

IRB Requirements and Submission Process Guide



Learning Objectives

- Evaluate research activities to determine IRB requirements and prepare appropriate pre-submission documentation.
- Understand the roles and responsibilities of researchers and Institution.
- Understand the IRB application process.
- Understand the different IRB review categories and potential IRB review outcomes.
- Manage post-approval monitoring and reporting requirements and study closure procedures

Overview: IRB Submission Journey Map

PRE-IRB SUBMISSION

- Determine if your planned activity is research
- Familiarise yourself with the applicable regulations
- Complete all minimum training requirements



DURING IRB SUBMISSION

- Set up an account on ECOS to submit your IRB Application
- Understand the role of researchers & institutions
- Understand IRBs and their review process



POST-IRB APPROVAL

- Understand what needs to be reported
- Prepare for study closure



IRB Submission Journey



Pre-IRB
Submission



During IRB
Submission



Post-IRB
Approval

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Determine If Your Planned Activity Is Research

Studies that do not require IRB review:



Clinical audits



Retrospective review of
1 – 2 case reports



Outbreak investigations,
disease management,
infection control

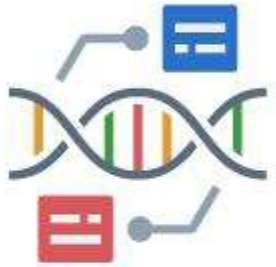


Animal research*

**If meets the definition of
Restricted Research under
HBRA, IRB review is required.*

Determine If Your Planned Activity Is Research

Studies that do not require IRB review:



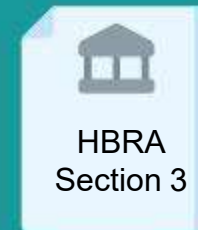
Studies involving
anonymised data or
anonymised Human
Biological Materials (HBM)*



Restricted HBR (rHBR)

***Exceptions:**

OR



Any research that meets
Section 3 (3) of the HBRA

Determine If Your Planned Activity Is Research

Studies that do not require IRB review:



Studies involving
anonymised data or
anonymised Human
Biological Materials (HBM)*



Quality Assurance (QA)
or Quality Improvement
(QI) projects



When the project is
designed to contribute to
generalizable knowledge.

***Exceptions:**

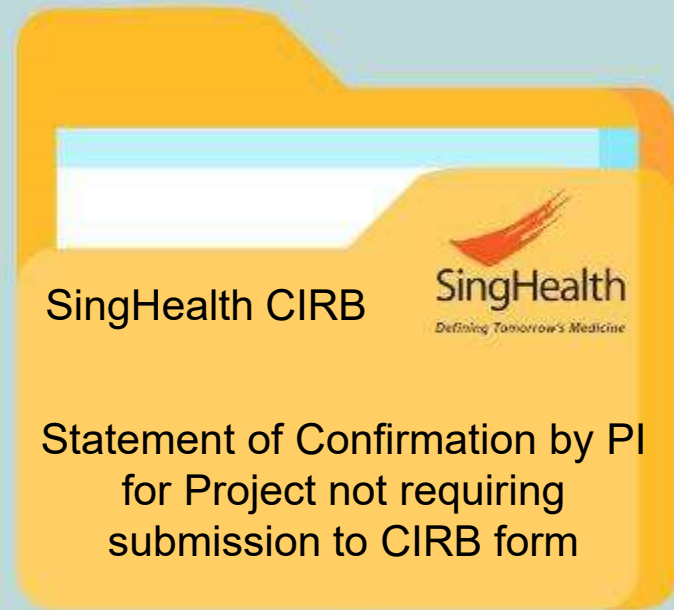
OR



Where participants are
subjected to additional risks or
burdens beyond usual clinical
practice.

Determine If Your Planned Activity Is Research

May use the following documents from the respective IRB to determine if submission to IRB is required:



For QA/QI and Use of Anonymised
data and/or Samples



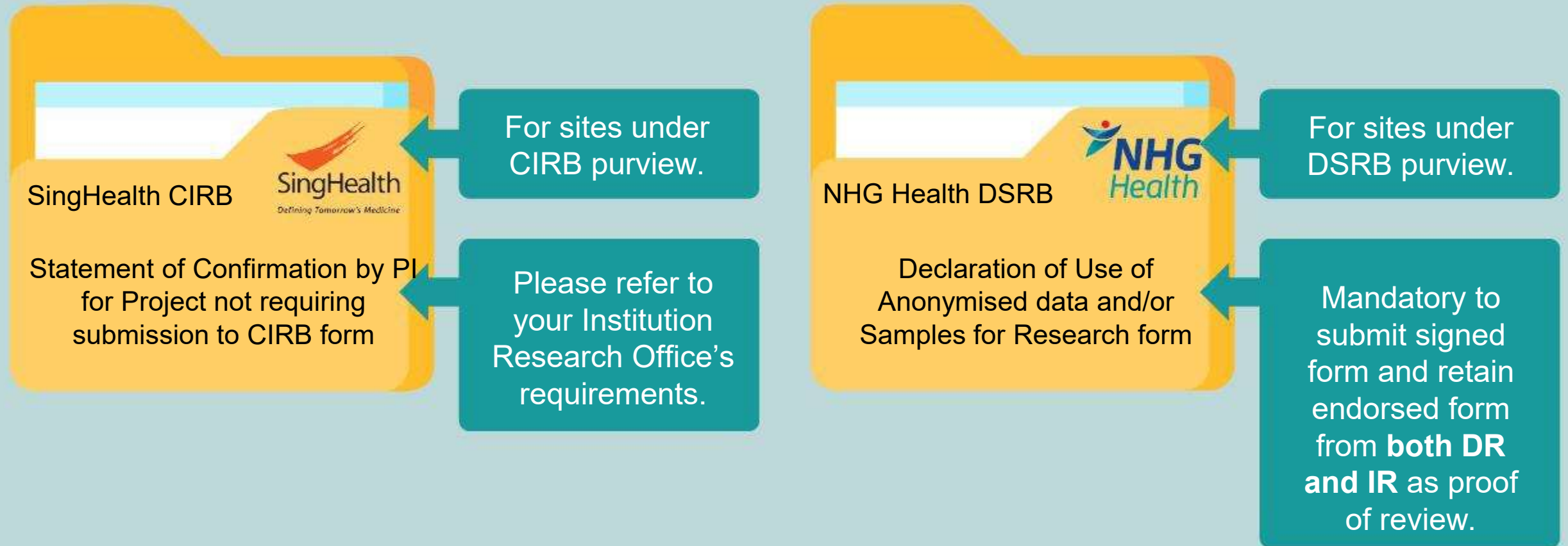
For QA/QI



For Use of Anonymised data and/or
Samples

Determine If Your Planned Activity Is Research

May use for institution determination to show that studies qualify as
'Not Human Subject Research':



Determine If Your Planned Activity Is Research

Department Representative (DR) and Institutional Representative (IR) review:



Both DR & IR agree 'Not Human Subject Research' condition is fulfilled.

- No IRB submission is needed.
- For sites under DSRB purview, the Researcher needs to:
 - Submit the signed form to appropriate departments to receive anonymised data/HBM
 - Retain endorsed form as proof of review.
- For sites under CIRB purview, please check with respective Institution Research Office.

Determine If Your Planned Activity Is Research

Department Representative (DR) and Institutional Representative (IR) review:



DR or IR determines that 'Not Human Subject' condition is **NOT** fulfilled.

- Researchers must submit to IRB for full review.

Familiarise Yourself with the Applicable Regulations

Research studies can be grouped into 3 categories:

Regulated under:



**Health
Products Act**



Medicines Act

[Click to find out more](#)

Regulated under:



**Human
Biomedical
Research Act**

[Click to find out more](#)

Others not
regulated under
HPA, MA, or HBRA



However,
institution policies or
application regulations
must be compiled.

Familiarise Yourself with the Applicable Regulations

All studies should also follow their institution policies and Standard Operating Procedures (SOPs) governing research, and all applicable regulations.

Take Note:

- All studies involving personal data should also comply with **Personal Data Protection Act (PDPA)** requirements.
- The PI should select the study classification in the ECOS IRB Application Form (Section D2) based on the applicable regulations.

Familiarise Yourself with the Applicable Regulations

Approvals Required Before Starting My Research Study



Institution
Review Board
(IRB)



Health Sciences
Authority (HSA)



Ministry of
Health (MOH)



Institutional
Animal Care and
Use Committee
(IACUC)



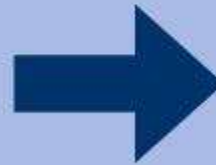
Familiarise Yourself with the Applicable Regulations

Approvals Required Before Starting My Research Study

Institution Review Board (IRB)

Considered Research

- ☒ Systemic investigation
- ☒ Designed to develop/contribute to generalizable knowledge



Requires review and approval by an IRB before study initiation, such as:

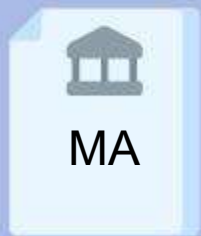
- Clinical trials
- Epidemiological research
- Retrospective medical records review research
- Genetic research

Familiarise Yourself with the Applicable Regulations

Approvals Required Before Starting My Research Study

Health Sciences Authority (HSA)

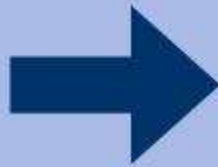
If regulated under:



Medicines Act



Health Product
Act



Should **additionally** be submitted to the HSA for Clinical Trial Notification (CTN), Clinical Trial Authorization (CTA), or Clinical Trial Certificate (CTC) before study initiation.



For all studies:
Ensure that necessary Clinical Research Material (CRM) notification was submitted to HSA.

Familiarise Yourself with the Applicable Regulations

Approvals Required Before Starting My Research Study

Ministry of Health (MOH)



Restricted Human Biomedical Research (as defined in HBRA) requires additional approval from MOH.

Familiarise Yourself with the Applicable Regulations

Approvals Required Before Starting My Research Study

Institutional Animal Care and Use Committee (IACUC)



Additional approval may be required for restricted Human Biomedical Research (where applicable).

Familiarise Yourself with the Applicable Regulations

Approvals Required Before Starting My Research Study



- Your institution may require **other approvals** before a study can commence (e.g. approvals for data extraction).
- To check with respective Institution CRU/ Research Office for information.

Note: Ensure that you have obtained all necessary approvals prior to starting your research study.

Complete All Minimum Training Requirements

Minimum Training Requirements



Required to complete the minimum research ethics and compliance trainings required by respective approving IRB and Research Institution.

Complete All Minimum Training Requirements

SingHealth CIRB's Minimum Training Requirements

Types of Research	Minimum Training Requirements
Human Subject's Research: Non-Human Biomedical Research (HBR) and Non-Clinical Trial (CT)	• Collaborative Institutional Training Initiative (CITI) Program – Biomedical Research Investigators and Key Personnel Module.
Human Biomedical Research (HBR) (HBRA-regulated)	• CITI Program – Biomedical Research Investigators and Key Personnel Module; and • SingHealth eHBRA training or equivalent.
Clinical Trials (CT) (HSA-regulated)	• CITI Program – Biomedical Research Investigators and Key Personnel Module; and • International Committee on Harmonization of Good Clinical Practice ICH-GCP E6 (R3) course.

