Policy

Pathology Imaging

NSWHP_PD_013

1. Purpose

This policy outlines the requirements for all NSW Health Pathology staff involved in collecting, retaining, storing and sharing pathology images.

2. Background

Pathology images are taken for many purposes including documentation, diagnosis, clinical communication and multidisciplinary team meetings. De-identified pathology images are used for education and research including analogue and digital publication. Identified pathology images are necessary for clinical care purposes.

3. Scope

This policy is mandatory and applies to all NSW Health Pathology staff involved in using photography, 3D photogrammetry, video recordings of pathology specimens and images from non-coronial autopsies.

This policy does not apply to digital microscopy images used for diagnostic purposes, clinical images, intraoperative images, radiology, nuclear medicine, cardiology/vascular, endoscopy and foetal radiological images.

Privacy obligations do not apply to personal health information where the identity of a person is not reasonably ascertainable. Where the identity of a person is reasonably ascertainable, then privacy obligations apply.

4. Definitions

Clinical Image: Any image that forms part of a patient's health care record. A clinical image may be a photograph, video or audio recording. A clinical image may be of the patient's body, such as an injury, skin lesion or images taken during a therapeutic session. Privacy requirements are applicable to clinical images in the same way that they are applicable to any clinical record.

Consent: To give approval, assent or permission for something to happen or agreement to do something.

De-identified Image: An image that contains no unique information or features which would make it reasonably likely or possible for the patient to be identified. This excludes identification of the image by the patient themselves, the treating team or the staff in the pathology laboratory. De-identification is further detailed in the NSW Health Privacy Manual for the Health Information ("the Privacy Manual") and the Office of the Privacy Commissioner NSW Fact Sheet: Reasonably Ascertainable Identity.

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Electronic Information: Information that is electronically created, processed, held, maintained and transmitted by NSW Health Pathology or other government or private entities.

Identified Image: Any image where a patient's identity can be ascertained or revealed.

Pathology Image: A photograph of macroscopic or microscopic specimens or video recording of any specimen. Included in this definition are macroscopic and microscopic images, photographs of tissue, blood or fluids, photographs of blocks and any type of slide, electron micrographs and photographs taken during a non-coronial autopsy.

Personal Health Information: Information which concerns: a person's health, medical history, past or future medical treatment; other personal information collected in the course of providing a health service; or information collected in the course of providing a health service.

Personal Storage Device: A personal device is a device which is not owned by a NSW Health Public Health Organisation. Examples of a personal mobile device include a phone, camera, iPad (or other tablet) or laptop computer.

Primary Purpose: The purpose for which the pathology image is collected. Pathology images are acquired for the purposes of pathology documentation and diagnosis.

Secondary Purpose: A secondary purpose is the use of pathology images for a purpose other than the primary purpose. This includes using and disclosing images for the purposes of:

a) Quality assurance
b) Multidisciplinary team meetings and other appropriate communications with clinical colleagues
c) Educating other pathologists, registrars, junior medical staff, medical students and scientific staff
d) Billing and
e) Performing research for example.

The health service may use or disclose information for a secondary purpose if this is covered by one of the exemptions listed in the Privacy Manual. Specifically this relates to:

i. Use or disclosure for a directly related purpose which would be "reasonably expected" by the individual. This applies in the circumstance where the images are released to other health care providers, used for communicating to clinical colleagues and multidisciplinary team meetings (Section 11.2.1) and

ii. Use or disclosure for management, training or research purposes. This applies to quality assurance, educating other pathologists, registrars, other junior medical staff, medical students and scientific staff and performing research (Section 11.2.2).

Unique (in the context of de-identification): Being the only one of its kind; unlike anything else; a person not otherwise aware of the patients identity, could reasonably infer the identity of the patient from which the specimen came.

