

ECOS User Guide: Institutional Review Board (IRB) Module

Contents

IRB Dashboard	<u>Submission List</u>
	<u>Endorsement</u>
	<u>My Study List</u>
New Application Form	<u>Creation of Application Form</u>
	<u>Study Site and Study Investigator</u>
	<u>Study Funding</u>
	<u>Exemption Application</u>
	<u>Clinical Trial</u>
New Application Form - Study Involving	<u>Human Biological Material</u>
	<u>Recording of Study Procedures on Audiotape, Film/video, or Other Electronic Medium</u>

Contents

New Application Form - Study Involving	<u>Use of Software or Mobile Applications</u>
	<u>Medical Device</u>
	<u>Vulnerable Populations</u>
New Application Form - Waiver of	<u>Documentation of Informed Consent</u>
	<u>Informed Consent for HBR and non-HBR</u>
	<u>Informed Consent during Emergency Situation for Clinical Trial and HBR</u>
New Application Form	<u>Consent obtained from research participant previously</u>
	<u>De-identified Data</u>
	<u>Features of Application Form</u>

Contents

<u>Submission Workflow</u>	
Other Forms	<u>Amendment (AMD)</u>
	<u>Study Status Report (SSR)</u>
	<u>Study Deviation/ Non-Compliance Report (DNC)</u>
	<u>Serious Adverse Event Report (SAE)</u>
	<u>UPIRTSO Report (UPT)</u>
	<u>Other Study Notification (OSN)</u>
<u>Track Changes</u>	
<u>Export</u>	
<u>Query - Pending PI Reply</u>	
<u>Study Summary</u>	

IRB Dashboard – Submission List

ECOS Submission List

+ New Application Form + New Other Forms Columns Export Filter(1)

ECOS Ref	IRB	Form Ref	Form Type	Form Status	Study Title	PI/Site-PI Name	Action
2023-0014	CIRB-Board B	2023-0014-APP2	Application	Pending PI Reply	QY05 (NCC) (Manual Unlock)	Dr NCC_BU(N	
2023-0373	CIRB-Board B	2023-0373-APP2	Application	Pending Endorsement	QY28 (For Triage) ROC raise query	Dr NCC_BU(N NCC_BU(Sing Unit (IMU))	
2023-0381	CIRB-Board B	2023-0381-APP1	Application	Pending Endorsement	QY30 (Retest) - to remove ttsh site	Dr NCC_BU(N	
2023-0380	CIRB-Board B	2023-0380-APP1					
2023-0369	CIRB-Board D	2023-0369-APP1					
2023-0155	CIRB-Board B	2023-0155-APP2					
2023-0063	CIRB-Board B	2023-0063-APP2					
2023-0066	CIRB-Board B	2023-0066-APP2					
2023-0177	CIRB-Board B	2023-0177-APP1	Application	Pending Endorsement	QY25 (NCC, TTSH - multi site, TTSH DR reject, TTSH remove)	Dr NCC_BU(N	
					QY24 (NCC, TTSH - multi	Dr NCC BU(N	

Configuration
CRMS
FCOI
IRB
Submission List
Endorsement
My Study List

- The **Submission List** shows all the forms submitted for the studies that the user is involved in.
- The **+ New Application Form** button allows the creation of a new study application.
- The **+ New Other Forms** button allows user to search for the approved study and select the different form type for submission.

IRB Dashboard – Endorsement

ECOS Endorsement

Columns Export Filter(2)

Form Ref	IRB	Study Title	PI/Site-PI Name	Department	Institution	Action
No Record						

- **Endorsement** displays the list of forms that requires:
 - Site-PI's declaration
 - Research Office Check (if applicable)
 - Endorsement by Department Representative and Institution Representative

IRB Dashboard – My Study List

ECOS My Study List Columns Export Filter

- Configuration
- CRMS
- FCOI
- IRB
 - Submission List
 - Endorsement
 - My Study List**

ECOS Ref	IRB	Study Status	Study Title	PI/Site-PI Name	Initial Review Category	Outcome Date	Action
2023-0033	CIRB-Board F	Review Process Terminated By IRB	CR11 Application K (NCC) with query (pending PI reply), IRB terminate	Dr NCC_PI 2(National Cancer Centre (NCC))	Administrative	23-Nov-2023	
2023-0074	CIRB-Board F	Review Process Terminated By IRB	CR09b Application I (NCC), without query IRB to terminate.	Dr NCC_PI 2(National Cancer Centre (NCC))	Administrative	23-Nov-2023	
2023-0075	CIRB-Board F	Pending Review	CR12 Application L (NCC) pending endorsement, PI submit withdraw request	Dr NCC_PI 2(National Cancer Centre (NCC))	-	-	
2023-0078	CIRB-Board F	Pending Review	CR04a Application D (SGH+NCC, sponsored (CRO, create CRMS), send to A, triage to F, triage F to F; remove SGH at Pending PI reply) and rHBR, to test withdraw requests	Dr NCC_PI 2(National Cancer Centre (NCC)),Dr SGH_PI(Singapore General Hospital (SGH))	-	-	
2023-0080	CIRB-Board F	Withdrawn	CR15 Application C pending secretariat up, PI submit withdraw request, withdraw				
2023-0084	CIRB-Board F	Ongoing	CR05 Application E (NCC and Exm S3+SSR); exempt review, change to expedited; PI submit withdraw request, reject withdraw (w/o dashboard); change to full board	Dr NCC_PI 2(National Cancer Centre (NCC))	-	28-Nov-2023	

My Study List shows all the studies that the user is involved in.

Creation of New Application Form

IMPORTANT NOTE! ×

1. Please save before navigating to the next section or when exiting the form.
2. Please ensure that you are added into the CRMS system to have continued access to this study, if you are not an Investigator listed at Section B2 of this Form.
3. Please do not paste tabular data (tables) or images in the textbox. If required, please submit them as Attachments in the relevant sections.
4. When a document has been amended to replace an existing document:
 - a. Please ensure that both the clean and tracked copies are uploaded.
 - b. A version number and date should be reflected within documents used for the purpose of this research. Where a version number and/ or date is included in the file name, do ensure that it is the same as that stated within the document.
 - c. Please remove the obsolete copies as only the latest version is required.

Close

- Click on '**Close**' button to proceed with the creation of form.
- Complete **Section A: Study Title, Section B: Submission IRB and Board, at least 1 Study Site and 1 Principal Investigator** to save draft.

Study Site and Study Investigator

ECOS Ref: - 📄

Form Detail

Application Form

No

B2. Study Site and Study Investigator

B2 (a) Please select the study sites and investigator:

Study Site List

Study Site	Location	Endorsement needed	Action
<input type="text"/>	<input type="text"/>	<input type="text" value="Yes"/>	Save Cancel

• For study site with multiple location, available options will appear in Section B2 (a). Please select the study location where applicable. Kindly note that multiple study location can be selected.

Investigator List

Study Site	Name	Study Role	Email	Designation

+ Add

Refer to next slide

B2. (b) Study Sites (For Information Only) ?

Note: Other local/ overseas site (The sites listed here)

• Please note that study site listed in B2 (b) is only for information and the IRB's approval will not include any of the sites.

Adding Study Investigator

Add Save

* Study Site **Only study site added would be available**

* Name **Search via full name or email address**

* Study Role **Select study role**

Profile and Minimum Training

-

* Conflict of Interest **Indicate if there are any conflict of interest**

Yes No

Complete the following questions if there are conflict of interest

* Conflict of Interest

Yes No

B2.(a)(i) Conflict of Interest: Please tick all the applicable boxes.

- Financial interests (e.g. stocks, stock options or other ownership interests) in the assets or liabilities of any organization that may benefit from the research activity.
- Payments (e.g. salary, consultation fees, speaking fees, or honoraria) from any organisation that may benefit from the research activity.
- Intellectual property rights or proprietary interests (e.g. patents, copyrights and royalties from such rights) related to the research.
- Options or other compensation arrangements that could be affected by the outcome of the research.
- The sponsor company supporting this study offers incentives connected with research participant recruitment or completion of research study (e.g. finder's fee, recruitment bonuses etc) that will be paid to the research staff.
- Others, to specify (financial/non-financial conflict):

B2.(a)(ii) Please provide details of all of the above Conflict of Interest.

B2.(a)(iii) Please describe the plan to manage all the above Conflict of Interest. You may include the mechanism and processes in place to manage the Conflict of Interest (e.g., resignation of position, independent data analysis, data safety monitoring, blinded study, ad hoc review committee). You may also include if the Conflict of Interest will be disclosed to the participants (e.g. through the written Informed Consent Form, oral presentation etc.).

Minimum Training Requirement

B2. Study Site and Study Investigator

B2 (a) Please select the study sites and investigator:

Study Site List

Study Site	Location	Endorsement needed
* Singapore Eye Research Institute (SERI) ▼	▼	* Yes ▼

Investigator List

Designation	Department	Institution	Profile and Minimum Training
Consultant	Glaucoma	Singapore Eye Research Institute (SERI)	Complete

- After user is added to study team, a link to 'Details' will be provided to view user profile and their minimum training status.
- Do a mandatory check to find out if the user had completed the minimum training requirement to conduct the study, the status will be as follows:
 - ✓ Complete: The user had fulfilled the minimum training requirement.
 - ✓ Incomplete: The user had not completed the minimum training requirement to conduct the type of study (e.g. Clinical Trials, HBR, non-HBR, SBE). Therefore, the form cannot be submitted.

