

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

1. 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

2. 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.

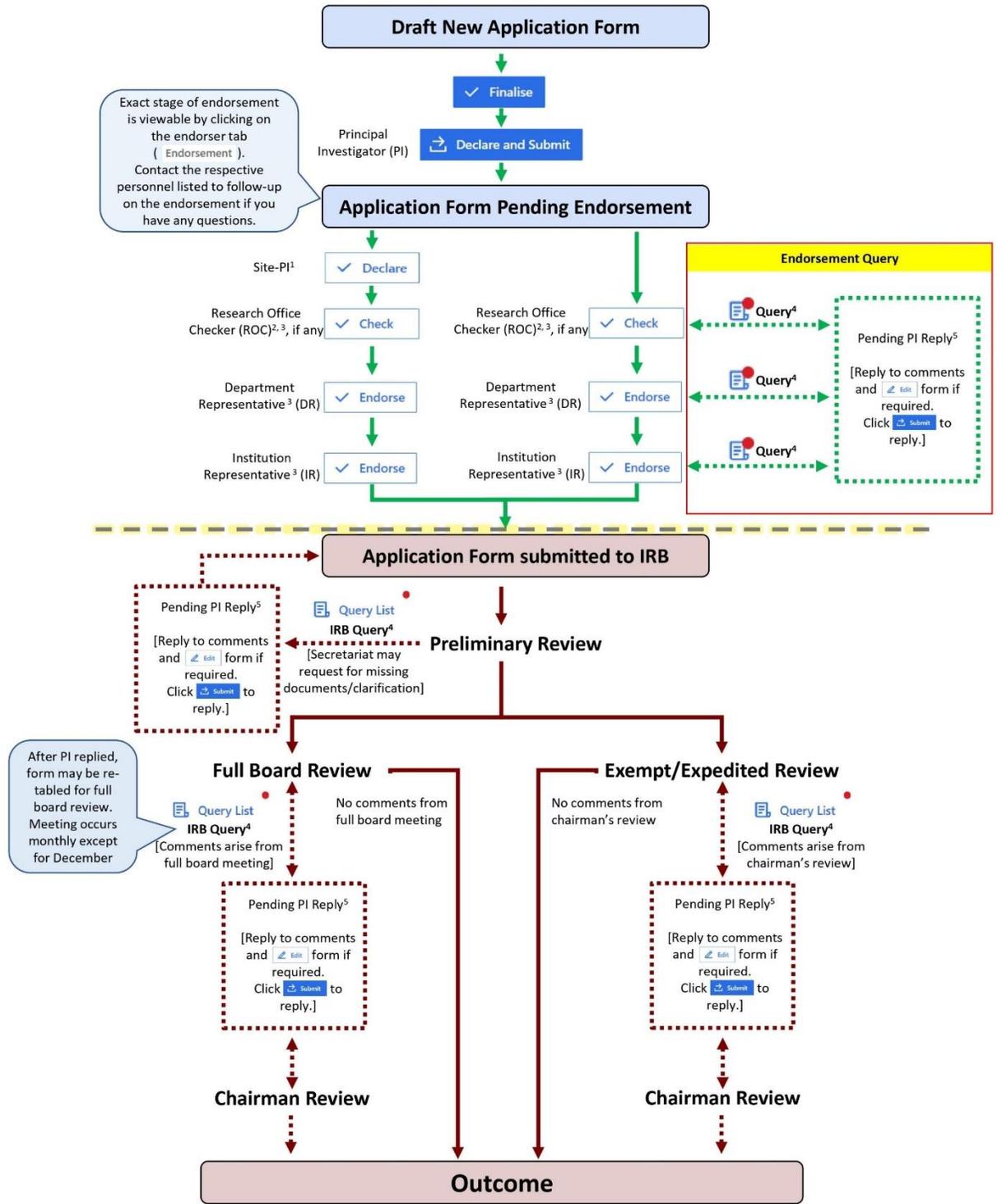
A.2 Endorsement Status

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.

The screenshot shows a web application interface for 'Submission Detail'. At the top, there is a navigation bar with a home icon, a back arrow, and the text 'Back to Submission List'. The main header area displays '2024-3415-APP1' with a 'Pending Endorsement' status indicator and 'ECOS Ref: 2024-3415'. Below this, there are two tabs: 'Form Detail' and 'Endorsement'. A yellow callout box with a black border points to the 'Endorsement' tab and contains the text: 'View Endorsement Status and contact next endorser if required to expedite process.' The main content area is titled 'Endorsement Status' and contains a table with the following data:

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

A green callout box with a black border points to the 'Action' button in the table and contains the text: 'Click to view endorsement history.'



Note:

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

² ROC check is only applicable for certain institutions.

