Use of Anatomical Pathology Specimens for Research

1 PURPOSE

The purpose of this policy is to outline the procedures to follow when a request has been made to use anatomical pathology specimens, currently held by the Pathology Queensland for research activities.

To ensure that Pathology Queensland complies with all legislative and accreditation requirements, as well as assisting in advancing knowledge through research.

2 SCOPE

This procedure shall apply to all Anatomical Pathology specimens held by Pathology Queensland.

3 DEFINITIONS

Anatomical Pathology specimens - include tissues, blocks and slides derived from surgical procedures, autopsies and cytopathology testing.

Research - includes work of direct relevance to the needs of commerce, industry, and to the public and voluntary sectors; scholarship; the invention and generation of ideas, images, performances, artefacts including design, where these lead to new or substantially improved insights; and the use of existing knowledge in experimental development to produce new or substantially improved materials, devices, products and processes, including design and construction. It excludes routine testing and routine analysis of materials, components and processes such as for the maintenance of national standards, as distinct from the development of new analytical techniques. It also excludes the development of teaching materials that do not embody original research.
(National Health and Medical Research Council. 2007, *National Statement on Ethical Conduct in Human Research*, p.7)

Human research - is conducted with or about people, or their data or tissue. Human participation in research is therefore to be understood broadly, to include the involvement of human beings through:

- taking part in surveys, interviews or focus groups;
- undergoing psychological, physiological or medical testing or treatment;
- being observed by researchers;
- researchers having access to their personal documents or other materials;
- the collection and use of their body organs, tissues or fluids (eg skin, blood, urine, saliva, hair, bones, tumour and other biopsy specimens) or their exhaled breath;

access to their information (in individually identifiable, re-identifiable or non-identifiable form) as part of an existing published or unpublished source or database.
(National Health and Medical Research Council. 2007, *National Statement on Ethical Conduct in Human Research*, p8.)

4 POLICY

Pathology Queensland has a commitment to fostering an environment that values and promotes research. However the guidelines, policies and legislations that govern the use and retention of Anatomical Pathology specimens must be met.

The Queensland Disposal Authority Number 614 *Qld Health (Pathology Laboratory Records) Retention and Disposal Schedule : QDAN 614 v.1,* sets out the legal retention times for Anatomical Pathology Samples, Slides and other related materials. In particular Histological Blocks, Slides and Cytopathological Slides must be kept for 20 years (and 20 years from the age of majority for Children)

Table 1. Qld Health Retention and Disposal Schedule

Reference	Description of Records	Status	Disposal Action
Anatomical Pathology			
2.1	**Laboratory Report Records** Pathology laboratory records relating to anatomical pathology reports of the analysis of samples/specimens, excluding autopsy report records. Includes reports and the analysis, calculations and observatiosn from which the result is derived, block keys, diagrams and representative images prepared.	Temporary	Retain for 20 years after date of reporting
2.2	**Slides** Slides of anatomical pathology specimens excluding immunofluorescence slides and autopsy specimens. Includes special stains	Temporary	Retain 20 years after date of collection / preparation
2.3	**Blocks** Blocks of anatomical pathology specimens excluding autopsy specimens	Temporary	Retain 20 years after date of collection / preparation
2.4	**Frozen Section Tissues** Paraffin blocks and frozen / paraffin sections of anatomical pathology specimens of frozen section tissues	Temporary	Retain 20 years after date of collection / preparation
2.5	Frozen Tissue Blocks Frozen tissue blocks of anatomical pathology specimens used for immunofluoescence studies	Temporary	Retains for 3 months after date of collection / preparation
Cytology			
3.1	**Laboratory Report Records** Pathology laboratory records relating to cytology reports of the analysis of samples / specimens. Includes reports and the analysis, calculations and observatiosn from which the result is derived, block keys, diagrams and representative images prepared.	Temporary	Retain for 20 years after date of reporting
3.2	**Exfoliative Cytology and FNA Specimens** Exfoliative cytology and fine needle aspirations (FNAs) cytology specimens including slides and cell blocks.	Temporary	Retain for 20 years after date of collection
3.3	**Gynaecological (Cervical) Cytology Slides** Slides of gynaecological (cervical) cytology specimens	Temporary	Retain for 14 years after date of collection

(Qld State Archives, 2006. *Qld Health Pathology Laboratory Records Retention and Disposal Schedule*)

Further guidance is provided by the Requirements for the Retention of Laboratory Records and Diagnostic Material (2007 edition) by the National Pathology Accreditation Advisory Council (NPAAC). This provides guidelines as to the minimum standards acceptable for good laboratory practice in relation to the holding of records.