Study Funding - Grant

Application Form

*C1. (b) (i) Name of Grant Agency:

*C1. (b) (i) Others chosen, please specify Name of Grant Agency

*C1. (b) (ii) Grant Holder:

Provide the name of the Grant Holder

*C1. (b) (iii) Grant Amount Applied for: ⓘ

Specify Grant Amount, if amount is in other currency, please amend accordingly.

C1. (b) (iv) Has the grant been approved?

Yes

No

*C1 (b) (iv) Attachment

Upload the grant approval letter if grant had been approved

If there are changes to Grant information after approval, please amend in CRMS module.

C1. (b) (v) Is the study's initiation dependent on grant approval?

Yes

No

*C1. (b) (v) (I) Please state alternate funding

State the alternate funding if study initiation is not dependent on grant approval

0 characters entered

C1. (b) (vi) Grant Reference Number

Study Funding - Pharmaceutical/ Industry Sponsored

Application Form

*C1. (c) (i) Name of Sponsor Company

Provide the name of the Sponsor Company

Please provide Sponsor and Clinical Research Organisation (CRO) details in CRMS module.

0 characters entered

*C1. (c) (ii) Is the sponsor offering any incentive connected with research participant recruitment or completion of research study (e.g. finder's fee, recruitment bonuses etc.) that will be paid to the research staff? ⓘ

- Yes
- No

*C1. (c) (iii) Will the sponsor be providing monitoring?

Indicate if sponsor would be providing monitoring

- Yes
- No

*C1. (c) (iv) Would the sponsor be responsible for the payment and compensation of injury or illness to research participants arising from participation in the study? ⓘ

- Yes
- No

*C2. Will the funding/sponsor cover all research-related costs e.g., drugs, devices, procedures, tests and visits?

- Yes
- No
- Not applicable - no research-related costs

Exemption Studies

[Back to Submission List](#)

Submission Detail



ECOS Ref: -



[Form Detail](#)

Application Form

[Cancel](#)

[Save](#)

***D1. Form Type: Please select the appropriate form for submission.**

Application Form

Exemption Application Form

***D1. (a) Please select the exemption application categories.**

Category S1 – Research in Established or Commonly Accepted Educational Settings

Category S2 – Research that Only Involves Educational Tests, Surveys, Interviews, or Observation of Public Behaviour

Category S3 – Research Involving Benign Behavioural Interventions

Category S4 – Secondary Research Using Biospecimens or Private Information.

Category S5 – Taste and Food Quality Evaluation and Consumer Acceptance Studies

Section A: Study Title

Section B: Submission ...

Section C: Study Fundi...

Section D: Study Type a...

Section E: Research M...

Section F: Exemption R...

- To submit studies for exemption, choose **'Exemption Application Form'** in **Section D1** and select the exemption application categories.
- **Section E: Research Methodology & Section F: Exemption Review Criteria** will then appear for completion.

Exemption Category S1

- ❖ **Research conducted in established or commonly accepted educational settings** that involves **normal educational practices** that are not likely to adversely impact student's opportunity to learn required educational content or the assessment of educators who provide instruction.

Examples

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

Exemption Category S2

- ❖ Research that only involves **educational tests, surveys, interviews, or observations of public behavior** that meets at least one of the following criteria:
 - a. Information obtained is recorded by investigator in such a manner that the identity of human subjects cannot readily be ascertained, directly or through identifiers to subjects;
 - b. Any disclosure of human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to subjects' financial standing, employability, educational advancement or reputation; or
 - c. Information obtained is recorded by the investigator in such a manner that the identity of the human subjects can be readily be ascertained, directly or through identifiers linked to the subjects and there are adequate provisions to protect the privacy of subjects and maintain the confidentiality of data.

Example

- Interview consisting of audio-recording but does not record any identifying information about the information. (This example meets criteria a. above.)

Exemption Category S3

- ❖ **Research involving benign behavioural interventions** which are brief in duration, harmless, painless, not physically invasive, not likely to have a significant adverse lasting impact on the subjects, and the investigator has no reason to think the subjects will find the interventions offensive or embarrassing. **Research involving benign behavioural interventions in conjunction with the collection of information** from an adult subject through verbal or written responses (including data entry) or audiovisual recording if the subject prospectively agrees to the intervention and information collection and at least one of the following criteria is met:
 - a) The information obtained is recorded by the investigator in such a manner that the identity of the human subjects cannot readily be ascertained, directly or through identifiers linked to the subjects.
 - b) Any disclosure of the human subjects' responses outside the research would not reasonably place the subjects at risk of criminal or civil liability or be damaging to the subjects' financial standing.

Examples

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

Exemption Category S4

- ❖ **Secondary research using identifiable biospecimens or private information**, if
 - a. It uses publicly available identifiable biospecimens or private information; or
 - b. The information will be recorded by the investigator in such a way that the identity of the subjects cannot be readily ascertained, and the investigator will neither contact the subjects nor re-identify subjects.

Note: Secondary research is re-using information and/ or biospecimens that are collected for some other “primary” or “initial” study. This exemption is not applicable for Human Biomedical Research regulated under the HBRA

Examples

- A researcher who examine an existing publicly-available database.

Exemption Category S5

- ❖ **Taste and food quality evaluation and consumer acceptance studies:**
 - a. If wholesome foods without additives are consumed, or
 - b. If a food is consumed that contains a food ingredient at or below the level and for a use found to be safe, or agricultural chemical or environmental contaminant at or below the level found to be safe.

Examples

- Participants were asked to taste a set of novel snacks to determine consumers' preferences. The set of novel snacks contain food ingredients found to be safe.

Clinical Trial

← Back to Submission List Submission Detail ↓ 📄 🔔 ⦿

ECOS Ref. - 📄

Form Detail

Application Form Cancel Save

***D1. Form Type: Please select the appropriate form for submission.**

Application Form

Exemption Application Form

***D2. Study Classification: Please determine which set of regulations would govern the study (or any part of the study).**

(a) Clinical Trial - Regulated by Health Products Act/ Medicines Act (HSA)

(b) Human Biomedical Research - Regulated by Human Biomedical Research Act (MOH)

(c) Restricted Human Biomedical Research – Regulated by Human Biomedical Research Act (MOH)

(d) Others – The study is not regulated by Health Products Act/ Medicines Act (HSA) nor Human Biomedical Research Act (MOH)

***D2. (a) Please indicate the Phase of the Trial.**

***D3. Does the study involve any of the following? Please select where applicable (more than one may apply)**

Questionnaire/ Survey/ Interview/ Focus Group Discussion

Medical Records Review

Human Biological Material

Recording of Study Procedures on Audiotape, Film/video, or Other Electronic Medium

Use of Software or Mobile Applications

Medical Device (including Telehealth Medical Device. Please refer to HSA website to determine if applicable)

Surgical / Radiotherapy Procedure

Interventions/ Invasive procedures

None of the above

- To submit clinical trial study, choose ‘**Application Form**’ in **Section D1** and select ‘**Clinical Trial – Regulated by Health Products Act/ Medicines Act (HSA)**’ in **Section D2**.
- **Section H: Research Details- Clinical Trials (Drug)** will then appear for completion.

Section A: Study Title

Section B: Submission ...

Section C: Study Fundi...

Section D: Study Type a...

Section G: Research M...

Section H: Research D...

Section T: Research Da...

Other Attachments

Declaration of Principal ...

Study Involving Human Biological Material

Application Form

✕ Cancel 📄 Save

***D1. Form Type: Please select the appropriate form for submission.**

Application Form

Exemption Application Form

***D2. Study Classification: Please determine which set of regulations would govern the study (or any part of the study).**

(a) Clinical Trial - Regulated by Health Products Act/ Medicines Act (HSA)

(b) Human Biomedical Research - Regulated by Human Biomedical Research Act (MOH)

(c) Restricted Human Biomedical Research – Regulated by Human Biomedical Research Act (MOH)

(d) Others – The study is not regulated by Health Products Act/ Medicines Act (HSA) nor Human Biomedical Research Act (MOH)

***D3. Does the study involve any of the following? Please select where applicable (more than 1 can be selected).**

Questionnaire/ Survey/ Interview/ Focus Group Discussion

Medical Records Review

Human Biological Material

Recording of Study Procedures on Audiotape, Film/video, or Other Electronic Medium

Use of Software or Mobile Applications

Medical Device (including Telehealth Medical Device. Please refer to HSA website to determine if your product is considered Medical Device in Singapore.)

Surgical / Radiotherapy Procedure

Interventions/ Invasive procedures

None of the above

• If study involves Human Biological Material, choose **‘Application Form’** in **Section D1** and select **‘Human Biological Material’** in **Section D3**.