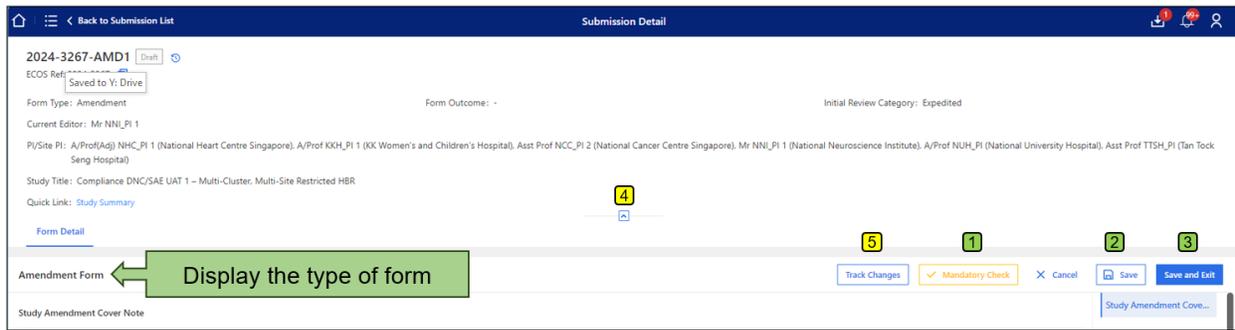
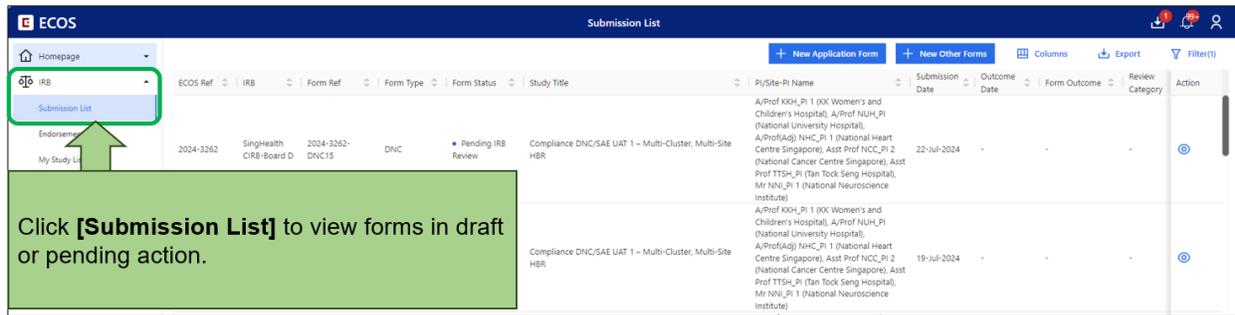
³ Please note that there may be queries from ROC, DR or IR during the endorsement process.

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

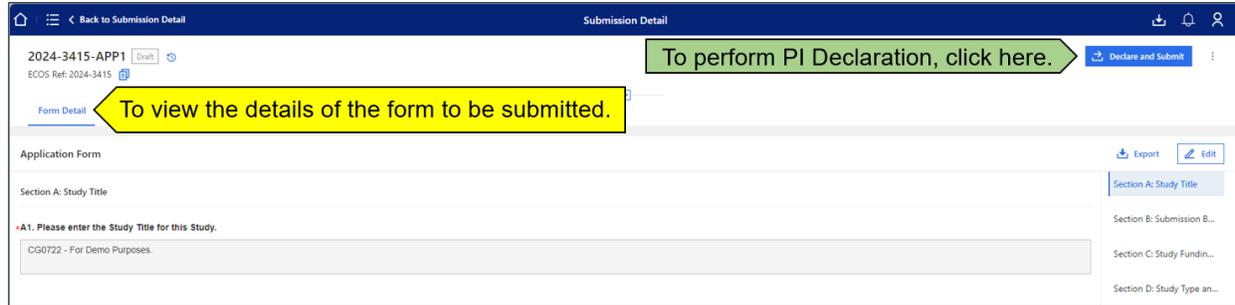
⁵ Re-declaration / Re-endorsement is required if there are major changes to the application form.

Section B: Principal Investigator (PI) Declaration

[IRB] > [Submission List]



- 1 Click to perform **[Mandatory Check]** to ensure all mandatory fields had been completed.
- 2 Click **[Save]** frequently to ensure all information are saved.
- 3 Click **[Save and Exit]** to save and exit editing mode.
- 4 Click to collapse or expand details of the study.
- 5 Click **[Track Changes]** to track the latest submission to the last approved version. **(NOTE: Feature is still under development.)**



Please click on **[Save and Exit]** to exit the editing mode to proceed with PI declaration.

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

[Dashboard]

On the Dashboard, for Site-PI declaration, the **[IRB]** tile will list the tasks under **[Endorsement]**.

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

IRB	Task Received Date	Endorsement Stage	My Role	Form Type	Form Ref	Study Title	Pi/Site-PI	Task Status	Action
SingHealth CIRB-Board A	12-Jul-2024	Pending Site-PI Declaration	Research Office Checker	Application	2024-3346-APP1	CG0712 - For Report	Asst Prof NNJ_Co-1 (National Neuroscience Institute)	Pending	ⓘ
SingHealth CIRB-Board A	22-Jul-2024	Pending Site-PI Declaration	Research Office Checker	Application	2024-3415-APP1	CG0722 - For Demo Purposes	Mr NNJ_P1 (National Neuroscience Institute)	Pending	ⓘ

You will be directed to **[My Tasks]** -> **[IRB]** tile following by **[Endorsement]** tab and it will display the tasks pending your action.

[IRB] > [Endorsement]

Alternatively, you may also access the **[Endorsement]** tab using the **[IRB]** on the side menu.

Click **[Declare]** to perform site-PI Declaration.

Check through the **[Form Detail]** before Site-PI Declaration.

