

### Navigating Ethics & Compliance Online System (ECOS) User Guide

# SDB Module For Endorsers



[ECOS User Guide – SDB Module For Endorsers, 02-October-2024]

© National Healthcare Group Pte Ltd

Adding years of healthy life

### Introduction – Standing Database (SDB) Module

 The SDB Module in ECOS allows the review and processing of Standing Database applications for NHG and NUHS.

#### In ECOS, researchers:

- May apply to set up SDB, including multi-site SDB & cross-cluster SDB (between NHG and NUHS only)
- Can respond to queries from reviewers & endorsers via ECOS
- Will need to report any SDB non-compliance via ECOS
- Can apply for renewal of SDB on ECOS

### **Table of Contents**

### A. Overview

- 1. Roles and Functions
- 2. SDB Approval Process

### **B.** Navigating The Module

- 1. Endorsing/ Rejecting an SDB Application
- 2. Send a Query
- 3. Close a Query (Individual)
- 4. Close a Query (Batch)
- 5. Re-Query
- 6. Track Change

### **A1. Roles and Functions**

| Research Office<br>Check (ROC)<br>(Optional) | <ul> <li>Individual who is assigned to check and ensure the applications<br/>completeness and compliance to the states and institutional<br/>policies and guideline.</li> </ul>   |
|--|---|
| Department<br>Representative (DR)            | <ul> <li>Individual who is appointed to ensure traction over the collection<br/>and storage of data and that the department can adequately<br/>support the set-up, maintenance and closure of the SDB.</li> <li>This is the same as IRB module DR role</li> </ul> |
| Institution<br>Representative (IR)           | <ul> <li>Individual who is appointed to ensure the custodian knows the institutional and legal responsibilities and is compliant to the institution policies.</li> <li>This is the same as IRB module IR role</li> </ul>  |

### **A2. SDB Approval Process**



ID **approval** to ensure that SDB application complies with NHG Research Data Policy and other necessary

IDA acknowledgement to ensure that the application complies with the institutional policies and regulation.

IRB acknowledgement and review to ensure that the recruitment and consent process of the participants complies with ethics requirements & regulations.

IR endorsement to ensure the custodian knows the institutional and legal responsibilities and is compliant to

DR/HOD endorsement to ensure traction over the collection and storage of data and that the department can adequately support the set-up, maintenance and

Research Office checker check to ensure the custodian had accurately provided all the needed information for

Custodian submits SDB Application/ Amendment Form.

### **B.** Navigating ECOS – Where to find the SDB-Related Tasks?



### **B. Navigating ECOS – Where to find the SDB-Related Tasks?**



# B. Navigating ECOS – Where to find the list of applications pending your endorsement?



# **B1. Navigating ECOS – How to Verify the Completeness & Compliance of an Application**

### To verify the SDB (ROC Only)

|                                   | Endorsement Detail | 🛨 🛱 🎗                                   |
|-----------------------------------|--------------------|---|
| Pending ROC/DR/IR Endorsement     | 3                  | E, Query List Send Query Confirm        |
| Form Type: Application            | Form Outcome: -    | Click on " Confirm" to confirm that you |
| SDB Custodian/SDB Site Custodian: |                    | have verified the completeness and      |
| SDB Title: NCID 12Sep24           |                    | compliance of the SDB.                  |
| Quick Link: SDB Summary           |                    |   |
| Form Detail Endorsement           |                    |   |
| Application Form                  |                    | Track Changes 🛃 Export                  |
|                                   |                    |   |
| Instruction                       |                    | Instruction                             |
|                                   |                    |   |
|                                   |                    | Database Site & Custodi                 |

