

# Clinical Research HIPAA Assessment Tool

<b>Facility:</b>	<b>Y or N</b>	<b>Date:</b>
<b>Department Name:</b>		<b>Auditor:</b>
<b>Research Director:</b>		<b>Facility Score:</b>
<b>Research Compliance Indicators</b>		<b>Comments</b>

<b>I</b>	<b>[Facility HIPAA Privacy Policy]</b>	
	1. Do you have a copy of [HIPAA Privacy Policy] or know where to find it?	
	2. Have all of the research staff been trained on [the facility's policy]?	
	3. Do you have a copy of the Authorization for Release of Health Information for Purpose of Research form or know where to find it?	
	4. Are you aware of a Spanish translation of the above release form?	
	5. Does a research subject have to sign more than one authorization form for the duration of the study?	
	6. Are appropriate attachments required to be submitted with the authorization form?	
	7. Is a copy of the Informed Consent required to be attached to the authorization form?	
	8. Are any research administrative signatures required on the authorization form?	

<b>II</b>	<b>SOP Re: PHI in Research Databases</b>	
	1. Do you have a copy of this SOP or know where to find it?	
	2. Have all of the research staff been trained on this SOP?	
	3. Does this SOP also apply to registries, which are created for health surveillance, when used for the purposes of research?	
	4. Does PHI in databases for research purposes fall under the purview of the IRB/Privacy Board?	
	5. Must authorization be obtained if a database is used for research purposes?	
	6. Can a database ever be used for research purposes without obtaining authorization?	
	7. Are you able to state 2 ways that PHI can be de-identified?	
	8. Can you name 2 of the 3 HIPAA templates in the HIPAA Investigator Guidelines utilized for de-identification purposes?	

<b>III</b>	<b>Waivers of Authorization</b>	
	1. Can you state the 3 criteria that must be met in order for the IRB to grant a Waiver of Authorization?	
	2. Can you state some ways to protect patient identifiers from improper use/disclosure?	
	3. Does the "minimum necessary" rule for access to PHI still apply under a Waiver of Authorization?	
	4. Is there a specific authorization process for screening/recruitment purposes?	
	5. Can you describe how you can access PHI for review preparatory to research?	
	6. Have all of the research staff been trained on the waiver process?	
	7. Must the Principal Investigator sign an assurance statement with the completion of waiver forms?	

<b>IV</b>	<b>HIPAA Compliance Summary</b>	
	1. Do you have a copy of the HIPAA Compliance Summary or know where to find it?	
	2. Have all research staff been trained on the proper completion of this form?	
	3. Do you know when this form needs to be completed?	
	4. Does this form allow you to designate if HIPAA regulations apply to your research or not?	
	5. Does this form let you describe HIPAA security procedures in place for your study whether electronic or hard copy data?	
	6. Does this form require you to explain to the research participant their level of access to the study data?	
	7. Can you state 2 of the 4 choices on this form for how data will be shared?	
	8. Can you state 2 of the 4 acceptable choices for subject recruitment outlined on this form?	
	9. Must the Principal Investigator sign an assurance statement with the completion of this form?	

<b>V</b>	<b>Tracking and Accounting for Disclosures</b>	
	1. Can you state 1 of the 2 types of disclosures that are exempt from this accounting requirement for research?	
	2. Do you know how disclosures made pursuant to a Waiver of Authorization are traced within [the facility]?	
	3. Are you aware of a simplified accounting procedure if the research use or disclosure involves more than 50 people?	
	4. Do you have an internal tracking system within your department/site for these disclosures?	

<b>VI</b>	<b>Frequently Asked Questions</b>	
	1. Is decedent research allowed to be done without authorization?	
	2. Should a primary care physician get a patient's authorization to disclose their information to a research staff member?	
	3. Do you do a new IRB protocol submission when you want to use existing data for a new research purpose?	
	4. Do you meet the additional HIPAA requirements of letting research subjects know the uses and disclosures of PHI related to research?	
	5. Can you name 2 of the 4 ways that research findings can be reported?	
	6. Does [the facility] utilize compound authorizations?	

<b>Persons Interviewed During Audit:</b>		<b>Total No's</b>
<b>Audit Reviewed With:</b>		<b>Facility Score (44 indicators)</b>