ECOS

IRB Guidebook:

Other Forms

- Amendment Form
- Study Status Report Form
- Study Deviation and Non-Compliance Report Form
- Serious Adverse Event Report Form
- Other Study Notification Report Form

Version 1 dated: 12 Apr 2024

SingHealth
Defining Tomorrow's Medicine

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Section A: Amendment Form

Section A1: How to complete Amendment Form

Section A1 explains how to complete the Amendment Form. You may refer to Section A2 for the questions of the Amendment Cover Note. For questions of the amendment form, please refer to the IRB Guidebook: Application Form – Section 2.

1.1 Amendment Cover Note

The IRB should be notified of any changes made to the approved applications. No implementation of the changes may be carried out without prior approval. All requests for modification are reviewed by an expedited review procedure unless there have been major changes to the approved applications where the risk/benefit ratio is altered.

Only 1 amendment can be submitted at a time. No amendment can be made until IRB approved the submitted amendment.

The amendment consists of two parts:

1. **Study Amendment Cover Note:**
   Each Amendment Form would include a new Amendment Cover Note. This Amendment Cover Note serves as a "Cover Letter" for the study team to summarize the changes made in the Amendment Form as well as providing the rationale of the proposed amendments.

2. **Amendment Form:** The Amendment Form would be a copy of the latest approved Application Form/Amendment Form. Please edit the sections and study documents to reflect the requested changes.

You can either complete the Amendment Cover Note before you edit the Amendment Form, or edit the Amendment Form then complete the Amendment Cover Note. Please ensure that the changes listed on the Amendment Cover Note tallies with the changes made on the Amendment Form.

When a document has been amended to replace an existing document:

- Please ensure that both the clean and tracked copies are uploaded.
- A version number and date should be reflected within documents used for the purpose of this research. Where a version number and/ or date is included in the file name, do ensure that it is the same as that stated within the document.
- Please remove the obsolete copies as only the latest version is required.

Please note that the following questions cannot be amended in the Amendment Form:

- Section B1 (a) The reviewing IRB.
- Section B1 (b) Board
- Section B1 (c) Specialty
- Section B2 – Study Sites cannot be removed. If an approved study site has completed or would be terminated, please submit the study status report form to update the study site status accordingly.
- Section C1 (b) Grant Information. If the study would like to add more grant, please manage it under the CRMS module.
- Section D1 Form Type

1.2 Declaration and Endorsement

Amendment Form would be submitted to IRB for review after PI declaration. Please note that when there are changes to the following sections, the Amendment Form will be unlocked for re-endorsement.

