# ECOS

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

## Monitoring Module

*[ECOS User Guide – Monitoring Module Ver 1, 06 Dec 2024]*

National Healthcare Group
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# What the ECOS Monitoring Module is All About

ECOS (Ethics and Compliance Online System)
- Replacing ROAM and NHG Monitoring Platform and iSHaRe
- Allows both intranet and internet access

**Monitoring module**
- One of the modules within ECOS system
- Allows the monitoring process workflow to be carried out by the relevant individuals involved in the monitoring of the research.
  - Visit planning/confirmation
  - Monitoring Plan
  - Monitoring Report
  - Monitoring observations and follow-up
  - Generation of reports to retrieve monitoring activities

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## Monitoring User Guide for:

Principal Investigator (PI) / Site Principal Investigator (Site PI)/ Co-Investigator (Co-I) and Study Team Member (STM)

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5. How to Respond to Issue
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7. How to View/Edit/Submit Study Closure Checklist (SCC)
8. How to Export the Monitoring Report/ Letters/ Issue List

# 1) Monitoring Module General Interface - Columns



**NOTE:** This screenshot was taken by using PI's account.

1. Click on **"Columns"** to **change the layout** of information presented.

2. You can adjust the **columns display order** by pulling the display information **up and down** and click on **"Save".**

3. To reset the columns to its default view, click on **"Clear"**

4. Study tasks are listed accordingly to the **user's assigned role.** Tab/ tasks shown here may vary across the users.

# 1) Monitoring Module General Interface – Export Listing



1. You can export the listing you are viewing by clicking on "**Export**".

2. Select **"Download Original"** as an Excel file or **"Safe Download"** as PDF file.

# 1) Monitoring Module General Interface – Filter



1. Click on "**Filter"** to tailor the listing you wish to view.

2. The default settings for the filter show only **pending** tasks for your action **(Task Status = Pending)**. To reset to default filter settings, click on "**Reset**".

3. After selecting the parameters to filter, click on "**Search**".

Note: To view all assigned tasks (including completed tasks), ensure all filters are cleared.

# 2) Locate your Monitoring task – via Homepage



## Via Homepage > Dashboard

1. You can locate your outstanding monitoring task via "**Homepage**" > "**Dashboard**" on the left navigation panel.

2. Locate the "**Monitoring**" tile and click on "**Monitoring**". It will lead you to **"My Tasks"**.

3. You can also access "**Homepage**" > "**My Task**" via the left navigation panel.

4. Click on the **"Monitoring"** tile.

5. The type and number of outstanding tasks are listed under the different sub-headers based on the user's role. Click on the sub-header to reveal the listing.

6. To view the monitoring task, click on ⊙ under the "**Action**" column.

# 2) Locate your monitoring task – via Monitoring Module



**Via Monitoring >**

1. You can also locate **all assigned monitoring tasks** via " **Monitoring"** on the left navigation panel. Expand the menu to view the various task types.

- "**My Issue**" > As the assigned "**Responsible Person",** you will see all the **site issues pending** your response to the Monitor.

- **"Plan Review" >** The **"Plan Reviewer"** will see all **Monitoring Plans (MP) pending endorsements.** For NHG Monitoring Programme for HBR study, the **PI** is assigned as the Plan Reviewer.

- **"Study Monitoring Information"** > you will be able to **access all monitoring information** (e.g. view monitoring plan, monitoring reports, issues list, confirmation and follow-up letters).

- **"Study Closure  Checklist (SCC)"** > you will be able to **draft/ submit** the SCC.

**Note:** The **PI, Co-I and active Study Team Member (STM)** listed in **Clinical Research Management System User Authorization List (CRMS UAL)** can **view and edit** the SCC.

By default, only the **PI** can submit the form.

# 3) View and Access Your Study Monitoring Information



**Via Monitoring > Study Monitoring Information**

1. This page is accessible by **Site Staff**(with some pages restricted to specific site staff, e.g. **Monitoring Plan (MP) review is only accessible by PI**.)

