ECOS

SDB Form Guidebook:

Application, Non-Compliance & Status Report Form

Version 1 dated 27 September 2024

National Healthcare Group
Adding years of healthy life

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Part 1: How to Complete Application Form

Part 1 of this guidebook will provide guidance for custodian to draft the Standing Database (SDB) Application Form. Do note that the guidance is only specific to some sections. Please approach the NHG Research Data Secretariat (RDS) if you require further guidance.

You may refer to Part 2 of the guidebook for the sample questions of the Application Form.

1.1 Applicable Cluster and Reviewing IRB

The establishment of Standing Database is for the purpose of future research.
NHG Custodian to select "NHG SDB Review Board" as the IRB Reviewing Board in Question A2b of the application form.

1.2 Database Site

Database site under the purview of NHG RDS should be added under Question 2a of the SDB Application Form if the database site is involved in the SDB.

- More than 1 database site can be selected if the SDB involves multi-sites. Please note that each site should appoint a site Custodian.
- For other local sites not under the NHG RDS's purview, you may list them under Question 2b of the Application Form, for the endorsers' information only. SDB approval will not include any of these sites. Please ensure there is an agreement in place and approach your respective institution' research office for more details.

1.3 Custodian & Database Team Member

Custodian is the overall person responsible for the proper management of the Standing Database. He or she will be the primary contact person for the endorsers (i.e., only Custodian would be able to submit (re-submit, in the case of query raised) the SDB Application Form.)

- For multi-site or cross-cluster Standing Database, each site should have a site custodian appointed. The site custodian should be from the respective database site.

Database Team Member is any individual member of the standing database team designated and supervised by the custodian to perform database-related activities that may or may not involve participant contact (e.g. database administrators).

Custodian and Database Team Member should be added under the database site(s) (Question 2b of the Application Form) through their registered ECOS accounts so that they will be notified of their participation in the Standing Database when the Application Form is submitted.

For users with multiple appointments, the correct appointment should be selected when users are being added to the Application Form.

- Example 1: Dr Yeo is a consultant at TTSH and visiting consultant at KTPH. The database activities will be conducted in KTPH and Dr Yeo is involved in the study in his KTPH capacity. The Standing Database should add Dr Yeo's KTPH visiting consultant appointment under the KTPH site.

1.4 Profile and Minimum Training

Each user is required to complete their profile in ECOS.

There is no minimum training requirements required for SDB.

1.5 Conflict of Interest

All Custodians must indicate under Question 4 of the Application Form if he/ she has any potential conflict of interest, which includes financial interest. The declaration is also for the immediate family members of the Custodians. The Custodian is responsible for checking and ensuring that accurate information is submitted for the application.

- Conflicting Interest – A conflicting interest can be broadly defined to refer to any interest of the Custodian or immediate family (includes spouse, children, parent(s)

and sibling(s)) that competes with the investigator's obligation to protect the rights and welfare of the participants.

- Financial Interest – Financial Interest means anything of monetary value, including but not limited to, salary or payments for services (e.g., consulting fees or honoraria); equity interests (e.g., stocks, stock options or other ownership interests); intellectual property rights (e.g., patents, copyrights, and royalties from such rights), and board or executive relationships. The Conflict-of-Interest Declaration Section must be submitted to the endorsers via an amendment if any of the circumstances relevant described herein change during the conduct of the Standing Database.

1.6 Recruitment and Consent

The Standing Database should select the applicable type of consent for the study.

- Consent will be obtained.
    - Informed Consent Document(s) would be used. Please ensure the Informed Consent Document meets the required regulatory requirements, e.g. the required consent elements are included.
    - It is important that the consent obtained previously met the HBRA Section 12 (1) requirements.
- Waiver of consent
    - In accordance with Personal Data Protection Act (PDPA) requirements, researchers may use personal data (e.g. medical records) without consent, subject to the following conditions:
        i. The research purpose cannot reasonably be accomplished unless the personal data is provided in an individually identifiable form;
        ii. It is impracticable to seek the consent of the individual for disclosure;
        iii. There is a clear public benefit to using the personal data for the research purpose;
        iv. The results of the research will not be used to make any decision that affects the individual; AND

v. In the event the results of the research are published, the results must be published in the form that does not identify the individual.