• **Section W: Biological Materials Usage & Storage** and **Section X: Data & Safety Monitoring** will then appear for completion.

- Section A: Study Title
- Section B: Submission ...
- Section C: Study Fundi...
- Section D: Study Type a...
- Section G: Research M...
- Section T: Research Da...
- Section W: Biological M...
- Section X: Data & Safet...
- Other Attachments
- Declaration of Principal ...

Study Involving Human Biological Material

Submission Detail

Back to Submission List

ECOS Ref. -

Form Detail

Application Form

W1. Please select where applicable:

- i. Human biological materials will be obtained prospectively
- ii. Existing human biological materials will be used

Please state the type of human biological materials used and describe the study. Please include the frequency of collection, the amount to be collected, how the human biological materials are identified, and where the human biological material will be stored during the study.

No Data

Add

W1. (a) (i) Type of human biological material:
 0 characters entered

W1. (a) (ii) How will they be collected?
 0 characters entered

W1. (a) (iii) Amount to be collected and frequency of collection:
 0 characters entered

W1. (a) (iv) Total amount required for the research study:
 0 characters entered

W1. (a) (v) How human biological material would be identified?

W1. (a) (vi) Where will human biological material be stored during the study?

Cancel Confirm

Select 'Human biological materials will be obtained prospectively' if excess (additional amount catered for research) or leftover clinical samples from prospective recruitment would be collected.

In **Section W1**, click on 'Add' and complete with the information of the Human Biological Material that will be used.

Study Involving Recording of Study Procedures on Audiotape, Film / Video, or Other Electronic Medium

[Back to Submission List](#) Submission Detail 📄 🔔 ⊙

ECOS Ref. - [📄](#)

[Form Detail](#)

Application Form

***D1. Form Type: Please select the appropriate form for submission.**

Application Form

Exemption Application Form

***D2. Study Classification: Please determine which set of regulations would govern the study (or a sub-study).**

(a) Clinical Trial - Regulated by Health Products Act/ Medicines Act (HSA)

(b) Human Biomedical Research - Regulated by Human Biomedical Research Act (MOH)

(c) Restricted Human Biomedical Research – Regulated by Human Biomedical Research Act (MOH)

(d) Others – The study is not regulated by Health Products Act/ Medicines Act (HSA) nor Human Biomedical Research Act (MOH)

***D3. Does the study involve any of the following? Please select where applicable (more than 1 can be selected).**

Questionnaire/ Survey/ Interview/ Focus Group Discussion

Medical Records Review

Human Biological Material

Recording of Study Procedures on Audiotape, Film/video, or Other Electronic Medium

Use of Software or Mobile Applications

Medical Device (including Telehealth Medical Device. Please refer to HSA website to determine if your product is considered Medical Device in Singapore.)

Surgical / Radiotherapy Procedure

Interventions/ Invasive procedures

None of the above

[Save](#)

Study Title

Submission ...

Study Fundi...

Study Type a...

Research M...

Section T: Research Da...

Section U: Research D...

Other Attachments

Declaration of Principal ...

- If the study involves recording of study procedures, choose **'Application Form'** in **Section D1** and select **'Recording of Study Procedures on Audiotape, Film/video, or Other Electronic Medium'** in **Section D3**.
- **Section U: Research Data – Recording of study procedures on audiotape, film/video, or another electronic medium.** will then appear for completion.

Study Involving the Use of Software or Mobile Applications

← Back to Submission List Submission Detail ↓ 🔔 ⊙

ECOS Ref: - 📄

Form Detail

Application Form

*D1. Form Type: Please select the appropriate form for submission.

Application Form

Exemption Application Form

*D2. Study Classification: Please determine which set of regulations would govern the study (or a sub-study) you are submitting.

(a) Clinical Trial - Regulated by Health Products Act/ Medicines Act (HSA)

(b) Human Biomedical Research - Regulated by Human Biomedical Research Act (MOH)

(c) Restricted Human Biomedical Research – Regulated by Human Biomedical Research Act (MOH)

(d) Others – The study is not regulated by Health Products Act/ Medicines Act (HSA) nor Human Biomedical Research Act (MOH)

*D3. Does the study involve any of the following? Please select where applicable (more than 1 can be selected).

Questionnaire/ Survey/ Interview/ Focus Group Discussion

Medical Records Review

Human Biological Material

Recording of Study Procedures on Audiotape, Film/video, or Other Electronic Medium

Use of Software or Mobile Applications

Medical Device (including Telehealth Medical Device. Please refer to HSA website to determine if your product is considered Medical Device in Singapore.)

Surgical / Radiotherapy Procedure

Interventions/ Invasive procedures

None of the above

- If the study involves the use of software or mobile applications, choose **‘Application Form’** in **Section D1** and select **‘Use of Software or Mobile Applications’** in **Section D3**.
- **Section V: Research Data – Use of software or mobile applications** will then appear for completion.

✕ Cancel 📄 Save

- Section A: Study Title
- Section B: Submission ...
- Section C: Study Fundi...
- Section D: Study Type a...
- Section G: Research M...
- Section T: Research Da...
- Section V: Research Da...
- Other Attachments
- Declaration of Principal ...

Study Involving the Use of Software or Mobile Applications

[Back to Submission List](#)

Submission Detail



ECOS Ref. -



[Form Detail](#)

Application Form

[Cancel](#) [Save](#)

*V1. Please select the type of software(s) applicable and state the name of software (including third party and mobile applications): ⓘ

- V1. (a) Telehealth Medical Device
- V1. (b) Telehealth Wellness Device
- V1. (c) Others

*V2. Please describe the following:

- What data would be collected via the telehealth device?
- Where the data would be stored?
- Who have access to the data?
- How would the research data confidentiality be protected?

In **Section V**, please provide the detailed information of the software or mobile applications that would be used.

0 characters entered

*V3. Assurances by Principal Investigator.

- The use of usage of the software or a mobile application and storage of data will be in compliance with institution policy.

I agree with the above statement.

- Section A: Study Title
- Section B: Submission ...
- Section C: Study Fundi...
- Section D: Study Type a...
- Section G: Research M...
- Section T: Research Da...
- Section V: Research Da...**
- Other Attachments
- Declaration of Principal ...

Study Involving Medical Device (including Telehealth Medical Device)

< Back to Submission List

Submission Detail



ECOS Ref: -



Form Detail

Application Form

*D1. Form Type: Please select the appropriate form for submission.

- Application Form
- Exemption Application Form

*D2. Study Classification: Please determine which set of regulations

- (a) Clinical Trial - Regulated by Health Products Act/ Medicines Act (H)
- (b) Human Biomedical Research - Regulated by Human Biomedical R
- (c) Restricted Human Biomedical Research – Regulated by Human B
- (d) Others – The study is not regulated by Health Products Act/ Medicines

*D3. Does the study involve any of the following? Please select where applicable (more than 1 can be selected).

- Questionnaire/ Survey/ Interview/ Focus Group Discussion
- Medical Records Review
- Human Biological Material
- Recording of Study Procedures on Audiotape, Film/video, or Other Electronic Medium
- Use of Software or Mobile Applications
- Medical Device (including Telehealth Medical Device. Please refer to HSA website to determine if your product is considered Medical Device in Singapore.)
- Surgical / Radiotherapy Procedure
- Interventions/ Invasive procedures
- None of the above

- If the study involves medical device (including telehealth medical device), choose 'Application Form' in Section D1 and select 'Medical Device (including Telehealth Medical Device. Please refer to HSA website to determine if your product is considered Medical Device in Singapore.)'
- Section I: Research Data – Use of Medical Device and Section X: Data & Safety Monitoring will then appear for completion.

Cancel

Save

Section A: Study Title

Section B: Submission ...

Section C: Study Fundi...

Section D: Study Type a...

Section G: Research M...

Section I: Research Det...

Section T: Research Da...


Section X: Data & Safet...

Other Attachments

Declaration of Principal ...

Study Involving Medical Device (including Telehealth Medical Device)

Back to Submission List Submission Details


ECOS Ref. - 

[Form Detail](#)

Application Form

11. Please state the name of the medical device(s) that will be tested or studied in this research (including product name and brand/ manufacturer)

[Add](#)



No Data

Medical Device

0 characters entered

#11. (a) Is the medical device used as a prototype (including modified devices) under in this study?

Yes
 No

#11. (b) Is the medical device locally registered?

Yes, it is registered as General Medical Device
 Yes, it is registered as an In-Vitro Diagnostic (IVD) Medical Device
 No, it is unregistered

#11. (c) Will you be submitting or have submitted the Clinical Research Material Notification (CRM-N) to HSA for the medical device?

Yes
 No

#11. (d) Is this a US FDA IDE study or data is intended to be reported to FDA in support of an IDE Application?

Yes
 No

#11. (e) Please determine the risk level of the medical device to research participants:

This is not a significant risk medical device
 This is a significant risk medical device

#11. (g) Please describe on the storage, inventory and control of the medical device?

0 characters entered

#11. (h) Who will be responsible for administering the medical device?

