National Healthcare Group

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ECOS Launch Frequently Asked Questions (FAQ)

VERSION #9 , DATED 30 APRIL 2024

INTRODUCTION

- The Ethics and Compliance Online System (ECOS) is the new ethics review infrastructure that is co-developed by NHG and SingHealth. The ECOS system will replace the current NHG ROAM system in mid 2024.

- This ECOS Launch FAQ document will be periodically updated with latest information as they become available.

- We recommend that you check back to the **ECOS Launch Support for NHG website (ECOS FAQs)** (https://for.sg/ecos-faq) *(Both NHG-Intranet & Internet accessible)* to obtain the latest version of the FAQ document.

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1. DSRB SUBMISSION DEADLINES

Qn 1.1: When is the Deadline for Researchers to submit their IRB Applications to DSRB for review & approval?

- Aside from critical submissions, the DSRB is temporarily not accepting new IRB applications and study amendments. Refer to Qn 1.7 on the types of critical submissions and how to submit to DSRB.
    - Non-critical IRB submissions to the DSRB will resume when ECOS is launched. **More details will be provided later.**

[1st published: FAQ #1, 27 Nov 23, Refreshed: FAQ #2, 20 Dec 23, FAQ #5, 29 Jan 24, FAQ #6, 28 Feb 24, FAQ #7 15 Mar 24, FAQ #9, 30 Apr 24]

Qn 1.2: Is there a Deadline to submit Study Renewals to DSRB?

- For submission of Study Status Report Forms to terminate, suspend or complete a study, please refer to Qn 1.7 on the revised submission mode.
- For ongoing studies with expiry dates between **1 February to 31 July 2024** (both dates inclusive), the DSRB has granted a one-time approval extension of 6 months. The adjusted expiry date is now reflected on ROAM and the extension letter has been issued by DSRB for each impacted study. If you have a study in this category, please wait for ECOS before submitting your SRF.

[1st published: FAQ #2, 20 Dec 23, FAQ #6, 28 Feb 24, FAQ #7 15 Mar 24, FAQ #8, 28 Mar 24, FAQ #9, 30 Apr 24]

Qn 1.3: Is there a Deadline to submit Safety Events (NCR, UPIRTSO, Expected SAE) to DSRB?

- DSRB will continue to accept the following reports **on ROAM through 15 May 2024:**

    i. Non-Compliance
    ii. UPIRTSO
    iii. Expected SAE
    iv. Other Study Notification (OTH)

    Note:

    *a. We strongly urge investigators to **submit only critical OTH** during this transition period. Non-critical miscellaneous documents under OTH can be submitted after ECOS is launched.*

    *b. For new reports submitted on ROAM during this transition period, study team may need to resubmit the reports on ECOS subsequently. **More details will be provided later.***

[1st published: FAQ #1, 27 Nov 23, Refreshed: FAQ #2, 20 Dec 23, FAQ #6, 28 Feb 24, FAQ #7 15 Mar 24, FAQ #8, 28 Mar 24, FAQ #9, 30 Apr 24]

Qn 1.4: Will I still have access to ROAM after the submission cut-off dates?

- Yes. Study teams can continue to **access ROAM to complete** the following:

  i. Address DSRB queries for IRB applications, study amendments and Study Status Report Forms.

  ii. Submit new Non-Compliance, UPIRTSO, Expected SAE reports and Other Study Notification and address DSRB queries of submissions under review (up till **15 May 2024**).

- ***Note:***
  i. Studies that have achieved all review outcome before 01 April 2024 will be eligible for Wave 1 study migration (end May 2024). If you submit new reports on ROAM (e.g., NCR, UPIRTSO) on or after 01 April 2024, you may be required to re-submit the report on ECOS subsequently. More details will be provided later.
  i. Remaining studies that are undergoing review beyond 1 April 2024 will need to achieve a review outcome by 1 June 2024 for Wave 2 migration into ECOS in July 2024.

- From 01 June 2024, you will have **read only access** to existing information on ROAM till 30 June 2024. Please ensure you download all required information from ROAM **by 30 June 2024**.

[1st published: FAQ #2, 20 Dec 23 , FAQ #6, 28 Feb 24, FAQ #7 15 Mar 24, FAQ #9, 30 Apr 24]

Qn 1.5: Am I required to submit my CY2024 Financial Conflict of Interest (FCOI) Declaration?

