



Protocol Title: Click or tap here to enter text.		
Principle Investigator: Click or tap here to enter text.		
Date Submitted to Privacy Office: Click or tap to enter a date.		
Criteria	Condition Is Met	Notes
HIPAA authorization required conditions:		
1	Description of the PHI to be used or disclosed. <i>The description should be in plain language.</i>	<input type="checkbox"/> Click or tap here to enter text.
2	The person or class of persons who are authorized to make the use or disclosure.	<input type="checkbox"/> Click or tap here to enter text.
3	The person or class of persons to whom the authorized use or disclosure may be made. <i>Ensure the list includes ancillary departments within the organization that will support the research department with oversight.</i>	<input type="checkbox"/> Click or tap here to enter text.
4	Description of the purpose of the use or disclosure.	<input type="checkbox"/> Click or tap here to enter text.
5	An expiration date or event for the authorization - "End of research study" or "none" may be used in authorizations for research or for a research database or repository.	<input type="checkbox"/> Click or tap here to enter text.
6	The signature, printed name of the individual and date. <i>When appropriate ensure that there is a signature line indicating that a legally authorized representative is signing on behalf of the subject.</i>	<input type="checkbox"/> Click or tap here to enter text.
HIPAA authorization required statements:		
7	The HIPAA authorization language must include:	<input type="checkbox"/> Click or tap here to enter text.
	1. the individual's right to revoke the authorization,	<input type="checkbox"/> Click or tap here to enter text.
	2. any exceptions to the individual's right to revoke the authorization and,	<input type="checkbox"/> Click or tap here to enter text.
	3. a description of how to revoke the authorization.	<input type="checkbox"/> Click or tap here to enter text.
8	The ability or inability to condition treatment, payment, enrollment or eligibility for benefits on the individual's authorization.	<input type="checkbox"/> Click or tap here to enter text.
9	The potential for PHI disclosed pursuant to the authorization to be subject to re-disclosure by the recipient and to be no longer subject to HIPAA.	<input type="checkbox"/> Click or tap here to enter text.
10	The covered entity must provide the subject with a signed copy of the authorization.	<input type="checkbox"/> Click or tap here to enter text.
Other possible conditions:		
	Research authorizations may be combined with "any other type of written permission for the same research study, which typically would be the informed consent required by the Common Rule and FDA regulations.	<input type="checkbox"/> Click or tap here to enter text.
	A covered entity may condition the provision of research-related treatment on the provision of an authorization by a patient (if applicable).	<input type="checkbox"/> Click or tap here to enter text.