

Navigating Ethics & Compliance Online System (ECOS) User Guide

SDB Module For Custodians and Database Team Members



[ECOS User Guide – SDB Module For Custodian and Database Team Member Ver 1, 20-Sep-2024]

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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. Submitting a new SDB application
- 2. Withdrawing an SDB Application
- 3. Features of the SDB Application Form
- 4. Responding to Queries
- 5. Submitting other forms

A1. Roles and Functions

Custodian	 Principal Investigator (PI) equivalent. Individual who has the primary responsibility for the Database establishment, conduct and maintenance, cooperative agreement, training and in compliance with the relevant laws and regulations of the institution and the state.
Site Custodian	 Site Principal Investigator (PI) equivalent. Individual who is responsibility for the site Database establishment, conduct and maintenance, cooperative agreement, training and in compliance with the relevant laws and regulations of the institution and the state.
Database Team Member (DTM)	 Study Team Member equivalent. Individual who is assigned by the Custodian to assist him/her in the preparation of the Standing Databases application submission and establishment.

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 your list of submitted SDBs?



B1. Submitting a New SDB Application (1/9)



B1. Submitting a New SDB Application (2/9)

C eSitePro			Submission			<mark>ل</mark> ع	ф ²⁹ с
Homepage	•		+ New SDB Application Form + New SDB Other Form	ns 🛄	Columns	🛃 Export	☆ Filter
о <u>т</u> о IRB	*	SDB Ref 🌲	IMPORTANT NOTE! X	dian 🌲 🛛	Form Type 🌐 🌲	Endorsing IRB	Action
CRMS	•	SDB-2024/0095	1. Please save before navigating to the next section or when exiting the form.		After clickin	g " + New A	Application
FCOI	×	SDB-2024/0094	 Please ensure you are listed as a database team member in Question 2 of this form to have access to this Standing Database / Tissue Bank (for NUHS). 	un a	appear.		
Submission		SDB-2024/0093	 Please do not paste tabular data (tables) or images in the textbox. If required, please submit them as attachments in the relevant sections. 	ids un F	Read and c	lick "Close"	
		SDB-2024/0078	 When a document has been amended to replace an existing document: a. Please ensure that both the clean and tracked copies are uploaded. 	ids un	SRF	NHG DSRB-NH Review Board	0
		SDB-2024/0078	b. Version number and date should be reflected within documents used for the purpose of this Standing Database/ Tissue Bank (for NUHS only). Where a version number and/or date is included in the file name, do ensure that it is the same as that stated within the	ids un	NCR	NHG DSRB-NH Review Board	0
		SDB-2024/0078	document. c. Please remove the obsolete copies as only the latest version is required.	ids un	NCR	NHG DSRB-NH Review Board	0
		SDB-2024/0084	Close NHG_SDB_54 (Yishun Comm	ids Tan Tock DB_42 unity	Application	NHG DSRB-NH Review Board	0
			Hospital)				
				Rows pe	r page: 100 🔻	1–13 of 13	< >

Note: User who click on "New SDB Application Form" will automatically be the Custodian of the application

B1. Submitting a New SDB Application (3/9)

Adding a Database Team Member

E K Back to Submission			Submission Detail			<u>ک</u> ر
DB Ref: - 🗐 Form Detail			V			
Application Form						X Cancel 🕞 Save
Database Site & Custodian Details *2: Does this Standing Database/Tiss Ves No	ue Bank involve more than one	e institution?				Instruction () Database Site & Custo Section A: Standing ()
2a: Database site(s)	Location		Endorsement Needed	Site Role	Action	Section B: Design Of St
* Tan Tock Seng Hospital (TTSH)	* testlocaltion2		Yes	* Main Site	Edit	Section C: How Data W
2b: Custodian and Database Team N	Aember(s)				+ /	dd Step 2
Database Site	Name	Database Role	Designation	Department	Action	Section E: Security Of
Tan Tock Seng Hospital (TTSH)	A/Prof shania3	Custodian	test	Gastroenterolo Hepatology		Section F: Transfer Of
						Section G: Retention A
EXTERNAL COLLABRATION						Section H: Monitorina

B1. Submitting a New SDB Application (4/9)

Adding a Database Team Member



B1. Submitting a New SDB Application (5/9)

Select your Reviewing IRB

e) Enter you're the title of your SDB.