Complete All Minimum Training Requirements

NHG Health DSRB & Research Institution’s Minimum Training Requirements

The training requirements are as follows:

Training Requirements		DSRB Minimum Training Requirements			RI HBR Minimum Training
Types of Research	Study Role	NHG Health CITI	NHG Health FCOI	ICH-GCP	
Non-Human Biomedical Research (HBR) and Non-Clinical Trials (CT)	PI, Site PI, Co-I	✓	✓		
	Other Study Team Members				
Human Biomedical Research (HBR) (HBRA regulated)	PI, Site PI, Co-I	✓			✓
	Other Study Team Members				
Clinical Trials (CT) (HSA regulated)	PI, Site PI, Co-I			✓	
	Other Study Team Members			✓	
Social, Behavioural, Educational Research	PI, Site PI, Co-I	✓			✓ (If regulated by HBRA)
	Other Study Team Members				

Complete All Minimum Training Requirements

Additional DSRB Requirement: Financial Conflict of Interest (FCOI) Declaration

Protection of
participants



Credibility of human
research protection
programme

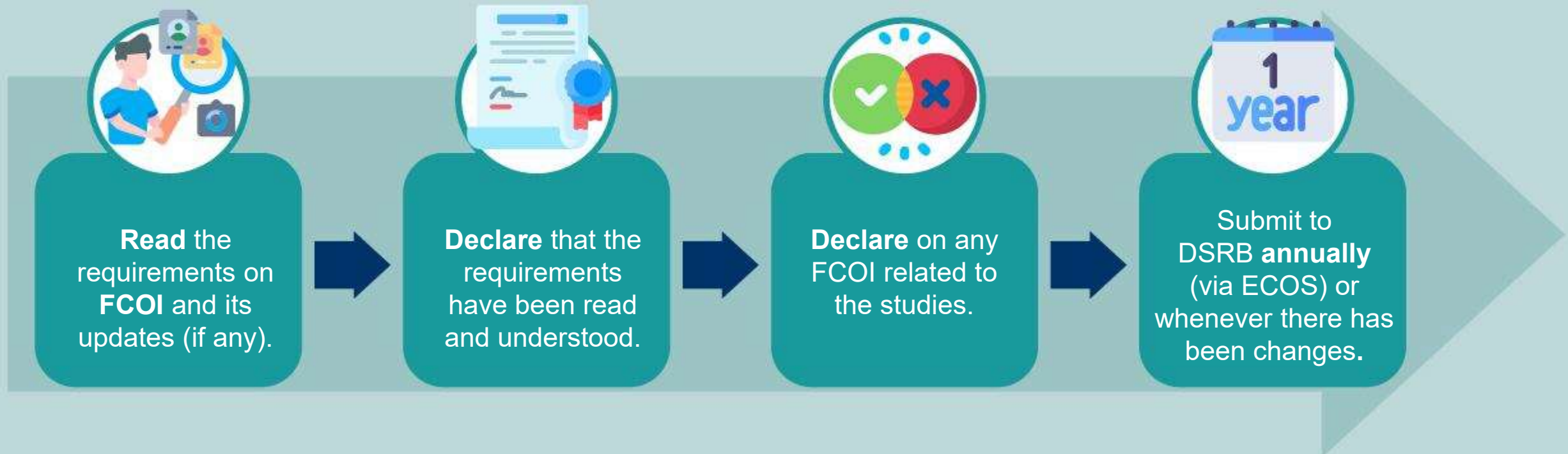


Investigators and study team members who are involved in research that is conducted under the oversight of NHG Health or partner institutions should not have conflicting interests.

Complete All Minimum Training Requirements

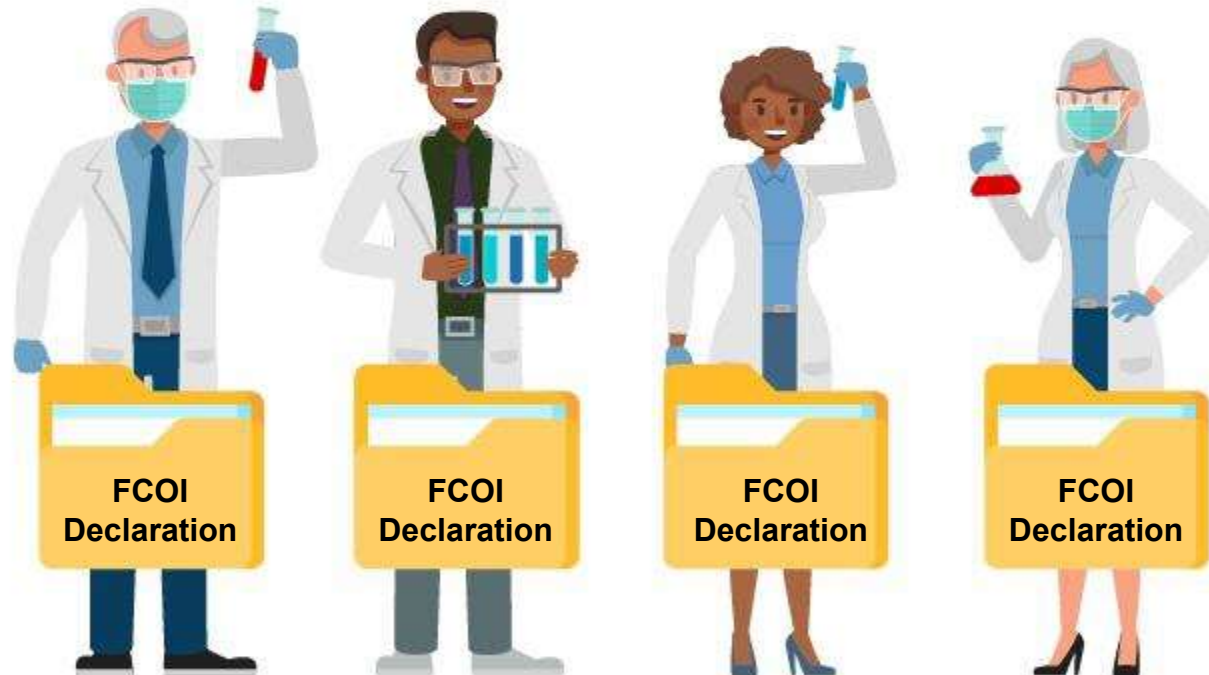
Additional DSRB Requirement: Financial Conflict of Interest (FCOI) Declaration

All investigators and study team members who are involved in the design, conduct or reporting of research that is conducted under the oversight of NHG Health or its partner institutions are required to:



Complete All Minimum Training Requirements

Additional DSRB Requirement: Financial Conflict of Interest (FCOI) Declaration



Note: FCOI Declaration is based on individual declaration annually, not on per study basis.



Learning Checkpoint

01

Which of the following studies will **NOT** require IRB review?

Studies involving anonymised data or anonymised Human Biological Materials (HBM)

Quality Assurance (QA) or Quality Improvement (QI) projects designed to contribute to generalizable knowledge

Retrospective review of 5 case reports

01

Which of the following studies will **NOT** require IRB review?

Studies involving anonymised data or anonymised Human Biological Materials (HBM)



Quality Assurance (QA) or Quality Improvement (QI) projects designed to contribute to generalizable knowledge

Retrospective review of 5 case reports

That's correct

Rationale: Studies that Do Not Require IRB Review



Clinical audits



Retrospective review of 1 – 2 case reports



Outbreak investigations, disease management, infection control



Animal research (unless meets the definition of Restricted Research under HBRA)



Studies involving anonymised data or anonymised Human Biological Materials (HBM)*

*Exceptions:

- Restricted HBR (rHBR)
- Any research that meets Section 3 (3) of the HBRA



Quality Assurance (QA) or Quality Improvement (QI) projects

Exceptions:

- When the project is designed to contribute to generalizable knowledge
- Where participants are subjected to additional risks or burdens beyond usual clinical practice

IRB Submission Journey



Pre-IRB
Submission



During IRB
Submission



Post-IRB
Approval



Overview: IRB Submission Journey Map

PRE-IRB SUBMISSION

- Determine if your planned activity is research
- Familiarise yourself with the applicable regulations
- Complete all minimum training requirements



DURING IRB SUBMISSION

- **Set up an account on ECOS to submit your IRB Application**
- **Understand the role of researchers & institutions**
- **Understand IRBs and their review process**



POST-IRB APPROVAL

- Understand what needs to be reported
- Prepare for study closure



Set Up an Account on ECOS to Submit Your IRB Application

1

Ethics and Compliance Online System (ECOS):

<https://www.ecos-research.com.sg>



All IRB submissions are done via ECOS.

2

Set up account and complete User Profile.



May refer to ECOS User Guides.

3

Upload Minimum Training Certificates for verification.



Set Up an Account on ECOS to Submit Your IRB Application



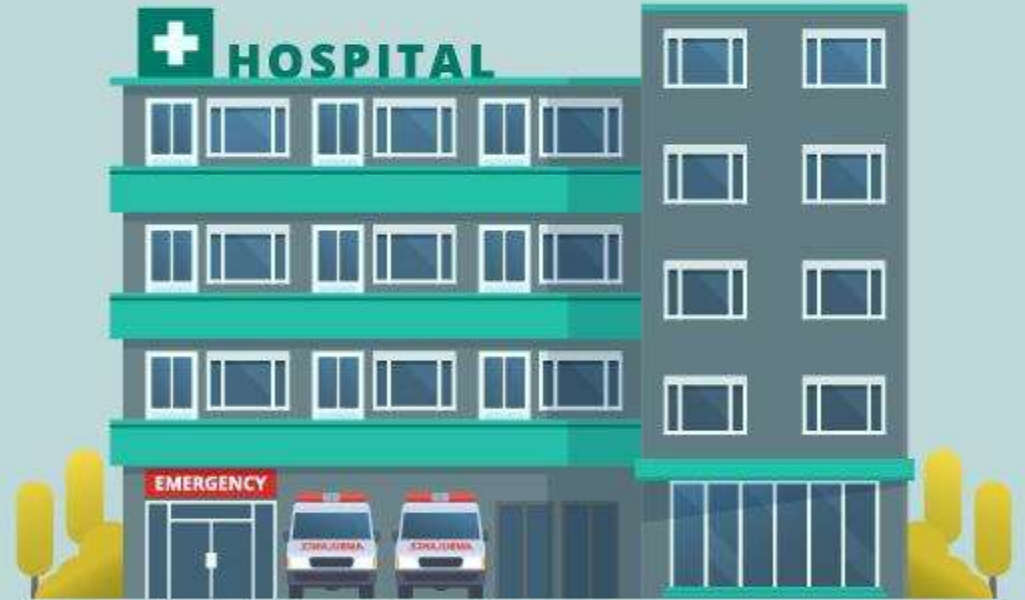
Ensure that all Site PIs & Co-Is have completed all required minimum training.