1.7 Standing Database involving De-identified Data

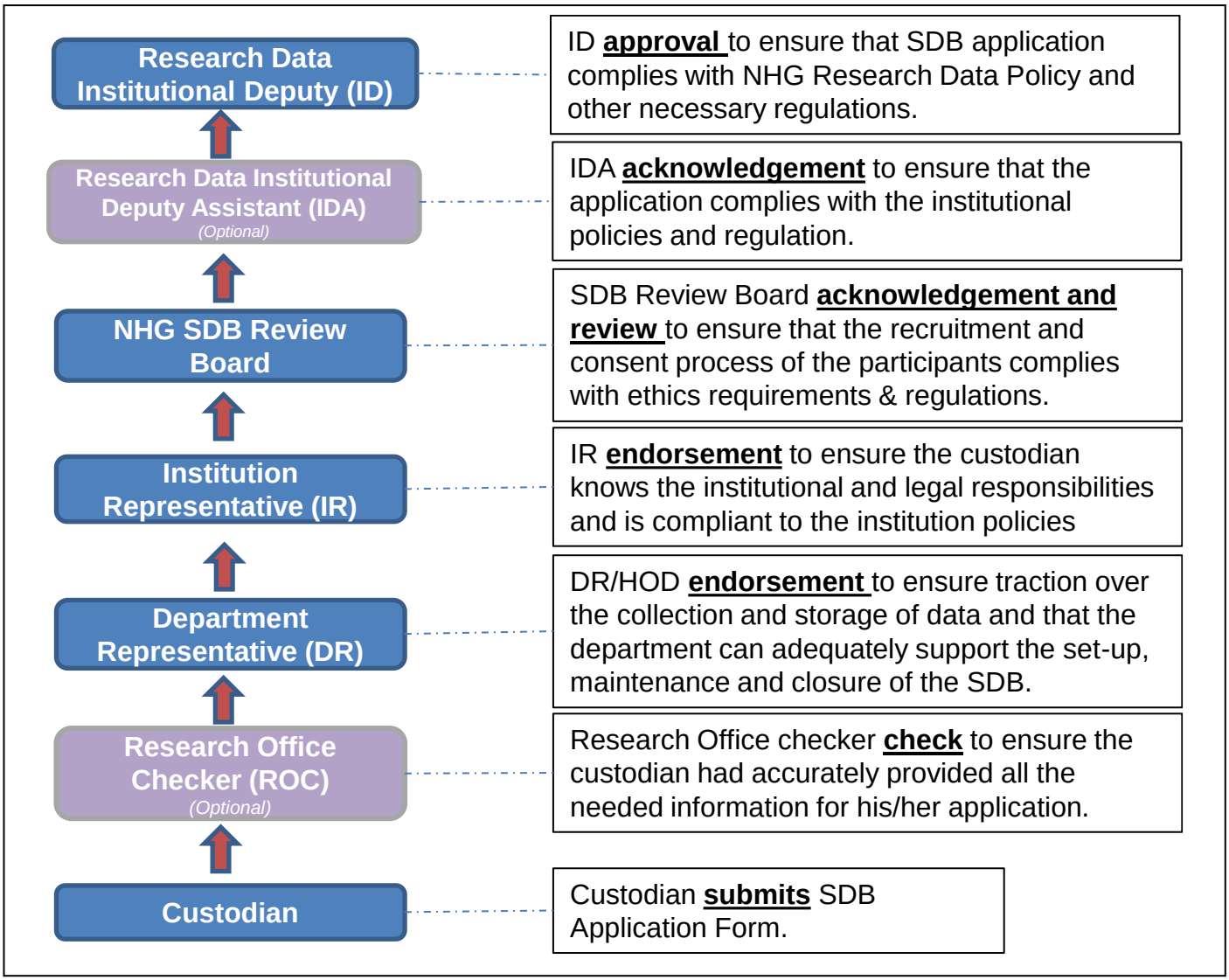
"De-identified data" refers to a data set from which personal identifiers have been extracted, which will disallow re-association with any of the people mentioned in the original record. It should be noted that de-identified data sets often contain a newly created unique identifier separate from any identifying characteristics in the original study data sets. This created identifier is not capable of being translated to identify the individual except through a Record Linkage Data, which links the created unique identifier with an established identifier. The record linkage data should be held by an individual who is not in the study team.

For research using unidentifiable data (e.g., de-identified by program coordinator, or Trusted Third Party), please describe the process. For instance, why, what, who and where how the unidentifiable data are obtained.

1.8 Declaration and Endorsement

All SDB applications would require Custodian's declaration and endorsement from the respective institutions before the SDB Application Form reaches the IRB and the Institutional Deputy for review.

