



19 May 2020

[REDACTED]

Dear [REDACTED]

Re: OIA request – Human tissue for diagnostic purposes

Thank you for your Official Information Act request received 23 March 2020 seeking a copy of Waitematā DHB's best practice protocol for the archiving, storage or biobanking of human tissue for diagnostic purposes and other information about retention of tissue samples.

You requested the following information:

I am writing to request a copy of your best practice protocol for the archiving, storage or biobanking of human tissue for diagnostic purposes, whether they are formalin-fixed, paraffin-embedded or pathology slides and the standards, legislation or scientific evidence which provides the basis for our protocol.

Waitematā DHB's Surgical Pathology department is IANZ accredited and follows the National Pathology Accreditation Advisory Council (NPAAC) standards which state that blocks and slides must be kept for a minimum of 10 years with the exception of paediatric samples, which must be kept for 25 years. Paediatric samples are managed by Auckland DHB.

Tissue banking samples are kept indefinitely with the consent of the patient (at time of surgery). Patient specimens reported by the Surgical Pathology department are formalin-fixed, paraffin-embedded tissue samples and cover filmed pathology slides.

Please see **Attachment 1** - Retention of laboratory records and samples policy.

Is your DHB protocol-based on a universally adopted standard within New Zealand or has your DHB determined its own policy?

Waitematā DHB's policy aligns with the NPAAC standards, 'Requirements for the retention of laboratory records and diagnostic material (seventh edition 2018)'.

Explain the potential hazards of leaving formalin-fixed, paraffin-embedded or pathology slides in an unsecure, non-temperature and non-humidity regulated environment for two months over a New Zealand summer: say on an employee's desk which is open to the public and in a repurposed house adjacent to the hospital from mid-December to late February.

The surgical pathology department at Waitematā DHB is a secure facility which is accessible only via electronic swipe card. The laboratory, pathologist offices and archival areas are not accessible to the public at any time. The department operates according to the Privacy Act 1993 and local Waitematā DHB policies to safeguard against loss, misuse, or disclosure of personal and health information.

On production of the formalin-fixed, paraffin-embedded (FFPE) block, a pathology slide is generated. The slide is transported from the laboratory to the pathologist office for microscopic examination. These slides remain with the pathologist for the duration of the examination and often for a period of time after the report has been released.

Understandably, complex cases can often require a long period of evaluation; and may be subjected to ancillary testing and referrals to expert external consultants. Slides may also be retained for an extended period by the pathologist in instances where the case is to be discussed at a multidisciplinary meeting.

In the majority of cases, the blocks will remain in the laboratory area. However, there may be times when pathologists also request the blocks to accompany the slides to external sites for further opinion or as a result of a third party request. There is no adverse effect on the FFPE block if this request is made.

On conclusion of the case, the slides and blocks are returned to the laboratory where they are archived accordingly.

Both FFPE blocks and mounted slides are stored at ambient temperatures in a secure archival room. There are no specific temperature requirements for the storage of such materials.

Provide the name of the independent agency or agencies which provides oversight for your medical laboratory.

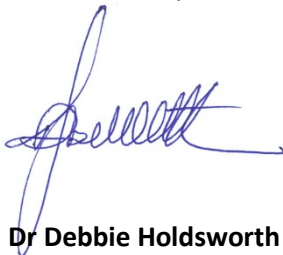
Waitematā DHB's laboratory is IANZ (International Accreditation of New Zealand) accredited. All laboratory staff members are governed by the New Zealand Medical Sciences Board and the pathologists are all Fellows of the Royal College of Pathologists of Australasia (RCPA).

I trust that this information is helpful.

Waitematā DHB supports the open disclosure of information to assist community understanding of how we are delivering publicly funded healthcare. This includes the proactive publication of anonymised Official Information Act responses on our website from 10 working days after they have been released.

If you consider there are good reasons why this response should not be made publicly available, we will be happy to consider your views.

