

CLINICAL INVESTIGATOR'S CORRECTIVE ACTION RESOLUTION FORM

Section I

Identified Issue:

Section II

Casual Analysis:

Section III

Proposed Resolution(s):

Section IV

Final Root Causal Analysis:

Issue Resolved on: _____

Continuing to be Reviewed: _____

Next Planned Assessment: _____

Section V

Documentation of Staff Retraining:

Members Required to Attend Retraining:
Attach attendance sheet with minutes.

Section VI

Continual Process Improvement:

Event Reoccurrence:
Address reoccurrences and further preventive measures and retraining and process improvements.

Section VII

Clinical Investigator's Review or Corrective Action Plan and Acknowledgement of Continual Improvement:

Clinical Investigator's Signature

Date of Review

Corrective Action Plan Preparer's Signature

Date of Signature

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