Policy

Release of Anatomical Pathology Tissue for Secondary Purposes

NSWHP_PD_035

1. Purpose

This Policy describes the minimum requirements and guidelines for the release of Anatomical Pathology (AP) tissue, under NSW Health Pathology's custodianship and control, for purposes beyond clinical diagnostic assessment, including:

a) research (including clinical trials);
b) ongoing care and management of patients who are relocating interstate or overseas or seeking their own second opinion;
c) 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);
d) legal requirements (such as a subpoena or court order); and
e) directly related to the care of a person other than the original patient.

2. Background

NSWHP frequently receives requests for tissue held by its Anatomical Pathology laboratories, following diagnostic testing conducted as part of an episode of care. Requests are made for a range of purposes, such as research and quality assurance, and are often not related to the episode of care. 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. This policy supports compliance with these requirements, and provides a standardised, statewide approach to the release of tissue.

3. Scope

This Policy is mandatory and applies to all persons who are employed or engaged by NSWHP (whether on a temporary or permanent basis, and includes contractors, consultants and volunteers) who receive, or are otherwise involved in handling requests for use of Anatomical Pathology tissue for Secondary Purposes.

It does not apply to:

- tissue removed during autopsies; or
- tissue removed for legitimate purposes outside of standard of care e.g. tissue collected solely for the purposes of consented, ethically approved research.

The Policy applies to release of tissue to organisations external to NSWHP including Local Health Districts, other NSW Health agencies, research laboratories, universities, research institutes, private pathology laboratories, interstate public pathology laboratories, overseas pathology laboratories, Quality Assurance Program providers (e.g. Royal College of Pathologists of Australasia Quality Assurance Programs, EMQN) and patients.

Release of data associated with AP Tissue, including pathology reports, is not covered by this Policy and will be assessed separately in accordance with other relevant policies (see, for example, the *NSW Health Privacy Manual*, NSWHP *Release of Results Policy* NSWHP_PD_016, NSWHP *Research Data Management Procedure* NSWHP_PR_076 and NSWHP *Responding to Subpoenas Procedure* NSWHP_PR_074).

4. Definitions

Access Request Form means the request form produced by NSWHP and to be completed by researchers requesting Tissue (with or without associated data and services), as updated from time to time and currently available at https://pathology.health.nsw.gov.au/research/research-services/research-access-requests/.

AP Tissue means Tissue created and/or used by NSWHP's Anatomical Pathology laboratories for a Primary Purpose. This includes Tissue from surgical resections, biopsies, and cytology samples, and retained in various forms including slides, formalin fixed paraffin embedded (FFPE) blocks and other forms. For the purposes of this Policy it does not include Tissue removed during an autopsy (whether coronial or non-coronial).

Clinical trial means any investigation in human subjects intended to discover or verify the clinical, pharmacological and/or other pharmacodynamics effects of an investigational product/s, and/or to identify any adverse reactions to an investigational product/s, and/or to study absorption, distribution, metabolism, and excretion of an investigational product/s with the objective of ascertaining its safety or efficacy. The terms clinical trial and clinical study are synonymous.

FFPE means formalin-fixed paraffin-embedded.

In Kind means a contribution of a good or a service other than money.

HREC means Human Research Ethics Committee.

IATA means International Air Transport Association.

MTA means Material Transfer Agreement.

NATA means National Association of Testing Authorities, the approved accrediting agency for pathology accreditation.

National Statement means the publication entitled 'National Statement on Ethical Conduct in Research Involving Humans' issued by the National Health and Medical Research Council in accordance with the *National Health and Medical Research Council Act 1992* (Cth) and any supplementary notes published by the National Health and Medical Research Council.

NHMRC means the National Health and Medical Research Council.

NPAAC means the National Pathology Accreditation Advisory Council established under subsection 9(1) of the *National Health Act 1953* (Cth) and responsible for developing and maintaining the accreditation standards for Australian pathology laboratories.

Pathology accreditation standards means the mandatory standards that must be met by accredited pathology laboratories in Australia, that are developed and maintained by NPAAC and underpin the accreditation requirements specified in the *Health Insurance (Accredited Pathology Laboratories—Approval) Principles 2017* (Cth).