- f) Under Section A2a, select "NHG DSRB".
- g) Under Section A2b, select "NHG SDB Review Board".

	Submission Detail		ቷ 🗘 🗞	
- SDB Ref: - 「目 Form Detail				
Application Form		× c	Cancel 🕞 Save	
Section A: Standing Database/Tissue Bank Title		© Section 20 characters entered	n A: Standing Data n B: Design Of Sta	
A2: Reviewing IRB		Section	n C: How Data Will	
A2a: The reviewing IRB would be:			Step 1: Selec	t "NHG DSRB"
NHG DSRB		✓ Section	E: Transfer Of Re	
A2b: Please select the board. NHG SDB Review Board Note:		~	Step 2: Selec Board"	ct "NHG SDB Review
For NHG user, please select NHG DSRB as the Reviewing IRB (Section A For NUHS users, please select "NUHS SDB Review Board" as the Review	42a) and select "NHG SDB Review Board" as the IRB board (Section A2b). w IRB and IRB board (Section A2a & A2b).	Section	Step 3: Proce rest of the set	eed to complete the ctions

Note: The IRB will reject applications with the wrong board selected. The custodian may edit the IRB board during the endorser (ROC/DR/IR) query stage before the IRB reviews the application.

B1. Submitting a New SDB Application (6/9)

When you are ready to submit

$:= : \in Back$ to Submission	Submission Detail		🕁 🗘 🔁	
SDB-2024/1385 Draft 🕚 SDB Ref: SDB-2024/1385 🗐			Declare and Submit	
Form Type: Application SDB Custodian/SDB Site Custodian: A/Prof shania3 (Tan Current Editor: A/Prof shania3 SDB Title: SDB_TRAINING_DEMO_04_Sep_01 Quick Link: SDB Summary Form Detail	Form Outcome: - 1 Tock Seng Hospital (TTSH))	Step 1: Click on "Mandatory Check"	Step 2: If there message (i.e. no required), proce and Exit"	is no prompt o action is ed to click " Save
Application Form		✓ Mand story Check X Cancel	Save Save and Exit	
Instruction			Instruction	
INSTRUCTION:			Database Site & Custo	
 For NHG users, this form is to be used for Standing For NUHS users, this form is to be used for Standing 	Database only. Please refer to NHG Tissue Compliance Committee (TCC) requirer g Database and Tissue Banks.	ments for tissue banks.	Section A: Standing Da	
MAIN PAGE			Section B: Design Of St	
 *1: This application is an amendment to a Standing Dat 	tabase Application in ROAM.		Section C: How Data W	
YesNo			Section D: Consent Re	
			0	

B1. Submitting a New SDB Application (7/9)

Pop-up after you clicked "Mandatory Check"

: < Back to My Tasks	Si	ıbmission Detail	
DB-2024/1385 Draft 🕥 DB Ref: SDB-2024/1385 🗐			
orm Type: Application	Form Outcome: -		
DB Custodiar (CDB Site Oustediary Albertury) urrent Editor ECOS	f shania9 (Tan Task Cons Haanital (TTOLIN)		
DB Title: SD	incomplete. You must complete all relevant sections be	ofore you can proceed to submit.	13
Section	Field	Reason	Action
Database Site & Custodia Details	3: Does this Standing Database/Tissue Bank involve external collaboration beyond the Clusters?	This is a mandatory field. Please fill in response.	ď
Database Site & Custodia Details	4: Does the Custodian and/or Database Team Member have a potential Conflict of Interest?	This is a mandatory field. Please fill in response.	ď
Instruction	1: This application is an amendment to a Standing Database Application in ROAM.	This is a mandatory field. Please fill in response.	ď
• For NHG • For NHG • For NUHS • For NUHS • For NUHS	B1: Please indicate the source of data for this Standing Database/Tissue Bank.	This is a mandatory field. Please fill in response.	C
MAIN PAGE			Confirm
: This application is an amendment to a	Standing Database Application in ROAM.		Section C: H

