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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 an Adverse Event Form. Update it as necessary for your specific study.** * This form is to be used as source documentation for adverse events. Depending on the event, this can be supplemental to a medical record or other clinical note or the sole documentation.
* This form is designed to complement an Adverse Event Log which can be used for overall study tracking while this is for individual event documentation. This form can be entirely built within REDCap and a report can be built to function as a log.
* Generally, adverse events are documented separately for each symptom or sign unless there is a clear clinical etiology. In this case, all symptoms or signs should be included in the description of the event.
* All events should be assessed for expectedness, relatedness, severity, and seriousness. The assessment and definitions used should be study-specific and based both on IRB of record policy and guidance as well as the protocol or IRB application. Assessments are generally only done by clinically licensed research team members who are delegated to the task.
* Relatedness, Expectedness, and Severity – study teams should make sure that the definitions are, as applicable, correct and as defined by their protocol, FDA, sponsor, IRB of record, or any other reporting authority or oversight body.
* Seriousness – this is defined by [HRPP Policy Definitions](https://www.bumc.bu.edu/ohra/hrpp-policies/hrpp-policies-procedures/#13) and should not be changed.
* 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/).
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| Start date of event: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_Stop date of event: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ *(can be entered at later date)*Date member of research team became aware of event: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Description of event:** *include resolution details and any resulting sequelae and if actions were required to treat or prevent event. The description of the event can be continued if necessary, on a separate progress note form or document.*   |
| \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ |
| **Adverse Event Category** |
| Relatedness | * Definite
* Possible - reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research
* Unrelated
 |
| Expectedness | * Unexpected
* Expected

*Defined: assess event 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) and (b) the characteristics of the patient population being studied* |
| Severity | * [Insert options for severity for specific study. Severity can include mild, moderate, severe – definitions should be provided on this form for consistent assessments. Other severity indexes or grading can be used including [CTCAE](https://ctep.cancer.gov/protocoldevelopment/electronic_applications/ctc.htm) for oncology or non-oncology studies.]
 |
| Seriousness | * Not Serious
* Serious
	+ Results in death
	+ Is life-threatening (places the subject at immediate risk of death from the event as it occurred)
	+ Results in inpatient hospitalization or prolongation of existing hospitalization
	+ Results in persistent or significant disability/incapacity
	+ Results in congenital anomaly/birth defect
	+ Based upon appropriate medical judgment, may jeopardize the subject’s health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition
 |
| Resolved by | * Death
* Resolved without additional problems (without sequelae)
* Resolved with additional problems (with sequelae)
* Resolved by convention (ongoing 30 days post last study visit)
 |
| IRB Reporting Assessment Criteria | * 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: \_\_\_\_\_\_\_\_\_\_\_*A staff member without licensure can complete the form but the actual assessment must be completed by a licensed and delegated clinician who signs below.*  |
| **LICENSED AND DELEGATED CLINICIAN COMPLETING ASSESSMENT** Printed Name: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_­­­\_\_\_\_\_ Signature: \_\_\_\_\_\_\_\_­­­­\_\_\_\_\_­­­­­­\_\_\_\_\_\_\_\_\_­­­­­\_\_\_\_\_\_\_\_\_ Date: \_\_\_\_\_\_\_\_\_\_\_*This person must possess licensure and expertise and be delegated to review and assess adverse events.* |
| Additional clinical notes from clinician review: * No additional notes

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| **Adverse Events Definitions, for reference** |
| **Severity** | **Mild:** Awareness of signs or symptoms, but easily tolerated and are of minor irritant type causing no loss of time from normal activities. Symptoms do not require therapy or a medical evaluation; signs and symptoms are transient. Non-prescription therapy may be used.  | **Moderate:** Events introduce a low level of inconvenience or concern to the participant and may interfere with daily activities but are usually improved by simple therapeutic measures; moderate experiences may cause some interference with functioning. | **Severe:** Events interrupt the participant’s normal daily activities and generally require systemic drug therapy or other treatment; they are usually incapacitating. Medical intervention or therapy required.  |
| **Seriousness** | **Not Serious****Serious** * Death
* A life-threatening adverse event
* Inpatient hospitalization, or prolonged of existing hospitalization
* A persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions
* A congenital anomaly/birth defect
* Important medical events that may not result in death, be life threatening, or require hospitalization may be considered serious, when based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.
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