

# Frequently Asked Questions

For the research community

## Why is NSW Health creating a new biobank?

NSW Government has invested \$12 million to create the NSW Health Statewide Biobank to support world-class medical research and a pathway to better treatment for patients.

As the first and largest facility of its kind in Australia, it will use large-scale robotic technology to store and process millions of human bio-specimens for population-based health studies and disease-specific research.

Researchers can be confident the state-of-the-art facility will process, store and provide high quality samples for health and medical research.

This vital infrastructure will help researchers gain a more in-depth understanding of the health of the NSW community, enable greater participation in major international research studies, and improve the way disease is detected, diagnosed and treated.

## What makes the NSW Health Statewide Biobank unique?

**Quality:** State-of-the-art, temperature-controlled storage systems will protect the long-term integrity of samples used in population and disease-specific collections. High quality standard operating procedures will also ensure researchers can trust that each sample has been treated in accordance with best practice international biobanking standards.

**Quantity:** Large-scale robotic technology will store up to three million samples enabling the world-class biobank to support large-scale population studies. Researchers across the state will be able to store and access a wide range of samples to advance contemporary medical research programs.

**Efficiency:** Advanced robotic technology will reduce the time it currently takes technicians and researchers to manage and retrieve samples. Specimens will be deposited and retrieved from the cold storage facility through a dedicated processing laboratory, developed in consultation with NSW Health Pathology. This will use streamlined workflows to allow for fast, efficient handling of a variety of samples.

**Effectiveness:** Supporting data links to NSW Health data will provide the opportunity to follow-up health data on donors with appropriate consent and ethics approval. Bringing together local health districts, universities, medical research institutes and industry, the modern facility will also help strengthen research collaborations across the state and beyond.

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## **What does the new facility mean for existing biobanks in NSW?**

The NSW Health Statewide Biobank will partner with medical researchers and existing biobanks to improve the overall management of bio-specimens used in health and medical research. Members of the NSW research community can choose to locate all or part of their existing collections in the modern facility.

It's estimated there are currently 50 resources in NSW that can be defined as a biobank. These vary in size and scope, and have an array of operating models and governance arrangements. These facilities also vary in complexity, from a simple freezer managed by one investigator to sophisticated networked set-ups for acquiring, preparing, storing and distributing bio-specimens.

In addition to the statewide biobank, work is also underway on the first statewide biobanking framework. Both the facility and framework will help ensure NSW has a world-class, sustainable approach to managing human biobanks and the specimens they house.

## **Who is developing this new facility?**

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

## **Where will it be located?**

The NSW Health Statewide Biobank is located in the Professor Marie Bashir Centre within Sydney Local Health District (LHD) in Camperdown. Building works have been overseen by Sydney LHD and the new facility is expected to be operational from September 2017.

Housed within this renowned health and medical research hub, the new biobank will help strengthen research collaborations and networks across the state and beyond.

The precinct is home to over 2,000 eminent health and medical researchers who are recognised for providing world-class healthcare, teaching and research. There are also 11 internationally renowned medical and health research centres in close proximity to the biobank covering a range of specialities including cancer, sleep and respiratory medicine, infectious diseases, inflammatory diseases, neurosciences, surgery, cardiovascular and metabolic diseases.

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## **Who is operating the new biobank?**

NSW Health Pathology will manage the NSW Health Statewide Biobank, which is expected to be operational from September 2017.

An advisory group of senior researchers from across NSW is also providing advice on the strategic directions for the collections housed in the facility.

With pathology at the core of the biobanking process, NSW Health Pathology has a wealth of experience in managing specimens to exacting legislative requirements, data management and traceability of specimens.

NSW Health Pathology is the largest public pathology organisation in Australia. It operates over 60 laboratories across the state's public hospital system, manages some 200 collection services in our hospital and community health settings, and performs and analyses more than 61 million tests each year.

