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| **GENERAL INSTRUCTIONS** – delete this box from the completed form. Red text represents instructions to you – to be deleted from the final version.**NOTE: This form is designed to be a starting point on a Protocol Deviation Form. Update it as necessary for your specific study.** * This form is to be used as source documentation for protocol deviations.
* Deviations could impact one or more participants depending on the event. Multiple participants can be documented on one form but that is at the study team’s discretion. It should be clear either in the Participant ID section in the header or in the Description of the Event which participants were impacted, including ID or study numbers.
* This form is designed to complement a Protocol Deviation Log which can be used for overall study tracking while this is for individual event documentation. This form can be entirely built within REDCap, as an electronic case report form to allow for data analysis. If built within REDCap, a report can be designed to function as a log.
* Deviations, including major and minor categorizations, are defined within the [HRPP Policies](https://www.bumc.bu.edu/ohra/hrpp-policies/hrpp-policies-procedures/#6.6.5) for BU Medical Campus and BMC IRB. Study teams should be aware of all definitions and reporting requirements for all that may have oversight or review authority including external IRBs that may be reviewing this study, sponsors, funders, lead teams, or regulatory agencies.
* If there is an external IRB, this form should be updated with sections added to reflect *both* BU Medical Campus and BMC IRB requirements as well as the IRB of record. Deviations that fit the reporting criteria are still required to be submitted to the BU Medical Campus and BMC IRB, regardless of the IRB of record’s requirements. See [HRPP Policy 6.6.3.2](https://www.bumc.bu.edu/ohra/hrpp-policies/hrpp-policies-procedures/#6.6.3.2) for more information.
* Additional resources for Protocol Deviations are available within the [Standard Operating Procedure guidance document](https://www.bumc.bu.edu/ohra/required-training/institutional-standard-operating-procedures-sops/).
* Delete the CRRO template version date and add in the study-specific version date of this document.
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| **Date** of event: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**Date** member of research team became aware of event: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Description of event:** *Include resolution details if applicable and available at this time. The description of the event can be continued if necessary, on a separate progress note form or document.*   |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Corrective and Preventive Action Plan**: *Include details on what has been done to correct the deviation and will be done to prevent deviation from occurring again. Continue plan, if necessary, on a separate progress note form or document.* ☐ Not Applicable: *See* [*CAPA plan*](https://www.bumc.bu.edu/irb/inspir-ii/irb-templates/) *submitted to the IRB as part of a Reportable New Information submission.* |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Deviation Categorization and Assessment** |
| **Type of Deviation** | * Eligibility Criteria
* Consent
* Study Procedures or Assessments
* Intervention-Related
* Drug-Related
* Device-Related
* Staff (Delegation, Training)
* Other, specify: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
 |
| **Major Deviation***See* [*HRRP 6.6.5.2*](https://www.bumc.bu.edu/ohra/hrpp-policies/hrpp-policies-procedures/#6.6.5.2) *for specific criteria* | Did deviation harm or pose a risk of harm to the participant’s rights, safety or well-being?  | * Yes
* No
 | * *Any* ***Yes*** *indicates a Major Deviation.*
* *Any* ***Yes*** *requires prompt reporting to the IRB.*
 |
| Did deviation significantly damage the overall reliability of the study data? | * Yes
* No
 |
| Does deviation represent noncompliance with IRB requirements that may be serious or continuing? | * Yes
* No
 |
| **Minor Deviation***See* [*HRRP 6.6.5.3*](https://www.bumc.bu.edu/ohra/hrpp-policies/hrpp-policies-procedures/#6.6.5.3) *for specific examples* | Does the deviation NOT have a major impact on the participant’s rights, safety, or well-being?  | * Yes
* No
 | * *Any* ***Yes*** *indicates a Minor Deviation to be reported in aggregate per policy.*
 |
| Does the deviation NOT have a major impact on the reliability of the overall study data?  | * Yes
* No
 |
| **BU Medical Campus/BMC IRB Unanticipated Problem Assessment***See* [*HRPP 6.6.3.*](https://www.bumc.bu.edu/ohra/hrpp-policies/hrpp-policies-procedures/#6.6.3.2)*2 for Reporting Requirements* | * Is *unexpected*
* Is *related or possibly related* to participation in the research
* Suggests that the research *places participant or others at a greater risk of harm* (including physical, psychological, economic, or social harm) than was previously known or recognized

***IF ALL THREE ARE CHECKED 🡪**** ***IS PROMPTLY REPORTABLE*** *TO BU MEDICAL CAMPUS/BMC IRB WITHIN 7 DAYS OF BECOMING AWARE OF EVENT (regardless if another IRB is the IRB of record)*
* ***IS CONSIDERED AN UNANTICIPATED PROBLEM***
 |
| **Promptly Reportable Events** |
| Promptly Reportable to BU MEDICAL CAMPUS/BMC IRB | * Yes – Date Reported: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* No
 |
| Promptly Reportable to [Insert Other Authority] | * Yes – Date Reported: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* No
 |
| Promptly Reportable to [Insert Other Authority] | * Yes – Date Reported: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_
* No
 |
| **Form Completion** |
| **STAFF COMPLETING FORM**Printed Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_­­­\_\_\_\_\_ Signature: \_\_\_\_\_\_\_\_­­­­\_\_\_\_\_­­­­­­\_\_\_\_\_\_\_\_\_­­­­­\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_ |
| **ADDITIONAL NOTES FROM PI OR LICENSED INVESTIGATOR IF NECESSARY*** *No additional notes*

\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Printed Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_­­­\_\_\_\_\_ Signature: \_\_\_\_\_\_\_\_­­­­\_\_\_\_\_­­­­­­\_\_\_\_\_\_\_\_\_­­­­­\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_ |