

CIRB Updates

16 Dec 2024

The CIRB Updates cover the following:

1. Non-Local SAE Reporting Requirement and Timeline
2. Statement of Confirmation by PI for Project Not Requiring Submission to CIRB

1. Non-Local SAE Reporting Requirement and Timeline

The reporting requirement and timeline for Non-Local SAE have been updated as summarised in the table below. The updated reporting requirement and timeline for SAE (version 12) can be downloaded from [CIRB website](#).

No.	Section	Change From	Change To	Explanation
1.	Non-Local SAE Reporting Requirement	<ul style="list-style-type: none"> Unexpected, Related and Death/ Life-threatening 	<ul style="list-style-type: none"> Unexpected, 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). 	Updates to the Non-Local SAE Reporting Requirement
2.	Non-Local SAE Reporting Timeline	<ul style="list-style-type: none"> Initial Report within 24 hours. 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.) 	<ul style="list-style-type: none"> Within 15 calendar days. Information in the submission report should be complete at the point of submission 	Updates to the Non-Local SAE Reporting Timeline

No.	Section	Change From	Change To	Explanation
3	General	-	[NEW] Reporting Requirement Flowchart	Added a flowchart to assist investigator in determining whether a SAE needs to be reported to CIRB.

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

For SingHealth project not requiring IRB review, PI can use this newly created form to seek the Head of Department and Institution Representative's endorsements before the commencement of the project. Kindly refer to the [form](#) for more details.

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