NSW Health Statewide Biobank Collection Strategy (2018–2022)

NSW GOVERNMENT

Health
Statewide Biobank

NSW Ministry of Health
73 Miller Street
NORTH SYDNEY NSW 2060
Tel. (02) 9391 9000
Fax. (02) 9391 9101
TTY. (02) 9391 9900
www.health.nsw.gov.au

Produced by: NSW Ministry of Health

SHPN (OHMR) 180571
ISBN 978-1-76000-933-5

Further copies of this document can be downloaded from
www.biobank.health.nsw.gov.au

August 2018

Contents

1. Introduction

This Collection Strategy (Strategy) has been developed to provide an overview of collections that will be supported and banked by the NSW Health Statewide Biobank (NSWHSB) in its first four years of operation (2018 to 2022). It establishes NSWHSB collection priorities and requirements to ensure that this world-class facility supports high value research. It covers the process for banking biospecimens and managing data for different collection categories including collection, processing and storage elements (see Appendix 1).

The NSWHSB will prioritise biospecimen collections that support research with statewide, national and international impact. The biospecimen collections banked at the facility will help researchers:

- better understand the health of the NSW population and contribute to cohorts that will promote better understanding of the health of Australian and global populations
- explore the underlying genetics of disease and identify new biomarkers to detect and treat diseases
- study biological mechanisms in human samples that relate to disease.

Funding for some collections is available via the Office for Health and Medical Research. Further information can be found in the *Biospecimen Collection Grants*.

NSW Health Statewide Biobank

The NSWHSB is a statewide resource with the capacity to undertake biospecimen collection activities across NSW. It supports the collection, processing and storage of high quality biospecimens and data linkage to other health information, including NSW Health data sets, via the Centre for Health Record Linkage (CHeReL). This flagship NSW Health facility has been built in partnership with NSW Health Pathology, Sydney Local Health District, Health Infrastructure, the research community and existing biobanks.

2. Eligibility Criteria for the NSWHSB

All collections seeking to access biobanking services at the NSWHSB will be required to complete the NSWHSB Collection Form, regardless of the proposed Collection Category.

Eligibility criteria

Collections seeking to be part of the NSWHSB should satisfy the following criteria:

- ***Human Research Ethics Committee (HREC) approval:*** The collection must be approved by a HREC which is accredited by the National Health and Medical Research Council, or will receive approval prior to the commencement of biospecimen and data collection.
- ***Verified ownership and governance arrangements:*** This includes having a verified custodian and an approved Site Specific Assessment (if on a NSW Health site), prior to the commencement of biospecimen and data collection.
- ***Compliance with relevant legislation***
- ***Compliance with the NSWHSB Consent Toolkit:*** Prospective collections should comply with the NSWHSB Consent Toolkit and demonstrate compliance using the NSWHSB Consent Toolkit – Compliance Checklist. For existing collections, previously approved Participant Information Sheets and Consent Forms will be permitted, however collections are encouraged to follow the principles in the toolkit.

3. Collection Categories

A collection in this Strategy is defined as a human biospecimen collection with associated participant data. This participant data is assembled from various data sources such as a patient's local medical records, participant surveys and other data sources (through the data linkage services of the CHeReL).

There are three Collection Categories applicable to biospecimen collections banked at the NSWHSB:

a. **Office for Health and Medical Research (OHMR) Supported Strategic Collections**: These collections will be supported by the OHMR through the *Biospecimen Collection Grants*. They can be:
   - existing collections that might require further biospecimen collection; or
   - prospective collections that have no biospecimens collected or stored and are looking to start collection.

b. **Fee for Service Collections and Commercial Services**: collections that are self-funded, administered by the applicants and/or closed collections

c. **Archival/Legacy Collections**: biospecimen collection has been completed.

Over its lifetime, the category of a specific collection may shift, depending upon funding decisions by the OHMR.

A tabulated summary of the key elements for each Collection Category can be found in *Appendix 2*.

