NHG ROAM

Research Online Administration & Management

Online NHG Standing Database / Tissue Bank Application Guidebook
Version 1

NHG Research
Translating Research into Highest Quality Patient Care
www.research.nhg.com.sg

Standing Database / Tissue Bank FAQ

1. What standing databases / tissue banks are required to be registered with DSRB?

- Standing databases / tissue banks that are created primarily for clinical / service-related purposes (e.g. patient care, clinical quality assurance or improvement, hospital or institution operations) that **may** be used for research (in parts, or in future).
- Standing databases / tissue banks that are created primarily for the purposes of possible future research (e.g. database of names, contact information, diagnoses for the purposes of identifying potential research subjects, or tissue repositories).
- Standing databases / tissue banks that are created as part of a previous DSRB-approved research project that has since completed (e.g. data from which may be stored for possible future research).

Important: Databases / tissue banks that are created for a specific research project should be submitted using the Online DSRB Ethics Application Form.

2. Who is the 'Custodian' of a standing database / tissue bank?

The "custodian" of a standing database / tissue bank is appointed by the "owner" to be the overall person responsible for its set up and maintenance. For standing databases / tissue banks set up between across NHG institutions, the owners should agree upon the most suitable custodian. For standing databases / tissue banks set up with an external institution, institutions within NHG should appoint an NHG custodian for registration with DSRB.

3. Who is the 'Owner' of a standing database / tissue bank?

The respective institutions own standing databases / tissue banks set up by their staff members. The Head of Department (HOD) will be the owner of standing databases / tissue banks created within his/her department. Standing databases / tissue banks that straddle more than one institution will be owned by the Chairman Medical Board (CMB) or equivalents of all institutions concerned.

Online NHG Standing Database / Tissue Bank Application Form Guide

Section 1: Custodian Profile

1. Please select your Institution and Department that you will be collecting the data / tissue under. If the populated details are inaccurate, please update your ROAM profile before continuing with the application.

Section 2: Registration Details

1. **Type of Application:**
   - **Standing Database:** These contain electronic data stored and arranged for the purposes of patient care/services and/or as a potential resource for future research.
   - **Tissue Bank:** These contain tissue specimens stored for the purposes of patient care/services and/or as a potential resource for future research. Tissue specimens include all kinds of human biological materials derived from living or cadaveric donors, including solid body tissues, organs, fetuses, blood or any other body fluids and their derivatives, cord blood, embryos, gametes or any part or derivative thereof.

2. **Application will be submitted to which domain:** Please select the DSRB domain according to the specialty of your standing database / tissue bank. The Domains are as follows:

Domain A	Domain B	Domain C	Domain D	Domain E
• Opthalmology • Psychiatry • Neurology/ Neurosurgery • Genetics • Geriatric Medicine	• Oncology • Haematology • Paediatrics • Respiratory Medicine • Pathology	• Cardiovascular Science • Pharmacology • Emergency Medicine • Endocrinology • Diagnostic Imaging	• Obstetrics/ Gynaecology • Anaesthesia • Surgery • ENT • Dentistry • Sports and Rehab Medicine • Allied Health	• Infectious Disease • Gastroenterology • Renal Medicine • Rheumatology/ Immunology • Dermatology

Name of Standing Database / Tissue Bank: For registration purposes, please name the database / tissue bank.

3. **Type of database system**: Please indicate the database system used (e.g. Oracle, MS Access). This is applicable for standing databases only. Select 'Others' if not applicable.

4. **Links to other Standing Database / Tissue Banks**: If the standing database / tissue bank is linked other data systems / tissue banks (e.g. ODS, CDMS, Singapore Tissue Network etc.), please indicate the names of these data systems / tissue banks.

5. **DSRB Reference Number**: If the data / tissue have been collected within the ambit of a previously-approved DSRB study that has since ended, please indicate the DSRB reference number here.

6. **Date of Creation**: If the collection of data / tissue has been initiated before this registration, please indicate the date of initiation. For prospective collections, please indicate the estimated date of initiation.

7. **Date of Completion:** If the collection of data / tissue has been completed before registration, please indicate date of completion. For prospective collections, please indicate the estimated date of completion (if any).

8. **Owner(s) of Standing Database / Tissue Bank:** Please select and add all the Institution(s) and Department(s) that will be involved in the collection of data / tissue. The endorsers should be automatically populated with your selection. If this information is missing, please save your application and contact DSRB (Email: researchonline@nhg.com.sg; Tel: 6496 6979).

9. **Purpose(s) of Standing Database / Tissue Bank:**

   A database / tissue bank may be set up to fulfil multiple purposes. Please select all the broad categories that apply. (e.g. if hospital appointment records are used routinely to identify volunteers for research, please check "Hospital / Institution Operations" **AND** "Possible Future Research")

   Patient Care – Data / tissue specimens collected to ensure proper delivery of patient care (e.g. for therapeutic purposes, clinical/pathological diagnosis, as part of medical records etc.)
   Clinical Quality Assurance or Improvement – Data / tissue specimens collected to support activities carried out to monitor, evaluate or to improve quality and appropriateness of medical services, practices and procedures in the hospital/institution.
   Hospital or Institution Operations – Data collected to support activities carried out to ensure the normal running of business of the hospital / institutions (e.g. billing records, appointment records etc.)
   Possible Future Research - Data / tissue specimens collected for future general research, without any specific restrictions on its future research uses***. If the standing database / tissue bank is created for a specific research project, please submit the application via the Online DSRB Ethics Application Form instead.***
   Please describe the standing database / tissue bank in more detail, according to the options selected above and any other additional pertinent information.

10. **Design & Maintenance of Data / Tissue Bank:** Describe the design, procedures for setting-up, storage and utilization. The following key information should be provided:

    i. **Type(s) of data / tissue specimens collected** *(e.g. patient name/diagnosis, type of cancer tissue etc.).* It is recommended that a data collection form is created and attached to the registration form. Please attach the data collection form in the Attachments tab.
    i. **Origin and method of collection of data / tissue specimens** *(e.g. medical records, leftover samples post-surgery, direct from patient / other clinicians etc.)*
    ii. **Storage location of the database / tissue bank** *(e.g. PC, Laptop, Laboratories etc.)*
    iii. **The person(s) responsible for controlling access to the database / tissue bank** (e.g. custodian, research assistant etc.) Please note that the specific names should be maintained by the custodian.

iv. **The person(s) who would be granted access to the data / tissue for research purposes** *(e.g. custodian, other NHG researchers, study coordinators etc.)* The specific names should be maintained by the custodian.

v. **Describe the process to ensure that individual research projects utilizing the database / tissue bank will not be conducted without prior DSRB review** (*e.g. the requirement for requestor to provide DSRB approval letter before data/tissue can be released etc.)*

11. **Informed Consent:**

Informed Consent is implied – For databases / tissue banks that are created primarily for **patient care, clinical quality assurance or improvement, hospital or institution operations**, informed consent is considered implied.

Informed Consent will be taken – For databases / tissue banks that are intended for use in **possible future research** (regardless of whether the primary function is for research or not) informed consent from patients is required. Please attach the Informed Consent Form for review.

Informed Consent will not be taken – For databases / tissue banks that are intended for use in **possible future research** (regardless of whether the primary function is for research or not) informed consent from patients is required. However, in certain circumstances, informed consent may be waived. The custodian should be able to justify the following four criteria, which are similar to the NHG DSRB's requirements for waiver of informed consent for research.

i. **The data / tissue collected involve no more than minimal risk to patients / subjects.** (*E.g. The data or tissue specimens collected are not sensitive in nature, and the data / tissue specimens are derived from clinically indicated procedures or from the normal running of business operations etc.)*

ii. **The waiver or alteration will not adversely affect the rights and welfare of the subjects.** *(E.g. The data / tissue specimens have already been collected as part of patients' clinically indicated procedures or as part of the normal running of business operations, regardless of research. None of the data / tissue specimens collected would affect clinical decisions about the individual's care. Patients are not being deprived of clinical care to which they would normally be entitled to.)*

iii. **The data / tissue specimen collection could not practicably be carried out without waiver of informed consent.** *(E.g. Identifying and contacting thousands of patients / subjects, although not impossible, would not be feasible for a collection of data / tissue specimens that would not change the care they would already have received.)*

iv. **Whenever appropriate, patients / subjects will be provided with additional pertinent info after participation.** *(E.g. It would not be appropriate to provide these subjects with additional pertinent information as the collection of information / tissue specimens for possible future research, would have no effect on the patients / subjects.)*

Please indicate these justifications in the **Waiver of Consent** section on the next page.

Verbal Informed Consent will be taken – In certain circumstances, the requirement to obtain written informed consent may be waived and verbal consent is taken. This is only acceptable provided that:

- The data / tissue collection presents no more than minimal risk of harm to subjects, AND
- The data / tissue collection involves no procedures for which written consent is normally required outside of the clinical setting.

Please justify this under the section - **Design & Maintenance of Data / Tissue Bank.**

Others – Please specify.

12. **Confidentiality of stored data / tissue***:*

i. Describe the security measures used to maintain confidentiality of the stored data / tissue *(e.g. password protected, coding methods etc.).*

ii. Please indicate whether the data / tissue specimens will be:
Identifiable - i.e. contains information that allows identification of an individual
Reversibly De-identified - i.e. contains information in which personal identity information has been removed, and a code substituted, so that the identity of the person could be restored under strict conditions
Irreversibly De-identified - i.e. identifying information has been permanently stripped off and therefore identification of an individual is not possible

Section 3: Assurance by Appointed Custodian

This is the Custodian's declaration:

As the appointed custodian stated in Section 1, I hereby declare that the data / tissue bank complies fully with the NHG Good Practice Guidelines for Standing Databases and Tissue Banks for Research (hereafter referred to as Guidelines). I assure the owner(s) of the data / tissue that the:

- Acquisition, storage, utilisation and disposal of any data / tissue specimens in the data / tissue banks shall protect the confidentiality of the information contained.
- Ensure that any access to the data / tissue granted to a third party will be consistent with the Guidelines
- Check for any new update to the Guidelines and henceforth comply fully with the updated version.
- Update in writing to the Registry in NHG within one calendar month of any changes to the details of the data / tissue bank or this assurance.
- Write in advance to the owner(s) of the data / tissue bank should I leave my current employment so that a suitable alternative can be appointed as custodian.

I make this statement of assurance in full knowledge that any deviation from the Guidelines or this statement shall render this assurance null and void, in which event the data / tissue bank shall be deregistered accordingly.

By checking the 'I Agree' box, you confirm that you have read, understood and accepted the Custodian's declaration.