SingHealth CIRB: Illuminaté
"To Énlighten... Ethics, above all"
Adapted version for researchers, investigator and study
SingHealth
Defining Tomorrow's Medicine
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Revised non-local SAE Reporting Requirements and Timeline

With effect from 1 Jan 2025, the non-local SAE reporting requirements for clinical trials regulated by HSA are:

- Report related non-local SAE event where the sponsor determined that the event:
  - Is unexpected,
  - Is related and
  - Suggests that the research places participant or others at greater risk of harm (which may necessitate modification to the IRB-approved consent document(s), and/or the IRB-approved application/protocol).
- Non-local SAE should be reported via SAE report form on ECOS within 15 calendar days. Information in the submission report should be complete at the point of submission.

Note: Non-local SAE refers to events occurring in other study sites not reviewed by CIRB.

Industry sponsored clinical trials regulated by HSA

Upon receipt of sponsors' report with assessment of event at another site, only report if SAE met the above requirements, within 15 calendar days of PI awareness.

Investigator-initiated trials (IITs)

The institution as the lead local sponsor shall review the event for relatedness before deciding if reporting is required.

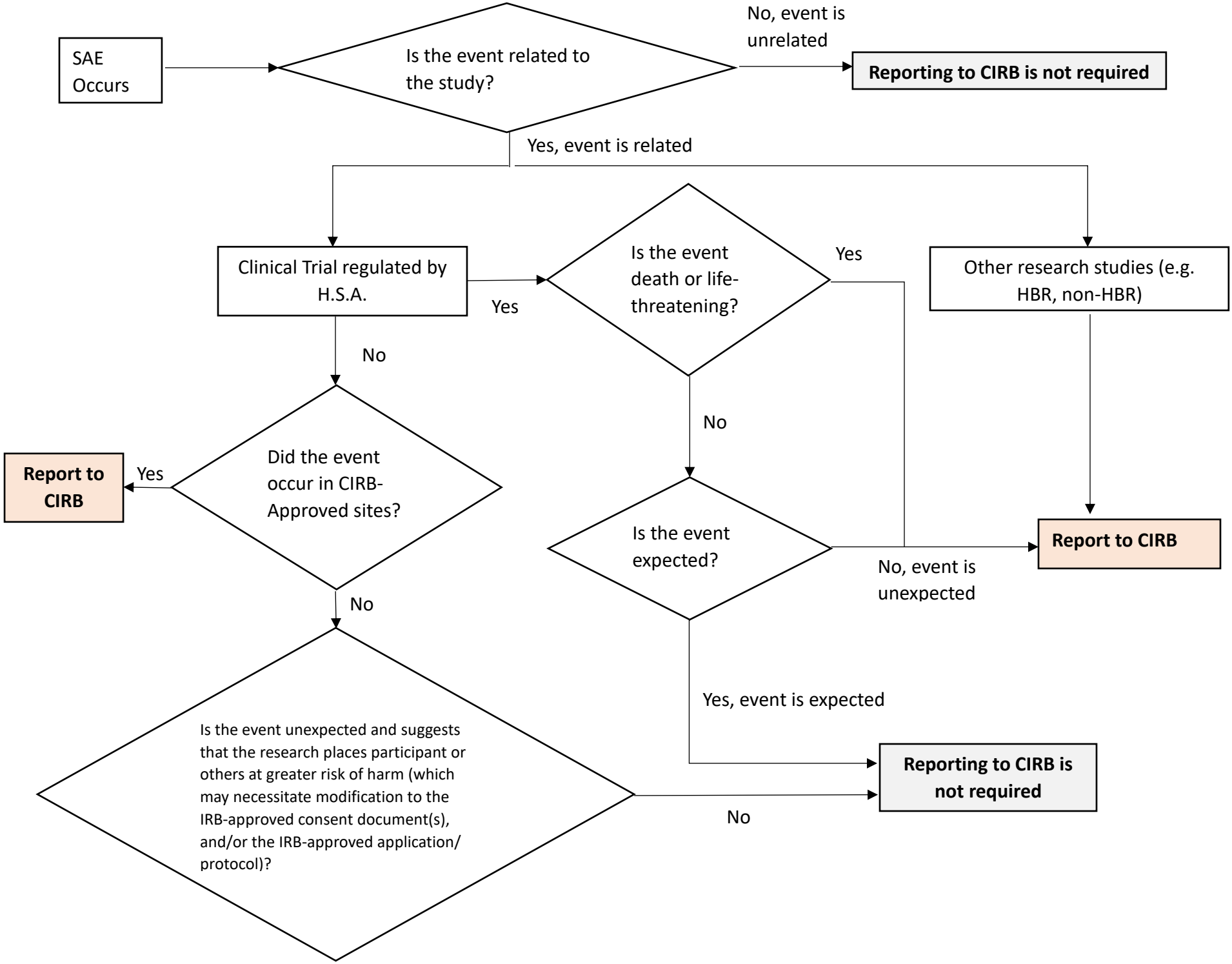
**There is no change in local SAE reporting requirement for clinical trial regulated by HSA and no change in SAE reporting requirement for HBR studies*.

For more information, please refer to the CIRB website for CIRB SAE Reporting Requirement and Timeline.

Revised SAE Reporting Requirements and Timeline Table

Relatedness (Causality)	**Only Related SAE needs to be reported to CIRB.**			
Study Type	**Clinical Trial regulated by H.S.A**		**Other research studies (e.g. HBR, non-HBR)**	
Local SAE				
SAE	Death or Life-threatening	All other SAE	Death or Life-threatening	All other SAE
Expectedness (Nature)	Unexpected Expected	Unexpected	Unexpected Expected	Unexpected Expected
Timeline for Initial Report	Report within 24 hours. Note: Information in the submission report should be complete at the point of submission.	Report as soon as possible but not later than 15 calendar days. Note: Information in the submission report should be complete at the point of submission.	Report within 24 hours. Note: Information in the submission report should be complete at the point of submission.	Report as soon as possible but not later than 15 calendar days. Note: Information in the submission report should be complete at the point of submission.
Timeline for Follow-up Report	Within 8 calendar days of initial report. (Follow-up report should only be submitted if information in the initial report is incomplete.)		Within 8 calendar days of initial report. (Follow-up report should only be submitted if information in the initial report is incomplete.)	
Non-Local SAE				
Non-Local SAE Reporting Requirement	Report related SAE event where the sponsor determined that the event: • Is unexpected, • Is related and • Suggests that the research places participant or others at greater risk of harm (which may necessitate modification to the IRB-approved consent document(s), and/or the IRB-approved application/protocol). SAE should be reported via SAE report form on ECOS within 15 calendar days. Note: Information in the submission report should be complete at the point of submission.		It follows the local SAE reporting requirement and timeline.	

SAE Reporting Requirements and Timeline Workflow



Statement of Confirmation by PI for Project Not Requiring Submission to CIRB

Human Subject Research must be reviewed and approved by CIRB before its conduct.

There are projects which do not meet the definition of HSR. Example of projects: Quality Assurance (QA)/ Service Improvement (SI), Studies involving Use of anonymised data and / or human biological materials.

PI can use this newly created form to seek the Head of Department and Institution Representative's endorsements before the commencement of the project.

More details can be found in the form.

Takeaway message...

It is the responsibility of sponsor and investigators to report events which could adversely affect the safety of subjects, impact the conduct of the trial, or alter the IRB approval/favourable opinion to continue the trial to the IRB.

If you have any questions, please contact CIRB at irb@singhealth.com.sg