4. OHMR Supported Collections

These are collections of statewide importance that have been previously established (existing) or are new (prospective).

These collections will be supported by the OHMR via the *Biospecimen Collection Grants*. These grants will cover NSWHSB services for biospecimen receipt, processing, and storage. Data linkage through the CHeReL, a dedicated data linkage centre within NSW Health will be funded separately by OHMR.

These collections will need to satisfy the NSWHSB eligibility criteria (see Section 2 above) as well as the following eligibility criteria.

Eligibility Criteria:

- Research team based in NSW
- Collection stored at and distributed from the NSWHSB, and
- Open access.

For more details please see the *Biospecimen Collection Grants*.

5. Fee-For-Service Collections, Commercial Services and Archival/Legacy Collections

These are collections that are self-funded and administered by the applicants.

Fee-For-Service Collections and Commercial Services will bank their biospecimens and/or data in the NSWHSB for a fee. This model allows for NSWHSB to accept and facilitate the private collection of samples for both commercial and scientific purposes. The NSWHSB aims to support clinical trials, clinical specimen storage, contingency back-up and sample support services.

Costs will be tailored for each collection's requirements, following discussions with NSWHSB. These collections will pay the NSWHSB for services including collection, processing, storage and/or selection for shipping of biospecimens. Researchers will pay CHeReL through NSWHSB for any costs associated with data linkage that they request.

Requests for funding under this collection category might arise from the following scenarios:

- Investigators who have directly sought to utilise the NSWHSB services in exchange for a fee
- Investigators who are unsuccessful in securing funding from OHMR via the *Biospecimen Collections Grant*, or
- Commercial entities, including pharmaceutical companies, subject to the Collection Review Process (see *Appendix 3)* and at the discretion of the NSWHSB.

6. Governance Arrangements for NSWHSB Collections

Governance

Each collection banked within the NSWHSB is to be held under an agreed governance arrangement.

Supported Strategic Collections will be governed by NSW Health Pathology. All other collections will be governed by external entities. These arrangements will remain in place and will only be altered with the agreement of the relevant Human Research Ethics Committee (HREC), and collaborating partners such as local health districts and medical research institutes.

Custodianship

A custodian of the biospecimen collection is the primary entity (not-for-profit organisation, university, government organisation, company) that is responsible for the collection. The custodian will be responsible for:

- signing agreements
- holding HREC approval
- determining access to the samples via their Access Committee (for open access collections)
- determining any cost recovery for the biospecimens/data within the collection
- funding ongoing costs for the collection.

A framework for best practice custodianship is currently being developed by the NSWHSB.

All Collections will appoint an external custodian. For existing collections that transition to OHMR Supported Strategic Collections, custodianship can be transferred from an external custodian to NSWHSB, with joint custodianship as a middle step.

The NSWHSB will connect researchers to the relevant custodian as needed.

Access Committee

The custodian of all open access collections should be supported by an Access Committee/s. This committee will be managed either by the NSWHSB (with core representation and invited expertise), or externally.

NSWHSB will maintain the right of representation on any external Access Committees, with appropriate management of any declared conflicts of interest. The custodian will report annually to the NSWHSB Scientific Advisory Group (SAG) (see *Appendix 4 – Governance Framework*).

Collection Logistics

Biospecimen and data collection for OHMR Supported Strategic Collections will occur through NSW Health Pathology's statewide services and facilities, as well as partnerships with local health districts, medical research institutes and universities. These organisations will support both the patient consent activities and the collection of clinical and participant information for each patient (see more on this below under: Data Management, Linkage and Storage). For the Fee-For-Service Collection category, biospecimen and data collection can occur privately or as per OHMR Supported Strategic Collections.

