it must be reviewed and approved by the investigator's IRB prior to use. If no Authorization exists and PHI will be recorded, it makes sense for the IRB to

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6. Referrals			review it relative to the criteria for granting a Waiver for this activity. The waiver can then be granted at the same time.
a. Treating physician refers patients to investigators.	This practice must be described in the <i>treating physician's</i> Privacy Notice.	The <i>treating physician</i> must obtain patient Authorization or Waiver ^a from an IRB/Privacy Board to disclose to investigator /allow access to PHI. AND The <i>investigator</i> must also verify that Authorization or Waiver ^a was obtained.	The <i>investigator's</i> IRB must review and approve any material that the treating physician (source of record) may provide to patients to describe the study prior to its use.
b. Investigator reviews records/database outside of the investigator's covered entity.	Ditto	Ditto	Ditto
c. Investigator reviews records/database outside of his/her covered entity using an "honest broker" ^c .	<i>Treating physician</i> (source of records) must have a Business Associate contract with the honest broker that includes this service. AND The honest broker may not be one of the investigators.	Ditto	Ditto
d. Investigator request referrals from colleagues (other physicians)			
i. General, non-targeted, resulting in self-referral. (extension of advertising).	This practice must be described in the <i>treating physician's</i> Privacy Notice.	<i>No HIPAA requirement</i>	Ditto
ii. Targeted referral (other physician reviews his/her own records and identifies patients to contact and tell about the study.	This practice must be described in the <i>treating physician's</i> Privacy Notice.	The <i>treating physician</i> must obtain patient Authorization or Waiver ^a from an IRB/Privacy Board to subsequently disclose PHI. AND	When the treating physician contacts his/her patients using a "Physician – to – Patient" Letter, it must be reviewed and approved by the <i>investigator's</i> IRB prior to use. "

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<p>e. Investigator receives patient contact information from a recruitment center^d (non-covered entity)^e.</p> <p>i. Recruitment center is using marketing materials / distributing information about the study.</p> <p>ii. Recruitment center refers patient(s) to the nearest investigator conducting the study and the patient initiates contact with the investigator (a form of self-referral).</p> <p>iii. Recruitment center is conducting trial-specific screening interviews.</p> <p><i>(Privacy rule does not apply if the source of the data is a non-covered entity. However, most recruitment centers operate a system where people “opt-in” and give permission for the activity, and may “opt-out” at any time.)</i></p>	<p><i>No HIPAA prerequisite</i></p> <p><i>No HIPAA prerequisite</i></p> <p><i>No HIPAA prerequisite</i></p>	<p>The investigator must also verify that Authorization or Waiver^a was obtained.</p> <p><i>No HIPAA requirement</i></p> <p><i>No HIPAA requirement</i></p> <p><i>No HIPAA requirement</i></p>	<p>All trial-specific marketing material / information about the study that prospective recruits may see must be reviewed and approved by the investigators’ IRB(s) prior to use.</p> <p>Ditto</p> <p>Any trial-specific screening interview script must be reviewed and approved by the investigators’ IRB(s) prior to use.</p>
<p>C. Identify Study Staff/</p>			
<p>The research site should identify all personnel participating in research, paying attention to whether sub-investigators or other research personnel are outside the investigator’s covered entity (constitutes a disclosure that must be represented).</p>	<p><i>No HIPAA prerequisite</i></p>	<p>Authorizations must identify all people/organizations using and disclosing data, including secondary uses and disclosures</p>	<p>The IRB should verify the scope of organizations and / or consultants that have access to the patient’s data. The consent form accounting of these possible disclosures should be consistent with the HIPAA Authorization.</p>

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2. Review or disclose records outside of the investigator's covered entity.	This practice must be described in the <i>treating physician's</i> (source of the records) Privacy Notice.	The <i>treating physician</i> must obtain Authorization from decedent's personal representative or Waiver ^a from an IRB/Privacy Board to allow access or disclosure.	<i>No IRB requirement</i>
B. Identifiable Data		Authorization, Waiver or a data use agreement (for a limited dataset) is required to use existing PHI to conduct the research.	IRB-approved protocol and informed consent, or waiver of consent is necessary for investigator to conduct the research.
C. De-Identified Data			
1. Coded Data (includes a link to patient identity)	<i>No HIPAA prerequisite</i>	<i>No additional HIPAA requirement</i>	IRB-approved protocol and informed consent (or waiver of consent) is necessary for patient to participate in the study, AND ... The IRB will need to evaluate: 1) Whether the HIPAA safe-harbor provisions have been met (stripped of 18 defined identifiers); or 2) The expert opinion that the patients risk of identification is "very low"; and 3) The qualifications of such expert.
2. Anonymized Data (no link to patient identity)	<i>No HIPAA prerequisite</i>	<i>No HIPAA requirement</i>	<i>No IRB requirement. (Protocol is exempt from IRB review.)</i>
3. Creating de-identified data	Must be created within the covered entity.	If outsourced, a Business Associate contract is required that includes this service.	<i>No IRB requirement</i>
4. Sharing de-identified data (coded or anonymized)	No HIPAA prerequisite	If coded, the link code to patient identity must not be shared.	<i>No IRB requirement</i>