## **How will specimens be stored and handled?**

The NSW Health Statewide Biobank will use large-scale robotic technology to store up to three million human bio-specimens – a first in Australia. High quality standard operating procedures will ensure researchers can trust each sample has been treated in accordance with best practice international biobanking standards.

State-of-the-art robotic technology will dramatically reduce the time taken by technicians and researchers managing and retrieving samples, and offer stabilised temperature controlled storage. Other equipment to support long-term storage of samples will include a -80°C robotic cold storage system and -196°C cryogenic vats.

Specimens will be deposited and retrieved from the cold storage facility through a dedicated processing laboratory, developed in consultation with NSW Health Pathology. This will use streamlined workflows to allow for fast, efficient handling of a variety of sample types – including those processed externally, fresh liquid samples (such as blood, urine and saliva) and fresh and fixed solid samples (such as tissues).

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## What are the main features?

The NSW Health Statewide Biobank will partner with medical researchers and existing biobanks to improve the overall management of bio-specimens used in health and medical research.

Major features include:

- Large-scale robotic technology to store and process around three million human bio-specimens
- Capacity to support large-scale population studies
- Fully automated barcode tracking system to ensure traceability and custody control of samples
- Ultra-low temperature storage to support long-term storage of samples using:
  - Brooks BioStore II automated -80°C storage facility
  - Mechanical -80°C freezers
  - Reticulated nitrogen to cryovats for -196°C
- Blood collection facilities including:
  - Phlebotomy service
  - Automated fractionation of blood into its components (plasma, serum, buffy coat, RBCs etc.)
- Automated DNA extraction
- Histopathology tissue processing capabilities
- Laboratory information management system
- Linkages to other health data sets through the Centre for Health Record Linkage (CHeReL)
- Integrated collection across NSW Health Pathology's extensive network of laboratories and collection centres
- World's best practice management systems ensuring bio-specimens of the highest quality e.g.ISO 9001:2015
- Shipping of samples to end users in accordance with industry and regulatory standards

## Who owns the samples stored at the new biobank?

### Legacy collections

Ownership of the samples from legacy collections and associated data will be in line with the Human Research Ethics Committee (HREC) approval for the specific study. Ownership typically resides with the study investigators. Decisions regarding use of the samples will be made by the investigators on a case-by-case basis.

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## New Projects

Ownership of samples for new research projects and associated data will be in line with HREC approval for the project. As with existing collections, ownership of the samples typically resides with the study investigators.

## Excess tissue for unspecified research

Where study participants consent to the use of excess tissue for future unspecified research, donation of surplus tissue will be encouraged. This will add to the biobank's holdings. Further use of these tissues will require approval from a HREC and the Biobank Access Committee.

NSW Health is developing a collection aligned to health and medical research priorities, where the statewide biobank will be custodian and hold the appropriate ethics and governance approvals.

## What will it cost to store samples at the NSW Health Statewide Biobank?

The NSW Health Statewide Biobank will offer a range of service options for the storage of external collections. Costs will vary depending on the research partners' requirements.

Service models and the associated costs are currently being finalised and will include:

- Transitioning legacy collections into the statewide facility
- Management of existing collections
- Collection, processing and management of new collections
- Specimen retrieval when the automated BioStore II is used.

Other factors that could impact cost include:

- Compatibility of sample format of legacy bio-specimens with the new statewide biobank
- Requirements for ongoing maintenance of equipment
- Data migration requirements.

For further information on storage options and costs, please contact NSW Health Pathology's Biobank Project Manager, Jane Carpenter: [NSWPATH-Biobanking@health.nsw.gov.au](mailto:NSWPATH-Biobanking@health.nsw.gov.au).

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## **When will researchers be able to access samples for medical research needs?**

To ensure secure, high quality storage of bio-specimens at the NSW Health Statewide Biobank, the facility will have restricted access and will be monitored 24/7.

NSW Health Pathology staff will be on-site to manage the facility during normal working hours from Monday to Friday. Access to samples outside this time will be assessed on a case-by-case basis. Best practice standard operating procedures will be used for the retrieval of all samples in order to protect their safety and quality.

