

Healthcare Compliance Forms and Tools

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 a "Yes" response)	Additional notes
1.1	Do you have a written policy(s) and procedure(s) that describes compliance expectations for research?	☐	☐		
1.2	Have you implemented the operation of research compliance program?	☐	☐		

#	Description	Yes	No	Evidence of compliance or action required (Include specific references to documents that support a “Yes” response)	Additional notes
1.3	Do you have a written policy and procedure that provides guidance to employees on dealing with potential research compliance issues?	☐	☐		
1.4	Do you have a written policy and procedure that provides guidance on how to communicate research compliance issues to appropriate compliance personnel?	☐	☐		
1.5	Do you have a written policy and procedure that provides guidance on how potential research compliance problems are investigated and resolved?	☐	☐		

Area 2: Designate an employee vested with responsibility

#	Description	Yes	No	Evidence of compliance or action required (Include specific references to documents that support a “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?	☐	☐		
2.2	Are the designated employee’s duties clearly defined?	☐	☐		
2.3	If the designated employee’s research compliance duties are combined with other duties, are the research compliance responsibilities satisfactorily carried out?	☐	☐		

#	Description	Yes	No	Evidence of compliance or action required (Include specific references to documents that support a “Yes” response)	Additional notes
2.4	Is there a subject matter expert outside of the designated employee with oversight of research compliance?	☐	☐		
2.5	Does the subject matter expert have qualifications satisfactory to be an expert?	☐	☐		
2.6	Does the designated employee periodically report directly to the governing body on the activities of the research compliance program?	☐	☐		

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