Figure 1 – NHG Standing Database Review Process



Note:

1. Research Office Checker, DR, IR, IRB, and ID may raise queries during the endorsement process. The endorsement process will be halted when there are queries pending PI's reply.
2. When a query (during the endorsement process) is raised, the Application Form becomes editable and SDB team can update it.
3. Once the SDB application form is endorsed and there are significant / major changes to it, there is no re-endorsement process. The endorsers may simply reject the application and the SDB team will have to re-submit the application.

Part 2: Application Form (For Reference Only)

Below listed all the sections and questions of the SDB Application Form. Depending on the options selected, only certain sections and questions will be displayed.

STANDING DATABASE APPLICATION FORM

SDB Ref: SDB-20YY/XXXXX *(auto generated upon creating (draft) the application)*

INSTRUCTION:

- **For NHG users, this form is to be used for Standing Database only. Please refer to NHG Tissue Compliance Committee (TCC) requirements for tissue banks.**
- **For NUHS users, this form is to be used for Standing Database and Tissue Banks.**

MAIN PAGE

1: This application is an amendment to a Standing Database Application in ROAM.

☐ Yes
☐ No

1a: If yes, please state the reference number of the Standing Database in ROAM. *(If "Yes" is selected in 1, qn 1a will appear.)*

E.g. SDB-20YY/XXXX

1b: Please attach a PDF copy of the Standing Database Application in ROAM. *(If "Yes" is selected in 1, qn 1b will appear.)*

Attached documents here

DATABASE SITE & CUSTODIAN DETAILS

2: Does this Standing Database/Tissue Bank involve more than one institution?

☐ **Yes**
☐ **No**

2a: Database site(s): *(First line is auto populated from the person's user profile who created this application)*

Database Site	Location	Endorsement needed	Site Role

2b: Custodian and Database Team Member(s): *(First line is auto populated from the user profile of the person who created this application, and the person's database role is the custodian by default.)*

Database Site	Name	Database Role	Department	Institution	Profile	Email
					<link to user profile>	

EXTERNAL COLLABORATION

3: Does this Standing Database/Tissue Bank involve external collaboration beyond the Clusters?

☐ Yes
☐ No

3a: If yes, please indicate all the external partner(s) for this Standing Database/Tissue Bank. *(If "Yes" is selected in 3, qn 3a will appear)*

4: *Does the Custodian and/or Database Team Member have a potential Conflict of Interest? *(If "Yes" is selected in 4, qn 4a will appear.)*

☐ Yes
☐ No

4a: If yes, please specify who and the details of the potential conflict of interest and provide a management plan to eliminate or mitigate it.

Note: Conflicting Interest – A conflicting interest can be broadly defined to refer to any interest of the custodian and/or database team member that competes with the custodian's and/or database team member's obligation to protect the rights and welfare of database participants.

Conflicting interests may arise in the duration of the Standing Database/Tissue Bank. If such interests arise, the custodian and database team member should declare these to your institution's Standing Database Secretariat as soon as possible but not later than 30 calendar days.

SECTION A – STANDING DATABASE/TISSUE BANK TITLE

A1: Please enter title of Standing Database/Tissue Bank

Title of Standing Database/Tissue Bank:

A2: Reviewing IRB

A2a: The reviewing IRB would be:

-Choose from Dropdown list-
NHG DSRB

A2b: Please select the board.

-Choose from Dropdown list- Available options will be based on the IRB selected in Section A2a)
NHG SDB Review Board

Note:
For NHG users, please select NHG DSRB as the Reviewing IRB (Section A2a) and select "NHG SDB Review Board" as the IRB board (Section A2b).
For NUHS users, please select "NUHS SDB Review Board" as the Review IRB and IRB board (Section A2a & A2b).

SECTION B: DESIGN OF STANDING DATABASE (WHAT DATA IS COLLECTED?)

B1: Please indicate the source of data for this Standing Database/Tissue Bank.

Check all that are applicable:

- ☐ Hardcopy Medical Records
- ☐ Surveys/Questionnaires
- ☐ Department Database
- ☐ Institution Clinical Database
- ☐ DSRB Acknowledged Standing Database
- ☐ IRB Approved Study

B1a: Please indicate in detail which Database/Approved Study data will be used? *(If "Department Database", "Institution Clinical Databases", "DSRB Acknowledged Standing Database" or "IRB Approved Study" is selected in B1, qn B1a will appear.)*

B1b: Custodian declaration of National Electronic Health Records (NEHR) as source document.

