

## **ECOS ANNOUNCEMENT #1.1 (24 Nov 2023)**

***Revision Note:***

*ECOS ANNOUNCEMENT #1 (8 Nov 2023) had been superseded with this revised version #1.1 (24 Nov 2023).*

- *Key update: Page 2 & 3 -Data Migration date of **9 April** 2024 had been revised to **1 April** 2024.*

Dear ROAM user

**RE: [ECOS Announcement #1.1] Transition from ROAM To New ECOS IT System**

The NHG ROAM system will be replaced by **Ethics and Compliance Online System (ECOS)** in mid-2024.

ECOS is co-developed by NHG and SingHealth to meet the evolving needs of the local research community and facilitate research ethics reviews and monitoring from cradle to grave.

In preparation for the transition, the ROAM System will **cease accepting new applications and amendments from 1 Feb 2024.**

For more details, please refer to **ECOS Announcement #1.1** posted on the “**ECOS Launch Support for NHG**” **Announcements** page on our NHG Research website: <https://for.sg/ecos-announcements>

Sincerely,

NHG Office of Human Research Protection Programme (OHRPP)  
*National Healthcare Group*  
*Adding Years of Healthy Life*

## NHG OHRPP – ECOS Announcement #1.1 (24 Nov 2023)

### (1) What is ECOS?

The NHG ROAM system will be replaced by a new **Ethics and Compliance Online System (ECOS)**, expected to be launched in mid-2024. This system will include the following modules:

Module	Function
<b>1. Institutional Review Board (IRB) Module</b>	For submission of IRB applications
<b>2. Compliance Module</b>	<ul style="list-style-type: none"> <li>▪ For completion of PI-self assessment forms (PISAF)</li> <li>▪ For review of reportable events (safety events and non-compliances) to MOH for HBRA regulated studies</li> </ul>
<b>3. Audit &amp; Monitoring Module</b>	For auditing and monitoring activities
<b>4. Clinical Research Management System (CRMS)</b>	For tracking of study & site milestones and recruitment
<b>5. Standing Database (SDB) Module</b>	For submission of standing databases applications (NHG & NUHS sites only)
<b>6. Financial Conflict of Interest (FCOI) Module</b>	For submission of annual FCOI declarations

### (2) Important Things to Note:

#### (a) Migration of Research Study from ROAM to ECOS

A study will be migrated to ECOS if **on** the scheduled Data Migration Date of **1 Apr 2024\***:

a. Study is Approved (all sub-status) Or recently Expired\*

**AND**

b. Has **0** submissions which are pending DSRB review or pending PI reply

*\*Expired from 01 Nov 2023 onwards.*

We seek your cooperation to respond promptly to the DSRB to ready your study for the migration.

#### (b) DSRB Submission Cut-off Dates in ROAM

To allow sufficient time for PIs, Study Teams and DSRB to prepare studies for the data migration, the following cut-off dates will be implemented for the submissions in ROAM.

No	Submission Type	Cut-off Date in ROAM	Expectation
1	New Studies	1 February 2024*	For studies to be readied for migration, all pending tasks must be completed <b><u>before 1 April 2024.</u></b>
2	Study Amendments		
3	Study Status Report Forms (SRF)		
4	Non-Compliance/Study Deviation Reports (NCR)#	1 March 2024*	
5	Unanticipated Problems involving Risks to Subjects or Others (UPIRTSOs)#		
6	Expected Serious Adverse Events (SAE)#		
7	Other Study Notifications (OTH)#		

\* All dates are correct at the time of publication and may be subjected to further changes.

- The submissions must reach DSRB **before** the cut-off date.
- For New Studies and Study Amendments, **both** the Department Representative (DR) and Institution Representative (IR) must have endorsed the New Study or Study Amendment (where applicable) **before** the cut-off date.

**DSRB will not be able to receive any submissions after the scheduled cut-off dates**

- PIs and Study Teams are reminded to buffer sufficient time and submit their submissions in ROAM early, especially if it requires multiple DRs and IRs to endorse
- DRs and IRs are also reminded to endorse their staff's New Studies or Study Amendments (where applicable) promptly in ROAM.

**(c) Reporting of Safety Events After the Cut-off Date**

It is still important for safety events (NCR, UPIRTSO, Expected SAE) and critical amendments to mitigate the risks to subjects to be reported/submitted to DSRB. There will be a provision for these submissions to be submitted to DSRB for review/approval via an alternative route. More details will be provided later.

However, all other non-urgent submissions will have to be submitted in ECOS when it is launched.

**(d) 6-Months Extension of DSRB Approval for Studies Expiring on 01 Feb to 31 Jul 2024**

For studies that are expiring during the period of 1 February to 31 July 2024 (both dates inclusive), the DSRB will grant a **one-time approval extension of 6 months**. This is to avoid a surge in Study Status Report Forms (SRFs) submitted to DSRB in ROAM before the DSRB Submissions Cut-off Date and to avoid lapses in renewal of DSRB approvals during the transition period.

Examples:

Current DSB Approval Expiry Date	New DSRB Approval Expiry Date
1 February 2024	1 August 2024
15 March 2024	15 September 2024
31 July 2024	31 January 2025

The new approval expiry date will be updated backend so there is no action required by Principal Investigators (PIs) or Study Teams.

## **(2) ECOS Launch Support for NHG Information Portal:**

As part of NHG's preparations to ensure a smooth transition from the current ROAM System to the new ECOS system, NHG OHRPP has created an **ECOS Launch Support for NHG** portal to act as a central information portal.

All announcements and guides related to the ECOS system and the decommissioning of the NHG ROAM System will be made available on the portal.

Please stay tuned to this website for the latest updates.

**ECOS Launch Support Website:** <https://for.sg/ecos> (both NHG-Intranet & Internet accessible) or use the QR code below.



**NOTE:** "ForSG" is an official link shortener for the healthcare institutions in Singapore.