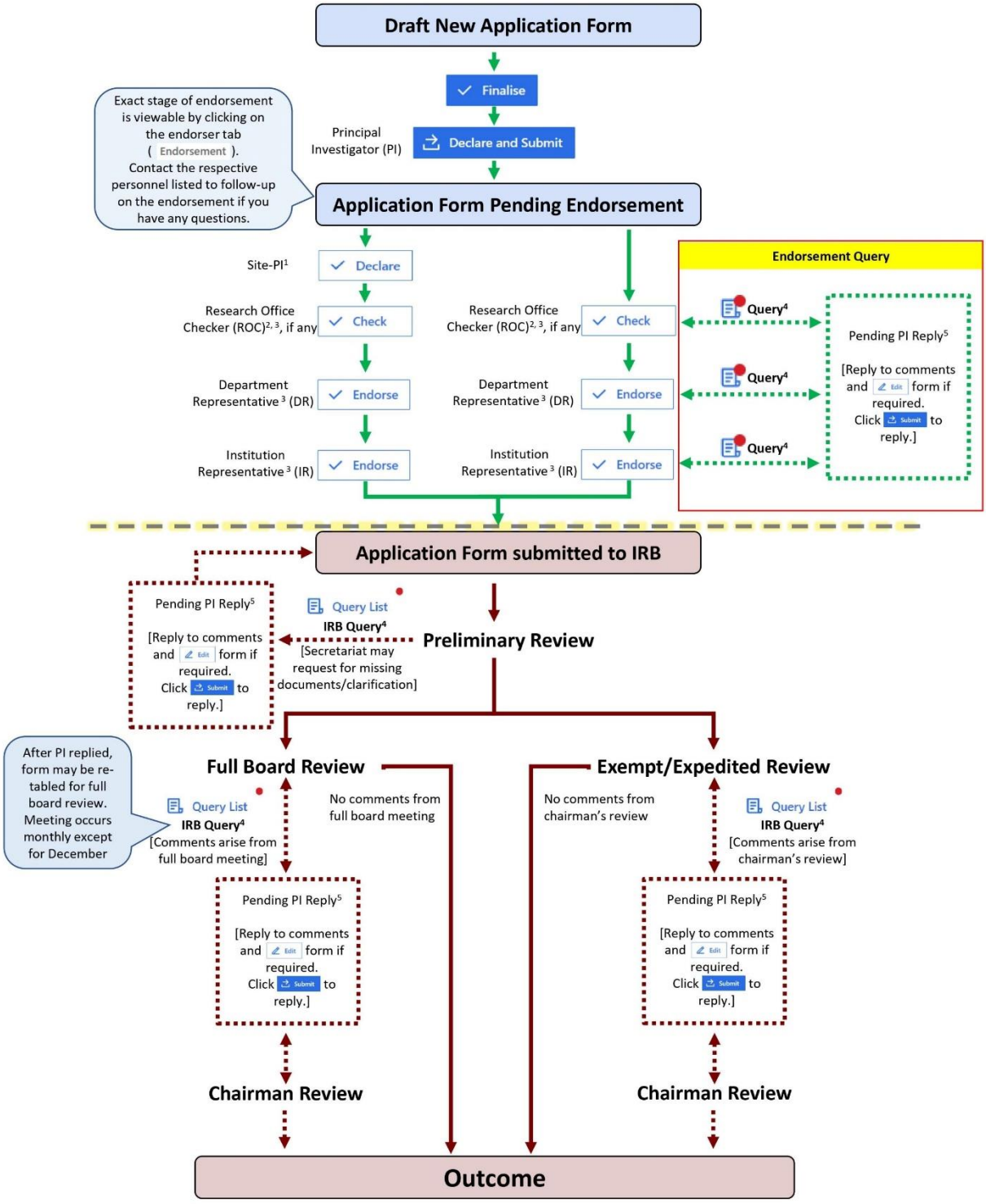
- Section B2: Addition of study sites (Endorsement for the additional sites only)
- Section B2: Change/ Addition of PI/ Site-PI (Endorsement for the sites involved only)
- Section D2: Change Study Classification to “Clinical Trial”
- Section D3: Inclusion of Vulnerable Participants
- Section H4: Change to Placebo Controlled Trial

For re-endorsement, it would include the following:

- PI Declaration
- Site-PI Declaration (for multi-site study)
- Research Office Checker (if applicable)
- Department Representative (DR) Endorsement
- Institution Representative (IR) Endorsement

Note:

1. Research Office Checker, DR and IR may raise queries during the endorsement process. It is important to respond to the query so that the endorsement process can continue. The queries are from Institutions and not IRB. Please contact your Research Office if any clarification is required.
2. When query (during the endorsement process or during IRB review process) is raised, the Amendment Form becomes editable and study team could update the application form.
3. When there are significant changes to the section as described above, the Application Form will be unlocked for re-endorsement.
4. If major changes were noted during the IRB review process, the IRB secretariat may unlock the form for re-endorsement.



Note:

[1] This is only applicable for study involving multi-sites.
[2] ROC check is only applicable for certain institutions.
[3] Please note that there may be queries from ROC, DR or IR during the endorsement process.
[4] There may be multiple returns depending on the quality and completeness of application and reply.
[5] Re-declaration / Re-endorsement is required if there are major changes to the application form.

Section A2: Amendment Cover Note (For Reference Only)

For questions of the amendment form, please refer to the IRB Guidebook: Application Form – Part 2. Below listed all the questions of the Amendment Cover Note. Depending on the form type or questions selected, only certain sections and questions will be displayed. Only questions with "#" indicated are optional.

1. Describe the proposed change(s) to the research and include a rationale for each proposed change.

- Insert text-

2. Will the enrolled research participants be informed of these changes?

- No
- Yes

2. (a) Please justify why enrolled research participants will not be informed of these changes. **(If no is selected)**

- Insert text-

2. (b) Please described how enrolled research participants will be informed. **(If yes is selected)**

- Insert text-

3. Will the enrolled research participants be re-consented?

- No
- Yes

3. (a) Please justify why enrolled research participants will not be re-consented. **(If no is selected)**

- Insert text-

3. (b) Please describe the process to obtain re-consent from enrolled research participants. **(If yes is selected)**

- Insert text-

4. Do the proposed amendments: #

- ❑ Significantly change the original objectives, innovation and scientific methodology (e.g., re-design of study methodology, change in investigational product used, etc) and/or the alignment of the study to the institutions' research objectives, image and standards of the research study?
- ❑ Require additional resources (e.g., expertise, manpower, time, budget) for the study to be properly conducted?
- ❑ Significantly increase the overall risk or negatively alter the risk benefit ratio to the research participants?