2. Click on ◎ **"View Plan"** to enter "**View Monitoring Plan"** page**.**

# 3) View and Access Your Study Monitoring Information



1. **PI/Site PI** may **view their respective site's Monitoring Plan.**

2. To export a copy of the Monitoring Plan, click on "**Export**".

3. The "**Download List**" will appear at the bottom of the browser.

4. When the export is complete, click "**Download To Local**". The PDF copy of the form will be saved to your computer local drive.

# 3) View and Access Your Study Monitoring Information



**Via Monitoring > Study Monitoring Information**

5. You can also click on 📅 "**View Schedule**" to enter **Monitoring Schedule Detail** page to view the monitoring information of the study.

6. In the "**Monitoring Schedule Detail**" page under the left navigation panel, you can view the past monitoring reports, issue list, confirmation and follow-up letters according to the monitoring visits type (e.g. Site Monitoring Visit, Remote Monitoring Visit).

# 4) How to Query and Endorse the Monitoring Plan (MP)



Only **assigned "Plan Reviewer" will be able to access the task.** For NHG **Monitoring Programme for HBR study**, the **PI** is assigned as the Plan Reviewer.

**Via Dashboard > My Tasks**

1. The Plan Reviewer can locate all assigned MPs for review **via "Dashboard"**

2. Locate the **"Monitoring"** tile, click on "**Plan Reviewer**" and you will enter "**My Tasks**" > "**Plan Reviewer**" page.

3. Click on ⊙ "**View**" button under the "**Action**" column to view the Issue Details.

# 4) How to Query and Endorse the Monitoring Plan (MP)



**Via Monitoring > Plan Review**

1. You can also locate the list of MPs for review via the Monitoring Module > "**Plan Review**" sub-header.

2. By default, you will see tasks which are pending your action (**Monitoring Plan Status = Pending Review/ Query Pending Reply**).

3. Click on ⊙ "**View**" button under the "**Action**" column to view the **Monitoring Plan.**

# 4) How to Query and Endorse the Monitoring Plan (MP)



4. Click on **"Fullscreen"** to expand the Monitoring Plan for easy viewing.

5. After reviewing the MP, the Plan Reviewer may **query** the Monitor. To query, click on the **"Query List".** A **red dot** indicates that there is an action pending (i.e. to send the query).

6. A sliding window will appear**,** where you can add/ close the query(ies). Click on **"+ General Query**" to **add a query**.

7. Enter **query description**. You can upload an **attachment** if needed. Query description will be **auto-saved.**

8. To close a query, click on "**X Close Query**" or to re-query on a previous query, click on **"+ Further Query**".

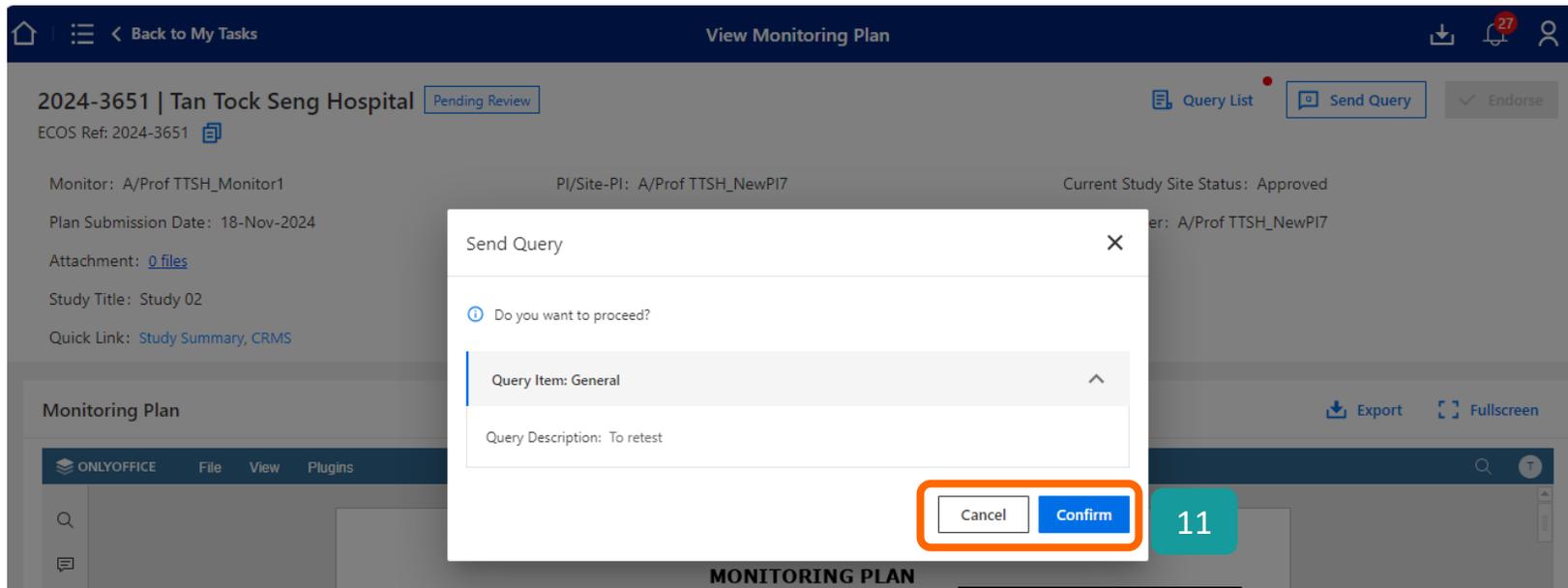9. To close query in batches, check the query box and click on "**Batch Close**".