Section D: Research Office Checker (ROC) Check

[Dashboard]

On the Dashboard, for endorsement by ROC, the [IRB] tile will list the tasks under [Endorsement].

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

IRB	Task Received Date	Endorsement Stage	My Role	Form Type	Form Ref	Study Title	Pi/Site-Pi	Task Status	Action
SingHealth CIRB-Board A	12-Jul-2024	Pending Research Office Check	Research Office Checker	Application	2024-9346-APP1	CG0712 - For Report	Asst Prof NNJ_Co-1 (National Neuroscience Institute)	Pending	
SingHealth CIRB-Board A	22-Jul-2024	Pending Research Office Check	Research Office Checker	Application	2024-3415-APP1	CG0722 - For Demo Purposes	Mr NNJ_P1 (National Neuroscience Institute)	Pending	

Click to complete ROC [Check].

Check through the [Form Detail].

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].

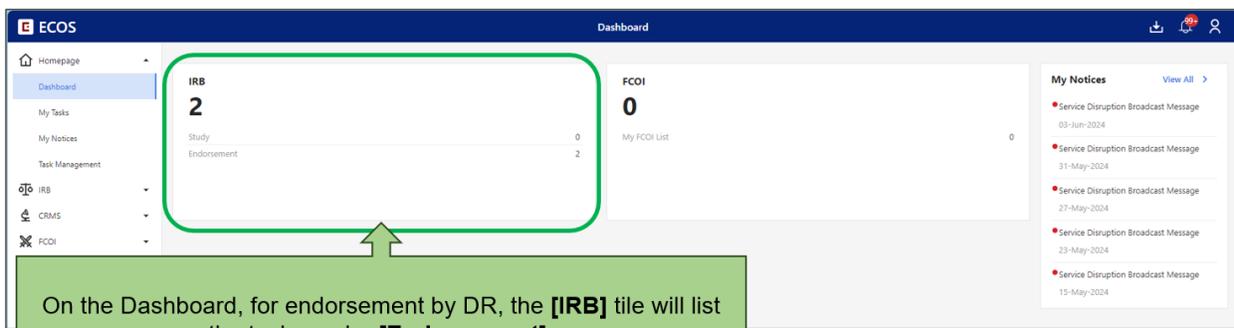
Section E: Department Representative (DR) Endorsement

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):

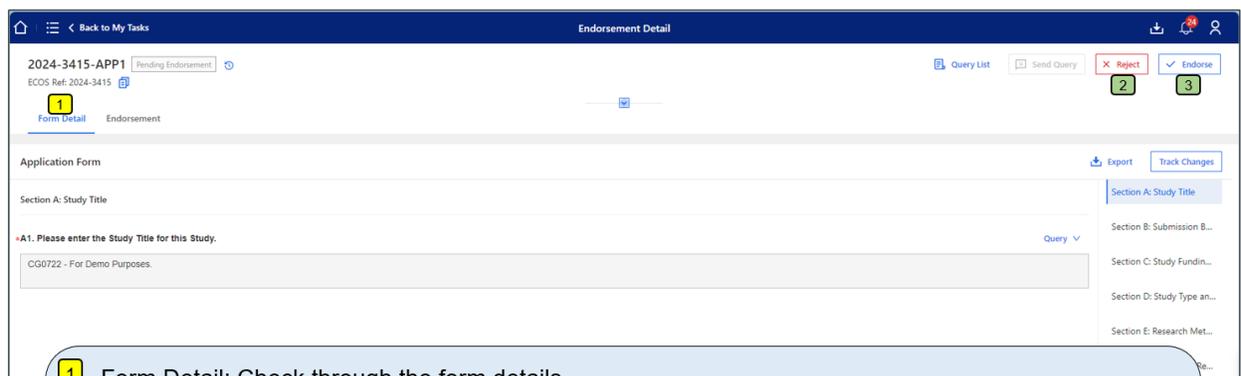
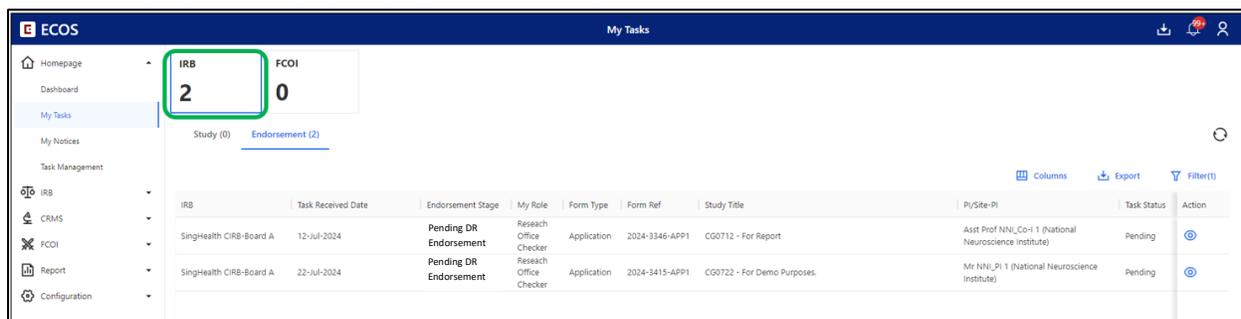
- The Department Representative is usually the Head of Department or equivalent of the PI's and Site-PI's department. Where appropriate, the Head/Director of Division who oversees several departments may endorse in lieu of the Head of Department.
- When the DR is involved in a study, he/she will not 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.

