

# ECOS User Guide: Institutional Review Board (IRB) Module

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# IRB Dashboard – Submission List

ECOS

Submission List

Configuration

CRMS

FCOI

IRB

Submission List

Endorsement

My Study 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	

- 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

Download

Notification

Profile

Configuration

CRMS

FCOI

IRB

Submission List

Endorsement

My Study List

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

Configuration

CRMS

FCOI

IRB

Submission List

Endorsement

My Study List

My Study List

Columns

Export

Filter

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

[Back to Submission List](#)

Submission Detail



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"/>	<a href="#">Save</a> <a href="#">Cancel</a>

#### Investigator List

Study Site	Name	Study Role	Email	Designation

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

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

- 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.

- 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.

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

Section A: Study Title

Section B: Submission ...

Section C: Study Fundi...

Section D: Study Type a...

[+ Add](#)

Refer to next slide

# Adding Study Investigator

Add

Save

\* Study Site

Only study site added would be available

\* Name

Search via full name or email address

Please enter

\* Study Role

Select study role

Profile and Minimum Training

-

\* Conflict of Interest

Indicate if there are any conflict of interest

Yes

No

\* 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.).

Restricted, Sensitive - Normal

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# 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)	<a href="#">Complete</a>

- 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:

Others

▼

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

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

ⓘ

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

SGP-

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

☒ Yes

☐ No

\*C1 (b) (iv) Attachment

 Upload

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

☐ Yes

☒ No

\*C1. (b) (v) (i) Please state alternate funding

0 characters entered

C1. (b) (vi) Grant Reference Number

Provide the name of the Grant Holder

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

Upload the grant approval letter if grant had been approved

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

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

# 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

X 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 device is regulated)

☐ Surgical / Radiotherapy Procedure

☐ Interventions/ Invasive procedures

☐ None of the above

Section A: Study Title

Section B: Submission Information

Section C: Study Funding

Section D: Study Type and Design

Section E: Study Objectives

Section F: Study Design

Section G: Research Methodology

Section H: Research Details- Clinical Trials (Drug)

Section I: Research Details- Clinical Trials (Device)

Section J: Research Details- Clinical Trials (Biological)

Section K: Research Details- Clinical Trials (Other)

Section L: Research Details- Clinical Trials (Other)

Section M: Research Details- Clinical Trials (Other)

Section N: Research Details- Clinical Trials (Other)

Section O: Research Details- Clinical Trials (Other)

Section P: Research Details- Clinical Trials (Other)

Section Q: Research Details- Clinical Trials (Other)

Section R: Research Details- Clinical Trials (Other)

Section S: Research Details- Clinical Trials (Other)

Section T: Research Details- Clinical Trials (Other)

Section U: Research Details- Clinical Trials (Other)

Section V: Research Details- Clinical Trials (Other)

Section W: Research Details- Clinical Trials (Other)

Section X: Research Details- Clinical Trials (Other)

Section Y: Research Details- Clinical Trials (Other)

Section Z: Research Details- Clinical Trials (Other)

Other Attachments

Declaration of Principal Investigator

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.

# Study Involving Human Biological Material

[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 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

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 W: Biological M...

Section X: Data & Safet...

Other Attachments

Declaration of Principal ...

- 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.

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# Study Involving Human Biological Material

Back to Submission List

Submission Detail

Download

Alert

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 details of collection, storage and use.

- Please include the frequency of collection, the amount to be collected and the frequency of collection.

- How are the human biological materials identified?

- Where will human biological material 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.




Restricted, Sensitive - Normal


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# 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 all components).

☐ (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

X Cancel

Save

Section A: Study Title

Section B: Submission Information

Section C: Study Funding

Section D: Study Type and Design

Section E: Study Objectives

Section F: Study Design

Section G: Research Methodology

Section H: Data Management

Section I: Ethics Approval

Section J: Regulatory Compliance

Section K: Financial Disclosure

Section L: Declaration of Principal Investigator

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.

# 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.

\*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.

0 characters entered

- 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/ Medicine

\*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

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 ...

- 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.

