

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"/>		

Area 3: Training and education

#	Description	Yes	No	Evidence of Compliance or action required Include specific references to documents that support and “Yes” response	Additional Notes
3.1	Is training and education provided to all affected employees on research compliance issues and the research compliance program operation?	<input type="checkbox"/>	<input type="checkbox"/>		
3.2	Is research compliance training offered periodically?	<input type="checkbox"/>	<input type="checkbox"/>		
3.3	Is research compliance training part of orientation for affected new employees?	<input type="checkbox"/>	<input type="checkbox"/>		
3.4	Are education/training sessions evaluated for effectiveness?	<input type="checkbox"/>	<input type="checkbox"/>		

Area 4: Communication lines to the responsible research compliance position

#	Description	Yes	No	Evidence of Compliance or action required Include specific references to documents that support and “Yes” response	Additional Notes
4.1	Are there lines of communication to the designated employee referred to in item 2.1 that are accessible to all employees to allow research compliance issues to be reported?	<input type="checkbox"/>	<input type="checkbox"/>		
4.2	Are there lines of communication to the designated employee referred to in item 2.1 that are accessible to all governing body members to allow research compliance issues to be reported?	<input type="checkbox"/>	<input type="checkbox"/>		
4.3	Is there a method in place for anonymous and/or confidential good faith reporting of potential research compliance issues as they are identified?	<input type="checkbox"/>	<input type="checkbox"/>		

Area 5: Disciplinary policies to encourage good faith participation

#	Description	Yes	No	Evidence of Compliance or action required Include specific references to documents that support and “Yes” response	Additional Notes
5.1	Do disciplinary policies exist to encourage good faith participation in the research compliance program by all affected individuals? <i>For purposes of Area 5, “affected individuals” shall mean those persons who are required to receive training and education under Area 3 above.</i>	<input type="checkbox"/>	<input type="checkbox"/>		
5.2	Are there policies in effect that articulate expectation for reporting compliance issues for all affected individuals?	<input type="checkbox"/>	<input type="checkbox"/>		
5.3	Are there policies in effect that articulate expectations for assisting in the resolution of	<input type="checkbox"/>	<input type="checkbox"/>		

	research compliance issues for all affected individuals?				
5.4	Is there a policy in effect that outlines sanctions for failing to report suspected problems for all affected individuals?	<input type="checkbox"/>	<input type="checkbox"/>		
5.5	Is there a policy in effect that outlines sanctions for participating in non-compliant behavior for all affected individuals?	<input type="checkbox"/>	<input type="checkbox"/>		
5.6	Is there a policy in effect that outlines sanctions for encouraging, directing, facilitating or permitting non-compliant behavior for all affected individuals?	<input type="checkbox"/>	<input type="checkbox"/>		
5.7	Is there a policy on non-intimidation and/or non-retaliation for good faith participation in the research compliance program, including but not limited to reporting potential issues, investigation issues, self-evaluations, audits and remedial actions, and reporting to appropriate officials?	<input type="checkbox"/>	<input type="checkbox"/>		
5.8	Are all research compliance-related disciplinary policies fairly and firmly enforced?	<input type="checkbox"/>	<input type="checkbox"/>		

Area 6: A system for routine identification of research compliance risk areas

#	Description	Yes	No	Evidence of Compliance or action required Include specific references to documents that support and “Yes” response	Additional Notes
6.1	Do you have a system in place for routine identification of research compliance risk areas specific to your provider type?	<input type="checkbox"/>	<input type="checkbox"/>		
6.2	Do you have a research compliance work plan and goals?	<input type="checkbox"/>	<input type="checkbox"/>		
6.3	Do you have a system in place for self-evaluation of the risk areas identified in 6.1, including internal audits and as appropriate external audits?	<input type="checkbox"/>	<input type="checkbox"/>		

6.4	Do you have a system in place for evaluation of potential or actual non-compliance as result of self-evaluations and audits identified in 6.3?	<input type="checkbox"/>	<input type="checkbox"/>		
6.5	Do you have a system in place to mitigate the research compliance risks identified in 6.1?	<input type="checkbox"/>	<input type="checkbox"/>		
6.6	Do you have a designated individual assigned to oversee any necessary mitigation or corrective actions identified in 6.5?	<input type="checkbox"/>	<input type="checkbox"/>		

Area 7: A system for responding to research compliance issues

#	Description	Yes	No	Evidence of Compliance or action required Include specific references to documents that support and “Yes” response	Additional Notes
7.1	Is there a system in place for responding to research compliance issues as they are raised?	<input type="checkbox"/>	<input type="checkbox"/>		
7.2	Is there a system in place for investigating potential research compliance problems?	<input type="checkbox"/>	<input type="checkbox"/>		
7.3	Is there a system in place for responding to research compliance problems as identified in the course of self-evaluations and audits?	<input type="checkbox"/>	<input type="checkbox"/>		
7.4	Is there a system in place for correcting research compliance problems (as referred to in 7.3) promptly and thoroughly?	<input type="checkbox"/>	<input type="checkbox"/>		
7.5	Is there a system in place for implementing procedures, policies and systems as necessary to reduce the potential for recurrence?	<input type="checkbox"/>	<input type="checkbox"/>		
7.6	Is there a system in place for identifying and reporting research0175 compliance issues to Federal agencies, if necessary?	<input type="checkbox"/>	<input type="checkbox"/>		
7.7	Is there a system in place for refunding Medicare/Medicaid overpayments?	<input type="checkbox"/>	<input type="checkbox"/>		
7.8	Is there a process for notifying the governing body of any potential violations?	<input type="checkbox"/>	<input type="checkbox"/>		