

Reportable Events/New Information Supplemental Form

Instructions

Use to supplement reportable information submitted in eBridge to provide additional information for the Children's Wisconsin HRPP's consideration.

For reports of Protocol Deviations/Violations/Noncompliance, please review our guidance entitled [Developing a Corrective and Preventive Action Plan \(CAPA\)](#) prior to completing this form.

Please contact the Children's HRPP Office if you have questions or need guidance at, (414) 337-7133 or cwhrpp@childrenswi.org.



If the event is an Unanticipated Problem, you must also consider Children's clinical reporting requirements [here](#).

The goal of safety event reporting is to improve systems, thus it is everyone's responsibility to report events. If this is a high level risk event or something that caused serious harm to patient (subject)/visitor/staff, contact risk management as soon as possible in addition to the Children's Wisconsin HRPP. Refer to Policy and Procedure: Safety Event Reporting.

If this reporting requirement applies to the unanticipated problem, please provide the date of the report to document that you have complied with Children's clinical expectation (which will be verified by the HRPP staff):

Additional Information to eBridge Submission

eBridge RE #:

Date event occurred (for reports of noncompliance):

Date PI became aware of event / new information:

Event occurred:

Is the study currently open to enrollment?

Current subject disposition:

If this is being attached to an Unanticipated Problem, you can stop here.

Corrective and Preventative Action (CAPA) Plan: **Complete the following sections when addressing a report of non-compliance**

For reports of **non-compliance/protocol deviations**- please review our [Guidance on Developing Corrective and Preventative Action \(CAPA\) Plans](#) prior to completing this section and answer the following:

NA – this is not a report of non-compliance

For all noncompliance, describe proposed Corrective and Preventive Action (CAPA) plan. The plan should be in sufficient detail to address what is being done for subjects affected, and what is being done so the noncompliance does not happen again (if the plan involves re-education, provide names of individuals and timeline for the education).

Root Cause Analysis

For information on how to appropriately complete this section, refer to the guidance entitled Developing a Corrective and Preventive Action Plan (CAPA).

In order to develop an appropriate CAPA, a root cause (or multiple causes) must be identified.

There are several strategies that can be used to assess the root cause of the non-compliance including:

- Things that should have happened (and didn't)
- Five Rules of Causation
- Asking the "Five Whys"
- Completing a Fishbone Diagram of Cause and Effect

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Please include an attachment showing the root cause analysis using one of the above tools, or a combination of tools

Root Cause:

Corrective Action Plan

Target Date:

Has already been implemented on

Will be implemented on

What will the PI's role be in this Corrective Action?

In addition to the PI, who else was/or will be assisting with the implementation of this Corrective Action:

If the implemented Corrective Action plan has already been implemented, how has it been successful?

If the Corrective Action plan has not yet been implemented, please note that the Children's Wisconsin HRPP may ask for an assessment of its effectiveness at time of a quality review.

Preventative Action Plan

Include the PI's role in the plan:

How is the preventative action plan going to be communicated to members of the study team?

How will the effectiveness of the plan be monitored (how will it be measured)?

Will the monitoring be continuous, or one-time? For example, training.

Duration of the monitoring plan:

How will implementation of the plan be documented? For example, if there is training involved, who is providing the training, who is involved, will there be a newly developed checklist to avoid the problem?

Target date for completion:

In addition to the PI, who else will be coordinating the implementation of this CAPA:

Please note that the Children's Wisconsin HRPP may ask for an assessment of the effectiveness of the Preventative Action plan at the time of a quality review.