Reporting Unanticipated Problems and Adverse Events to the IRB

Investigators are to notify the local Michigan IRB of record according to Unanticipated Problem (UP) and Adverse Event (AE) Reporting IRB Policy

	Participant Death		Internal UP/AE		External UP/AE
	Unanticipated	**Anticipated**	**Unanticipated**	**Anticipated**	
Reporting Criteria	✓ Internal; ***and*** ✓ Possibly, probably, or definitely related to the study; ***or*** ✓ Associated with the device	✓ Internal; ***and*** ✓ Due to disease progression; ***or*** ✓ Not related or unlikely related; ***or*** ✓ Not a greater risk of harm than was previously known or recognized	✓ Unexpected in nature, severity, or frequency; ***and*** ✓ possibly, probably, or definitely related to the study; ***and*** ✓ serious; ***or*** ✓ suggests greater *risk* of harm than previously known or recognized ***(OHRP regulated studies)*** ✓ ***for devices:*** Serious problem or affect associated with device	✓ Unlikely to be related; ***or*** ✓ Not Serious; ***or*** ✓ Not a greater risk of harm than was previously known or recognized	✓ results in a change to the informed consent, protocol, or investigator brochure, ***and*** ✓ Unexpected in nature, severity, or frequency; **and** ✓ Possibly/probably/definitely related to the study; ***and*** ✓ Serious; ***or*** ✓ suggests greater risk of harm than previously known or recognized (***OHRP***)
Report to the IRB	~ **Report Within 24 hours** of knowledge via email, phone, or fax; ***and*** ~ **Within 5 business days** submit the e**vent to the IRB on the *AE/UP Form** ~ In addition, report at ***continuing review (CR)** in the summary of adverse events**; or*** ~ At ***study closure** if occurring before CR, if AE was not previously reported to the IRB ~ Report in **Trinity Health VOICE system** ~ **For device studies** submit any updates received, i.e., cause of death, attribution, etc.	~ Report at ***continuing review** in the summary of adverse events**; or*** ~ At ***study closure** if occurring before CR, if AE was not previously reported to the IRB; ***or*** ~ Earlier if requested by sponsor	~ **Report Within 3 business days** of knowledge to the IRB on the ***AE/UP Form**; ***and*** ~ In addition, report at ***continuing review** in the summary of adverse events**; or*** ~ At ***study closure** if occurring before CR, if AE was not previously reported to the IRB	~ Report at ***continuing review** in the summary of adverse events**; or*** ~ At ***study closure** if occurring before CR, if AE was not previously reported to the IRB	~ **Report Within 5 business days** of knowledge by submitting to the IRB a ***Request for Revision** with applicable supporting documentation for required changes, i.e., Action Letter, investigator brochure, protocol, etc.
			Device Studies: ~ Report *Unanticipated Adverse Device Effect (UADE) **as soon as possible but no later than 10 business days after investigator first learns of the event; and** ~ Report at ***continuing review** in the summary of adverse events**; or*** ~ At ***study closure** if occurring before CR, if UADE was not previously reported to the IRB; ***and*** ~ Report to the **sponsor**. The sponsor must provide an UADE evaluation report to the IRB within 10 business days of receiving notification. ~ For sponsor terminations due to a UADE presenting an unreasonable risk to participants; ***and*** ~ For resuming terminated studies requiring FDA and IRB approval [Refer to 21 CFR 812.46 for further information]		
	Device Studies (when the hospital is the device user facility/hospital)**:** The investigator or hospital must report participant **serious injuries to the device manufacturer** and **deaths to the FDA** when suspected to be **medical device related **Within 10 business days of knowledge**, obtained from any source that **reasonably suggests device may have caused or contributed to the serious injury or death at the facility. Regulations also require that user facilities submit an annual summary report to FDA of all reportable adverse events submitted to manufacturers or the FDA during a designated reporting period. [Refer to 21CFR 803.30 for further information].				

*For IRB submission of AE/UP Events, continuing reviews, revisions, and study closures, go to IRBs and Research Compliance website and select the applicable location for submission process and forms

**You are not required to evaluate or investigate the event by obtaining or evaluating information that you do not reasonably know.