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| **Other Event Reporting Worksheet** *Use this worksheet to help gather all of the information needed for IRB review.*Please note that if the study is ceded to an external reviewing IRB, include documentation of the external IRB’s determination of the event with your other event submission to the MGB IRB |
| **Event Description and Root Cause Analysis** |
| **Provide a detailed description of the event** (If only limited or preliminary information is available, provide as many details about the event as possible at the time of initial reporting.)**:** |
| **Where (what location) did the event occur?**\*For multisite studies, please include the enrolling site’s PI and the name of the site where the event occurred.  |  |
| **When did you first learn of the event?*** If the event is not being reported within the time frame required by policy, provide an explanation for the delay in reporting the event and an appropriate corrective action plan
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| **How did you first learn of the event?** |  |
| **How many total participants have consented to and enrolled in the study?**   |  |
| **How many participants were impacted?** |  |
| **Have all study records been checked to identify all affected participants or data?** * If not, what are the plans to do so?
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| **What is/was the source of the event/problem?** * Why/how did the event/problem occur?
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| **Is the problem specific to this study, or is it systemic** (e.g., research group or department-wide)**?** |  |
| **PI Assessment of Event** |
| **In the opinion of the PI, did the event have any impact on participant safety or potential to have an impact on participant safety?** Why or why not?\*Please note, if this is a single IRB study where MGB is the IRB of record, then please describe the assessment of the site PI who enrolled the participant.  |  |
| **In the opinion of the PI, was data integrity negatively impacted by the event?** Why or why not?\*Please note, if this is a single IRB study where MGB is the IRB of record, then please describe the assessment of the site PI who enrolled the participant.  |  |
| **\*\*Include the following for Adverse Events and Other Events that may be Unanticipated Problems\*\*** |
| **Was the event/problem unexpected (in terms of nature, severity, or frequency)?**  | [ ] Yes [ ] No [ ] N/A-Event was not an AE or UP |
| Why or why not: |  |
| How did the Investigator make that determination? |  |
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| **Was the event/problem more likely than not related to participation in the research, or in other words, is there a >50% likelihood of the event having been caused by the procedures involved in the research?** | [ ] Yes [ ] No [ ] N/A-Event was not an AE or UP |
| Why or why not: |  |
| How did the Investigator make that determination? |  |
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| **Is the adverse event or unanticipated problem serious (Yes or No)?**  | [ ] Yes [ ] No [ ] N/A-Event was not an AE or UP |
| Why or why not: |  |
|  |  |
| **Does the event/problem indicate that the research places participants or others at an increased risk of harm than was previously known or recognized?** | [ ] Yes [ ] No [ ] N/A-Event was not an AE or UP |
| Why or why not: |  |
| How did the Investigator make that determination? |  |
| **Corrective and Preventive Actions** |
| **Describe the actions(s) already taken to address the event/problem.** * Including who was responsible for implementing the corrective actions and
* a timeline for when the actions occurred.
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| **Describe the future action(s) that will be taken to address the event/problem. Please describe:*** what is being done to prevent the event/problem from recurring in the future,
* including who will be responsible for implementing the corrective actions and
* a timeline for when the actions will be implemented.

Potential corrective actions could include, but are not limited to:* Careful review of all study records, including informed consent, to identify similar issues.
* Re-education of study staff (must be documented)
	+ Re-education could include completion of relevant courses in HealthStream available from the HRA Compliance and Education Office [Pages - Education (Human Research) (sharepoint.com)](https://partnershealthcare.sharepoint.com/sites/phrmInitiate/iqore/Pages/QI-Education-Activities.aspx)
	+ Develop an internal study team monitoring plan to periodically assess compliance with approved protocols, research regulations, institutional policies, and compliance with the corrective actions.
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| **Have participants been notified, or will they be notified of the event?** * Why or why not?
* If notifying, specify which participants, e.g., all active participants, all consented participants, etc., along with justification for this plan.
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| **When applicable, will participants need to be re-consented considering the event?** * If they do, please describe the timeline for re-consent.
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| **Will a study amendment (e.g., revisions to the protocol and/or consent form(s)) be needed to address the event?** * **Note:** An amendment may be required for patient-facing documents/notifications, such as emails, letters, phone scripts, etc.
	+ Revised Investigator Brochures (IB) should be submitted via Amendment if there are changes being made to the protocol, consent, or other study documents.
* If **yes**, include:
	+ What is the timeline for the amendment?
	+ Whether an amendment has already been submitted to the IRB or when an amendment will be forthcoming (e.g., The sponsor is working on changes to the protocol and informed consent, and an amendment will be submitted once received.
 |  |
| **How will the effectiveness of the corrective and preventive actions (CAPA) be determined?*** How will effectiveness be determined and defined?
* Who will be responsible for evaluating the effectiveness of the CAPA, and when will this occur?
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