

Perlmutter Cancer Center 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 # _____	Event Type: Serious Adverse Event Event of Special Interest Reportable Event
---	--	--

Trial Type: Industry-sponsored Cooperative Group
IIT – email NYUPCCsafetyreports@nyumc.org within 24 hours of event notification

Subject Information:			
Initials:	Subject ID #	Sex: Female Male	Date of Birth:
Ht: _____ <input type="checkbox"/> cms <input type="checkbox"/> in.	Date Informed Consent Obtained:		ICF Version Date:
Wt: _____ <input type="checkbox"/> kgs <input type="checkbox"/> lbs			

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:	Hospitalized at NYULH or 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*
Did the event abate when treatment was discontinued? Yes No N/A Contributing cause if unrelated or unlikely related: _____ Date of reduction/discontinuation: _____ New Dose: _____ Reason for reduced/discontinuation: _____							

Perlmutter Cancer Center 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

Perlmutter Cancer Center 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:**

Perlmutter Cancer Center 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 (eg. Labs, scans, procedures):		Not Applicable		Date	Results
See attached					
Relevant Medical History (Pre-existing/ concurrent conditions):				Start Date	Stop Date or Ongoing
Not Applicable					
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 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
------------	-----------	------