SingHealth CIRB: Illuminaté

"To Énlighten... Ethics, above all"

Adapted version for researchers, investigator and study coordinators

SingHealth
Defining Tomorrow's Medicine

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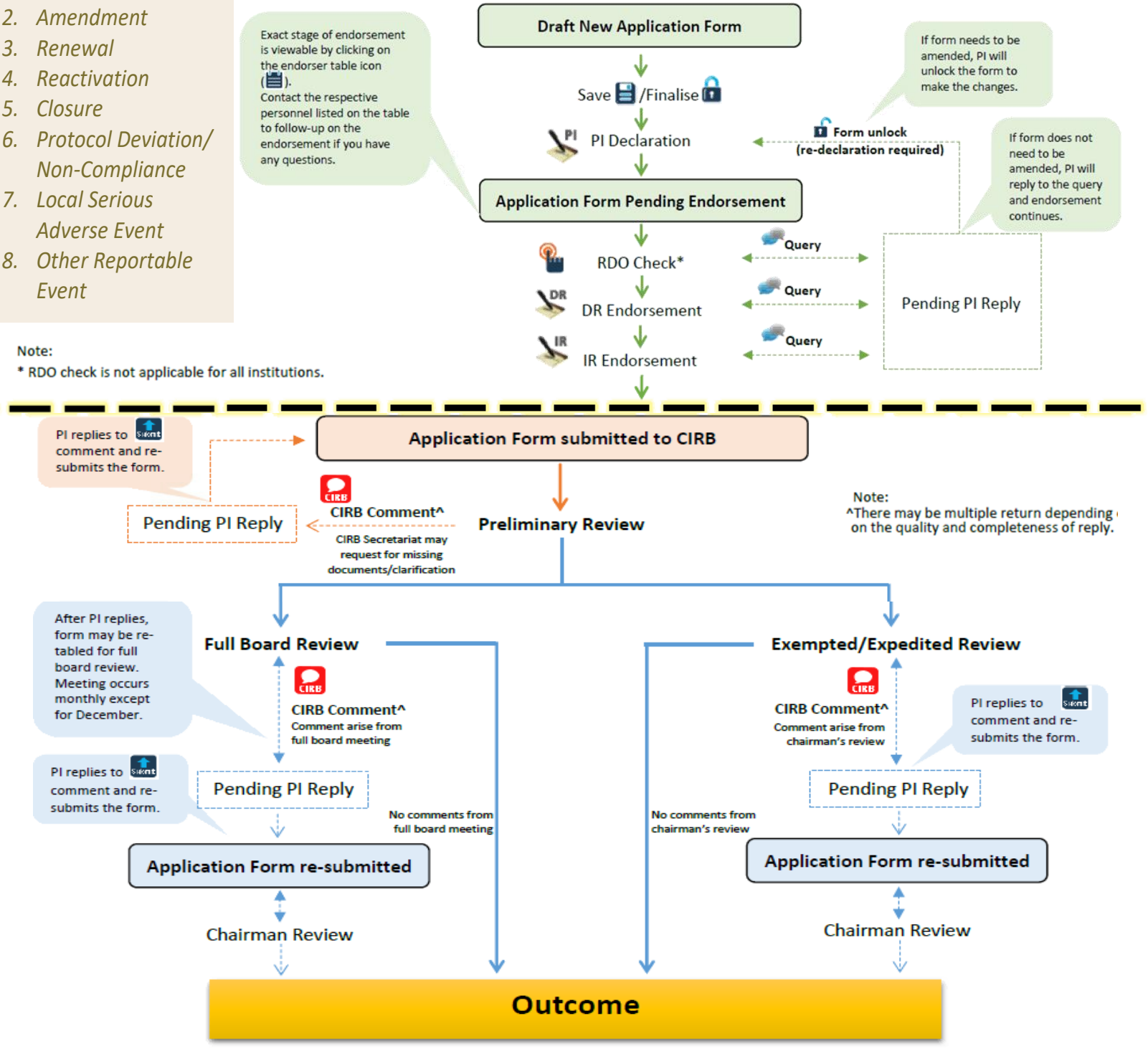
Types of Submissions to IRB

1. Initial Application >>>

Research studies requiring IRB approval must be submitted via iSHaRe for review. No research activities may be carried out prior to the approval.