- The validity period of CY2023 FCOI Declarations has been extended **till 30 June 2024**. If there are no changes to your FCOI status, no action is required.

- If there are changes to your CY2023 FCOI status, please inform DSRB (*DSRB_FCOI@nhg.com.sg)* promptly for timely assessment of potential impact to your current study involvements.

- FCOI declarations submitted after 1 March 2024 may have a downstream impact on involved studies. Studies affected may not be reviewed in time for migration into ECOS in May.

[1st published: FAQ #3, 08 Jan 24, FAQ #7, 15 Mar 24]

Qn 1.6: Is there a Deadline to submit Standing Database Applications (SDB)?

- New SDB applications will not be accepted **from 01 April 2024.**

- New SDB applications will only resume when ECOS SDB Module is launched in mid-2024.

[1st published: FAQ #3, 08 Jan 24, FAQ #9, 30 Apr 24]

Qn 1.7: If I have an (a) international sponsor / funded / awarded study, (b) local funded / awarded study that are tied to business or whole of government strategies (c) hit or miss rare disease study proposals (d) pandemic / endemic studies (e) other funded and time sensitive studies, will I be able to submit them to DSRB after the submission cut-off date?

Do contact OHRPP@nhg.com.sg with the required information below if you have such critical submissions.

Submission Type		Steps
New Studies		1. Write to **OHRPP@nhg.com.sg** with: **Email Subject: Seeking Exception Review of New Study** i. Name, Dept, Inst and Email of PI ii. Name, Dept, Inst and Email of Site PI(s) iii. Strong justifications why new study cannot wait till ECOS launch 2. Prof Benjamin Seet/ designee will determine if exception will be granted. 3. DSRB will provide instructions to PI on submission process.
Study Amendments (AMDs)		1. Write to **OHRPP@nhg.com.sg** with: **Email Subject: Seeking Exception Review of AMD** i. DSRB Ref No. ii. Study Title iii. PI Name iv. List of changes in point-form v. Strong justifications why AMD cannot wait till ECOS launch 2. Prof Benjamin Seet/ designee will determine if exception will be granted. 3. DSRB will provide instructions to PI on submission process.
Study Status Report Forms (SRFs)	**Reactivation of a study which expired between 1 Nov 2023 & 31 Jan 2024**	**1.** Write to **OHRPP@nhg.com.sg** with: **Email Subject: Seeking Exception to Reactivate Study** i. DSRB Ref No. ii. Study Title iii. PI Name 2. DSRB will provide instructions to PI on submission process.
	Suspended	1. Write to **OHRPP@nhg.com.sg** with: **Email Subject: Seeking to Submit Notification of Suspension** i. DSRB Ref No. ii. Study Title iii. PI Name 2. DSRB will provide instructions to PI on submission process.
	Completed/Terminated	1. Write to **OHRPP@nhg.com.sg** with: **Email Subject: Seeking to Close Study (Completed/Terminated)** i. DSRB Ref No. ii. Study Title iii. PI Name 2. DSRB will provide instructions to PI on submission process.

[1st published: FAQ #5, 29 Jan 24]

Qn 1.8: Is DSRB still conducting reviews after the submission cut off dates?

- Yes, the DSRB has received a 4-fold increase in submissions in the weeks leading to the submission cut-off date of 1 Feb 2024 for new study applications, amendments and study status reports.

- DSRB is currently working on the received submissions and are committed to clear them in time for the migration to ECOS. DSRB is also coordinating with other public and private sector IRBs to increase their capacity to accept new studies over this period.

- DSRB will continue to process safety related reports and amendments, as well as accept on a selective basis, urgent studies and amendments over this period (refer to Qn 1.7).

- To manage the transition to ECOS, DSRB had also previously reached out to public grant funding agencies and local institutions to defer grant calls and awards over this period.

[1st published: FAQ #6, 28 Feb 24]

2. DATA MIGRATION FROM ROAM TO ECOS

Qn 2.1: Will all my approved DSRB studies be migrated to ECOS?

- Only **Approved and Ongoing** studies will be migrated to ECOS.