If there is a pop-up message after you clicked "Mandatory Check", update the fields mentioned. Once completed,

- Custodians, proceed to click "Save and Exit"
- Site Custodians/ DTMs, proceed to click "Save and Exit", followed by "Finalise".

Edit

Da...

f... !

a... 🕛

B1. Submitting a New SDB Application (8/9)

Submit the application (By Main Custodian only)

	Submission Detail	년 🔁 🗙	
SDB-2024/0103 Draft SDB Ref: SDB-2024/0103		∠ Declare and Submit Step	1: Click "Declare & Submit"
Form Type: Application Form	n Outcome: -		
SDB Custodian/SDB Site Custodian: Mr NHG_SDB_54 (Yishun Communi	ty Hospital)		
Current Editor: -			
SDB Title: Testing 1992024	ECOS	×	
Quick Link: SDB Summary	Declaration Of Custodian		
Form Detail	As the appointed custodian of this Standing Database/Tissue Bank^, I declare the following: • I am aware of the Institutional Research Data Policy, Personal Data Protection Act (PDPA), HealthTech Instru IRB policies, and to the best of my ability, will ensure that there are no contraventions of these obligations in • I will not initiate any changes in the Standing Database/ Tissue Bank without obtaining nor written annoval	ction Manual, relevant institutional data management policies and my custodianship.	
Application Form	 I will ensure the acquisition, storage, utilisation and disposal of any data in the Standing Database/ Tissue Bi I will ensure the acquisition, storage, utilisation and disposal of any data in the Standing Database/ Tissue Bi I will ensure the database system I intend to use complies with Synapxe requirements, Institutional Research I will ensure that any access to the data granted to individuals/third parties, including the transfer of data 	ank shall protect the confidentiality of the information contained. a Data Policy and other relevant policies. overseas, will be consistent with the institutional policies and local	
Instruction	 regulations. I will ensure that there are processes in place to ensure that the data collected is accurate and complete priprior to disclosure to outside parties. I have taken all reasonable steps and safeguards that are necessary to protect the data against breaches, are unauthorized access, disclosure and copying use. 	or to any use to make a decision that affects the individual and/or ccidental and unlawful loss, modification or destruction or	
INSTRUCTION: • For NHG users, this form is to be used for Standing Database only • For NUHS users, this form is to be used for Standing Database and	I understand that failure to comply with the applicable regulations, institutional and research data policies m Database/Tissue Bank. I declare that there are no existing or potential conflicts of interest for any of the team members involved in tinterest have been declared in the relevant section of the application form. Applicable to NUHS users only.	ay result in the suspension or termination of this Standing this Standing Database/ Tissue Bank. Any potential conflicts of	
	By checking, the 'I agree' box, you confirm that you have read, understood and accept the Custodian's Decl	laration.	
		Cancel Confirm	Step 2: Read the declaration and Click "Confirm"

B1. Submitting a New SDB Application (9/9)