5. If any of the above is true, please elaborate. #

- Insert text-

Section B: Study Status Report Form

Section B1: How to complete Study Status Report Form

Section B1 explains how to complete the Study Status Report Form. The available options in Question 1 are:

- Study Renewal
- Study Status Update
- Study Reactivation
- Study Closure

Please refer to the respective sections for details on each option.
You may refer to Section B2 for the Study Status Report Form questions.

Note: Please note that the form can only be submitted by the PI and one Study Status Report Form at one time.

1.1 Study Renewal

The study renewal report is to be used for renewing of IRB approval. It is the responsibility of the PI to submit the study status report form (study renewal) with sufficient time prior to the expiration of the current IRB approval, so that no lapse in the study approval. It is recommended for the form to be submitted at least 2 months (60 days) before the expiry.

Continuing review of expedited or full board approved applications will be conducted with the same diligence as utilised during the initial review of the research. Continuing review of full board approved applications may be considered for expedited review if (i) the enrolment of new participants is permanently closed, all participants have completed all research-related interventions and the research remains active only for long-term follow-ups, (ii) no participants have been enrolled and no additional risks have been identified or (ii) the remaining research activities are limited to data analysis. For exemption studies, the requirement for continuing review is waived.

1.2 Study Status Update

Study Status Update should be used when there is an update to the study status. For example, change of study status from “ongoing” to “suspended”. Study Status Update can be submitted at any time.

1.3 Study Reactivation

The study reactivation is to be used to re-open a research study which is previously closed or where the approval has lapsed. All studies must retain an active IRB approval in order for research activities to be carried out. Otherwise, all research activities, including screening, enrolment, interventions, and interactions and collection of data and samples, or analysis of data and samples that have already been collected, or use of study data must stop.

Review of the form will be conducted with the same diligence as utilised during the initial review of the research.

For reactivation of expired study, please submit a Study Deviation/ Non-Compliance Report Form if the study team had continued to carry out research activities during the lapse period before IRB approval is renewed.

1.4 Study Closure

The study closure is to be used for the reporting of study completion or termination.

Study Completion: The study may be completed when all research-related interventions or interactions with participants have been completed and data analysis involves only unidentifiable data. For multi-site studies, the study may be closed regardless of the completion status of the global study. For study completion, please submit the Study Status Report Form within 30 days.

Study Termination: The study may be terminated by the PI, Institution or sponsor if the study is stopped after IRB approval. For study termination, please submit the Study Status Report Form within 7 days.

1.5 Status and Recruitment Information

The recruitment table from the last Study Status Report Form will be auto-populated by the system under "Previous Study Status Report Form" for your reference. If this is the first time the study status report form is being submitted, you will only see one recruitment table.

How to fill up the recruitment table:

1. Recruitment Numbers:
    - Proposed Enrolment Target: Enrollment target maximum as approved in the latest application/ amendment form.
    - Total No. of Screen Failures: Total number of participants who have signed an informed consent form; or who gave verbal consent on a study conducted under a waiver of documentation of consent but do not qualify for research participation after screening.
    - Total No. of Research Participants Enrolled: Total number of participants who have signed an informed consent form; or who gave verbal consent on a study conducted under a waiver of documentation of consent, minus total number of screen failures.
    - Total No. of Research Participants Who Have Completed Study: Total number of participants who have completed all interventions and follow-up.
    - Total No. of Research Participants Withdrawn from Study: Total number of participants who consented to participate in research, but later discontinued their participation in research at any point for various reasons (e.g. serious adverse events). This does not include screen failures.
        - Please state the reason(s) for each participant's withdrawal from study. Please submit as an attachment if required.

    Note: If your study involves only the use of human biological samples/records, please state the number collected for each study site.