Understand the Role of Researchers and Institutions

Important to understand the roles and responsibilities of:



PI, Site-PI & Study Team Members



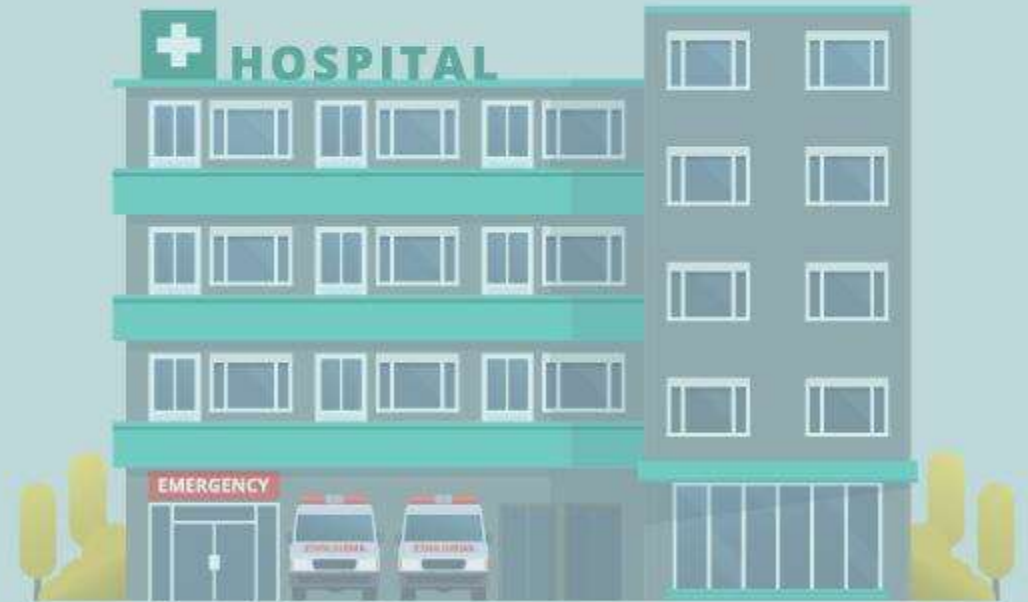
Institutions

Understand the Role of Researchers and Institutions

Important to understand the roles and responsibilities of:

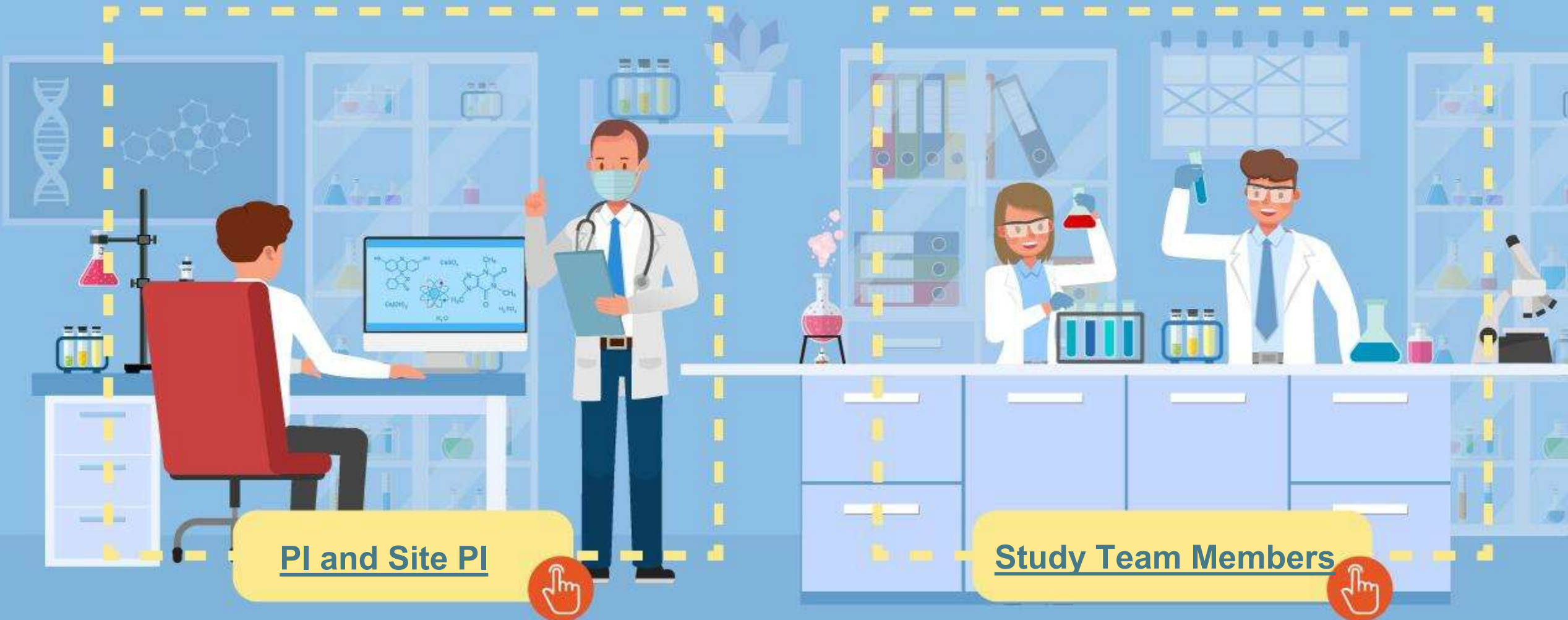


PI, Site-PI & Study Team Members



Institutions

Understand the Role of Researchers and Institutions



Understand the Role of Researchers and Institutions

Roles & Responsibilities of PI and Site PI



Ensure proper research conduct.



Complete and submit IRB Application Form on ECOS



Safeguard rights, safety, and well-being of research participants.



Oversee research team if multiple individuals involved.

Understand the Role of Researchers and Institutions

Roles & Responsibilities of PI and Site PI



Delegate and train study team members.



Maintain the investigator file and essential records.



Provide adequate medical care to participants throughout the study (e.g. at screening, enrollment, study visits, managing adverse events).



Obtain informed consent from participants.

Understand the Role of Researchers and Institutions

Roles & Responsibilities of PI and Site PI



Communicate with the IRB regarding approvals, continuing reviews, safety reporting, non-compliances, etc.



Manage the investigational products (if any).



Ensure all IRB submissions are prepared and completed, maintaining oversight even when tasks are delegated.

Understand the Role of Researchers and Institutions

Roles & Responsibilities of Study Team Members



Co-Investigators



Other Study Team Members

Understand the Role of Researchers and Institutions

Roles & Responsibilities of Study Team Members



Co-Investigators

Members of the research/clinical trial team designated by the PI to:

- Perform study related procedures, and/or
- Make important research related decisions.

Understand the Role of Researchers and Institutions

Roles & Responsibilities of Study Team Members



Individuals who are directly involved in a research study.

- Roles and responsibilities of each study team member varies.
- This would be recorded in the study delegation log.

Other Study Team Members

Understand the Role of Researchers and Institutions

Roles on ECOS

Only the following are required to be listed in IRB application form:



**Principal
Investigator**



**Site Principal
Investigator**



Co-Investigator

Understand the Role of Researchers and Institutions

Roles on ECOS

Update your list of study team in the Clinical Research Management System (CRMS) module if access to the study on ECOS is required for other study team members:

Study Team Role	Role on ECOS	ECOS Module
Site Investigators directly involved in the research.	PI, Site PI & Co-I	IRB Module
Site personnel <u>directly</u> involved in the research conduct e.g. CRC, Study Nurses, Pharmacists, etc.	Study Team Member (STM)	IRB CRMS Module
Site personnel <u>not directly</u> involved in the research but provides administrative support only e.g. Executives, CRCs not involved in the conduct of research.	Study Administrator (SA)	
Sponsor / CRO personnel e.g. CTAs, CRAs, CTMs etc.	Study Sponsor (SS)	

Understand the Role of Researchers and Institutions

Roles on ECOS

Update your list of study team in the Clinical Research Management System (CRMS) module if access to the study on ECOS is required for other study team members:

Study Team Role	Role on ECOS	ECOS Module
Site Investigators directly involved in research	Study Principal Investigator (PI)	ECOS Module
Site personnel <u>directly</u> involved in research and conduct e.g. CRC, Study Nurse	Study Sub Investigator (SI)	CRMS Module
Site personnel <u>not directly</u> involved in research but provides administrative support e.g. Research Executives, CRCs not involved in research.	Study Sub Investigator (SI)	CRMS Module
Sponsor / CRO personnel e.g. CTAs, CRAs, CTMs etc.	Study Sponsor (SS)	



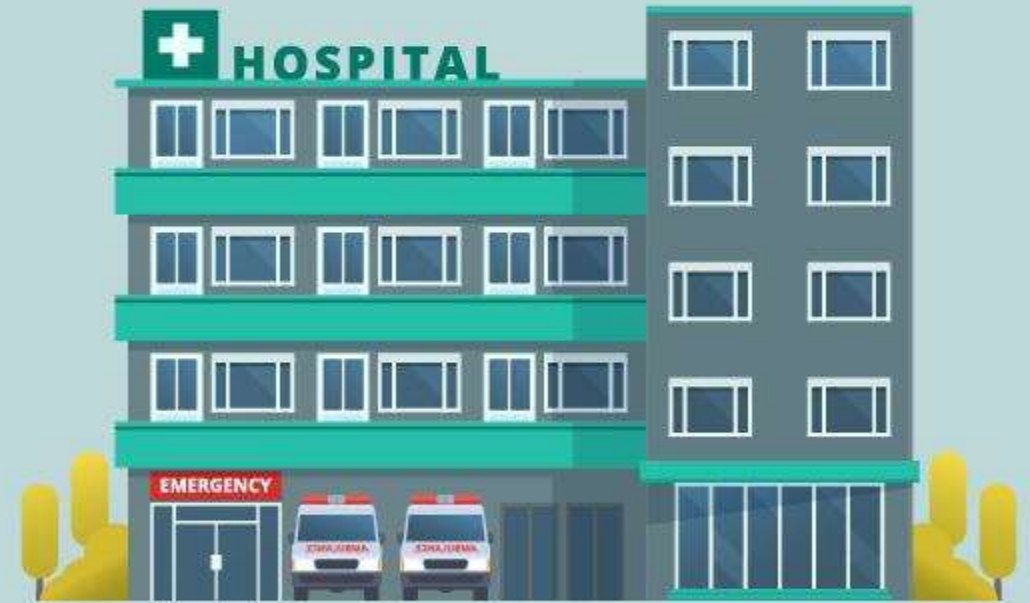
STM, SA or SS roles on ECOS can all view and edit the IRB forms. However, submissions can only be performed by the PI.

Understand the Role of Researchers and Institutions

Important to understand the roles and responsibilities



PI, Site-PI & Study Team Members



Institutions

Understand the Role of Researchers and Institutions

Roles and Responsibilities of Institutions



Research Office
Checker (ROC)



Department
Representative (DR)



Institution
Representative (IR)



Understand the Role of Researchers and Institutions

Roles and Responsibilities of Institutions

Research Office Checker (ROC)

Plays a key role in ensuring that a research study is in keeping with the Institution's research objectives, reputation and standards.



Determine whether the PI is adequately trained, qualified, possesses sufficient time and resources to carry out the research study.



Ensure that the study submitted meets the institution requirements, in compliance with regulatory requirements and ethical standards.

For Institutions that opted for ROC role, study submissions will be checked by the ROC before it goes to the Department Representative (DR).

Hence additional time should be catered by the PI for the review.

Understand the Role of Researchers and Institutions

Roles and Responsibilities of Institutions

Department Representative (DR)

The DR will be:

Head of Department

Chief

Department Research Head

Plays a key role in ensuring that a research study is in keeping with the relevant departments' and institutions' research objectives, reputation, and standards.

Complete an assessment of the significance, concept and innovation of a research study.

Determine whether the PI is adequately trained, qualified, possesses sufficient time and resources to carry out the research study.

Endorse all applications made to the IRB.



DR endorsement is required before the submission to the Institution Representative (IR) for endorsement.

Understand the Role of Researchers and Institutions

Roles and Responsibilities of Institutions

Institution Representative (IR)

Determined by each institution as the authority to approve any research study to be conducted in the institution.



To assess whether the research aligns with the institution's research objectives, reputation, and standards.



To evaluate the scientific/ethical merits of the research study.



IR endorsement is required before the submission to the IRB for review.

Understand IRBs and Their Review Process

Introduction to Institutional Review Board (IRB)

STRUCTURE

- Independent Committee constituted of medical, scientific and non-scientific members.



RESPONSIBILITY

- To ensure protection of the rights, safety and well-being of human participants involved in research.



HOW

- By reviewing, approving and providing continuing review of research studies and amendments.



WHY

- To facilitate safe and ethical research.



Understand IRBs and Their Review Process

Role of IRB

IRBs will review all research studies involving:



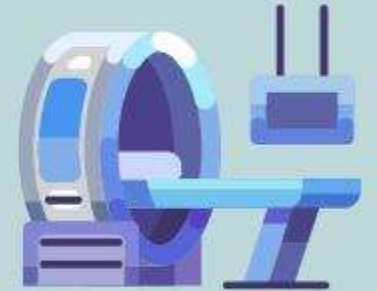
Patients



Staff



Premises



Facilities

For all institutions under the purview of the respective IRBs.