Save your draft regularly

		Submission Detail		අ දි ර
-				
SDB Ref: - 🗐				
Form Type: Application	Form Outcome: -			
SDB Custodian/SDB Site Custodian: -	} │	Submission Detail	F1 🐮 8	
Current Editor: -				Step 1: Click "Save"
SDB Title: -	SDB Ref: ECOS		×	
Form Detail	SDB Cut Your application is incomplete. You must complete all relevant s	ections before you can proceed to submit.		
	Current Section Field	Reason	Action	
Application Form	Section A: Standing Database/Tissue Bank Title Title of Standing Database/Tissue Bank:	This is a mandatory field. Please fill in response.	ß	X Cancel Save
Instruction	Applic		ave	Instruction
	Instruct			Datahase Site & Custodi
INSTRUCTION: • For NHG users, this form is to be u	INSTEL	Step 2: A pop-up	i	
For NUHS users, this form is to be	• Foi • Foi	message will appear.		Section A: Standing Data
MAIN PAGE	MAIN PAGE	Click "Confirm" to proceed	Section B: Design Of Sta	Section B: Design Of Sta
*1: This application is an amendment t	o a Standing Database Application in ROAM.			Section C: How Data Will
⊖ Yes				Section E: Security Of Sta
∩ No				

Note: Click "Save" regularly to ensure that your edits are captured in the system.

B2. Withdrawing an SDB Application (Before the SDB is approved)

Withdrawal of SDB Application

	Submission Detail	🛃 🔂 🖓
SDB-2024/0102 Pending ROC/DR/IR SDB Ref: SDB-2024/0102	Endorsement 🕥	: Step 1: Click the icon, followed by
Form Type: Application	ECOS ×	dropdown menu
SDB Custodian/SDB Site Custodian: A/Pro	f N	withdraw the SDE
Current Editor: -	▲ Do you want to withdraw this form?	application
SDB Title: SDB Application 19Sep24	* Withdraw Reason: Step 2: input the reason for	
Quick Link: SDB Summary	withdrawing the application and click	
Form Detail Endorsement	on the "confirm" button to proceed with the withdrawal.	
Application Form		Track Changes 🛃 Export
Instruction	Cancel Confirm	Instruction
INSTRUCTION:		Database Site & Custodi
 For NHG users, this form is to be use For NUHS users, this form is to be us 	d for Standing Database only. Please refer to NHG Tissue Compliance Committee (TCC) requirements for tissue banks. ed for Standing Database and Tissue Banks.	Section A: Standing Data
MAIN PAGE		Section B: Design Of Sta
*1: This application is an amendment to	a Standing Database Application in ROAM.	Section C: How Data Will

B3. Features of the SDB Application Form – Form History



B3. Features of the SDB Application Form – SDB Summary



B3. Features of the SDB Application Form – Track Changes

Track Changes

		Submission Detail	± 4ª ×
SDB-2024/1320-AMD003 Review Com SDB Ref: SDB-2024/1320	Track Changes	Close Export	Click on the "Track Changes" button
Form Type : Amendment SDB Custodian/SDB Site Custodian : A/Prof shania:	Current Version SDB-2024/1320-AMD003 03-Sep-2024 15:44:04	Previous Version SDB-2024/1320 03-Sep-2024 11:01:31 V	and a popup will appear with the difference between the versions.
Current Editor: -	Database Site & Custodian Details		
Quick Link: SDB Summary	2: Does this Standing Database/Tissue Bank involve more than o No Yes	one institution?	Track Changes
Amendment Form	2a: Database site(s) Tan Tock Seng Hospital (TTSH)		Track Changes 🛃 Export
Instruction	Database Site	Tan Tock Seng Hospital (TTSH)	Instruction
INSTRUCTION	Location	• testlocaltion2	Database Site & Custo
New/ Revised information: Revised information:	tion: Green highlight	Yes Sub Site	Section A: Standing Da
DETECTED INFORMATION	diple night with suite though		Section B: Design Of St
*1. Describe the proposed change(s) to the datab	2b: Custodian and Database Team Member(s) Ng Teng Fong General Hospital (NTFGH) / Database Team Memb	eer / A/Prof TTSH_STM1 Deleted	Section C: How Data W
test	Database Site	Ng Teng Fong General Hospital (NTFCH)	Section D: Consent Re
	Name	A/Prof TTSH_STM1	Section E: Security Of
	Database Role	Database Team Member	Section F: Transfer Of
	Designation	• 1	Section G: Retention A
	Department	Medical Openlogy	
			Section H: Monitoring

