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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 Log. Update it as necessary for your specific study.** * This log is meant to document overall study tracking of protocol deviations and is not meant to provide any documentation or source information on a specific event or participant. This tracking log is only designed to supplement other documentation.
* 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.
* If Protocol Deviations are documented in REDCap, a report can be built to function as a log so this separate document is not needed.
* Additional pages should be printed or rows added as required for study needs.
* Page numbers do not automatically update as it is unknown how many pages will be necessary for the entire study. The page information in the footer should be added when study data collection is complete and no additional deviations are expected to occur.
* 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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| **Participant ID or N/A** | **1-2 Word Description** | **Deviation Type** | **Deviation Category** | **Prompt Reporting Required** |
| --- | --- | --- | --- | --- |
|  |  | * [Insert all options from Protocol Deviation Form]
 | * Major
* Minor
 | BUMC/BMC IRB: [ ]  Yes [ ]  No |
| [Insert Authority]: [ ]  Yes [ ]  No |
| [Insert Authority]: [ ]  Yes [ ]  No |
|  |  | * [Insert all options from Protocol Deviation Form]
 | * Major
* Minor
 | BUMC/BMC IRB: [ ]  Yes [ ]  No |
| [Insert Authority]: [ ]  Yes [ ]  No |
| [Insert Authority]: [ ]  Yes [ ]  No |
|  |  | * [Insert all options from Protocol Deviation Form]
 | * Major
* Minor
 | BUMC/BMC IRB: [ ]  Yes [ ]  No |
| [Insert Authority]: [ ]  Yes [ ]  No |
| [Insert Authority]: [ ]  Yes [ ]  No |
|  |  | * [Insert all options from Protocol Deviation Form]
 | * Major
* Minor
 | BUMC/BMC IRB: [ ]  Yes [ ]  No |
| [Insert Authority]: [ ]  Yes [ ]  No |
| [Insert Authority]: [ ]  Yes [ ]  No |
|  |  | * [Insert all options from Protocol Deviation Form]
 | * Major
* Minor
 | BUMC/BMC IRB: [ ]  Yes [ ]  No |
| [Insert Authority]: [ ]  Yes [ ]  No |
| [Insert Authority]: [ ]  Yes [ ]  No |
|  |  | * [Insert all options from Protocol Deviation Form]
 | * Major
* Minor
 | BUMC/BMC IRB: [ ]  Yes [ ]  No |
| [Insert Authority]: [ ]  Yes [ ]  No |
| [Insert Authority]: [ ]  Yes [ ]  No |
|  |  | * [Insert all options from Protocol Deviation Form]
 | * Major
* Minor
 | BUMC/BMC IRB: [ ]  Yes [ ]  No |
| [Insert Authority]: [ ]  Yes [ ]  No |
| [Insert Authority]: [ ]  Yes [ ]  No |