

Clinical : Laboratory Services
Proactive Release: 08 April 2020



23 March 2020

9(2)(a)

Email 9(2)(a)

Dear 9(2)(a)

Official Information Act (1982) Request

I write in response to your Official Information Act request, received by us on 11 March 2020. You requested the following information.

Request 1:

- I am writing to request a copy of the CMDHB 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 the CMDHB protocol.

Request 2:

- Is the CMDHB 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, is a standard which is universally adopted by all NZ DHB's and medical laboratories, or does each DHB or medical laboratory determine their own best practice?

Request 3:

- Please explain the potential hazards of leaving formalin fixed, paraffin embedded or pathology slides in an unsecure, non-temperature regulated environment (say a on an employee's desk outside of the laboratory) for 2 months.

Request 4:

- Please provide me with the name of the independent agency or agencies which provides oversight for medical laboratories in NZ.

Thank you for your assistance in this matter.

Please note, this request is for my information and is not a reflection upon the practices at CMDHB, but to ascertain if there is a universal standard within NZ. I will be making this same request to every DHB in NZ.

As context, Counties Manukau Health (CM Health) provides health and support services to people living in the Counties Manukau region (approx. 569,400 people). Our services are delivered via hospital, outpatient/ ambulatory and community-based models of care. We provide regional and supra-regional specialist services (for orthopaedics, plastics, burns and spinal services). There are also several

specialist services provided for our community via other metro Auckland DHBs, including tertiary surgical/ medical services, some mental health and addiction services.

Our responses to each of your questions are below.

Request 1:

- I am writing to request a copy of the CMDHB 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 the CMDHB protocol.

Retention of specimens/ blocks/ slides after diagnostic testing by CM Health Histology Laboratory is in accordance with the National Pathology Accreditation Advisory Council (NPAAC) Seventh Edition 2018 (**attached**). That publication defines the minimum retention times, and is used in Laboratories throughout New Zealand and Australia.

CM Health Laboratory: documented retention requirements:

| Department | Reference/Requirement | Actual Retention times | |
|---|--|--|---|
| | | ON SITE | ⁷ OFF SITE |
| HISTOLOGY & NGC | NPAAC Guidelines 2018 | | |
| ⁶ Reports/Records | Copy of original or ability to reprint 10 years ⁶ | ² Electronic - Indefinite from April 1993 | |
| Slides - Routine - FNA Cytology - Frozen section | 10 years ⁶ | 2 years Current year | 1974 to 2 year ago 1997 to last year |
| NGC & FNA Slides & Cell blocks | 10 years ⁶ | | |
| Blocks - all | 10 years ⁶ | 20 years (1 year on site) | back to 1956 |
| Containers with residual tissue | 1 month from reporting | 1 month post reporting | None |
| Unblocked wet tissue from specimens removed at surgery | 1 month from reporting | | |
| Containers with no residual tissue | 1 month from date report issued | 1 month post reporting | None |
| External QC - slides | | 10 years | |
| Request forms | GDA DA262 - 2.6/18 months | Current year | 1996 to last year |

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Where the report or specimen pertains to a paediatric patient retention should be 10 year, or 7 year from age of majority (18 year), whichever is the greater.

The CM Health Laboratory onsite storage is secure and within the Laboratory facilities. Off-site storage is at a secure facility.

Request 2:

- **Is the CMDHB 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, is a standard which is universally adopted by all NZ DHB's and medical laboratories, or does each DHB or medical laboratory determine their own best practice?**

The NPAAC requirements for the retention of diagnostic material noted above are used throughout New Zealand and Australia.

Request 3:

- **Please explain the potential hazards of leaving formalin fixed, paraffin embedded or pathology slides in an unsecure, non-temperature regulated environment (say a on an employee's desk outside of the laboratory) for 2 months.**

At the CM Health Laboratory, no employee in Histopathology has a work-desk outside of the secure purpose-built Laboratory facility. Paraffin blocks and slides are stable, and do not pose a hazard.

Request 4:

- **Please provide me with the name of the independent agency or agencies which provides oversight for medical laboratories in NZ.**

International Accreditation New Zealand (IANZ) assesses all NZ Medical Laboratories against the International Standard: *Medical laboratories – Requirements for quality and competence*, ISO 15189:2012.

I trust this information satisfactorily answers your query. If you are not satisfied with this response you are entitled to seek a review of the response by the Ombudsman under section 28(3) of the Official Information Act.

Please note that this response or an edited version of this may be published on the Counties Manukau DHB website.

Yours sincerely,



Fepulea'i Margie Apa
Chief Executive Officer
Counties Manukau Health

06 April 2020

9(2)(a)

E-mail: 9(2)(a)

Dear 9(2)(a)

Official Information Act (1982) Request

I write in response to your Official Information Act request, received by us on 23 March 2020. You requested the following information:

The Royal College of Pathologists Australasia has a policy titled "Provision of second opinions with particular reference to morphological examination", which addresses the best practice with regards to referral for second and subsequent opinion of pathology specimens.

Request 1:

- **I respectfully request your DHB's policy on Second Opinions requested by a third party who is a medical practitioner, currently involved in the medical care of the patient from whom the pathological material was originally obtained.**

Request 2:

- **In the event that your DHB deviates from the aforementioned RCPA policy, I request an explanation for why your DHB deviates from best practice.**

Please note, my request does not reflect the standard of care provided at your DHB, but is to ascertain whether there is consistent adherence to RCPA best practice amongst all NZ DHBs.

For context on our response, CM Health Services provide health and support services to more than 569,400 people residing in South Auckland, both in hospitals and community settings. Our services are delivered via hospital, outpatient/ ambulatory and community-based models of care. We also provide regional and supra-regional specialist services for Burns, Plastics and Orthopaedics. Some services are provided to our community by other DHBs for the entire Auckland region.

Our responses are below:

CM Health follows the Royal College of Pathologists Australasia policy "Provision of second opinions with particular reference to morphological examination" and the linked policies within that document.

For clarity, we provide the link to the document, which is publicly available:

- <https://www.rcpa.edu.au/Library/College-Policies/Policies/Provision-of-Second-and-Subsequent-Opinions-Histop>

I trust this information satisfactorily answers your query. If you are not satisfied with this response you are entitled to seek a review of the response by the Ombudsman under section 28(3) of the Official Information Act.

Please note that this response or an edited version of this may be published on the Counties Manukau DHB website.

Yours sincerely,

A handwritten signature in blue ink, appearing to read 'F. Apa', with a stylized flourish above the name.

Fepulea'i Margie Apa
Chief Executive Officer
Counties Manukau Health