[Dashboard]



The screenshot shows the ECOS Dashboard interface. On the left is a navigation menu with options: Homepage, Dashboard (selected), My Tasks, My Notices, and Task Management. Below this are icons for IRB, CRMS, and FCOI. The main dashboard area features three tiles: 'IRB' with a large '2' and a table listing 'Study' (0) and 'Endorsement' (2); 'FCOI' with a large '0' and a 'My FCOI List' link; and 'My Notices' with a 'View All' link and a list of five 'Service Disruption Broadcast Message' notifications with dates from 03-Jun-2024 to 15-May-2024. A green box with an arrow points to the IRB tile, containing the text: 'On the Dashboard, for endorsement by DR, the [IRB] tile will list the tasks under [Endorsement].'

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



- 1 Form Detail: Check through the form details.
- 2 : This button should only be used if you do not support the conduct of the study.
- 3 : Click to endorse the study.

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]**.

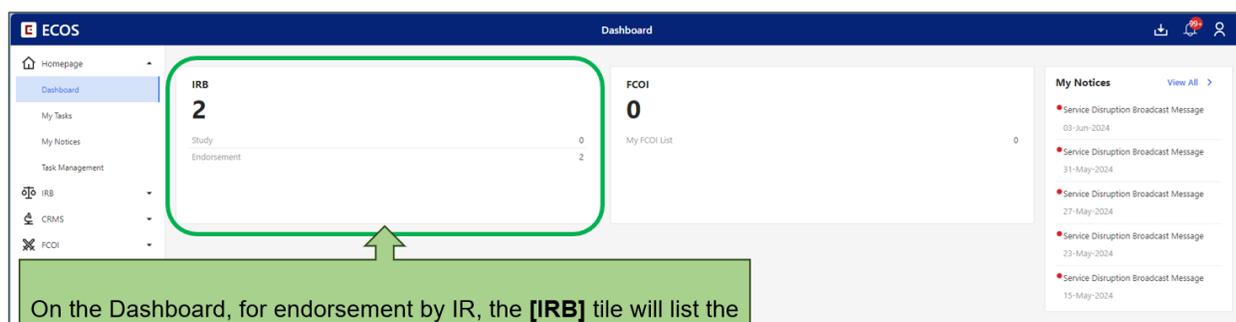
Section F: Institution Representative (IR) Endorsement

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.

[Dashboard]



The screenshot shows the ECOS Dashboard interface. On the left is a navigation menu with options like Homepage, Dashboard, My Tasks, My Notices, Task Management, IRB, CRMS, and FCOI. The main content area features three tiles: 'IRB' with a count of 2, 'Study' with 0, and 'Endorsement' with 2; 'FCOI' with a count of 0 and a 'My FCOI List' link; and 'My Notices' with a 'View All' link and a list of service disruption broadcast messages. A green box highlights the IRB tile, and a green callout box with an arrow points to it.

On the Dashboard, for endorsement by IR, the [IRB] tile will list the tasks under [Endorsement].

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

IRB	Task Received Date	Endorsement Stage	My Role	Form Type	Form Ref	Study Title	PI/Site-PI	Task Status	Action
SingHealth CIRB-Board A	12-Jul-2024	Pending R Endorsement	Research Office Checker	Application	2024-3346-APP1	CG0712 - For Report	Asst Prof NNI_Co-1 (National Neuroscience Institute)	Pending	🔍
SingHealth CIRB-Board A	22-Jul-2024	Pending IR Endorsement	Research Office Checker	Application	2024-3415-APP1	CG0722 - For Demo Purposes.	Mr NNI_P1 (National Neuroscience Institute)	Pending	🔍

2024-3415-APP1 Pending Endorsement

ECOS Ref: 2024-3415

Form Detail Endorsement

Application Form

Section A: Study Title

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

CG0722 - For Demo Purposes.

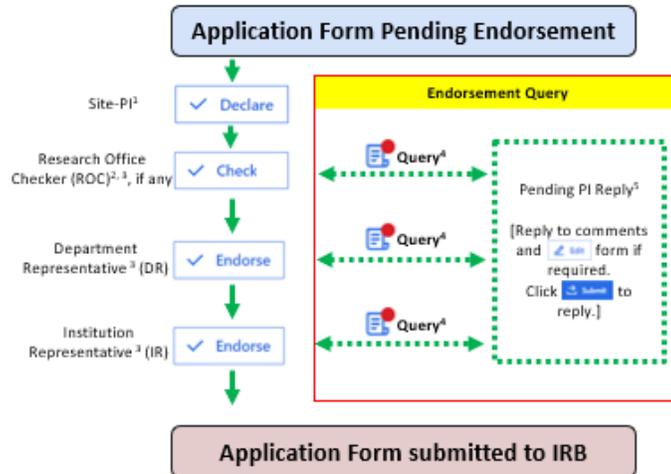
Query List Send Query Reject Endorse

- 1 Form Detail: Check through the form details.
- 2 : This button should only be used if you do not support the conduct of the study.
- 3 : Click to endorse the study.

For endorsement by IR,

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]**.