- ☐ I am aware that NEHR is prohibited for use and will not use it as a data source.

B1c: Please state the reference number(s) of the IRB Approved Study and/or DSRB Acknowledged Standing Database. *(If "DSRB Acknowledged Standing Database" or "IRB Approved Study" is selected in B1, qn B1c will appear.)*

E.g. 2020/01004

B2: Please indicate the purpose of this Standing Database/Tissue Bank

- ○ Only for future research
- ○ Beyond just future research

B2a: If beyond just future research, please specify the purpose of this Standing Database/Tissue Bank. *(If "Beyond just future research" is selected in B2, B2a will appear.)*

B3: Please attach the surveys/questionnaires or document(s) containing the list of variables which will be collected for the Standing Database/Tissue Bank. Document footers containing the Standing Database reference number, title, custodian name, document name, version number and date must be provided for each document.

Attached documents here.

B4: Please verify whether data collected is from

☐ Completed Study(ies)
☐ On-going Study(ies)
☐ Prospective Data Collection
☐ Others

B4a: If others, please specify the data collected. *(If "Others" is selected in B4, qn B4a will appear.)*

B5: Will the Standing Database/Tissue Bank team be obtaining de-identified data from a trusted third party and/or be handling only de-identified data at any point in time?

☐ Yes
☐ No

B5a: If yes, please specify. *(If "Yes" is selected in B5, qn B5a will appear.)*

Note: To access the hospital records/clinical database for data collection, approval from Data Exchange Office (DXO)/Office of Data Management (ODM) or equivalent must be obtained.

PDPA Obligation – Accuracy

- Make reasonable effort to ensure that the personal data collected is accurate and complete.

SECTION C: HOW DATA WILL BE COLLECTED

C1: Please select all the applicable consent scenarios.

☐ Informed Consent
☐ Waiver of Informed Consent

C1a: For Informed Consent, please select all the applicable scenarios. *(If "Informed Consent" in C1 is selected, qn C1a will appear.)*

☐ Informed Consent has been obtained from an IRB approved study and/or existing IRB Acknowledged Standing Database to store data for future research.
☐ Informed Consent will be taken from participants [i.e. Prospective data collection (e.g. any time period on or after the Standing Database/ Tissue Bank application)]

C1b: For Waiver of Informed Consent, please select all applicable scenarios and complete Section D. *(If "Waiver of Informed Consent" in C1 is selected, qn C1b will appear.)*

☐ Waiver of Informed Consent for identifiable data collection
☐ Waiver of Informed Consent for de-identified data collection

C1c: If a combination of both Informed Consent and a Waiver of Informed Consent is required, please state which population(s) / dataset(s) are involved for the combination selected. *(If "Informed Consent" & "Waiver of Informed Consent" are both selected in C1, qn C1c will appear.)*

C2: Does the Standing Database/Tissue Bank involve the collection and storage of data from any of the following populations?

Check <u>all</u> that are applicable:

☐ Children (Persons less than 21 years of age & who were never married)
☐ Persons who lack mental capacity (within the meaning of Section 4 of the Mental Capacity Act (Cap, 177A))
☐ Pregnant Women and Foetuses
☐ None of the Above

C3: Please provide detailed justifications to describe the need to include these populations. *(If "Children", "Person who lack mental capacity" or "Pregnant Women and Foetuses" is selected in C2, qn C3 will appear.)*

C4: For the population(s) selected under Section C2: *(If "Children (Persons less than 21 years of age & who were never married", Persons who lack mental capacity (within the meaning of Section 4 of the Mental Capacity Act (Cap, 177A))" or "Pregnant Women and Foetuses" is selected in C2, qn C4 will appear.)*

Check all that are applicable:

C4a: Children (Persons less than 21 years of age & who were never married) *(If "Children (Persons less than 21 years of age & who were never married)" is selected in C2, qn C4a will appear.)*

☐ Assent will be obtained from all children 6 years old and above, and consent will be obtained from their legal representative.
☐ Assent will not be obtained from all children 6 years old and above, and only consent will be obtained from their legal representative.
☐ Only assent will be obtained. Consent will not be obtained from their legal representative.
☐ Neither the child's assent nor consent of their legal representative will be obtained.