Understand IRBs and Their Review Process

Role of IRB

IRB reviews proposed research involving human participants to ensure:



Risk to participants are minimized.



Participants are assured that their privacy and confidentiality are protected.



Additional safeguards are included to protect vulnerable participants such as minors and individuals with cognitive impairment.

Understand IRBs and Their Review Process

Role of IRB

IRB reviews proposed research involving human participants to ensure:



Potential benefits outweigh the risk to the participants



Participants are selected in a fair and equitable manner.



Participants are fully informed of the potential risks and benefits participating in the research and their consent is documented.



Informed consent may be waived on a case-by-case basis, depending on the nature of the research and participant to IRB review.

Understand IRBs and Their Review Process

Different Boards and Domains



DSRB



CIRB



Understand IRBs and Their Review Process

Different Boards and Domains

NHG Health Domain Specific Review Board (DSRB)

Independent committee constituted of:



Medical
members



Scientific
members



Non-scientific
members

Understand IRBs and Their Review Process

Different Boards and Domains

NHG Health Domain Specific Review Board (DSRB)

Providing comprehensive ethics review of research protocols to protect:



Rights



Safety



Well-being

For human participants in NHG health institutions and NUHS.

Understand IRBs and Their Review Process

Different Boards and Domains

NHG Health Domain Specific Review Board (DSRB)

Domain A

- Ophthalmology, Psychiatry, Neurology/Neurosurgery, Genetics, Geriatric Medicine, Palliative Medicine

Domain B

- Oncology, Hematology, Pathology, Paediatrics, Respiratory Medicine

Domain C

- Cardiovascular Science, Pharmacology, Emergency Medicine, Endocrinology, Diagnostic Imaging, Family Medicine

Domain D

- Obs/Gynaecology, Anaesthesia, Surgery, ENT, Dentistry, Sports and Rehab Medicine, Allied Health

Domain E

- Infectious Disease, Gastroenterology, Renal Medicine, Rheumatology/Immunology, Dermatology

Domain F

- Health Services and Outcomes Research, Education Research, Research on Prevention and Health Promotion Programmes, Social and Behavioural Research, Epidemiological Research, Community-based Participatory Research

Understand IRBs and Their Review Process

Different Boards and Domains

SingHealth Centralised Institutional Review Board (CIRB)

Independent body constituted of:



Medical
members



Scientific
members



Non-scientific
members

Understand IRBs and Their Review Process

Different Boards and Domains

SingHealth Centralised Institutional Review Board (CIRB)

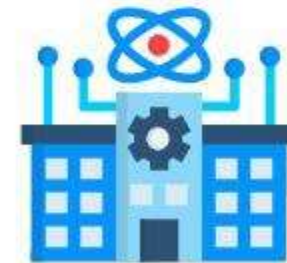
Provides independent and timely review of research studies:



Involving
SingHealth
patients, staff,
facilities



Conducted in
premises of
institutions
under CIRB
oversight



Research
institutions who
appointed CIRB
as reviewing IRB

Understand IRBs and Their Review Process

Different Boards and Domains

SingHealth Centralised Institutional Review Board (CIRB)

Domain A

- Ophthalmology, Psychiatry, Neurology/Neurosurgery, Geriatric Medicine, Nursing, Health Service Research

Domain B

- Oncology

Domain C

- Cardiovascular Science, Pharmacology, Emergency Medicine, Endocrinology, Diagnostic Imaging, Respiratory Medicine

Domain D

- Obs/Gynaecology, Anaesthesia (including acupuncture), Surgery, ENT, Dentistry

Domain E

- Gastroenterology, Renal Medicine, Rheumatology/Immunology, Dermatology, Paediatric Medicine, Family Medicine

Domain F

- Genetics, Palliative Medicine, Haematology (including malignancies), Pathology, Sports & Rehab Medicine, Allied Health, Infectious Disease

Understand IRBs and Their Review Process

Mutual IRB Recognition and Single IRB Review for Collaborative Studies

With effect from 1 April 2025, all new IRB applications involving the following institutions will only need to be reviewed by one (1) IRB:



Research studies involving a single site, or multiple sites that are under the purview of only one (1) IRB, will continue to be reviewed by the respective cluster/institution IRBs.

Understand IRBs and Their Review Process

IRB Review Categories

Exempt Review	Expedited Review	Full Board Review
≤ Minimal Risk	Minimal Risk	≥ Minimal Risk

What is Minimal Risk?

“The probability and magnitude of harm or discomfort anticipated in the research are not greater in and of themselves than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.”

Understand IRBs and Their Review Process

IRB Review Categories

Exempt Review	Expedited Review	Full Board Review	
≤ Minimal Risk	Minimal Risk	≥ Minimal Risk	
- Includes all new applications/amendments/study renewals. - New applications and significant amendments would require DR and IR endorsement on ECOS before IRB can start on the review.		- Includes all new applications/amendments/study renewals. - New applications and significant amendments would require DR and IR endorsement on ECOS before IRB can start on the review. - Includes studies with collection of blood exceeding allowable volume, clinical trial studies and studies with collection of data by invasive means. - Includes studies that do not qualify for Exempt or Expedited Review.	
Submissions can be done anytime during the month.		Submission to DSRB Domain A, B2, C, D and E: 15th calendar date of every month or earlier.	Submission to CIRB (all boards) and DSRB Domain B1: 1st working day of every month or earlier.

Understand IRBs and Their Review Process

IRB Review Categories

Exempt Review	Expedited Review	Full Board Review	
≤ Minimal Risk	Minimal Risk	≥ Minimal Risk	
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Take Note:
Full board schedules for each calendar year are posted on the respective IRB's websites

Understand IRBs and Their Review Process

Research That May Qualify for Exempt Review ($\leq$ Minimal Risk)



S1: Normal
Education
Practices &
Settings



S2: Educational
Tests, Surveys,
Interviews or
Observations



S3: Benign
Behavioural
Interventions



S4: Secondary
Research For
Which Consent
is Not Required



S5: Taste and
Food
Evaluation and
Acceptance



Understand IRBs and Their Review Process

Research That May Qualify for Exempt Review ($\leq$ Minimal Risk)



S1: Normal
Education
Practices &
Settings



- Research on regular and special education instructional strategies.
- Research on the effectiveness of/comparison among instructional techniques, curricula, or classroom management methods.



S4: Secondary
Research For
Which Consent
is Not Required



S5: Taste and
Food
Evaluation and
Acceptance



Understand IRBs and Their Review Process

Research That May Qualify for Exempt Review ($\leq$ Minimal Risk)



S1: Normal
Education
Practices &
Settings



S2: Educational
Tests, Surveys,
Interviews or
Observations



S4: Secondary
Research For
Which Consent
is Not Required



S5: Taste and
Food
Evaluation and
Acceptance



- Research that only includes interactions involving educational tests, survey procedures, interview procedures, or observation of public behaviour.

Understand IRBs and Their Review Process

Research That May Qualify for Exempt Review ($\leq$ Minimal Risk)

Research requiring participants to play an online game, solve a puzzle under various noise conditions, or having them decide how to allocate a nominal amount of received cash between themselves and someone else.



S3: Benign
Behavioural
Interventions



S4: Secondary
Research For
Which Consent
is Not Required



S5: Taste and
Food
Evaluation and
Acceptance

Understand IRBs and Their Review Process

Research That May Qualify for Exempt Review ($\leq$ Minimal Risk)



S1: Normal
Education
Practices &
Settings



S2: Educational
Tests, Surveys,
Interviews or
Observations



S3: Benign
Behavioural
Interventions



S4: Secondary
Research For
Which Consent
is Not Required



- Examining an existing, publicly-available database.



Understand IRBs and Their Review Process

Research That May Qualify for Exempt Review ($\leq$ Minimal Risk)



S1: Normal
Education
Practices &
Settings



S2: Educational
Tests, Surveys,
Interviews or
Observations



S3: Benign
Behavioural
Interventions



Asking participants to taste a set of novel snacks, containing food ingredients found to be safe, to determine consumers' preferences.



S5: Taste and
Food
Evaluation and
Acceptance



Understand IRBs and Their Review Process

Research That May Qualify for Exempt Review ($\leq$ Minimal Risk)



S1: Normal
Education
Practices &
Settings



S2: Educational
Tests, Surveys,
Interviews or
Observations



S3: Benign
Behavioural
Interventions



S4: Secondary
Research For
Which Consent
is Not Required



S5: Taste and
Food
Evaluation and
Acceptance



Understand IRBs and Their Review Process

Research That May Qualify for Exempt Review ($\leq$ Minimal Risk)

Exempt review is not applicable for research



Involving prisoners



Involving children



Regulated by US FDA



Recording of **identifiable** information is **NOT** permitted for S4: Secondary Research For Which Consent is Not Required.

Research that may qualify for exempt review is to be submitted to IRB using **Exempt Application Form (Section D: Study Type and Nature)**.



Understand IRBs and Their Review Process

Documents Required for IRB Submission

For New Submission

- ✓ ICF / application for waiver of informed consent.
- ✓ Study protocol (for clinical trials, involving drugs, medical devices and surgical procedures).
- ✓ Questionnaires, surveys, videotapes and other such research tools (if used).
- ✓ Copy of approved grant application/ notification of award (if the study is a US federally funded research, the approved grant application, study protocol and sample consent form etc.).
- ✓ Investigator's Brochure or other available safety information (for all HSA regulated clinical trials).
- ✓ Written information intended to be provided to participants (if used).

Additional

- ✓ Data collection form.
- ✓ Financial Disclosure statement.
- ✓ Documentation relating to non-approval of study by another IRB.
- ✓ Grant approval letter/sponsorship letter.
- ✓ Any other relevant documentation to be given to participants, in the judgment of the IRB would add meaningfully to the protection of the rights/ safety and/ or well being of the participant.
- ✓ Any other relevant documentation that the reviewing IRB may specifically request.

*Note: The above lists of documents required for IRB submission are not exhaustive.
Kindly check with the respective IRBs for documents required.*

Understand IRBs and Their Review Process

Documents Required for IRB Submission



Translated Informed Consent Forms (e.g. fully translated or short consent forms) and all translated documents (e.g. posters, flyers, brochures, patient diaries/ cards, questionnaires, assessments) **will NOT need to be submitted to IRB** for acknowledgement/ approval.

The PI should ensure the **accuracy of the translations** and ensure that **correct versions** of the translated documents are used.

All versions of the translated documents to be used should be **tracked in the investigator file**.

Understand IRBs and Their Review Process

ECOS Endorsement Process

**Single
Site**

PI Declaration
& Submission



ROC Check
(if applicable)



DR
Endorsement



IR
Endorsement

**Multi
Site**

PI Declaration
& Submission



ROC Check
(if applicable)



DR
Endorsement



IR
Endorsement



Site-PI
Declaration &
Submission



ROC Check
(if applicable)



DR
Endorsement



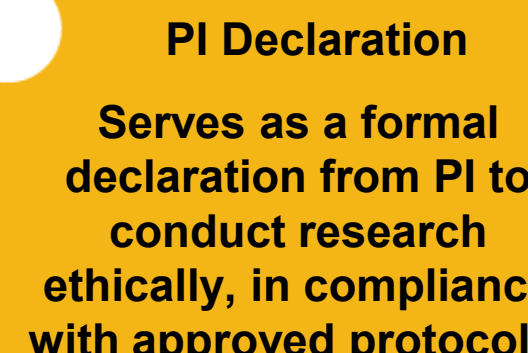
IR
Endorsement

N number of Site-PI declarations and submissions for N number of sites.