Primary Purpose means the "dominant purpose" for which Tissue is removed from the body of a person. Most often the dominant purpose will be to provide care, or an episode of care, in the form of a diagnostic pathological assessment and associated reporting of Tissue removed from the body of a person based on macroscopic and microscopic examination of the Tissue. Primary Purpose includes second opinions or reviews by another pathologist requested by the original reporting pathologist or a

member of the treating clinical team; or additional tests performed after the initial diagnostic report required for ongoing clinical care such as a clinically indicated molecular test accompanied by a request form, for non-pathologist determinable tests.

Quality Assurance (QA) or Quality Improvement (QI) means carrying out analyses or tests:

a) that are part of a program (including any quality assurance program, quality control program, audit or evaluation) to ensure, or improve, the quality of services carried out at or by a hospital, a forensic institution, a laboratory, an educational or research institution; or
b) that are necessary for the delivery of services or for the accreditation under any Act of services carried out at or by a hospital, a forensic institution, a laboratory, an educational or research institution. Such activities may include clinical audits, management of health services, teaching and training activities, incident and sentinel event monitoring and investigation, root cause analysis, peer review, morbidity and mortality review and other forms of audit.

Research means the creation of new knowledge and/or the use of existing knowledge in a new and creative way to generate new concepts, methodologies, inventions and understandings.

Research Governance Framework means the NSWHP *Research Governance Framework* NSWHP_CG_013 that is available in the NSWHP Policy Library and applies to all research at sites under the control of NSWHP or involving participants, data or Tissue accessed via NSWHP.

Secondary Purpose means the use of Tissue for a purpose other than the Primary Purpose and includes without limitation:

a) Research (e.g. for clinical trials or other research);
b) Requests made or authorised by the patient from whom the Tissue was removed where they are relocating interstate or overseas or seeking their own second opinion;
c) Management of laboratory services (e.g. Quality Assurance or Quality Improvement, quality control, audits) or teaching/training purposes;
d) Complying with legal requirements (such as a subpoena or court order);
e) Use directly related to the care of a person other than the patient from whom the Tissue was removed.

Secondary Purpose does not include uses covered by the definition of Primary Purpose.

Third Party means any person or any entity outside NSWHP, and includes other NSW Health agencies, research laboratories, universities, research institutes, other public or private pathology providers, Quality Assurance Program providers and patients**.**

Tissue includes an organ, or part, of a human body and a substance extracted from, or from a part of, the human body.

5. General Principles

5.1 General Principles apply in addition to specific requirements

5.1.1 The general principles set out in Section 5.2 apply to all requests for release of AP Tissue for Secondary Purposes. Depending on the reason for the request, additional or more specific requirements are set out in section 6. Those additional or more specific requirements must also be met.

5.2 General Principles for Release of AP Tissue for Secondary Purposes

5.2.1 NSWHP is the custodian of AP Tissue held by its Anatomical Pathology laboratories following diagnostic testing conducted as part of an episode of care.

5.2.2 NSWHP supports the release of AP Tissue to a Third Party if the request meets all legal, ethical and regulatory (including accreditation) requirements. This includes but is not limited to the:

a) *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;
b) Pathology accreditation standards, including NPAAC *Requirements for the Retention of Laboratory Records and Diagnostic Material* (Ninth Edition 2022) which provides the minimum standards which pathology laboratories in Australia must comply with in order to maintain their accreditation; and
c) Various policies and standards regulating the use of Tissue for the purposes of research or quality assurance or control (as applicable).

5.2.3 All Third Party requests for release of AP Tissue for Secondary Purposes must be made in writing. This includes email or fax. If a verbal request from a Third Party is received, the caller is to be advised to provide the request in writing.

5.2.4 The NSWHP staff member receiving the written request shall clarify the purpose for which the release is being sought and satisfy themselves that the request is clear. Where the request is unclear, there is insufficient information provided by the requestor, or the staff member receiving the request has concerns about the request, clarification should be sought from the requestor and if concerns persist, the matter should be escalated to the relevant NSWHP approver or the NSWHP Legal team for advice.

