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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1. Training Resources >>>

All SingHealth researchers who are involved in the design, conduct, oversight or management of research are required to attend the minimum research ethics and compliance training to help them understand and apply to the day-to-day practice of research. This helps to ensure 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
Clinical Trials	CITI Program	✓	✓
	ICH Good Clinical Practice ICH GCP E6 (R2)	✓	
Human Biomedical Research (HBR), Tissue Banking activities and all other human subject research	CITI Program	✓	✓
	SingHealth eHBRA training or equivalent	✓	✓

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

1.1 CITI (Biomedical Research Investigators & Key Personnel Module) Programme >>

The online Collaborative Institutional Training Initiative (CITI) programme is designed to educate researchers about research involving human subject. 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 (internet)

Study team members who are not from SingHealth or NHG and Partner Institutions are encouraged to complete the online CITI course. However, they may request for waiver of this requirement. The form is available at the "Templates" section under the "Forms & Resources" page.

Note: For studies that are mutually recognised, minimum training requirement for NHG and Partner Institutions staff would apply.

There will be a series of learning modules and for SingHealth, the required course is:

a. "Biomedical Research Investigators and Key Personnel"
or
b. Required CITI modules:

- Belmont Report and CITI Course Introduction
- History and Ethics of Human Subjects Research
- Informed Consent
- Social and Behavioral 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

1.2 Good Clinical Practice (GCP) Training >>

GCP training aims to ensure:

- The rights, safety and well-being of human subjects are protected
- Clinical trials are conducted in accordance with approved protocols with integrity and reproducibility

SingHealth PIs and Site-PIs conducting clinical trials regulated by the following are to complete the local GCP course:

- Health Products Act and Health Products (Clinical Trials) Regulations
- Medicines Act and Medicines (Clinical Trials) Regulations

Ethics approval will not be granted for clinical trials applications until the proof for the completion of the local GCP course is provided.

Certificate obtained from the GCP workshops conducted by the following institutions is acceptable:

- SingHealth Academy
- National Healthcare Group (classroom-based or online)
- National University Health Systems (NUHS)
- Online iGCP course with National University of Singapore

1.3 Human Biomedical Research Act (HBRA) Essentials >>

A minimum HBRA training curriculum has been implemented and all researchers involved in Human Biomedical Research (HBR) are required to complete the online training.

This minimum HBRA training is in addition to the CITI training.

Upon completion, a copy of the completion certificate should be kept in the study file. It is not required to be submitted to CIRB.

The HBRA Essentials training can be accessed from here (intranet).

2. Who Can be PI? >>>

Principal Investigator (PI)'s requirements are based on the risk involved in the research study.

2.1 Minumum Risk Studies >>

The research proposals that qualify for Exemption Review/ Expedited Review will be considered to be minimal risk studies.

To be a PI for a minimal risk study, the individu… should at least be:

a) Clinician - Fully Registered … practitioner, or a C… medical pra…
b) Denti…

…ed allied …ntists, research fellows and …services research staff, or as determined to be eligible by the CIRB

2.2 Greater than Minimum R…

The research propo… Review /Exp… are co… …y that does …C) and Clinical Trial …dual should at least be:

…ate Consultant and above.
…ally Registered, Conditionally Registered …emporarily Registered dentist who are Associate Consultants and above.

c) Nursing - SSN - Must have an Associate Consultant and above on the research team.
d) Allied Health staff - Senior therapist/pharmacist - must have an Associate Consultant and above on the research team.

For clinical trial or other clinical research that requires CTC and CTA, the PI should be a:
- Locally Registered doctor or dentist who is an Associate Consultant and above.

Please refer to Illuminaté – Issue 8 for updated PI's requirement

Takeaway message...

Research ethics and compliance training is important to help ensure safety, integrity and quality of research, in compliance with local laws, regulations and international standards.

PI's requirements are based on the risk involved in the research study.

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