2021

HEALTH+MEDICAL RESEARCH

Biospecimen Collection Grants Round 3

(2022 - 2026)

Guidelines

NSW GOVERNMENT

NSW Health

1 Reserve Road

St Leonards NSW 2065

(02) 9391 9228

www.health.nsw.gov.au

www.medicalresearch.nsw.gov.au

Further copies of this document can be downloaded from the NSW Health website: www.medicalresearch.nsw.gov.au

SHPN: (OHMR) 210997

Table of contents

Table of contents 3

Call for applications 4

The NSW Health Statewide Biobank 4

The Centre for Health Record Linkage 5

Biospecimen Collection Grants Round 3 5

Eligibility criteria 6

Selection criteria 8

Selection process 9

Onboarding the collection 10

Reporting requirements 10

Implementation assessment and evaluation 10

APPENDIX 1: NSWHSB EOI 11

APPENDIX 2: Data Linkage EOI 14

APPENDIX 3: Data Types 16

APPENDIX 4: Components that the Biospecimen Collection Grants will fund – table 18

APPENDIX 5: Components that the Biospecimen Collection Grants will fund – diagram 19

Call for applications

NSW Health invites eligible individuals to apply for the NSW Biospecimen Collection Grants Round 3. Funding for this program will be distributed over the funding period 2022-2026. Researchers from culturally and linguistically diverse backgrounds, Aboriginal and Torres Strait Islander origin, and primary carers who have experienced career disruptions, are encouraged to apply.

Purpose

The program supports the development of collections of high quality biospecimens and associated data. The aim is to build biospecimen research assets for the State that can be used to investigate priority health issues affecting the NSW population.

The biospecimens will be collected via the statewide NSW Health Pathology network and processed and stored in the NSW Health Statewide Biobank (NSWHSB). The Centre for Health Record Linkage (CHeReL) will support linkage of the biospecimens to NSW Health data collections. In this way each biospecimen collection is curated with data that is intended to build over time.

Submission of applications

All applications must be completed using the NSW Biospecimen Collection Grants - Round 3 application form and include any requested supporting evidence. The form can be found at: https://www.medicalresearch.nsw.gov.au/biospecimen-collections/.

All applications must be emailed to MOH-OHMRGrants@health.nsw.gov.au. Submission dates are below.

Indicative program timeline

Activity	Dates
Call for Applications	4 November 2021
Information sessions	12 noon, 16 and 18 November 2021
Data Linkage EOI form submitted to the CHeReL for feasibility assessment	30 November 2021
NSWHSB EOI form submitted to NSWHSB for feasibility assessment and quote	30 November 2021
Feasibility letter issued by CHeReL	28 January 2022
Quote and feasibility letter issued by NSWHSB	28 January 2022
Applications close	31 January 2022
Announcement of successful applicants	May 2022

Support to apply

Information sessions will be delivered via teleconference. These sessions will provide an opportunity to clarify the intent and scope of the program and to answer questions about the application process, data linkage and biobanking at the NSWHSB. Register for **November 16** at: https://www.eventbrite.com.au/e/biospecimen-collection-grants-round-3-information-session-tickets-200638423927. Register for **November 18** at: https://www.eventbrite.com.au/e/biospecimen-collection-grants-round-3-information-session-tickets-200639828127

All supporting documentation including the Consent Toolkit, standard agreements, policies and protocols can be found at https://biobank.health.nsw.gov.au/researchers/

Answers to frequently asked questions are available at https://www.medicalresearch.nsw.gov.au/biospecimen-collections/, we encourage you to check regularly.

The Office for Health and Medical Research is available to support the development of applications. Please email queries to MOH-OHMRGrants@health.nsw.gov.au

The NSW Health Statewide Biobank

The NSW Government invested $12 million to create the NSWHSB to support world-class health and medical research across the State. The facility and services are designed to support, enrich and enable medical research projects, clinical trials or biospecimen collections. From breakthroughs in cancer, diabetes, heart disease and rare genetic diseases, the state-of- the-art facility will help revolutionise our research efforts across NSW.

The Biobank was built as a partnership between OHMR, NSW Health Pathology, Sydney Local Health District and Health Infrastructure. It is supported by the NSW Health Pathology network of collection centres and couriers and has the capacity to process and store millions of high quality biospecimens. It is staffed by a team of biobanking and research experts, is ISO 9001certified, and also certified by the NSW Health Pathology Biobank Certification Program.