5.2.5 All Third Party requests for release of AP Tissue for Secondary Purposes must be approved as follows:

a) Where the request is for the purposes of Research or QA/QI – by the Clinical Director or Local Pathology Director as required by the NSWHP Delegations Manual;
b) Where the request is for a Secondary Purpose other than Research or QA/QI - by a NSWHP Anatomical Pathologist.

Before approving the request, the relevant NSWHP approver should ensure that the other requirements specified or referred to in this Policy are met (including the General Requirements in this section and the specific requirements applicable to the type of request, per section 6).

5.2.6 For Third Party requests to access AP Tissue for Secondary Purposes, informed consent from the patient from whom the AP Tissue was removed is generally required for the use of the Tissue and should be obtained in accordance with the NSW Health Policy Directive_Organ and Tissue Donation, Use and Retention (PD2022_035). Consent can also be obtained from the Senior available next of kin (or their delegate) where the AP Tissue relates to a child or a deceased person, or the person responsible for the patient under Part 5 of the *Guardianship Act 1987* (NSW). In a limited number of circumstances consent is not required e.g. where AP Tissue is required to be provided by a subpoena or other court order; use of small samples of AP Tissue for QA purposes (e.g. scientific control material); or use of small samples of AP Tissue, in the form of blocks or slides, for Research where the HREC has specifically granted a waiver of

consent and NSWHP has other sufficient stores of AP Tissue to ensure it can comply with future testing and Pathology accreditation standards – refer to section 5.2.8).

5.2.7 Where consent by or on behalf of a patient to the use of AP Tissue for Secondary Purposes is required, and there is suspicion about the legitimacy of the request, or identity or authority of an individual making a request, additional documentation to verify identity or authority of requestor/patient should be obtained. Proof of identity can be obtained by sighting an original or certified photocopy of drivers' license, Australian passport or two other ID documents bearing patient name, date of birth and signature. Proof of authority for a Senior next of kin (or their delegate) or person responsible for a patient under Part 5 of the *Guardianship Act* can be obtained via a signed statutory declaration from the requestor that he/she is legal guardian of the minor, or is next of kin of deceased, etc. or a certified copy of the guardianship appointment document (if applicable).

5.2.8 NSWHP has a duty of care to its patients including the protection and appropriate use of their Tissue. NSWHP strongly favours the retention of original AP Tissue slides and at least one original diagnostic AP Tissue block per patient episode to ensure sufficient AP Tissue is available for future testing as part of clinical treatment, as well as to ensure NSWHP meets the Pathology accreditation standards. Accordingly, **subject to the other requirements in this Policy having been met**:

a) 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; and
   - If AP Tissue slides and/or scrolls are insufficient for the proposed Secondary Purpose, and the request is for a Secondary Purpose that informs treatment of the patient (such as a clinical trial in which the patient is enrolled), NSWHP will not release the Tissue block without 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 Tissue block if the request is for a Secondary Purpose that does not inform treatment of the patient.

b) If more than a single AP Tissue block per patient episode is available, NSWHP will consider the release of the Tissue block, slides and/or scrolls in accordance with the other requirements of this Policy.

c) In general, NSWHP will not release original AP Tissue slides used for diagnosis for Secondary Purposes, except where necessary for the ongoing care and treatment of the patient from whom the Tissue was removed.

5.2.9 Any release of AP Tissue to a Third Party must be covered by appropriate documentation which records the transfer of possession. The form of documentation will vary depending on the purpose of the request – refer to the specific requirements detailed in section 6 for further guidance.

5.2.10 All documentation must require the recipient to return to NSWHP any AP Tissue that is in the form of a block or original stained diagnostic slides in a timely manner, unless alternative arrangements have been agreed by NSWHP (for instance where the patient is relocating permanently overseas). For AP Tissue that is in other forms (i.e. that is not a block or original stained diagnostic slides) the documentation must require the recipient to dispose of the Tissue

in accordance with the *Public Health Regulation 2022* (NSW) and HREC approval requirements (if applicable) once it is no longer required for the approved Secondary Purpose.

