

IRB Guidebook:

- PI/Site-PI Declaration
- Research Office Check (ROC)
- Department Representative (DR) Endorsement
- Institution Representative (IR) Endorsement



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Section A: Submission Process

A.1 Overview of Submission Process

- All Application Forms would require PI/Site-PI declaration and endorsement from the respective institutions before the forms will reach the IRB for review. Declaration and endorsements would be required from the following roles:
 - PI Declaration
 - Site-PI Declaration (for multi-site study)
 - Research Office Checker (ROC) (if applicable)
 - Department Representative (DR) Endorsement
 - Institution Representative (IR) Endorsement
- Amendment Form would be submitted to IRB for review after PI submission. Please note that when there are changes to the following sections, the Amendment Form will be unlocked for re-endorsement.
 - Section B2: Addition of study sites (Endorsement for the additional sites only)
 - Section B2: Change/Addition of PI/Site-PI (Endorsement for the sites involved only)
 - Section D2: Change Study Classification to "Clinical Trial"
 - Section D3: Inclusion of Vulnerable Participants
 - Section H4: Change to Placebo Controlled Trial

For re-endorsements, actions from the following roles would be required:

- PI Declaration
- Site-PI Declaration (for multi-site study)
- Research Office Checker (ROC) (if applicable)
- Department Representative (DR) Endorsement
- Institution Representative (IR) Endorsement

3. The other forms (Study Status Report Form, Serious Adverse Events Report Form, Study Deviation/ Non-Compliance Report Form and Other Study Notification Report Form) would be submitted to IRB review after PI declaration. Endorsement is not required.

Note:

- 1. ROC, DR and IR may raise queries during the endorsement process. It is important to respond to the query so that the endorsement process can continue. The queries are from Institutions and not IRB. Please contact your Research Office if any clarification is required.
- 2. When query (during the endorsement process or during IRB review process) is raised, the Application/Amendment Form becomes editable and study team can update the Application/Amendment Form.
- 3. When there are significant changes to the section(s) as described above, the Application/Amendment Form will be unlocked for re-endorsement.
- 4. If major changes were noted during the IRB review process, the IRB secretariat may unlock the form for re-endorsement as well.

A.2 Endorsement Status

After PI declaration, the status of the form will be updated to "Pending Endorsement". To check on the current endorsement status, please click on the "Endorsement" tab.

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			Click to view endorseme	ent history.



Note:

¹ This is only applicable for study involving multi-sites.

² ROC check is only applicable for certain institutions.

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

⁴There may be multiple returns depending on the quality and completeness of application and reply.

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

Section B: Principal Investigator (PI) Declaration

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Section C: Site- Principal Investigator (Site-PI) Declaration

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For endorsement by ROC

- 1. Please use the Form Detail to view the details of the form and ensure all information is in accordance with the institution's standards.
- 2. To perform ROC check, click on [Check].

Section E: Department Representative (DR) Endorsement

As a DR, one would need to support and endorse the study via ECOS-IRB Module. If the study involves multi sites, the Site-Principal Investigator's DR would need to endorse the study as well. The DR is to ensure that the proposed study is keeping with standards set by his/her department. Only when the endorsement by the DR is completed, the Application will be routed to the IR for review and endorsement.

Department Representative (DR):

- The Department Representative is usually the Head of Department or equivalent of the Pl's and Site-Pl's department. Where appropriate, the Head/Director of Division who oversees several departments may endorse in lieu of the Head of Department.
- When the DR is involved in a study, he/she will not be allowed to endorse his/her own CIRB application. The research office will appoint another DR to endorse the application.
 Please check with your institution's research office if the main DR is not available to perform the endorsement.
- Should the DR have conflict of interest in the study pending his/her endorsement, he/she should refrain from endorsing the application and contact his/her institution's research office to assign an alternate DR.