See Appendix 1 for a NSWHSB EOI that must be submitted to the NSWHSB before applications are due. See more information about the NSWHSB at http://biobank.health.nsw.gov.au/.

The Centre for Health Record Linkage

The CHeReL is a dedicated data linkage centre within NSW Health and part of Australia's first national data linkage network. The CHeReL manages secure, high-performing data linkage infrastructure and provides services that enable research, planning and policy.

Data linkage brings together information that relates to the same individual from different data sources. Longitudinal linkage of existing data sources is a relatively quick and cost-effective way to add value to biospecimen research cohorts.

See more information about data linkage and the CHeReL at Appendix 2 and https://www.cherel.org.au/apply-for-biolink.

Biospecimen Collection Grants Round 3

Objectives

The aim of the grant is to build research assets for NSW. The objectives are to:

- support biospecimen collections that support research on priority health issues in NSW
- build NSW capacity in research that draws from linking biospecimens with administrative health data (see definition in Appendix 3).
- reduce the time from evidence generation to implementation

Scope

Round 3 grants will support two categories of collections:

(a) existing collections that will continue to collect biospecimens and data within the grant timeframe

(b) prospective collections, where biospecimen collection will commence during the grant timeframe

Flagship research project

Collection custodians must be able to describe one research project that utilises the biospecimens and data in the proposed collection. Although the Biospecimen Collection Grant does not cover funding for research (see Appendix 4), applicants must demonstrate the feasibility of the research project that uses the proposed collection to investigate a priority health issue for NSW.

Details of funding

Funding up to $100,000 per collection is available. Funding will be used to support collections for up to four years, from 2022, for the following services:

- biospecimen collection, transport to NSWHSB, receipt, processing, storage;
- biospecimen retrieval, dispatch and transport from NSWHSB to researchers within NSW;
- storage of biospecimen related data.

Beyond the $100,000 grant, successful applicants will also be supported for:

- storage of the biospecimen and metadata beyond the period of the grant, pending continued research utility of the collection;
- linkage of the collection to a range of NSW Health datasets listed at Appendix 2 via the CHeReL as well as additional NSW Health datasets pending detailed feasibility assessment.

Further details are in Appendix 4 and 5.

Funding conditions and exclusions

1. All funds under this grant will be paid directly to the Host/Administrative organisation of the grant recipients.
2. All funds for data linkage will be paid by the OHMR to the CHeReL separately and will not incur costs to the grantees.
3. Applications are required to declare any source, duration and level of funding already held for research drawing from the collection.
4. Funding is conditional on the Principal Investigator and the Chief Executive of the host organisation signing the declaration on the application form, which outlines the host organisation's obligations to the Project.
5. One application will be accepted per Principal Investigator. No co-investigator should be associated with more than five applications.
6. The grant funded collection must be physically stored in the NSWHSB. In case of existing collections or partially funded collections, the funded portion must be stored at the NSWHSB.

Letter of support and quote

Applicants will need to seek a feasibility assessment/letter of support and quote from the NSWHSB for their collection. The letter of support/feasibility and quote will need to be submitted with the application. Applicants will need to submit a completed NSWHSB EOI form (Appendix 1) to the NSWHSB by 30 November. The NSWHSB can be contacted on 02 4920 4140 or NSWPATH-Biobanking@health.nsw.gov.au.

Applicants will also need to seek a feasibility assessment from the CHeReL for the data linkage aspect of their research. A letter of support/feasibility from the CHeReL will need to be submitted with the application. Applicants will need to provide a completed data linkage EOI form (Appendix 2) to the CHeReL by 30 November. The CHeReL can be contacted at MOH-Biolink-CHeReL@health.nsw.gov.au.

Program logic

Proposed collections and flagship research should have the potential to lead to changes in clinical practice or policy in the short and/or long-term. The expected pathway for this to occur should be clearly described in the application.

Therefore, applicants are required to submit a program logic diagram with their application, which should include the collection aim, inputs, activities, outputs, and short and long-term outcomes.

A template for the Program Logic is included in the Biospecimen Collection Grant application form.