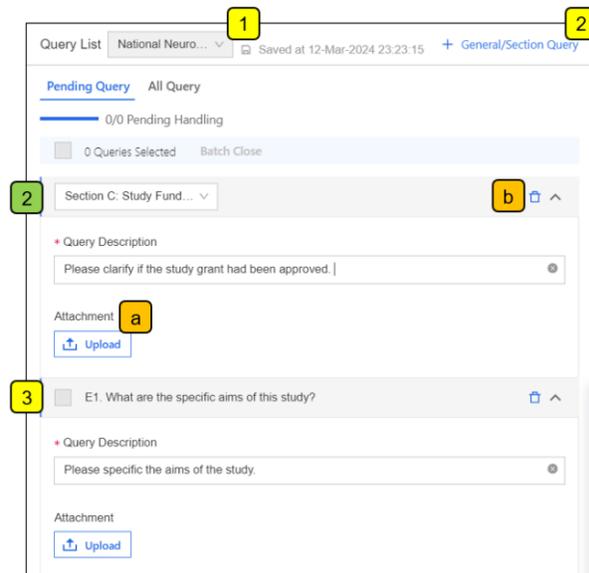
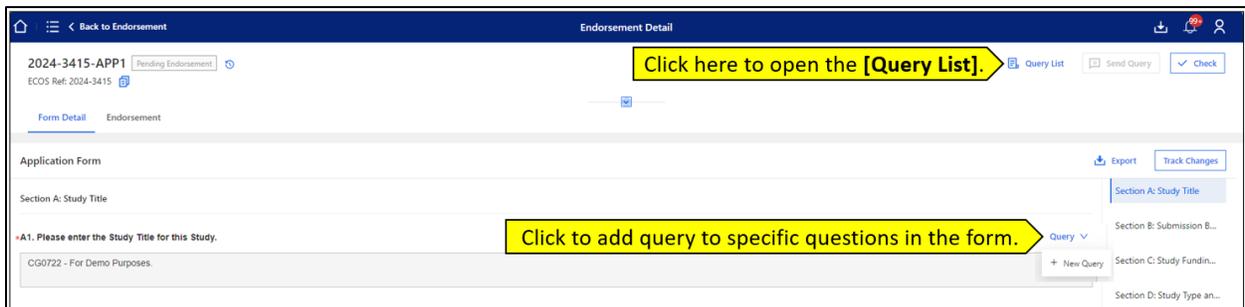
Section G: Endorsement Query (ROC/DR/IR)



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.

G.1 Query List



- 1 Display the site which the questions are directed to.
- 2 For '+ General/Section Query', general or specific section can be selected.
- 3 Example of question added via specific questions.
- a Attachments can be uploaded if required.
- b Questions can be deleted if not required.

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

G.2 Send Query

The red dot on **[Query List]** indicate that there are queries pending your action.

Review the queries drafted and click **[Confirm]** to send query.

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:

[Send Query] and **[Check]** button are greyed out to signify that study is pending PI reply.

The Endorsement Information and red dot on the icon indicates that the form is pending PI reply.

Institution	Department	Endorsement Information	Endorser Name	Action
National Neuroscience Institute Main Site	Neurology (SDH Campus)	Pending PI Reply	Mrs NNL/ROC1	

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.

[\[Dashboard\]](#) > [\[My Task\]](#) > [\[IRB\]](#) > [\[Endorsement\]](#)

IRB	FCOI
1	0

IRB	Task Received Date	Endorsement Stage	My Role	Form Type	Form Ref	Study Title	Pi/Site-Pi	Task Status	Action
SingHealth CIRB-Board A	22-Jul-2024	Pending DR Endorsement	DR	Application	2024-3415-APP1	CG0722 - For Demo Purposes.	Mr NNI_Pi 1 (National Neuroscience Institute), A/Prof SNEC_Pi_1 (Singapore National Eye Centre)	Pending	

indicates that there is no action required.

[\[IRB\]](#) > [\[Endorsement\]](#)

Form Ref	IRB	Study Title	Pi/Site-Pi Name	Department	Institution	Form Type	Form Status	Endorser Name	Action
2024-3415-APP1	SingHealth CIRB-Board A	CG0722 - For Demo Purposes.	Mr NNI_Pi 1 (National Neuroscience Institute), A/Prof SNEC_Pi_1 (Singapore National Eye Centre)	Neurology (SGH Campus)	National Neuroscience Institute	Application	Pending Endorsement	Mr NNI_DR 1	

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.

[\[Dashboard\]](#) > [\[My Task\]](#) > [\[IRB\]](#) > [\[Endorsement\]](#)