- **For Ongoing Studies***, the following Study Status in ROAM will be included in the migration:
  a. NOT YET INITIATED
  b. ONGOING
  c. ENROLMENT CLOSED, SUBJECTS ON FOLLOW UP ONLY
  d. LAST PATIENT LAST VISIT OVER, DATA ANALYSIS ONGOING
  e. SUSPENDED

  **Ongoing studies are studies that have a valid DSRB approval.*

- Studies that are **Completed**, **Withdrawn**, **Terminated** or **Review Not Required** will **NOT** be migrated to ECOS.

- Studies that have achieved all review outcome before 01 April 2024 will be eligible for Wave 1 study migration (end May 2024).

- **Studies** that are undergoing review beyond 1 April 2024 will need to achieve a review outcome before 1 June 2024 for migration into ECOS in July 2024.

[1st published: FAQ #1, 27 Nov 23, Refreshed: FAQ #2, 20 Dec 23, FAQ #4, 19 Jan 24, FAQ #6, 28 Feb 24, FAQ #9, 30 Apr 24]

Qn 2.2: Will Expired Studies be migrated to ECOS?

- Expired studies will not be eligible for migration to ECOS, except for studies that **are recently expired** (i.e., between 1 November 2023 – 31 January 2024).

[1st published: FAQ #1, 27 Nov 23, Refreshed: FAQ #2, 20 Dec 23, FAQ #6, 28 Feb 24]

Qn 2.3: Will my existing ROAM User Account be automatically migrated over to the ECOS system?

- Unfortunately, **ONLY** specific ROAM Users will have their ROAM Account Profile migrated over to the ECOS system.

- The ROAM User must meet the following criteria for their Account Profile to be designated for migration to ECOS:
  - The User is currently listed as the **Principal Investigator (PI)**, **Site Principal Investigator (Site-PI)** or **Co-Investigator (Co-I)** in an **Active Study** [A] which has been designated for migration to ECOS.

    OR

  - The User is currently designated as a **ROAM System Key Appointment Holder** *(such as Dept Rep, Inst Rep, DSRB Domain Chair & Member etc)*.

    AND

  - In addition to meeting the above Appointment requirements, the User must have a **valid and completed** [B] ROAM Account Profile.

- For Users who do not qualify for their ROAM Account Profiles to be migrated to ECOS, they would need to create a new ECOS User Account when the new system is launched.

[A] ***What is an Active Study?***

- *A DSRB-Approved Study, which is Ongoing (or recently expired from 1 November 2023 onwards).*

[B] ***What is a valid and completed ROAM Account Profile?***

- *User has provided a **valid Email Address*** * *which is consistent with their Employment information.*
- *User has provided a **valid Primary Appointment** consistent with their Appointment/Job Title/Research role in their ROAM Account Profile.*
- *User has updated and validated their **Minimum Training Certifications** as required by the DSRB.*

* **FOR PHI-STAFF:** *The provided Email Address must be a **valid Public Healthcare Institution (PHI) Email Address** (eg: name**@nhg.com.sg** , name**@nuhs.com.sg** etc) in their ROAM Account Profile.*

FOR NON-PHI STAFF: *The provided Email Address must be a **valid corporate Email Address** from their Organization in their ROAM Account Profile.*

[1st published: FAQ #1, 27 Nov 23, Refreshed: FAQ #4, 19 Jan 24, FAQ #6, 28 Feb 24]

Qn 2.4: What happens to existing ROAM Account Profile of Collaborators and Study Administrators?

- The ROAM Account Profile of Collaborators and Study Administrators will **NOT** be migrated to ECOS **even if they are involved in active studies**.
- In ECOS, only the PI, Site PI and Co-I are required to be listed in the IRB application form.
- Collaborators and Study Administrators who require access to the IRB documents and submissions will need to register for an ECOS User Account and be added in the new Clinical Research Management System (CRMS) module on ECOS upon launch. On the CRMS module, 3 roles can be assigned:
  - Study Sponsor
  - Study Administrator - Not directly involved in research but only provides administrative support to study
  - Study Team Member - Directly involved in research
- Addition / removal of the Study Sponsor, Study Administrator and Study Team Member on ECOS will not require IRB review and approval. Changes will be managed at the site level. **More details on CRMS will be provided later.**

[1st published: FAQ #6, 28 Feb 24, Refreshed FAQ #7, 15 Mar 24]

Qn 2.5: I am an investigator (PI/ Site PI / Co-I) and all the studies I am involved in are completed. Will my ROAM Account Profile be migrated to ECOS?