Restricted, Sensitive - Normal

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# Study Involving Medical Device (including Telehealth Medical Device)

Back to Submission List

Submission Details

ECOS Ref: -

Form Detail

Application Form

I1. Please state the name of the medical device(s) that will be tested or studied in this research (including product name and brand/ manufacturer) (C)

Add

No Data

Medical Device

0 characters entered

¶I1. (a) Is the medical device used as a prototype (including modified devices) under in this study?

☐ Yes

☐ No

¶I1. (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

¶I1. (c) Will you be submitting or have submitted the Clinical Research Material Notification (CRM-N) to HSA for the medical device?

☐ Yes

☐ No

¶I1. (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

¶I1. (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

¶I1. (g) Please describe on the storage, inventory and control of the medical device?

0 characters entered

¶I1. (h) Who will be responsible for administering the medical device?

☐ Trained study team member

☐ Research participants

☐ Others

¶I1. (i) Please describe how the unused or returned medical device will be managed at the completion of this research study.

0 characters entered

¶I1. (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 I1**, 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.

X Cancel

Save

Section D: Study Type... ⚠

Section G: Research Methodology...

Section H: Research Design...

Section J: Recruitment ...

Section K: Research Participants... ⬅

Section T: Research Data...

Other Attachments

Declaration of Principal Investigator...

# Study Involving Vulnerable Populations – Children

ECOS Re

Form D

Applicati

Submission Detail

Download

Alert

Menu

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

Restricted, Sensitive - Normal

## Study Involving Vulnerable Populations – Cognitive Impaired Person

< Back to Submission List

Submission Detail

ECOS Ref: - [REDACTED]

Form Detail

Application Form

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.

\*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

X 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 ...


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# 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.**

0 characters entered

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

 Upload

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 for more information)

☐ 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 must be selected if the study involves recruitment

☐ 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 shows the 'Submission Detail' header with a 'Back to Submission Detail' link and icons for download, notifications, and a profile. Below the header, the form ID '2024-0193-APP1' is displayed with a 'Draft' status and a clock icon. The ECOS Ref is '2024-0193'. A 'Declare and Submit' button is visible. The 'Form Detail' tab is selected. The 'Application Form' section contains a text input field with the value 'CG23 - For Training Purposes' and a character count of '28 characters entered'. To the right of the input field are three buttons: 'Mandatory Check' (highlighted with a green box and callout 1), 'Cancel' (with a blue 'X' icon), 'Save' (highlighted with a green box and callout 2), and 'Save and Exit' (highlighted with a green box and callout 3). A sidebar on the right lists sections: 'Section A: Study Title', 'Section B: Submission ...', and 'Section C: Study Fundi...'.

- 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

3

Declare and Submit

ECOS Ref: 2024-0193

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

Current Editor: -

PI/Site PI: Mrs SNEC\_Basic1(Singapore National Eye Centre (SNEC))