IRB	FCOI
1	0

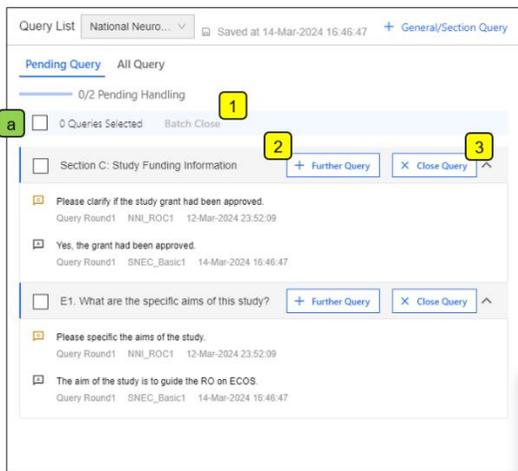
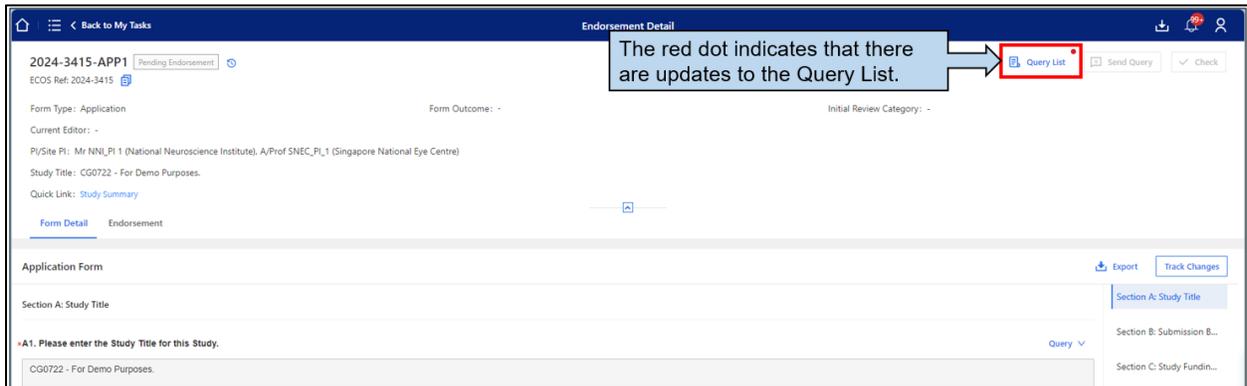
IRB	Task Received Date	Endorsement Stage	My Role	Form Type	Form Ref	Study Title	Pi/Site-Pi	Task Status	Action
SingHealth CIRB-Board A	22-Jul-2024	Pending DR Endorsement	DR	Application	2024-3415-APP1	CG0722 - For Demo Purposes.	Mr NNI_Pi 1 (National Neuroscience Institute), A/Prof SNEC_Pi_1 (Singapore National Eye Centre)	Pending	

indicates that further action is required.

[\[IRB\]](#) > [\[Endorsement\]](#)

Form Ref	IRB	Study Title	Pi/Site-Pi Name	Department	Institution	Form Type	Form Status	Endorser Name	Action
2024-3415-APP1	SingHealth CIRB-Board A	CG0722 - For Demo Purposes.	Mr NNI_Pi 1 (National Neuroscience Institute), A/Prof SNEC_Pi_1 (Singapore National Eye Centre)	Neurology (SGH Campus)	National Neuroscience Institute	Application	Pending Endorsement	Mr NNI_DR 1	

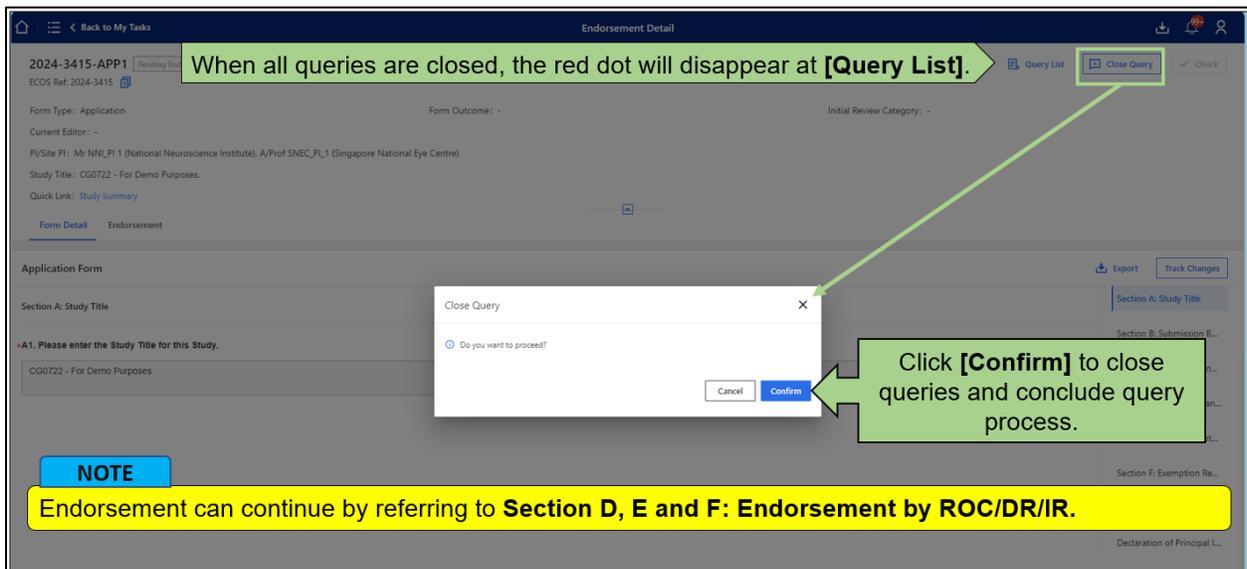
indicates that further action is required.



- 1 If multiple queries had been addressed, **a** can be checked and do a Batch Close.
- 2 When there is Further Query to the respective question, use this button.
- 3 Query that had been addressed can be closed with this button.

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

NOTE
New queries can be added by referring to **Section G.1 Query List**.