C4b: Persons who lack mental capacity (within the meaning of Section 4 of the Mental Capacity Act (Cap, 177A)) *(If "Persons who lack mental capacity (within the meaning of Section 4 of the Mental Capacity Act (Cap, 177A))" is selected in C2, qn C4b will appear.)*

☐ Assent will be obtained from persons who have been established to lack mental capacity and consent will be obtained from their legal representative.
☐ Assent will not be obtained from persons who have been established to lack mental capacity and only consent will be obtained from their legal representative.

C4c: Pregnant Women and Foetuses *(If "Pregnant Women and Fetuses" is selected in C2, qn C4c will appear.)*

☐ Consent will be obtained from the pregnant women.
☐ Consent will also be obtained from the father because the research holds out the prospect of direct benefit solely to the foetus.

C4ci: Consent will be obtained from the pregnant women because *(If "Consent will be obtained from the pregnant women" is selected in C4c, qn C4ci will appear.)*

☐ Research holds out the prospect of direct benefits to the pregnant women.
☐ Research holds out the prospect of direct benefits to both the pregnant women and the foetus.
☐ Risk to the foetus is not greater than minimal and the purpose of the research is the development of important biomedical knowledge that cannot be obtained by any other means.

C4d: Please justify the reason for not obtaining assent/consent from this population. *(If "Assent will not be obtained from all children 6 years old and above, and only consent will be obtained from their legal representative.", "Only assent will be obtained. Consent will not be obtained from their legal representative' or "Neither the child's assent nor consent of their legal representative will be obtained." is selected in C4a, or "Assent will not be obtained from persons who have been established to lack mental capacity and only consent will be obtained from their legal representative." Is selected in C4b, qn C4d should appear.)*

C5: Please attach all copies of the Informed Consent Form(s)/Assent Form(s) used. (If applicable)

Attached documents here.

Note:

1. If Standing Database data is planned to be used in future Human Biomedical Research studies which are under the purview of the Human Biomedical Research Act (HBRA), the Standing Database Informed Consent Form must contain the Section 12 (1) Appropriate Consent elements of the HBRA.
2. For NUHS Standing Tissue Bank Consent Form, it must contain the Section 12(1) & (2) Appropriate Consent elements of HBRA.

PDPA Obligations

Consent and Notification

- Only collect, use or disclose individuals' personal data for purposes for which an individual has given his or her consent. Allow individuals to withdraw consent with reasonable notice and inform them of the likely consequences of withdrawal.
- Notify individuals of the purposes for the collection, use or disclosure of their personal data.

Access and Correction

- Upon request, provide individuals with their personal data and in which their personal data were collected, used or disclosed in the past year.
- Correct any error or omission in individuals' personal data upon their request.

SECTION D: CONSENT REQUIREMENTS – USE OF PERSONAL DATA WITHOUT CONSENT (For NUHS Standing Tissue Bank applications procced to Section I)

D1: Please provide justifications for each of the questions below to request for a Waiver of Informed Consent if the Standing Database team will be in contact with identifiers during data collection and/or if the Standing Database data contains identifiers. *(If "Wavier of Informed Consent" is selected in C1, Section D will appear.)*

D1a: The research purpose cannot reasonably be accomplished unless the personal data is provided in an individually identifiable form.

D1b: It is impracticable for the organisation to seek the consent of the individual for the use.

D1c: The personal data will not be used to contact persons to ask them to participate in the research.

D1d: Linkage of the personal data to other information is not harmful to the individuals identified by the personal data and the benefits to be derived from the linkage are clearly in the public interest.

SECTION E: SECURITY OF STANDING DATABASE/TISSUE BANK

E1: Is NHG Research Electronic Data Capture (REDCap) used for this Standing Database/Tissue Bank?

☐ Yes
☐ No

E1a: If no, please specify the reasons why and what alternative system is used for this Standing Database/Tissue Bank.

E1b: If applicable, please attach supporting document(s) to show that the alternative system is in compliance with Synapxe Security recommendations.

Attached documents here.

Note: With reference to the NHG Research Data Policy, the NHG REDCap is strongly recommended for capturing for all NHG research data. Custodians could explore alternatives if their data requirements cannot be fulfilled by NHG REDCap.

If alternatives to REDCap are used, custodians are to attach supporting documents to show that they are in compliance with Synapxe security recommendations.

You may contact your respective Chief Information Officer (CIO) offices for assistance as well as to verify if the alternative/s suggested are viable.

E2: Please indicate the security mechanisms established to prevent the unauthorised access, collection, use or disclosure of the stored data.