Data Management, Linkage and Storage

There are five types of data that can be associated with the collection and subsequently requested by researchers:

- ***Biospecimen Related Data*** – Data directly associated with the biospecimen including meta-data (e.g. biospecimen storage information) and participant data (name, address, date of birth, etc)
- ***Clinical Data*** – Health information that is collected from each patient's medical record (e.g. drugs prescribed)
- ***Self-Reported Data (participant information)*** – Health information collected from each patient via participant and clinician surveys
- ***Administrative Health Data (e.g. routinely collected data)*** – Data that is collected routinely in administrative datasets by the health system (e.g. hospitalisation data) or through other government departments (e.g. Births, Deaths and Marriages)
- ***Commonwealth Data*** – Medical Benefits Scheme or Pharmaceutical Benefits Scheme data collected by the Commonwealth Department of Health. This data cannot currently be accessed by the researcher.

Each data category has different processes for collection, management, storage and custodianship. These are summarised in *Appendix 5*.

Data linkage services via the CHeReL can be requested via the NSWHSB. Details on funding for data management and data linkage for Supported Strategic Collections can be found in the *Biospecimen Collection Grants*.

Data provided to researchers via the CHeReL will be without identifying details but will be linkable to the biospecimen and other associated data.

Research

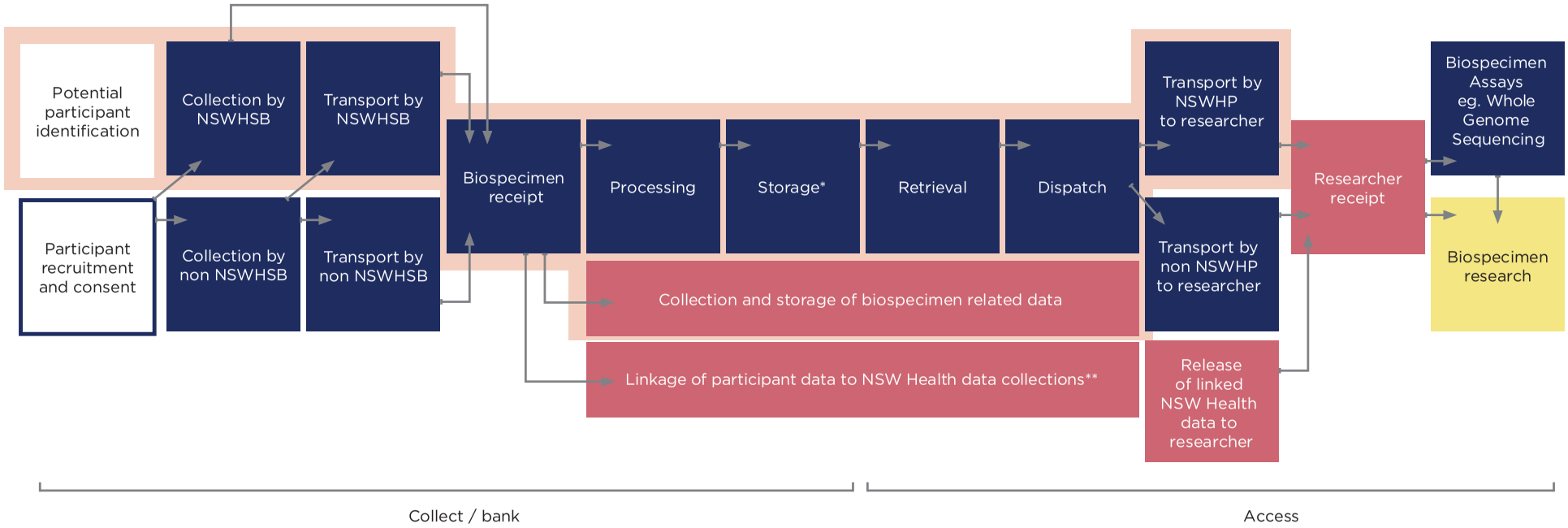
Access to the biospecimens and data by researchers will be facilitated by clinical and research partners and an on-line specimen locator website (currently in development). Opportunities to leverage the collection for external grant applications (e.g. NHMRC, philanthropic grants) are encouraged.

