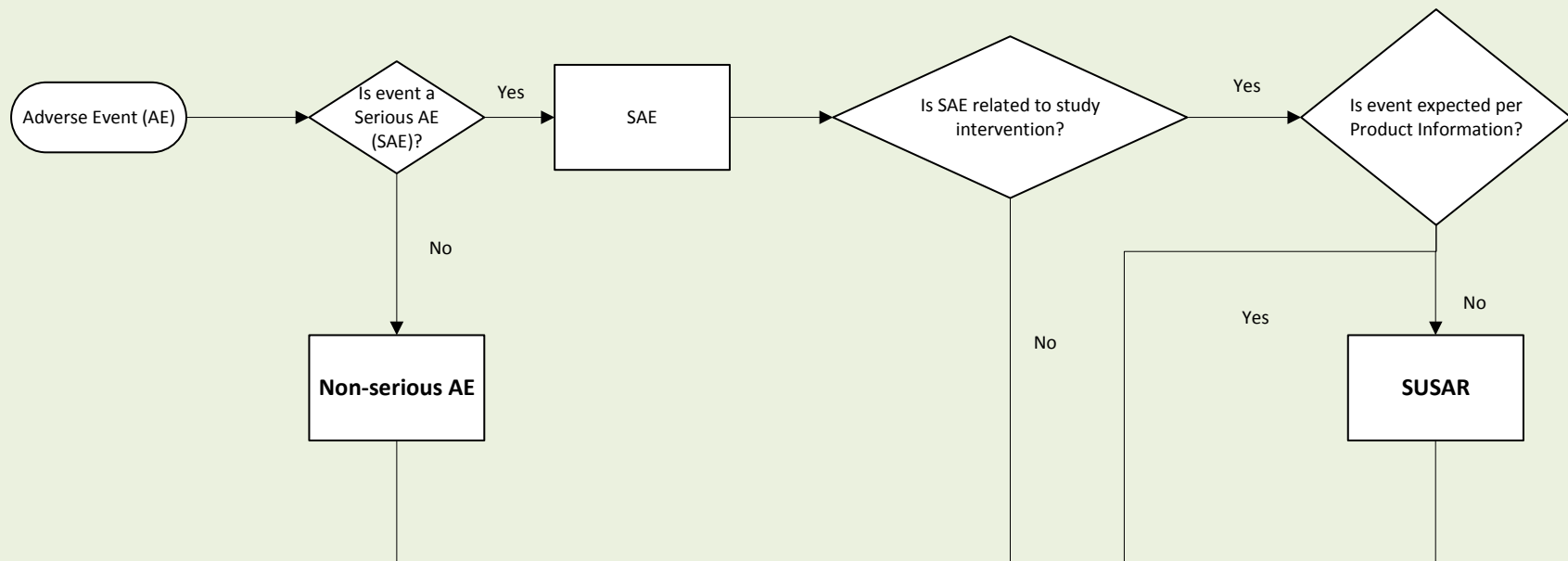
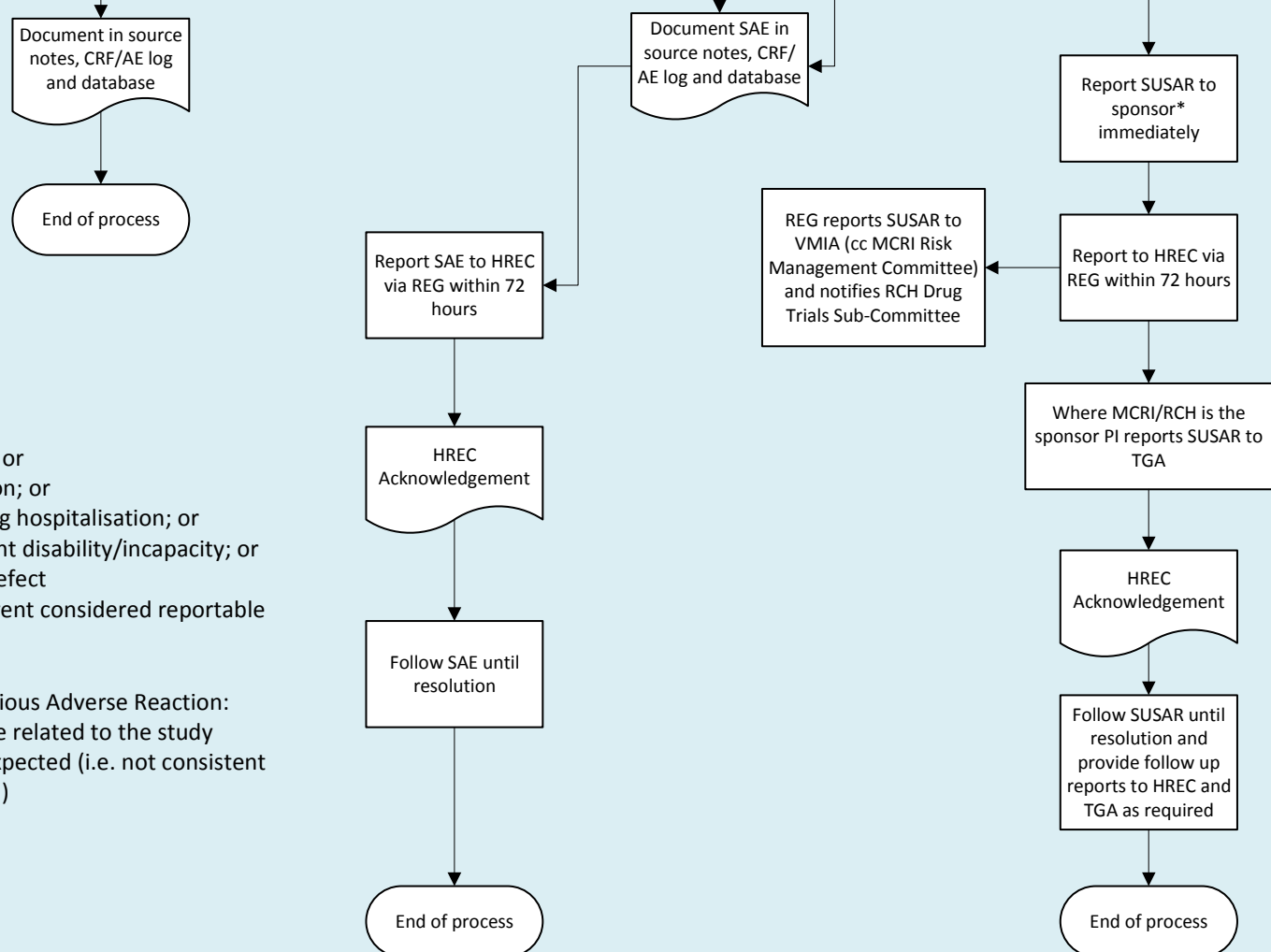


Safety reporting for events occurring in RCH study participants for single site studies only
 See guidance below for multi-centre studies where a) RCH/MCRI is the lead site and b) where RCH/MCRI is the accepting site

EVENT



DOCUMENTATION and REPORTING



Definitions

SAE = Serious Adverse Event:

- results in death; or
- is immediately life threatening; or
- requires inpatient hospitalisation; or
- requires prolongation of existing hospitalisation; or
- results in persistent or significant disability/incapacity; 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

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

Other reporting is required when RCH is involved in a multisite study.

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.