2. Site status:
    - Not yet initiated: No research-related activities have been performed since first approval.
    - Ongoing: Research-related activities are still being performed.
    - Ongoing (Enrolment Closed, Participant Follow Up Only): The research is permanently closed to the enrolment of new participants AND all participants have completed all research-related interventions AND the research remains active only for long-term follow-up of participants.
    - Ongoing (Last Participant Last Visit Over, Data analysis Ongoing): There will be no more contact with participant and the remaining research activities are limited to data analysis involving identifiable data.
    - Completed: There will be no more research activities, including contact with participant or any data analysis of identifiable data. (For multi-centre studies, the study may be said to be completed at the sites when no further data will be collected from the sites, regardless of whether the global study has been completed or not.)

- Terminated: The study is stopped after IRB approval.
- Suspended: An action initiated by the Institution, Principal Investigator, Sponsor or Regulatory Authority to temporarily stop some or all research activities.

1.6 Consent Document being used at the study site

Snapshot on Section J13 of the latest application/amendment form would be displayed. Please confirm if the version number and/or date of all the consent documents currently used at the study site in the textbox provided.

If the following scenario applies, you may select "Not Applicable" instead:

- If the study does not involve informed consent document
- The status of the all the study site are:
  - Ongoing (Enrolment Closed, Participant Follow Up Only)
  - Ongoing (Last Participant Last Visit Over, Data analysis Ongoing)
  - Completed
  - Terminated

1.7 Unanticipated Events Involving Risks to Participants or Others

Please check and declare that all the unanticipated event(s) involving risks to participants or others (including serious adverse events) at the study site(s) has/have been reported. For event(s) that has/have yet to be reported to the IRB, please submit the Serious Adverse Events Report Form (if the initial Application was approved by SingHealth CIRB) or UPIRTSO Report Form (if the initial Application was approved by NHG DSRB).

1.8 Management of Research Data and Human Biological Material after Study Closure

Snapshot on Section T4 (research data) and W5 (human biological materials) of the latest application/ amendment form would be displayed. Please confirm that research data and human biological material after study closure would be managed as per described in the latest application/ amendment form.

Section B2: Study Status Report Form (For Reference Only)

Below listed all questions of the Study Status Report Form. Only questions with "#" indicated are optional.

1. **I am requesting for:**

-Choose from Dropdown list-
Study Renewal
Study Status Update
Study Reactivation
Study Closure

1. (a) Please provide reason for IRB re-approval. **(if "Study Reactivation" is selected in Question 1.)**

- Insert text-

2. **Status and Recruitment Information**

Study Site	**Proposed Enrolment Target**	**Total No. of Screen Failures**	**Total No. of Research Participants Enrolled**	**Total No. of Research Participants Who Have Completed Study**	**Total No. of Research Participants Withdrawn from Study#**	**Site Status**	**Date of Completion/ Termination/ Suspension:** (if "completion", "termination" or "suspension" is selected)	**Reason:** (if "Not Yet Initiated", "termination" or "suspension" is selected)	**Date of Study Closure:** (If study closure is selected)

2. (a) Please state the reason(s) for each research participant's withdrawal from study. Please submit as an attachment if required. **(if "Total No. of Participants Withdrawn from Study" is more than 1.)**

- Insert text-

2. (a) Attachment	**Uploaded Date (DDMMYYYY)**
(Upload File Icon)	

3. **Research Participants Enrolment by Gender: Please give us a break down of the total enrolled research participants as follows:**

3. (a) Number of Male Adult: *- Insert number-*

3. (b) Number of Female Adult: *- Insert number-*

3. (c) Number of Children: *- Insert number-*

4. **Description of Research Participants Enrolled: Were research participants from these categories being enrolled into the study?**

- ❑ Non-English Speaking Research Participants

- ❑ Pregnant Women, Foetuses & Non-Viable Neonates
- ❑ Children
- ❑ Prisoners
- ❑ Cognitively Impaired Persons
- ❑ Not Applicable

4. (a) Additional Comments (if any). *

- Insert text-

5. Report on Research to Date

5. (a) Consent procedures and documentation

I confirmed that the consent procedures and documentation were conducted as per IRB-approved application form and in accordance to applicable regulations and guidelines.

- o Not Applicable, my study does not involve recruitment
- o Yes
- o No

5. (a) (i) please explain: **(if "no" is selected)**

- Insert text-

5. (b) Consent documents being currently used at the study site(s) if applicable.

- o Not Applicable
- o The document version number and/or version date of all the consent documents being currently used at the study site were:

5. (b) (i) Please state:

- Insert text-

5. (c) Are there any unanticipated events involving risks to research participants or others (including serious adverse events) at your study site(s)?