Examples of outputs include:

- new treatments, diagnostics or drug targets
- new clinical or medical prototypes
- award of national or international grants and fellowships
- peer-reviewed publications and presentations at conferences
- media coverage and other non-peer-reviewed publications
- patent applications.

Examples of outcomes include:

- changes in clinical practice that lead to better patient outcomes
- changes in clinical or public health policy
- reduced costs to the health system.

Budget

Applicants should supply a high-level budget that outlines the planned expenditure for the Collection. This should be developed in consultation with the NSWHSB. Contributions from the host and other organisations for the collection and flagship research should also be outlined.

Eligibility criteria

Applicants must meet the following eligibility criteria:

1. **The Principal Investigator is NSW based**

The Principal Investigator must reside in or plan to move to NSW prior to the granting period and must be employed by a NSW based organisation:

- local health district
- medical research institute
- university
- non-government organisation.

2. **At least 50% of the research team is based in NSW**

The project must be conducted in NSW and at least 50% of the team must be based in NSW. The application must demonstrate engagement and consultation with relevant stakeholders (such as clinicians, consumers, researchers, patients, and/or policy makers).

3. **If the collection is already funded by a previous Biospecimen Collection Grant:**

    a. **funding must be used for the collection of additional biospecimens to increase the available pool within the collection, and**

    b. **the previously funded biospecimens must be onboarded by the date the BCG3 funding agreements are executed**

Projects are eligible to apply with the condition that the grant funds the collection, transport and/or storage of additional biospecimens to increase the pool within the original collection.

If the previously funded collection was not onboarded (ie. signed the NSWHSB service agreement and Material Transfer Agreement I) by the date when Biospecimen Collection Grant 3 funding agreements are executed, the collection will not be eligible to receive Biospecimen Collection Grant 3 funding.

Applicants must also provide details on how any ongoing collection of biospecimens, beyond the period of this grant, will be funded.

4. **Participants are consented using the NSW Health Consent Toolkit**

Applicants must consent participants with the consent materials in the Toolkit. Where the collection is unable to use the exact wording in these consent materials (eg. existing collection that has already consented participants), applicants should explain why, and seek permission from the Ministry of Health. These collections must still adhere to the consent principles in the Toolkit. Permission can be sought by emailing MOH-OHMR@health.nsw.gov.au. The NSW Consent Toolkit is available at https://biobank.health.nsw.gov.au/researchers/nsw-health-consent-toolkit/.

5. **Agree to the collection becoming accessible to researchers**

Applicants must agree to their collection becoming accessible to researchers beyond the investigator team as described in the NSWHSB Access Policy. Applicants must indicate a reasonable milestone at which point their collection will become accessible. The milestone can be a timepoint or measure or a combination of measures (eg. 12 months after the completion of the collection). We encourage you to discuss the milestone with the NSWHSB. The NSWHSB Access Policy outlines the conditions of access and is available at: https://biobank.health.nsw.gov.au/wp-content/uploads/2020/06/NSWHSB-290620-Strategic-Collection-Access-Policy-FINAL_.pdf.

6. **Agree to onboard to NSWHSB within six months**

To facilitate the timely project progression, the applicants must agree to onboard with NSWHSB, by signing the NSWHSB standard agreement and Material Transfer Agreement I (for depositing the collection in the NSWHSB), within six months of executing the funding agreement with NSW Health.

If this criterion is not satisfied, NSW Health will withdraw the awarded Biospecimen Collection Grant 3 funds.

7. **Agree to provide participant information to the CHeReL to enable data linkage of the collection to the Biospecimen Linked Standard Data Asset**

To facilitate future research, applicants must agree to the linkage of their collection to the Biospecimen Linked Standard Data Asset (BLSDA). This includes agreeing to provide the CHeReL with sufficient personal information about their participants to enable this linkage. Applicants must also indicate a reasonable milestone at which point the required information has been provided for data linkage. We encourage you to discuss this milestone with the CHeReL. Information about BSLDA is at Appendix 2.

8. **Feasibility Assessment**

The NSWHSB and CHeReL have assessed the application as feasible. Feasibility is confirmed in the Letter of Support.

9. **Submit a complete application**

The application form must be fully completed with all relevant and required documentation attached including Letters of Support from the NSWHSB and CHeReL and a NSWHSB quote. The declarations on the form must be signed.