Trained study team member
 Research participants
 Others

#11. (i) Please describe how the unused or returned medical device will be managed at the completion of this research study.

0 characters entered




#11. (j) Please attach the supporting documents for the medical device (e.g., device brochure, product catalogue(s), product information sheet/leaflet(s), directions/instructions for use, insert, labelling (if appropriate and/or applicable), safety data, image/photograph/diagram of device(s), etc.)


[Upload](#)

[Cancel](#) [Confirm](#)

In **Section 11**, click on 'Add' and complete with the information of the Medical Device that will be used.

Study Involving Vulnerable Populations

← Back to Submission List Submission Detail   

ECOS Ref: - 

[Form Detail](#)

Application Form

*D4. Would the study involve recruitment?

Yes
 No

*D4. (a) Would the study involve recruitment of any of the following as research participants?

Not applicable, the study does not involve vulnerable participants
 Pregnant Women, Foetuses & Neonates
 Children
 Prisoners
 Cognitive Impaired Person
 Other Vulnerable Population

*D5. Please select the applicable type(s) of consent for the study.

- If the study involves Vulnerable Populations, choose ‘**Application Form**’ in **Section D1**. In Section D4, select ‘**Yes**’ for involvement of recruitment and select the group of vulnerable populations that would be involved in **Section D4(a)**.
- The following sections will then appear for completion based on selection:
 - **Section K: Pregnant Women, Foetuses & Neonates**
 - **Section L: Children**
 - **Section M: Prisoners**
 - **Section N: Cognitive Impaired Person**

Section D: Study Type a...


Section G: Research M...

Section J: Recruitment ...

Section T: Research Da...

Study Involving Vulnerable Populations – Pregnant Women, Foetuses & Neonates

← Back to Submission List Submission Detail ↓ 🔔 ⦿

ECOS Ref: - 

[Form Detail](#)

Application Form

***K1. Please indicate if your research involves:**
Note: If the study involves Viable Neonates, please select “Children” under Section D4.

Pregnant Women and Foetuses
 Neonates of Uncertain Viability and/or Nonviable neonates

***K2. Describe if preclinical studies, including studies on pregnant animals, and clinical studies including studies on non-pregnant women, have been conducted and data is available to assess risks to pregnant women and foetus.**

0 characters entered

***K3. Describe how the risks to the foetus will be minimized.**

0 characters entered

***K4. Describe the additional safeguards that will be provided to protect the rights, safety and welfare of these vulnerable research participants.**

✕ Cancel 📄 Save

Section D: Study Typ... ⚠

Section G: Research M...

Section H: Research D...

Section J: Recruitment ...

Section K: Research Pa...

Section T: Research Da...

Other Attachments

Declaration of Principal ...

If the study involves Viable Neonates, please select ‘Children’ under Section D4(a) instead.

Study Involving Vulnerable Populations – Children

← Back to Submission List Submission Detail ↓ 🔔 ⦿

ECOS Re
Form D
Applicati

- Please indicate if study involved **removal of human tissues not primarily for therapeutic or diagnostic purpose from children who lacks sufficient understanding and intelligence to give consent?** Note: Human tissues refer to any human biological materials, except those excluded from definition of human tissue per First Schedule of HBRA)
 - To provide more information about the human tissues that would be removed.

***L3. Does the study involve removal of human tissues not primarily for therapeutic or diagnostic purpose from children who lacks sufficient understanding and intelligence to give consent? Note: Human tissues refer to any human biological materials, except those excluded from definition of human tissue per First Schedule of HBRA)**

Yes
 No

***L3. (a) Please state the type of human tissues.**

0 characters entered

***L3. (b) The removal of the tissue involves no more than minimal risk to children who lacks sufficient understanding and intelligence to give consent. Please justify how your study meets this criterion.**

0 characters entered

***L3. (c) There are reasonable grounds for believing that the proposed areas of research cannot be carried out without the use of the tissue from children who lacks sufficient understanding and intelligence to give consent. Please justify how your study meets this criterion.**

Section A: Study Title

Section B: Submission ...

Section C: Study Fundi...

Section D: Study Type a...

Section G: Research M...

Section J: Recruitment ...

Section L: Research Pa...

Section T: Research Da...

Other Attachments

...

Study Involving Vulnerable Populations – Cognitive Impaired Person

[Back to Submission List](#)

Submission Detail



ECOS Ref: - []

[Form Detail](#)

Application Fo

- Please indicate if study involved **removal of human tissues not primarily for therapeutic or diagnostic purpose from (1) an adult who lacks mental capacity; OR (2) children who lacks mental capacity?** Note: Human tissues refer to any human biological materials, except those excluded from definition of human tissue per First Schedule of HBRA)
 - To provide more information about the human tissues that would be removed.

[Save](#)

*N2. Does the study involve removal of human tissues not primarily for therapeutic or diagnostic purpose from (1) an adult who lacks mental capacity; OR (2) children who lacks mental capacity? Note: Human tissues refer to any human biological materials, except those excluded from definition of human tissue per First Schedule of HBRA)

Yes

No

*N2. (a) Please state the type of human tissues.

0 characters entered




*N2. (b) The removal of the tissue involves no more than minimal risk to this group of participants. Please justify how your study meets this criterion.


0 characters entered

*N2. (c) There are reasonable grounds for believing that the proposed areas of research cannot be carried out without the use of the tissue to this group of participants. Please justify how your study meets this criterion.

- Section A: Study Title
- Section B: Submission ...
- Section C: Study Fundi...
- Section D: Study Type a...
- Section G: Research M...
- Section J: Recruitment ...
- Section N: Research Pa...**
- Section T: Research Da...

Waiver of Documentation of Informed Consent

[← Back to Submission List](#) **Submission Detail**   

ECOS Ref: - 

[Form Detail](#)

Application Form

Interventions/ Invasive procedures

None of the above

***D4. Would the study involve recruitment?**

Yes

No

***D5. Please select the applicable type(s) of consent for the study.**

Consent will be obtained

Waiver of documentation of consent (Verbal or Implied Consent) - This option mostly applicable for Questionnaire/ Survey/ Interview/ Focus Group Discussion

Waiver of consent during emergency situation

Wavier of consent

Not applicable as study involves De-identified Data

Consent obtained from research participants previously

Section G: Research M...

Section O: Consent Pro...




Section T: Research Da...


Other Attachments

...

- If the study is requesting for waiver of documentation of consent, choose **'Application Form'** in **Section D1** and select **'Waiver of documentation of consent (Verbal or Implied Consent)'** in **Section D5**.
- **Section O: Consent Process – Waiver of documentation of consent (Verbal or Implied Consent)** will then appear for completion.

Waiver of Informed Consent

[← Back to Submission List](#) **Submission Detail**   

ECOS Ref: - 

[Form Detail](#)

Application Form

Interventions/ Invasive procedures

None of the above

*D4. Would the study involve recruitment?

Yes

No

*D5. Please select the applicable type(s) of consent for the study.

Consent will be obtained

Waiver of documentation of consent (Verbal or Implied Consent) - T... Discussion

Waiver of consent during emergency situation

Wavier of consent

Not applicable as study involves De-identified Data

Consent obtained from research participants previously




Section I: Research Da...


Other Attachments

Declaration of Principal ...

- If the study is requesting for waiver of informed consent, choose **'Application Form'** in **Section D1** and select **'Waiver of consent'** in **Section D5**.
- Based on the selection in **Section D2**, the following sections will appear for completion:
 - For Clinical Trial and non-HBR studies:
Section R: Consent Process – Waiver of consent (non-HBR)
 - For HBR and rHBR studies:
Section S: Consent Process – Waiver of consent (HBR)

Waiver of Informed Consent (HBR)

[← Back to Submission List](#) **Submission Detail**   

ECOS Ref: - 

[Form Detail](#)

Application Form [Cancel](#) [Save](#)

***S1. Please select the type of waiver required.**

I. Waiver of appropriate consent under HBRA Fifth Schedule, Part 2, Section 3 (individually identifiable health information or human biological material obtained or compiled before, on and/ or after 1 Nov 2017)

II. Waiver of appropriate consent under HBRA Fifth Schedule, Part 2, Section 4 (individually identifiable health information obtained or compiled before 1 Nov 2017)

III. Waiver of appropriate consent under HBRA Fifth Schedule, Part 2, Section 5 (individually identifiable human biological material obtained or compiled before 1 Nov 2017)

Section A: Study Title

Section B: Submission ...

Section C: Study Fundi...

Section D: Study Type a...

- It is not required to submit PDPA Practicability Calculator.
- Please ensure that the study meets the 'Greater Public Good' criteria.

Waiver of Consent during Emergency Situation

[← Back to Submission List](#)

Submission Detail



ECOS Ref: -

[Form Detail](#)

Application Form

- Interventions/ Invasive procedures
- None of the above

*D4. Would the study involve recruitment?

- Yes
- No

*D5. Please select the applicable type(s) of consent for the study.