Round-the-clock monitoring of the facility will also ensure immediate response to emergencies such as power or compressor failures. This will ensure optimal conditions for sample storage can be maintained and will also help minimise the possibility of damage or loss.

## **Will the bio-specimens be linked to electronic medical records and other health datasets?**

Discussions are currently underway with a range of stakeholders to determine the best way to link bio-specimens to electronic medical and administrative datasets.

The NSW Health Statewide Biobank database will have capacity to link data to the bio-specimens in the future.

## **Can bio-specimens from the NSW Health Statewide Biobank be recalled for use for diagnostic or treatment purposes of the participant?**

In general, tissues that are excess to diagnostic requirements are supplied to biobanks where patient consent has been obtained.

Within NSW Health Pathology and other diagnostic pathology facilities, there is a legal requirement to retain tissue samples for potential validation and future testing for the benefit of the patient.

Pathology departments would need to be approached to access such samples for biobanking purposes. It would be unlikely that once banked a bio-specimen would need to be recalled from the NSW Health Statewide Biobank. If this was required for diagnostic or treatment purposes, the biobank would release the material under the direction of a clinical request.

Patients or research participants can withdraw consent for use of their bio-specimens and associated data at any time.

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## **Can researchers be notified if there is a rare sample available to ensure use of the sample is maximised?**

Access to bio-specimens stored at the NSW Health Statewide Biobank will depend on the governance of the specific study it is linked to.

As part of a new statewide biobank framework, a Statewide Tissue Specimen Locator is being developed, which will help identify specimens stored in biobanks across the state. Researchers interested in access to specific samples will be able to approach the bio-specimen custodians directly via this resource.

The new statewide biobank will have an advanced Laboratory Information Management System (LIMS) with an inventory management capability that will also help identify rare samples. Availability of such specimens will be able to be reported to their custodians who will determine use.

## **How will pre-analytic variation of the samples be managed?**

Quality management systems are being put in place by NSW Health Pathology to cover chain of custody information, as well as data relating to bio-specimen processing and storage.

There will be regular detailed reporting and auditing of work practices. NSW Health Pathology is employing qualified staff to help manage the NSW Health Statewide Biobank and they will be regularly tested for competency.

## **Can researchers use bespoke standard operating procedures for collection and processing?**

Yes, the NSW Health Statewide Biobank will use a suite of standard operating procedures (SOPs) recognised as global best practice.

Researchers will be encouraged to use these SOPs to reduce cost and increase standardisation of research practices.

There will be occasions where these SOPs are not fit for purpose. NSW Health Pathology's team of experts at the new biobank will work with researchers to ensure specific protocols can be met in these instances.

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## **What processes and systems will be in place to support the new statewide biobank?**

NSW Government has also invested \$1.5 million in developing the first statewide biobanking framework. This will ensure NSW has a world-class, sustainable approach to managing human biobanks and the specimens they house.

Led by NSW Health Pathology, the framework will improve integration between research, diagnostics and clinical care, and help provide a more standardised approach to biobanking.

It includes a new voluntary certification program to improve the quality of biobanking in NSW by sharing education and best practice guidance.

With patient consent vital to medical research and biobanks, NSW Health's Office for Health and Medical Research is also currently developing a standardised consent process with a template consent form and associated policy guidance.

Other key initiatives include a new Statewide Tissue Specimen Locator to improve access to collections across the NSW biobanking community and standardised agreements to support the transfer of human bio-specimens between hospitals, biobanks and researchers.

The Centre for Health Record Linkage (CHeReL) is developing a data linkage service to support follow-up data from NSW Health administrative data sets to be accessed by collections housed at the statewide biobank.

**For more information about the NSW Health Statewide Biobank or service framework, contact NSW Health Pathology's Biobank Project Manager, Jane Carpenter:**

**[NSWPATH-Biobanking@health.nsw.gov.au](mailto:NSWPATH-Biobanking@health.nsw.gov.au)**