Guidelines to IRB Submission and Monitoring Process

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Table of Contents

Summary of Changes		
Document Version	**Date of Change**	**Summary of Changes**
1.0	TBC	First release of document.

1 BEFORE SUBMISSION

1.1 TYPES OF ROLES IN A STUDY TEAM

1.1.1 Principal Investigators and Site-Principal Investigators

Principal Investigators and Site-Principal Investigators are responsible for ensuring the proper conduct of the research study/clinical trial and the safety of the participants by adhering to the relevant local regulations and guidelines. PIs and Site-PIs conducting clinical trials are strongly advised to complete and obtain the local GCP certificate. Certificates obtained after attending the GCP workshop from SingHealth Academy, National Healthcare Group (classroom-based or online), National University Health Systems (NUHS) or the online iGCP course with the National University of Singapore are acceptable.

1.1.2 Co-Investigators

Co-Investigators (Co-Is) are members of the research/clinical trial team designated by the Principal Investigator to perform study-related procedures and/or make important research-related decisions. Study Team Members are personnel responsible for the design, conduct or reporting of the research. All personnel who have a responsibility for the consent process and/or direct data collection for this study must be listed as Study Team Members (STMs). Co-Is are strongly recommended to complete and obtain a Collaborative Institutional Training Initiative (CITI) certificate. See Section 1.2.1 Collaborative Institutional Training Initiative (CITI) for more details.

1.1.3 Protocol Administrators

Protocol Administrators are persons who are responsible for administrative matters related to the Study. They can be the Study Coordinators, Research Nurses or Clinical Research Associates, and are not considered to be part of the study team members. While the Principal Investigator remains the primary contact person, the IRB may contact the Protocol Administrators for clarification of administrative matters related to the Study. This section is optional but Principal Investigators are encouraged to nominate at least one Protocol Administrator. You may select up to 5 Protocol Administrators.

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1.2 TRAINING REQUIREMENTS FOR TCM RESEARCHERS

All TCM researchers who are involved in the design, conduct, oversight or management of research are required to attend research ethics and good document practice training to help them understand and apply the training to the day-to-day practice of research. This helps to ensure the safety, integrity and quality of research, in compliance with local laws, regulations and international standards. The training requirements are as follows:-

Types of Research	Training Requirement (s)	PI/Site-PI	Co-I/STM
	CITI Program	✓	✓

Observational, Descriptive studies, Retrospective studies		✓	

PI: Principal Investigator, Site-PI: Site Principal Investigator, Co-I:Co-Investigator, STM: Study Team Member

1.2.1 Collaborative Institutional Training Initiative (CITI)

The online CITI programme is designed to educate researchers on research involving human subjects. Upon completion, a certificate will be issued. All researchers should maintain a valid (non-expired) CITI certificate. The CITI programme can be accessed from here.

The required CITI modules are:

