

RISK RESPONSE ACTION PLAN

Modify this form as needed to fit risk context. The level of the risk will determine the depth of the action plan required. Review and update a master copy of this form regularly to track progress, to provide to required Board and Management Committee(s), and to distribute to responsible stakeholders / risk owners collaborating on the action plan.

DATE OF THIS UPDATE: _____ PERSON SUBMITTING: _____

PURPOSE (What is the risk issue that needs remediation/mitigation?)			
Risk Domain	<input type="checkbox"/> Research Operations	<input type="checkbox"/> Participant Rights, Safety, Welfare	Risk Category
	<input type="checkbox"/> Research Finance	<input type="checkbox"/> Research Integrity	Human Subjects Research
Risk Definition / Audit Item Description & Scope			

OVERSIGHT			
Regulatory Citation	Documentation Reviewed	System/Process Reviewed	Stakeholders / Risk Owners
			•

CURRENT STATE: Observations/ Observation Category / Observation Classification		
Observations	Category	Classification
1) Delegation of authority logs missing principal investigator's signature.	Regulatory / Source Data / Documentation	Minor
2)		
3)		
4)		

ACTION PLAN (all should be completed within 30 days)					
Action	Corrective Course of Action/ Preventative Course of Action (Resolve the weaknesses, deficiencies, deviation patterns, or areas of noncompliance.)	Accountability Who Will Do It?	Timeline By When? (MM/DD/YY)	Report How should we report progress, issues, or concerns? To whom should we report these matters?	Status Update
1)	a)				
	b)				
	c)				
2)	a)				
	b)				
	c)				
3)	a)				
	b)				
	c)				

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QUALITY ASSURANCE PLAN					
Describe the monitoring to prevent the weaknesses, deficiencies, deviation patterns, or areas of noncompliance from reoccurring.					
Action	Corrective Course of Action/ Preventative Course of Action (Monitor the completed course of actions.)	Accountability Who Will Do It?	Frequency Arrange periodic reviews.	Report How should we report progress, issues, or concerns? To whom should we report these matters?	Status Update
1)	a)				
	b)				
	c)				
2)	a)				
	b)				
	c)				