U-M IBC Adverse Event Reporting Requirements for Human Gene Transfer Clinical Trials

Type of Event	Relatedness	Expectedness	Report to IBC?	Report to IRB?
Serious Adverse Event resulting in death or life threatening outcome	Related	Unexpected	Report ASAP (within 7 days)	
Serious Adverse Event resulting in death or life threatening outcome	Unrelated	Unexpected	Report ASAP (within 7 days)	
Serious Adverse Event	Related	Unexpected	Report within 14 days	
Serious Adverse Event	Related	Expected	Report within 14 days	
Serious Adverse Event	Unrelated	Unexpected	IBC does not review	Report in conjunction with SCR
Non-serious Adverse Event	Related	Unexpected	IBC does not review	Report in conjunction with SCR
Non-serious Adverse Event	Related	Expected	Do not report (unless occurring at a greater frequency than expected)	
Non-serious Adverse Event	Unrelated	Unexpected	Do not report	
Non-serious Adverse Event	Unrelated	Expected	Do not report	
Unanticipated Problem that is not a SAE	Related	Unexpected	Report within 14 days (via ORIO)	

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For questions regarding IBC requirements for human gene transfer clinical trials, contact ibcstaff@umich.edu.