Table 2**. Minimum** retention times for Anatomical Pathology

	Record/Material	**Minimum retention time**
Anatomical Pathology		
2.1	Slides: Sections of fixed tissue preserved in mounting medium Sections of unfixed tissue not in permanent mounting medium (including immunofluorescence slides)	 10 years for adults To age 25 years for children* 7 days from date of receipt or until 2 days after the date of the issue report (whichever is longer), under appropriate storage conditions and reliable retrieval
2.2	Blocks of tissue embedded in paraffin wax or any other permanent embedding medium	10 years for adults To age 25 years for children*
2.3	Specimens for intra-operative frozen section diagnosis: i) The original section(s) used for diagnosis, preserved in permanent mounting medium ii) Residual tissue from which the sections in (i) were prepared, embedded in paraffin iii) All other blocks of paraffin-embedded tissue from the same specimen or specimens from which tissue has been selected for frozen section examination	10 years
2.4	Frozen tissue blocks, including samples for immunofluorescence studies	1 month at -70°C or lower
2.5	i) Containers with no residual tissue ii) Unblocked tissue from specimens removed at surgery iii) Unblocked tissue from specimens retained at autopsy	1 month 1 month from date of issue of specimen report 3 months after autopsy unless a limitation is imposed, such as the need to reunite retained specimens with the body before a funeral has been stipulated by next-of-kin
2.6	Autopsy - register, report duplicate, blocks and slides, records of tissue and organ disposal	10 years for autopsy other than forensic or other medico-legal autopsy
2.7	Forensic and medico-legal	In accordance with jurisdiction requirement or 20 years if not specified.
Cytology		
4.1	Exfoliative cytology and fine needle aspirations (FNAs) including slides and cell blocks	10 years
4.2	Gynaecological (cervical) cytology slides	10 years
* This requirement to retain paediatric paraffin blocks and slides until the patient has reached 25 years of age effectively sets a **minimum** retention time of 25 years for **all** archived Anatomical Pathology material under the single combined archival process in place across Pathology Queensland. The NPAAC requirement to retain details of genetic testing indefinitely (100 years) may significantly extend future minimum retention periods for AP archival material.		

(NPAAC, 2007. *Requirements for the Retention of Laboratory Records and Diagnostic material*)

1. Research activities

Research activities are projects that Pathology Queensland has agreed to support either in-kind or financially. When a request has been made to utilise Anatomical Pathology specimens in a research activity, evidence must be provided that the project has been adequately approved and adheres to the relevant legislation as explained in the *Queensland Health Research Management Policy and Framework 2008*.

The following information must accompany any request;

- Ethics approval
  - Protocol
  - Ethics clearance letter and study amendments
  - For longitudinal studies, copies of periodic reports to ethics committees
  - Copies of the Informed Consent Forms and Patient Information Sheet

- Administrative
  - Evidence of administrative approval from Chief Executive Officer of Clinical and Statewide Services. If this has not been obtained, the researcher will need to contact the Research Project Officer, Clinical and Statewide Services. (Administrative approval requires information on ethics clearance, and evidence that the project follows legal, financial and risk assessment requirements, as outlined in the Queensland Health Research Management Policy).
  - Evidence of funding source
  - Dates for start and finish of project
  - A copy of the letter of approval to access confidential information under the provision of the *Public Health Act 2005*.

Once the request and evidence have been obtained, the Director of Pathology Queensland, along with the Director of the relevant Pathology Department will consider access to the Anatomical Pathology specimens. The Director of Pathology Queensland has the right to refuse access, particularly if the use of the tissues or blocks will severely deplete the specimen that is held within the Pathology Queensland laboratory. Appropriate cost recovery must also be determined by Pathology Queensland for AP archival material retrieval and related laboratory services.

The Director of Pathology Queensland and the local Anatomical Pathology Director will normally allow unstained slides to be taken of the relevant material for approved research projects, Circumstances where approved research projects seeking blocks may be granted temporarily release for offsite processing and return to Pathology Queensland are:

1] Where Pathology Queensland Pathologists and Health Professionals are part of the research team then, with the prior approval of the Local Anatomical Pathology Director, Blocks may be taken to the research venue for processing under the direct control and responsibility of the Pathologist/Health Professional.