5.2.11 For AP Tissue that is in the form of a block or original stained diagnostic slides, the identifiable information must be retained on the block or slide and cannot be removed. Identification labels on AP Tissue blocks or original slides can be covered for patient confidentiality purposes so long as removal of the cover on return to NSWHP will not damage the original label.

5.2.12 Under no circumstances will NSWHP approve the sale or supply of AP Tissue in conflict with section 32 of the *Human Tissue Act*.

5.2.13 NSWHP reserves the right to charge the recipient for costs associated with the retrieval, data entry/handling and transport of AP Tissue where use for a Secondary Purpose is approved.

6. Specific Scenarios

6.1 Requests for AP Tissue for a Clinical Trial or Other Research Study

6.1.1 Where possible NSWHP will support Third Party requests to access AP Tissue for the purpose of ethically approved Research (including clinical trials). Such requests must be managed in accordance with the *Human Tissue Act*, *Health Records and Information Privacy Act 2002* (NSW), NSWHP *Research Governance Framework* and associated NSW Health policies (including PD2022_035 *Organ and Tissue Donation, Use and Retention* and GL2023_008 *Use of Human Tissue for Research*).

6.1.2 Consistent with the NSWHP Research Governance Framework:

a) For research projects that involve the conduct of research activities by NSWHP investigators *in addition to* the supply of AP Tissue - a site-specific assessment/site approval (SSA/STE) application will need to be submitted through NSW Health's Research Ethics and Governance Information System (REGIS). For further information please see NSWHP Research Governance Procedure (NSWHP_PR_049) or contact NSWPath-RGO@health.nsw.gov.au.

b) For research projects that do not involve the conduct of research activities by NSWHP investigators and only require support from NSWHP in the form of supply of AP Tissue – a SSA/STE is not required. However, an Access Request Form must be completed and submitted to NSWHP.

6.1.3 In both cases, NSWHP will ensure that appropriate due diligence is conducted before the request is sent to the relevant NSWHP delegate (Clinical Director or Local Pathology Director) for approval, including that all legislative, ethical and regulatory requirements have been met and that an appropriate agreement is entered into with the recipient (refer in particular to sections 4.1, 4.2 and 4.6 of the NSWHP Research Governance Framework).

6.1.4 Consistent with section 5.2.6, release of AP Tissue for Research typically requires patient consent. However, in limited circumstances consent may be not required, including where a HREC has granted a waiver of consent per Chapter 2.3 of National Statement and the use is of small samples of AP Tissue in the form of slides or FFPE tissue blocks or part thereof (though note the comments in the following paragraph indicating that consent may still be required for other reasons).

6.1.5 If a Third Party is requesting access to AP Tissue for the purpose of Research, then regardless of ethical approval, as Tissue custodian NSWHP holds the final authority to approve the use of the Tissue. The General Principles for release of Tissue outlined in section 5.2 must be adhered to. In relation to patient consent, this may mean that consent is required even where a HREC has granted a waiver, for instance:

- where the AP Tissue requested is more than a small quantity or is not in the form of a block or slide - in these circumstances consent would still be required under the *Human Tissue Act*; and/or
- where releasing the AP Tissue could adversely impact the patient's current or future testing needs or NSWHP's ability to comply with Pathology accreditation standards – informed consent will be required; refer to section 5.2.8; and/or
- where the request is for a whole AP Tissue Block or original diagnostic slides – as discussed at section 6.1.7, identifiable information must be retained on this material, and so informed consent will be required.

6.1.6 In addition, NSWHP will only supply AP Tissue to a Third Party located overseas for Research purposes if:

a) The patient has consented, as part of the informed consent process, to the Tissue being transferred to the overseas recipient and the purposes for which the Tissue will be transferred; and
b) The overseas recipient operates within a jurisdiction that has equivalent legal protections in relation to the use of Tissue and personal information.

Further advice from NSWHP Legal should be sought where required.

