eRESEARCH | REGULATORY MANAGEMENT SAND

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32-1. Data and Safety Monitoring Plan - AE Reporting

Adverse Event (AE) Reporting

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32-1.1* Adverse events will be reported to:

	Organization	Reporting Mechanism
☐	IRB	eResearch AE/ORIO submission
☐	DSMB/DSC/independent monitor	
☐	UMHS Cancer Center DSMB	
☐	Federal oversight agencies (FDA, RAC, etc)	
☐	Sponsor (federal, industry, private, etc)	
☐	Other	

If other, please specify:

32-1.2* Indicate the AE reporting timetable that will be used to report adverse events to the IRB:

NOTE: Clinical studies conducted in schools other than the Medical School should follow IRBMED reporting guidelines.

Select one:

- ○ Standard IRBMED AE reporting timetable
- ○ Study-specific guidelines

Clear

32-1.3* Affirm that the adverse events will be reported to the IRB according to the following generalized AE GRADING SCALE:

☐

- 0 - No adverse event
- 1 - Mild AE – No treatment needed
- 2 - Moderate AE – Resolved with treatment
- 3 - Severe AE – Inability to carry on normal activities, required professional medical attention
- 4 - Life-threatening or disabling AE
- 5 - Fatal AE

32-1.4* Will Serious Adverse Events (SAEs) be categorized according to the following FDA definition?

Select one:

- ○ Yes

Clear

Select one:

○ N/A - not FDA-regulated

Clear

- Death
- A life-threatening adverse drug experience
- Inpatient hospitalization or prolongation of existing hospitalization
- A persistent or significant disability/incapacity
- A congenital anomaly/birth defect
- Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse drug experience 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. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse.

32-1.5* Affirm that either the principal investigator or a co-investigator will determine the ATTRIBUTION/RELATEDNESS for each adverse event.

☐

- Definitely related
- Probably related
- Possibly related
- Unlikely to be related
- Definitely not related

32-1.6* Affirm that the EXPECTEDNESS will be assigned for each adverse event according to the following definitions:

☐

- Unexpected adverse events (i.e., has NOT been addressed or described in one or more of the following: Informed consent document(s) for this study, IRB application for this study, grant application or study agreement, protocol or procedures for this study, investigators' brochure or equivalent (for FDA regulated drugs or devices), DSMB/DSC Reports, published literature, other documentation)
- Expected adverse events (i.e., has been addressed or described in one or more of the following: Informed consent document(s) for this study, IRB application for this study, grant application or study agreement, protocol or procedures for this study, investigators' brochure or equivalent (for FDA regulated drugs or devices), DSMB/DSC Reports, published literature, other documentation, or characteristics of the study population)

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