AIC Institutional Review Board - Frequently Asked Questions

1. Who can submit applications to the AIC IRB?

The AIC IRB **only** accepts research applications from the community care and social service sectors. Contact the AIC IRB Secretariat by email at IRB@aic.sg if you are unsure.

Community Care Sector
Institutions providing community care services that are in line with the Singapore Ministry of Health's licensing or service requirements may apply to the AIC IRB. Community hospitals, nursing homes, hospices, home care providers, and centre-based care providers are eligible. Other organizations are not eligible.

Social Service Sector
Institutions providing social services that are in line with the National Council of Social Service (NCSS)'s licensing or service requirements may apply to the AIC IRB. Social Service Agencies and Institutions of a Public Character (IPC) are eligible. Other organizations are not eligible.

2. How do I know if my project requires an ethics review?

You can do a simple self-assessment using the "Checklist for Proposed Activity" available on the AIC IRB webpage to check whether your project requires ethics review. The outcome of your self-assessment may differ from that of the AIC IRB. In that case, the AIC IRB's determination is final.

3. How do I know if my research study is considered Human Biomedical Research?

Section A, 9 of the "IRB Application Form" contains a simple self-assessment. Do contact the AIC IRB Secretariat by email at IRB@aic.sg if you are unsure.

4. What is a Research Institution?

The term Research Institution (RI) refers to a Singapore-based entity that employs and supervises scientific researchers to conduct studies involving human participants. The Human Biomedical Research Act (HBRA) requires that all such research be supervised by RIs.

More information about the HBRA can be found at the Ministry of Health (MOH) website: https://www.moh.gov.sg/policies-and-legislation/human-biomedical-research-act

An organization can notify MOH of its intention to become an RI via the Tissue and Research Application System (TIARAS)

https://elis.moh.gov.sg/tiaras/#!/login, MOH's online portal for HBRA-related notifications. Declaration of RI status requires the appointment of a Principal Person-in-Charge (PPIC), whose role is to supervise the researchers conducting studies at that organization. As an RI, the organization is expected to (among other requirements):

- File annual declarations of compliance online. The costs payable to MOH are $1,000 for the organization's headquarters and $500 per additional study site not in the same postal code.
- Appoint an Institutional Review Board (IRB) (which may be external to the RI).
- Report unexpected adverse events that occur in the course of research studies.

5. Does my organization have to become a Research Institution?

Your organization only has to become a Research Institution (RI) if you are conducting human biomedical research. If this is needed, your organization may enter into an arrangement, contractual or otherwise, with an RI which agrees to supervise the conduct of your research project.

6. How soon will I know the outcome of my IRB application?

Members of the AIC IRB will only review applications that have been assessed by the AIC IRB Secretariat to be complete. The AIC IRB review process* for complete applications may take between 3 to 4 months depending on the complexity of the application.

A checklist to determine if the application is complete can be found on the last page of the AIC Application Form.

*Do note that the IRB review process will only start when the submitted documents have been assessed to be complete and in good order.

7. What is the AIC IRB review process like?

Details on submission can be found at the AIC IRB website. Once a complete application is submitted, a preliminary review will be conducted by the AIC IRB where the principal investigator may be required to provide further clarifications. If there are no further enquiries, the application will be classified into either "Exempt", "Expedited", or "Full" Review:

Exempt Review

- Research involves less than minimal risk to participants and no identifiable data is collected.

- Involves anonymous surveys and questionnaires, collection or study of anonymous existing data or tissue specimens etc.

Expedited Review

- Research involves no more than minimal risk to participants.
- Risks related to invasion of privacy and breach of confidentiality are no greater than minimal.
- Involves non-anonymous surveys, interviews, medical case note reviews, or collection of data through routinely employed non-invasive procedures.

Full Review

- Research involves more than minimal risk to participants
- Involves invasive procedures, new programmes that will affect the health of research participants or studying the safety and efficacy of a medicinal product or device etc.

8. If I am collaborating with other organisations (e.g. hospitals or academic institutions), can I submit our study to the AIC IRB for review?

You may submit your study to the AIC IRB for review if (i) you are the principal investigator of the study **and** (ii) your research team does not have access to another IRB.

However, if you are not the principal investigator (i.e. you are a co-investigator or collaborator), we recommend that the principal investigator submit the IRB application to the IRB affiliated to his/her organization. For example, if the principal investigator is from the National Healthcare Group (NHG), he/she should submit the IRB application to the NHG's IRB (DSRB).

9. What is the difference between the Principal Investigator, Co-Investigator and Collaborator?

- The **Principal Investigator** or **PI** is an individual who assumes the ultimate authority and responsibility for the conduct of a research study. The PI is responsible for promoting proper conduct of research by assuring adherence to approved study methodology, ensuring adequate resources to conduct the study, protecting the rights and welfare of participants, assuring the integrity of collected data and directing the conduct of research according to applicable regulations and guidance.

- The **Co-investigator** or **Co-I** refers to the person listed as such in the Institutional Review Board (IRB) application. This person is part of the research team, designated by the principal investigator to perform study-related procedures and / or make important research-related decisions.

- The **Collaborator** refers to the person recognised in approval or agreement documents (Eg. IRB documents, Research Collaboration Agreement, Service Agreement, Letter of Agreement, Letter of Understanding) as being a collaborator. This person is part of the research team but is not involved in study design, consent taking, primary data collection, and/or data analyses. His/Her primary contribution is in making connections between investigators and study sites to facilitate the study.

10. How much does AIC IRB charge to review an application?

The AIC IRB does not currently charge for reviews.

As such, the AIC IRB is only able to review applications from principal investigators who are from the community care and social service sectors.

11. What is the CITI Program?

CITI stands for "Collaborative Institutional Training Initiative". This organization provides online research ethics and compliance training. PIs and Co-I(s) who do not have valid CITI certificates from their current or previous places of employment or study may take CITI courses as individual learners. Investigators are advised to check with their employers if they have organization licenses to use CITI.

12. What CITI courses do I have to complete?

Principal investigators are required to complete the Biomedical (Biomed) or the Social-Behavioral-Educational (SBE) CITI courses, which cover basic ethical principles of Human Subjects Research.

13. How long would the CITI courses take to complete?

The CITI courses may take approximately 4 full hours to complete in one sitting.

14. Can I get funding support to complete the CITI course?

There are no standalone funding opportunities for CITI courses. Investigators who are grant recipients (e.g. NMRC Grants or Community Care Research Grant) may use a portion of their grants to pay for CITI courses. Investigators should check with their funders for more details.