Study Title: CG23 - For Training Purposes

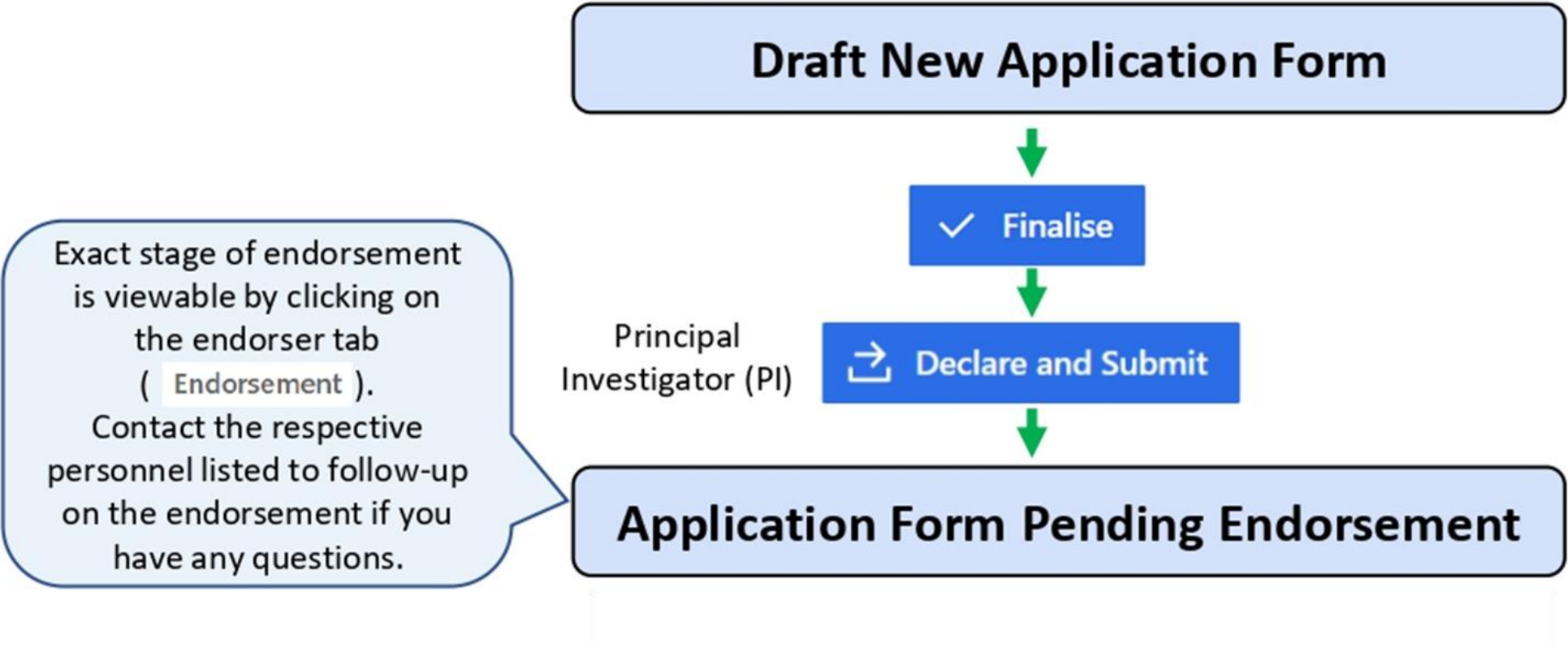
1

2

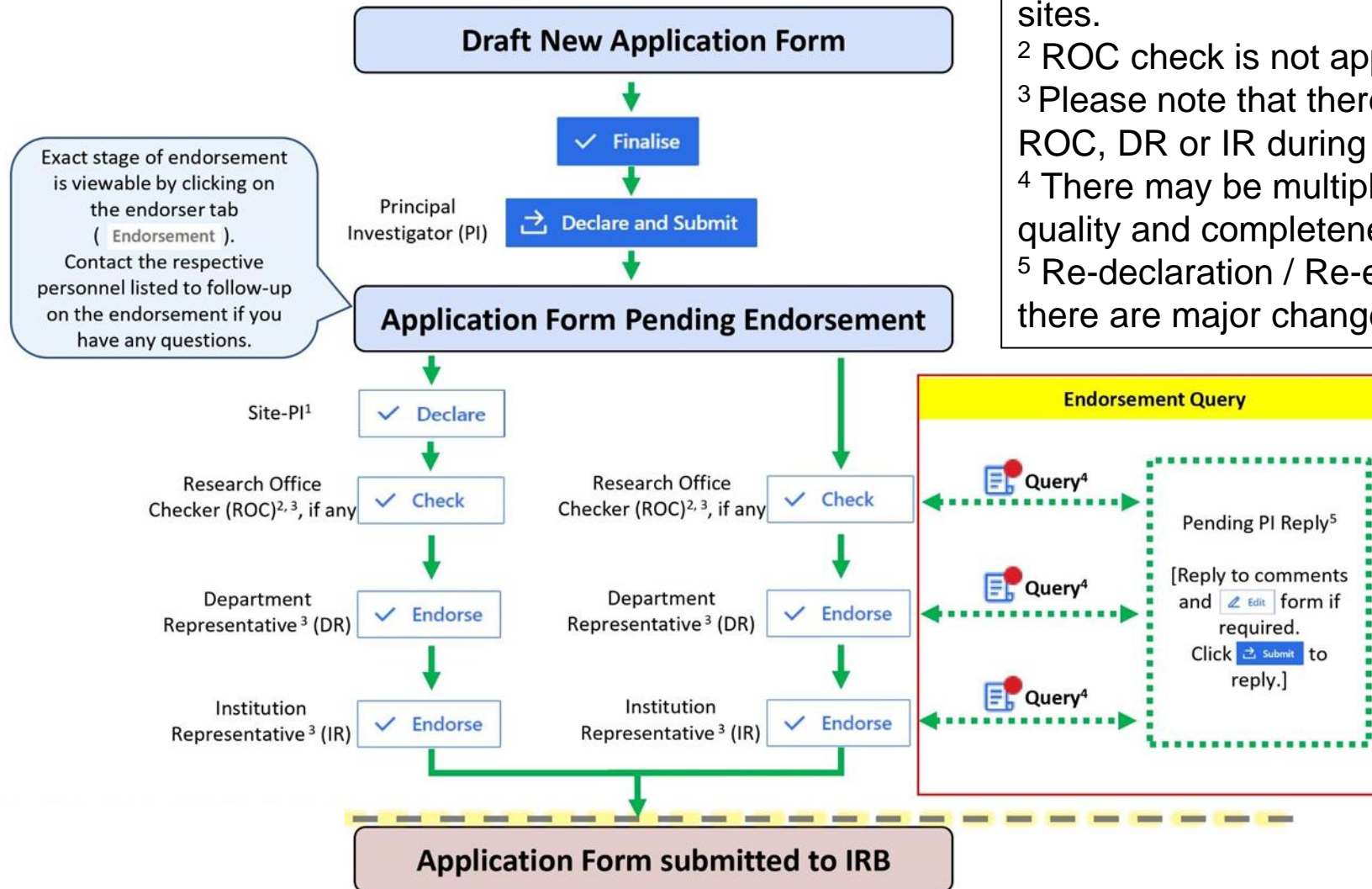
Quick Link: [Study Summary,CRMS](#)

- 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 ' Declare and Submit' button will be displayed, and form will be 'Pending Endorsement' upon submission.  
For all other roles, the ' Finalise' button will be displayed, and form will be 'Pending PI Declaration' upon submission.

# Submission Workflow



# Submission Workflow



Note:

<sup>1</sup> This is only applicable for study involving multi-sites.

<sup>2</sup> ROC check is not applicable for all institutions

<sup>3</sup> Please note that there may be queries from ROC, DR or IR during the endorsement process.

<sup>4</sup> There may be multiple returns depending on the quality and completeness of reply

<sup>5</sup> Re-declaration / Re-endorsement is required if there are major changes to the application form.

# Site-PI Declaration

ECOS

Endorsement

Columns

Export

Filter(2)

Homepage

IRB

Submission List

Endorsement

My Study List

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

Declare

ECOS Ref: 2024-0193

Form Detail

Endorsement

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

# Endorsement Status

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) <span>Main Site</span>	Glaucoma	<div><div></div>Pending DR Endorsement</div>	SNEC_DR 1	<div><div></div><div></div></div>

- 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)

Homepage

IRB

Submission List

Endorsement

My Study List

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

Query List

Send Query

1

Checked

2024-0193-APP1

Pending Endorsement

ECOS Ref: 2024-0193

Form Detail

Endorsement

1

For ROC:

Checked

For DR and IR:

Reject

Endorse

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

# Creation of Other Forms

ECOS

Submission List

Download

Alert

Homepage

IRB

Submission List

Endorsement

My Study List

CRMS

FCOI

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
2023-0131	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:

Please enter

Q

\* 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)


1. Search for study with ECOS Ref or Study Title

2. Select Form Type to be created

# 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 rational 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.




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# Study Status Report Form (SSR)

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Submission Detail




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.I 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)

[Back to Submission List](#)

Submission Detail



ECOS Ref: 2024-3201 

Form Detail

Study Deviation/Non-Compliance Report Form

Cancel

Save

Guidance

DNC Form

Declaration

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, deviation is not intended as a systematic change unless the change is necessary to eliminate an immediate hazard to the research participants.
- Study deviation is also used to refer to any other, unplanned, insubstantial change to the protocol or failures on the part of the research participant(s) that are not intended as a systematic change.