- No, your ROAM Account Profile will not be migrated. Only the ROAM Account Profile of PI, Site-PI or Co-I in an **active study** will be migrated.

[1st published: FAQ #6, 28 Feb 24]

3. MINIMUM TRAINING AND FINANCIAL CONFLICT OF INTEREST (FCOI)

Qn 3.1: Are there any changes to the DSRB minimum training requirements with the transition to ECOS?

DSRB Minimum Training Requirements:

- There are no changes to the current **Collaborative Institutional Training Initiative (CITI) and Financial Conflict of Interest (FCOI) CITI** minimum training requirements.

- For Clinical Trials regulated by HSA (Effective **01 April 2024**):

Who	Current DSRB Requirements	Revised CT Min DSRB Requirements *(Effective 1April 2024)*
Investigators (conducting clinical trial)	Mandatory for **PI & Site PIs** to complete GCP prior to IRB submission	**Mandatory** for PI, Site-PIs and **Co-Is** to complete GCP prior to IRB submission.
Other **Study Team Members (STM)** (conducting clinical trial)	GCP training is not mandatory per DSRB requirements.	**Mandatory** for **Study Team Members (STM)** conducting *significant trial related tasks to complete GCP before study involvement.

*For STM: * Significant trial related tasks include informed consent taking, eligibility assessment, IP management, key efficacy and safety assessment etc. You may refer to HSA website for more details.*

The DSRB will recognise generic GCP courses (such as CITI GCP) and trainings as meeting the acceptable minimum training standard. The DSRB does not mandate a specific validity period for these GCP training certificates. However, individuals should ensure that their trainings remain relevant.

A valid GCP training certificate is required to be uploaded and validated on ECOS, prior to the submission of new Clinical Trials and amendments.

Other Minimum Training Requirements:

- Your Research Institution may also require you to complete a Human Biomedical Research Act (HBRA) minimum training.

[1st published: FAQ #6, 28 Feb 24, Refreshed: FAQ #7, 15 Mar 24]

Qn 3.2: What are the Minimum Training Certifications that will be migrated from ROAM to ECOS?

- For **ROAM Users** whose profiles will be migrated to ECOS (refer to Qn 2.3), the following minimum training certificates will be migrated to ECOS if they were uploaded in the ROAM Account Profile **before 1 March 2024**:

  i. Collaborative Institutional Training Initiative (CITI) Training Completion Report
  ii. Financial Conflict of Interest (FCOI) CITI Training Completion Report
  iii. Good Clinical Practice (GCP) Training Certificate

- If your training records are not preloaded into ECOS, you will need to upload the training certificates on ECOS when it is launched.

- For **SingHealth ROAM Users**, please note that your ROAM training certificates will NOT be migrated to ECOS. You will need to submit your minimum training certificates on ECOS when ECOS is launched per SingHealth 's

requirements. The SingHealth Institutions' Minimum Training Secretariats will verify the minimum training certificates on ECOS (refer to qn 3.5).

- If your training certificates are not loaded onto ECOS, you will not be allowed to submit new applications and study amendments (refer to Qn 3.6).

[1st published: FAQ #3, 08 Jan 24, Refreshed: FAQ #7, 15 Mar 24, FAQ #9, 30 Apr 2]

Qn 3.3: My Research Institution requires that I complete HBRA minimum training. Do I need to upload my HBRA minimum training certificate on ROAM?

- Hold on to your HBRA minimum training certificate. You do not need to upload your HBRA minimum training certificate on ROAM. Instead, upload it on ECOS when it launches.

  Once your HBRA minimum training completion certificate has been validated on ECOS, you will be able to submit new HBR studies or new HBR amendments.

- For **NHG Staff**, you can refer to this guide on how to download your HBR ERC e-Certificate.

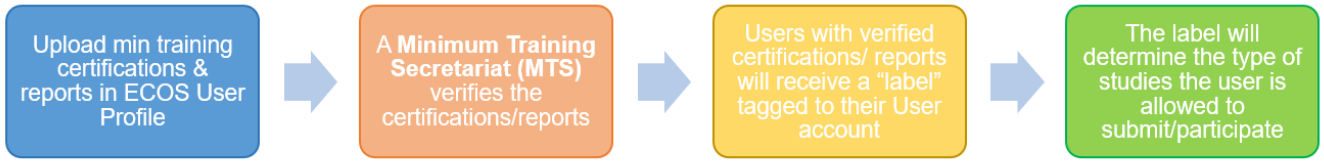
Please check with your specific Research Institution (RI) regarding the HBRA minimum training requirements, as these requirements may vary among different RIs.