- Consent will be obtained
- Waiver of documentation of consent (Verbal or Implied Consent) - This option requires a discussion
- Waiver of consent during emergency situation
- Waiver of consent
- Not applicable as study involves De-identified Data
- Consent obtained from research participants previously




- If the study is requesting for waiver of informed consent during emergency situation, choose **'Application Form'** in **Section D1** and select **'Waiver of consent during emergency situation'** in **Section D5**.
- Based on the selection in **Section D2**, the following sections will appear for completion:
 - For Clinical Trial: **Section P: Consent Process – Waiver of Informed Consent during Emergency Situation (Clinical Trial)**
 - For HBR and rHBR studies: **Section Q: Consent Process – Waiver of Informed Consent during Emergency Situation (HBR)**


Section T: Research Da...

Other Attachments

Declaration of Principal ...

Consent Obtained from Research Participants Previously

[← Back to Submission List](#) **Submission Detail**   

ECOS Ref: - 

[Form Detail](#)

Application Form

No

*D5. Please select the applicable type(s) of consent for the study.

Consent will be obtained

Waiver of documentation of consent (Verbal or Implied Consent) - This op

Waiver of consent during emergency situation

Wavier of consent

Not applicable as study involves De-identified Data

Consent obtained from research participants previously

*D5. (a) Please state the source. For approved study, please state the protocol title, IRB reference number and name of approving IRB. Please submit a copy of the approved Participant Information Sheet and Consent Form/ Informed Consent Document.

*D5. (a) Please submit a copy of the approved Participant Information Sheet and Consent Form/ Informed Consent Document.

Section G: Research M...

Section T: Research Da...


Other Attachments

Declaration of Principal ...

- If the study is using data/samples with consent obtained from research participants previously, choose **'Application Form'** in **Section D1** and select **'Consent obtained from research participants previous'** in **Section D5**.
- **Section D5(a)** and **Section D5(b)** will appear for completion.

Study Involves De-identified Data

[← Back to Submission List](#) Submission Detail ↓ 🔔 ⦿

ECOS Ref: - 

[Form Detail](#)

Application Form

Use of Software or Mobile Applications

Medical Device (including Telehealth Medical Device. Please refer to HSA website)

Surgical / Radiotherapy Procedure

Interventions/ Invasive procedures

None of the above

***D4. Would the study involve recruitment?**

Yes

No

***D5. Please select the applicable type(s) of consent for the study.**

Consent will be obtained

Waiver of documentation of consent (Verbal or Implied Consent) - This option may not be applicable for all studies

Waiver of consent during emergency situation

Waiver of consent

Not applicable as study involves De-identified Data

Consent obtained from research participants previously




- If the study involved the use of de-identified data, choose **'Application Form'** in **Section D1** and select **'Not applicable as study involved De-identified Data'** in **Section D5**.
- For research to be considered as working with de-identifiable information, the record linkage key must be held by a trusted third party.
- For research using unidentifiable data/samples (e.g. de-identified by Trusted Third Party), please describe the process such as why, what, who, where and how the unidentifiable data/samples are obtained.


Features of Application Form


The screenshot displays the 'Submission Detail' page for application 2024-0193-APP1. The page includes a navigation bar with a back button and the title 'Submission Detail'. Below the navigation bar, the application ID '2024-0193-APP1' is shown with a 'Draft' status and a refresh icon. The ECOS reference number '2024-0193' is also visible. A 'Declare and Submit' button is located in the top right corner. The main content area is titled 'Application Form' and contains a text input field with the value 'CG23 - For Training Purposes' and a character count of '28 characters entered'. A sidebar on the right lists sections: 'Section A: Study Title', 'Section B: Submission ...', and 'Section C: Study Fundi...'. Three numbered callouts highlight key features: 1. 'Mandatory Check' button (yellow), 2. 'Save' button (blue), and 3. 'Save and Exit' button (dark blue).

- 1 Click 'Mandatory Check' to ensure that all form fields are filled.
- 2 Use 'Save' frequently to ensure that all information are saved.
- 3 Use 'Save and Exit' to save and exit editing mode.

Features of Application Form

← Back to Submission Detail Submission Detail   

2024-0193-APP1 Draft 

ECOS Ref: 2024-0193 


Form Type: Application Form Outcome: - Initial Review Category: -

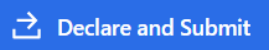
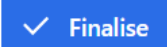
Current Editor: -

PI/Site PI: Mrs SNEC_Basic1(Singapore National Eye Centre (SNEC))

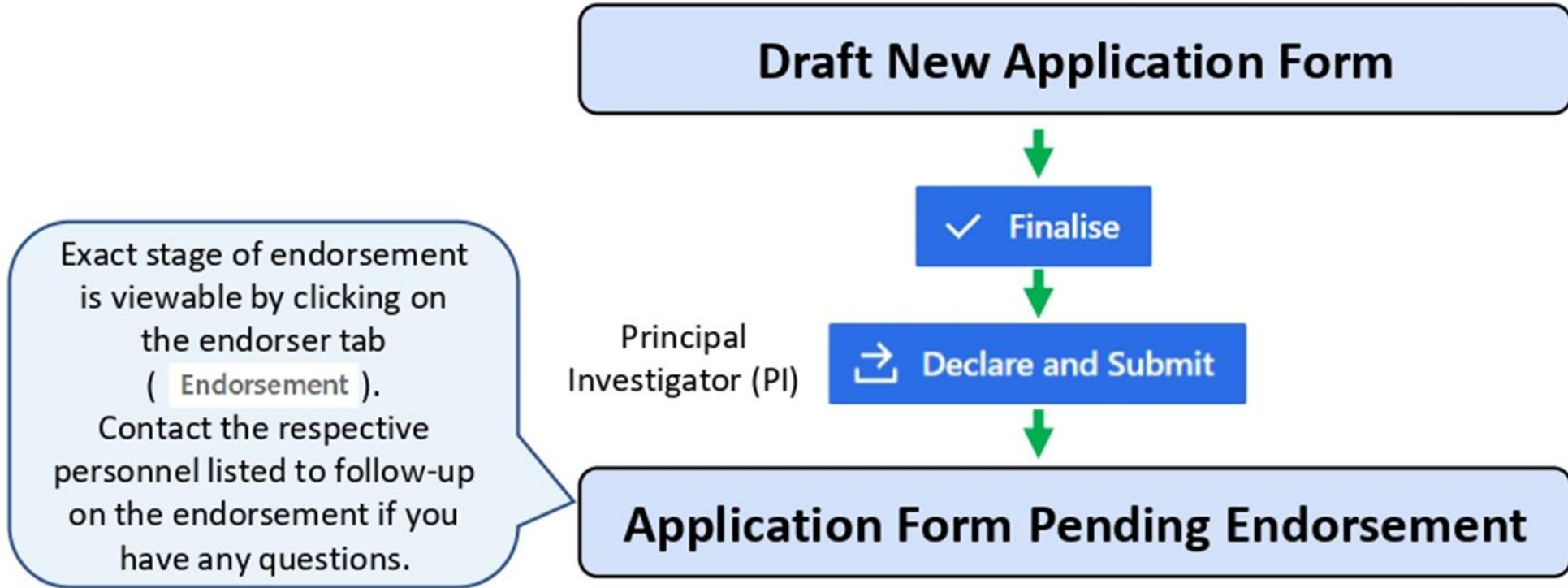
Study Title: CG23 - For Training Purposes