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 amendments
- Failure to report an adverse event report according to IRB timelines
- Performing 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)

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Submission Detail

Download

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ECOS Ref: 2024-3203

Form Detail

Serious Adverse Event Report

Note:

1. This form is for submission of

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: Determination of SAE

Section B: Basic Information

Section C: Investigation

Section D: Event Summary

Section E: Comments by ...

Section F: Investigator's ...

# UPIRTSO Report Form (UPT)

Back to Submission List

Submission Detail

ECOS Ref:

Form Detail

UPIRTSO Report Form

Events Summary Table (Maximum 20)

Attach any other document(s)

Upload

Cancel

Save

UPIRTSO Report

+ 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

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

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# UPIRTSO Report Form (UPT)

-UPT1

Draft

ECOS Ref:

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

+ New Event

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

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	<a href="#">Edit</a> <a href="#">Delete</a>

Attach any other document(s)

[Upload](#)



Save

Save and Exit



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

# UPIRTSO Report Form (UPT)

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

-UPT1 
 Draft
🔄

ECOS Ref:  📄

➔ Declare and Submit
⋮

---

[Form Detail](#)

### UPIRTSO Report Form

📥 Export
Edit

Events Summary Table (Maximum 20) <span>+ New Event</span>					
Report No	Event Onset Date	Study Site	Death at Study Site under oversight of DSRB	Event Keywords	Study's Risk-Benefit Ratio has changed
<input type="text"/> - UPT1-1	01-May-2024 <span>📅</span>	Test		Test	No

Attach any other document(s)

**UPIRTSO Report**

Declaration

8. Click  
Declare and  
Submit to  
submit the  
UPT Form

# Other Study Notification Form (OSN)

Back to Submission List

Submission Detail

Download

99+

ECOS Ref: 2024-3202

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.

OSN Form

Declaration

\*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.

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

2024-3260-APP1 17-Apr-2024 15:30:56

ECOS

For

Applic

Section

\*A1. Pl

CGO

2024-3260-APP1 17-Apr-2024 14:10:05

ECOS

For

Applic

Section

\*A1. Pl

CGO

Back to Submission List

Submission Detail

99+

NOTE

New/Revised information: Green highlight

Deleted information: Purple highlight with strikethrough

Track Change

Current Version2024-3260-APP1 17-Apr-2024 15:30:56Previous Version2024-3260-APP1 17-Apr-2024 14:10:05

Track Changes

Study Title

Submission B...

Study Fundin...

Study Type an...

Section E: Research Methodology (Exemption Application)

E1. What are the specific aims of this study?

~~CG11 (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.

~~CG11 (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.

~~CG11 (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.

Restricted, Sensitive - Normal

56

# Export

[Back to Submission List](#)

Submission Detail



2024-3260-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

ECOS

My Tasks

1

99+

Homepage

Dashboard

My Tasks

My Notices

IRB

CRMS

FCOI

Report

IRB

4

CRMS

2

FCOI

0

Study (4)

Endorsement (0)

Columns

Export

Filter(1)

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	<div></div>
Board A	10-Apr-2024	Pending	SSR	2024-3062-SSR2	CG01 (2 Apr 2024) - For retest [To check if track change	<div></div>
Board F	11-Apr-2024	Pending	SSR	2024-3183-SSR3	CWL - to test on closure template	<div></div>

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

2024-3121-APP1

ECOS Ref: 2024-3121

Pending Endorsement

Form Detail

Endorsement

Reply Query

The red dot indicates that there are endorsement queries.

Endorsement Status

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

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

Restricted, Sensitive - Normal

59

# ROC/DR/IR Query that is Pending PI Reply

Back to My Tasks

2024-3121-APP1

Pending Endorsement

🕒

ECOS Ref: 2024-3121

📄

Form Detail

Endorsement

Endorsement Status

Institution

National Neuroscience Institute

Singapore National Eye Centre

Department

Neurology (SDH Campus)

Glaucoma

Main Site

Removed

Query List

National Neuro...

