**Corrective and Preventative Action Plan (CAPA Plan)**

**Title of Project:**

**IRB Number:**

**Principal Investigator:**

**CAPA Version Number:**

**CAPA Version Date:**

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**I. Description of the Problem(s)**

*In this section, explain what happened. Provide a narrative of events and be sure to include:*

* *Description of the problem*
* *When the problem was first identified*
* *How the problem was first identified*
* *Timeline/dates of problem occurrence*
* *Number of participants affected by the problem (List subject study ID but do not list subject identifying information)*
* *Safety issues or potential safety issues that either caused harm or could have caused harm to the participant(s)*

**II. Causes of the Problem(s)**

*In this section, explain what caused the problem. How and why did it occur?*

* *Perform a root cause analysis to determine the cause of the problem. The* [***5 Why’s Tool***](https://www.cms.gov/medicare/provider-enrollment-and-certification/qapi/downloads/fivewhys.pdf)*and*[***Fishbone Tool***](https://www.cms.gov/medicare/provider-enrollment-and-certification/qapi/downloads/fishbonerevised.pdf) *are helpful tools to use when conducting a root cause analysis.*

**III. Corrective and Preventative Actions**

**Corrective Actions**

* + *In this section describe what corrective actions were taken to address the problem.*

**Preventative Actions**

* + *In this section describe what new processes were put in place to prevent the problem from happening again.*
    - *What is the preventative action?*
    - *Who will be involved with implementation?*
    - *How will involved parties be trained on the new process or procedure?*
    - *When will involve parties be trained on the new process or procedure? (timeframe of completion)*

**IV. Reporting**

*In this section list who the CAPA Plan was reported to. (i.e., IRB, sponsor, lead site, etc.)*

**IV. Evaluation of CAPA**

*In this section describe how and when the CAPA plan will be assessed for effectiveness.*