Understand IRBs and Their Review Process

PI Declaration

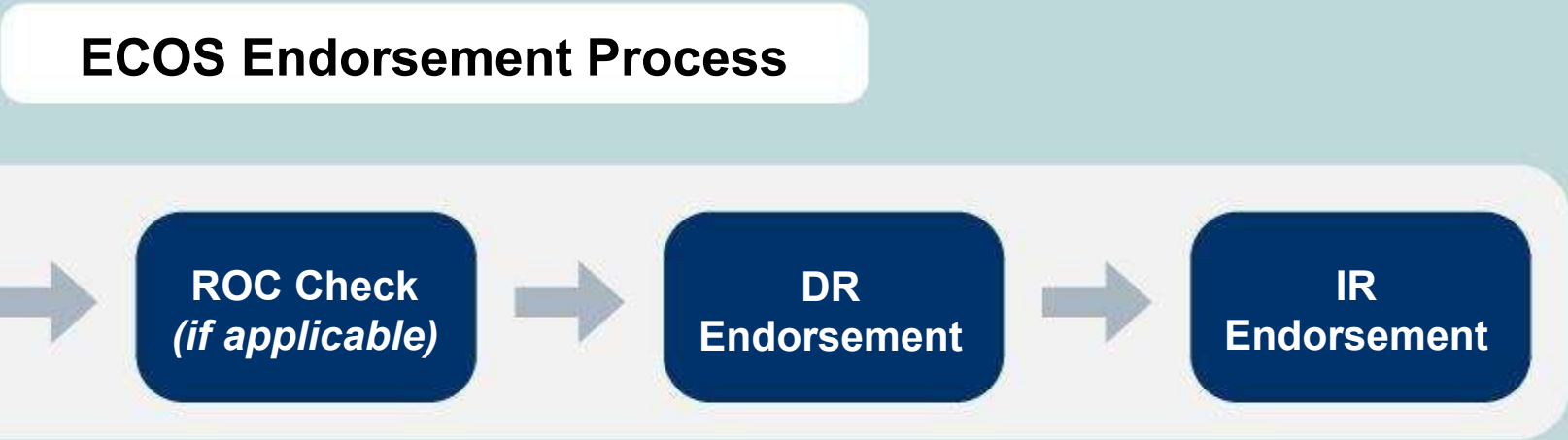
Serves as a formal declaration from PI to conduct research ethically, in compliance with approved protocols.



PI Declaration

Serves as a formal declaration from PI to conduct research ethically, in compliance with approved protocols.

ECOS Endorsement Process

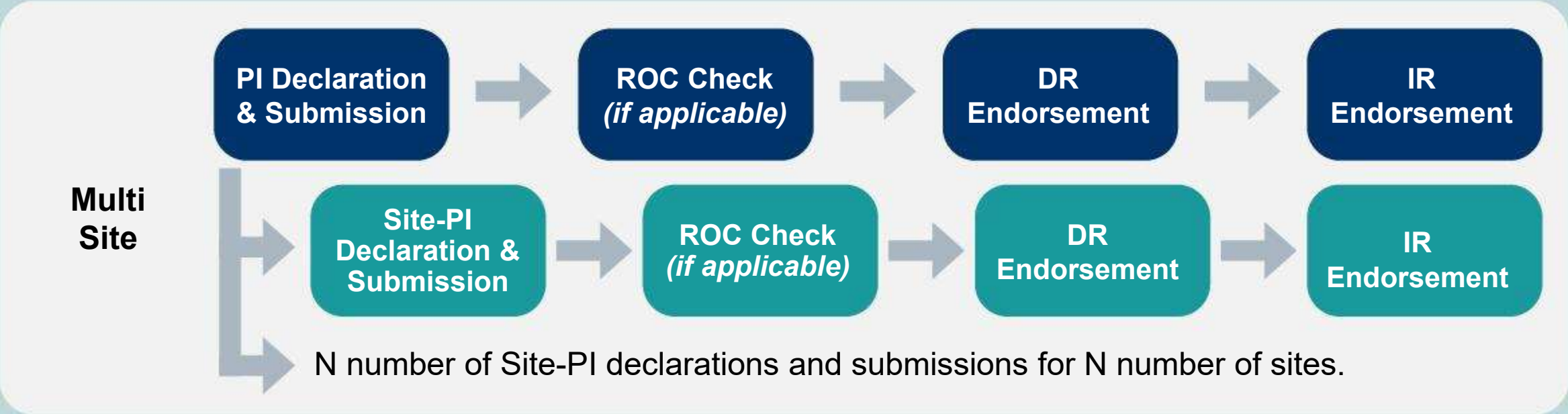


```

graph LR
    A[PI Declaration & Submission] --> B[ROC Check  
(if applicable)]
    B --> C[DR Endorsement]
    C --> D[IR Endorsement]
    A -- Multi Site --> E[Site-PI Declaration & Submission]
    E --> F[ROC Check  
(if applicable)]
    F --> G[DR Endorsement]
    G --> H[IR Endorsement]
    I[N number of Site-PI declarations and submissions for N number of sites.]
  
```

Multi Site

N number of Site-PI declarations and submissions for N number of sites.



```

graph LR
    A[PI Declaration & Submission] --> B[ROC Check  
(if applicable)]
    B --> C[DR Endorsement]
    C --> D[IR Endorsement]
    A -- Multi Site --> E[Site-PI Declaration & Submission]
    E --> F[ROC Check  
(if applicable)]
    F --> G[DR Endorsement]
    G --> H[IR Endorsement]
    I[N number of Site-PI declarations and submissions for N number of sites.]
  
```

Multi Site

N number of Site-PI declarations and submissions for N number of sites.

Understand IRBs and Their Review Process

ECOS Endorsement Process

Take Note:

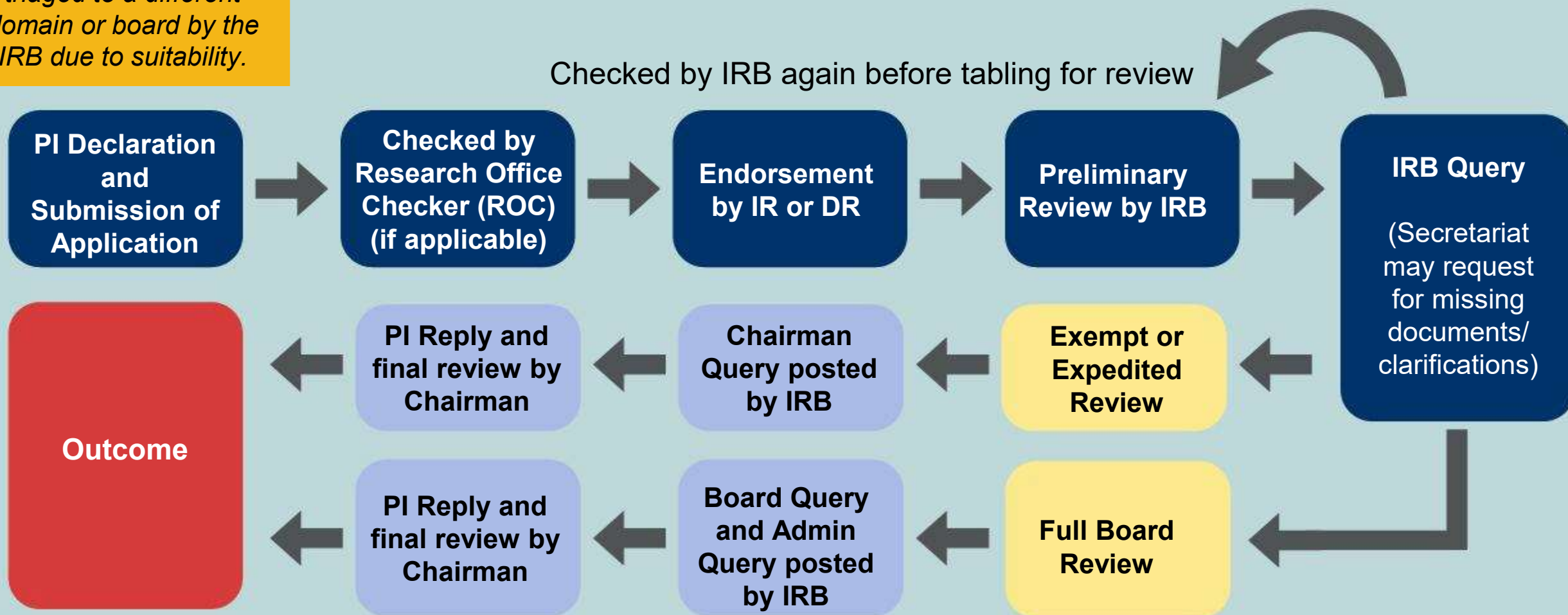
- ROC check is only applicable for certain Institutions.
- Queries from ROC, DR or IR can arise during endorsement process with multiple returns depending on the quality of responses.
- Re-declaration/Re-endorsement may be required if there are major changes to the application form.
- For multi sites, endorsement process occurs simultaneously.
- Submissions will only reach IRB when all IR endorsements have been completed and obtained.

Understand IRBs and Their Review Process

Application Submission and Review Process on ECOS

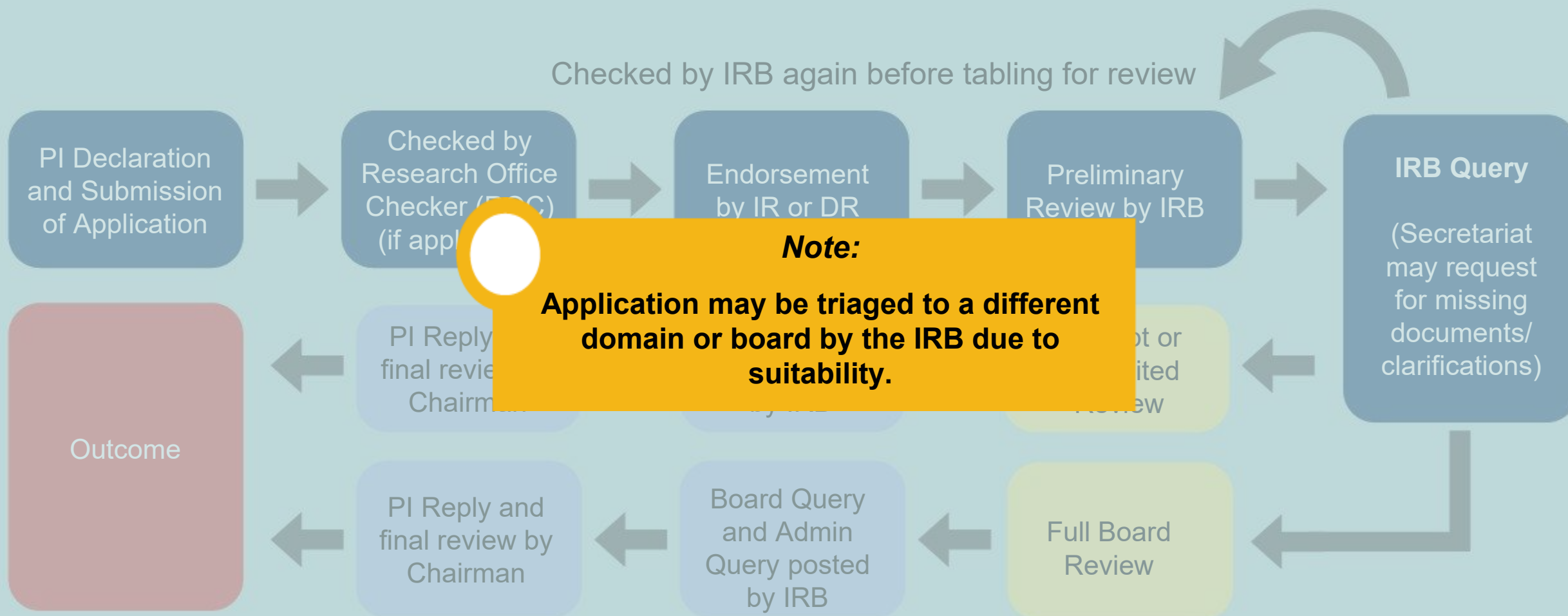
Note:

Application may be triaged to a different domain or board by the IRB due to suitability.