5. Policy Statement

This policy outlines:

a) How health information can be used and disclosed without patient consent in the context of patient care

b) The circumstances when consent is required for the acquisition of pathology images

c) How to protect the patient/guardian/carer's right to know what use is made of the material

d) How staff can acquire images with confidence for the purposes of pathology documentation and diagnosis, clinical communication, multidisciplinary team meetings, education, quality assurance and research

e) How staff must store visual and audio-visual files appropriately

f) How the patient can be informed of the use of the pathology images if the need arises and

g) The appropriate use of pathology images to promote optimal clinical assessment and documentation, improve communication and continuity of care, facilitate health promotion and prevention and enhance clinical education and research.

5.1 Consent

a) Privacy law recognises that there are a range of circumstances when consent is not required to lawfully use or disclose information.

b) Patient consent is not required where the capturing of images is a necessary part of diagnosis or clinical care or treatment. The most important examples include where:

i. The health service is using or disclosing the information for the **primary purpose** for which it was collected. Refer to Section 11.1 of the Privacy Manual on the use and disclosure for the "primary purpose"

ii. The health service is using or disclosing the information for a **directly related secondary purpose**

iii. The patient would **reasonably expect** use or disclosure. Reliance on a "directly related purpose" depends on what the patient would expect to happen to his or her information. As such it is important to ensure information about how the health service uses and discloses information is readily available for patients. Refer to Section 7.4 of the Privacy Manual on informing individuals about what is collected (HPP 4) and Section 11.2 on the use and disclosure for a "secondary purpose"

iv. The health service is **lawfully authorised** or required to use or disclose the personal health information. Refer to Section 11.3 of the Privacy Manual use and disclosure authorised by law [HPPs 10(2) and 11(2)].

c) Pathology images are captured for:

i. **Primary Purpose**: Pathology documentation and diagnosis and

ii. **Secondary Purpose**: Quality assurance, communicating to clinical colleagues, educating other pathologists, registrars, junior medical staff, medical students and scientific staff and performing research.

d) Tissue itself is routinely kept, stored and used for the same purposes, as specimens, in blocks or as slides.

e) When consenting to a procedure that requires the removal of tissue, blood or fluids, and pathological examination consent is implied for the pathologist to examine, analyse, process and diagnose.

f) Photography of both macroscopic and microscopic findings is a routine process in pathological diagnosis that does not require patient consent.

g) Additional consent is currently not required for photography of pathology specimens, for either a primary or secondary purpose.

h) The NSW Health Privacy Leaflet for Patients explains to patients that their information may be held in a variety of ways within the NSW public health service. Most commonly, patient information may be held as a paper health record, and/or an electronic health record forming part of a secure computerised database. Some information may also be held in the form of an image including x-ray or photograph or as an audio or video recording.

5.1.1 Obtaining Consent

a) For any pathology image that is de-identified, and the use is for a primary or secondary purpose, additional patient consent is not required. Refer to Section 5.1.1 (d) of this policy if applicable.

b) For any pathology image where a persons' identity can be obtained or revealed (an identified image) and the use is for a secondary purpose that is not directly related to the primary purpose or, that does not fall under an exemption of Section 11.2.4 of the Privacy Manual, then additional consent may be obtained. Identified images are any image that includes:

   i. The persons/patients identifiers (name, date of birth, address, health care record number) appear in the pathology image itself. This may also include the persons/patients identifiers (name, date of birth, address, health care record number) appearing in the file names and digital stamps

   ii. Any part of the person/patients face appears in the image, which a person not knowing the identity of the patient could use to reasonably infer the identity

   iii. The person/patient has a tattoo or unique identifying feature in the image, which a person not knowing the identity of the patient could use to reasonably infer the identity or

   iv. The person/patient has a unique wound, scar, skin lesion or external body surface in the image which is sufficiently unique that a person not knowing the identity of the patient could use to reasonably infer the identity.

c) Wounds, scars, skin lesions and external surfaces of the body that are visible in the image must not be unique. Unique wounds, scars, skin lesions and external surfaces of the body require consent to be obtained.

