

# Anatomical Pathology Tissue Release Policy

## Fact sheet



NSW Health Pathology (NSWHP) has released a statewide [Anatomical Pathology \(AP\) Tissue Release Policy](#).

### Why do we need a policy?

As the custodian of this Tissue, NSWHP must ensure that release of any tissue is ethically sound and meets regulatory, policy and accreditation requirements and standards.

We are seeing increased demand for access to samples with purposes beyond clinical diagnostic assessment, such as clinical trials to access different treatment options, as well as other research and retrospective studies.

We need a standardised, transparent statewide approach to provide a fair service to our customers, research partners and patients.

### Why is this important

This statewide approach helps us:

- Protect and preserve each precious sample in our care while facilitating research.
- Ensure we are compliant and following the latest legal and ethical guidelines as custodians.
- Demonstrate our commitment to people and patient care.

### What does the Policy include?

The Policy describes the minimum requirements and guidelines for the release of AP tissue, under NSWHP's custodianship and control, for purposes beyond clinical diagnostic assessment, including:

- Research (including clinical trials, other research studies and storage in a Biobank).
- Ongoing care and management of patients who are relocating interstate or overseas or seeking their own second opinion.
- The delivery of laboratory services or part of a program aimed at ensuring or improving the quality of services (e.g., quality assurance, quality control, audits, or teaching/training of staff).
- Legal requirements (such as a subpoena or court order).
- Directly related to the care of a person other than the original patient.
- Requests to return AP tissue to the patient for disposal.

### Who does the Policy apply to?

The Policy applies to NSWHP customers, partners and patients, including:

- Local Health Districts
- Other NSW Health agencies
- Research laboratories, universities, and institutes
- Private pathology providers, interstate public pathology providers, overseas pathology providers
- Quality Assurance Program providers
- Patients.

### When do we support the release of AP tissue?

NSWHP supports requests for AP tissue if:

- All legal, ethical and regulatory (including accreditation) requirements are met.

- ✓ Human Tissue Act 1983 (NSW) – the legislative framework governing the donation and use of Tissue from living and deceased persons for therapeutic and non-therapeutic purposes in NSW.
- ✓ Pathology accreditation standards, including NPAAC Requirements for the Retention of Laboratory Records and Diagnostic Material (Eighth Edition 2021) which, provide the minimum standards that pathology laboratories in Australia must comply with to maintain their accreditation, and
- ✓ Various policies and standards regulating the use of AP Tissue for the purposes of research or quality assurance, or control.
- All requests are made in writing.
- Patient consent has been addressed – identity and authority may need to be confirmed.

### Our duty of care to protect original diagnostic material

- NSWHP strongly favours retention of original AP tissue slides and at least one original diagnostic AP tissue block per patient episode.
- This ensures sufficient AP tissue is available for future testing as part of clinical treatment and ensures NSWHP meets pathology accreditation standards.

In general, NSWHP will not release original AP tissue slides used for diagnosis for secondary purposes, except where necessary for ongoing care/treatment of a patient from whom AP tissue was removed.

### Our duty of care to protect future testing

If there is only a single AP tissue block per patient episode available:

- NSWHP's preference is to supply AP tissue slides and/or scrolls to the third party for secondary purposes rather than the single block.
- If AP tissue slides and/or scrolls are insufficient for proposed secondary purpose, and request is for a secondary purpose that informs treatment of the patient (i.e. patient enrolled in a clinical trial), NSWHP will only release the AP tissue block with specific, informed consent from the patient, including in relation to potential implications for current and future testing needs of the patient.

- NSWHP will not release the AP tissue block (if only a single block is available) if the request is for a secondary purpose that does not inform the patient's treatment.

NSWHP will consider the release of AP tissue block in accordance with other requirements of this Policy where more than a single AP tissue block per patient episode is available.

### Block and slide identification

- Identifiable information must be retained on AP tissue blocks or original stained diagnostic slides and cannot be removed. Identification labels on AP tissue blocks or original slides can be covered for patient confidentiality so long as removal of cover on return to NSWHP will not damage the original label.

Original diagnostic slides are generally not made available for research purposes.

- Under no circumstances can AP tissue blocks or original diagnostic slides be released as unidentified.
- For third-party requests to access AP tissue derivatives (e.g. recut slides or scrolls) other than AP tissue blocks or original diagnostic slides, AP tissue can be de-identified where the key for re-identification is managed in line with legislative requirements for privacy and security, and AP tissue remains traceable.

### What this Policy does not cover

Areas that are out of scope are:

- Tissue removed during autopsies.
- Tissue removed for legitimate purposes outside of standard of care, e.g., Tissue collected solely for the purposes of consented, ethically approved research.
- Release of data associated with AP tissue, including pathology reports, is not covered by this Policy.
- Non-AP tissue such as blood, urine and respiratory swabs.

### Help and Support

Read the full policy [here](#).

For more information or to ask a question, contact Prof. Wendy Cooper, AP Clinical Stream Lead [NSWPATH-ClinicalStreams@health.nsw.gov.au](mailto:NSWPATH-ClinicalStreams@health.nsw.gov.au).