10. **Governance**

The application must provide a clear governance structure for the project which must include the Chief Executive (or equivalent) or delegate of the host organisation.

11. **Australian citizen, permanent residency status or appropriate visa**

The Principal Investigator must be an Australian citizen, a permanent resident of Australia or have an appropriate working visa for the full-term of the Grant. Principal Investigators who are neither Australian citizens nor permanent residents must provide evidence of residency status, and the right to remain in Australia for the duration of the funding period, certified by a Justice of the Peace or equivalent. Note that for electronic documents, an official Visa Entitlement Verification Online statement is sufficient, Justice of the Peace certification is not required. Australian Citizens and Permanent Residents are not required to provide evidence.

If there are any changes to the Principal Investigator during the period of the grant, the NSWHSB and CHeReL must be notified.

Host organisation

The host organisation is where the research is undertaken.

1. **Located in NSW**

The host organisation must be in NSW. Clinician scientists may undertake clinical work separately from where research is undertaken.

2. **Organisation conducts health and medical research**

The host organisation must conduct health and medical research in one of the following places:

- a department or research centre within a university
- an independent medical research institute
- a not-for-profit organisation, or a local health district.

3. **Infrastructure support**

The host organisation will provide the appropriate infrastructure support for the research project, including wet/dry lab space, computer equipment, and desk space.

4. **Research support**

The host organisation will support the flagship research undertaken through the provision of in-kind or financial support.

Selection criteria

All applications for funding that meet the eligibility criteria will be assessed against the following selection criteria. Applications should be written in plain English.

The collection (40%)

1. **Addresses a priority health issue in NSW**

The application must demonstrate how the collection (or expanded collection) will address a priority health issue in NSW and make a case for the priority health issue.

2. **A research asset for NSW**

The application must demonstrate how the collection (or expanded collection) can be a research asset for NSW.

The collection must show potential to lead to changes in clinical practice or policy in the short and/or long-term. The expected pathway for this to occur should be clearly described.

3. **Uniqueness**

The application must demonstrate how the collection is unique in Australia and/or globally. Applicants will be expected to determine the existence of any other similar collection in NSW and Australia or explain how the existing collection will not be suitable for their purpose or how the proposed collection extends its scope.

4. **Collaboration**

The application should describe any collaboration within Australia and internationally, whether partners are committed to ongoing engagement and support, and whether the collaboration will help leverage existing assets or infrastructure in NSW (eg. 45 and Up Study).

The flagship research (30%)

5. **Significance of concept and expected impacts**

The application must outline what new evidence the flagship research will generate. It must demonstrate the extent to which the project will result in a significant or major advance in treatment and/or knowledge in this field and how it will impact on patient care or health service delivery in NSW.

6. **Strong scientific basis for the proposed project**

The application must include:

- clear and well-defined objectives and research questions for the flagship research
- a strongly developed scientific approach relevant to the scope
- a robust study design.

The application should also cover, the evidence gaps the flagship research will explore, evidence development and what will be achieved in the study period. Clear links between activities, outputs and expected outcomes and between the collection and the flagship research should be articulated in the program logic.

7. **Feasibility of proposed research project**

The application must demonstrate that the resources are available beyond this grant to conduct the research proposed. An indicative timeline of research must be included.

8. **Use of health administrative datasets**

The application should describe how the flagship research will leverage the NSW Health administrative datasets linked to the collection. See more information about these datasets in Appendix 2 and 3.

9. **Key principles of quality research**

The application must demonstrate how the flagship research addresses key principles of quality research including:

(a) patient centred – demonstrate how the research aims to benefit patients

(b) collaboration – demonstrate collaboration with clinicians and other key stakeholders

(c) consumer engagement – demonstrate how consumers will be engaged throughout the project timeframe

(d) equitable – demonstrate how Aboriginal and Torres Strait Islander people, rural communities and other minority groups will be catered for

(e) transparent – demonstrate how the project will be communicated to key stakeholders in a transparent and accountable way.

Project management (10%)

10. **Strong governance**

The application should describe a governance structure for the Collection and the flagship research that is appropriate, clear and detailed.