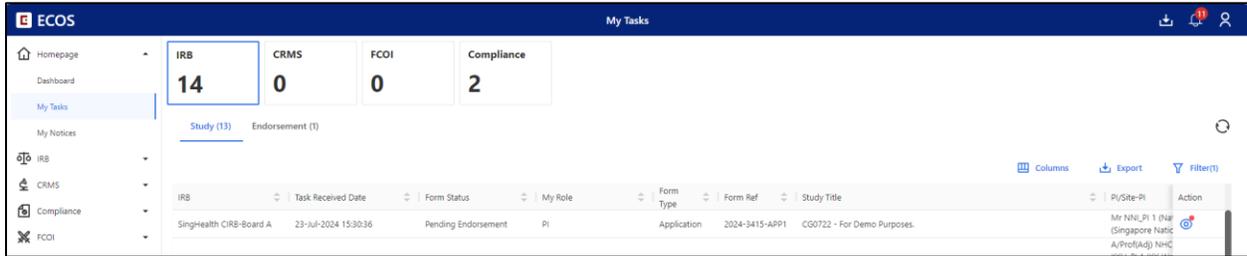


Section H: Endorsement Query (Study Team)

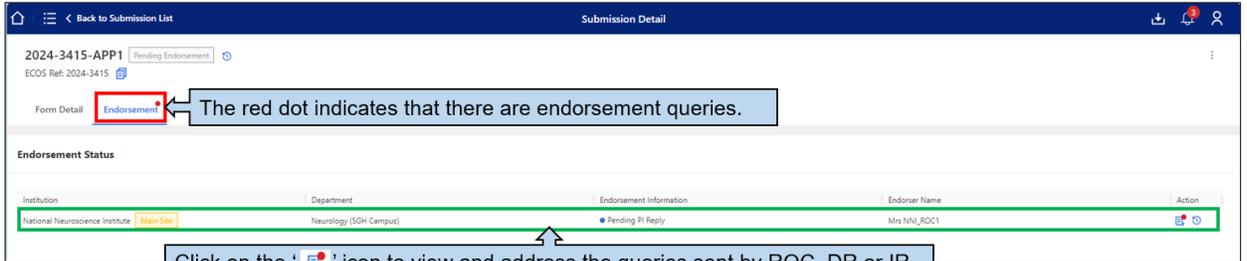
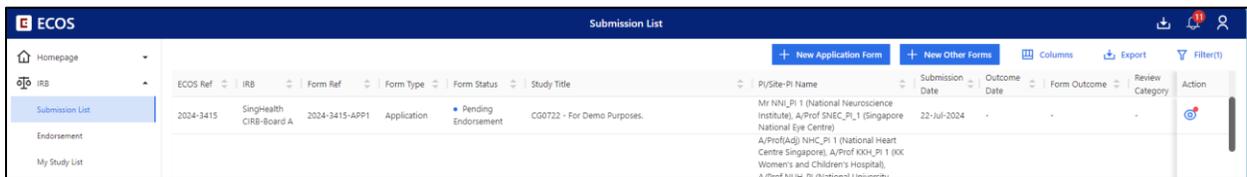
H.1 Replying to query

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.

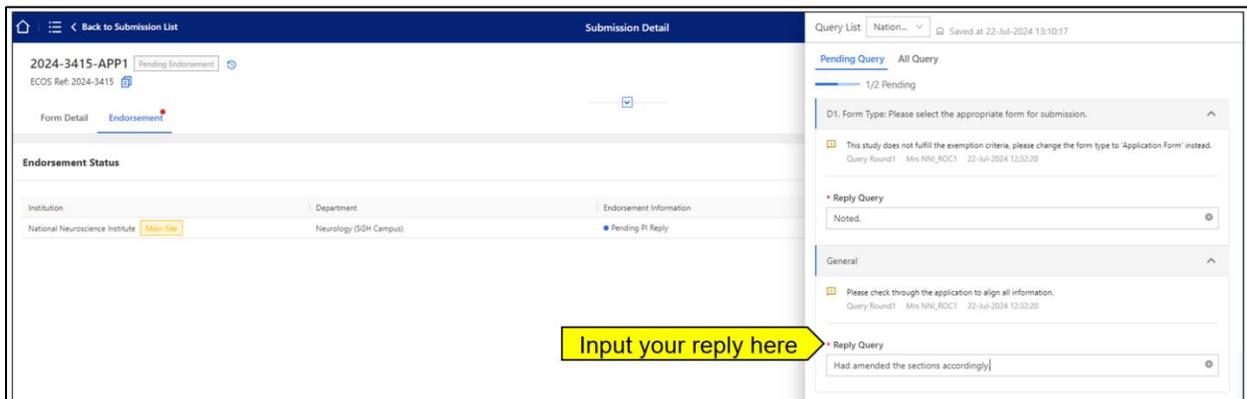
[Dashboard] > [My Task] > [IRB] > [Study]



[IRB] > [Submission list]



