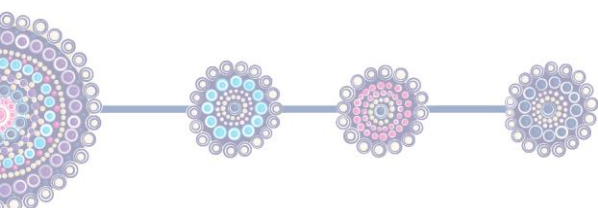


Biobanking Principles of Support

NSW Health Pathology's Support of Biobanks
external to the NSW Health Statewide Biobank



This document sets out the key principles applying to decisions by NSW Health Pathology to support Biobanks operating outside the NSW Health Statewide Biobank.

Background

The NSW Health Statewide Biobank (NSWHSB) is a NSW Government asset established by the Ministry of Health in 2017 to support world-class health and medical biospecimen research in NSW by providing a range of services and infrastructure including sample collection, storage, processing, data-linkage and access. It is a public resource that aims to support a high-quality model where biospecimens are co-located in a central biorepository to facilitate researcher access to biospecimens to undertake research that is in the public interest (Open-access Biobank).

The NSWHSB was built in partnership with NSW Health Pathology (NSWHP), Sydney Local Health District, Health Infrastructure, the Research Community and existing Biobanks. The Ministry of Health has selected NSWHP to manage the NSWHSB. **NSWHP will prioritise support for biobanks that utilise the services of the NSWHSB. Requests for support of other biobanks will be considered by NSWHP in accordance with the principles set out in this document.** Note: The NSWHSB is funded by the Ministry of Health and receives no Financial Support from NSWHP.

PRINCIPLES FOR DETERMINING NSWHP SUPPORT TO BIOBANKING ACTIVITIES

The following principles have been developed to provide clarity to NSWHP operational staff and researchers regarding the circumstances in which NSWHP will and will not provide support to the retrieval, processing and/or release of NSWHP Material and associated Data for new or existing biobanking activities locally, nationally, or internationally.

1. **NSWHP has an over-riding obligation to ensure that Material and associated Data provided by NSWHP for Biobanking is maximised for**

research use and made available to all researchers (Open-access Biobank).

2. **NSWHP will only support the Biobanking of NSWHP Material and associated Data if there is informed written consent from the participant from whom it was derived. The consent must clearly state that the participant is consenting to the use of the Material and associated Data for biobanking for future unspecified research. Adherence to the NSW Health Consent Principles and Consent Toolkit is encouraged.**
3. **NSWHP will only consider supplying NSWHP Material and associated Data to Biobanks In-kind if:**
 - a. the Biobank is located within Australia, operating under Australian legislation;
 - b. the Material and associated Data will not be used for commercial purposes;
 - c. NSWHP is represented on the Biobank's governance/access committee;
 - d. the supply of Material and associated Data will not compromise NSWHP's quality control, quality assurance or medicolegal requirements or compliance with its obligations under NATA accreditation relating to specimen retention;
 - e. the supply complies with the requirement of NSWHPs Research Governance Framework, Human Research Ethics Committee (HREC) approval and other applicable NSW Health or NSWHP policy documents, as well as applicable laws.
4. **For the supply of NSWHP Material and associated Data to a Biobank operating within Australia where the Material and associated Data may be used for commercial purposes, all services surrounding the supply must be paid for in full, under NSWHP's fee for service model.**
5. **NSWHP does generally not support the supply of Material and associated Data In-kind for Biobanks operating outside Australia.**

6. NSWHP takes a cautious and risk averse approach to the supply of Material and Data to overseas Biobanks. NSWHP will only supply Material and associated Data to an overseas Biobank if:

- a. the patient has expressly consented (as part of the informed consent process) to have the Material and Data transferred to the overseas Biobank (noting the patient's consent must include details of the location where Material and Data will be transferred) and the types of research that the overseas Biobank will support;
- b. It is under a fee for service model where all services surrounding the supply must be paid for in full (and not at the expense of the public) or can be provided in-kind if NSWHP is an active Research Partner in the Biobank; and
- c. The overseas Biobank operates within a jurisdiction that has equivalent protections in relation to the use of biospecimens and personal information.

MANAGING EXISTING BIOBANK RELATIONSHIPS

NSWHP has historical arrangements in place supporting Biobanks that were established prior to the formation of the NSWHSB and NSWHP Research Governance.

7. NSWHP will cease providing any direct financial support (incl. use of funds from the No 2 Accounts/Private Practice Trust Funds) to biobanks operating outside the NSWHSB by June 2023.
8. Any future Financial Support from NSWHP to Biobanks can only be supported if the Biobank is setup and maintained within NSWHSB.
9. NSWHP may honour existing arrangements involving in-kind support of Biobanks but will not increase the level of in-kind support it provides, unless the Biobank meets principles 1 to 4.

10. In all cases, NSWHP will consider waiving NSWHP fees associated with retrieval, data entry/handling and transport of Materials and associated Data, if a Biobank elects to use the NSWHSB for its research services.

DEFINITIONS

Biobank is a type of biorepository that stores biological samples for use in research and usually refers to a large collection of biological Material (biospecimens) linked to relevant personal and health information.

Biobanking activities refers to the process by which samples of bodily fluid or tissue are collected for research use to improve our understanding of health and disease.

Data means the Data (patient or other Data) or information provided by NSWHP to the Recipient relating to Material and supplied for the purposes of the Biobank.

Financial Support means money provided to support a Biobank.

In-kind means contribution of Material or Data (including the provision of services in connection with the supply of Material or Data) to a Biobank at nil cost.

Material means the human biological specimens being transferred by NSWHP to the Recipient for the purpose of Biobanking.

Open-access Biobank means a Biobank that makes available Material and Data to the Research Community on an open-access basis for future, ethically approved research.

Recipient means the sponsor of the Biobank receiving NSWHP support.

Research Community means people involved in the conduct of research.