Click on the background page to close the query sliding window.
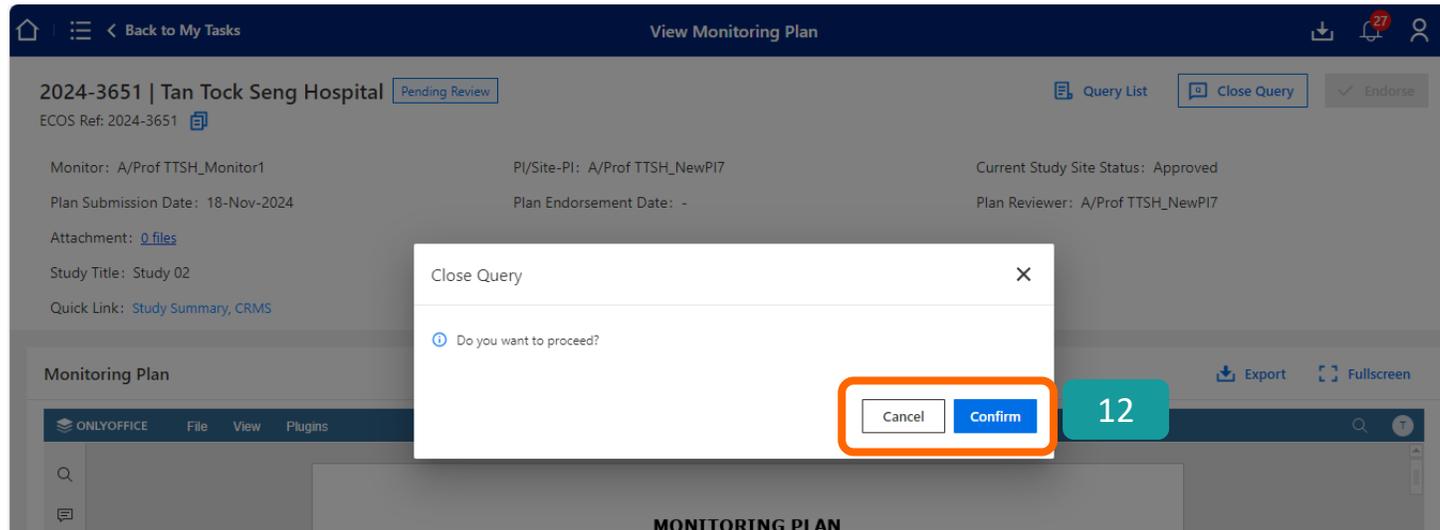
# 4) How to Query and Endorse the Monitoring Plan (MP)
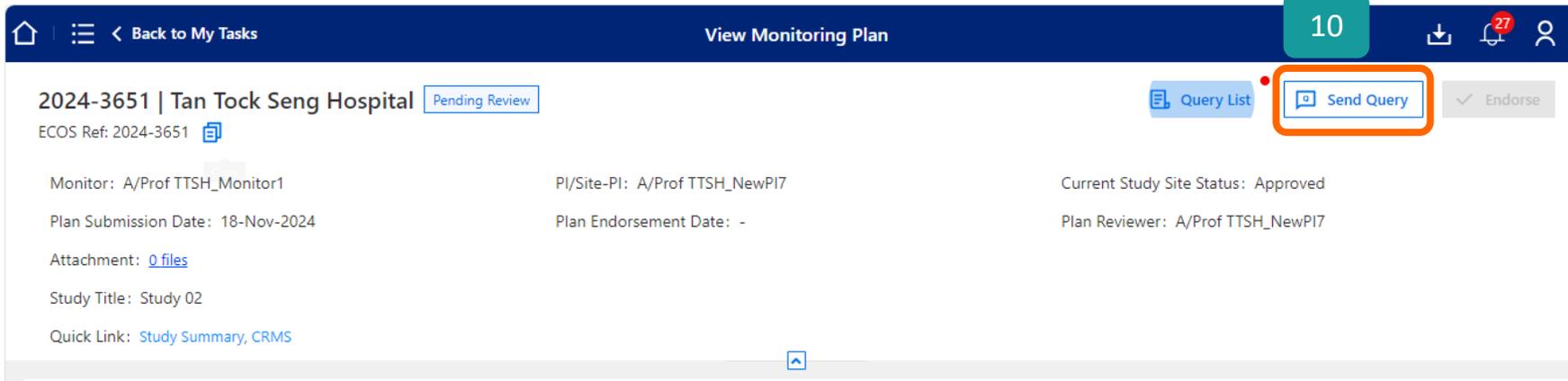