#### Refer to Section B2 on how to query the Database Team

# **B1. Navigating ECOS – How to Endorse or Reject an Application**

| orse an SDB (DR & IR Only)                                  |                      | Click on " <b>X Reject"</b> if you<br><b>support</b> the application | do not   |
|---|----------------------|--|--|
|   | Endorsement Detail   | <b>V</b>   | 🕁 🧘 🕹  |
| Pending ROC/DR/IR Endorsement 🕥                             |                      | E, Query List X Reject   | Send Query   |
| Form Type: Application<br>SDB Custodian/SDB Site Custodian: | Form Outcome: -      | ealth), Mr NHG_SDB_54 (Yishun Com th                                 | lick on "✓ Endorse" to endorse<br>the application after reviewing it |
| Quick Link: SDB Summary Form Detail Endorsement             |                      |  |  |
| Application Form  |                      |  | Track Changes 🛃 Export   |
| Database Site & Custodian Details                           |                      |  | Instruction  |
| *2: Does this Standing Database/Tissue Bank involve more t  | han one institution? | Query  | Database Site & Custodi<br>✓   |

### **B2.** Navigating ECOS – How to Query the Database Team (1/5)

On the Application Form page

You may issue queries for individual questions

| Application Form   | Tr   |
|--|--|
| Database Site & Custodian Details  | <b>Step 1</b> : Click on the " <b>Query</b> " button next to the question that you would like to query on. A drop-down button will be shown. |
| *2: Does this Standing Database/Tissue Bank involve more than one institution? | Query 🗸  |
| <ul> <li>Yes</li> <li>No</li> </ul>  | + New Query  |
| 2a: Database site(s)   | Step 2: Click on "+ New Query" to issue a new query.   |

# **B2.** Navigating ECOS – How to Query the Database Team (2/5)

#### To Query the Database Team

| Y ⊨ Ξ < Back to My Tasks  | Endors | Query List Vishun Commu 🗸  | + General/Section Query                               |
|---|--------|--|---|
| Pending ROC/DR/IR Endorsement 🕥   |        | Pending Query All Query 0/0 Pending  | You may delete the query by clicking on the bin icon. |
| Form Detail       Endo         Step 3: You will see the question of the application form reflected on the header of the query.        | ne     | 0 Queries Selected Batch Close 2: Does this Standing Database/Tissue Bank involve more tha | n one institution?                                    |
| Database Site & Custo Step 4: Enter your query in the text box.   | -      | Please enter   |   |
| <ul> <li>*2: Does this Standin</li> <li>Step 5: You may upload an attachment by clicking on the Upload button.</li> <li>No</li> </ul> | -      | Attachment       Upload  |   |

#### Note

A: Click on the application form main page in the background, and the sliding window will disappear. B: Query will be auto-saved by the system if connected to the Internet.

### **B2.** Navigating ECOS – How to Query the Database Team (3/5)



### **B2.** Navigating ECOS – How to Query the Database Team (4/5)

| viewing Your Drafted Queries   | Step 5: Cli<br>drafted que<br>indicates n | ck on " <b>Query List"</b> to review your<br>eries before sending. A red dot<br>ew information. |                         |
|--|---|---|-------------------------|
|  | Endorsement Detail                        |   | ታ 🤹                     |
| Pending ROC/DR/IR Endorsement 🕤  |   | E, Query List × Reject<br>Step 6: Click on  | Send Query CEndorse     |
| Application Form   |   | button to send th   | ne query.               |
| Database Site & Custodian Details  |   |   | Instruction             |
| *2: Does this Standing Database/Tissue Bank involve more than one institut | ion?                                      | Query 🗸   | Database Site & Custodi |

# **B2.** Navigating ECOS – How to Query the Database Team (5/5)

#### **Reviewing Your Drafted Queries**

| A → E < Back to My Tasks  | <b>Step 7</b> : A confirmation pop-up box will appear with the list of queries you had drafted |  |
|---|--|--|
|   |  | C Send Query   |
| Form Detail Endorsement   | Send Query   |  |
| Application Form  | Are you sure to send the following queries?  | Track Changes Export   |
| Database Site & Custodian Details   | Query Item: 2: Does this Standing Database/Tissue Bank involve more than one institution?      | Instruction  |
| <ul> <li>*2: Does this Standing Database/Tissue Bank invo</li> <li>● Yes</li> <li>● No</li> </ul> | Query Description: Please confirm number of site involved.           Cancel         Confirm    | <ul> <li>Step 8: Click on</li> <li>"Confirm" to send the query; or</li> <li>"Cancel" to return to the previous page, if you do not wish to send out the queries</li> </ul> |
| 2a: Database site(s)  |  |  |

After you have sent your query, return to the Endorsement Detail Page and this icon of will be seen next to the SDB application, indicating that you have queried the Custodian.