11. **Probability of achieving objectives**

The project plan for the Collection should be highly feasible within the grant period given the expertise, research tools, technical capability, and in-kind and/or financial support available in the relevant research environment. This includes a list of key project milestones and deliverables (activities, expected outputs and outcomes) with timeframes and management of perceived risks. There is an expectation that at the completion of the project, it will be possible to report on meaningful outcomes.

Projected timelines for flagship research related milestones such as funding, ethics approvals, research and experimentation, data collection, results/findings and publication must be included in the Project timelines (Section D) of the application form. These milestones do not need to be completed within the grant period.

The team (10%)

12. **The team demonstrates capability in their field of research, including biospecimen research, and a track record relative to opportunity**

The application should list all individuals in the team, their academic qualifications, and any relevant professional qualifications with the year awarded, the awarding body and country.

The application should list any research (journal articles, books, reports, patents or conference presentations), clinical and industry appointments, and positions held for the previous ten years, for all individuals in the team.

Applications should describe (for all individuals in the team) existing skills and experience that:

- directly relate to biospecimen research, the topic area and/or methodology of the project, or
- relate to the nominated area(s) for development (and how participation in the project will help to strengthen these skills).

To assess track record relative to opportunity, applications should highlight any significant career disruptions or clinical responsibilities that could reasonably be considered to have had an impact on their track record over the previous ten years, for all individuals in the team.

The application should describe the roles of each team member in the project.

13. **Engagement with mid-career researchers (researchers with 5-15 years research experience)**

Applications that include mid-career researchers as part of the team are strongly encouraged.

Budget (10%)

14. **Budget**

The budget for the Collection is reasonable and well justified for the timely completion of the project. An indicative budget should also be provided for the flagship research.

Selection process

Application review

STEP 1: Initial eligibility appraisal

Following the closing date for applications, the NSW Ministry of Health will appraise each application against ALL the eligibility criteria.

STEP 2: Scoring against the selection criteria

The Scientific Advisory Group, an independent panel of experts chaired by the Director of Biobanking, NSW

Health Pathology, will assess all eligible applications against the selection criteria.

STEP 3: Recommendation for funding

The Scientific Advisory Group will agree on the final ranking of all eligible applications and will make a recommendation for funding to the NSW Deputy Secretary, Population and Public Health Division, NSW Ministry of Health.

STEP 4: Decision and notification

The NSW Ministry of Health will make a determination on grant recipients and amounts. Applicants will be notified.

STEP 5: Grant Agreements initiated

The NSW Ministry of Health will contact the successful applicants to develop funding agreements with the host organisations.

Onboarding the collection

Once funding agreements have been executed, the following steps will be undertaken:

STEP 1: Agreements with the NSWHSB initiated

The NSWHSB will contact the successful applicants to discuss the:

- Standard Agreement
- Material Transfer Agreement I for the deposit of the biospecimen collection in the NSWHSB.

Execution of these agreements must occur within six months of signing the funding agreement.

STEP 2: Collection of biospecimens

Once participants are consented, the applicant and NSWHSB will work together to arrange the collection of the biospecimens from participants, if required.

STEP 3: Provision of participant information for data linkage

By the nominated milestone, the applicant and the CHeReL will work together to arrange the linkage of participants to the Biospecimen Linked Standard Data Asset.

Further information is at Appendix 1 and https://www.cherel.org.au/apply-for-biolink.

Reporting requirements

The host organisation will enter into a funding agreement with NSW Health for the Biospecimen Collection Grant that sets out obligations. A schedule for reporting will be outlined in the funding agreement and will include a requirement to provide:

- annual progress reports
- a final report following the conclusion of the term of the grant.

Implementation assessment and evaluation

The grant will periodically be assessed to ensure it is meeting its objectives. This will be undertaken in collaboration with the grant recipients.

Grant recipients may be asked to meet with staff from the Ministry of Health from time to time during the funding period. Meeting with recipients will facilitate feedback and inform the future direction of the scheme.

APPENDIX 1: NSWHSB EOI

Please submit to the NSWHSB by 30 November 2021 at NSWPATH-Biobanking@health.nsw.gov.au.