10. If there are outstanding query(ies) to the Monitor, the **"Send Query"** button will be activated. Click on "Send Query".

11. A pop-up window with a list of query(ies) to be sent will be shown. Click "Confirm" to send the query or "Cancel" to return to the previous page.

# 4) How to Query and Endorse the Monitoring Plan (MP)



12. The MP can only be endorsed if there is **no** outstanding query. After all query has been closed, a pop-up window to confirm the action will be shown. Click on "**Confirm**" to proceed or "**Cancel**" to return to the previous page.

13. To proceed to endorse the MP, click on the "**Endorse**" button.
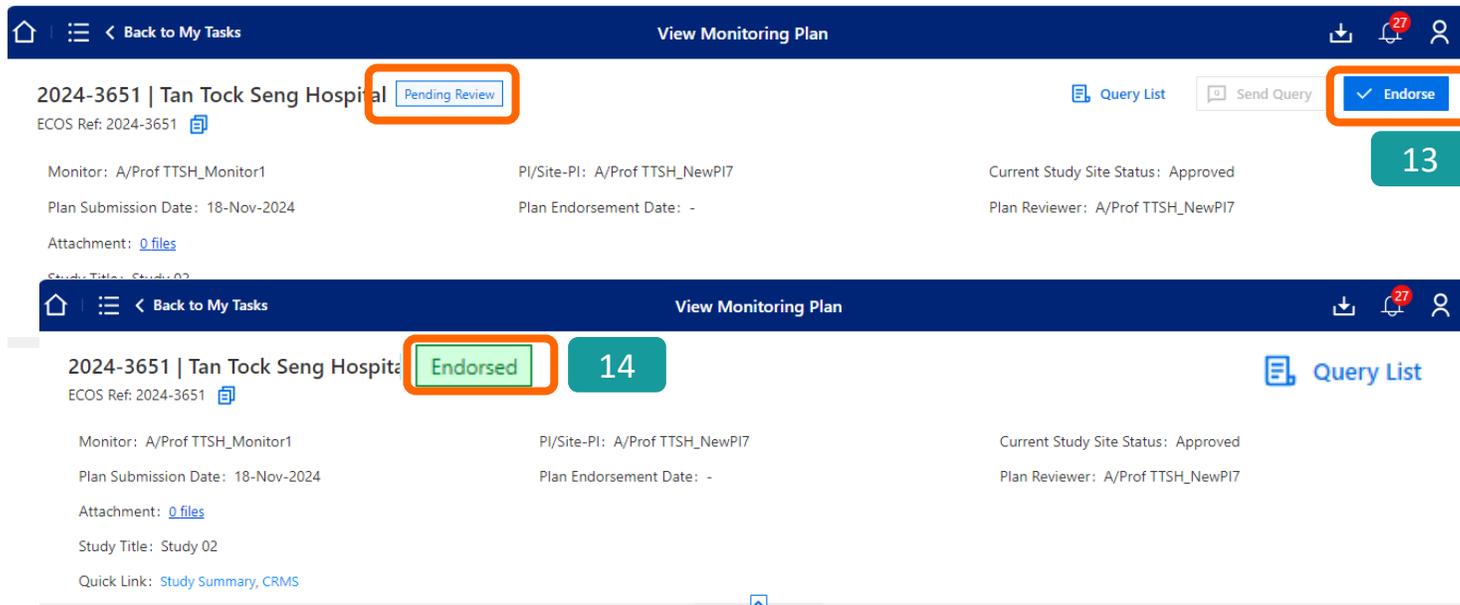
14. The MP status will be changed to "**Endorsed**".