☐ Encryption or Password Protection
☐ Access Control to Limit Access to Only Authorized Persons
☐ Regular Backups of Stored Information
☐ Restricting Use of Devices to Corporate Issued Thumb Drives and Computers/Laptops
☐ Others

E2a: If others, please specify the security mechanisms. *(If "Others" is selected in E2, qn E2a will appear.)*

Note: Custodians should adopt or adapt from the existing Synapxe or IT security guidelines in the management of Standing Database/Tissue Bank.

PDPA Obligation – Protection

- Put in place reasonable security arrangements to protect personal data from unauthorised access, collection, use, disclosure, and similar risks.

SECTION F: TRANSFER OF RESEARCH DATA

F1: Please select the type of data that will be stored in the Standing Database/Tissue Bank.

Check all that are applicable:

- ☐ **Unclassified**
- ☐ **Restricted, Non-Sensitive**
- ☐ **Restricted, Sensitive-Normal**
- ☐ **Restricted, Sensitive-High**

Note: Please refer to the HealthTech Instruction Manual – Data Management (HIM-DM) (Point M6.2.3-R) for the table of data classification for common public healthcare sector data domains. For the release/sharing of the stored data, custodian must seek the necessary approval and comply with the prevailing instructional polices and regulations.

PDPA Obligation – Transfer

- Ensure that the standard of protection accorded to personal data is comparable to the PDPA when it is transferred overseas.

SECTION G: RETENTION AND DISPOSAL OF RESEARCH DATA

***G1: Please specify the number of years the research data would be retained. You may enter 'NA' if only anonymized data is stored.**

E.g. 6

Note: With reference to the NHG Research Data Policy, the recommended minimum retention period is 6 years.

G2: Stored data will be decommissioned/disposed in accordance with prevailing institutional data policies after the retention period.

☐ **Yes**
☐ **No**

G2a: If no, please state the reasons why. *(If "No" is selected in G2, qn G2a will appear.)*

Note: With reference to the NHG Research Data Policy -

- Institutions can opt to destroy research files in-house or outsource to external vendors. If outsourcing, the institution must maintain the evidence of destruction (e.g. certificate from vendor engaged to conduct destruction for hardcopies and list of data files deleted for softcopies).
- Personal data residing in documents should be disposed of properly and must not be used as recycled paper and personal data residing on devices (e.g. laptops/ medical equipment) must be deleted appropriately before the devices are disposed.

PDPA Obligation – Retention

- Cease retention or anonymise personal data when it is no longer necessary for any business or legal purposes.

SECTION H: MONITORING OF STANDING DATABASE/TISSUE BANK

***H1: Describe the measures that will be put in place to monitor and maintain the Standing Database/Tissue Bank to ensure the data collected is verified appropriately.**

Note: With reference to HealthTech Instruction Manual – Data Management (HIM-DM) (Point M5.4.1-R), entities should set up processes to collect and maintain quality data as is appropriate for different data types according to the following criteria: (a) Accurate; (b) Consistent; (c) Timely; (d) Relevant; and (e) Complete.

PDPA Obligation – Accountability

- Ensure organisation complies with the PDPA, including the implementation of personal data protection policies within the organisation.
- Make information about organisation's data protection policies, practices and complaints process is available on request.

SECTION J: ADDITIONAL DOCUMENT(S) (if applicable)

J1: Please attach any other relevant documents (if applicable).

Attached documents here.

DECLARATION OF CUSTODIAN

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 Instruction Manual, relevant institutional data management policies and IRB policies, and to the best of my ability, will ensure that there are no contraventions of these obligations in my custodianship.
- I will not initiate any changes in the Standing Database/ Tissue Bank without obtaining prior written approval from the Approving Officer and will maintain all relevant documents and recognize that the Approving Officer may inspect these documents.
- I will ensure the acquisition, storage, utilisation and disposal of any data in the Standing Database/ Tissue Bank shall protect the confidentiality of the information contained.
- I will ensure the database system I intend to use complies with Synapxe requirements, Institutional Research Data Policy and other relevant policies.
- I will ensure that any access to the data granted to individuals/third parties, including the transfer of data overseas, will be consistent with the institutional policies and local regulations.
- I will ensure that there are processes in place to ensure that the data collected is accurate and complete prior to any use to make a decision that affects the individual and/or prior to disclosure to outside parties.
- I have taken all reasonable steps and safeguards that are necessary to protect the data against breaches, accidental and unlawful loss, modification or destruction or unauthorized access, disclosure and copying use.
- I understand that failure to comply with the applicable regulations, institutional and research data policies may result in the suspension or termination of this Standing Database/ Tissue Bank.
- I declare that there are no existing or potential conflicts of interest for any of the team members involved in this Standing Database/ Tissue Bank. Any potential conflicts of interest have been declared in the relevant section of the application form.

