

3 June 2020

Amy S Van Wey Lovatt

E mail: fyi-request-12508-476774c1@requests.fyi.org.nz>

Dear

Subject: Official Information Act request Re:

Thank you for your request for information under the Official Information Act received by Lakes DHB on 29 May 2020. You have asked:

Request 1:

I am writing to request a copy of the your DHB's 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 your DHB's protocol.

Request 2:

Is your DHB protocol for the archiving, storage, or biobanking of human tissue for diagnostic purposes, whether they are formalin fixed, paraffin embedded or pathology slides, based on a universally adopted standard within NZ or has your DHB determined its own policy.

Request 3:

Please explain the potential hazards of leaving formalin fixed, paraffin embedded or pathology slides in an unsecure, non-temperature and non-humidity regulated environment for 2 months over a NZ summer: say a 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.

Request 4:

Please provide me with the name of the independent agency or agencies which provides oversight for your medical laboratory.

Please see the following answer which has been provided by Lakes DHB's Laboratory provider Pathlab.

1-2) There is a standard for laboratories to meet regarding the handling of tissue sample. New Zealand Medical testing laboratories are required to comply with ISO 15189.2012 standards for clinical testing and the NPAAC guidelines for the storage and retention of tissue samples for diagnostic testing. We also abide by the Human Tissue act 1996 a NZ law. These are international standards, and a NZ law, and our policies and procedures are created in accordance with these standards. Our policies and procedures are documented and held in the laboratory.

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.

In terms of tissue integrity FFPET are quite stable as long as they are not in direct heat above 30C degrees for any length of time. The paraffin melts at high temperature and is not good for tissue or anyone's desk.

We are required to keep FFPET and slides for a minimum of 10 years so two months isn't a problem. Slides and FFPET are all auditable and traced i.e the laboratory must know where the slides and FFPET are and so as long as the case has been issued to a particular employee, if there is a reason for the case to be with them for two months it is ok.

Privacy and confidentiality are covered as the employee is bound by confidentiality as part of their employment contract and will have had the security of the patient samples/records explained to them.

We have policies and procedures on the security of samples and with working remotely becoming an issue security of patient information is discussed, a good reference point is the <https://www.rcpa.edu.au/Library/Practising-Pathology/NCRPQF/Docs/Guidelines-for-Digital-Microscopy-in-Anatomical-Pa> these standards are due for review and state the security of working using a digital system (in the lab or remotely).

For example- this is our check sheet in our manual for digital reporting.

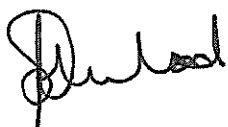
Privacy, Confidentiality and Security	Check
<p>The digital microscopy system must ensure the privacy, confidentiality and integrity of records is maintained at all times.</p> <p>The system must comply with national and state privacy regulations.</p> <p>Digital slide images may be embedded with patient metadata so digital slide images must be stored and displayed on devices that provide privacy features. Portable storage devices, such as USB sticks, etc. must also comply with all privacy and security requirements.</p> <p>Devices used to display digital slide images should be positioned so they cannot be seen by unauthorised people. This is especially important when using smartphones, tablets and other mobile devices for remote diagnosis.</p>	
<p>The digital microscopy system and supporting utilities should be secured and</p>	

<p>The digital microscopy system and supporting utilities should be secured and maintained, both on-site or if taken off-site.</p>	
<p>The digital microscopy system must incorporate reasonable measures to protect all images and case information from misuse, unauthorised access, modification and improper disclosure.</p> <p>The system must authenticate all access to information by verifying user access.</p> <p>Restricting access by multi-factor authentication including a passphrase is highly recommended.</p> <p>The system should provide a user-defined no activity timeout periods of less than 15 minutes.</p> <p>The system should have protection from malicious software (e.g. viruses, Trojans or worms).</p>	
<p>Other security considerations include:</p> <ul style="list-style-type: none"> - Ability to remotely disable or wipe devices; - Periodic purging of digital microscopy files and data from remote devices; - Logging and investigating all security breaches; - Internal audits of all devices. 	

4)The agency responsible for ensuring compliance for New Zealand entities is IANZ who inspect us against the ISO standard above.

Please note we may publish this letter and enclosed documents (with your personal information removed) on Lakes DHB's website.

Yours sincerely



Nick Saville-Wood
Chief Executive

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