Understand IRBs and Their Review Process

Application Submission and Review Process on ECOS



Understand IRBs and Their Review Process

IRB Review Outcomes

**Exempt or
Expedited
Review**

Approved

For example, if the expedited review date was 1 January, the approval would expire on 1 January of the following year.

Not Approved

Unless otherwise indicated by IRB.



Understand IRBs and Their Review Process

IRB Review Outcomes

Full Board Review

Approved

Expiry date of approval is 1 year from the date when approval was granted.

Conditionally Approved*

**Only applicable for DSRB*

Formal approval will only be granted after PI has addressed all queries and made amendments, which will be reviewed through expedited review unless substantial changes made.

Re-Tabled

Not Approved

Expiry date of approval is 1 year from the date when conditional approval was granted.

Understand IRBs and Their Review Process

IRB Review Outcomes

Full Board Review

Approved

Conditionally Approved*

**Only applicable for DSRB*

Re-Tabled

Not Approved

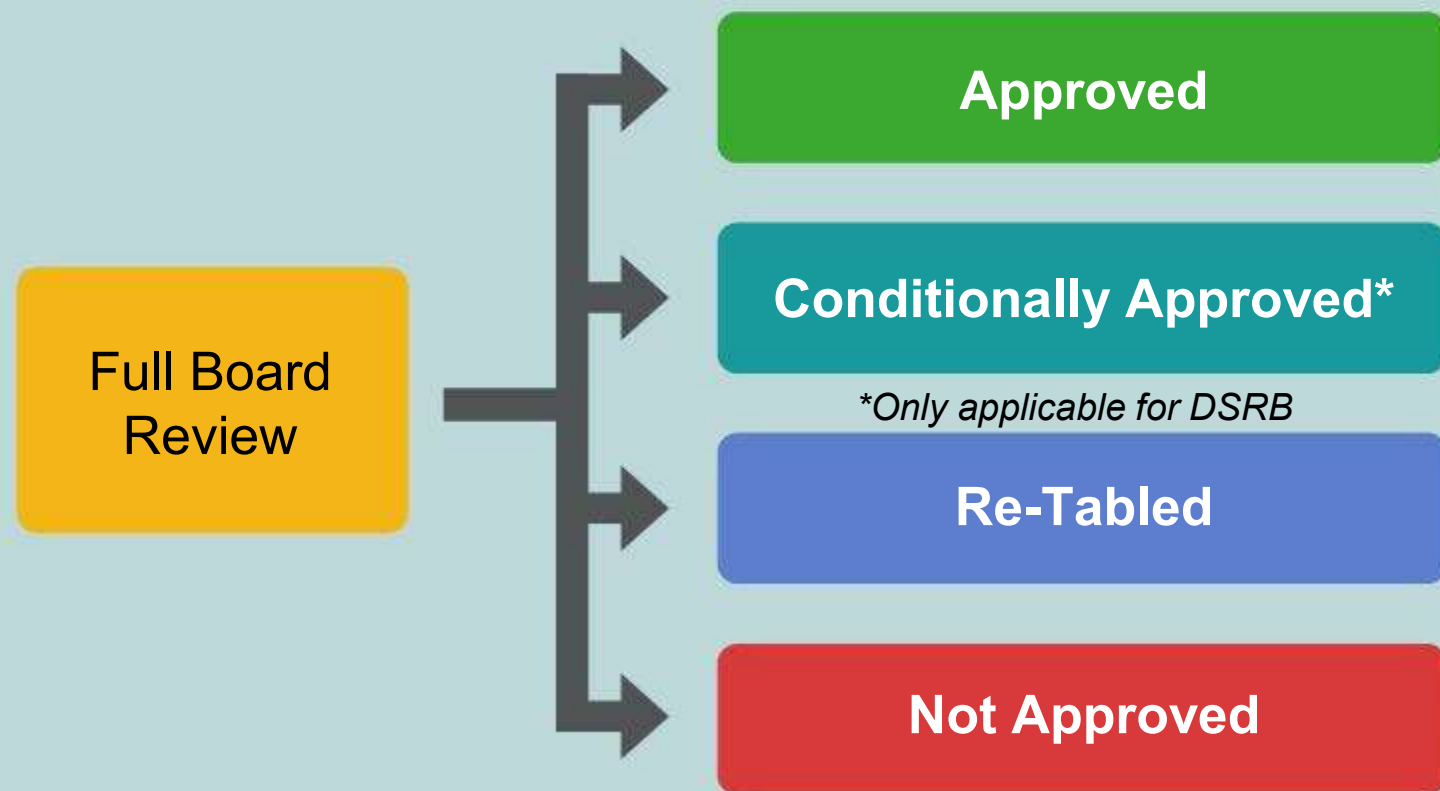
Have significant queries or issues raised by IRB and need substantial modifications/further information.

PI may be invited to attend full board meeting to clarify, and proposal may be sent to Independent Consultant for further review.

Responses and amendments will be reviewed at next full board meeting.

Understand IRBs and Their Review Process

IRB Review Outcomes



If Not Approved due to not meeting one or more criteria, PI may appeal via ECOS, subject to Chairman's final decision.

Disapproval cannot be given through expedited review, only by majority vote at full board meeting.



Learning Checkpoint

01

Dr Lam is submitting an IRB application to propose conducting a clinical trial to evaluate the efficacy and safety of a new anti-cancer drug in patients.

Which review process is it likely to undergo?

Expedited Review

Exempt Review

Full Board Review

01

Dr Lam is submitting an IRB application to propose conducting a clinical trial to evaluate the efficacy and safety of a new anti-cancer drug in patients.

Which review process is it likely to undergo?

Expedited Review

Exempt Review

Full Board Review



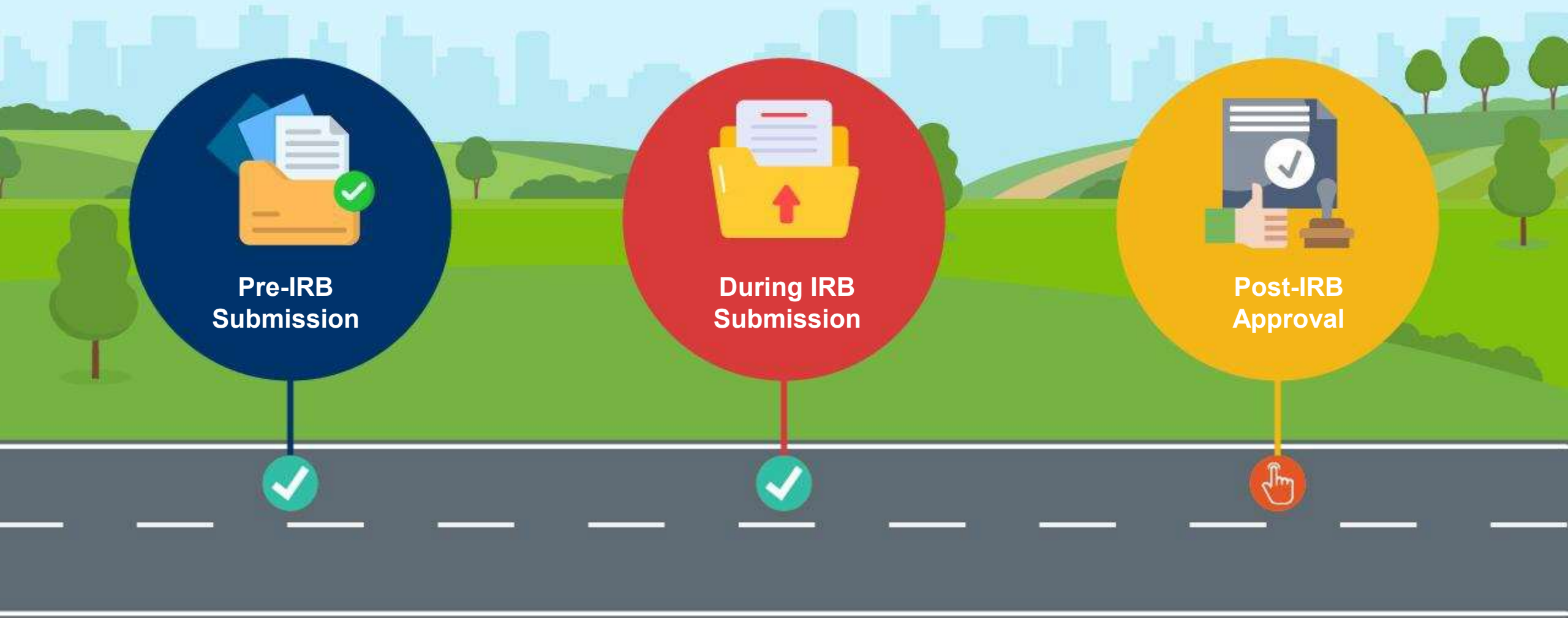
That's correct!

Rationale: Type of Review Process



Testing a new drug in a clinical trial would be considered **more than minimal risk**, which requires **Full Board Review**

IRB Submission Journey



Overview: IRB Submission Journey Map

PRE-IRB SUBMISSION

- Determine if your planned activity is research
- Familiarise yourself with the applicable regulations
- Complete all minimum training requirements



DURING IRB SUBMISSION

- Set up an account on ECOS to submit your IRB Application
- Understand the role of researchers & institutions
- Understand IRBs and their review process



POST-IRB APPROVAL

- Understand what needs to be reported
- Prepare for study closure



Understand What Needs to Be Reported

IRB Post Approval Reporting Requirements

Approved Studies

Post Approval Monitoring & Reporting to IRB

Study
Status
Report
(SSR)

Amendment
(AMD)

Serious
Adverse
Event
(SAE)

Unanticipated Problems
Involving Risks To
Subjects Or Others
(UPIRTSO)
*(For DSRB approved
studies only)*

Study
Deviation/
Non-
Compliance
(DNC)

Other
Study
Notification
(OSN)

- Continuing Review not less than 1x/year.
- For DSRB, studies in data analysis only stage are not required to submit.

- For DSRB, only studies regulated by Human Biomedical Research Act (HBRA) must submit to DSRB.
- If unexpected, must be submitted under UPIRTSO.

Understand What Needs to Be Reported

IRB Post Approval Reporting Requirements



For submissions on ECOS, Study Sponsors and site staff (i.e. Study Administrators or Study Team Member) can view all and edit the IRB forms provided they are listed under CRMS.

**Study
Status
Report
(SSR)**

PI

**Amendment
(AMD)**

PI

**Serious
Adverse
Event
(SAE)**

PI

Site PI

Co-I

**Unanticipated Problems
Involving Risks To
Subjects Or Others
(UPIRTSO)**
*(For DSRB approved
studies only)*

PI

Site PI

**Study
Deviation/
Non-
Compliance
(DNC)**

PI

**Other
Study
Notification
(OSN)**

PI

Understand What Needs to Be Reported

IRB Post Approval Reporting Requirements

**Study
Status
Report
(SSR)**



**Amendment
(AMD)**



**Serious
Adverse
Event (SAE)**



**Unanticipated
Problems
Involving Risks To
Subjects Or Others
(UPIRTSO)**
*(For DSRB approved
studies only)*



**Study Deviation/
Non-Compliance
(DNC)**



**Other Study
Notification
(OSN)**



Understand What Needs to Be Reported

Study Status Report (SSR)

Continuing Review (not less than 1x/year):



Monitoring mechanism that assures continuing safeguards in place to protect participants' rights and welfare.