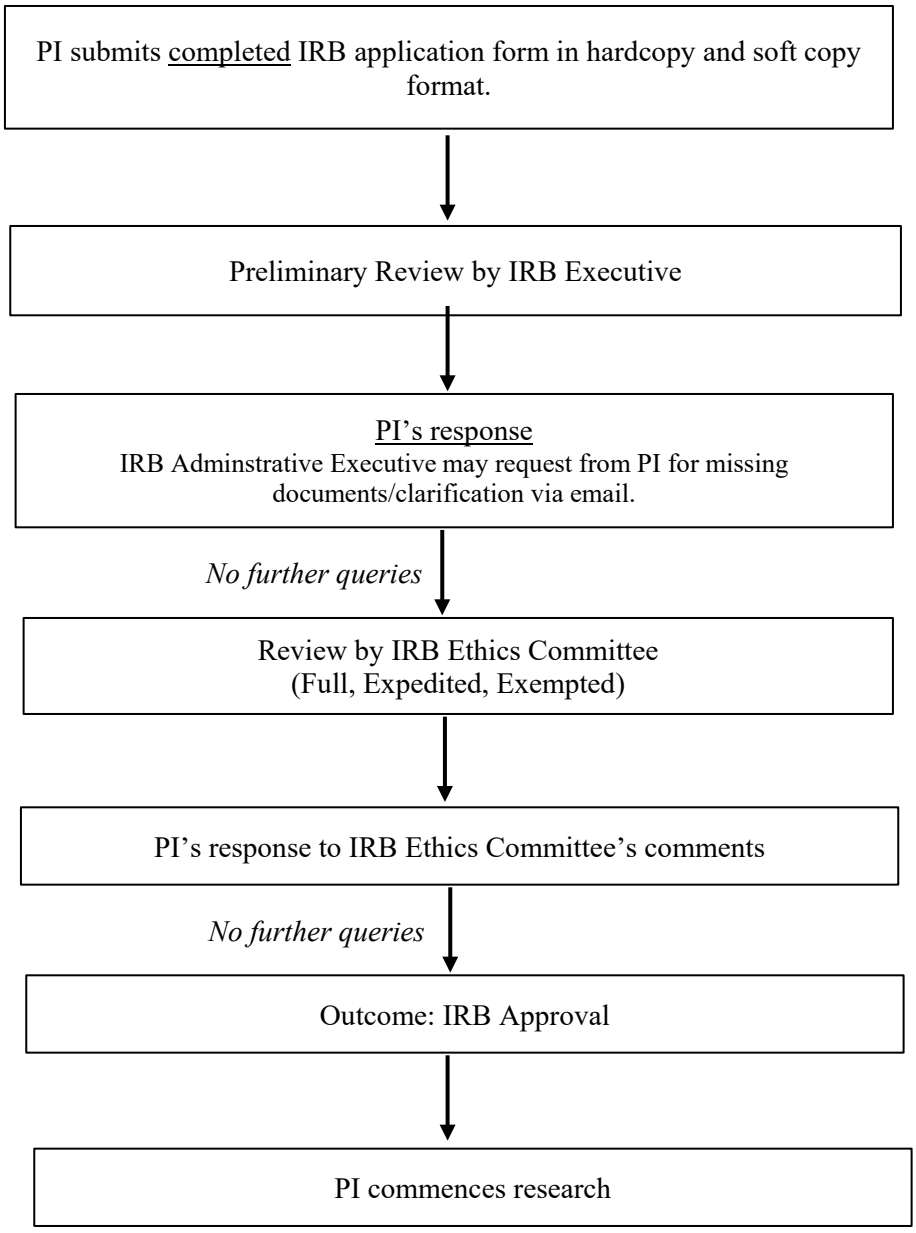
- Belmont Report and CITI Course Introduction
- History and Ethics of Human Subjects Research
- Informed Consent
- Social and Behavioural Research (SBR) for Biomedical Researchers
- records-Based Research
- Genetic Research in Human Populations
- Populations in Research Requiring Additional Considerations and/or Protections
- Vulnerable Subjects - Research Involving Prisoners
- Vulnerable Subjects - Research Involving Children
- Vulnerable Subjects - Research Involving Pregnant Women, Human Fetuses, and Neonates
- Conflicts of Interest in Research Involving Human Subjects

Even though ACMS-IRB will not be reviewing research studies which involve interception of treatment or therapies on human subjects at this moment, all researchers are highly recommended to obtain this certificate.

2 INITIAL SUBMISSION

Research studies requiring IRB approval must be submitted in both hardcopy and softcopy for review. No research activities may be carried out before approval is granted.

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



Once submitted, a preliminary review will be conducted on the completeness of the submission and suitability of the review type. For studies that require exemption and expedited review, they will

be reviewed by the Board Chairperson or a nominated IRB member. For studies that require full board review, they will be reviewed at convened meetings at which a quorum is present. The PI may be called into the review meeting to provide with more information on the study proposal. Notifications of approval or revisions will be communicated by the Administrative Executive.

The review type is determined based on the level of risk to which research participants are exposed. The determination of the type of review is to be made by IRB. Below is a summary of the information.

	Exempted Review	**Expedited Review**	**Full Board Review**
Exemption Category	One of the exemption categories (1-10) has to be met	-	-
Risk[1]	Minimal/ less than minimal risk	Minimal/ less than minimal risk	More than minimal risk
Submission Deadline	Submitted any time	Submitted any time	First working day of the month (except December)
Review Timeline[2]	Within 30 calendar days from the date of receipt	Within 30 calendar days from the date of receipt	Within 60 calendar days from the date of receipt

[1]*Note: Minimal risk is defined as "the probability and magnitude of harm or discomfort anticipated in the research are not greater than those ordinarily encountered in daily life, or during the performance of routine physical or physiological examinations or tests."*

[2]*Note: This could vary depending on several factors such as the completeness, and quality of the application, the complexity of the study and response time to IRB's queries.*

3 IRB MEETING DATES

The IRB will conduct full board review at a convened meeting 3 times a year or at an ad hoc basis.