[1st published: FAQ #3, 08 Jan 24, Refreshed: FAQ #6, 28 Feb 24, FAQ #9, 30 Apr 24]

Qn 3.4: What happens when I upload my training certificates on ECOS?

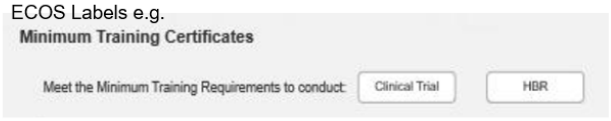
- Your training certifications will go through a validation process as per below.

ECOS Validation Process



Note: Migrated ROAM profiles (with verified FCOI, CITI, GCP records) will receive the applicable ECOS labels upon ECOS launch.

ECOS Labels e.g.

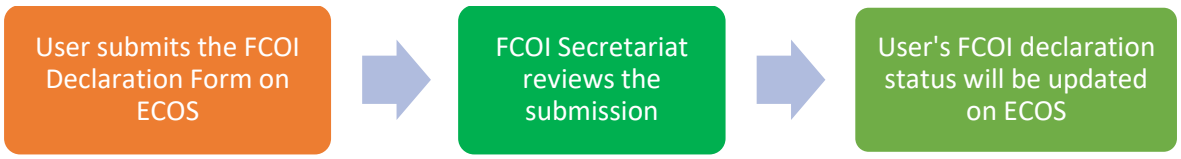


[1st published: FAQ #6, 28 Feb 24, FAQ #9, 30 Apr 24]

Qn 3.5: Are there any changes to the Financial Conflict of Interest (FCOI) Declaration process with the transition to ECOS?

- The FCOI declaration will continue to be an annual exercise. However, to help with the transition to ECOS:
  - A one-time extension of the validity period of CY2023 FCOI Declarations has been given (up **till 30 June 2024). More details on the next declaration cycle will be provided later.**
  - CY2022 and CY2023 annual FCOI declarations of PI, Site PI or Co-I (**in active studies only**) would also be preloaded into ECOS.

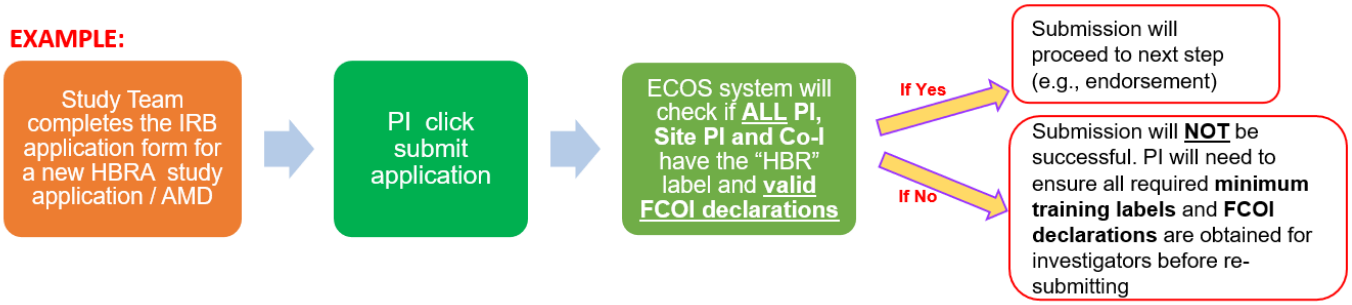
- When ECOS is launched, the FCOI declarations will be submitted via ECOS.



[1st published: FAQ #6, 28 Feb 24, FAQ #9, 30 Apr 24]

Qn 3.6: What happens if PI/Site PI/ Co-I do not have the required minimum training requirements or valid FCOI declaration on ECOS?

- In ECOS, only the PI, Site PI and Co-I are required to be listed in the IRB application form.
- If the PI, Site PI or Co-I **do not** have the required **minimum training requirements** or **valid FCOI declaration**, ECOS will not allow the investigator to submit new study applications and amendments.



- We strongly urge **PI, Site PI and Co-I** to **promptly check and submit** all minimum training requirements and FCOI declarations as needed upon ECOS launch.

