|  |
| --- |
| **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 an Adverse Event Log. Update it as necessary for your specific study.** * This log is meant to document overall study tracking of adverse events 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.
* Relatedness, Expectedness, and Severity should all be updated to reflect actual study definitions and what is included on the Adverse Event Form.
* If Adverse Events 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 adverse events will occur.
* Additional resources for Adverse Events are available within the [Standard Operating Procedure guidance document](https://www.bumc.bu.edu/ohra/required-training/institutional-standard-operating-procedures-sops/).
 |

| **Participant ID** | **1-2 Word Description** | **Relatedness** | **Expectedness** | **Severity** | **Seriousness** | **Prompt Reporting Required** |
| --- | --- | --- | --- | --- | --- | --- |
|  |  | [ ]  Definite[ ]  Possible[ ]  Unrelated | [ ]  Unexpected[ ]  Expected | [Insert options] | [ ]  Not Serious[ ]  Serious | BUMC/BMC IRB: [ ]  Yes [ ]  No |
| [Insert Authority]: [ ]  Yes [ ]  No |
| [Insert Authority]: [ ]  Yes [ ]  No |
|  |  | [ ]  Definite[ ]  Possible[ ]  Unrelated | [ ]  Unexpected[ ]  Expected | [Insert options] | [ ]  Not Serious[ ]  Serious | BUMC/BMC IRB: [ ]  Yes [ ]  No |
| [Insert Authority]: [ ]  Yes [ ]  No |
| [Insert Authority]: [ ]  Yes [ ]  No |
|  |  | [ ]  Definite[ ]  Possible[ ]  Unrelated | [ ]  Unexpected[ ]  Expected | [Insert options] | [ ]  Not Serious[ ]  Serious | BUMC/BMC IRB: [ ]  Yes [ ]  No |
| [Insert Authority]: [ ]  Yes [ ]  No |
| [Insert Authority]: [ ]  Yes [ ]  No |
|  |  | [ ]  Definite[ ]  Possible[ ]  Unrelated | [ ]  Unexpected[ ]  Expected | [Insert options] | [ ]  Not Serious[ ]  Serious | BUMC/BMC IRB: [ ]  Yes [ ]  No |
| [Insert Authority]: [ ]  Yes [ ]  No |
| [Insert Authority]: [ ]  Yes [ ]  No |
|  |  | [ ]  Definite[ ]  Possible[ ]  Unrelated | [ ]  Unexpected[ ]  Expected | [Insert options] | [ ]  Not Serious[ ]  Serious | BUMC/BMC IRB: [ ]  Yes [ ]  No |
| [Insert Authority]: [ ]  Yes [ ]  No |
| [Insert Authority]: [ ]  Yes [ ]  No |
|  |  | [ ]  Definite[ ]  Possible[ ]  Unrelated | [ ]  Unexpected[ ]  Expected | [Insert options] | [ ]  Not Serious[ ]  Serious | BUMC/BMC IRB: [ ]  Yes [ ]  No |
| [Insert Authority]: [ ]  Yes [ ]  No |
| [Insert Authority]: [ ]  Yes [ ]  No |
|  |  | [ ]  Definite[ ]  Possible[ ]  Unrelated | [ ]  Unexpected[ ]  Expected | [Insert options] | [ ]  Not Serious[ ]  Serious | BUMC/BMC IRB: [ ]  Yes [ ]  No |
| [Insert Authority]: [ ]  Yes [ ]  No |
| [Insert Authority]: [ ]  Yes [ ]  No |
|  |  | [ ]  Definite[ ]  Possible[ ]  Unrelated | [ ]  Unexpected[ ]  Expected | [Insert options] | [ ]  Not Serious[ ]  Serious | BUMC/BMC IRB: [ ]  Yes [ ]  No |
| [Insert Authority]: [ ]  Yes [ ]  No |
| [Insert Authority]: [ ]  Yes [ ]  No |