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

HERBERT IRVING COMPREHENSIVE CANCER CENTER

Data and Safety Monitoring Committee

SERIOUS ADVERSE EVENT REPORTING FORM

1 – Trial Information	
Trial Type	☐ Single Center Investigator Sponsored ☐ Multicenter Investigator Sponsored
SITE & SITE NUMBER	
OVERALL SPONSOR INVESTIGATOR	
LOCAL PRINCIPAL INVESTIGATOR	
CUIMC IRB NUMBER	
STUDY TITLE	
Study team member reporting event	

2 – Event Type (mark all that apply)		
Are you reporting a UP? (Unanticipated Problem) Event meets ***all*** the following criteria: ___Unanticipated (in terms of nature, severity, or frequency, given the procedures described in the IRB approved protocol/consent, and given the characteristics of the subject population being studied) ___At least possibly related to participation (i.e., there is a reasonable possibility that the incident, experience, or outcome was caused by the procedures involved in the research or related to the research) ___Does this incident/experience/outcome suggest that the research places subjects or others at a greater risk of harm (including physical, psychological, economic, or social harm) than was previously known or recognized?	Yes ☐	No ☐
Are you reporting a SAE (serious adverse event)? Event meets *at least one* of the following criteria: __ Death __ Life threatening __ Hospitalization or prolongation of hospital stay __ Persistent or significant disability or incapacity __ Congenital abnormality or birth defect __ Otherwise considered serious	Yes ☐	No ☐

3 – Report Update	
Initial ☐	Follow Up ☐ # ____

4 – Timeline of the event			
Event Start Date/time		**Date/time Investigator Notified**	
Event End Date		**Date/time of Report Update**	

5 – Subject information			
SUBJECT STUDY ID		**AGE**	
GENDER	**Male** ☐ **Female** ☐		

6 – Description of the Event(s)			
Primary Diagnosis			
CTCAE term for Primary SAE		**Grade**	
		CTCAE Version	
Event Causality	☐ Study Agent/Drug (see details below) ☐ Study Procedure ______________________ ☐ Disease Progression	☐ Medical History _____________________ ☐ Other: __________________	
Expectedness (event related to study drug)	☐ Expected ☐Not Expected	**Attribution (event related to study drug or protocol)**	☐ Not related ☐ Unlikely ☐ Possibly ☐ Probably ☐ Definitely
Date of Hospital Admission		**Date of Hospital Discharge**	

Study Treatment Information:

Study Agent/Drug	Dose/ Freq.	Route	Date of First Dose	Date of Last Dose	Study Drug Attribution	Study Drug Expectedness (Per study drug IB / package insert)	Action Taken with Study Drug
					☐ Not related ☐ Unlikely ☐ Possibly ☐ Probably ☐ Definitely	☐ Expected ☐Not Expected	☐ Dose Stopped ☐ Dose Reduced ☐ Dose Unchanged ☐ Dose increased
					☐ Not related ☐ Unlikely ☐ Possibly ☐ Probably ☐ Definitely	☐ Expected ☐Not Expected	☐ Dose Stopped ☐ Dose Reduced ☐ Dose Unchanged ☐ Dose increased
					☐ Not related ☐ Unlikely ☐ Possibly ☐ Probably ☐ Definitely	☐ Expected ☐Not Expected	☐ Dose Stopped ☐ Dose Reduced ☐ Dose Unchanged ☐ Dose increased
					☐ Not related ☐ Unlikely ☐ Possibly ☐ Probably ☐ Definitely	☐ Expected ☐Not Expected	☐ Dose Stopped ☐ Dose Reduced ☐ Dose Unchanged ☐ Dose increased
					☐ Not related ☐ Unlikely ☐ Possibly ☐ Probably ☐ Definitely	☐ Expected ☐Not Expected	☐ Dose Stopped ☐ Dose Reduced ☐ Dose Unchanged ☐ Dose increased

Relevant Adverse Events occurring during hospitalization (if applicable)

CTCAE term	Grade	Start date of AE	End date of AE	Attribution	Comments

Brief description and treatment of events

Outcome			
☐ Recovered Date of Recovery:	☐ Recovered with sequelae Date of recovery:	☐ Event On-going	☐ Fatal Date of Death: Cause of Death:

Did patient Resume study treatment following event recovery?	
☐ Yes Date Resumed: _____	☐ No Last date of treatment: _____

7 - Relevant Assessments (e.g. Progress/consult notes, labs, scans, procedures)		
Assessment	**Date**	**Results**
		☐ Results Attached ☐ Results Pending
		☐ Results Attached ☐ Results Pending
		☐ Results Attached ☐ Results Pending
		☐ Results Attached ☐ Results Pending
		☐ Results Attached ☐ Results Pending
		☐ Results Attached ☐ Results Pending
		☐ Results Attached ☐ Results Pending
		☐ Results Attached ☐ Results Pending
		☐ Results Attached ☐ Results Pending

8 – Relevant Concomitant Medications		
☐ Not Applicable		
Drug Name	**Start/Stop Dates**	**Dose/Frequency**

9 – Relevant Medications to Treat Event		
☐ Not Applicable		
Drug Name	**Start/Stop Dates**	**Dose/Frequency**

10 – Reporting Time Line (CUIMC CPDM ONLY)	
Date Event Reported to Sponsor Investigator	
Date Event Reported to Industry Collaborator ☐ **Not Applicable**	
Name of Industry Collaborator ☐ **Not Applicable**	

CONTACT DETAILS	
Research Nurse	
Signature Date	
Email	
Telephone	

CONTACT DETAILS	
Clinical Research Coordinator	
Signature Date	
Email	
Telephone	

CONTACT DETAILS	
Affiliate Site Principal Investigator	
Signature Date	
Email	
Telephone	

CONTACT DETAILS	
CUMC Sponsor Investigator	
Signature Date	
Email	
Telephone	