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For endorsement by DR,

- 1. Please use the Form Detail to view the details of the form and ensure all information is in accordance with the department and institution's standards.
- 2. To view the endorsement status, click on the Endorsement tab and the information of the next endorser would be shown.
- 3. The Reject button should only be used by the DR and IR if they do not support the conduct of the study. If there is a need for the submission to be edited, please use the Query function.
- 4. To endorse the study, click on [Endorse].

Section F: Institution Representative (IR) Endorsement

As an IR, one would need to support and endorse the study via ECOS-IRB Module before the study can be submitted to CIRB for review. If the study involves multi sites, the Site-PI's IR would need to endorse the study as well. The IR is to ensure that the proposed study is keeping with standards set by his/her Institution. Only when the endorsement by the IR is completed, will the CIRB application be forwarded to CIRB for review.

Institution Representative:

- The IR is usually the Institution's Director of Research (or equivalent) or Chairman of Medical Board. The IR is determined by each Institution, and he/she is given the authority to determine if the proposed research activity is keeping with the Institution's research objectives, reputation and standards.
- Conflict of Interest Institution Representative: When the Institution Representative is involved in a study, he/she will not be allowed to endorse his/her own CIRB application. The research office will appoint another IR to endorse the application. Please check with your institution's research office if the main IR is not available to perform the endorsement.
- Should the IR have conflict of interest in the study pending his/her endorsement, he/she should refrain from endorsing the application and inform his/her institution's research office whom shall be the alternate IR to endorse the application/amendment.

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- 1. Please use the Form Detail to view the details of the form and ensure all information is in accordance with the department and institution's standards.
- 2. To view the endorsement status, click on the Endorsement tab and the information of the next endorser would be shown.
- 3. The Reject button should only be used by the DR and IR if they do not support the conduct of the study. If there is a need for the submission to be edited, please use the Query function.
- 4. To endorse the study, click on [Endorse].



Section G: Endorsement Query (ROC/DR/IR)

ROC, DR, and IR may seek clarification with the study team before deciding to Endorse or Reject the application. To send endorsement query to the study team, click Query List.

* Do note that in ECOS, the checker and endorser can add query to specific questions.

	Endorsement Detail	ት 😨 ୪
2024-3415-APP1 Pending Endorsement S ECOS Ref: 2024-3415	Click he	ere to open the [Query List]. B Guery List Send Query 🗸 Check
Form Detail Endorsement	V	
Application Form		🛃 Export 🛛 Track Changes
Section A: Study Title		Section A: Study Title
⇒A1. Please enter the Study Title for this Study.	Click to add query to	specific questions in the form.
CG0722 - For Demo Purposes.		+ New Query Section C: Study Fundin
		Section D: Study Type an
Query List National Neuro V Saved at 12-Mar-2024 23:23:15 + Gen	veral/Section Query	
Pending Query All Query	1	Display the site which the questions are directed to.
0/0 Pending Handling		
0 Queries Selected Batch Close	2 2	For '+ General/Section Query', general or specific section can
Section C: Study Fund V	b t ^	be selected.
Query Description	3	Example of question added via specific questions.
Please clarify if the study grant had been approved.	8	
Attachment		Attachments can be uploaded if required.
E1. What are the specific aims of this study?	ů ^ Ď	Questions can be deleted if not required.
+ Query Description		
Please specific the aims of the study.	**Note:	Click the area outside to close the Querv List.**
Attachment		,
1 Upload		