Yours sincerely



Dr Debbie Holdsworth
Acting Director Hospital Services
Waitematā District Health Board

Retention of laboratory records and samples

The department is electronically secured with access available to authorised personnel only.

All records are secure, identifiable, and legible and stored in readily retrievable form. Electronic records may be stored in place of hard copies.

All records containing patient information requiring disposal are to be placed in confidential rubbish.

Retention Times are based on the NPAAC 2018 Guidelines, and local policy.

Reference	General	Minimum Retention Time	Storage	Disposal
NPAAC 2.1.2	Assessments <i>Systems, compliance, environment, quality</i> <i>Both internal and external</i>	4 years	Quality Manager, Medialab, IANZ	Destroy
NPAAC 2.1.2	Quality <i>MRM minutes, meeting minutes</i> <i>Quality Improvement projects</i> <i>Incident reports</i>	4 years	Quality Manager, Medialab, IANZ	Destroy
NPAAC 2.1.4	Operating Procedures	Retain historical versions	Medialab, Network Folder	
	EQA assessment records	4 years	Quality Manager, Medialab	Destroy
Local SPU Policy	Complaints and Actions	15 years	Unit Manager Office	Destroy
NPAAC 2.1.1	Personnel Records	Employment + 4 years	Personnel Files	Destroy
NPAAC 2.1.3	Equipment Maintenance Records	Life span of equipment + 4 years	Network Equipment Folder	Archive
Local SPU Policy	Accession Log Books	Indefinite	Cut Up, Cytology	
Local SPU Policy	Laboratory Workbooks	4 years	Cut Up	

Retention of laboratory records and samples

Reference	Specimen and Patient material	Minimum Retention Time	Storage	Disposal
NPAAC 2.1.5 NPAAC 2.2.3	Laboratory Request Forms and digital images of specimens	4 years	SPU Records Room	Destroy
NPAAC 2.2.1 Local SPU Policy	Reports, copy of original, or ability to reprint an original report	10 years 7 years from the age of majority for minors	1984-95; SPU Records Room 1995-1999 APS 27 10 1999-Present DAP	
NPAAC 2.2.4 Local SPU Policy	Paraffin blocks	10 years 7 years from the age of majority for minors	Retained indefinitely NSH blocks 1984-2017; Crown Storage 2017-Present; SPU Storage Room Medlab blocks 1995-1999; APS	
NPAAC 2.2.2	Histology Slides; sections of fixed tissue preserved in mounting medium	10 years	Slides prior to 2002; Destroyed 2003-2017; Crown Storage 2018-Present; SPU Storage Rooms	Discard
NPAAC 2.2.5	Frozen Section Slides Frozen section blocks processed to paraffin Residual tissue processed to paraffin	10 years	Slides prior to 2002; Destroyed 2003-2017; Crown Storage 2018-Present; SPU Storage Rooms Blocks retained indefinitely	

Retention of laboratory records and samples

Reference	Specimen and Patient material	Minimum Retention Time	Storage	Disposal
NPAAC 2.2.7	Wet Specimens	1 month from date of issue of report	Stored for 8 weeks post reporting in specimen filing room Wet specimens may be retained for a longer time period at the request of the reporting pathologist depending on complexity and reporting TAT.	Discard
NPAAC 2.2.7	Containers with no residual tissues	1 month from date of issue of report	Stored for 4 weeks in dated bags	Discard
NPAAC 2.2.2	Cytology Slides	10 years	1999-2009; Crown Storage 2010-Present; SPU storage room	
NPAAC 2.1.7	Cytology Specimens	7 days from receipt or 2 days after final report (whichever is longest)	Prep Room for 7 days	Discard
Reference	Bio-banking	Retention Time	Storage	
ARB MOH Guidelines for the use of Human Tissue for future unspecified research purposes 2007	Samples of specimens that have been consented for bio banking	Indefinitely at -80°C	Retained indefinitely at the WDHB Bio bank space permitting before transfer to ARB Auckland Regional Bio bank at Auckland University	