Allows IRB to determine whether **risks and benefits** of study have changed as the study progresses.



Period of approval and **category of continuing review** is determined by the IRB at the time of initial review.



Prior to expiry of the approval period, a continuing review is to be performed for renewal of IRB approval.

Understand What Needs to Be Reported

Study Status Report (SSR)

What should Principal Investigators do?

The PI should submit a **completed Study Status Report Form** to IRB at least **2 months before expiry**.



If approval **expires**, no research activities can be conducted on/after the expiry date, including:



Screening



Enrolment



Interventions,
interactions



Collection
of identifiable
data

Understand What Needs to Be Reported

Study Status Report (SSR)

Take Note:



Continuing review is not applicable for Exempt Studies.*
**Study closure is still required.*



DSRB does not require studies in data analysis only stage to undergo continuing review.

Understand What Needs to Be Reported

Continuing Review – Special Arrangement for DSRB For Studies in Data Analysis Stage

Unless otherwise determined by the DSRB, studies that have submitted a Study Status Report (SSR) indicating the study status as:

- 
- ✓ Ongoing
 - ✓ Last Subject
 - ✓ Last Visit Over
 - ✓ Only Data Analysis Ongoing



**Waiver
from
continuing
review.**

Understand What Needs to Be Reported

Continuing Review – Special Arrangement for DSRB For Studies in Data Analysis Stage

The study team will need to submit the Study Status Report (SSR) when:



Study is completed



Changes to the study status,
e.g. resume the recruitment/data
collection

The PI **must** continue to submit other reports
(AMD, UPIRTSO, Expected SAE and DNC) to
DSRB.

Understand What Needs to Be Reported

IRB Post Approval Reporting Requirements

**Study
Status
Report
(SSR)**



**Amendment
(AMD)**



**Serious
Adverse
Event (SAE)**



**Unanticipated
Problems
Involving Risks To
Subjects Or Others
(UPIRTSO)**
*(For DSRB approved
studies only)*



**Study Deviation/
Non-Compliance
(DNC)**



**Other Study
Notification
(OSN)**



Understand What Needs to Be Reported

Study Amendments (AMD)

Types of Study Amendments:

Administrative Amendments



E.g. change in addresses, contacts, correction of typographical and grammatical errors.

Minor Amendments



Changes that pose any increase in risk which are **no more than minimal risk**.

Major Amendments



Changes that **significantly affect the risk-benefit ratio** and will be reviewed by the full board.

Understand What Needs to Be Reported

Study Amendments (AMD)

When study amendments need to be made, submit via ECOS:



A Study Amendment Form
(including summary and rationale
of amendments)



Any other relevant
documentation

- Indicate all proposed changes and include the rationale for each proposed change.
- State if enrolled study participants would be informed and re-consent.
- Check if proposed amendment would significantly affect the study aims or study participants.
- Any documentation that the IRB may specifically request.
- Other relevant documentation to be given to participants to add meaningfully to the protection of the rights, safety and/or well-being of participants.

Understand What Needs to Be Reported

Study Amendments (AMD)

Take Note:



No changes to the approved study should be implemented **without documented IRB approval except where necessary to eliminate apparent intermediate hazard** to the study participants.



Any deviation from the protocol to eliminate an immediate hazard should be documented and promptly reported **within 7 calendar days** (for DSRB) and **as soon as possible but not later than 14 calendar days after 1st knowledge by Investigator** (for CIRB).

Understand What Needs to Be Reported

IRB Post Approval Reporting Requirements

**Study
Status
Report
(SSR)**



**Amendment
(AMD)**



**Serious
Adverse
Event (SAE)**



**Unanticipated
Problems
Involving Risks To
Subjects Or Others
(UPIRTSO)**
*(For DSRB approved
studies only)*



**Study Deviation/
Non-Compliance
(DNC)**



**Other Study
Notification
(OSN)**



Understand What Needs to Be Reported

Serious Adverse Event (SAE) – Reportable to CIRB

Relatedness (Causality)	Only <u>Related</u> SAE needs to be reported to CIRB.			
Study Type	Clinical Trial regulated by HSA		Other research studies (e.g. HBR, non-HBR)	
	Local SAE			
SAE	Death or Life-threatening	All other SAE	Death or Life-threatening	All other SAE
Expectedness (Nature)	Unexpected Expected	Unexpected	Unexpected Expected	Unexpected Expected
Timeline for Initial Report	Report within 24 hours. Note: Information in the submission report should be complete at the point of submission.	Report as soon as possible but not later than 15 calendar days. Note: Information in the submission report should be complete at the point of submission.	Report within 24 hours. Note: Information in the submission report should be complete at the point of submission.	Report as soon as possible but not later than 15 calendar days. Note: Information in the submission report should be complete at the point of submission.
Timeline for Follow-up Report	Within 8 calendar days of initial report. (Follow-up report should only be submitted if information in the initial report is incomplete.)		Within 8 calendar days of initial report. (Follow-up report should only be submitted if information in the initial report is incomplete.)	

Understand What Needs to Be Reported

Serious Adverse Event (SAE) – Reportable to CIRB

Relatedness (Causality)	Only <u>Related</u> SAE needs to be reported to CIRB.	
Study Type	Clinical Trial regulated by HSA	Other research studies (e.g. HBR, non-HBR)
Local SAE		
Non-Local SAE Reporting Requirement	Report SAE event where determined to be: • Is unexpected, • Is related and • Suggests that the research places subject or others at <u>greater risk of harm</u> (which may necessitate modification to the IRB-approved consent document(s), and/or the IRB-approved application/protocol). SAE should be reported via SAE report form on ECOS within 15 calendar days. Note: Information in the submission report should be complete at the point of submission.	It follows the local SAE reporting requirement and timeline.

Understand What Needs to Be Reported

Expected SAE (for HBR Studies) – Reportable to DSRB

For **DSRB**, only research studies that are regulated by Human Biomedical Research Act (HBRA) will need to submit **Expected SAEs** to DSRB.



Expected SAE

Unexpected SAEs for HBRA studies also need to be submitted to **DSRB** under **UPIRTSO**.

Understand What Needs to Be Reported

Expected SAE (for HBR Studies) – Reportable to DSRB

Definitions:

Expected SAE

A problem that is:



Related or possibly
related to HBR



Expected



Serious

Reportable to DSRB



Meets criteria for expected
SAE



Applies to both local Singapore
sites and overseas sites

(e.g. multi-center HBR involving local and overseas research sites for the same research protocol, any SAE at the overseas site must also be reported to IRB.)

Understand What Needs to Be Reported

Expected SAE (for HBR Studies) – Reportable to DSRB

Reporting Timelines for Expected SAE – For HBR Studies

Expected SAE

Initial Report

Within 7 days of PI's 1st knowledge of the event.



**Any additional information
pertaining to the initial
report**

Within 8 days of making
the initial report.

Understand What Needs to Be Reported

Expected SAE (for HBR Studies) – Reportable to DSRB

Take Note: For studies approved by other IRB(s) via mutual recognition arrangement, expected SAE(s) reporting should follow the requirements set by the approving IRB.



Understand What Needs to Be Reported

IRB Post Approval Reporting Requirements

**Study
Status
Report
(SSR)**



**Amendment
(AMD)**



**Serious
Adverse
Event (SAE)**



**Unanticipated
Problems
Involving Risks To
Subjects Or Others
(UPIRTSO)
(For DSRB approved
studies only)**



**Study Deviation/
Non-Compliance
(DNC)**



**Other Study
Notification
(OSN)**



Understand What Needs to Be Reported

UPIRTSO (for DSRB Approved Study) – Reportable to DSRB

UPIRTSO

(Unanticipated Problems Involving Risks To Subjects or Others)



Unexpected



Related or possibly related



Suggests that the research places participants or others at greater risk of harm

Reportable to DSRB

Matching UPIRTSO criteria:



Unexpected



Related or possibly related



Suggests that the research places participants or others at greater risk of harm

Understand What Needs to Be Reported

UPIRTSO (for DSRB Approved Study) – Reportable to DSRB

The **PI** is responsible for:



Accurate
documentation



Investigation



Follow-up



Timely reporting

Understand What Needs to Be Reported

UPIRTSO (for DSRB Approved Study) – Reportable to DSRB

Important Note:

There are events that are **not associated with the use of drugs**, but qualify for **UPIRTSO** reporting:



Loss of sensitive data
(a breach of confidentiality).



Change in protocol taken without
prior DSRB review to eliminate
an apparent immediate hazard
to a research participant.



Sponsor imposed
suspension for risk.



Complaint of a participant
indicating unexpected risks or
cannot be resolved by the
research team.

Understand What Needs to Be Reported

UPIRTSO – DSRB Reporting Timeline

UPIRTSO & Local Deaths Reporting Criteria – Based on Risk Profile of the Study

Risk Profile of study	More than Minimal Risk (Reviewed via Full Board)	No more than Minimal Risk (Reviewed via Expedited/ Exempt)	Regardless of Risk Profile	
Event/ Problem	Local death (<i>Local is defined as institution under the oversight of the NHG DSRB</i>).		Life-threatening Problems.	All other Problems.
When to Report	Regardless of causality and expectedness.	Must be related/possibly related to the study.	Related/Possibly related to the study and unexpected	
Initial Report Timeline	Soonest possible but Not later than 7 calendar days after first knowledge by the investigator.		Not later than 7 calendar days after first knowledge by the investigator.	Not later than 15 calendar days after first knowledge by the investigator.
Follow-up Report Timeline	Within 8 calendar days of the initial report.			

Understand What Needs to Be Reported

DSRB Reporting Requirements for Local Deaths in Oncology Studies

Conditions for study:



Most of such deaths occur when the participants are in the treatment free follow-up phase (due to natural disease progression).



The local deaths are unrelated to the investigational product.



The local deaths yield no clinically meaningful information that allows assessment of the risk-benefit relationship of the study.



There are no significant implications on the rights and welfare of the participants.

Understand What Needs to Be Reported

DSRB Reporting Requirements for Local Deaths in Oncology Studies

Reporting Timelines

Local Death Occurring Within 60 Days (or Less) After Last Dose of Treatment	Local Death Occurring More Than 60 Days After Last Dose of Treatment
Related (expected or unexpected) Preliminary report by PI within <u>7 calendar days</u> of first knowledge	Related (expected or unexpected) Preliminary report by PI within <u>7 calendar days</u> of first knowledge
Unrelated (expected or unexpected) Preliminary report by PI within <u>7 calendar days</u> of first knowledge	Unrelated (expected or unexpected) Routine reporting for Annual Continuing Review
Report to DSRB as UPIRTSO.	Report during annual continuing review.

The PI is required to follow up with the detailed report within 8 calendar days after the preliminary report.

Wherever possible, all unrelated and expected local death reports should be reviewed by a data and safety monitoring entity.

Understand What Needs to Be Reported

IRB Post Approval Reporting Requirements

**Study
Status
Report
(SSR)**



**Amendment
(AMD)**



**Serious
Adverse
Event (SAE)**



**Unanticipated
Problems
Involving Risks To
Subjects Or Others
(UPIRTSO)**
*(For DSRB approved
studies only)*



**Study Deviation/
Non-Compliance
(DNC)**



**Other Study
Notification
(OSN)**



Understand What Needs to Be Reported

Study Deviation/Non-Compliance (DNC)

Definitions:

Study Deviation

An unplanned excursion from the study that is not implemented or intended as a systemic change:



Failure to perform test required by protocol



Failure of participants to complete scheduled visits as required by protocol

Understand What Needs to Be Reported

Study Deviation/Non-Compliance (DNC)

Definitions:

Non-Compliance



A failure by an investigator to abide by the policies and procedures of IRB or applicable regulations governing the protection of human participant research.