Contact Details

1. Details of the contact person for this application:

Contact Person	*Please insert details here*
Name	
Title	
Organisation	
Position	
Mailing address	
Email	
Phone number	
Relationship to project	☐Principal Investigator ☐Co-Investigator ☐Other

Collection Details

2. Which of the following describes your collection?

Please tick one

☐ Existing Collection *(Recruitment of participants and biospecimen collection ongoing)*

☐ Prospective Collection *(Recruitment of participants and biospecimen collection not yet started)*

3. How many participants have been / will be recruited?

Current	*Target*	*Cohort type*
		e.g. disease

Biospecimen Collection

4. Will biospecimens be collected by NSW Health Pathology (NSWHP) collection centres?

☐Yes ☐ No

*If no, skip to **Next Section.***

If yes, please nominate Local Health Districts or specific NSWHP collection centres:

- ☐ Sydney
- ☐ Western Sydney
- ☐ Northern Sydney
- ☐ South Western Sydney
- ☐ South Eastern Sydney
- ☐ Central Coast
- ☐ Hunter New England
- ☐ Mid North Coast
- ☐ Northern NSW
- ☐ Far West
- ☐ Illawarra Shoalhaven
- ☐ Murrumbidgee
- ☐ Nepean Blue Mountains
- ☐ Southern NSW
- ☐ Western NSW

OR *enter specific collection centres here*

Biospecimen Processing

5. Do you require biospecimen processing by the NSW Health Pathology/Statewide Biobank?

☐Yes ☐No

If no, please skip to ***Next Section***

If yes, please attach the relevant processing protocols OR complete the following table:

Collection Container (if known)	Product	**Protocol Summary** (incl centrifuge details)	**Storage Conditions**			Analysis and other requirements
			Temp	Max Number of Aliquots	Aliquot volume (mL)	
e.g. EDTA	*whole blood*		*-70°C*	*4*	*0.5*	*For DNA extraction*
e.g. lithium heparin	*plasma*		*-70°C*	*4*	*1*	
e.g. SST	*serum*		*-70°C*	*6*	*0.5*	
e.g Kit for self-collection (Genotek)	*saliva*		*-180°C (LN)*	*2*	*0.5*	*Microbiome*

Please detail any special processing requirements e.g. washes

6. Please detail any other processing requests not mentioned above and attach relevant protocols

Biospecimen Transport

7. How are biospecimens being transported?

NSW Health Pathology Collection Centres are linked to the NSW Health Statewide Biobank via couriers. The courier routes may be used to transport non-urgent specimens. Note that the frequency of couriers may not suit all projects, particularly projects with specific time requirements.

☐ Own transport arrangements - *skip to* ***Next Section***

☐ NSWHSB to investigate the utility of NSWHP transport for your project arrange transport - *please complete table below*

8. Please complete the following table to specify transportation requirements to NSWHSB:

Sample type	Transit conditions	Max time from collection until processing	Place of departure	Frequency	Contact
EDTA		*4 hours*	*RNSH*		

9. Please specify any other transport requirements.

Data Management

NSWHSB tracks pre-analytical, processing and storage information.

10. Do you have any other data requirements outside receipt of the standard data elements (e.g. preanalytical SPREC data) ?

☐Yes ☐ No

APPENDIX 2: Data Linkage EOI

Please submit to the CHeReL by 30 November 2021 at MOH-Biolink-CHeReL@health.nsw.gov.au.

Principal Investigator, Primary Contact	Name, Title, Institution and Email Address for the PI and the Contact
Description of Biospecimen Collection	Name of Biospecimen Collection or Grant How many people do you anticipate will be included in the biospecimen collection? How many people do you intend to recruit over the four years of the grant? Is the biospecimen collection existing or prospective or both? If an existing collection, how many people does the collection currently include?
Data Linkage	When do you anticipate the first linkage to occur? Are you requesting updates of the linkage? For example, annual until 2025 or one update in 2023
NSW Health Datasets	Please indicate which of the following NSW Health statewide collections you intend to request for research purposes ☐ Admitted Patient Data Collection (from 2001) ☐ Death Registrations (from 1985) ☐ Cause of Death Unit Record File (from 1985) ☐ Birth Registrations (from 1994) ☐ Perinatal Data Collection (from 1994) ☐ Emergency Department Data Collection (from 2005 onwards) ☐ Cancer Registry (registrations from 1972 and clinical data items from 2013) ☐ Notifiable Conditions Information Management System (from 1993) ☐ Mental Health Ambulatory Data Collection (from 2001) ☐ NSW Ambulance Electronic Medical Record and Patient Health Care Record (from 2009) ☐ NSW Ambulance Computer Aided Dispatch (from 2009) ☐ Controlled Drugs Data Collection (from 1985) ☐ Non-Admitted Patient Data Collection (from 2015) ☐ BreastScreen NSW (from 1988) ☐ Other NSW Health data collections (please specify, for example, NSW Pathology, Neonatal Intensive Care Unit data collection) Detailed descriptions of these datasets are available at https://www.cherel.org.au/data-dictionaries or on request from the CHeReL at MOH-Biolink-CHeReL@health.nsw.gov.au