6.1.7 Consistent with section 5.2.8, NSWHP is generally unable to release original stained diagnostic slides for Research purposes. If a Third Party requests access to AP Tissue blocks for Research purposes, the identifiable information must be retained on the block and cannot be removed. Under no circumstances can AP Tissue blocks be released as unidentified. The agreement entered into by NSWHP with the recipient Third Party will require the recipient to return the blocks to NSWHP in a timely manner. Identification labels can be covered for patient confidentiality purposes so long as removal of the cover on return to NSWHP will not damage the original label.

6.1.8 If a Third Party requests access to AP Tissue derivatives (e.g. recut scrolls or slides) other than Tissue blocks, the Tissue can be de-identified where the key for re-identification is managed in line with legislative requirements for privacy and security, and the Tissue remains traceable by NSWHP. The agreement entered into by NSWHP with the recipient Third Party will require the Third Party to dispose of the Tissue in accordance with the *Public Health Regulation 2022* (NSW) and HREC approval requirements once it is no longer required for the approved Research.

6.2 Requests to Store Tissue in Biobanks for Research Purposes

6.2.1 Requests by Third Parties for AP Tissue for biobanking purposes will be managed by NSWHP consistent with section 6.1 and the Biobanking Principles published on NSWHP's website.

6.3 Requests for Transfer of AP Tissue from Patient Relocating Overseas or Interstate

6.3.1 NSWHP understands that a patient relocating overseas or interstate, may seek to have AP Tissue that was removed from their body transferred to the new location for ongoing clinical care and management. NSWHP supports the transfer of AP Tissue overseas or interstate where necessary for the patient's ongoing care and management, provided the request is made in writing and accompanied by a written consent from the patient from whom the Tissue was removed, or their Senior available next of kin or delegate or authorised guardian. The consent must specify the purpose for which the AP Tissue is to be used.

6.3.2 NSWHP does not take responsibility for the transfer of AP Tissue overseas or interstate. NSWHP may assist with appropriate packaging and transport of material, including laboratory to laboratory transfer if required, however the patient or their Senior available next of kin (or delegate) or authorised guardian must take responsibility for their AP Tissue. NSWHP will do its best to ensure the Tissue is appropriately packaged to IATA requirements and NPAAC requirements. NSWHP is not obliged to cover the cost of transport.

6.3.3 Per section 6 of the NSW Health Policy Directive *Organ and Tissue Donation, Use and Retention* (PD2022_035), NSWHP will return custodianship rights to the patient for release overseas or interstate under an *Authorisation and Release of Human Tissue to a Patient or senior available next of kin* form (SMR020033), signed by the Clinical Director or Local Pathology Director, with acknowledgement from the reporting pathologist. (SMR020033 can be ordered through the online portal of Finsbury Green, the NSW Health statewide printing provider, or by contacting the relevant NSWHP Senior Operations Manager). As required by section 6 of PD2022_035, NSWHP will provide a copy of the form and a letter certifying that the person is travelling with Tissue in their possession (refer to Appendix A for example letter).

6.3.4 NSWHP will not require the return of AP Tissue released to or at the request of the patient if they are permanently relocating overseas or interstate. However, NSWHP will require the return of AP Tissue back once the patient has returned if only travelling for short-term treatment.

6.4 Requests for Second Opinions from the Patient

6.4.1 A patient may request access to AP Tissue to obtain a second opinion. Requests for second opinions are only considered a Secondary Purpose if they do not come from the reporting pathologist or a member of the treating clinical team. (Requests from referring clinicians or a member of the treating clinical team for second opinions is directly related to the Primary Purpose as it is presumed this relates to primary patient care).

6.4.2 NSWHP supports the transfer of AP Tissue for a patient-requested second opinion, provided the request is made in writing and accompanied by a written consent from the patient from whom the Tissue was removed, or their Senior available next of kin (or delegate) or authorised guardian.

6.4.3 For these requests, NSWHP will retrieve the AP Tissue and transport it by secure method directly to the organisation providing the second opinion subject to a cover letter which includes requirements for:

a) Return of all slides and any other residual AP Tissue to NSWHP within a nominated timeframe; and
b) Provision of a copy of the second opinion report to NSWHP.