An email notification will be triggered to notify the Monitor of the endorsement.

# 5) How to Respond to Issue



Note: **Site issues** noted during the Monitoring visit that require resolution will be assigned to the "**Responsible Person**" by the Monitor.

## Via Dashboard > My Tasks

1. The Responsible Person can locate all assigned Issues **via "Dashboard"**

2. Locate the **"Monitoring"** tile, click on "**Responsible Person**" and you will enter "**My Tasks**" > "**Responsible Person**" page.

3. Click on ⊙ **"View"** button under the **"Action"** column to view the Issue Details.

# 5) How to Respond to Issue

## Via Monitoring > My Issue

1. You can also locate the issue listings via the Monitoring Module > "**My Issue**" sub-header.

2. By default, you will see tasks which are pending your action (**Issue Status =Issue Pending Completion/ Query Pending Reply**).

3. The list is sorted by **Issue Due Date** (newest to oldest)**.**

4. Click on ⊚ "**View**" button under the "**Action**" column to view the **Issue Details**.

5. In the **"Issue Detail"** page, you can see the details of the monitoring observations which require a **Corrective Action and Preventive Action (CAPA)** plan from the PI/study team.

# 5) How to Respond to Issue



Only **assigned Responsible Person** can edit the "**Issue Detail**" page. The PI, Co-I and active Study Team Member (STM) listed in Clinical Research Management System User Authorization List (CRMS UAL) can be assigned as the "**Responsible person**" to respond to the Issue.

1. Click "**Edit**" to complete the CAPA.

2. Fields marked with * are **mandatory** for completion.

3. Click on **"Save"** to ensure the edits have been saved successfully. After the form has been saved, click on **"Save and Exit"** to exit editing mode.

4. The **"Submit"** button will be enabled. Click on the "Submit" button to procced.

5. A **confirmation pop-up window** will appear. Click **"confirm"** to proceed.

Note: To respond to query on Issue, refer to Section 6.

# 6) How to View/ Reply to CAPA Query



1. To view query(ies), click on the **"Query List"** button. A sliding window will appear, where you can **view and respond to** the query(ies). A **red dot** indicates that there is an action pending (i.e. to address the query).

2. To address each **CAPA query** that is currently pending response, enter your reply under **"Pending Query" tab** > **"Reply Query"**

3. You can view all queries throughout the review under **"All Query"** tab. Query response will be **auto-saved.** Click on the background page to close the sliding window.

4. A **pop-up window** will appear for the user's confirmation to proceed with the task. Click on **"Confirm"** to proceed or **"Cancel"** to return to the issue detail page.

5. When all the query(ies) have been **answered**, the red dot indicator will disappear.

# 6) How to View/ Reply to CAPA Query



6. An **email notification** will be triggered after the form has been submitted. The task is now with the **monitor to review** the query response.