# **B3. Navigating ECOS - Close a Query (Individual) (1/4)**

#### To Close a Query (Individual)

Free Datell Frederics

| Back to Endorsement   | Endorsement Detail                   | нер 🕁 🗘 1  | <b>9</b> ( |
|---|--------------------------------------|--|------------|
| Form Type: Application  | Form Outcome : -                     | Cuery List Send Query X Reject V E   | ndoria     |
| Current Editor: -<br>PUSite Pt                                      | Step 1: 0<br>a red dot<br>there is r | Click on " <b>Query List</b> " button,<br>t indicator appears whenever<br>new query information. |            |
| Study Title Overall UAT Testing (Single site, sponsored) Quick Link |                                      |  |            |
| Form Detail Endorsement   |                                      |  |            |

| Application Form                                  | 🕁 E          |
|---|--------------|
| Section A: Study Title                            | s            |
| *A1. Please enter the Study Title for this Study. | S<br>Query ∨ |
| Develop User Guide for Users                      | + New Query  |
|   | Manage Query |
|   |              |

- After the Custodian/ Database Team Member have replied to a query, the task will be made available on your Dashboard, and you will see this icon of beside the application
- Locate the task and return to **Endorsement Detail** page.
- A query window will appear in the foreground

**Step 2:** You can also locate the **Query** button under each individual section of the SDB application form and click on **"Manage Query"** to view existing queries.

# B3. Navigating ECOS - Close a Query (Individual) (2/4)



# B3. Navigating ECOS - Close a Query (Individual) (3/4)

#### To Close a Query (Individual) Query List Tan Tock Seng... 🗸 + General/Section Query Saved at 23-Apr-2024 10:43:14 Pending Query All Query Step 7: The status of the queries have also been updated (e.g., 1/3 Pending Handling). 1/3 Pending Handling 0 Queries Selected Step 9: Click on "Undo" to reverse the action. A1. Please enter the Study Title for this Study. Closed Undo 🗸 Please revise the study title 9 Pending Query All Query Query Round1 Mr TTSH Step 8: The query status have been Step 10: You may amend the query action again. 0/3 Pending Handling updated. You will see a green label A Revised Study Title [Closed] next to the query. Query Round1 Dr TTSH 0 Queries Selected A1. Please enter the Study Title for this Study. + Further Query X Close Query Please revise the study title Click on the Endorsement Detail Page to Ouery Round1 Mr TTSH ROC01 23-Apr-2024 10:26:40 close the query sliding window Revised Study Title A Query Round1 Dr TTSH\_P1 23-Apr-2024 10:32:55