G.1 Query List

Version 1 dated 11 Sep 2024

G.2 Send Query

C : E < Back to Endorsement	Endorsement Detail	또 🕹 🎖
2024-3415-APP1 Fending Endorsement COS Ref: 2024-3415		Query List Send Query Check
Form Detail Endorsement	The red dot on [Query List]	indicate that
Application Form	there are queries pending y	/OUR ACTION. 📩 Export Track Changes
Section D: Study Type and Nature		Section A: Study Title
+D1. Form Type: Please select the appropriate form for submission.	Send Query X	Query ∨ Section B: Submission B
Application Form Exemption Application Form	Do you want to proceed?	Section C: Study Fundin
=D1. (a) Please select the exemption application categories.	Query Item: D1. Form Type: Please select the appropriate form for submission.	Query V
Category S1 – Research in Established or Commonly Accepted Educational Settings ③ Category S2 – Research that Only Implies Educational Tests Superior Interviews or Observation	Query Description: This study does not fulfill the exemption criteria, please change the form type to 'Application Form' instead.	Section E: Research Met
Category S3 – Research Involving Benign Behavioural Interventions ()		Section F: Exemption Re
Category S4 – Secondary Research Using Biospecimens or Private Information. Category S5 – Taste and Food Quality Evaluation and Consumer Acceptance Studies	Query Item: General	Other Attachments
*D2. Study Classification: Please determine which set of regulations would govern the study (or a	Query Description: Please check through the application to align all information.	
(a) Clinical Trial - Regulated by Health Products Act/ Medicines Act (HSA)		eview the queries drafted and
(b) Human Biomedical Research - Regulated by Human Biomedical Research Act (MOH)		ick [Confirm] to send query.
🔘 (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 Bio	medical Research Act (MOH)	
=D2. (d) Please justify why the study is not regulated by Health Products Act/ Medicines Act (HSA)) or Human Blomedical Research Act (MOH).	Query 🗸
Others		

- 1. After query has been drafted, there will be a red dot on the Query list to indicate that there are queries drafted.
- 2. Click on **[Send Query]** if there are no further queries to be included and click **[Confirm]** to send.

After query is sent:

Cr □ Ξ < Back to My Tasks		Endorsement Detail		ች 🖕 ୪
2024-3415-APP1 Pending Endorsement ECOS Ref: 2024-3415				E. Query List Send Query Check
Form Detail Endorsement			[Send Query] and [Che	ck] button are greyed
Research Office Checker			out to signify that study	is pending PI reply.
Institution	Department	Endorsement Information	Endorser Name	Action Research Office Checker
National Neuroscience Institute Main Site	Neurology (SGH Campus)	Pending PI Reply	Mrs NNI_ROC1	E S Endorsement Status
	The Endorse icon indicate	ement Information and s that the form is pend	red dot on the ' डऀ ' ding PI reply.	

To view the sent query, click on [Endorsement tab] > Query List icon '

After query is sent, the task will remain on the Dashboard and Endorsement list. Tasks with queries sent are indicated with an Orange dot and no further action is required.

[Dashboard] > [My Task] > [IRB] > [Endorsement]

E ECOS					м	y Tasks				÷	א 🛱 נ
☆ Homepage	IRB	FCOI									
Dashboard	1	0									
My Tasks											
My Notices	Study (0) En	dorsement (1)									0
TRB *									Columns	🛃 Export	Filter(1)
CRMS	IRB	Task Received Date	Endorsement Stage	My Role	Form Type	Form Ref	Study Title	PI/Site-	PI	Task Status	Action
Report -	SingHealth CIRB-Boar	d A 22-Jul-2024	Pending DR Endorsement	DR	Application	2024-3415-APP1	CG0722 - For Demo Purposes.	Mr NNI Institute Nationa	_PI 1 (National Neuroscie e), A/Prof SNEC_PI_1 (Sing al Eye Centre)	nce Japore Pending	o

'^o ' indicates that there is no action required.

ECOS						Endorsement								🕁 🗘	<u></u> 2
Homepage	•										(Columns	🛃 Export	🖞 Fil	ilter(2)
olo IRB	•	Form Ref 🗘	IRB ‡	Study Title	÷	PI/Site-PI Name	÷	Department	÷	Institution	Form Type 👙	Form Status	⊕ Endorser I	Name Acti	tion:
Submission List	_	2024-3415-APP1	SingHealth CIRB-Board A	CG0722 - For Demo Purposes.		Mr NNI_PI 1 (National Neurosc Institute), A/Prof SNEC_PI_1 (Si	ience ngapore	Neurology (SGH Campus)		National Neuroscience Institute	Application	 Pending Endorsement 	Mr NNI_D	R 1 0	5
Endorsement						National Eye Centrej									
My Study List															
Institution Study List															
🔮 CRMS	•														
K FCOI	-														
Report	-														

'of' indicates that there is no action required.