2] Where the research is of national or international significance and where the Principal Researcher is known to be of good standing amongst Pathology Queensland's Senior Anatomical Pathology Management. In addition, they must also have a good track record in regard to the care and return of Blocks. With the prior approval of the Director of Pathology Queensland and the local Anatomical Pathology Director. Blocks may be released temporarily to the researchers within Australia (and only very rarely overseas) for processing and collection of relevant microarrays.

Under no circumstances will blocks be released for long term care or storage by any research group. All blocks will be tracked using existing AUSLAB procedures or other approved tracking software mechanism and it will be the responsibility of the local

Anatomical Pathology Director to ensure the blocks are returned in a timely fashion, generally within 6 – 12 weeks.

2. Fee-for-service activities

If the request for access to specimens is part of a fee-for-service activity, approval must be obtained from the Director of Pathology Queensland and the Business Manager. At no time can approval be provided by other staff.

The following information must accompany any request;

- Ethics Approval
  - Protocol
  - Ethics clearance letter and study amendments
  - For longitudinal studies, copies of periodic reports to ethics committees
  - Copies of the Informed Consent Form and Patient Information Sheet

- Administrative
  - Signed quote
  - Evidence of administrative approval from financial delegate and laboratory manager
  - Evidence of funding source
  - Dates for start and finish of project
  - A copy of the letter of approval to access confidential information under the provision of the *Public Health Act 2005*

Queensland Health reserves the right to refuse access, particularly if the use of the tissues or blocks will severely deplete the specimen that is held within the Pathology Queensland laboratory. Pathology Queensland also reserves the right to charge for time to access these specimens.

The Director of Pathology Queensland and the local Anatomical Pathology Director will normally allow unstained slides to be taken of the relevant material for approved research projects, Circumstances where approved research projects seeking blocks may be granted temporarily release for offsite processing and return to Pathology Queensland are:

1] Where Pathology Queensland Pathologists and Health Professionals are part of the research team then, with the prior approval of the Local Anatomical Pathology Director, Blocks may be taken to the research venue for processing under the direct control and responsibility of the Pathologist/Health Professional.

2] Where the research is of national or international significance and where the Principal Researcher is known to be of good standing amongst Pathology Queensland's Senior Anatomical Pathology Management. In addition, they must also have a good track record in regard to the care and return of Blocks. With the prior approval of the Director of Pathology Queensland and the local Anatomical Pathology Director, Blocks may be released temporarily to the researchers within Australia (and only very rarely overseas) for processing and collection of relevant microarrays.

3] Where the Blocks are for use as examination and learning material by the Royal College of Pathologists of Australasia and have been approved for such de-identified use by the CaSS Research Committee and the costs are covered by the Royal College of Pathologists of Australasia.

Under no circumstances will Blocks be released for long term care or storage by any research group. All blocks will be tracked using existing AUSLAB procedures or other approved tracking software mechanism and it will be the responsibility of the local Anatomical Pathology Director to ensure the blocks are returned in a timely fashion, generally within 6 – 12 weeks.

5 RECORDS

Nil.

6 ASSOCIATED DOCUMENTATION

Queensland Health Research Management Policy and Framework 2008
24718 Management of research applications by CaSS Research Committee

7 REFERENCES

National Pathology Accreditation Advisory Council, 2007. *Requirements for the Retention of Laboratory Records and Diagnostic Material*.

National Health and Medical Research Council, 2007. *National Statement on Ethical Conduct for Research*, Australian Government.

Qld State Archives, 2006. *Qld Health (Pathology Laboratory Records) Retention and Disposal Schedule : QDAN 614 v.1*, Queensland Government.

8 AMENDMENT HISTORY

Revision	Date	Author/s	Amendments
0	22 August 2006	Suzanne Cheshire	
1	Sept 2008	Kate Norman	Updated
1	Dec 2008	Suzanne Cheshire Alan Sutton	Updated NPAAC guidelines Clarified AP requirements
1	Dec 2008	QIS2 Migration Project	Document updated to the new template and Business references updated to reflect the new CaSS structure
2	May 2009	S Cheshire/ M Whiley	Amended to reflect restricted release of blocks