B4. SDB Application – Responding to Queries

On "Submission Detail" page

C □ Ξ < Back to Submission	Submission Detail	± ↓ ႙
SDB-2024/0085 Pending Custodian Reply 🕥	Query List Tan Tock Seng V 🕞 Saved at 27-Sep-2024 14:15:13	E, Query List
SDB Ref: SDB-2024/0085	Pending Query All Query	
Form Type: Application SDB Custodian/SDB Site Custodian: A/Prof NHG_SDB_19 (Tan Tock Seng H	0/1 Pending	Click the "Query List"
Current Editor: - SDB Title: Database for 123456790	General dropdown list to view gueries from the	to view the queries.
Quick Link: SDB Summary	query query	
Form Detail Endorsement	Query Round 1 A/Prof NHG_SDB_30 27-Sep-2024 14:15:13	
Application Form	* Reply Query	Changes 🛃 Export 🖉 Edit
Instruction	Please enter	Instruction

B5. Submission of New SDB Other Forms

Submission of New SDB Other Forms

			Submission						
SDB Re	ef 🔷 🗘 SDB Form Ref 🗘 🗍	SDB Title	+ New SDB Appl	ication Form + New s	SDB Other Forms Endorsing IRB	Step 1: Click " Step 2: Enter 1 click "Search" Step 3: Select	New SDB C he "SDB Tit button. the SDB tha	Other Form" Ie" or "SDE at you like t	Ref" and to submit the
SDB-2	New SDB form				× B-NHG	form for. Step 4: Select	the Form T	ype and cli	ck "Confirm".
SDB-2	* SDB Title or SDB Ref:				ard	Noto: If SDR h	ad boon "Cl	ocod" or "T	orminated"
SDB-2	2 SDB Title	SDB Ref	SDB Custodian/SD	3 Site Custodian	© Q B-NHG	you can only s	ubmit an NC	CR.	eminaleu,
SDB-2	shania_test_03_sept_01	SDB-2024/1320	A/Prof shania3 (Ng TTSH_STM1 (Tan	Teng Fong General Hospital (NTFGH)), ⁻ ock Seng Hospital (TTSH))	A/Prof B-NHG	SDB ROC/DR/IR		0	
SDB-2	shania_test_03_Sep_02	SDB-2024/1333	A/Prof shania3 (Ng shania3 (Tan Tock	Teng Fong General Hospital (NTFGH)), Seng Hospital (TTSH))	A/Prof B-NHG	SDB • Pending Custodian Reply	-	୍ଷ	
SDB-2	shania_test_03_sept_03 shania_test_04_Sep_fixed_organge_dot	SDB-2024/1336 SDB-2024/1373	A/Prof shania3 (Ng A/Prof shania3 (Ng	Teng Fong General Hospital (NTFGH)) Teng Fong General Hospital (NTFGH))	B-NHG stard	SDB • Review Completed	Approved	0	
SDB-2			Rows per	oage: 10 👻 1−5 of 5 <	> B-NHG	SDB • Review Completed	To be Closed	0	
SDB-2	* Form Type :				B-NHG :	SDB • Review Completed	To be Suspende	0	
SDB-2		Form Type includes:Amendment,			B-NHG	 Pending IDA/ID Approval 		©	
SDB-2		 Non-compliance (NCR) a Study Status Report Forn 	nd n (SRF)	Cancel	B-NHG	SDB • Review Completed	To be Terminate	0	
SDB-20	024/0044 SDB-2024/0044- NCR004	Standing Database NCD D	Hospital)	ng NCR	NHG DSRB-NHG Review Board	SDB • Review Completed	Approved	0	
SDB-20	024/0044 SDB-2024/0044- NCR003	Standing Database NCID D	A/Prof NHG_SDB_32 (Tan Tock Se Hospital)	ng NCR	NHG DSRB-NHG Review Board	SDB • Review Completed	Acknowledged	0	

23