7. Review

This strategy will be reviewed by NSW Health and the NSWHSB SAG periodically. Public input may be sought with feedback to be considered by NSW Health.

APPENDIX 1

Process for collecting, banking and accessing biospecimens and associated data



Biospecimen

Data

Funded through the *Biospecimen Collection Grant* for the period of the grant only

* For successful applications to the grant, storage of the specimen collection beyond the period of the grant will be supported by NSW Health Pathology.
** For successful applications to the grant, linkage of the biospecimen collection to NSW Health data is funded by the Office of Health and Medical Research (outside the grant), for the period of the grant.

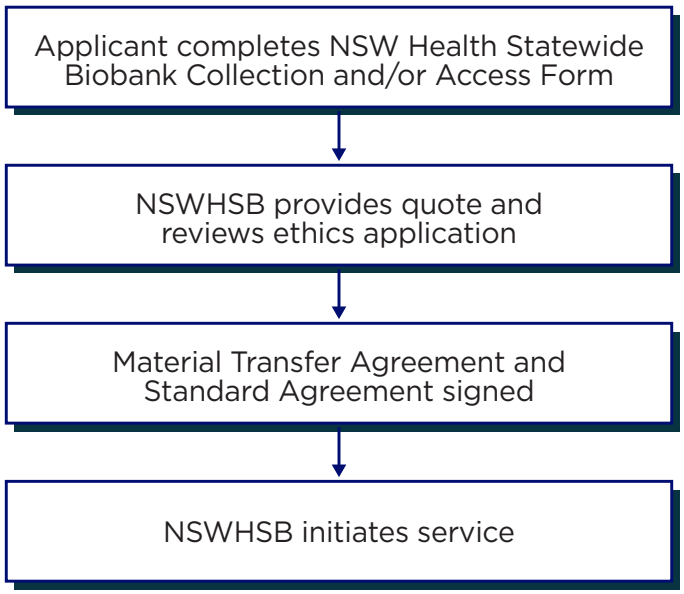
APPENDIX 2

Summary of collection models for NSWHSB

	a) OHMR Supported Strategic Collections	b) Fee-For-Service Collections, Commercial Services and Archival/Legacy Collections
Requirement to meet NSWHSB Eligibility Criteria	Yes	Yes
Requirement to meet OHMR *Biospecimen Collection Grant* Eligibility Criteria	Yes	No
Funding available from OHMR	Yes. Support will be at the discretion of the NSWHSB and the OHMR (for details see *Biospecimen Collection Grant*).	No. Any collection, processing and storage of biospecimens will be charged.
Custodian of the biospecimen collection	Primary supporting institution of the collection.	Primary supporting institution of the collection.
Data management	*Biospecimen Related Data* will be stored at the NSWHSB. *Clinical and participant information* will be stored at an agreed partner organisation such as an LHD. CHeReL will assess applications to store *Clinical and participant information* on a case by case basis. *Routinely collected data* used for data linkage will be stored or accessed by the CHeReL.	Custodians will manage their own biospecimen related data. *Clinical and participant information* will be stored at an agreed partner organisation such as an LHD. CHeReL will assess applications to store *Clinical and participant information* on a case by case basis. *Routinely collected data* used for data linkage will be stored or accessed by the CHeReL.
Researcher access to biospecimens/ data	Collection must be open access to NSW researchers at a minimum.	Researcher access to biospecimens/data will be dependent upon the custodian's governance structure.
Reporting framework	Reporting will be to the custodian, with annual reporting of Access Committee activities to the NSWHSB SAG.	There is no requirement for an Access Committee, however there may be an Access Committee if the collection is open access. In this case, the Access Committee will report to the Custodian, with annual reporting to the NSWHSB SAG. The custodian will need to contact NSWHSB to gain access to biospecimens and data.
Services agreement required	Yes	Yes
Model best suited for:	> Existing and prospective collections that align with NSW Health strategic priorities and/or contribute to NSW leading research. > Collections that would benefit from enabling researcher access to linked NSW Health datasets. > Researchers that have partnered with LHD clinicians where the NSWHSB is best placed to have custodianship of the collection.	> Commercial or not-for-profit custodians seeking to store their biospecimens in a secure and high quality environment. > Custodians that don't have access to biospecimen processing and/or storage facilities at their institution.

