Human Research Protection Program
Reportable Events/New Information

Instructions

Use to report both internal and external events, problems, and new information to the IRB. See page 3 for definitions and examples.

Reminder: The Children's IRB expects a summary of all Unanticipated Problems and Protocol Deviations/Violations/Noncompliance that have occurred since the last CR. The Reportable Events Log can be used for this purpose to log these types of events at the time of reporting so they will already be compiled when preparing the CR submission.

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/IRB Office if you have questions or need guidance at, (414) 337-7133 or cwhrpp@childrenswi.org.

STOP

If the event meets the definition of a UPIRSO, you must also consider Children's clinical reporting requirements. Link: https://connect.chw.org/en/employee-resources/safety-event-reports/patient-or-non-patient-safety-event. *Midas+ Remote Date Entry is used to enter patient and non-patient safety events. Event reporting is integral to our patient safety program by giving us valuable information about system failures and other process deficiencies. The events reported allow us to analyze and make critical changes to ensure our children's and staff safety.* If this reporting requirement applies to the unanticipated problem, please provide the MIDAS+ report # to document that you have complied with Children's clinical expectation: _____

Principal Investigator's Report

IRBNet #: / Protocol Title:	
Principal Investigator:	Phone or Email:
Contact Person for Questions:	Phone or Email:
This submission is a: Choose One	In the PIs opinion, does this meet prompt reporting requirements? Choose One
Date event occurred (or N/A):	Subject ID (no PHI) / Sponsor Tracking # (or N/A):
Date PI became aware of event / new information:	Event occurred: Choose One
Is the study currently open to enrollment? N/A	Current subject disposition: Choose One
Does information indicate local research subjects are currently at risk of harm? Choose One	
This is an ☐ initial report to IRB / ☐ follow-up report to IRB (if follow-up, provide IRBNet package number of initial report:).	
Provide name of sponsor (when applicable):	
☐ Check if this is an IND Safety Report from a sponsor that meets the criteria for reporting to FDA under 21 CFR 312.32 as a Serious Unexpected Suspected Adverse Reaction. ***NOTE: The report must be accompanied by confirmation that the Sponsor/Sponsor-Investigator has submitted the report to the FDA.***	

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For Information that Requires *prompt reporting* (within 5 business days), include a complete description of the event (include supporting documents with this package):

Description must be in sufficient detail to allow the IRB to make a determination [include timeline, cause, immediate actions taken or changes made, disposition of the subject(s)] and describe how subject(s)/others are affected. Indicate if an event is anticipated but is occurring more frequently or is more severe than anticipated. If subjects are not currently enrolled, address how event could affect future subjects.

For Information that Does Not Require *prompt reporting*, indicate type and briefly describe (include supporting documents with this package):

Examples: routine DSMB report [state below that report indicates study can continue as planned]; typical revised Investigator Brochure (version # dated ##/##/####) [indicate below that revisions do not include new risks or alter risk profile]; sponsor update or action letter.

Risk Mitigation Plan – Complete the following section when the report is something other than non-compliance

In the PI's opinion, does the protocol require revision? Choose One / If yes, briefly describe and submit an Amendment Form:

In the PI's opinion, does the consent document require revision? No / If yes, briefly describe and submit an Amendment Form:

Is action necessary to protect subjects or others (Risk Mitigation Plan)? Choose One If yes, describe:

If no action is necessary, explain rationale:

In the case of an industry-sponsored study, if the Risk Mitigation Plan requires IRB approval of an amendment and the documents are pending, explain and provide an anticipated timeframe for submission (the IRB may require interim action to protect subjects):

Required for IND Safety Reports from a sponsor that meet the criteria for reporting to the FDA under 21 CFR 312.32 as a Serious Unexpected Suspected Adverse Reaction: Has the sponsor determined the event meets the definition of an Unanticipated Problem Involving Risks to Subject or Others (you may need to request that the sponsor provide a determination)? Choose One

Provide confirmation from the sponsor/sponsor-investigator that the UAP has been reported as required by federal regulations (and include the date of the report):

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

For reports of **non-compliance/protocol deviations**- please review our guidance entitled Developing a Corrective and Preventive Action Plan (CAPA) 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).

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Root Cause Analysis

For information on how to appropriately complete this section, refer to the **Guidance on Developing Corrective and Preventative Action (CAPA) Plans.** This is also available in IRBNet

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

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

Describe the Corrective Action:		
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 IRB will ask for an assessment of its effectiveness at time of Continuing Review.		

