Safety reporting for events occurring in RCH study participants for single site studies only
See guidance below for multi-centre studies where a) RCH/MRCI is the lead site and b) where RCH/MCRI is the accepting site

### Definitions

**SAE** = Serious Adverse Event:
- results in death; or
- is immediately life threatening; or
- requires inpatient hospitalisation; or
- requires prolongation of existing hospitalisation; or
- is a congenital anomaly/birth defect
- any other important medical event considered reportable by PI

**SUSAR** = Suspected Unexpected Serious Adverse Reaction:
Any SAE that is both suspected to be related to the study treatment (drug/device) and is unexpected (i.e. not consistent with applicable product information)

**CRF** = Case Report Form

### EVENT

- **Adverse Event (AE)**
  - Is event a Serious AE (SAE)?
    - Yes: **SAE**
      - Is SAE related to study intervention?
        - Yes: Is event expected per Product Information?
          - Yes: **SUSAR**
            - Document SAE in source notes, CRF/AE log and database
            - REG reports SUSAR to VMIA (cc MCRI Risk Management Committee) and notifies RCH Drug Trials Sub-Committee
            - Report SUSAR to HREC via REG within 72 hours
            - Where MCRI/RCH is the sponsor PI reports SUSAR to TGA
        - No: End of process
      - No: Non-serious AE
        - Document in source notes, CRF/AE log and database
        - End of process
    - No: Non-serious AE
      - Document in source notes, CRF/AE log and database
      - End of process

### DOCUMENTATION and REPORTING

- **Document SAE in source notes, CRF/AE log and database**
- **Document SUSAR in source notes, CRF/AE log and database**
- **REG** reports SUSAR to VMIA (cc MCRI Risk Management Committee) and notifies RCH Drug Trials Sub-Committee
- **Report** SUSAR to HREC via REG within 72 hours
- **Where MCRI/RCH is the sponsor** PI reports SUSAR to TGA
- **Report** SAE to HREC via REG within 72 hours
- **Follow** SAE until resolution
- **Follow** SUSAR until resolution and provide follow up reports to HREC and TGA as required
- **End of process**

### OTHER SIGNIFICANT EVENTS

Report to HREC via REG if any event impacts on the research and/or action is planned and/or there are ethical implications.

### OTHER REPORTING REQUIREMENTS

#### RCH Participant where RCH is the lead site and approving HREC
- As per single site workflow above.

#### RCH Participant where RCH is an accepting site and the lead site and approving HREC is external to RCH
- **RCH PI**
  - Reports SAE/SUSAR to CPI (lead site) for submission to approving HREC
  - Submits SAE/SUSAR to RCH HREC via REG.

#### Non RCH Participant where RCH is the lead site and approving HREC
- **Accepting site PI**
  - Reports SAE/SUSAR to CPI (at RCH).
  - Reports SAE/SUSAR and all subsequent correspondence to their governance office.
- **CPI at RCH**
  - Reports SUSAR to RCH HREC via REG.
  - Ensures all subsequent correspondence with RCH HREC is provided to accepting site.

### Periodic SUSAR line listings:

- **Where RCH is a lead site**: Submit listings to HREC via REG and circulate listings to accepting sites.
- **Where RCH is an accepting site**: On receipt of these listings from CPI (lead site), RCH PI submits to RCH REG.