An overview of the initial application submission and review process is as follows.



2. Amendment >>>

The CIRB should be informed 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 expedited review procedure unless there have been major changes to the approved applications where the risk/benefit ratio is altered.

For exempted studies, unless the changes made alter the exempt status, amendment submission is not required.

The amendment form is not required to go through the endorsement process by the RDO, DR and IR, unless the following changes are made to the approved application.

- Change in PI/ Site-PI
- Addition of study site(s)
- Significant changes to protocol
- Changes in form type

All amendment request should be submitted via iSHaRe for review. The amendment consists of two parts:

1) Study Amendment Cover Note: To identify the reason for the amendment
2) Amendment Form: To edit the sections and study documents to reflect the requested changes.

The amendment can be initiated in iSHaRe by any study team member listed in the approved application.

After completing the amendment cover note, the system will create the amendment form by copying the approved application/ the latest approved amendment form, and opening a copy for editing.

The required changes can then be made and submitted by the PI to the IRB for review.

3. Study Renewal >>>

The study renewal report form is to be used for renewing of IRB approvals. The approval period granted by CIRB for approved applications is one year (12 months). For research studies which will continue beyond one year, the PI must submit a request for renewal via iSHaRe.

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

Note: In the event where the approval has lapsed, both the study reactivation report form and protocol deviation/non-compliance report form have to be submitted to CIRB.

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 research is permanently closed to the enrolment of new participant, all participants have completed all research-related interventions and the research remains active only for long-term follow-ups,
(ii) no participant has been enrolled and no additional risk has been identified, or
(iii) the remaining research activities are limited to data analysis.

For exemption studies, the requirement for continuing review is waived.

iSHaRe will send email and system notifications beginning 3 months (90 days) before the study expiration. The notifications sent are as follows.

- 1st Study Expiry Reminder – 90 days prior to expiry of ethics approval
- 2nd Study Expiry Reminder – 60 days prior to expiry of ethics approval
- Final Study Expiry Notification – 30 days prior to expiry of ethics approval

4. Study Reactivation >>>

The study reactivation report form is for reopening a research study which is previously closed or where the approval has lapsed.

All studies must have valid IRB approval 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.

5. Study Closure >>>

The study closure report form is to be used for the reporting of study closure, termination or withdrawal. The completed form has to be submitted to CIRB via iSHaRe within the following timeframe.

Study Completion – Within 30 days
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.

Study Termination – Within 7 days
The study may be terminated by the PI, Institution or sponsor if the study is stopped after site initiation.

Study Withdrawal – Within 7 days
The study may be withdrawn by the PI, Institution or sponsor if the study is stopped before site initiation.

6. Protocol Deviation/ Non-Compliance (PD/NC) >>>

All PIs and the study teams are responsible for reporting information regarding the approved study in a timely manner, understanding and adhering to the reporting timeline.

Any incidence of unplanned excursion from the approved protocol (i.e. deviation) or failure to abide by the CIRB and other applicable regulatory requirements (i.e. non-compliance) should be reported to the CIRB via iSHaRe immediately using the Protocol Deviation/Non-compliance Report form.

Multiple PD/NC report form can be submitted at any one time.

7. Local Serious Adverse Event (LSAE) >>>

All PIs and the study teams are responsible for reporting information regarding the approved study in a timely manner, understanding and adhering to the reporting timeline.

Any serious untoward medical occurrence in participants recruited by any study site that is reviewed by CIRB constitutes a local serious event. It should be reported to the CIRB via iSHaRe using the LSAE Report Form. The reporting timeline is available under the "Guidelines" section of the "Forms & Resources" page.

This form can be submitted by the PI, Site-PI and Co-I.

Multiple LSAE report forms can be submitted at any one time.

8. Other Reportable Event (ORE) >>>

The ORE Report Form is to be used to report to CIRB about any non-LSAEs for e.g., CIOMS, SUSAR or other applicable notifications.

Multiple ORE report forms can be submitted at any one time.

Takeaway message...

IRB submissions do not end at just the initial applications. Reviews are continuous and ongoing, to ensure that the conduct of the study had been carried out according to the regulations.

PIs and study teams are responsible to report any incidence of unplanned excursion from the protocol, as well as any serious untoward medical occurrence in recruited participants to the IRB.

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