Performing study procedures during lapse of approval



Failure to obtain informed consent when required



Failure to adhere to approved protocol



Performance of unapproved research procedure

Understand What Needs to Be Reported

Study Deviation/Non-Compliance (DNC)

Definitions:

Non-Compliance

Types of Non-Compliance:

Serious Non-Compliance

Neither Serious
nor Continuing



Continuing
Non-Compliance

Understand What Needs to Be Reported

Study Deviation/Non-Compliance (DNC)

When study deviation or non-compliance has occurred, the PI is **encouraged to report the incident**, regardless of if it was conducted by the PI, members of the research team or others.



Information may be from:

- Other members of the research team
- Other staff of the institution
- Monitoring reports
- Audit reports
- Complaints from research participants

Must be reported:



Within 14 calendar days (DSRB).



As soon as possible but not later than 14 calendar days after 1st knowledge by PI (CIRB).



Submitted in ECOS via the Study Deviation/Non-Compliance Report Form (DNC).

Understand What Needs to Be Reported

IRB Post Approval Reporting Requirements

**Study
Status
Report
(SSR)**



**Amendment
(AMD)**



**Serious
Adverse
Event (SAE)**



**Unanticipated
Problems
Involving Risks To
Subjects Or Others
(UPIRTSO)**
*(For DSRB approved
studies only)*



**Study Deviation/
Non-Compliance
(DNC)**



**Other Study
Notification
(OSN)**



Understand What Needs to Be Reported

Other Study Notification (OSN)

OSN Form used to report to IRB on:



Data and Safety
Monitoring Board
(DSMB) Report



Interim Data
Analysis



Letter from Study
Sponsors



Other Notification

Understand What Needs to Be Reported

Other Study Notification (OSN)

Take Note:

Currently no requirement for submission of:



Periodic
line listings



Development
Safety Update
Reports (DSUR)



Annual/
periodic
safety
reports

However, IRB may request for these reports to be submitted when deemed necessary.

Understand What Needs to Be Reported

IRB Post Approval Reporting Requirements

**Study
Status
Report
(SSR)**



**Amendment
(AMD)**



**Serious
Adverse
Event (SAE)**



**Unanticipated
Problems
Involving Risks To
Subjects Or Others
(UPIRTSO)**
*(For DSRB approved
studies only)*



**Study Deviation/
Non-Compliance
(DNC)**



**Other Study
Notification
(OSN)**



Understand What Needs to Be Reported

Study Suspension & Termination



A study may be closed before completion due to:

- Termination by the PI
- Termination by other parties (e.g. sponsors, IRB, Institution Representatives)

Understand What Needs to Be Reported

Study Suspension & Termination

A study may be suspended/terminated by IRB when:



Inappropriate involvement of human participants in research.



Not conducted in accordance with the IRB's requirements.



Serious or continuing non-compliance with regulations or IRB policies.



Associated with unexpected serious harm to participants.

Understand What Needs to Be Reported

Study Suspension & Termination

A study may be suspended/terminated by IRB when:



A study suspension/termination letter with reasons and specific terms to be carried out by the Investigator.



Inhibition of the rights or welfare of participants.



New information regarding increased risk to human participants.



Expiry of approval.

Understand What Needs to Be Reported

Study Suspension & Termination

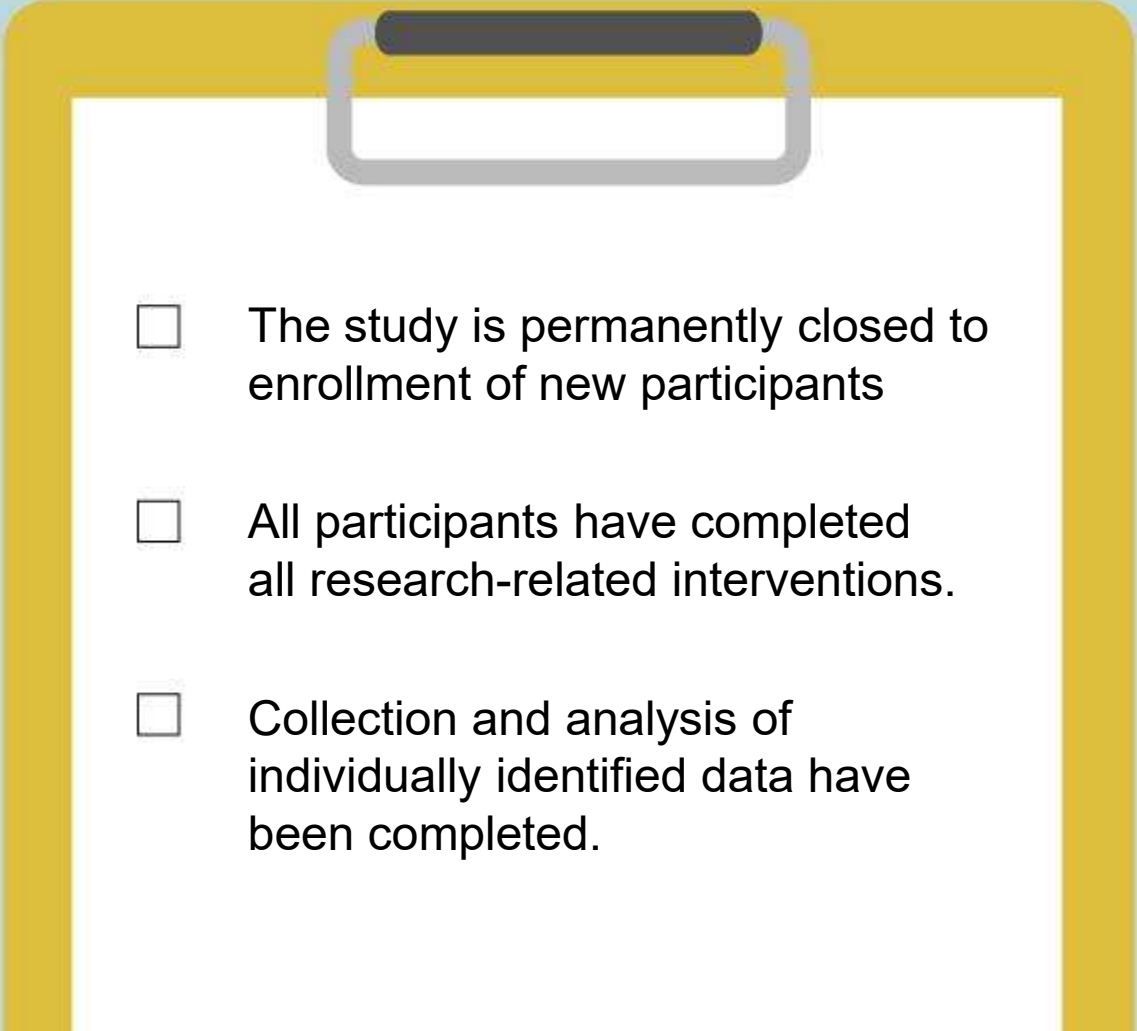


When a study has been suspended or terminated by Institution, PI, or Sponsor, the PI should submit a report **within 7 days** to IRB.



Understand What Needs to Be Reported

A research study is said to be **completed** when **all** of the following criteria are fulfilled:

- 
- ☐ The study is permanently closed to enrollment of new participants
 - ☐ All participants have completed all research-related interventions.
 - ☐ Collection and analysis of individually identified data have been completed.

Understand What Needs to Be Reported

Actions to Be Taken

1



PI



2



IRB



Understand What Needs to Be Reported

What PI Should Do



Study Status Report
(SSR) Form



PI should submit a study completion report **within 30 Days** after completion of the study using the IRB **Study Status Report (SSR)** form.

Understand What Needs to Be Reported

Actions to Be Taken



IRB will review the Study Status Report Form and obtain any outstanding information or documentation from PI.

If there is any inconsistency or if clarification is needed, additional information will be requested.



Learning Checkpoint

01

If Dr Lam's clinical trial on the efficacy and safety of the anti-cancer drug lasts for 5 years and closes upon completion, what is the minimum number of Study Status Reports (SSR) he would have submitted in total?

4

5

6

7

01

If Dr Lam's clinical trial on the efficacy and safety of the anti-cancer drug lasts for 5 years and closes upon completion, what is the minimum number of Study Status Reports (SSR) he would have submitted in total?

4

5



6

7

That's correct!

Rationale: Number of SSRs

Approved Studies

Post Approval Monitoring & Reporting to IRB

Study
Status
Report
(SSR)

Amendment
(AMD)

Serious
Adverse
Event

Unanticipated
Problems
Involving Risks To
Subjects Or Others

Study Deviation/
Non-Compliance

Other Study
Notification
(OSN)

Dr Lam submits **minimum 4 SSRs** for IRB's
Continuing Review for **2nd to 5th year** of his study:

Continuing Review
not less than 1x/year.

Initial IRB
approval

1st SSR

2nd SSR

3rd SSR

4th SSR

Year 1

Year 2

Year 3

Year 4

Year 5

Rationale: Number of SSRs



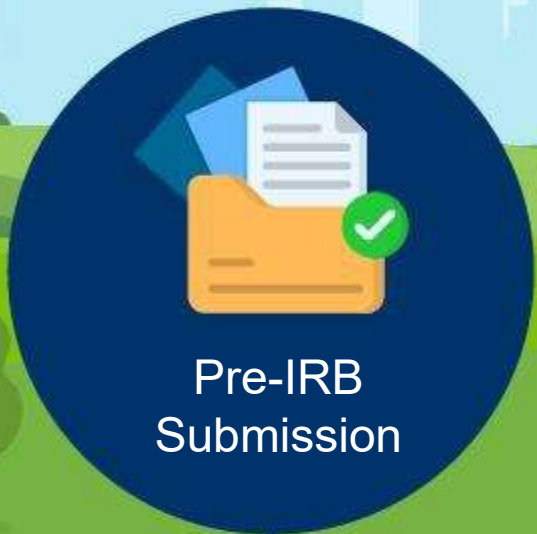
Recall:

PI should also submit a study completion report **within 30 Days** after completion of the study using the IRB **Study Status Report (SSR)** form.



Dr Lam submits minimum **5** SSRs
(**4+1**)

IRB Submission Journey



Resources & IRB Contact Information

1



NHG Health OHRPP & DSRB



2



SingHealth CIRB



Resources & IRB Contact Information

NHG Health OHRPP & DSRB

NHG Health OHRPP Website

<https://for.sg/nhghealth-ohrpp-ethics>

**ECOS User Support Portal for NHG Health
Research Community**

<https://for.sg/nhghealth-ecos-support>

**NHG Health Domain Specific Review
Board (DSRB)**

For any queries:

+65 6471 3266
nhggroup.ohrpp@nhghealth.com.sg

Resources & IRB Contact Information

1



NHG Health OHRPP & DSRB



2



SingHealth CIRB



Resources & IRB Contact Information

SingHealth CIRB

SingHealth RICE Website

<https://www.singhealthdukenus.com.sg/research/rice>

SingHealth ECOS Information Page

<https://www.singhealthdukenus.com.sg/research/rice/ecos>

**SingHealth Centralised Institutional
Review Board (CIRB)**

For any queries:

+65 8126 3660
irb@singhealth.com.sg

Resources & IRB Contact Information

1



NHG Health OHRPP & DSRB



2



SingHealth CIRB



Learning Summary

- Evaluate research activities to determine IRB requirements and prepare appropriate pre-submission documentation.
- Understand the roles and responsibilities of researchers and Institution.
- Understand the IRB application process.
- Understand the different IRB review categories and potential IRB review outcomes.
- Manage post-approval monitoring and reporting requirements and study closure procedures.