- o No
- o Yes

I confirm that all the unanticipated event(s) involving risks to research participants or others (including serious adverse events) at the study site(s) has/have been reported.

5. (d) Has there been any updates (e.g., DSMB reports, evaluation reports of study-wide adverse events, interim findings, recent literature, or any other information) since the last

review? Please provide the relevant information (including those previously submitted at the last renewal), especially information about risks associated with research.

- No
- Yes

5. (d) (i) Please attach the reports. **(if "yes" is selected")**

5. (d) (i) Attachment	Uploaded Date (DDMMYYYY)
(Upload File Icon)	

5. (d) (ii) Please provide a current assessment of the risk/benefit relationship of the research based on results, internal and external adverse event(s) and other factors. Also, in your opinion, should any changes in the consent form be made based on these results? **(if "yes" is selected")**

- Insert text-

5. (e) Have there been any complaints about the research?

- No
- Yes

5. (e) (i) Please provide details of the complaints. **(if "yes" is selected")**

- Insert text-

5. (f) Please provide a summary of your research findings (e.g., interim analyses, multi-centre trial reports etc.).

- Insert text-

5. (g) Have you published your research findings?

- No
- Yes

5. (g) (i) Please provide details (e.g., report, dissertation, thesis, journal article, book, etc). Include details such as where it has been published (e.g. name of journal, book chapter, etc). **(if "yes" is selected")**

- Insert text-

5. (g) (i) Attachment	Uploaded Date (DDMMYYYY)
(Upload File Icon)	

5. (h) How will the research data be managed upon study completion? **(if "Study Closure" is selected in question 1)**

I confirmed that the research data will be managed as per described above.

- Yes
- No, please explain:

- Insert text-

5. (i) How will the leftover human biological materials be managed upon study completion? (if "Study Closure" is selected in question 1)

I confirmed that the leftover human biological material will be managed as per described above.

- Not Applicable, my study does not involve the use of human biological material
- Yes
- No

5. (i) (i) Please explain: (if "no" is selected)

- Insert text-

6. Other Attachments #

Note: Please attach only documents that are not relevant to the above questions. The relevant documents should be attached in the specific questions.

Attachment	Uploaded Date (DDMMYYYY)
(Upload File Icon)	

Section C: Study Deviation and Non-Compliance Report Form

Section C1: How to complete Study Deviation and Non-Compliance Report Form

Section C1 explains how to complete the Study Deviation and Non-Compliance (DNC) Report Form.

This report form should be submitted once Principal Investigator is aware of the study deviation/ non-compliance according to the reviewing IRB's requirement. All sections must be completed. Principal Investigators are obliged to suspend their research immediately pending their report to the IRB if deviations are substantial or are likely to result in greater harm or greater likelihood of harm to the research participants.

Definitions

Study Deviation: is an unplanned excursion from the study that is not implemented or intended as a systematic change.

- A study deviation could be a limited prospective exception to the protocol (e.g. agreement between sponsor and investigator to enroll a single research participant who does not meet all inclusion/exclusion criteria). Like study amendments, deviations initiated by the investigator must be reviewed and approved by the IRB and the sponsor prior to implementation, unless the change is necessary to eliminate an immediate hazard to the research participants.
- Study deviation is also used to refer to any other, unplanned, instance(s) of study non-compliance. For example, situations in which the investigator failed to perform tests required by the protocol or failures on the part of the research participant(s) to complete scheduled visits as required by the protocol.

Non-Compliance: is a failure by an investigator or any study team member to abide by the policies and procedures of the IRB or applicable regulations governing the protection of human subject research. Some examples of non-compliance include but are not limited to:

- Failure to obtain prior approval for research
- Failure to obtain informed consent when required
- Failure to use the latest IRB approved version of the protocol or consent form
- Failure to report an adverse event report according to IRB timeline and procedure
- Performance of research at an unapproved study site
- Performing an unapproved research procedure
- Failure to adhere to the approved protocol
- Failure to submit study amendments for review and approval
- Performance of a drug trial without a valid HSA Clinical Trial Authorisation (CTA), Clinical Trial Notification (CTN) or Clinical Trial Certificate (CTC)
- Any other failure to adhere to regulations, policies and procedures related to research

1.1 Study Sites

Question 1 lists all the approved sites (based on the latest approved application/amendment form). Please select the study sites where the Study Deviation/ Non-Compliance occur. If the event occurred in more than 1 site, please select multiple sites in Question 1. Multiple events of similar nature to be submitted using 1 form.

