Frequently Asked Questions
For the research community

Why has NSW Health created a new biobank?
NSW Government invested $12 million to create the NSW Health Statewide Biobank to support world-class health and medical research, and a pathway to better treatment for patients.

As the first and largest facility of its kind in Australia, it uses large-scale robotic technology to store and process over three million 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 even more 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 have been installed to protect the long-term integrity of samples used in population and disease-specific collections. High quality standard operating procedures also ensure researchers can trust that each sample has been treated in accordance with best practice international biobanking standards.

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

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

**Effectiveness:** Supporting data linkage to NSW Health data provides the opportunity to obtain 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 also helps 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 is partnering 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, framework activities to increase efficiencies and build stronger collaborations between biobanks are also underway. Both the facility and framework will help ensure NSW has a world-class, sustainable approach to managing human biobanks and the specimens they house. For more information, visit: www.biobank.health.nsw.gov.au.

Who developed this new facility?

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

Where is it?

The NSW Health Statewide Biobank is located in the Professor Marie Bashir Centre within Sydney Local Health District (LHD) in Camperdown. Building works were overseen by Sydney LHD and delivered on time and within budget.

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 – Australia’s largest public pathology provider – is managing the day-to-day operation of the biobank. 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. It also has a statewide network of 60 laboratories and over 200 collection centres that will also be of great benefit.

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

How are specimens being stored and handled?

Large-scale robotic technology is being used to store over three million human bio-specimens – a first in Australia. High quality standard operating procedures also ensure researchers can trust each sample has been treated in accordance with best practice international biobanking standards.

State-of-the-art robotic technology dramatically reduces the time taken by technicians and researchers managing and retrieving samples, and offers stabilised temperature controlled storage. Other equipment supporting long-term storage of samples includes a -80°C mechanical freezers and -196°C cryogenic vats.

Specimens are deposited and retrieved from the cold storage facility through a dedicated processing laboratory, developed in consultation with NSW Health Pathology. Streamlined workflows 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 biobank is partnering with NSW 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 that can store and process over three million human bio-specimens
- Capacity to support large-scale population studies
- Fully automated barcode tracking system ensuring 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
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Who owns the samples stored at the new biobank?

Legacy collections
Ownership of 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.

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. 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. Study participants will consent to the use of excess tissue for future unspecified research. This will add to the biobank’s holdings. Further use of these tissues will require approval from a HREC and the Biobank Access Committee.

What are the consent requirements for the biobank?
The NSW Health Statewide Biobank Consent Toolkit has been developed to guide the consent requirements for the NSW Health Statewide Biobank. This provides standards and guidance on consent requirements for other NSW biobank collections.

The toolkit is designed to help ensure high ethical research standards are being met, and to help improve sample and data availability for researchers. It covers use of broad-based consenting, the return of incidental findings and linkage to NSW Health datasets.

It contains a range of consent principles and protocols, participant information sheet, consent form, Ethically Defensible Plan and a compliance checklist.

Compliance with the Consent Toolkit is mandatory for prospective collections of the NSW Health Statewide Biobank, and is encouraged to be used by any NSW research biobank seeking consent from potential biobanking participants. The Consent Toolkit can be downloaded at www.health.nsw.gov.au/ohmr or www.biobank.health.nsw.gov.au.
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When can researchers access samples?
NSW Health Pathology staff are on-site managing the facility during normal working hours, Monday to Friday. Access to samples outside this time is being assessed on a case-by-case basis. Best practice standard operating procedures are used for the retrieval of all samples in order to protect their safety and quality.

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

Round-the-clock monitoring is also in place to ensure immediate response to emergencies such as power or compressor failures. This will ensure optimal conditions for sample storage are maintained and will minimise the possibility of damage or loss. Data from the monitoring system is available for regulatory purposes.

Will the bio-specimens be linked to electronic medical records and other health datasets?
The NSW Health Statewide Biobank will link all consented data through the Centre for Health Record Linkage (CHeReL). This linkage allows for medical records and other data sets on donors with biobank samples to be accessed to provide clinical data which may be required for future research.

The application process between health data and the biobanked samples is a joint process facilitated by both the NSW Health Statewide Biobank and CHeReL. The biobank does not routinely store health related data on individual donors, only specimen related data.

Can bio-specimens from the NSW Health Statewide Biobank be recalled 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.
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 depends 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. This will help identify specimens stored in all biobanks across the state including at NSW Health Statewide Biobank. Researchers interested in access to specific samples will be able to approach the bio-specimen custodians directly via this resource.

