

DAIDS Corrective and Preventive Action (CAPA) Form for Clinical Research Sites

Section 1: Incident Identification

CRS Name	
CRS #	
Protocol #/ (s), if applicable	
Person completing form (Name and Role)	

Date identified	
Date of occurrence	
Provide a detailed description of site non-compliance. Include PIDS impacted, if applicable.	

Section 2: Corrective Action

Describe immediate action/s taken by site to correct the non-compliance. Include the name and role(s) of individual(s) involved in implementing corrective action(s).	
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Section 3: Root Cause Analysis

<p>Describe the underlying reason for the problem which if eliminated or corrected would prevent the problem from existing or recurring.</p> <p><i>*(Tools for RCA may include but are not limited to: The 5 Why's, Fishbone diagram, Scatter Diagram, Pareto Chart)</i></p>	
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Section 4: Preventive Action

<p>Describe action/s taken in order to prevent the non-compliance from reoccurring. Please include name and roles of individual/s involved in implementing preventive action/s, if known.</p> <p>Also, include projected date for implementation.</p>	
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Section 5: Effectiveness Evaluation

Describe plan/procedure to evaluate the implementation	
Date/Timeframe for evaluation	
Name of Person responsible for evaluation	

IOR or CRS Leader Name	Print Name/Signature	Date: