NHG GOOD PRACTICE GUIDELINES FOR STANDING DATABASES AND TISSUE BANKS FOR RESEARCH

Definitions

1. "Standing databases" contain electronic data stored for the purposes of patient care/ services and/or as a potential resource for future research. For the purposes of these guidelines, any collected and arranged private information stored electronically will be considered a database.

2. "Tissue Banks" 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, foetuses, blood and other body fluids and their derivatives, cord blood, embryos, gametes (sperm or eggs) or any part or derivative thereof.

Registration of Standing Databases / Tissue Banks

3. As part of patient care, clinical quality assurance or improvement, hospital or institution operations, many databases are created. Similarly, tissue samples are collected and stored in hospital pathological departments. Though such databases and tissue collections are created and maintained primarily for clinical / service-related purposes, they serve as a valuable resource for future research projects. Where there is a possibility for such clinical / service-related databases / tissue banks to be used for research (in parts, or in future), such databases / tissue bank should be registered.

4. Databases and 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 should be registered.

5. Databases and tissue banks that are created as part of a previous DSRB-approved research project that has since completed, may be stored for possible future research. Such databases / tissue banks should be registered upon completion of the DSRB project.

6. If the data / tissue specimens are collected for a **specific** research project, approval from the NHG Domain Specific Review Board (DSRB) is required.

7. Prior permission must be sought from the relevant institutional authorities before the setting up of the database / tissue bank. These databases / tissue banks should then be registered with NHG RDO.

Owner and Custodian of Standing Database / Tissue Banks

8. The respective institutions shall own the databases / tissue banks set up by their staff members ("Owner"). The owners of the database / tissue banks shall appoint a suitable staff member as the overall responsible for the set up and maintenance (including security and access) of the database / tissue bank ("Custodian"). For large IT systems the "Custodian" shall be synonymous with the appointed "System Owner". Where there is shared ownership of a database / tissue banks amongst various NHG institutions, the owners should agree upon the most suitable custodian. Should a database / tissue bank be set up with an external institution, institutions within NHG should appoint an NHG custodian to protect NHG's interest in the joint database.

9. The custodian does not possess any ownership of database / tissue banks. Should the custodian later leave the employment of the institution, another employee should be appointed as the new custodian by the institution. The custodian should inform the owner(s) when the database that has ceased to be useful and therefore "shut down".

10. These guidelines apply to the owner(s), the appointed custodian and any staff who have been granted access to a standing database / tissue bank.

Setting up of Standing Database / Tissue Bank

11. The procedure for setting up the database / tissue bank and subsequent acquisition of data / tissue specimens should be written and adhered to. This written procedure should include:

    a. A description of the types, origin, method of collection, and storage location of the data / tissue specimens.
    b. A list of names and designation of personnel given access to the database / tissue bank. This "access list" should be updated regularly. Access to the database / tissue bank should be restricted to authorised personnel only and should be supervised closely by the appointed custodian and kept to a justifiable minimum.
    c. A description of the process to ensure that individual research projects utilizing the database / tissue banks will not be conducted without prior DSRB review.
    d. Security measures used to maintain confidentiality of data.

12. Informed Consent

12.1. **Informed Consent is Implied** – For databases / tissue banks that are created primarily for patient care, clinical quality assurance or improvement, hospital or institution operations (as described in Para 3), informed consent is considered implied.

12.2. Should additional information not directly relevant to patient care or service be collected, informed consent is required, unless the process or any part thereof has been waived by the DSRB (See Para 9.5 and 9.6).

12.3. Such implied consent does not remove or diminish the obligation of all staff that have access to the standing database / tissue bank to use it in a responsible and appropriate manner.

12.4. **Informed Consent is Required** - 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. Custodians are strongly advised to use the NHG Standard Informed Consent Form for Tissue / Data Banking to ensure that all required elements of an informed consent are present.

12.5. **Informed Consent is Waived** – In certain circumstances the requirement to obtain 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 **(Annex E: Waiver of Consent**).

    a. The data / tissue collected involve no more than minimal risk to patients / subjects. *(E.g. The information or tissue specimens collected are not sensitive in nature, and*

the data / tissue specimens are derived from clinically indicated procedures or derived from the normal running of business operations).

b. The waiver or alteration will not adversely affect the rights and welfare of the subjects. *(E.g. The information / 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 information / tissue specimens collected would affect the clinical decisions about the individual's care. Patients' are not being deprived of clinical care to which they would normally be entitled to)*

c. 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 information / tissue specimens that would not change the care they would already have received)*

d. 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)*

12.6. The justifications for waiver of informed consent **(Annex E: Waiver of Consent**) should be submitted to the NHG RDO in the application for registration of the standing database / tissue bank.

12.7. **Informed Consent Requirements are Altered -** In certain circumstances the requirement to obtain a signed consent form (e.g. verbal consent and documentation of verbal consent in medical records) may be waived provided that:

a. The research presents no more than minimal risk of harm to subjects, and
b. The research involves no procedures for which written consent is normally required outside of the research context

13. **Confidentiality**

14. Harms that may occur as a result of such data and tissue banking activities are mostly related to threats to privacy and breaches in confidentiality. There should be adequate policies and procedures in place to ensure adequate protections for privacy and maintenance of confidentiality. Such procedures should be regularly reinforced by the appointed custodian to all staff who have been granted access to the standing database / tissue banks. Owners and appointed custodians of standing databases / tissue banks may undertake regular internal audits to monitor compliance with these guidelines and to ensure that there are adequate protections for privacy and maintenance of confidentiality.

14.1. The confidentiality of the private information contained in the databases / tissue banks is primarily the responsibility of their respective custodians. Custodians need to put in place data security features to prevent and to monitor regularly for unauthorised access to the database / tissue banks. Such precautions could range from structural or IT-based solutions features (e.g. firewalls, password protection) to organisational and administrative measures (e.g. regular audits).

14.2. Databases should be stored in secured computers / storage media. These computers / storage media must be password-protected, and stored under lock & key (e.g. in a locked cupboard / office). There should be scheduled changes (at least every 6 months) to the password.

14.3. Standing databases / tissue banks that are for the purposes of patient care or service, often contains identifiers. The custodian should demonstrate that when utilizing such stored data / tissue specimens, the patient's rights for confidentiality had been maintained.

14.4. For Standing databases / tissue banks that are are for the purposes of possible future research, patient identifying information should be stored separately in a different location with links maintained in the main database / tissue specimens. The custodian should oversee and control access to the identifying links on a strictly need-to-know basis, to maintain the confidentiality of the data.

14.5. Owners and Custodians are responsible for taking active steps to ensure that all staff who are given access to the database / tissue bank as part of their work, maintain the confidentiality at all times.

Utilisation of Stored Data / Tissue Specimens

15. Each subsequent research project (including research projects initiated by the custodian and all staff listed in the "access list") utilising any standing database / tissue specimens, will require prior approval from NHG DSRB before project initiation. The concurrence of the custodian should also be obtained.

16. Depending on the nature of the study, the DSRB will determine if access to the standing database / tissue bank may require additional consent. Some considerations by the DSRB will include whether any patient contact is proposed, the practicability of getting informed consent for the research, and whether the data extracted and used for the research will be de-identified or aggregated etc.

17. In general, recipients of the data / tissue specimens should not be provided with identifiable information or to information through which identities of patients or subjects may be readily ascertained.

Disposal of Stored Data / Tissue Specimens

18. When the database / tissue bank is no longer required and the institution so agrees, all data / tissue specimens and identifying links must be destroyed immediately. Should the owner deem it necessary to archive a database for future reference, the owner should continue to comply with the guidelines on storage of data. The owner shall be responsible for the safekeeping of archived databases.