d) The situation may arise where a de-identified pathology image is still so unique that a person not knowing the identity of the patient could reasonably infer the identity despite the precautions outlined above. If an image is so unique that patient identity is likely to be inferred despite precautions (for example pixilation and/or disguising clinical history), consent must be obtained.

e) The timing and location of an image may also contextualise and identify a patient and therefore consent must be obtained.

f) Personal health information is covered by privacy principles only until 30 years after a person has died.

g) In circumstances where identifiable images are required for a secondary purpose that is not related to the primary purpose of patient care, patient consent is required as follows:

   i. It must be explained to the patient, either verbally or preferably in written form, what the image depicts, where the image is to be sent (if it is to be distributed to a third party), where the image will be displayed, and what purpose the image is to be used for

   ii. The patient must sign to agree that they have consented

   iii. The consent must be in written form, with a copy kept in the patient's health care record, and a copy kept with their pathology request/report (either in paper form or electronically)

   iv. The patient's participation must be completely voluntary. Patients can choose not to participate at all

   v. Consent may be withdrawn by the patient in writing at any time in the future.

h) If the patient is unable to consent, is a minor or deceased, a senior next of kin, or guardian may consent on their behalf.

5.1.2 Managing Refusal and Withdrawal of Consent

a) Patients have the right to refuse any pathology image being taken. However the patient should be advised that in this circumstance there is no alternative method for documenting pathology other than with descriptive text and diagrams and this may compromise their treatment if images are needed later for review or to communicate information to treating clinicians. Refer to Section 11.2.1.3 of the Privacy Manual for further guidance on managing the use or disclosure of patient information when it is outside a patient's "reasonable expectation".

b) A patient may refuse to provide consent to have an identified image taken to be used for quality assurance, educating other pathologists, registrars, other junior medical staff, medical students and scientific staff and/or performing research.

c) Refusal or withdrawal of consent must be documented in the health care record and the supervising pathologist must be informed.

d) Consent can be withdrawn by the patient at any time.

5.2 Collection

a) A laboratory camera must be used to collect pathology images. The image must be transferred to an authorised laboratory information system. Refer to Section 9.2.2 of the Privacy Manual for further guidance.

5.3 Ownership and Copyright

a) Images, recordings and documentation produced by NSW Health Pathology staff in a NSW Health Pathology facility remain the property of NSW Health Pathology including those taken by visiting medical officers. They may also form part of the patient's health care record, like any other patient record.

b) Copyright of all recordings is owned by the Crown in right of the State of New South Wales through NSW Health Pathology.

5.4 Retention and Storage

a) Due to the volume of pathology images that are taken for primary and secondary purposes, data retention of the images is not required. The images may be deleted at any time providing that the block and slide are retained. However if the images are required for ongoing care or are central to a particular decision on treatment, data retention of these images must be maintained, stored on an authorised laboratory information system, indexed and easily accessible and retrievable.

b) All specimens of blood, tissue or fluids may be photographed during processing. Thus it is ordinarily not a requirement to specifically document whether a specimen has been photographed in the patients' health care record or pathology report.

c) Patients can request access to view the copies of their retained pathology images however the original images will not be released. In the case where the images have been deleted, they may request new images to be taken if possible.

d) In order to maintain the integrity of images, manipulation may be carried out to the whole image within the scope of accepted professional practice. The manipulation should be used to assist with clinical or educational interpretation. Examples of digital manipulation which are currently acceptable practice include, but are not limited to, cropping, adjustment of resolution, contrast and brightness, sharpness, correction of colour balance, vignetting, the image processing of 2D still photographs for the purposes of 3D photogrammetry, the addition of arrows, labels or clinically relevant markers and the digital removal of identifying features.