6.4.4 Approval for the provision of AP Tissue must be made by the reporting pathologist, Clinical Director or Local Pathology Director. Details of the release and return of the Tissue must be recorded in the Laboratory Information Management System.

6.5 Requests to return AP Tissue to patient for disposal

6.5.1 Requests by a patient (or their Senior next of kin or delegate or authorised guardian) to take AP Tissue home to dispose of it once it is no longer required for the purposes of future care and treatment or Pathology accreditation standards will be managed in accordance with section 6 of the NSW Health Policy Directive Organ and Tissue Donation, Use and Retention (PD2022_035).

6.5.2 The request will be assessed by the Clinical Director or Local Pathology Director and, if approved, the form *Authorisation for the release of human tissue to a patient or senior available next of kin* (SMR020033) will be completed and signed by the Clinical Director or Local Pathology Director, with acknowledgement from the reporting pathologist (refer to section 6.3.3 for details on accessing the form). A copy of the form and a letter certifying that the person is travelling with human tissue in their possession (refer to Appendix A for example letter) must accompany the person with the Tissue. It must be made clear to the person who receives the Tissue that they are responsible for the safe and secure storage, or disposal, of the transferred Tissue.

6.5.3 Tissue returned to the patient/senior available next of kin or their delegate for appropriate storage or disposal will be triple packed as required by the NPAAC Guidelines.

6.5.4 If the organ and/or tissue to be returned is from a deceased person, the senior available next of kin is to be asked to provide copies of appropriate identification for documentation.

6.6 Requests for Supply of AP Tissue for Service Delivery, Quality Assurance, Training or Teaching Purposes

6.6.1 Under the *Human Tissue Act*, small samples of AP Tissue in the form of slides, block/s or parts of a tissue block (e.g. core biopsy from a FFPE block for control material) can be used by Third Parties for the following purposes without patient consent:

a) the delivery of services carried out at or by, or the accreditation of, a hospital, a forensic institution, a laboratory, an educational or research institution;
b) part of a program (including any QA program, quality control program, audit or evaluation) to ensure or improve the quality of services carried out at or by a hospital, a forensic institution, a laboratory, an educational or research institution or
c) medical or scientific training or teaching purposes (and not for research).

However, as custodian of the AP Tissue, NSWHP holds the final authority to approve the use of the Tissue. As such, consent may still be required for other reasons – refer to the discussion at sections 6.1.5 - 6.1.6, which also applies to release of AP Tissue for the purpose of service delivery, Quality Assurance, audits and evaluations, teaching or training.

6.6.2 Third Party requests to access NSWHP Tissue for the purpose of service delivery, Quality Assurance, audits and evaluations, teaching or training should be made via an Access Request Form completed and submitted to NSWHP's Research Office (see https://pathology.health.nsw.gov.au/research/research-services/research-access-requests/.)

6.6.3 Consistent with the NSWHP Research Governance Framework and NSWHP's Delegations Manual, use of AP Tissue by Third Parties for the purpose of service delivery, Quality Assurance, audits and evaluations, teaching or training must be approved by the local Clinical Director or Local Pathology Director, and be subject to a Material Transfer Agreement or similar document detailing the conditions on use of the Tissue and any requirement for the Tissue to be returned to NSWHP for storage if necessary in order to comply with Pathology accreditation standards (refer to section 5.2.10). The Clinical Director or Local Pathology Director should seek advice from NSWHP Legal on an appropriate form of agreement or other documentation where necessary.

6.6.4 NSWHP may request evidence of a Quality Improvement determination in cases where the application outlines potential ethical risks, consistent with the NSW Health *Human Research Ethics Committees - Quality Improvement & Ethical Review: A Practice Guide for NSW GL2007_020*.

6.6.5 If services are required to support the Third Party access to Tissue, the request should be submitted to a NSWHP Research Service Coordinator for a quote. For further information go to https://www.pathology.health.nsw.gov.au/research-and-innovation/research-services .