G.3 Close Query

After PI replied to the query, the Orange dot would be changed to Red dot to indicate that action is required by the ROC/DR/IR.

[Dashboard] > [My Task] > [IRB] > [Endorsement]

E ECOS						м	y Tasks			÷	¢ 9 8
Homepage	•	IRB	FCOI								
Dashboard		1	0								
My Tasks											0
My Notices		Study (0) En	dorsement (1)								0
OTO IRB	•								Columns	🛃 Export 💦	Filter(1)
CRMS	Ť	IRB	Task Received D	Date Endorsement Stage	My Role	Form Type	Form Ref	Study Title	PI/Site-PI	Task Status	Action
FCOI	•	SingHealth CIRB-Board	d A 22-Jul-2024	Pending DR Endorsement	DR	Application	2024-3415-APP1	CG0722 - For Demo Purposes.	Mr NNLPI 1 (National Neurosciet Institute), A/Prof SNEC_PI_1 (Sing National Eye Centre)	nce Japore Pending	୍ତ

'of ' indicates that further action is required.

[IRB] > [Endorsement]

C ECOS						E	ndorsement									Ł	୍ <u>କ</u> ୪
Homepage	•													Columns	e	έ Export γ	Filter(2)
OTO IRB	•	Form Ref 🗦	IRB $ arrow$	Study Title	÷	PI/Site-PI Nam	e	÷ I	Department	÷	Institution	For	m Type	Form Status	÷	Endorser Name	Action
Submission List		2024-3415-APP1	SingHealth CIRB-Board A	CG0722 - For Demo Purposes.		Mr NNI_PI 1 (N Institute), A/Pr	lational Neuroscience of SNEC_PI_1 (Singapor	e	Neurology (SGH Campus)		National Neuroscience Institut	e App	plication	 Pending Endorsement 	t	Mr NNI_DR 1	0
Endorsement						National Eye C	entre)										
My Study List																	
Institution Study List																	

'of' indicates that further action is required.

Comparison Comparison 2024-3415-APP1 Pending Endorsement ECOS Ref: 2024-3415 Image: Comparison	End	The red dot indicates that there are updates to the Query List.	E. Query List	t ₽ ス
Form Type: Application Current Editor: -	Form Outcome: -	Initial Review Category: -		
PI/Site PI: Mr NNI_PI 1 (National Neuroscience Institute), A/Prof SNEC_PI_1 (Singapore	National Eye Centre)			
Study Title: CG0722 - For Demo Purposes.				
Quick Link: Study Summary Form Detail Endorsement				
Application Form			ف	Export Track Changes
Section A: Study Title				Section A: Study Title
+A1. Please enter the Study Title for this Study.			Query 🗸	Section B: Submission B
CG0722 - For Demo Purposes.				Section C: Study Fundin



		Endorsement Detail		F 🐞 X
2024-3415-APP1 Pending Env ECOS Ref: 2024-3415	When all queries are o	losed, the red dot will disap	pear at [Query List] . 🖉 🛯 👓	List Close Query Check
Form Type: Application Current Editor: -	F	orm Outcome: -	Initial Review Category: -	
PI/Site PI: Mr NNI_PI 1 (National Neu	roscience Institute). A/Prof SNEC_PI_1 (Singapore National Eye C	entre)		
Study Title: CG0722 - For Demo Purp	oses.			
Quick Link: Study Summary				
Form Detail Endorsement				
Application Form				Export Track Changes
Section A: Study Title		Close Query	×	Section A: Study Title
*A1. Please enter the Study Title for th	nis Study.	Do you want to proceed?		Section B: Submission B
CG0722 - For Demo Purposes.			Click [Confirm	n] to close
		Cancel	🗌 🚾 🤇 🔄 queries and cor	clude query
			proces	ss.
NOTE				Section F: Exemption Re
				_
Endorsemen	t can continue by referr	ing to Section D, E and F: E	Endorsement by ROC/DR/I	R.
				Declaration of Principal I