^Applicable to NUHS users only.

☐ **I have read and agree to the above declaration.**

Part 3: Non-Compliance Report Form (For Reference Only)

The non-compliance report (NCR) form is used for reporting of non-compliance and lifting of suspension status.

STANDING DATABASE (SDB) NON-COMPLIANCE / DEVIATION FORM

Form Status	<to be auto populated from system> - ***(Draft, Noted, Pending IDA/ID's action, Pending Custodian's action, Withdrawn & Pending Database Secretariat's action)***
Form ID	<to be auto populated from system > (SDB ref –NCRXXX)
SDB Reference Number	<to be auto populated from application form >
SDB Title	<to be auto populated from application form >
Custodian	<to be auto populated from application form >
Institution	<to be auto populated from application form >
Department	<to be auto populated from application form >
Date of Submission	<to be auto populated from application form >

INSTRUCTION:

- For NHG users, this form is to be used for Standing Database only. Please refer to NHG Tissue Compliance Committee (TCC) requirements for tissue banks.
- For NUHS users, this form is to be used for Standing Database and Tissue Banks.
- This report form should be submitted once Custodian is aware of the non-compliance/ deviation according to the reviewing IRB's requirement and institution Research Data policies.
- Custodians are obliged to suspend their Standing Database/Tissue Bank immediately pending their report to the Institutional Deputy if deviations are substantial or are likely to result in greater harm or greater likelihood of harm to the subjects.

LIFTING OF SUSPENSION STATUS

A. Is this submission for the lifting of suspension status for your Standing Database?

○ **No**

○ **Yes**

Non-Compliance/ Deviation Report (NCR) Form

S/N	Question
1	**Which is/are the site(s) responsible for this non-compliance/ deviation?** Drop down list of the institutions (multi-selection)
2a	**Date of non-compliance/ deviation.** *Enter text here*
2b	**Date on which custodian was first made aware of the non-compliance/deviation.** *Enter text here*
3a	**In chronological order, describe in detail why or how the non-compliance/ deviation occurred (include date of occurrence).** *Enter text here*
3b	**The actions/ steps taken to rectify the non-compliance/ deviation.** *Enter text here*
3c	**The outcome of the non-compliance/ deviation (include date of outcome).** *Enter text here*
4	**In your judgement, did the non-compliance/ deviation affect the rights, safety, or welfare of the subject(s) and/or others?** *Enter text here*
5	**In your judgement, did the non-compliance/ deviation increase the actual/ potential risk to the subject(s) and/or others?** *Enter text here*
6a	**Describe in detail any follow-up action taken to prevent this non-compliance/ deviation from occurring in the future.** *Enter text here*
6b	**Target completion/ implementation date.** *Enter text here*

S/N	Question
7	**If this non-compliance/ deviation involved the access/ storage/ sharing of research data, has this been reported to the Institutional Data Exchange Office (DXO) or Office of Data Management (ODM) or equivalent?** ○ Yes. Please complete question 7a. ○ No. Please complete question 7b. ○ This non-compliance/ deviation did not involve the access/ storage/ sharing of research data.
7a	**Please provide the response(s) from the respective party(ies).** *Enter text here*
7b	**Please provide the rationale for not reporting.** *Enter text here*
8	**If this non-compliance/ deviation involved a breach of security of the research data, has this been reported to the Research Office/ ITD office or Group Information Security Office (GISO)?** ○ Yes. Please complete question 8a. ○ No. Please complete question 8b. ○ This non-compliance/ deviation did not involve a breach of security of the research data.
8a	**Please provide the response from the respective party(ies).** *Enter text here*
8b	**Please provide the rationale(s) for not reporting.** *Enter text here*
9	**If this non-compliance/ deviation involved a breach of security of personal data, has this been reported to your Institutional Data Protection Office (DPO)?** ○ Yes. Please complete question 9a. ○ No. Please complete question 9b. ○ This non-compliance/ deviation did not involve a breach of security of the personal data.

