

Complete Healthcare Compliance Manual

Sample Research Compliance Assessment Form

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RESEARCH COMPLIANCE ASSESSMENT FORM

Organization	
Person Completing Assessment:	
Title of Person Completing Assessment:	
Date Assessment Completed:	
Notes:	

Area 1: Written policies and procedures

#	Description	Yes	No	Evidence of Compliance or action required Include specific references to documents that support and “Yes” response	Additional Notes
1.1	Do you have a written policy(s) and procedure(s) that describe compliance expectations for research?	<input type="checkbox"/>	<input type="checkbox"/>		

1.2	Have you implemented the operation of research compliance program?	<input type="checkbox"/>	<input type="checkbox"/>		
1.3	Do you have a written policy and procedure that provides guidance to employees on dealing with potential research compliance issues?	<input type="checkbox"/>	<input type="checkbox"/>		
1.4	Do you have a written policy and procedure that provides guidance on how to communicate research compliance issues to appropriate compliance personnel?	<input type="checkbox"/>	<input type="checkbox"/>		
1.5	Do you have a written policy and procedure that provides guidance on how potential research compliance problems are investigated and resolved?	<input type="checkbox"/>	<input type="checkbox"/>		

Area 2: Designate an employee vested with responsibility

#	Description	Yes	No	Evidence of Compliance or action required Include specific references to documents that support and “Yes” response	Additional Notes
2.1	Has a designated employee been vested with responsibility for the day-to-day operation of the research compliance program?	<input type="checkbox"/>	<input type="checkbox"/>		
2.2	Are the designated employee’s duties clearly defined?	<input type="checkbox"/>	<input type="checkbox"/>		

2.3	If the designated employee's research compliance duties are combined with other duties, are the research compliance responsibilities satisfactorily carried out?	<input type="checkbox"/>	<input type="checkbox"/>		
2.4	Is there a "subject matter expert" outside of the designated employee with oversight of research compliance?	<input type="checkbox"/>	<input type="checkbox"/>		
2.5	Does the "subject matter expert" have qualifications satisfactory to be an "expert"?	<input type="checkbox"/>	<input type="checkbox"/>		
2.6	Does the designated employee periodically report directly to the governing body on the activities of the research compliance program?	<input type="checkbox"/>	<input type="checkbox"/>		

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