COLUMBIA UNIVERSITY MEDICAL CENTER
Discover. Educate. Care. Lead.

HERBERT IRVING COMPREHENSIVE CANCER CENTER

Data and Safety Monitoring Committee

SERIOUS ADVERSE EVENT / UP REPORTNG FORM COMPLETION INSTRUCTIONS

1. **TRIAL INFORMATION**
   - **a. Trial Type –** indicate if this is a Single Center or Multicenter IST
     - i. All affiliate site personnel must mark *Multicenter*
   - **b. Site & Site Number –** Full name of treating site & Site Number
     - i. Site number is indicated on formal Site Activation Letter
   - **c. Overall Sponsor Investigator –** CUIMC Sponsor Investigator listed on protocol face sheet
   - **d. Local Principal Investigator –** Affiliate site PI
     - i. CUIMC Sponsor Investigator and Principal Investigator will be the same
   - **e. CUIMC IRB Number –** CUIMC IRB number is listed on study protocol (AAA*XXXXX)*
     - i. Affiliate sites may enter local IRB number in parentheses in addition to CUIMC IRB number
   - **f. Study Title –** Enter full study title as listed on protocol
   - **g. Study Team Member reporting event –** Name of person completing form

2. **EVENT TYPE**
   - **a. Are you reporting an Unanticipated Problem?**
     - i. Check each UP criteria event meets
     - ii. Check yes if event being reported *meets all 3 criteria listed* (unanticipated, at least possibly related to participation in study, places subject/others at greater risk than previously known
   - **b. Are you reporting a Serious Adverse Event?**
     - i. Check applicable seriousness criteria event meets
     - ii. Check yes if event meets *at least one* of the seriousness criteria listed

3. **REPORT UPDATE**
   - **a.** Select whether you are submitting an initial notification of an event or submitting a follow up to an initial report.
     - i. Mark *Initial* if this is first notification of event to CUIMC Sponsor Investigator
     - ii. Mark *Follow up* and include follow up report number in chronological order when reporting any updates after initial notification

4. **TIMELINE OF THE EVENT**
   - **a. Event Start Date/Time** – Enter date/time event was determined to meet UP/SAE criteria
   - **b. Event End Date –** If applicable, enter date event was determined to be resolved. If event has *not* yet resolved, enter "*Ongoing*"
   - **c. Date/Time Study Team Informed** – the date/time the PI was made aware of event
   - **d. Date of Report** – Enter the date the report was completed

5. **SUBJECT INFORMATION**
   - **a. Subject Study ID** – Enter full subject study ID number assigned at time of enrollment
     - i. *** DO NOT include any identifiable personal information***
   - **b. Age –** Enter age at time of event
   - **c. Gender –** Indicate if patient is male or female

6. **DESCRIPTION OF EVENT**

- **a. CTCAE term for Primary Event** – Enter term as listed in CTCAE
- **b. Grade –** Please enter event grade using CTCAE guidelines.
- **c. CTCAE Version –** Enter as listed in the protocol
- **d. Event Causality –** indicate root cause of event
    - i. If checking Study Procedure, Medical History, or Other: provide details
- **e. Event Expectedness –** Indicate if event is expected / not expected in relation to study agent under investigation according to the study protocol, ICF, and/or Investigator Brochure
- **f. Attribution –** Indicate if cause of event can be attributed to study drug and/or patient participation in study
- **g. Date of Hospital Admission/Discharge –** Enter dates of patient hospital admission. If patient was not admitted, enter *"N/a"*
- **h. Study Treatment Information** –
    - i. Enter name, dose/frequency, route, and dates of **each** study agent subject is receiving
    - ii. Indicate **each** study drug attribution/expectedness per Principal Investigator determination following review of risks indicated in protocol, ICF and Investigator Brochure
    - iii. Check action taken with study agent following start of event
- **i. Related Adverse Events** – List relevant adverse events occurring simultaneously to primary event
- **j. Brief description and treatment of events –** Enter brief summary of event and any additional relevant clinical information
- **k. Outcome -** Check the applicable box
    - i. If event has recovered (or recovered with sequelae) selected, enter date of recovery.
    - ii. If the event is ongoing, no dates should be entered.
    - iii. If the event was fatal, please enter date of death.
- **l. Did patient resume study treatment following event recovery?**
    - i. Indicate either date treatment resumed or date of last treatment

7. RELEVANT ASSESSMENTS

- **a.** Enter a list of clinically significant assessments performed to diagnose and/or follow recovery of event
- **b.** Enter date each assessment was performed
- **c.** Attach redacted results of each assessment listed or mark assessment as Results Pending

8. RELEVANT CONCOMITANT MEDICATIONS

- **a.** List all concomitant medication names being administered to patient,
- **b.** Enter start/stop dates and dose/frequency of each medication

9. RELEVANT MEDICATION TO TREAT EVENT

- **a.** List all medications administered to patient to treat event
- **b.** If no medications were administered, mark "Not Applicable"

10. REPORTING TIME LINE (CUIMC CPDM ONLY)

- **a.** Section 10 will be completed by CUIMC CPDM personnel only. Affiliate Site personnel are not required to complete this section

11. SIGNATURES

- **a.** Both e-signature and wet-ink signatures are permissible
- **b.** Affiliate Site PI or designee must sign report prior to submitting report to MCT Core