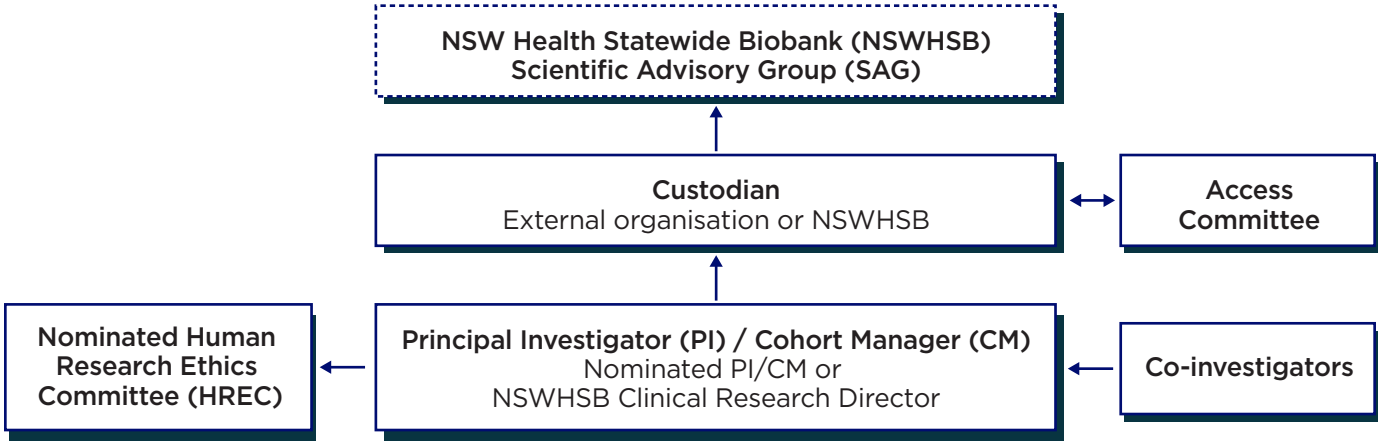
APPENDIX 3

Review Process for Fee-For-Service Collections, Commercial Services and Archival/Legacy Collections



APPENDIX 4

Governance Framework



APPENDIX 5

Data Management Components for OHMR Supported Strategic Collections

Data management component	Biospecimen Related Data	Clinical and Self- Reported Data	Administrative Health Data (routinely collected data)	Commonwealth Data
Description	Data directly associated with the biospecimen and includes: biospecimen meta-data (eg. biospecimen storage information) and participant data (name, address, date of birth, etc).	Medical records and health information collected from each patient via participant and clinician surveys.	Data that is collected routinely in administrative datasets by the health system (e.g. hospitalisation data) or through other government departments (e.g. Births, Deaths and Marriages) and can be linked to data about the cohort through the Centre for Health Record Linkage (CHeReL).	PBS/MBS data.
Data storage details	NSWHSB Laboratory Information Management System (LIMS)	Data will need to be stored at an agreed partner organisation such as an LHD. NSWHSB will not store this data. CHeReL will assess applications on a case by case basis.	Data about the cohort can be stored by the CHeReL for the purpose of data linkage.	Not yet available.
Staffing arrangements	NSWHSB staff	Cohort Managers/s (funded by external grants).	CHeReL staff.	Not yet available.
Source/s of data	Technical reporting by Collection staff and NSWHSB.	> Participant surveys > Clinician surveys > Patient medical records	Can include datasets that are routinely linked in the Master Linkage Key (MLK) http://www.cherel.org.au/master-linkage-key or any other datasets, subject to feasibility assessment and relevant approvals.	Not yet available.
Data field examples	> Participant information: (name, address, DOB, etc) > Biospecimen technical information: date and time of collection, number of aliquots and derivatives, volume of aliquots, unique identifier, storage conditions, type of biospecimens.	> Diagnosis > Treatment details > Pathology reports > Relevant family history > Co-morbidities > Lifestyle choices	Varies depending on dataset (For examples see: www.cherel.org.au/data-dictionaries)	Not yet available.