6.7 Requests for Supply of Tissue as Required by Law

6.7.1 NSWHP must comply with Third Party requests for AP Tissue required by law (including, but not limited to, subpoenas or court orders). Refer to the NSWHP *Responding to Subpoenas and other lawful requests for Materials Procedure* NSWHP_PR_074.

6.8 Requests for Supply of Tissue for Clinical Care of a Person Other than the Original Patient

6.8.1 Where possible NSWHP endeavours to support requests, from persons other than the patient from whom Tissue was removed, for access to AP Tissue where this access may be important for their clinical care. For instance, where the purpose of the request is to guide decisions regarding clinical treatment of living family members (e.g. for investigation of a familial cancer syndrome).

6.8.2 All requests for supply of AP Tissue for clinical care of a person other than the original patient must be made to, and under the approval of, the relevant Clinical Director. The Clinical Director should obtain advice from NSWHP Legal before approving the request.

6.8.3 In cases where the original patient is still alive, their written consent to the release of their AP Tissue for the specified purpose will be required.

6.8.4 In cases where a living family member requests access to AP Tissue of a deceased family member, the request must be accompanied by a written request from a clinical specialist (such as a familial cancer specialists) and written consent from the senior available next of kin (or delegate) of the deceased person.

7. Roles and Responsibilities

The following is a summary of the roles and responsibility of NSWHP in relation to effective Tissue release processes (in accordance with the NSWHP Delegation Manual).

Role	Responsibilities
Chief Executive	Approval of certain agreements such as material transfer agreements, service or collaboration agreements (incl. termination and/or variation), valued (cash and in-kind) between $500,000 and $5,000,000, subject to approval of supply of Tissue for the purposes of research or quality improvement/assurance/control by the AP Clinical Directors or Local Pathology Director.
Director, Clinical Operations	Approval of certain written agreements such as material transfer agreements, service or collaboration agreements (incl. termination and/or variation), valued (cash and in-kind) between $250,000 and $500,000, or agreements that are statewide, subject to approval of supply of Tissue for the purposes of research or quality improvement/assurance/control by the relevant Anatomical Pathology Clinical Director or Local Pathology Director.
Operations Directors	Review and sign-off of local written agreements such as material transfer agreement, service or collaboration agreements (incl. termination and/or variation), valued (cash and in-kind) between $30,000 and $250,000, subject to approval of supply of Tissue for the purposes of research or quality improvement/assurance/control by the AP Clinical Director or Local Pathology Director.
Anatomical Pathology Clinical Directors or Local Pathology Director	• Approve the use and supply of biospecimens (held under local custodianship) for Secondary Purposes in accordance with this Policy. • Review and sign-off local written agreements such as material transfer agreements, service or collaboration agreements (incl. termination and/or variation), up to the total value (cash and in-kind) of $30,000. • Review and sign-off send-away material requests; • Sign the 'Authorisation for the release of human tissue to a patient or senior available next of kin' (SMR020033) • Sign the letter certifying that the person is travelling with human tissue in their possession (refer Appendix A for example letter)
Anatomical Pathology Laboratory Managers/Operations Managers	• Review applications to access and use NSWHP biospecimens, ensuring laboratory staff are able to conduct services; • Provide feedback to Research Coordinators and/or Anatomical Pathology Clinical Directors/Local Pathology Directors.

Role	Responsibilities
Research Coordinators	• Receive Third-Party requests; and • Liaise with Anatomical Pathology Laboratory/Operations Managers and/or Clinical Directors/Local Pathology Directors to discuss Third Party access requests; • Coordinate the provision of a quote for Third Party requests (if required) using NSWHP Statewide Pricing Model under guidance from local Clinical Directors; • Develop written agreements such as material transfer agreements and service agreements; • Ensuring appropriate account is setup by Finance and invoicing of services, based on written agreement.
Research Strategy Lead	• Develop collaboration agreements.
Research Governance Lead	• Coordinate the approval of SSAs

8. Legal and Policy Framework

International Guideline

- WMA Declaration of Helsinki – Ethical Principles for Medical Research involving Human Subjects