For studies with multiple study locations, please specify the study location in Question 4.

1.2 Date of Occurrence of Study Deviation/ Non-Compliance

If the event(s) span over a period of time, please indicate the start date/ earliest date of the event in Question 2.

When reporting multiple events, please indicate the earliest date here.

Section C2: Study Deviation and Non-Compliance Report Form (For Reference Only)

Below listed all questions of the Study Deviation and Non-Compliance Report Form. Only questions with "#" indicated are optional.

1. **Which study site(s) did this/ these Study Deviation/ Non-Compliance occur?**
   - ❑ *Site 1*
   - ❑ *Site 2*
   - ❑ *Site 3*
   - ❑ *(continue the list of approved site(s))*

2. **Date of Occurrence of Study Deviation/ Non-Compliance.**

   - Select date-

3. **Number of research participant(s) affected.**

   - Insert number-

4. **Please describe in detail the nature of the Study Deviation/ Non-Compliance and chronology of events, including why or how the Study Deviation/ Non-Compliance occurred. For studies with multiple study locations, please specify the study location.**

   - Insert text-

5. **Did the Study Deviation/ Non-Compliance cause harm/death to the research participant and/or others?**
   - ○ (a) Yes
   - ○ (b) No

   5. (a) Please explain: **(If "Yes" is selected at 5.)**

   - Insert text-

   5. (b) Please explain: **(If "No" is selected at 5.)**

   - Insert text-

6. **Will the Study Deviation/ Non-Compliance potentially increase the risk or cause harm to the research participant and/or others?**

   - (a) Yes
   - (b) No

   6. (a) Please explain: (If "Yes" is selected at 6.)

   - Insert text-

   6. (b) Please explain: (If "No" is selected at 6.)

   - Insert text-

7. **Did the Study Deviation/ Non-Compliance affect the rights or welfare of the research participant and/or others?**

   - (a) Yes
   - (b) No

   7. (a) Please explain: (If "Yes" is selected at 7.)

   - Insert text-

   7. (b) Please explain: (If "No" is selected at 5.)

   - Insert text-

8. **<u>Corrective Action Plan:</u> Please describe the steps taken to rectify/correct Study Deviation/ Non-Compliance.**

   - Insert text-

9. **Please explain/describe the outcome of the Study Deviation/ Non-Compliance.**

   - Insert text-

10. **<u>Preventive Action Plan:</u> Please describe any follow up action taken to prevent the recurrence of the Study Deviation/ Non-Compliance in future.**

    - Insert text-

11. **If this Study Deviation/ Non-Compliance had been reported to the Study Sponsor or Regulatory Authorities, please describe if there were any comments from the Study Sponsor or Regulatory Authorities?**

- Insert text-

12. **Any other comments.** #

- Insert text-

13. **Attachment.** #

Attachment	Uploaded Date (DDMMYYYY)
(Upload File Icon)	

Section D: Serious Adverse Event Report Form

Section D1: How to complete Serious Adverse Event Report Form

Section D1 explains how to complete the Serious Adverse Event (SAE) Report Form.

Note:

1. This form is for submission of related SAE only.
2. For DSRB reviewed studies, if the related SAE is unexpected, please submit using the UPIRTSO Report Form.
3. Do not use terms such as "Refer to attached document" or similar.

Please refer to your respective IRBs for the reporting requirements. All reporting timelines are counted from the day that the PI becomes aware of the event.

For DSRB reviewed studies, the PI and Site-PI are able to submit the SAE report form.

For the other IRB reviewed studies, the PI, Site-PI and Co-I are able to submit the SAE report form.

Regulatory Requirements:

- For clinical trials of health products/medicinal products conducted in accordance with the Health Product Act (Cap. 122D)/ Medicines Act (Cap. 176), PIs/Sponsors/Institutions should report to HSA within the stipulated timeline according to HSA requirement.
- For studies regulated under Human Biomedical Research Act 2015, SingHealth RI will report required SAE to MOH.

1.1 Local SAE

Local SAE refers to SAE occurring in participants recruited by sites that were reviewed by CIRB/ DSRB/ A*STAR IRB/ NUS IRB/ NTU IRB. Section B1 will list all the approved sites (based on the latest approved application/amendment form). Please select the study sites where the SAE occur. If there is a specific location listed in B2(a) of the application/amendment form, please specify it under Section D, question 2.