Section H: Endorsement Query (Study Team)

H.1 Replying to query

For study team, there will be task listed in **[My Tasks] > [IRB]** with a red dot to signify that the form is pending PI reply. Alternatively, via **[IRB] > [Submission list]**, you will see the submission with a red dot to signify that form is pending PI reply.

[Dashboard] > [My Task] > [IRB] > [Study]

ECOS						My Tasks				d	Ł
Homepage	•	IRB	CRMS	FCOI	Compliance						
Dashboard		14	0	0	2						
My Tasks		Church (12)	Federation (1)								
My Notices		Study (13)	Endorsement (I)								
IRB IRB	•								Columns	🛃 Export	Y
CRMS	•	IRB	💠 🕴 Task Received	Date 💠 Form	Status 💠 My R	⇒ Form	🗘 Form Ref 🛛 🗘	Study Title		PI/Site-PI	A
Compliance	•	SingHealth CIRB-Bo	ard A 23-Jul-2024 15	5:30:36 Pendi	ng Endorsement PI	Applicati	on 2024-3415-APP1	CG0722 - For Demo Purposes.		Mr NNLPI 1 (N (Singapore Nat	la' tic
FCOI	•									A/Prof(Adj) NH	HC.

[IRB] > [Submission list]

ECOS		Submission List	± 🦨
Homepage	÷		+ New Application Form + New Other Forms 🕮 Columns 🕹 Export 🛛 🖓 Filter
No IRB	•	ECOS Ref $\ \diamondsuit$ IRB $\ \diamondsuit$ Form Ref $\ \diamondsuit$ Form Type $\ \diamondsuit$ Form Status $\ \diamondsuit$ Study Title	
Submission List		2024-3415 SingHealth CIRB-Board A 2024-3415-APP1 Application Endorsement CG0722 - For Demo Purposes.	Mr NNLPI 1 (National Neuroscience Institute), A/Prof SNEC, PI_1 (Singapore 22-Jul-2024
Endorsement			National Eye Centre) A/Prof(Ad) NHC, PI 1 (National Heart
My Study List			Centre Singapore, Arron Kingri Tink Women's and Children's Hospital), A/Zerch NIH B/ Kindonal University.

G ⊢ Ξ < Back to Submission List		Submission Detail		ች 🐞 ୪
2024-3415-APP1 Pending Endorsement 3 ECOS Ref: 2024-3415				I
Form Detail Endorsement The	red dot indicates that there	e are endorsement queries.		
Endorsement Status				
Institution	Department	Endorsement Information	Endorser Name	Action
National Neuroscience Institute Main Site	Neurology (SGH Campus)	Pending PI Reply	Mrs NNL_ROC1	6 3
Click o	on the ' 📑 ' icon to view and	ے ک d address the queries sent by R(OC, DR or IR.	

- To view Endorsement query, click on the Query List from the endorsement tab. You may input your reply in the text box below each query.
- To close Query List, click the area outside to close the Query List.

		Submission Detail	Query List Nation V G Saved at 22-Jul-2024 13:10:17
2024-3415-APP1 Pending Endorsement ECOS Ref: 2024-3415			Pending Query All Query //2 Pending
Form Detail Endorsement			D1. Form Type: Please select the appropriate form for submission.
Endorsement Status			This study does not fulfill the exemption criteria, please change the form type to 'Application Form' instead. Chargy Round 1. Mrs NNLROC1. 22-34-2024 12:32:20
Institution	Department	Endorsement Information	* Reply Query
National Neuroscience Institute	Neurology (SGH Campus)	Pending PI Reply	Noted.
			General
			Please check through the application to align all information. Query Round1 Mrs NNU,ROC1 22-Jul-2024 12:32:20
		Input your reply he	
			Had amended the sections accordingly

Scenario 1: If no changes to the form is required.