[1st published: FAQ #6, 28 Feb 24, FAQ #9, 30 Apr 24]

4. NEW ECOS SYSTEM

Qn 4.1: Who can access and login to the ECOS system?

- ECOS (internet based) can be accessed by both Public Healthcare Institution (PHI) and non-PHIs (e.g. Sponsors, CROs, academic institutions). Please refer to training resources on ECOS Launch Website for more details on how to login to ECOS.

[1st published: FAQ #6, 28 Feb 24, FAQ #9, 30 Apr 24]

Qn 4.2: When will ECOS be launched?

- The ECOS system will include the following modules:

Module (Phase 1)	Function
1. Institutional Review Board (IRB) Module	▪ For submission of IRB applications ▪ Includes minimum training validation
2. Clinical Research Management System (CRMS)	For tracking of study & site milestones and recruitment
3. Financial Conflict of Interest (FCOI) Module	For submission of annual FCOI declarations
Modules (Phase 2)	**Function**
4. Compliance Module	▪ For completion of PI-self assessment forms (PISAF) ▪ For review of reportable events (safety events and non-compliances) to MOH for HBRA regulated studies
5. Audit & Monitoring Module	For auditing and monitoring activities
6. Standing Database (SDB) Module	For submission of standing databases applications (NHG & NUHS sites only)

- ECOS modules will be launched in phases.
    - Modules targeted for Phase 1 launch (May 2024) are **IRB, CRMS** and **FCOI** modules:
        - ❖ **Soft Launch (Early-Mid May)** - where Users will be able to:
            - ✓ Check & update migrated user profiles
            - ✓ Submit new studies, FCOI declaration and min training records
            - ✓ Update CRMS
            - ✓ Create new ECOS account (for users who are not migrated)
        - ❖ **Launch (End May)** - where Users will be able to:
            - ✓ Check studies that are migrated in Wave 1 migration
              → Submit all other forms
    - For the remaining modules launch (from July 2024 onwards), **more details will be provided later**.

Dates are correct at the time of publication and may be subjected to further changes.

[1st published: FAQ #7, 15 Mar 24, FAQ #9, 30 Apr 24]

Qn 4.3: With the launch of ECOS, will there be changes in the IRB review structure for NHG DSRB?

- Although NHG DSRB will be using a common IRB review platform (ECOS) as SingHealth CIRB, both IRBs will continue to function as independent review boards. Please refer to the respective IRB's policies and requirements.

- If there are cross cluster studies, the IRB review will be done in accordance with the current mutual recognition / cooperative agreements. For more information, please refer to the NHG Research website NHG :: RDO :: DSRB Frequently Asked Questions (FAQs).

[1st published: FAQ #7, 15 Mar 24]

5. ECOS USER TRAINING & RESOURCES

Qn 5.1: Will there be training or User Guides to familiarise users with the ECOS platform / modules?

- Yes, there are training materials and training sessions (Webinars conducted in April 24) to familiarise users with ECOS and its functions:

  ✓ **Slides** for the ECOS Onboarding Training Webinar is available on 'ECOS Launch Support Portal > Training'

  - For NHG staff only, the **recording** of this Webinar has been uploaded on NHG eLEARN Marketplace (https://elearn.sg/).
  - For NUHS staff, you may approach your Research Office for more info to access the Webinar recording.

  ✓ **ECOS Module-specific training materials** will be made available soon on '**ECOS Launch Support Portal > User Guides'.**

  Do regularly check the ECOS Launch Support Website for the latest information.

[1st published: FAQ #7, 15 Mar 24, FAQ #9, 30 Apr 24]

Qn 5.2: Will there be changes to the DSRB submission forms and reporting requirements with the launch of ECOS?

- There will be no changes to the DSRB reporting requirements (Non-compliance, study status report, expected SAE, UPRITSO, other notifications).

- DSRB and CIRB have aligned the main IRB application form and some of the supplementary forms (e.g., non-compliance, study status reports). The updated IRB application form and supplementary forms will be available upon ECOS launch.

- An IRB Guidebook: Application Form is now available on the ECOS Launch Support Webpage > User Guides Tab to guide users on how to complete the ECOS IRB application form.

[1st published: FAQ #7, 15 Mar 24, FAQ #8, 28 Mar 24]