Data management component	Biospecimen Related Data	Clinical and Self- Reported Data	Administrative Health Data (routinely collected data)	Commonwealth Data
Data Custodian	Collection's nominated institution.	Collection's nominated institution.	Each dataset has a data custodian nominated by the collection's institution.	Not yet available.
OHMR funding covers:	Data collection, management and custodianship (in concert with the biospecimen collection, also covered by this funding). Storage (paid directly to NSWHSB).	Nil.	Linkage of the biospecimen collection to NSW Health data by the Centre for Health Record Linkage for the period of this grant, including: > access to routinely linked NSW Health data collections or other NSW Health data, subject to feasibility assessment, for the purpose of specific research projects; > linkage to data collections managed by NSW Health for the purpose of administration (e.g. cancer verification).	Nil.
OHMR funding does not cover:		Data collection, management, linkage, storage and custodianship.	Data collection, management, storage (external to MLK) and custodianship.	Not yet available.

APPENDIX 6

Definitions

Term	Definition
Administrative health data (routinely collected)	Data that is collected routinely in administrative datasets by the health system (e.g. hospitalisation data) or through other government departments (e.g. Births, Deaths and Marriages).
Biospecimen metadata	Biospecimen storage information (e.g. date and time of collection, number of aliquots and derivatives, volume of aliquots, unique identifier, storage conditions, type of biospecimen).
Biospecimen related data	Data directly associated with the biospecimen and includes: metadata (e.g. biospecimen storage information) and participant data (name, address, etc).
Centre for Health Record Linkage (CHeReL)	A dedicated data linkage centre within NSW Health
Cohort Manager	The individual who oversees day–to-day management of the activities relating to the biospecimens, and clinical and participant information collection
Collection	A biospecimen collection with related data (see biospecimen related data in this list).
Collection custodian	An individual who has clear responsibility for the day-to-day operation of the biospecimen collection. They also have responsibility to ensure that biospecimen related data is used responsibly and respectfully, and that privacy of participants is safeguarded.
Data associated with the biospecimen	There are several types of data that can be associated with the collection and linked to the biospecimens, and subsequently requested by researchers. Researchers can access this data through the NSWHSB Access Form.
Data custodian	An individual with day-to-day responsibility for data collection and management. This includes ensuring that data are used responsibly and respectfully, and that privacy of participants is safeguarded.
Data linkage	Data or record linkage brings together information that relates to the same individual, family, place or event from different data sources or from different files.
CHeReL Master Linkage Key	A system of continuously updated links within and between core health-related datasets in NSW and the ACT
Clinical and participant information	Participant health information including medical records and surveys.
Principal Investigator	The individual who takes responsibility for the overall conduct, management, monitoring and reporting of research conducted at a site.
Site-specific assessment (SSA)	A mechanism used by Public Health Organisations to ensure that the proposed research project complies with minimum governance requirements, and to consider whether the research should be conducted and supported at the proposed site.

NSW Health Statewide Biobank is a flagship facility of NSW Health developed in partnership with the Office for Health and Medical Research. NSW Health Pathology, Sydney Local Health District and Health Infrastructure.

NSW Health Statewide Biobank
Level 1
Professor Marie Bashir Centre
67-73 Missenden Road
Camperdown NSW 2050
T: +61 2 4920 4140

NSWPATH-Biobanking@health.nsw.gov.au
www.biobank.health.nsw.gov.au

NSW GOVERNMENT

SHPN (OHMR) 180571