7. The label will be changed from **"Query Pending Reply" to "Issue Pending Review".** The form cannot be edited further.

8. If changes were made to the CAPA, you can see the **prior changes** when you click on the **"Track Changes"** function.

# 7) How to View/ Edit/ Submit Study Closure Checklist (SCC)



**Via Dashboard > My Tasks**

1.  The PI/ Site-PI/ Co-I/ Study Team Members can view all SCC tasks **via "Dashboard".**

2.  Locate the **"Monitoring"** tile, click on "**PI/Site PI**" and you will enter "**My Tasks**" > "**PI/Site-PI**" page.

3.  Click on ◎ "**View**" button under the "**Action**" column to view the "**Study Closure Checklist Detail**" page.

**Note:** The **PI, Co-I and active Study Team Member (STM)** listed in **Clinical Research Management System User Authorization List (CRMS UAL)** can **view and edit** the study closure checklist.

By default, only the **PI /Site PI** can submit the SCC form.

# 7) How to View/ Edit/ Submit Study Closure Checklist (SCC)



## Via Monitoring > Study Closure Checklist

1. You can also locate the SCC task via the Monitoring Module > "**Study Closure Checklist**" sub-header.

2. By default, you will see tasks which are pending your action (**SCC Status =Draft/ Queried by Monitor**).

3. Click on ⊙ "**View**" button under the "**Action**" column to view the "**Study Closure Checklist Detail**" page.

# 7) How to View/ Edit/ Submit Study Closure Checklist (SCC)



1. This is the SCC **Form reference no.**

2. The label indicates the **task status** of the SCC.

3. These quick links will bring you to **IRB Module - Study Summary** and **Clinical Research Management System (CRMS) information**.

4. Click on **"Edit"** to start completing the form.

# 7) How to View/ Edit/ Submit Study Closure Checklist (SCC)



1. Scroll down to complete the rest of the SCC form. Fields marked with * are **mandator**y for completion.

2. Click on **"Save"** to ensure the edits have been saved successfully.

3. Click on **"Save and Exit"** to exit editing mode.

# 7) How to View/ Edit/ Submit Study Closure Checklist (SCC)



1. After the form has been saved, the **"Submit"** button will be enabled (colour change from **grey to blue**).

2. By default, **only the PI/Site PI** is able to see and click on the **"Submit"** button. **Co-I and active STM listed in CRMS UAL** can **only view and edit** the Study Closure Checklist (SCC).

# 7) How to View/ Edit/ Submit Study Closure Checklist (SCC)



1. After the PI clicks on the **"Submit"** button, **a pop-up window** will appear for the user's confirmation to proceed with the task. Click on "**Confirm**" to proceed or "**Cancel**" to return to the Study Closure Checklist Detail page.

2. Click "**Confirm**" to proceed with the submission. The label will be changed from "**Draft**" to **"Submitted By PI".** The form **cannot** be edited further**.**

An email notification will be triggered after the SCC has been submitted. The task is now with the Monitor to complete the review.

The SCC will be further reviewed by the Monitoring Report Reviewer. If there is no further query from **both** Monitor and Monitoring Report Reviewer, the SCC will be **approved.**

The monitoring of the study is now **complete**.

# 8) How to Export the Monitoring Report/ Letters/ Issue List



You can export a copy of the monitoring visit information via **Monitoring > Study Monitoring Information > View Schedule.**

1. Click on the selected **Monitoring visit** and expand the menu to see the Confirmation Letter, Monitoring Report, Issue List and Follow up Letter.

2. To export a copy, locate the respective document "**Export**" button.

# 8) How to Export the Monitoring Report/ Letters/ Issue List



3. The "**Download List**" will appear at the bottom of the browser.

4. When the export is complete, click "**Download To Local**". The PDF copy of the form will be saved to your computer local drive.

# 8) How to Export the Monitoring Report/ Letters/ Issue List



5. For **Issue List (table format)**, a popup window will be shown. Click on the download icon ⬇

6. Select **"Download Original"** as an Excel file or **"Safe Download"** as PDF file.

# Thank You

Please contact Research Quality (NHGHQ) researchquality@nhg.com.sg if you have any question about ECOS Monitoring module.