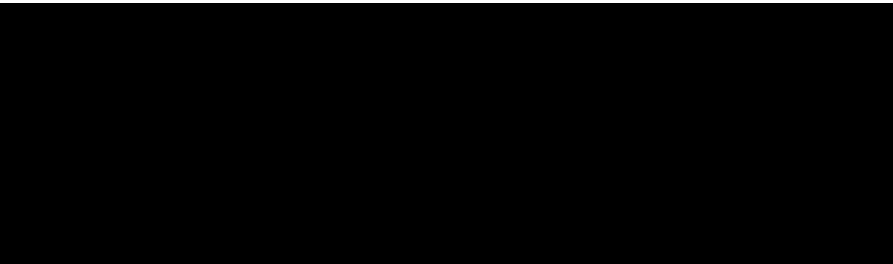


31 March 2020



**Re Official Information Request – Archiving, storage, bio-banking of human tissue for diagnostic purposes**

I refer to your official information request dated 11 March 2020 requesting the following information.

**Request 1:**

I am writing to request a copy of the ADHB 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 ADHB protocol.

**Request 2:**

Is the ADHB 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.**

You have requested a copy of the Auckland DHB best practice protocol for the archiving, storage, or bio-banking of human tissue for diagnostic purposes. We do not have a single policy that covers all best practice protocols; rather we refer to a number of local documents, guidelines and national legislation that govern our activities detailed in your request. I have attached a copy of the ADHB policy 'Body Parts & Tissue - Storage, Cremation and Return' for you to refer to. In addition to this I have attached a copy of the Human Tissue Act 2008 which was established to regulate activities concerning the removal, storage, use and disposal of human tissue. Locally the laboratory has developed a policy that details the retention of laboratory records and samples 'LPADMQASIN018 Retention of Laboratory Records / Samples'. This has also been attached for you to refer to.

Within the Anatomic Pathology documentation, and referenced in our retention document, we are guided by, and refer to, many standards and legislation including but not limited to:

1. DHB General Disposal Authority 2007 (Archives Act)
2. NPAAC Requirements for the Retention of Records and Diagnostic Material, Seventh Edition, (2018)
3. The Royal College of Pathologists (IBMS) – The Retention and storage of Pathological Records and Specimens, 5<sup>th</sup> Edition, (2015)
4. Human Tissue Act 2008

These documents have been attached for your review.

You have asked if the Auckland DHB documentation is based on a standard that has been universally adopted by all DHBs and Medical Laboratories. Unfortunately we are unable to offer advice or comment on the adoption of standards, legislation and guidance by other DHBs or laboratories in NZ.

You have asked us to explain the potential hazards of leaving formalin fixed, paraffin embedded blocks or pathology slides in an unsecure, non-temperature regulated environment. The retention and storage of slides and blocks is managed carefully within the Anatomic Pathology department. These would not be located outside the lab environment apart from within secure long term storage with our agreed off-site storage partner TiMG.

Finally, you have requested the name of the independent agent that governs the activities of Medical Laboratories. In New Zealand, IANZ operates as an accreditation authority by providing independent assessment of Medical Laboratories.

I trust this information answers your questions.

You are entitled to seek a review of the response by the Ombudsman under section 28(3) of the Official Information Act. Information about how to make a complaint is available at [www.ombudsman.parliament.nz](http://www.ombudsman.parliament.nz) or freephone 0800 802 602.

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

Yours faithfully



Ailsa Claire, OBE  
Chief Executive