Quick Link: Study Summary,CRMS

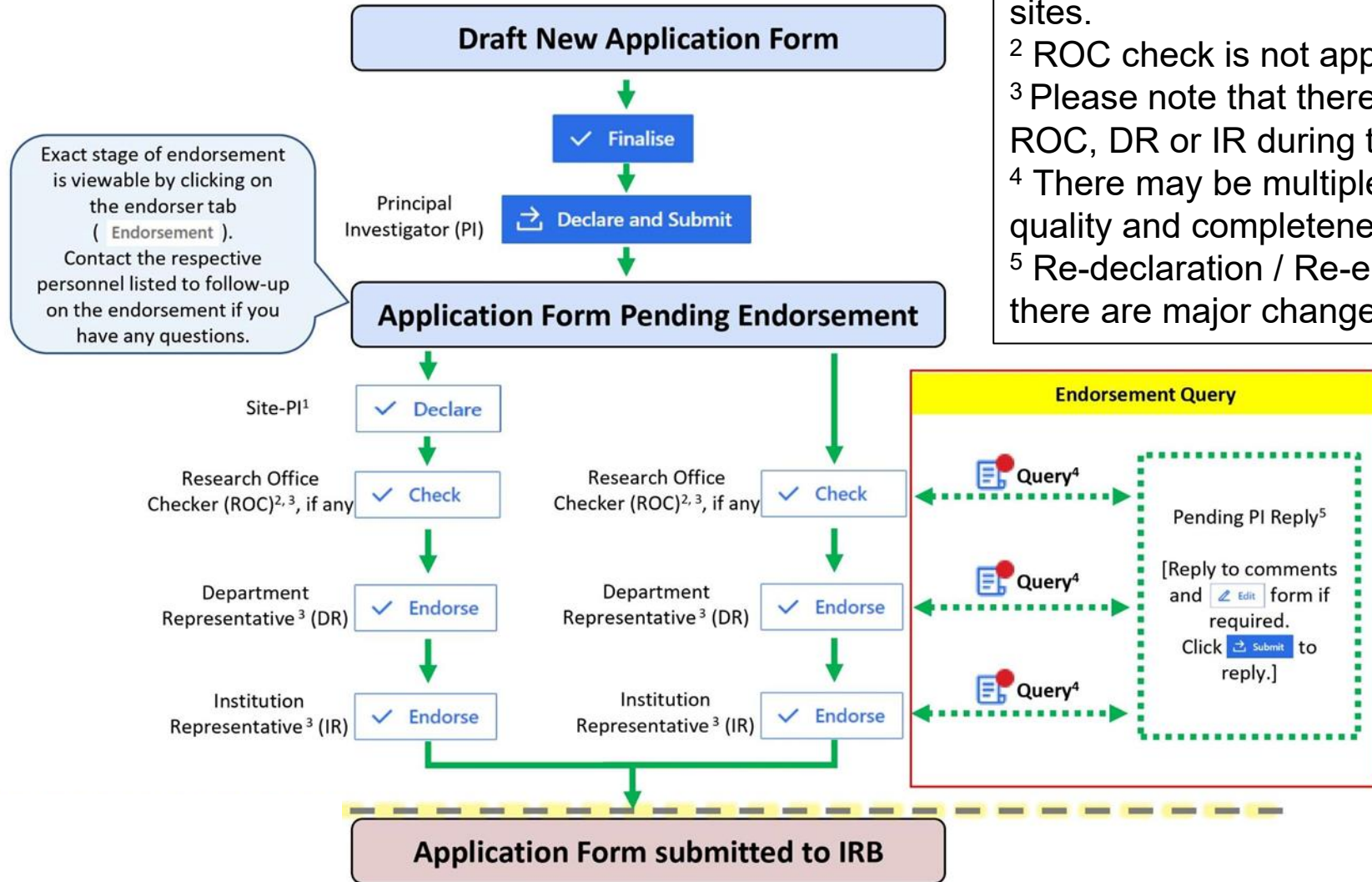


- 1** View the 'Study Summary' such as Forms, Forms Attachments and Study Letter submitted for the study.
- 2** Refer to the training for CRMS module for more information.
- 3** For PI, the '' button will be displayed, and form will be 'Pending Endorsement' upon submission.
For all other roles, the '' button will be displayed, and form will be 'Pending PI Declaration' upon submission.

Submission Workflow



Submission Workflow





Note:


- ¹ This is only applicable for study involving multi-sites.
- ² ROC check is not applicable for all institutions
- ³ Please note that there may be queries from ROC, DR or IR during the endorsement process.
- ⁴ There may be multiple returns depending on the quality and completeness of reply
- ⁵ Re-declaration / Re-endorsement is required if there are major changes to the application form.

Site-PI Declaration


ECOS Endorsement


Columns Export Filter(2)

Form Ref	IRB	Study Title	PI/Site-PI Name	Department	Action
2024-0193-APP1	CIRB-Board A	CG23 - For Training Purposes	Mrs SNEC_Basic1(Singapore National Eye Centre (SNEC)),Dr NNI_PI 1(National Neuroscience Institute (NNI))	Neurology (
2024-0146-APP1	CIRB-Board C	PP01 - Round 4 Prep	Dr KKH_PI 1(KK Women's and Children's Hospital (KKH)),Dr NNI_PI 1(National Neuroscience Institute (NNI)),Prof NHC_PI 1(National Heart	Neurology (


- For studies involving multi-sites, site-PI will click on the [Endorsement] tab, followed by the ‘’ icon to view the study.

Back to Endorsement Endorsement Detail

2024-0193-APP1 Pending Endorsement 

ECOS Ref: 2024-0193 

Form Detail Endorsement

 **Declare**

- Site-PI will click on ‘ **Declare**’ to perform site-PI declaration.

Endorsement Status

[Back to Submission List](#)

Submission Detail



2024-0192-APP1

Pending Endorsement



ECOS Ref: 2024-0192



Form Detail

Endorsement

Click on 'Endorsement' tab for endorsement related information.

Endorsement Status

Institution	Cluster-Institution-Department	Endorsement Information	Endorser Name	Action
Singapore National Eye Centre (SNEC) Main Site	Glaucoma	● Pending DR Endorsement	SNEC_DR 1	

- 1 View the endorsement status.
- 2 View the name of endorser to complete the pending task.
- 3 Click to view query raised by endorsers.
- 4 View the endorsement history.

How to Endorse? (For ROC, DR and IR)

ECOS Endorsement

Columns Export Filter(2)

Form Ref	IRB	Study Title	PI/Site-PI Name	Department	Action
2024-0193-APP1	CIRB-Board A	CG23 - For Training Purposes	Mrs SNEC_Basic1(Singapore National Eye Centre (SNEC)),Dr NNI_PI 1(National Neuroscience Institute (NNI))	Neurology (
2024-0146-APP1	CIRB-Board C	PP01 - Round 4 Prep	Dr KKH_PI 1(KK Women's and Children's Hospital (KKH)),Dr NNI_PI 1(National Neuroscience Institute (NNI)),Prof NHC_PI 1(National Heart	Neurology (

- For all endorser, click on the [Endorsement] tab, followed by the '🎯' icon to view the study.

Back to My Tasks Endorsement Detail

2024-0193-APP1 Pending Endorsement

ECOS Ref: 2024-0193

Query List Send Query Checked

Form Detail Endorsement

1 For ROC:

For DR and IR:

Reject button should only be used if you do not support the conduct of the study.

Creation of Other Forms

The screenshot shows the ECOS Submission List interface. The 'New Other Forms' button is highlighted with a red box. A modal window titled 'New Study Form' is open, showing a search field and a dropdown menu for form types. Two blue callout boxes provide instructions:

1. Search for study with ECOS Ref or Study Title
2. Select Form Type to be created

ECOS Ref	IRB	Form Ref	Form Type	Form Status	Study Title	PI/Site-PI Name	Action
2023-0131	CIRB-Board D	2023-0131-AMD1	Amendment	• Draft	LLY -1	Prof SERI_PI1(Singapore Eye Research (SERI)),A/Prof SGH_Site-PI1(Singapore Hospital (SGH))	🔍
2024-0219	CIRB-Board A	2024-0219-APP1	Application	• Pending Endorsement	CG/JY/KT - Testing (26-Jan-2024)	Dr SERI_PI(Singapore National Eye Cer	🔍




New Study Form


* ECOS Ref or Study Title:

* Form Type:

- Amendment Form (Amendment)
- Study Deviation/ Non-Compliance Report Form (DNC)
- Other Study Notifications Report Form (OSN)
- Serious Adverse Event Report Form (SAE)
- Study Status Report Form (SSR)

Amendment Form (AMD)

[← Back to Submission List](#) Submission Detail ↓   

ECOS Ref: - 

[Form Detail](#)

Amendment Form

*Describe the proposed change(s) to the research and include a rationale for each proposed change.

*Will the enrolled study participants be informed of these changes?

Yes

No

*Will the enrolled study participants be re-consented?

Yes

No

Do the proposed amendments:

Significantly change the original objectives, innovation and scientific methodology (e.g., re-design of study methodology, change in investigational product used, etc) and/or the alignment of the study to the institutions' research objectives, image and standards of the research study?

Require additional resources (e.g., expertise, manpower, time, budget) for the study to be properly conducted?

Significantly increase the overall risk or negatively alter the risk benefit ratio to the research participants ?

If any of the above is true, please elaborate

Section S: Consent Pro...

Section T: Research Da...

Other Attachments

Declaration of Principal ...

- Indicate all the proposed changes to the research and include the rationale for each proposed change.
- State if enrolled study participants would be informed and re-consented.
- Check if proposed amendment would significantly affect the study aims or study participants.

Study Status Report Form (SSR)

ECOS Ref: 2023-0392 

Form Detail

Study Status Report Form

✕ Cancel 📄 Save

NOTE:

1. For renewal of IRB approval, please submit the Study Deviation /Non-Compliance Report Form expiry.
2. For reactivation of expired study, please submit a Non-Compliance/Study Deviation Report Form if the study team had continued to carry out research activities during the lapse period before IRB approval is renewed.
3. For study closure, please submit the Study Status Report Form within 30 days after study completion.

*1.1 am requesting for:

Study Status Report Form

Declaration of Principal ...

Select the reason for submission of SSR as follows:

- Study Renewal
- Study Reactivation
- Study Closure

Study Deviation/ Non-Compliance Report Form (DNC)

Submission Detail

ECOS Ref: 2024-3201

Form Detail

Study Deviation/Non-Compliance Report Form

Cancel Save

Guidance

This report form should be submitted once Principal Investigator is aware of the non-compliance/ study deviation according to the reviewing IRB's requirement. All sections must be completed. Principal Investigators are obliged to suspend their research immediately pending their report to the IRB if deviations are substantial or are likely to result in greater harm or greater likelihood of harm to the research participants.