5.5 Disposal

a) Disposal of electronic health records must be in accordance with the General Retention and Disposal Authority – Health Services, Public: Patient/Client records (GDA17).

b) Authorised disposal of health records (images) should be done in such a way as to render them unreadable and leave them in a format from which they cannot be reconstructed in whole or in part.

c) Personal health information must be deleted from hardware including computer hard drives, printers and photocopiers before being recycled, disposed of or sent back to a leasing agent or contractor.

d) The hard disk drive should be removed from redundant personal computers. The contents should then be disposed of securely and safely.

5.6 Electronic Transmission

a) De-identified pathology images may be electronically transmitted for the purposes of education or research. Refer to Section 9.2.5 of the Privacy Manual for further guidance on the use of email.

5.7 Publication

a) De-identified pathology images may be electronically or physically published by a third party educational entity, space or site for the purposes of education or research.

b) In releasing any de-identified pathology images to third parties, NSW Pathology must require that the third party educational entity undertakes to ensure that images are stored securely such that they are only accessed for educational or research purposes in accordance with the *Health Records and Information Privacy Act 2002.*

c) Copyright of all material published in an academic journal or online is generally owned by the publishing company.

5.8 Research

a) The use of images obtained under this policy for research projects will generally be governed by the guidelines and approvals of the Local Health District Human Research Ethics Committee and the research requirements in the *Health Records and Information Privacy Act 2002* [Health Privacy Principles 10(1)(f) and 11(1)(f), in Schedule 1 of the Act].

5.9 Legal and Other Purposes

a) There are certain circumstances where use and/or disclosure of clinical images must occur as permitted by law, for example, subpoenas, warrants and court orders. Refer to the NSW Health Subpoenas Policy for further guidance.

b) The Executive Director, Clinical Governance and Quality must approve the release of any images on behalf of NSW Health Pathology.

6. Roles and Responsibilities

All NSW Health Pathology staff must, collect, retain, store and share pathology images in accordance with this policy and all other legislative and policy obligations.

7. Legal and Policy Framework

ACI NSW Agency for Clinical Innovation, *Guidelines for the Use of Telehealth for Clinical and Non Clinical Settings in NSW*, 2015

Australia and New Zealand Policing Advisory Agency, National Institute of Forensic Science Australia, *Guidelines for Digital Imaging Processes*, 2013

Australian Government, Australian Privacy Principles Guidelines

Australian Government, Research Council, National Statement on Ethical Conduct in Human Research (2007 – updated 2015)

Australian Medical Association Clinical Images and the Use of Personal Mobile Devices

General Retention and Disposal Authority – Health Services, Public: Patient/Client records (GDA17)

Health Records and Information Privacy Act 2002

Human Tissue Act 1983

NSW Government, State Archives & Records, General Retention and Disposal Authority, Health Services, Public: Patient/Client records (GDA17)

NSW Health Consent to Medical Treatment – Patient Information PD2005_406

NSW Health Electronic Information Security Policy PD2013_033

NSW Health Privacy Manual for Health Information

NSW Health Health Care Records – Documentation and Management Policy Directive PD2012_069

NSW Health Subpoenas Policy

Office of the Privacy Commissioner NSW Fact Sheet: Reasonably Ascertainable Identity

Privacy Act 1988

8. Review

This policy will be reviewed by 30 June 2019.

9. Risk

Risk Statement	This policy ensures that NSW Health Pathology staff effectively and efficiently manage the risk of data breaches caused by: • Accidental or malicious unauthorised access • Misuse, misappropriation and • Modification or destruction of information and information systems that may impact service delivery.
Risk Category	Clinical Care and Patient Safety

10. Further Information

For further information, please contact:

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For privacy matters including privacy complaints, please contact:

Privacy Contact Officer	Position: Privacy Contact Officer
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For further information on managing privacy obligations in NSW Health Pathology, please refer to the intranet.

11. 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	Risk Rating	Sections Modified
1.0	11/07/2017	Clinical Governance and Quality Committee	11/07/2017	Medium	New Policy.