# Medical Events Form

Please email this medical event form and all relevant attachments (medical history, con med, AE tracker forms and all other applicable documents) to the data manager within **24 hours** of event notification

**NYU Trial ID #:** _____

**Principal Investigator:**

_____

**Report Updates:**

- ○ Initial
- ◉ Follow-up # ____

Duplicate Form

**Event Type:**

- ☐ Serious Adverse Event
- ☐ Event of Special Interest
- ☐ Reportable Event

**Trial Type:** ☐ Industry-sponsored ☐ Cooperative Group ☐ **IIT – email**

**within 24 hours of event notification**

| **Subject Information:** | | | |
|---|---|---|---|
| **Initials:** | **Subject ID #** | **Sex:** ○ Female ○ Male | **Date of Birth:** |
| **Ht:** ○ cms ○ in.<br>**Wt:** ○ kgs ○ lbs | **Date Informed Consent Obtained:** | **ICF Version Date:** | |

| **Seriousness Criteria or Reportable Reason** | |
|---|---|
| ☐ Death / Date of Death: | ☐ Congenital Anomaly |
| ☐ Life-threatening | ☐ Required Intervention |
| ☐ Hospitalization-Initial or Prolonged | ☐ Medically Important Condition/Reportable Event |
| ☐ Disability | ☐ Other: |

| **Adverse Event Information:** ☐ **CTCAE 4.03** ☐ **CTCAE 5.0** ☐ **N/A (Reportable event)** | | | |
|---|---|---|---|
| Event Description: | | Grade: | Date of Event Notification: |
| Event Start Date: | Event End Date: | ☐ Outside hospital: | DM to request records? ○ Yes ○ No |
| Outcome of Event: ☐ Unresolved/Ongoing ☐ Resolved with sequelae ☐ Resolved without sequelae ☐ Fatal | | | |

**Study Treatment Information**

| Drug | Dose | Route of Adminis. | Freq. | Start Date of Treatment | Date of Last Treatment | Relationship^ | Action Taken* |
|---|---|---|---|---|---|---|---|
| | | | | | | Choose One | Choose One |
| | | | | | | Choose One | Choose One |
| | | | | | | Choose One | Choose One |
| | | | | | | Choose One | Choose One |
| | | | | | | Choose One | Choose One |
| | | | | | | Choose One | Choose One |

Did the event abate when treatment was discontinued? ○ Yes ○ No ○ N/A

Contributing cause if unrelated or unlikely related: _____

Date(s) of reduction/discontinuation: _____ New Dose(s): _____

Reason for reduced/discontinuation/delay: _____

**Medical Events Form**

Please email this medical event form and all relevant attachments (medical history, con med, AE tracker forms and all other applicable documents) to the data manager within **24 hours** of event notification

| **Narrative Description of Event:** |
| --- |
| |

Narrative continues to next page? (•) Yes ( ) No

**Medical Events Form**

Please email this medical event form and all relevant attachments (medical history, con med, AE tracker forms and all other applicable documents) to the data manager within **24 hours** of event notification

| **Continuation of Narrative Description of Event:** |
| --- |
| |

| **Tracked changes to the form:** |
| --- |
| ☐ Narrative was changed.<br>☐ Event description (AE term) and/or Grade were changed. Explain change below:<br><br>☐ Other form fields were changed. Please list each field with your name and today's date: |

**Medical Events Form**

Please email this medical event form and all relevant attachments (medical history, con med, AE tracker forms and all other applicable documents) to the data manager within **24 hours** of event notification

| **Relevant Information:** ☐ No relevant information as of this report, await follow-up report | | |
|---|---|---|
| **Assessments** ☐ Not Applicable<br>(eg. Labs, scans, procedures): | Date | Results |
| ☐ See attached | | |
| | | |
| | | |
| | | |

| **Relevant Medical History** ☐ Not Applicable<br>(Pre-existing/ concurrent conditions): | Start Date | Stop Date or Ongoing |
|---|---|---|
| ☐ See attached | | |
| | | |
| | | |
| | | |

**Medications used to treat event** ☐ Not Applicable

| Drug | Dose | Route of admin. | Frequency | Start Date | Indication |
|---|---|---|---|---|---|
| | | | | | |
| | | | | | |
| | | | | | |

Concomitant Medication: please attach the subject's study concomitant medication log.

## Attach all relevant emails, logs and source documentation for this event.

Is this event ***immediately*** reportable (within 5 calender days) to the IRB based on the below criteria:

☐ Unexpected; ☐ Related to the research study; ☐ Harmful to the subject (including confidentiality)

○ Yes ◉ No

If the answer to the above question is "Yes", notify the regulatory specialist.

Principal/Sub-Investigator: _____
Print Name Signature Date

RN/CRC: _____
Print Name Signature Date

Draft email to PCCReports