Applications should be submitted with sufficient lead time for the ACMS IRB to review. A preliminary review to evaluate the completeness of the submitted application will be conducted. This may include requests for additional information and clarifications.

All IRB applications will require full board review and applicants are to observe the submission deadline.

Applicants are required to submit 1 hardcopy and 1 softcopy of the research application form.

Hardcopy is to be mailed to the following address:

新加坡中医研究院科研道德委员会秘书
705 Serangoon Road Singapore 328127

Softcopy is to be emailed to research@academycms.org and addressed to the secretariat of ACMS IRB.

Submission Deadline: 1st working day of the month

This deadline is only applicable to research studies that require full board review. Most minimal risk studies are reviewed through the exempted or expedited procedures by the Chairman or assigned IRB member which occurs on an ongoing basis. This determination will be made by the IRB.

4 IRB AMENDMENT FORM

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.

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 unless the following changes are made to the approved application.
• Change in PI/ Site-PI
• Addition of study site(s)
• Significant changes to the protocol
• Changes in the form type

All amendment requests should be submitted to IRB Administrative Executive via softcopy for review. Softcopy is to be sent via email to research@academycms.org and addressed to the secretariat of ACMS IRB.

The IRB Amendment Form should have the edited sections and study documents marked out to indicate the requested changes.

The form can only be submitted by the PI and only one amendment form can be submitted at any one time.

5 STUDY RENEWAL

For renewing of IRB approvals, the PI is to use the Status Report Form. The study renewal report form is to be used for renewing IRB approvals. The approval validity period granted by IRB for approved applications is one year (12 months). For research studies that will continue beyond one year, the PI must submit a request for renewal via email to IRB Administrative Executive. It is the responsibility of the PI to submit the Status Report Form with sufficient time before 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 IRB application for protocol deviation and non-compliance report form has to be submitted to IRB.

IRB Administrative Executive will send email notifications beginning 3 months (90 days) before the study expiration. The notifications sent are as follows.

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

Continuing review of expedited or full board approved applications will be conducted with the same diligence as 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 participants, 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 exempted studies, the requirement for continuing review is waived.

All renewal requests should be submitted to IRB Administrative Executive via email for review.

The form can only be submitted by the PI and only one Status Report Form can be submitted at any one time.

6 STUDY REACTIVATION

To re-open a research study that was previously closed or where approval has lapsed, the IRB application form (with any amended changes highlighted in yellow) and the Status Report Form is to be used. All studies must retain an active 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.

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

The form can only be submitted by the PI and only one IRB application form and Status Report Form can be submitted at any one time.

7 STUDY CLOSURE

To report study closure, termination or withdrawal, the Status Report Form is to be used. The form is to be submitted to IRB via email to IRB Administrative Executive within the following timeframe.

Study Closure – Within 30 days

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.

Study Termination – Within 7 days

The study may be terminated by the PI, Institution or sponsor if the study is stopped before site initiation.

Study Withdrawal – Within 7 days

The study may be withdrawn by the PI, Institution or sponsor if the study is stopped after site initiation.

The form can only be submitted by the PI and only one Status Report Form can be submitted at any one time.

8 PROTOCOL DEVIATION & NON-COMPLIANCE REPORT FORM

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 IRB and other applicable regulatory requirements (i.e. non-compliance) should be reported to the IRB Administrative Executive via email immediately using the Protocol Deviation/Non-compliance Report form.

The form can only be submitted by the PI. Multiple protocol deviation & non-compliance report forms can be submitted at any one time.

9 LOCAL SERIOUS ADVERSE EVENT (LSAE) REPORT FORM

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 IRB constitutes a local serious event. It should be reported to the IRB via email to the IRB Administrative Executive using the LSAE Report Form. For the reporting timeline, refer to the guidelines on reporting timeline on LSAE.

The form can only be submitted by the PI, Site-PI and Co-I. Multiple LSAE report forms can be submitted at any one time.