Commonwealth Acts, Regulations and Guidelines

- Civil Aviation Act 1988;
- Civil Aviation Safety Regulations 1998, part 92 – Consignment and carriage of dangerous goods by air (including part 92 advisory documents)
- Biosecurity Act 2015
- Gene Technology Amendment Act 2007
- Health Insurance (Accredited Pathology Laboratories—Approval) Principles 2017
- International Air Transport Association Dangerous Goods Regulations (IATA DGRs);
- National Pathology Accreditation Advisory Council's (NPAAC) 'Requirements for the retention of laboratory records and diagnostic material *(Ninth Edition 2022)'*
- NHMRC Australian Code for the Responsible Conduct of Research 2018
- NHMRC Ethical considerations in quality assurance and evaluation activities

NSW Government Acts and Regulations

- Dangerous Goods (Road and Rail Transport) Act 2008 No 95
- Dangerous Goods (Road and Rail Transport) Regulation 2014
- Health Administration Act 1982
- Guardianship Act 1987
- Health Records and Information Privacy Act 2002
- Health Records and Information Privacy Regulation 2012
- Human Tissue Act 1983
- Information and Privacy Commission Information and Privacy Commission Statutory Guidelines on Research
- Privacy and Personal Information Protection Act 1998
- Public Health Regulation 2022
- SafeWork NSW Guideline Cytotoxic Drugs and Related Waste – Risk Management
- State Records Act 1998
- State Records General Retention and Disposal Authority – Health Services, Public: Patient/Client records (GDA17) (2019)

NSW Health Policies

- NSW Health Organ and Tissue Donation, Use and Retention (PD2022_035)
- NSW Health Privacy Manual for Health Information
- NSW Health Research – Ethical and Scientific Review of Human Research in NSW Public Health Organisations (PD2010_055)
- NSW Health Research – Authorisation to Commence Human Research in NSW Public Health Organisations (PD2010_056)

NSW Health Guidelines

- NSW Health Human Research Ethics Committees - Quality Improvement & Ethical Review: A Practice Guide for NSW (GL2007_020)
- NSW Health Use of Human Tissue for Research (GL2023_008)
- NSW Health Operations Manual: Research Governance Officers (GL2010_015)
- NSW Health Research Governance in NSW Public Health Organisations (GL2011_001)

NSWHP Policies & Frameworks

- NSWHP Delegations Manual (NSWHP_CG_001)
- NSWHP Research Publication Authorship, Affiliation and Acknowledgement Policy (NSWHP_PD_026)
- NSWHP Research Governance Framework (NSWHP_CG_013)
- NSWHP Responding to Subpoenas and other lawful requests for Materials Procedure (NSWHP_PR_074).

9. Review

This policy will be reviewed by 31/12/2025.

10. Risk

Risk Statement	Compliance with this policy will ensure that NSWHP is aligning to best practices, meeting all auditing requirements and acting in the best interest of the public, thus reducing the likelihood of patient, legal or reputational harm.
Risk Category	Clinical Care and Patient Safety

11. Further Information

For further information, please contact:

Policy Contact Officer	Position: Anatomical Pathology Clinical Stream Lead
	Name: Professor Wendy Cooper
	Telephone: 9515 7458
	Email: wendy.cooper@health.nsw.gov.au

12. Version History

The approval and amendment history for this document must be listed in the following table.

Version No	Effective Date	Approved By	Approval Date	Procedure Author	Risk Rating	Sections Modified
1.0	10/11/2023	SLT	11/10/2023	AP Clinical Stream	Low (U)	Initial policy document

Appendix

Appendix A: Example of letter to be issued to person travelling with human tissue in their possession (on facility letterhead)

To whom it may concern,

This is to certify that _____ [Name of person authorised to travel with human tissue in their possession]

is travelling with human tissue in their possession. The tissue is sealed inside a container and there is no risk associated with transporting the tissue stored in this manner.

Person certifying the packaging of the tissue:

Name: _____

Designation: _____

Institution/Hospital: _____

Contact: _____

Signature of authorising person: _____ Date: ____/_____/____