4.7.5.2. The PI may be requested to provide additional information or submit additional documents within 7 to 10 working days.

### 4.7.6. Files Management

4.7.6.1. The IRB Chair signs the **MDHIRB FORM 3(I)2021: QUERIES OR COMPLAINTS.**

4.7.6.2. The Secretariat stores the signed documents in the study protocol file folder.



## 5. SAE and SUSAR

### Work Flow for Review of SAE's and SUSAR's

| ACTIVITY | RESPONSIBILITY |
|---|---|
| Receives submission SAE Report and logs report in SAE Submissions Log and submits to IRB Chair ↓ | Secretariat |
| All SAE's submitted will be reviewed by the IRB Chair, SAE's shall be analyzed for significance ↓ | IRB Chair<br>Primary Reviewer |
| Presentation of significant SAE's recommendations in a Full Board meeting ↓ | IRB Chair/ Primary Reviewer |
| Communication to PI of Board action ↓ | Secretariat |
| Manages post-approval review requirements | Secretariat |

**DETAILED INSTRUCTIONS**

## 5.1 Management of On-Site SAE/SUSAR reports upon submission

5.1.1. Serious adverse events (SAE) are events temporally associated with the subject's participation in research that meets any of the following criteria:

- Results in death
- Is life-threatening (places the subject at immediate risk of death from the event as it occurred)
- Requires inpatient hospitalization or prolongation of existing hospitalization
- Results in a persistent or significant disability/incapacity
- Results in a congenital anomaly/birth defect
- Any other adverse event that, based upon appropriate medical judgment, may jeopardize the subject's health and may require medical or surgical intervention to prevent one of the other outcomes listed in this definition

5.1.2. Suspected Unexpected Serious Adverse Reactions (SUSARs)

- Unanticipated Problems

  Unanticipated problems, in general, include those events that :

  (a) Are not expected given the nature of the research procedures and the subject population being studied; and

  (b) Suggest that the research places subjects or others at a greater risk of harm or discomfort related to the research than was previously known or recognized.

- Unexpected Adverse Event

An unexpected adverse event is an event not previously known or anticipated to result from:

(a) The interventions and interactions used in the research;

(b) The collection of identifiable private information under the research;

(c) An underlying disease, disorder, or condition of the human subject; and/or

(d) Other circumstances unrelated to the research or any underlying disease disorder, or condition of the subject

5.1.3. The PI must report on-site Serious Adverse Events (SAE) which are **fatal/life threatening** to the MDH IRB **within 24 hours from knowledge of the event**. On-site SAEs which are **non-fatal/non-life threatening** should be reported to the MDH IRB within seven **(7) working days from knowledge of the event.**

5.1.4. Reporting of on-site SAEs is facilitated through the submission of an electronic copy and 1 hard copy of **MDH IRB FORM 3(G) 2021: SERIOUS ADVERSE EVENT/S REPORT**, together with the documents deemed relevant by the investigator to clarify information indicated in the report. Investigator assessment of (Certain, Probable, Possible, Unlikely, Unclassified, Unclassifiable) for all on-site SUSARS should be completed. This comprises the study protocol serious adverse event/s report package.

5.1.5. The SPONSOR and Principal Investigator must report all on-site SUSARs which are fatal/life threatening as soon as possible and not later than seven (7) working days from knowledge of the event in 1 electronic copy and a cover letter.

5.1.6. Incomplete initial reports should be completed within a total of fifteen (15) working days from knowledge of the event.

5.1.7. Queries emerging from the on-site SAE reports should be responded to within 7 working days.

5.1.8. Investigator should submit a documentation of the patient's follow-up visit after initial SAE report to address outcome or resolution of SAE.

5.1.9. The Secretariat checks the submission for completeness and gives a receiving copy of **MDH IRB FORM 3(G)2021: SERIOUS ADVERSE EVENT/S REPORT** to the PI or his/her representative.

5.1.10. The Secretariat logs the data on the submission database for on-site SAEs.

## 5.2 Presentation of On-site SAE during Board Meeting

5.2.1 The secretariat collates all SAE's, logs it in **SAE Summary Log/Database.**

5.2.2 The MDH IRB Chair shall be initially informed of any SAE submissions. The secretariat then submits on-site SAEs and sponsor submissions to the-designated primary reviewer for analysis.

5.2.3 The on-site SAE report shall be taken up in a full board meeting. A special meeting may be called by the MDH IRB for those requiring immediate action. Board should assess causality (Unlikely, Possible, Probable, Definite) for all on-site SUSARS.

5.2.4 The MDH IRB deliberates on the SAE and recommends a course of action. The MDH IRB Chair calls on the Board Members to recommend any of the following actions:

a. Uphold original approval with no further action
b. Request information
d. Recommend further action

5.2.5 The board action shall be communicated to the PI by the secretariat by using **MDH IRB FORM 4(F)2021 Notification Letter (Request Information) or MDH IRB FORM 4(L) 2021 Notification Letter (Uphold approval) to Progress/Annual Report, Final Report, Deviation, SAE, Site Visit**.

5.2.6 The secretariat manages the post-approval review requirements and preparation for site visit if indicated**.**