1.2 Non-local SAE (Overseas SAE)

Non-local SAE refers to SAE occurring in participants recruited by sites that were not reviewed by CIRB/ DSRB/ A*STAR IRB/ NUS IRB/ NTU IRB.

For Non-local SAE, please select “others” and list the overseas study site in Section B1. If the participant was recruited by local site but the event occurred in overseas, please report under “study site”.

1.5 Type of report

‘Initial Report’ should be selected if the event is being reported for the first time. If the information is incomplete at the point of initial report submission, the PI should adhere to the reporting timeline and complete it as much as possible.

Any additional relevant information must be submitted through SAE Report Form by selecting ‘Follow-up Report’. Please provide the Form Ref of the SAE Report(s) that had been submitted in relation to this event.

If information is already complete at the point of initial report submission, there is no need to submit ‘Follow-up Report’.

1.4 Others

- If the SAE event does not involve investigational product, Section C2 to C5 will not appear in the SAE report form.
- If event is unresolved and investigation is ongoing, the resolution date/ end date of adverse event date may be left blank. A Follow Up Report must be submitted.

Section D2: Serious Adverse Event Report Form (For Reference Only)

Below listed all questions of the Serious Adverse Event Form. Only questions with "#" indicated are optional.

Section A: Determination of SAE

A1. Please determine if the event is related:

- Related: Related means there is a reasonable possibility that the incident, experience or outcome may have been caused by the procedures involved in the research. Also includes reasonable possibility that the event occurred as a result of participation in the research.

A2. Please classify the SAE into at least one of the following categories:

- ❑ Resulted in or contributed to death
- ❑ Was life-threatening
- ❑ Required inpatient hospitalisation or prolongation of existing hospitalisation
- ❑ Resulted in or contributed to persistent or significant disability or incapacity
- ❑ Resulted in or contributed to a congenital anomaly or birth defect
- ❑ Resulted in transmission of communicable disease
- ❑ Resulted in any misidentification or mix-up of any type of tissue, gametes or embryo
- ❑ Required intervention to prevent permanent impairment or damage (devices)
- ❑ Medical event that may jeopardize the patient and may require medical or surgical intervention to prevent one of the outcomes listed above
- ❑ Others

A2. (a) please specify: **(if "others" is selected)**

- Insert text-

A3. Please determine the expectedness of the event:

- Expected: These are risks or events reported and listed in the study protocol, informed consent form or other study documents.
- Unexpected: These are any unexpected untoward event or medical occurrence in a participant that is not consistent with the known, predicted possible effects of the research protocol. An unexpected adverse event can therefore be any unanticipated, unfavourable and unintended sign (including an abnormal laboratory finding), symptom or disease temporally associated with the study that was not listed in the protocol, informed consent document or Investigator's Brochure (IB). This includes adverse drug reactions, the nature or severity of which is not consistent with the applicable product information (e.g. IB for an unapproved investigational product or product insert/ summary of product characteristics for an approved product) and any experience that suggests a significant hazard, contraindication or side effect. In addition to this definition, the IRB will interpret any adverse event not included in the Informed Consent Document as a risk to be "unanticipated" or "unexpected".

Section B: Basic Information

B1. Study site:

- Study site(s) -List of approved study sites from the application/amendment form for selection-
- Others (including overseas study site)

  B1. (a) Please specify: **(if** "others" **is** selected**)**

  - Insert text-

B2. Onset Date: *- Select date-*

B3. Date of First Knowledge by Investigator: *- Select date-*

B4. Type of Report:

- Initial
- Follow Up

B4. (a) Please provide the Form Ref of the SAE Report(s) that had been submitted in relation to this event. **(if "**Follow Up**" is** selected**)**

- Insert text-

B5. Research Participant Number/Code: *- Insert text-*

B6. Age: *- Insert number-*

B7. Gender: O Male O Female

B8. Is the research participant still in the study? O Yes O No

B9. Which study arm is the research participant in?

- Study Intervention (i.e. drug, device and experimental procedures)
- Comparator (including Placebo)
- Unknown (Research Participant is blinded)
- Not applicable as there is no study arms
- Others

B9. (a) Please specify: *- Insert text-*

Section C: Investigational Product (Drug/Device/Biological/Other Agent)

C1. Does this event involve an investigational product? O Yes O No

C2. Investigational Product Name: *- Insert text-*

C3. Was the study blind broken? O Yes O No

O This is not a blinded study

C4. Is the investigational product registered in Singapore? O Yes O No

C5. The investigational product was:

- Continued
- Discontinued
- Temporarily Stopped

C5. (a) State the stop date: (If "discontinued" or "temporarily stopped" is selected) *- Select date-*

Section D: Event Summary

D1. Please use keywords, e.g. Liver Failure, to concisely describe the event.