Preventative Action Plan

Describe the preventative action plan (this should be both detailed and measurable:
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 IRB will ask for an assessment of the effectiveness of the preventative action plan at the time of Continuing Review.

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Principal Investigator Acknowledgement

In order to meet the IRB's prompt reporting requirements, the event may need to be submitted for review prior to sign-off in IRBNet by the Principal Investigator. Please have the PI personally sign-off in IRBNet as soon as possible.

***For reports that are required to be submitted promptly: When the PI is unable to sign the package at the time of submission, enter initials here _____ to document that the Principal Investigator has been made aware of this information and print name of individual completing this report on behalf of the Principal Investigator*: _____**

Children's Wisconsin Working Definitions
Please review Children's policies for additional definitions, or call 414-337-7133 with questions.

Unanticipated Problem (general term) or Unanticipated Problem Involving Risks to Subjects or Others ("UPIRSO").
Information that is:

1. **Unexpected:** in terms of nature, severity, or frequency given (a) the research procedures that are described in the protocol-related documents, such as the IRB-approved research protocol and informed consent document, or the Investigator Brochure; and (b) the characteristics of the subject population being studied;
2. **Related or possibly related:** to participation in the research (possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the drugs, devices or procedures involved in the research); **AND**
3. **Involves risk:** the information suggests that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized, warranting action.

Non-Compliance is any:

1. Failure to follow any regulation or CW policy that governs human subject research; or
2. Failure to follow the requirements or determinations of the IRB; or
3. Deviation or departure from an IRB-approved protocol.

Examples of Events to be Reported Promptly to the IRB (review policy for details)

Examples of information that indicates subjects or others are at increased risk of harm (this list is not inclusive):

- An interim analysis, interim findings, safety or action letter, DSMB report, publication in the literature, sponsor report, new information from the sponsor [including permanent or unscheduled closure to enrollment for safety reasons] or investigator finding that indicates an increase in the frequency or magnitude of a previously known risk, or uncovers a new risk.
- An investigator brochure, package insert, or device labeling revised to indicate an increase in the frequency or magnitude of a previously known risk, or describe a new risk.
- Withdrawal, restriction, or modification of a marketed approval of a drug, device, or biologic used in a research protocol.
- IND Safety Report from a sponsor that meets the criteria for reporting to the FDA under 21 CFR 312.32 as a Serious Unexpected Suspected Adverse Reaction. NOTE: The report must be accompanied by confirmation that the Sponsor/Sponsor-Investigator has submitted the report to the FDA.
- Unanticipated Adverse Device Effect "UADE" (FDA definition).
- Protocol violation that harmed subjects or others or that indicates subjects or others might be at increased risk of harm.
- Medication or laboratory errors.
- Complaint that indicates subjects or others might be at increased risk of harm or at risk of a new harm.
- Any problem experienced by a subject (including death) or other individual, which in the opinion of the investigator is unexpected and at least probably related to the research procedures.
- Noncompliance or allegation of noncompliance that is serious or continuing.
- Audit, inspection, inquiry, or enforcement action – e.g. an unfavorable audit report; suspension or disqualification of an investigator; FDA Form 483 or Warning Letter – issued by a federal agency.

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- Failure to follow the protocol due to the action or inaction of the investigator or research staff (protocol "violations" or "deviations").
- Breaches of confidentiality/HIPAA violations.
- Change to the protocol initiated without prior IRB review to eliminate an apparent immediate hazard to a subject.
- Incarceration of a subject in a study not approved by the IRB to involve prisoners.
- Unanticipated pregnancy (if research presents risk to pregnant subject or unborn child).
- PI unexpectedly not able to oversee study (due to death, termination or other unforeseen circumstance).
- Reports of injuries.
- Suspensions or terminations.

Examples of Events that Do Not Need to be Reported Promptly

- Written reports of study monitors that do not identify serious or continuing noncompliance.
- New information from the sponsor (including permanent or unscheduled closure to enrollment) which do not indicate a problem.
- Complaint that cannot be resolved by the research team but that does not indicate subjects or others might be at increased risk of harm or at risk of a new harm.
- Revised Investigator's Brochures/Instructions for Use or Device Manuals/Package Inserts that do not indicate new risks.
- Multisite reports or new scientific literature showing that the risks or potential benefits of the research may be different than initially presented to the IRB.
- Newspaper articles that relate to the research.
- IRB-required report.
- Changes or revisions to grant that do not require an amendment.