Briefly outline the purpose of requesting the datasets above? How will the datasets you have requested be leveraged for the flagship research described in your grant application?	The grant application (Question 10) requires that you address in 200 words or less the question of how the linked administrative datasets will be leveraged for your flagship research
Please indicate if the participant personal identifiers listed will be collected and available for data linkage	☐ Full Name ☐ Date of Birth ☐ Residence Address ☐ Date associated with the address ☐ MRN and associated Hospital Code

Information on Data Linkage

The CHeReL will review the EOI and provide comment and/or a letter of support for your grant application. Please be aware that the CHeReL review is limited in scope and future data access will require approval from data custodians and a relevant ethics committee in accordance with NSW Health policy.

The NSW Health Consent Toolkit is recommended as a resource to assist in appropriately consenting participants to data linkage of NSW Health data collections.

As a condition of the grant you will be asked to provide sufficient personal information for consenting participants to the CHeReL to enable data linkage that can support future research. Typically, the information used for data linkage will include the full name, date of birth and address of the participant. The intent of providing this information is to enable specific NSW Health data for consenting participants to be included in a **Biospecimen Linked Standard Data Asset (BLSDA).** The BLSDA will be maintained by the CHeReL and be limited in scope to appropriately consented participants from collections funded by NSW Health through the Strategic Collection Grants. For these participants the BLSDA will contain a small number of different NSW Health datasets at the time of first linkage. New participants in collections will be added over time and the NSW Health datasets in the scope of the asset expanded.

The BLSDA is being created to simplify access to longitudinal data for future research. Access will require appropriate approvals for the project and be managed in accordance with the *NSW Health Statewide Biobank Access Policy.*

Further information is available from the CHeReL at MOH-Biolink-CHeReL@health.nsw.gov.au

APPENDIX 3: Data Types

Data management component	Tier 1 - Biospecimen Related Data	Tier 2 - Clinical and Self- Reported Data	Tier 3 - Administrative Health Data or data held by other Government agencies	Tier 4 - Research Results
Description	Data about the biospecimen. This is de-identified data directly associated with the biospecimen i.e. biospecimen storage. This category will include meta-data on Tier 2 and 4.	Data that accompanies the biospecimen. This may include clinical health information that has been collected by the custodian or survey data collected by the custodian from participants or clinicians.	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) or the Commonwealth[1] (MBS and PBS data).	Data that is generated from the biospecimens by the researchers through their effort and resources eg. genomic data. As this data is not the responsibility of the NSWHSB, the NSWHSB does not validate these findings.
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 to store this data on a case by case basis.	Data about the cohort can be stored by the CHeReL for the purpose of data linkage.	Data will need to be stored at an agreed partner organisation such as an LHD.
Staffing arrangements	NSWHSB staff	Collection Custodian (funded by external grants).	CHeReL staff.	Collection Custodian
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.	Data generated by researchers through their effort and resources.
Data field examples	> 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)	> Genomic > Proteomic > Metabolomic > Imaging > Immunohistochemistry > Antibody data > Any data/results to be returned by researchers

Data management component	Tier 1 - Biospecimen Related Data	Tier 2 - Clinical and Self- Reported Data	Tier 3 - Administrative Health Data or data held by other Government agencies	Tier 4 - Research Results
Data Custodian	Data custodian for the biospecimen meta-data is the NSWHSB.	Collection's nominated institution.	Each dataset has a data custodian nominated by the collection's institution.	Collection's nominated institution.
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 CHeReL and custodianship.	Data collection, management, linkage, storage and custodianship.