- Insert text-

D2. Please provide a detailed description of the event (including details on what actions were taken to resolve the problem). For studies with multiple study locations, please specify the study location.

- Insert text-

D3. Did the event have any impact on the research participant? E.g. Research participant was withdrawn from study

- No
- Yes

D3. (a) Please specify the impact: **(if "yes" is selected)**

- Insert text-

D4. Did the event have any impact on the other research participants in the study?

- ○ No
- ○ Yes

D4. (a) Please specify the impact: (if "yes" is selected)

- Insert text-

D5. Outcome of the event:

- ○ Resolved
- ○ Unresolved
- ○ Unable to assess
- ○ Death

D6. Resolution/End Date of Adverse Event: #

- Select date-

D7. Please attach any supporting documents you may have regarding this event (e.g. CIOMS reports) (if applicable). #

D7. Attachment	Uploaded Date (DDMMYYYY)
(Upload File Icon)	

Section E: Comments by Investigator

E1. Has the study's risk-benefit ratio changed?

- ○ Yes
- ○ No
- ○ Unable to assess

E2. Should past and/or current enrolled participants be notified about this event or be re-consented for research participation?

- ○ (a) Yes
- ○ (b) No

E2. (a) Please explain and describe the mechanism to be employed. (if "yes" is selected)

- Insert text-

E2. (b) Please explain your rationale. (if "no" is selected)

- Insert text-

E3. Is this event already listed/described in the informed consent document/protocol?

- No
- Yes

E3. (a) Is the frequency and/or severity of the event consistent with the consent document/ protocol? (if "yes" is selected)

- No
- Yes

E3. (a) (i) State where the information on this expected event can be found (e.g. Informed Consent Form / Protocol; Section X, Page XX etc.):

- Insert text-

E4. Should the protocol and/ or informed consent document be revised?

- Yes - Please submit the amendments for IRB approval.
- No

E4. (a) Please explain the rationale for your decision.

- Insert text-

E5. Any other Comments: #

- Insert text-

Section E: Other Study Notification Report Form

Section E1: How to complete Other Study Notification Report Form

Section E1 explains how to complete the Other Study Notification (OSN) Report Form. Please use Other Study Notification Report Form if you are submitting:

- DSMB Report
- Annual/Interim /Periodic Safety Report
- Interim Data Analysis
- Letter from Study Sponsors
- Other Notification

If the notification (i) affects the research participants' risk benefit ratio, (2) requires changes to the study design and/or study documents or (3) affect enrolled research participants' decision to continue in study, please submit amendment form along with OSN report form if required. If the amendment submission is not ready at the point of submission of OSN report, please explain in question 2 accordingly.

Note: Submission of Overseas Serious Adverse Events (OSAE) should be done via the Serious Adverse Events (SAE) reporting form.

Section E2: Other Study Notification Report Form (For Reference Only)

Below listed all questions of the Other Study Notification Report Form. Only questions with "#" indicated are optional.

1. **Notification type**

   Please select:

   - ❑ DSMB Report
   - ❑ Annual/Interim /Periodic Safety Report
   - ❑ Interim Data Analysis
   - ❑ Letter from Study Sponsors
   - ❑ Other Notification

     1. (a) please use keywords to concisely describe the type of notification: **(If "Other Notification" is selected in 1.)**

- Insert text-

2. **Please describe the contents of this notification.**

- Insert text-

3. **Does this notification contain any information that changes the research participants' risk-benefit ratio of participating in the study?**

   - ○ Yes - Please submit this notification and its amendments using the Study Amendment Form.
   - ○ No

4. **Does this notification require amendments to the study design and/or to any of the study documents?**

   - ○ Yes - Please submit this notification and its amendments using the Study Amendment Form.
   - ○ No

5. **Does this notification contain any information that may affect the enrolled research participants' decision to continue in the study?**

   - ○ Yes - Please submit this notification and its amendments using the Study Amendment Form.
   - ☐ ○ No

6. **Attachment** #

Attachment	Uploaded Date (DDMMYYYY)
(Upload File Icon)	