Definitions

Study Deviation: is an unplanned excursion from the study that is not implemented or intended as a systematic change.

- A study deviation could be a limited prospective exception to the protocol (e.g., all inclusion/exclusion criteria). Like study amendments, deviations are not intended unless the change is necessary to eliminate an immediate hazard to the subject or research.
- Study deviation is also used to refer to any other, unplanned, inconsistency with the protocol or failures on the part of the research participant(s) or the study team.

Non-Compliance: is a failure by an investigator or any study team member to abide by the policies and procedures of the IRB or applicable regulations governing the protection of human subject research. Some examples of non-compliance include but are not limited to:

- Failure to obtain prior approval for research
- Failure to obtain informed consent when required
- Failure to use the latest IRB approved version of the protocol or procedures
- Failure to report an adverse event report according to IRB timelines
- Performance of research at an unapproved study site
- Performing an unapproved research procedure
- Failure to adhere to the approved protocol
- Failure to submit study amendments for review and approval

Study Deviation: An unplanned excursion from the study that is not implemented or intended as a systematic change.

Non-Compliance: Failure by an investigator or any study team member to abide by the policies and procedures of the IRB or applicable regulations governing the protection of human subject research.

Serious Adverse Event Report Form (SAE)

Submission Detail

ECOS Ref: 2024-3203

Form Detail

Serious Adverse Event Report

Note:

1. This form is for submission of related SAE only.
2. For DSRB reviewed studies, if the related SAE is unexpected, please submit using the UPIRTSO Report Form.
3. Do not use terms such as "Refer to attached document" or similar.

Section A: Determination of SAE

*A1. Please determine if the event is related:

Related: Related means there is a reasonable possibility that the incident, experience or outcome may have been caused by the procedures involved in the study. Also includes reasonable possibility that the event occurred as a result of participation in the study.

*A2. Please classify the SAE into at least one of the following categories:

Resulted in or contributed to death

Was life-threatening

Cancel Save

Section A: Determinatio...

Section B: Basic Informat...

Section C: Investigationa...

Section D: Event Summary

Section E: Comments by ...

Section F: Investigator's ...

UPIRTSO Report Form (UPT)

Submission Detail

ECOS Ref: [redacted]

Form Detail

UPIRTSO Report Form

Events Summary Table (Maximum 20)

Report No	Event Onset Date	Study Site	Death at Study Site under oversight of DSRB	Event Keywords	Study's Risk-Benefit Ratio has changed
-----------	------------------	------------	---	----------------	--

Attach any other document(s)

Upload

+ New Event

Cancel Save

UPIRTSO Report

ECOS

Please confirm that you want to create new event. This will save a new UPT form. Please click on new event again to fill in the UPT Single Event Report.

Cancel Confirm

1. The UPIRTSO Report Form is for DSRB approved studies only.
2. Up to 20 Single Event Report Forms can be submitted in the same UPT Form.

1. Click on New Event to unlock the Main UPT Form first
2. Click on Confirm

UPIRTSO Report Form (UPT)

Submission Detail

Back to Submission Detail

-UPT1 Draft

ECOS Ref: [redacted]

Form Details

Declare and Submit

The Main UPT Form is now unlocked for editing and up to 20 Single Event Report Forms can be added

UPIRTSO Report Form

Mandatory Check Cancel Save Save and Exit

Events Summary Table (Maximum 20)

+ New Event

Report No	Event Onset Date	Study Site	Death at Study Site under oversight of DSRB	Event Keywords	Study's Risk-Benefit Ratio has changed

UPIRTSO Report

Declaration

3. Click on New Event again to start a new Single Event Report Form

UPIRTSO Report Form (UPT)

4. Click on Edit to update the UPT details

UPIRTSO Single Event Report

*A1. Study Site:

- Study Site(s)
 Others (including overseas study site) ?

*A3. Event Onset Date:

Select date

*A4. Date of First Knowledge by Investigator:

Select date

*A5. Type of Report:

- Initial Follow Up

Edit

Section A: Basic Inform...

Section B: Participant In...

Section C: Investigation...

Section D: Problem Ass...

Section E: Event Summ...

Section F: Comments b...

5. Click on Save to Main UPT Form

UPIRTSO Single Event Report

Cancel

Save to Main UPT form

Related - Includes possibly related problem. Possibly related means there is a reasonable possibility that the incident, experience, or outcome may have been caused by the procedures involved in the research.

Unexpected - An unexpected problem is one whereby the nature, severity or frequency is not consistent with information in the approved study documents and relevant sources of information or the characteristics of the subject population being studied.

*D1. Opinion of Investigator submitting this report

- Related
 Unexpected

*D2. Opinion of Sponsor (for sponsored research)

- Related
 Unexpected

Section A: Basic Inform...

Section B: Participant In...

Section C: Investigation...

Section D: Problem Ass...

Section E: Event Summ...

Section F: Comments b...

Reminder for **Section D1**:

If the event is not a local death that occurred at local Study Site, then the PI must assess the event to be **both Related and Unexpected** to fulfill the UPT reporting criteria.

UPIRTSO Report Form (UPT)

6. The key details will be displayed in the Main UPT Form. Click on Save to save the Single Event Report Form in the Main UPT Form

Remember to save each time a new Single Event Report Form is added

UPIRTSO Report Form

✓ Mandatory Check ✕ Cancel

Events Summary Table (Maximum 20) + New Event

Report No	Event Onset Date	Study Site	Death at Study Site under oversight of DSRB	Event Keywords	Study's Risk-Benefit Ratio has changed	Action
UPT1-1	01-May-2024	Test		Test	No	Edit Delete

Attach any other document(s)

Upload



7. Once all the Single Event Reports have been saved in the Main UPT Form, click on Save and Exit

UPIRTSO Report Form (UPT)

Submission Detail

Back to Submission Detail

██████████-UPT1 Draft 🕒

ECOS Ref: ██████████ 📄

[Form Detail](#)

UPIRTSO Report Form Export Edit

Events Summary Table (Maximum 20) + New Event

Report No	Event Onset Date	Study Site	Death at Study Site under oversight of DSRB	Event Keywords	Study's Risk-Benefit Ratio has changed
██████████ UPT1-1	01-May-2024 📅	Test		Test	No

Attach any other document(s)

UPIRTSO Report

Declaration

Declare and Submit

8. Click Declare and Submit to submit the UPT Form

Other Study Notification Form (OSN)

[← Back to Submission List](#) Submission Detail 📄 🔔 99+ ⊙

ECOS Ref: 📄

⌵

[Form Detail](#)

Other Study Notification [✕ Cancel](#) [📄 Save](#)

NOTE: Miscellaneous study documents that DO NOT require IRB approval may be submitted for acknowledgment using this Other Study Notifications Form.

***1. Notification type**
Please select

DSMB Report

Annual/Interim /Periodic Safety Report

Interim Data Analysis

Letter from Study Sponsors

Other Notification

***2. Please describe the contents of this notification.**

OSN Form

Declaration

1. For submission of miscellaneous study documents for acknowledgment that DO NOT require IRB approval.
2. Safety report should be submitted via SAE (1 Event / Form)

Track Changes

Submission Detail

NOTE

New/Revised information: Green highlight

Deleted information: Purple highlight with strikethrough

Track Change

Current Version [redacted]-APP1 17-Apr-2024 15:30:56 Previous Version [redacted]-APP1 17-Apr-2024 14:10:05

Section E: Research Methodology (Exemption Application)

E1. What are the specific aims of this study?
GG11 (~~To test another adding site by Amendment~~)What are the specific aims of this study?


E2. What are the hypothesis of this study? For qualitative studies, please provide the research question(s) instead.
GG11 (~~To test another adding site by Amendment~~)What are the hypothesis of this study? For qualitative studies, please provide the research question(s) instead.

E3. Discuss in detail the experimental design and procedures to be used to accomplish the specific aims of the study. Please list all procedures/activities that are carried out as part of research in this study.
GG11 (~~To test another adding site by Amendment~~)Discuss in detail the experimental design and procedures to be used to accomplish the specific aims of the study. Please list all procedures/activities that are carried out as part of research in this studv.

Track Changes

Export

[Redacted] -APP1 Pending Endorsement 


ECOS Ref: 2024-3260 



Form Detail Endorsement

Application Form

Click to Export the form in PDF.

 **Export**

[Track Changes](#)

Section A: Study Title

***A1. Please enter the Study Title for this Study.**

CG0417 - To test exported draft

- Section A: Study Title
- Section B: Submission B...
- Section C: Study Fundin...
- Section D: Study Type an...
- Section E: Research Met...
- Section F: Exemption Re...

