# Corrective and Preventive Action (CAPA) Plan

## Study Details

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| **Principal Investigator:** |  |
| **IRB Number / Sponsor Number:** |  |
| **Study Title:** |  |
| **Responsible Party:**  (person responsible for overseeing the CAPA Plan) | The following individual, designated by the PI, is responsible for documenting the Problem, Root Cause, and CAPA Plan, updating/revising the Plan as applicable, tracking the CAPA Plan’s completion, and verifying that appropriate documentation related to its completion is included, where applicable, in the study files:  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Printed Name of Responsible Party Responsible Party Role**  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **Responsible Party Signature Date** |

## Problem and Root Cause

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| **Description of Problem** | *Describe the problem including when and how it was identified. Note policy and/or regulations that should have been followed.* |
| **IRB Reporting Requirements**  *Refer to* [*IU HRPP Policy on Reportable Events*](https://research.iu.edu/policies/human-subjects-irb/reportable-events.html) | **\_\_\_\_\_ Yes**, problem should be promptly reported to IRB  **If yes**, date reported to IRB:  **\_\_\_\_\_ No**, problem does not meet prompt reporting criteria  **Additional notes:**  *Include any additional notes pertaining to whether the problem is promptly reportable to the Reviewing IRB and/or IU as an institution.* |
| **Root Cause Analysis (RCA) Process** | *Document the RCA process including when and how the process took place and who was involved. Refer to the RCA Information and Tools handout for more information on this step.* |
| **Ultimate root cause** | *Describe the ultimate root cause of the problem identified during the RCA process.* |

## Corrective and Preventive Actions

*Refer to IU HRPP Policy to* [*determine what changes require IRB review*](https://research.iu.edu/compliance/human-subjects/submissions/amendments.html)

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| **List all corrective actions** | **Individual Assigned to Complete the Action** | **Proposed Date of Completion** | **Actual Date of Completion** |
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| **List all preventive actions** | **Individual Assigned to Complete the Action** | **Proposed Date of Completion** | **Actual Date of completion** |
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## CAPA Plan Resolution

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| **Assessment** | *Describe how the CAPA Plan will be and/or was assessed for effectiveness, including when the assessments took place, who was involved, what decisions were made and why.* |
| **Closeout** | *Describe the process to arrive at closure, including discussions and/or meetings that took place to come to this determination, when they took place and who was involved.* |
| **PI Attestation**  (to be completed when CAPA Plan is closed) | As Principal Investigator, I attest to the completion of the CAPA Plan and confirm that it is considered closed at this time.  **\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**  **PI Signature Date** |