S/N	Question
9a	**Please provide the response(s) from the respective party(ies).** *Enter text here*
9b	**Please provide the rationale for not reporting.** *Enter text here*
10	**Do you have any other comments on the non-compliance/ deviation?** *Enter text here*
11	**Attach any document(s) that may be relevant to this non-compliance/ deviation.** *Attached documents here*

DECLARATION BY CUSTODIAN
□ **I confirm that the information submitted in the above non-compliance/ deviation report is true and accurate at the time of submission.**

Part 4: Status Report Form (For Reference Only)

The Status Report Form (SRF) is for the renewal or closure of the SDB.

STANDING DATABASE (SDB) STATUS REPORT FORM

Form Status	**<to be auto populated from system> - *(Draft, Noted, Pending IDA/ID's action, Pending Custodian's action, Withdrawn & Pending Database Secretariat's action)***
Form ID	<to be auto populated from system > (SDB ref –SRFXXX)
SDB Reference Number	<to be auto populated from system >
SDB Title	<to be auto populated from application form>
Custodian	<to be auto populated from application form >
Institution	< to be auto populated from application form >
Department	< to be auto populated from application form >
Date of Submission	< to be auto populated from application form >

INSTRUCTION:

1. **For NHG users, this form is to be used for Standing Database only. Please refer to NHG Tissue Compliance Committee (TCC) requirements for tissue banks.**
2. **For NUHS users, this form is to be used for Standing Database and Tissue Banks.**
3. **For renewals, please submit the Status Report Form at least 90 days before expiry.**

STATUS REPORT FORM (SRF)

S/N	Question
1	**I would like to submit this SRF for** ○ All sites ○ A specific site. Please select the affected site: Drop down list of the institutions (multi-Selection)
2	**The SRF submission is a request to** ○ Continue maintaining the approved Standing Database/ Tissue Bank ○ Close of the Standing Database/ Tissue Bank

S/N	Question
3	**Is there a change in the source data* for this Standing Database/ Tissue Bank from what was previously approved?** ○ No ○ Yes
3a	**If yes, please specify.** *Enter text here*
4	**Is there a change in the list of data variables?** ○ No ○ Yes
4a	**If yes, please specify and whether the change has been approved by the Institutional Data Exchange Office (DXO) / Office of Data Management (ODM) or equivalent.** *Enter text here*
5	**Please state the number of subjects or donors recruited for this Standing Database/ Tissue Bank. If no subject was recruited, please state "NA".** *Enter text here*
6	**Since the approval of the Standing Database/ Tissue Bank application or last Status Report Form:**
6a	**Was there any deviation or non-compliance to the approved Standing Database/ Tissue Bank plan?** ○ No ○ Yes
6ai	**If yes, please specify the details and Non-Compliance Report (NCR)/ deviation form reference number.** *Enter text here*
6b	**Has the data from the Standing Database/ Tissue Bank been shared with/ used by any party or research study?** ○ No ○ Yes

S/N	Question
6bi	If yes, please specify. *Enter text here*
6c	**Has there been any change(s) to how the data/ tissue is stored (e.g., change in method of storage, security measures to protect data)?** ○ No ○ Yes
6ci	If yes, please specify. *Enter text here*
6d	**Has there been any data breach? (e.g., loss of data, unauthorize access to the standing database)** ○ No ○ Yes
6di	**If yes, please specify.** *Enter text here*
6dii	**Was an NCR/ deviation form submitted for data breach?** ○ No ○ Yes
6diii	**If no, please explain why.** *Enter text here*
6div	**If yes, please provide the Standing Database NCR/deviation form reference number**. *Enter text here*
6e	**Is there any new risk associated with this Standing Database/ Tissue Bank?** ○ No ○ Yes
6ei	If yes, please specify. *Enter text here*

S/N	Question
7	**The following questions are only applicable and compulsory to NUHS Standing Tissue Bank application.**
7a	**Is there a change in the source, type, method and/or amount of tissue collected?** ○ NA ○ No ○ Yes
7ai	If yes, please specify. *Enter text here*
7b	**Has tissue from the tissue bank been shared/ used by any party or research study?** ○ NA ○ No ○ Yes
7bi	If yes, please specify. *Enter text here*
7c	**Was there any unauthorised collection, use, or distribution of the tissue from the tissue bank?** ○ NA ○ No ○ Yes
7ci	If yes, please specify. *Enter text here*

Attachment

Attach any document(s) that may be relevant to this submission.

Attached documents here

DECLARATION BY CUSTODIAN

□ I confirm that the information submitted in the above SDB status report form is true and accurate at the time of submission.

□ I confirm that all database members and myself have read through the latest Policy & Requirements.