# **B3. Navigating ECOS - Close a Query (Individual) (4/4)**

### To Close a Query (Individual)

| K Back to Endorsement                                    | Endorsement Detail                                   | Нер                       | ) 🕹 (                      |  |
|--|--|---------------------------|----------------------------|--|
| Pending Endursement 3                                    |  | Close Query               | 4                          | <b>Step 11:</b> The <b>Close Query</b> button will only be enabled after all queries have been closed. Click on " <b>Close Query</b> " to proceed. |
| Form Type : Application                                  | Form Outcome: -                                      | Initial Review Category - |                            |  |
| Current Editor -   |  |                           |                            |  |
| Study Title Overall UAT Testing (Single site, sponsored) |  |                           |                            |  |
| Quick Link: Study Summary, CRMS                          |  |                           |                            |  |
| Form Detail Endorsement                                  |  |                           |                            |  |
| C Back to Endorsement                                    | Endorsement Detail                                   | Не                        | ē 🕁                        | Q 🧷 🔴  |
| Pensing Ennorsement                                      |  | Guery List 🗍 Close Query  |                            | w. Indirine  |
| Form Type - Application                                  | Form Outcome: -                                      | Initial Review Category   |                            |  |
| Current Editor: -  |  |                           |                            |  |
| PuSae PI   | Close Query  | Ste                       | ep 12: A                   | confirmation pop-up box will appear.   |
| Study Title Overall UAT Testing (Single site, spons red  |  |                           |                            |  |
| Quick Link Study Sommary CRMS                            | Are you sure to close the following queries?         |                           |                            |  |
| Step 13: If you do no<br>on "Cancel" to retur            | ot wish to proceed, click<br>n to the previous page. |                           | <b>p 14</b> : C<br>ed suce | ick on " <b>Confirm"</b> to proceed. The query has been<br>cessfully! You will return to Endorsement Detail Page                                   |
| Application Form   |  |                           | 🛃 Laport                   | Track Changes  |
|  |  |                           | Decourses                  | Second State   |

### B4. Navigating ECOS - Close a Query (Batch) (1/3)

#### **To Close a Query (Batch)** Step 1: Click on Query List Pending Endorsement E, Query List button. A red dot indicator appears whenever query action is needed. Form Type: Application Form Outcome: -Initial Review Category: -Current Editor: -PI/Site PI Study Title: Develop User Guide for Users + General/Section Query Query List Tan Tock Seng... V Saved at 23-Apr-2024 10:57:09 Quick Link: Study Summary Pending Query All Query Query window will appear in 0/3 Pending Handling **Step 2:** Check the box next to overall the foreground. -> 0 Queries Selected Batch Close query count to select ALL queries. A1. Please enter the Study Title for this Study. + Further Query X Close Ouery $\overline{}$ Please revise the study title Query Round1 Mr TTSH\_ROC01 23-Apr-2024 10:26:40 Revised Study Title Query Round1 Dr TTSH\_P1 23-Apr-2024 10:32:55 Step 3: If you wish to close only • selected queries, check each box B1. (b) Please select the board. + Further Query X Close Query $\sim$ next to the header of the query. Revise to Domain B Query Round1 Mr TTSH\_ROC01 23-Apr-2024 10:26:40 Revised to Domain B Query Round1 Dr TTSH\_P1 23-Apr-2024 10:32:55 D1. (a) Please select the exemption application + Further Query X Close Query ~ categories. Revise to Category S2 Ouery Round1 Mr TTSH ROC01 23-Apr-2024 10:26:40

### B4. Navigating ECOS - Close a Query (Batch) (2/3)

#### To Close a Query (Batch)



### **B4. Navigating ECOS - Close a Query (Batch) (3/3)**

To Close a Query (Batch)



### **B5. Navigating ECOS - Re-Query (1/3)**

|   | Endorsement Detail |                                |  |
|---|--------------------|--------------------------------|--|
| Form Type: Application                  | Form Outcome: -    | Step 1: Click on<br>Query List |  |
| Current Editor: - Pi/Site PI:           |                    |                                |  |
| Form Detail Endorsement                 |                    |                                |  |
|   |                    |                                |  |
| Application Form                        |                    | ٹ 🗄                            |  |
| Application Form Section A: Study Title |                    | tu ⊧<br>s                      |  |

- You can also re-query to seek further clarification after the query has been responded to.
- Locate the task and return toEndorsement Detail page.

You can also locate the **Query** button under each individual section of the IRB application form and click on **Manage Query** to view existing queries.