Query - Pending PI Reply

The screenshot displays the ECOS 'My Tasks' interface. The top navigation bar includes the ECOS logo, 'My Tasks' title, and notification icons (1, 99+). The left sidebar contains navigation options: Homepage, Dashboard, My Tasks (highlighted), My Notices, IRB, CRMS, FCOI, and Report. The main content area features three summary cards: IRB (4), CRMS (2), and FCOI (0). Below these is a 'Study (4)' link and an 'Endorsement (0)' label. A table lists tasks with columns: Board, Task Received Date, Task Status, Form Type, Form Ref, Study Title, and Action. The first row is highlighted with a red border and has a red dot on its action button. The table data is as follows:

Board	Task Received Date	Task Status	Form Type	Form Ref	Study Title	Action
Board A	05-Apr-2024	Pending	Application	2024-3121-APP1	CG01 (5 Apr 24) - Ready for retest	Action (with red dot)
Board A	10-Apr-2024	Pending	SSR	2024-3062-SSR2	CG01 (2 Apr 2024) - For retest [To check if track change	Action
Board F	11-Apr-2024	Pending	SSR	2024-3183-SSR3	CWL - to test on closure template	Action

For PI, when there are endorsement or IRB query pending PI reply, the PI will receive a task in [My Tasks] and the action button would be with a red dot to symbolize that there are action required.

ROC/DR/IR Query that is Pending PI Reply


Submission Detail

2024-3121-APP1 Pending Endorsement


ECOS Ref: 2024-3121

Form Detail **Endorsement**

Endorsement Status

Institution	Department	Endorsement Information	Endorser Name	Action
National Neuroscience Institute Main Site	Neurology (SGH Campus)	● Pending PI Reply	Mrs NNI_ROC1	 

The red dot indicates that there are endorsement queries.

Click on the '' icon to view and address the queries sent by ROC, DR or IR.

ROC/DR/IR Query that is Pending PI Reply

The screenshot displays a web application interface. On the left, a sidebar contains a navigation menu with 'Back to My Tasks' and 'Endorsement' (highlighted with a red dot). Below this, the main content area shows '2024-3121-APP1' with a 'Pending Endorsement' status and 'ECOS Ref: 2024-3121'. A table lists institutions: 'National Neuroscience Institute' (Main Site) and 'Singapore National Eye Centre' (Removed). On the right, a 'Query List' is shown for 'National Neuro...'. It includes a 'Pending Query' section with '1/1 Pending Handling' and a 'General' section containing a query 'ABCDEF' from 'Mrs NNI_ROC1' on '05-Apr-2024 16:39:18'. Below this is a '* Reply Query' section with a text input field containing 'GHIJKLM'. A yellow arrow points to this input field with the text 'Input your reply here'.

****Note: Click the area outside to close the Query List.****

ROC/DR/IR Query that is Pending PI Reply

The screenshot displays the 'Submission Detail' page for application 2024-3121-APP1, which is in a 'Pending Endorsement' state. A teal callout box points to the 'Reply Query' button, stating: 'If there is no amendment to the form, click on [Reply Query]'. A modal dialog titled 'ECOS' is open, asking 'Are you sure to submit the following replies with the latest form?'. It lists a query from the 'National Neuroscience Institute' with two items: 'ABCDEF' and 'GHIJKLM'. The dialog has 'Cancel' and 'Confirm' buttons. In the background, the 'Application Form' section is visible, with a red box highlighting the 'Edit' button and a red arrow pointing to it from a callout box below.

Click on [Edit] to amend the form if required.

IMPORTANT

- All roles will have the [Reply Query] button if there are no changes to the form.
- If there are changes to the form, only Overall PI will have the [Submit] button.

ROC/DR/IR Query that is Pending PI Reply - PI Reply with Amendment to Form

Back to My Tasks Submission Detail

2024-3121-APP1 Pending Endorsement

ECOS Ref: 2024-3121

Form Detail

Application Form

*A1. Please enter the S

CG01 (5 Apr 24) - Tra

ECOS

Please confirm to submit. If applicable, the form will be routed for the necessary checks and endorsements.

Query

National Neuroscience Institute 1 Query ^

Query Item: General ^

- ABCDEF
- GHIJKLM

Cancel Submit

Back Changes Edit

Section A: Study Title

Section B: Submission B...

Section C: Study Fundin...

Section D: Study Type an...

et...

Re...

IMPORTANT

- For all other roles, there will be no buttons available if there is changes to form.
- Please inform your PI when the form is ready for submission.

IRB Query that is Pending PI Reply

The screenshot shows a web interface for submission details. At the top, there is a dark blue header with a back arrow and the text "Back to My Tasks" on the left, and "Submission Detail" in the center. On the right of the header are icons for download, notifications, and a profile. Below the header, the submission ID "2024-3238-APP1" is displayed next to a "Pending PI Reply" status box and a refresh icon. Below this is the ECOS reference number "2024-3238" with a document icon. A grey callout box with a black border points to a red dot on the "Query List" button, containing the text: "The red dot symbolized that there is IRB queries pending reply". The "Query List" button is highlighted with a red box. Below the submission information are two tabs: "Form Detail" (active) and "Endorsement". The main content area is titled "Application Form" and includes "Export", "Track Changes", and "Edit" buttons. The "Edit" button is highlighted with a red box. A teal callout box with a black border points to the "Edit" button, containing the text: "Click on [Edit] to amend the form if required.". Below the form title, there is a section for "Section A: Study Title" with a required field label "*A1. Please enter the Study Title for this Study." and a text input field containing "CG0415 - Study 3 (IRB Reminder)". On the right side, a vertical list of sections is visible: "Section A: Study Title", "Section B: Submission B...", "Section C: Study Fundin...", and "Section D: Study Type an...".

IRB Query that is Pending PI Reply

The screenshot displays a web interface for an IRB application. On the left, the application details for '2024-3238-APP1' are shown, with a 'Pending PI Reply' status. The 'Form Detail' tab is active, showing 'Section A: Study Title' with the text 'CG0415 - Study 3 (IRB Reminder)'. A yellow arrow points to this text with the label 'Input your reply here'. On the right, a 'Query List' is open, showing a 'Pending Query' with the message 'Please check the aims of the study in Section E1'. Below the query, there is a '* Reply Query' section with a text input field containing 'Please enter'.

****Note: Click the area outside to close the Query List.****


Unlocking of Form for Re-Endorsement

- Section B2: Addition of study sites (Endorsement for additional sites only)
- Section B2: Change/ Addition of PI/ Site-PI (Endorsement for additional sites only)
- Section D1: Change of study classification to 'Clinical Trial'
- Section D3: Inclusion of Vulnerable Participants
- Section H4: Change to Placebo Controlled Trial
- IRB may unlock the Application Form if there are major changes made besides the scenario described above.

Study Summary

ECOS My Study List

Columns Export Filter

ECOS Ref	IRB	Study Status	Study Title	PI/Site-PI Name	Initial Review Category	Action
2024-0063	CIRB-Board A	Approved	CG19 - Round 3 Ready for Retest v1	Mrs SNEC_Basic1(Singapore National Eye Centre (SNEC)),Dr SERI_PI(Singapore Eye Research Institute (SERI))	Expedited	

- Click on [My Study List].
- Find the study and click on ‘’ to view the study summary.

Study Summary

2024-0063 Approved

1

All Forms

2

All Forms Attachments

3

Study Letter

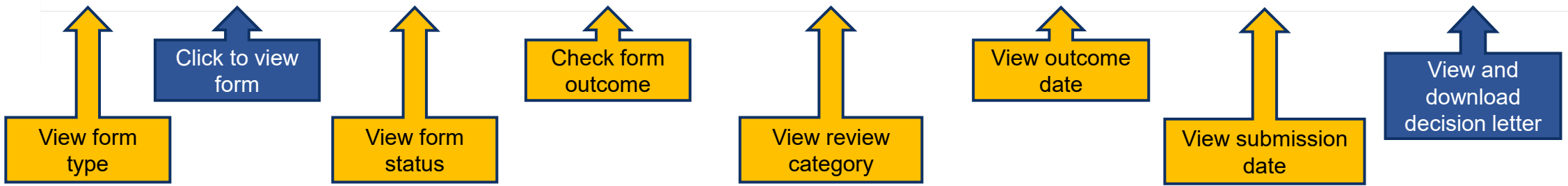


ALL(2) Application(1) Amendment(1)

Change tab to view specific form type created.

Columns Export Filter

Form Type	Form Ref	Form Status	Form Outcome	Review Category	Outcome Date	Submission Date	Letter
Amendment	2024-0063-AMD1	● Pending Endorsement	-	-	-	12-Jan-2024	-
Application	2024-0063-APP1	● Review Completed	Approved	Expedited	12-Jan-2024	11-Jan-2024	CIRB APP Letter



1 Display all forms that had been created for the study.

2 Display the list of attachments uploaded in all forms

3 Display the study letter issued by IRB (e.g. Suspension or Termination letter)



Thank You

Tan Tock Seng Hospital • Khoo Teck Puat Hospital • Woodlands Hospital • Yishun Community Hospital • TTSH Integrated Care Hub
Institute of Mental Health • National Skin Centre • National Centre for Infectious Diseases • NHG Cancer Institute • NHG Eye Institute • NHG Heart Institute
Population Health • NHG Polyclinics • Diagnostics • Pharmacy • Community Care • NHG College • Centre for Healthcare Innovation