An advanced Laboratory Information Management System (LIMS) with an inventory management capability to help identify rare samples is also being installed at the statewide biobank. Availability of such specimens will be reported to their custodians who will determine use.

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

Quality management systems have been 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 has also employed qualified staff to help manage the NSW Health Statewide Biobank and staff will regularly undergo training to keep up to date with best practice.

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

Yes, the NSW Health Statewide Biobank is using a suite of standard operating procedures (SOPs) recognised as global best practice. These SOPs are aligned with the Biobanking Certification Program, which has been developed by NSW Health Pathology in conjunction with the Office of Biobank Education and Research (OBER) at the University of British Columbia (UBC) and Canadian Tissue Repository Network (CTRNet).

Researchers are 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 will it cost to store samples at the NSW Health Statewide Biobank?
The NSW Health Statewide Biobank offers a range of service options for the storage of external collections. Costs vary depending on the research partners’ requirements, but all costs are based on a cost recovery model to ensure long-term viability of the biobank.

Service models and the associated costs take into account:

- Transitioning legacy collections into the statewide facility
- Management of existing collections
- Collection, processing and management of new collections
- Specimen retrieval

Other factors that could impact cost include:

- Compatibility of sample format of legacy bio-specimens with the BioStore
- Requirements for ongoing maintenance of equipment
- Data migration requirements
- Transportation requirements

For further information on storage options and costs, please contact NSW Health Pathology’s Biobank: 02 4920 4139 or NSWPATH-Biobanking@health.nsw.gov.au.

You can also download our service model and cost fact sheet from: www.biobank.health.nsw.gov.au.

What processes and systems are in place to support the new statewide biobank?

NSW Government has also invested $1.5 million in the development of 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, with a:

- New voluntary certification program to improve the quality of biobanking in NSW by sharing education and best practice guidance. To become certified or learn more visit the NSW Health Pathology Biobank Certification Program website or email NSWPATH-Biobanking@health.nsw.gov.au.
- Standardised consent process with associated policy guidance, developed by NSW Health’s Office for Health and Medical Research.
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- Statewide Tissue Specimen Locator to improve access to collections across the NSW biobanking community.
- Standardised agreements to support the transfer of human biospecimens between hospitals, biobanks and researchers.
- A data linkage service for the facility that will support follow-up data from NSW Health administrative data to be accessed by collections housed at the statewide biobank. Under development by the Centre for Health Record Linkage (CHeReL).
- Standardised documents, such as transfer agreements, will help to expedite processes between researchers, and biobank collections to accelerate research.

Want to know more?
Visit www.biobank.health.nsw.gov.au to:

- Sign up for NSW Health Statewide Biobank e-news
- Read about the inaugural statewide facility and framework
- Download a copy of the NSW Health Statewide Biobank Consent toolkit

For more information about the NSW Health Statewide Biobank or service framework, contact NSW Health Pathology’s Biobank on 02 4920 4139 or NSWPATH-Biobanking@health.nsw.gov.au
REGISTER YOUR INTEREST TO TOUR
THE NSW HEALTH STATEWIDE BIOBANK

On behalf of NSW Health Pathology, the Office for Health and Medical Research is pleased to invite you to tour NSW Health’s new Statewide Biobank.

The NSW Health Statewide Biobank is the first and largest facility of its kind in Australia designed to support health and medical research across the state and we want to partner with you.

Come and tour the Biobank to see first-hand, the state-of-the-art infrastructure for storing and accessing a vast range of human biospecimens to support your research efforts, such as:

- large-scale robotic technology to store and process more than 3 million samples of DNA, tissue, blood and tumour cells
- highly sophisticated automated equipment reducing the time it takes to manage and retrieve samples
- capacity to support large-scale population studies
- ultra-low temperatures to preserve samples including cryogenics at -196 C

There are no tours scheduled at this time, but please register your interest by contacting

Renee Mantle, Strategic Communications, NSW Health Statewide Biobank on 02 4920 4063 or renee.mantle@health.nsw.gov.au

This vital infrastructure will help us gain a more in-depth understanding of the health of the people of NSW, support participation in even more major international studies and improve the way disease is detected, diagnosed and treated.

We look forward to taking you on a behind-the-scenes tour of this world-class facility and forging partnerships that will support your vital research efforts.