### **B5. Navigating ECOS – Re-Query (2/3)**

#### **To Close a Re-Query** Query window will appear in the foreground. All Query Pending Query 2/3 Pending Handling Step 2: Click on + Further Query 0 Oueries Selected J A1. Please enter the Study Title for this Study + Further Query X Close Query $\sim$ Please revise the study title 9 Query Round1 Mr TTSH\_ROC01 23-Apr-2024 10:26:40 Query List Tan Tock Seng... V Saved at 23-Apr-2024 11:05:38 + General/Section Query A Revised Study Title Pending Query All Query Query Round1 Dr TTSH\_P1 23-Apr-2024 10:32:55 2/3 Pending Handling 0 Queries Selected Batch Close A1. Please enter the Study Title for this Study. Undo 🔨 Query Description You will be able to enter a new query. Follow Section 3(a) to send out the query. Attachment 1 Upload Please revise the study title You will see the past queries here Query Round1 Mr TTSH\_ROC01 23-Apr-2024 10:26:40 A Revised Study Title Query Round1 Dr TTSH\_P1 23-Apr-2024 10:32:55

### **B5. Navigating ECOS - Re-Query (3/3)**

To Close a Re-Query

Go to the **Endorsement Detail** Page and click on **Query List**. The query window will appear on the foreground.



### **B6. Navigating ECOS - Track Changes**

| v Track Changes  |  |  | You can also view the changes (if any) made on the form since your last review.                               |
|--|--|--|---|
| 企   三 く Back to My Tasks                               | Endorsement Detail                               | E, Query List X Reject Send Query $\checkmark$ Endorse |   |
| Form Detail Endorsement                                | V  |  |   |
| Application Form                                       |  | Track Changes Clic                                     | k on <b>Track Changes</b>   |
| •2: Does this Standing Database/Tissue Bank involve mo | re than one institution?                         | Query ∨  |   |
| Track Changes  |  | Ciose  | A pop-up box detailing the changes will appear. <ul> <li>Purple reflects the previous information.</li> </ul> |
| Current Version SDE<br>Database Site & Custodian       | 03-Sep-2024 15:44:04 V Pr<br>Details             | revious Version SC 2024 11:01:31                       | <ul> <li>Click on Export to export the list of changes into a separate file.</li> </ul>                       |
| 2: Does this Standing Databas<br>No<br>Yes             | e/Tissue Bank Involve more than one institution? |  | Click on Close to return to Endorsement Deta page.  |
| 12a: Database site(s)<br>Tan Tock Seng Hospital (TTSH  | 0  |  |   |

### **B7. Features of the SDB Application Form – Form History**

| View Form History   | Click the icon to view the form history.   | ]  |  |        | You would be able to view the  |  |
|---|--|--|--|--------|--|--|
| C ☐ E < Back to Submission  |  | Form History                 ROC/DR/IR Endorsement           Tan Tock Seng Hospital (TTSH)    Main                     |  | -      | history including the endorsement<br>and/ or withdrawal details and<br>comments. |  |
| Form Type: Application<br>SDB Custodian/SDB Site Custodian:<br>Current Editor: -        | Form Type: Application<br>SDB Custodian/SDB Site Custodian:<br>Current Editor: - |  | <ul> <li>Tan Tock Seng Hospital (TTSH) Research Office Checker sent query.</li> <li>A/Prof shania1+ View Query 05-Sep-2024 17:11:13</li> </ul> |        |  |  |
| SDB Title: SDB_TRAINING_DEMO_04_S<br>Quick Link: SDB Summary<br>Form Detail Endorsement | ep_01  | <ul> <li>Application was declared and submitted.</li> <li>A/Prof shania3</li> <li>Application was finalised</li> </ul> | 05-Sep-2024 17:05:39   |        |  |  |
| Endorsement Status  |  | A/Prof TTSH_STM1   | 05-Sep-2024 17:04:28   | Г      | Reload For Dev   |  |
| Institution Tan Tock Seng Hospital (TTSH) Main Site                                     | Department<br>Gastroenterology & Hepa  | A/Prof TTSH_STM1   | 05-Sep-2024 17:04:24   | ania1+ | Action   |  |
|   |  | A/Prof shania3<br>Application was edited.<br>A/Prof shania3  | 05-Sep-2024 16:18:10<br>05-Sep-2024 16:17:49   |        |  |  |
|   |  | Application was edited.<br>A/Prof shania3  | 05-Sep-2024 16:16:26   |        |  |  |

### **B7. Features of the SDB Application Form – SDB Summary**