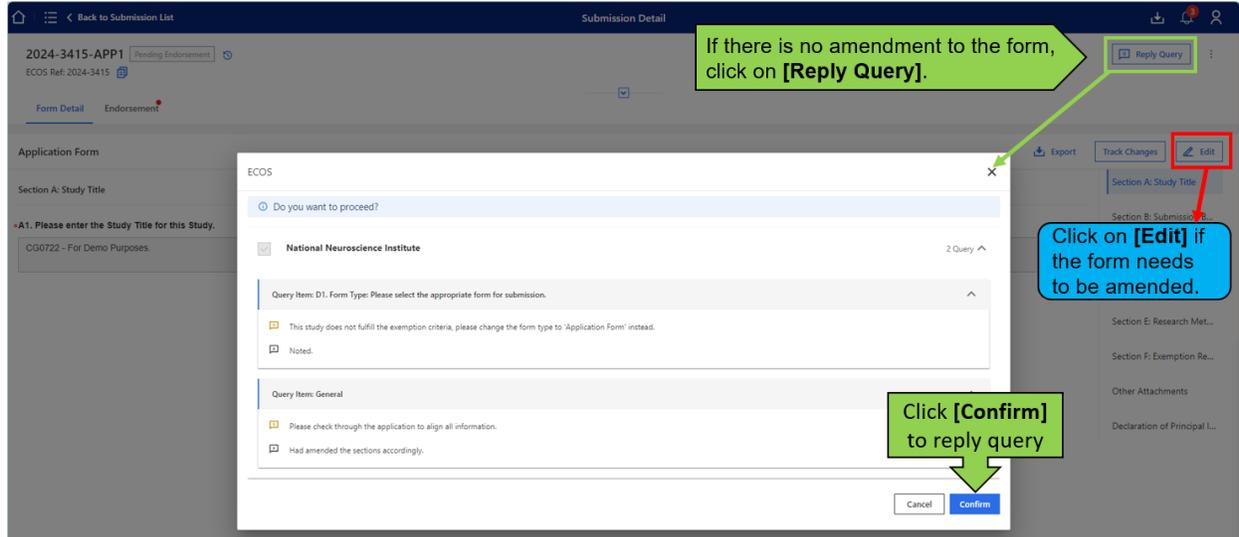
- To view Endorsement query, click on the Query List from the endorsement tab. You may input your reply in the text box below each query.
- To close Query List, click the area outside to close the Query List.



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]**.

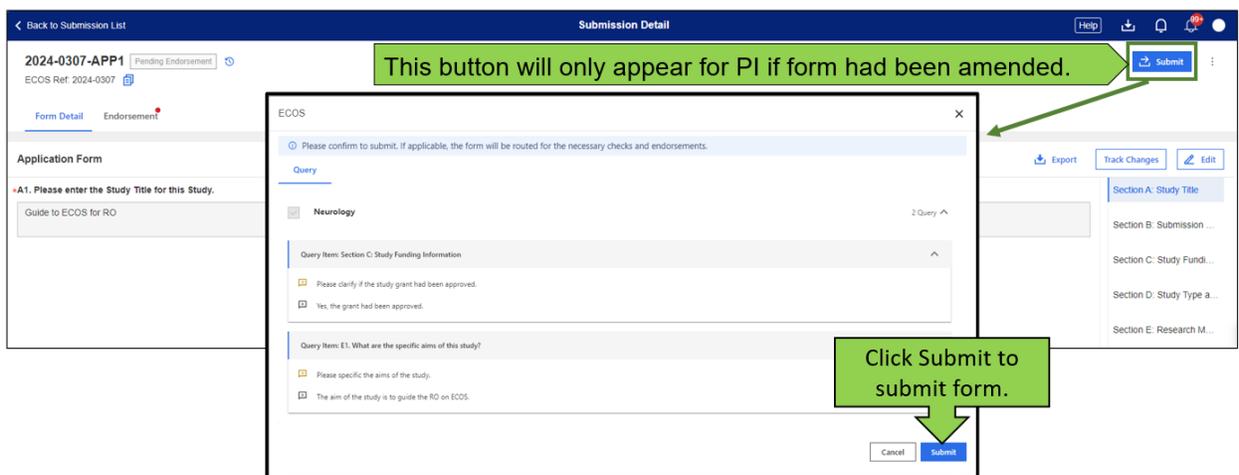
Note: Any of the study team can reply and submit the form if there is no changes made to the form.



Scenario 2: Changes to the form is required.

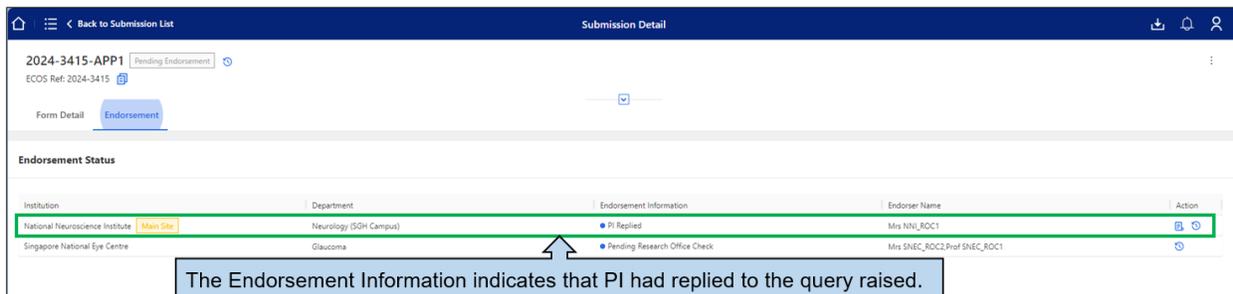
Study team have responded to all the queries raised and edited the form accordingly.

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



H.2 PI replied

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



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.