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D. Limited Data Set			IRB-approved protocol and informed consent / waiver of consent to conduct the research, AND ...
Creating a Limited Data Set a. Creating	This practice must be described in the covered entity's Privacy Notice. AND Must be created within the covered entity.	If outsourced, a Business Associate contract is required that includes this service.	<i>No additional IRB requirement</i>
b. Sharing	The practice of sharing must be described in covered entity's Privacy Notice as above.	A "data use agreement" must be in place with the recipient.	<i>No additional IRB requirement</i>
4. Research Authorization			
1. Combined with research informed consent form.	<i>No prerequisite</i>	Consent must contain the elements required under federal human research policies AND the elements required by the HIPAA Privacy Rule.	The consent/Authorization must be reviewed by the IRB.
2. Separate from research informed consent form.	<i>No prerequisite</i>	Authorizations must include the elements required by the Privacy Rule: <ol style="list-style-type: none"> 1. A description of what information will be used 2. Who will use the information 3. To whom the information will be disclosed 4. For what purpose 5. An expiration date ("end of study" or "none") 6. Notification of right to revoke, conditioned treatment and potential for redisclosure. 7. A patient's dated signature. 	IRB review of the HIPAA Authorization is not required. HOWEVER The investigator must submit any information requested by his/her IRB to ascertain that appropriate privacy protections are in place, including Privacy Rule protections. This information may include the Authorization form or representations that Authorization is/will be obtained as appropriate.

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<p>5. Application for alteration of Authorization or Waiver</p>	<p>The investigator must identify the “designated record set” to which the waiver specifically refers and provide sufficient information for the IRB or Privacy Board to make the judgments listed in the far-right column.</p>	<p>The investigator (or record holder) must keep track of and account for disclosures made under a Waiver.</p> <p>The investigator must receive documentation of the granting of the Waiver from a IRB / Privacy Board. The documentation must contain the following specific elements:</p> <ol style="list-style-type: none"> 1) The identity of the IRB/Privacy Board. 2) The Waiver approval date. 3) A brief description of the PHI involved. 4) The review procedures used (i.e., full board or expedited review.) 5) The signature of the Chair or other designated member. 	<p>The IRB will need to make the following four judgments:</p> <ol style="list-style-type: none"> 1) The use/disclosure involves “no more than minimal risk”^f to the privacy of the individuals. 2) The research could not practicably be conducted without the Waiver. 3) The research could not be done without access to and use of the PHI. 4) There are adequate written assurances that the investigator and others involved will protect the PHI by HIPAA Privacy Rule standards.

^a The Privacy Rule allows for a Waiver to share PHI to be granted by the requesting investigator’s IRB/Privacy Board. However, the treating physician’s covered entity is not bound to accept it and may make its own evaluation.

^b The third party does not receive any information or combination of information that could reveal the patient’s identity. Each patient record contains a code that would allow only the investigator to re-identify the patient PHI. After screening the data, the third party provides the investigator with a report confirming those records that passed the initial screening. The investigator then re-identifies the subset of patient records, makes an assessment about whether the individuals selected are appropriate candidates and subsequently contacts the patients to find out if they are interested in taking part in the trial.

^c An honest broker is a disinterested party that, in this context, de-identifies data but codes it so that it can be re-identified. The coded data is provided to the investigator to identify eligible patients. The honest broker re-identifies those patients and informs their treating physicians.

^d “Recruitment center” refers to any patient recruitment service or organization, whether independent, part of a contract research / site management organization, or sponsor.

^e If the recruitment center is a covered entity, the requirements would be the same as for a referring physician (above)

^f The investigator has an adequate plan to protect identifiers from improper use or disclosure throughout time of use and to destroy the identifiers at an appropriate time.