



Corrective and Preventive Action Plan Template

A CAPA is written to identify a discrepancy/problem in the conduct of a clinical research study, note the root cause of the identified problem, identify the corrective action to prevent the recurrence of the problem, and document that the corrective action has resolved the problem. In general, the tone of CAPA should be forward-looking and not seek to explain an error discovered in the conduct of a clinical research study.

Date:	<i>Date that the CAPA is written</i>
To:	<i>Sponsor, HREC, etc</i>
From (Person responsible for overall CAPA):	<i>Name, Title, the site/institutional affiliation of the person authoring the CAPA, including their signature</i>
Protocol Title / Research Study:	
HREC Number:	
Issue / Deficiency Identified:	<i>Brief description or outline of the topic/process/problem being documented. This can be formatted as a paragraph, numbered list, or bulleted items.</i>
Root Cause:	<i>The reason(s) that the issue arose. Root-cause analysis is a class of problem solving methods used to identify the root causes of problems or events.</i>
Corrective Action Plan:	<i>Description of the correction action(s) taken or planned by the site. If the site was instructed to perform these corrective actions (i.e. by the sponsor or monitor), indicate by whom and as of what date. If status of reports, records or data will remain incomplete or unavailable, make a statement regarding your failed attempts or describe when/how the records will be retrieved or completed.</i>
Implementation:	<i>Description of the procedures used to document resolution of the problem, the persons who are responsible for the procedures, etc.</i>
Effective Date of Resolution:	<i>Effective date for corrective action</i>
Preventive Action:	<i>Description of the preventive actions taken or planned by the site. If the site was instructed to perform these preventive actions, indicate by whom and as of what date. Preventive actions are taken to eliminate the root-cause of a potential problem, including the detection/identification of problems</i>
Evaluation/Follow up:	<i>Any plan/procedure to evaluate the implementation and completion, persons who are responsible for the evaluations, timeframe for the evaluation, etc.</i>

Comments: *Any additional comments or information not noted above.*

Principal Investigator Signature: _____ Date: _____



Principal Investigator Printed Name: _____