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

Death Occurred Internally During the Research Study

Anticipated | ****Unanticipated**

Anticipated Events, i.e., due to disease progression or events not or unlikely to be related, or risk of harm is not greater than previously known or recognized

Report at ***continuing review(CR)** in the summary of adverse events**; or at *study closure** if **it** occurs before CR, if AE was not previously reported to the IRB

Serious Adverse Event, Problem or Effect Occurred Internally During the Research Study

Death or serious event was possibly, probably, or definitely related to the research or associated with the device.

*****OHRP studies:** Event placed participants or others at a greater risk of harm than previously known or recognized, includes physical, psychological, economic, or social harm), or is considered serious.

Report death **Within 24 Hours** of knowledge via email, phone, or fax; ***and*** **Within 5 Business Days** submit on the IRB ***AE/UP Form**

AND

YES

NO

YES

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 serious event Within 3 business days of knowledge of serious event to the IRB on the ***AE/UP Form**

AND

External Events Requiring Changes to Study Documentation and/or Change in Risk-Benefit Ratio

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.

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

**Unanticipated and/or unexpected in terms of nature, severity, or frequency given the procedures that are described in the IRB approved research protocol and informed consent, and the characteristics of the participant population being studied.

*** Office for Human Research Protections (OHRP)