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Research and HIPAA Privacy Protections

Georgia Institute of Technology - Group 2 Social / Behavioral Research Investigators and Key Personnel

Quiz Results

You correctly answered **5 of 5** quiz questions.

Question 1

Question	The HIPAA "minimum necessary" standard applies...
Your Answer	To all human subjects research that uses PHI without an authorization from the data subject.
Result	**Correct**
Comment	Uses and disclosures of data for research that are allowed to bypass the authorization requirement are still subject to the "minimum necessary" standard - that is, the uses/disclosures must be no more than the minimum required for the described research purpose. A covered entity may rely on a researcher's documentation - or the assessment of an IRB or Privacy Board - that the information requested is the minimum necessary for the research purpose. By contrast, research information obtained using an authorization is not bound by the minimum necessary standard – on the theory that the

data subject has given explicit permission in accordance with the signed authorization. However, be aware that while HIPAA may not require a minimum necessary justification at all times, an IRB's evaluation of risks and burdens on human subjects arguably does.

Question 2

Question	When required, the information provided to the data subject in a HIPAA disclosure accounting ...
Your Answer	must be more detailed for disclosures that involve fewer than 50 subject records.
Result	**Correct**
Comment	Where fewer than 50 subjects' records are involved, the listing must be more specific and detailed, commensurate with the requirements for other kinds of PHI disclosure accounting, including: specific date(s) of disclosures; names of entities to which PHI was disclosed; description of the PHI involved in the disclosure; and purpose of the disclosure.

Question 3

Question	Recruiting into research ...
Your Answer	Can qualify as an activity "preparatory to research," at least for the initial contact, but data should not leave the covered entity.
Result	**Correct**
Comment	It is still permissible under HIPAA to discuss recruitment into research with patients for whom such involvement might be appropriate. This common practice is considered to fall within the definition of treatment, at least when the conversation is undertaken by one of the patient's healthcare providers. If the contact will be made by someone other than the patient's healthcare provider, permission will be required.

Question 4

Question	HIPAA’s protections for health information used for research purposes...
Your Answer	Supplement those of the Common Rule and FDA.
Result	**Correct**
Comment	HIPAA's relatively new data-focused protections, which took effect starting in 2003, supplement Common Rule and FDA protections; they are not a replacement. Institutional Review Board (IRB) protocol reviews using Common Rule and FDA criteria remain as before, including aspects related to data protection. IRBs may have the responsibility for addressing HIPAA's additional requirements in their reviews when those apply; or some responsibilities may be given to another kind of body that HIPAA permits (a Privacy Board) or to an institutional official that HIPAA requires (a privacy officer). These federal standards complement states’ and accreditation bodies’ requirements.

Question 5

Question	A HIPAA authorization has which of the following characteristics:
Your Answer	Uses "plain language" that the data subject can understand, similar to the requirement for an informed consent document.
Result	**Correct**
Comment	Authorizations are required unless the proposed use meets one of the exceptions listed in the HIPAA regulation. It is never at the researcher's discretion. When they are required, authorizations must be: In "plain language" so that individuals can understand the information contained in the form, and thus able to make an informed decision. Executed in writing, and signed by the research subject (or an authorized personal representative). Authorizations must include a specific description of the PHI to be used or disclosed, the name(s) or other identification of persons involved in the research, and description of each purpose of the requested use or

disclosure. Authorizations can be combined with other documents and can always be revoked by the data subject.

You scored 100% on the quiz.

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