Study team have responded to all the queries raised, and no changes to the form is required. The study team can proceed to click on **[Reply Query].**

Note: Any of the study team can reply and submit the form if there is no changes made to the form.

	Submission Detail		표 🔓 ୪
2024-3415-APP1 Pending Endorsement T ECOS Ref: 2024-3415		If there is no amendment to the form click on [Reply Query] .	Reply Query
Form Detail Endorsement			
Application Form	FCOS	*	Export Track Changes Z Edit
Section A: Study Title	O Do you want to proceed?		Section A: Study Title
*A1. Please enter the Study Title for this Study.			Click on [Edit] if
CG0722 - For Demo Purposes.	National Neuroscience Institute	2 Query 🔨	the form needs
	Query Item: D1. Form Type: Please select the appropriate form for submission.	^	to be amended.
	This study does not fulfill the exemption criteria, please change the form type to 'Application Form' instead.		Section E: Research Met
	Noted.		Section F: Exemption Re
	Query Item: General	Click [Confirm]	Other Attachments
	Please check through the application to align all information.	to rophy quopy	Declaration of Principal I
	Had amended the sections accordingly.		
		Cancel	

<u># Scenario 2:</u> Changes to the form is required.

Study team have responded to all the queries raised and edited the form accordingly.

Please note that the **[Submit]** button will only appear for the PI. For all other roles, there is no button avaliable. Do inform the PI when the form is ready for re-submission.

A Back to Submission List	Submission Detail	нер 🕁 🗘 🤩 🔵
2024-0307-APP1 Pending Endorsement ECOS Ref: 2024-0307	This button will only appear for PI if for	m had been amended.
Form Detail Endorsement	ECOS	×
Application Form	Please confirm to submit. If applicable, the form will be routed for the necessary checks and endorsements. Query	🕁 Export 🛛 Track Changes 🖉 Edit
•A1. Please enter the Study Title for this Study.		Section A: Study Title
Guide to ECOS for RO	Veurology	2 Query A Section B: Submission
	Query Item: Section C: Study Funding Information	Section C: Study Fundi
	Please clarify if the study grant had been approved.	Section D: Study Type a
	Yes, the grant had been approved.	Section D. Study type a
	Query Item: E1. What are the specific aims of this study?	Section E: Research M
	Please specific the aims of the study.	
	The aim of the study is to guide the RO on ECOS.	submit form.
		Casef

H.2 PI replied

After PI has replied, the status will be updated in the Endorsement tab.

		Submission Detail		τ¢Χ
2024-3415-APP1 Pending End	dorsement			I
Form Detail Endorsement				
Endorsement Status				
Institution	Department	Endorsement Information	Endorser Name	Action
National Neuroscience Institute Main Site	Neurology (SGH Campus)	PI Replied	Mrs NNL_ROC1	E. 13
Singapore National Eye Centre	Glaucoma	Pending Research Office Check	Mrs SNEC_ROC2, Prof SNEC_ROC1	0
	The Endorsement Information indica	ates that PI had replied to the	e query raised.	

The endorser (ROC/DR/IR) will review the reply to the query. Once endorser is satisfied with the reply, the endorser will close the query and continue with the endorsement process. After endorsement is complete (all study sites' IR endorsed the application), the form status will be updated to "Pending IRB review". Endorsement status will be updated to "Endorsement Completed" for study sites where IR had endorsed the application.

Please always check on the status of the application through the Endorsement tab and follow up with the endorser to ensure timely submission of the application.