▼

Saved at 05-Apr-2024 16:39:34

Pending Query

All Query

1/1 Pending Handling

General

⌵

ABCDEF

Query Round1 Mrs NNI\_ROC1 05-Apr-2024 16:39:18

\* Reply Query

GHIJKLM

✕

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 shows 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 window 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 modal has 'Cancel' and 'Confirm' buttons. In the background, the 'Application Form' section is visible, showing 'Section A: Study Title' and 'Section B: Submission B...'. A red box highlights the 'Edit' button next to 'Section A: Study Title', with a red arrow pointing to a text 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

Download

Notification

Profile

2024-3121-APP1

Pending Endorsement

Refresh

This button will only appear for PI if there is changes to

Submit

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...

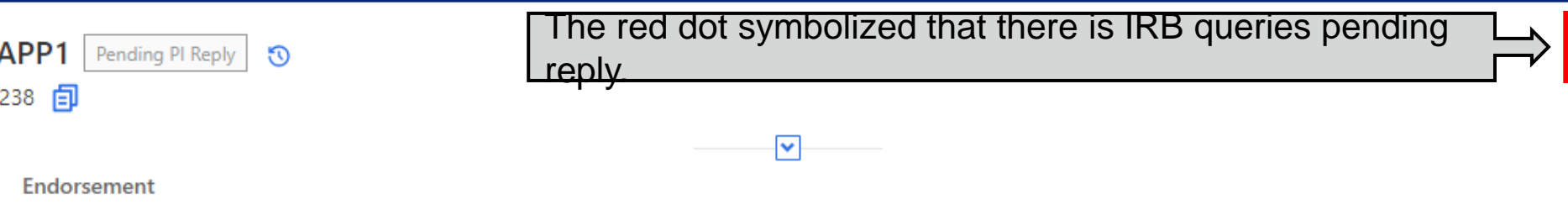
et...

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 the 'Submission Detail' page for application 2024-3238-APP1. The status is 'Pending PI Reply'. The page has two tabs: 'Form Detail' (active) and 'Endorsement'. Under 'Form Detail', there is a section titled 'Section A: Study Title' with a required field 'A1. Please enter the Study Title for this Study.' containing the text 'CG0415 - Study 3 (IRB Reminder)'. On the right side, there are three buttons: 'Export', 'Track Changes', and 'Edit'. The 'Edit' button is highlighted with a red box and a red hand icon. A teal callout box points to the 'Edit' button with the text 'Click on [Edit] to amend the form if required.' At the top right, there is a 'Query List' link with a red dot, also highlighted with a red box and a red hand icon. A grey callout box points to this link with the text 'The red dot symbolized that there is IRB queries pending reply.'

## IRB Query that is Pending PI Reply

< Back to My Tasks

SUBMIT Query List Saved at 18-Apr-2024 07:40:26

2024-3238-APP1 Pending PI Reply

ECOS Ref: 2024-3238

Form Detail Endorsement

Application Form

Section A: Study Title

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

CG0415 - Study 3 (IRB Reminder)

Pending Query All Query

0/1 Pending Handling

General ^

Please check the aims of the study in Section E1  
Query Round2 Ms CIRB\_A\_IRBSec1 18-Apr-2024 07:40:26

\* Reply Query

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

Download

Notification

Profile

Homepage

IRB

Submission List

Endorsement

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	<div></div>

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

# Study Summary

Back to My Study List

Study Summary

Download

Alert

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 created.

Columns

Export

Filter

Form Type	Form Ref	Form Status	Form Outcome	Review Category	Outcome Date	Submission Date	Letter
Amendment	2024-0063-AMD1	<div>Pending Endorsement</div>	-	-	-	12-Jan-2024	-
Application	2024-0063-APP1	<div>Review Completed</div>	Approved	Expedited	12-Jan-2024	11-Jan-2024	<a href="#">CIRB APP Letter</a>

View form type

Click to view form

View form status

Check form outcome

View review category

View outcome date

View submission date

View and download decision 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