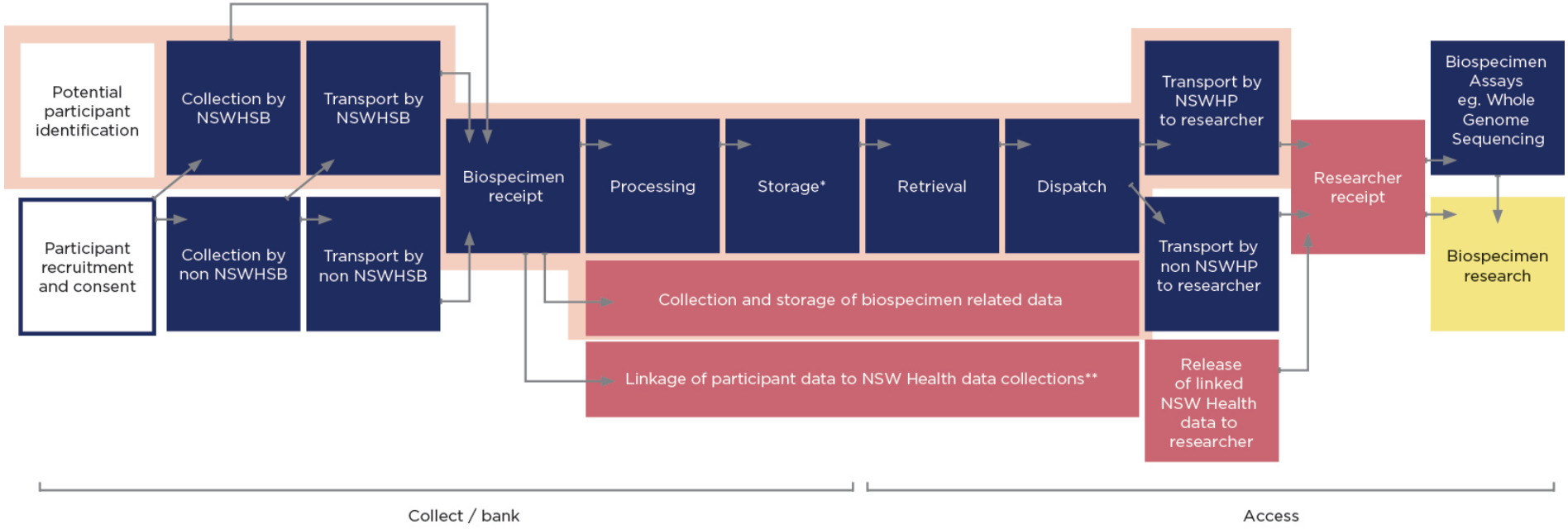
APPENDIX 4: Components that the Biospecimen Collection Grants will fund – table

Grant will fund (for the period of the grant)	Paid directly to NSWHSB/ NSWHP	• biospecimen collection and transport from NSW Health Pathology (NSWHP) centres • biospecimen receipt at NSWHSB • biospecimen processing by NSWHP/NSWHSB • DNA/RNA extraction by NSWHSB • biospecimen storage at NSWHSB • biospecimen access/retrieval and preparation for dispatch • storage of and access to Biospecimen Related Data[1] • biospecimen transport to research sites within NSW via NSWHP Courier Service
NSW Health will fund outside the grant	Paid directly to NSWHP	• storage of the biospecimen and metadata beyond the period of the grant, pending the continued utility of the collection
	Paid directly to CHeReL	• access to routinely linked NSW Health data collections[2] 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 (eg. cancer verification)
NSW Health will not fund		• biospecimen collection from centres other than NSWHP • participant recruitment • participant consenting • value-add assays e.g. whole genome sequencing • linkage to data collections not managed by NSW Health • data related costs outside NSWHSB and CHeReL services • ongoing biospecimen collection, transport, receipt and processing costs beyond the life of the grant. • the collection's flagship research project.

[1] Data directly associated with the biospecimen and includes: Biospecimen Meta-data (eg. biospecimen storage information) and Participant Data (name, address).

[2] Routinely linked data is shown at http://www.cherel.org.au/master-linkage-key. Access is subject to relevant HREC and data custodian approval.

APPENDIX 5: Components that the Biospecimen Collection Grants will fund – diagram



* For successful applications to the grant, storage of the specimen collection beyond the period of the grant will be supported by NSW Health Pathology, pending the continued utility of the collection.

** 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.