

Guideline

Subject: **Biobanking**
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Introduction

Biospecimen storage is fundamental to contemporary practice in diagnostic pathology. Pathologists are required to store biospecimens (principally as formalin-fixed paraffin embedded tissue blocks, although also as fresh tissue, genetic material, serum, cultures etc) regulated by NPAAC guidelines under NATA/RCPA scrutiny and State and Territory legislation. Guidelines also exist, with variable compliance, for biospecimens stored solely for research purposes through international professional bodies including the International Society for Biological and Environmental Repositories (ISBER).

Pathologists and pathology practices are central to patient multidisciplinary care and to research. The requirements of clinical care and the interests of researchers often overlap and the governance arrangements for the annotation, storage, access and use of biospecimens is critical to the management of this limited resource.

1. Ethics and Governance

In Australia, the law regulating the ownership, control and consent for use of human biospecimens and related clinical information varies between States. A Nationally consistent approach would support consistent diagnostic practice and facilitate research. A uniform consent process could allow for the future use of biospecimens for quality and research purposes as well as storage for future diagnostic purposes.

Where a stored biospecimen is available for use in research, pathology services should have a procedure for ensuring the research has been approved in accordance with the National Statement on Ethical Conduct in Human Research. The National Statement sets out specific guidelines regarding ethical review of proposed access to and use of biospecimens and associated personal information including pathways for low and non low-risk review. Pathology practices need to ensure that access is consistent with Federal and State legislation regarding privacy and human tissue.

Biobanks, as with all pathology practices, should have operational governance and quality assurance procedures for the collection, processing, storage, security, retrieval and transfer (including appropriate Material Transfer Agreement) of biospecimens and associated patient information. It is strongly recommended that a pathologist be appointed with responsibility for oversight of these procedures.

There must be clear ongoing operational governance arrangements for biobanks, including when there are laboratory mergers, changes of ownership or closures or when research funds are exhausted or National research collaborations cease.

2. Funding and Workforce issues

Biobanking is a costly activity that is not self-sustaining. Diagnostic biospecimen archive management including storage facilities, information technology, accreditation, specimen retrieval, ancillary processing and pathologist validation is a significant cost to health services. Historically long term storage of formalin-fixed, paraffin embedded tissue was funded from pathology service fees; however, the scale, complexity and cost of supplying the demands of health and medical research greatly exceeds the funding available. In addition most supplementary diagnostic testing of archival specimens is not funded in Australia. A proposal currently under consideration by the Medical Services Advisory Committee for Medicare funding of biospecimen retrieval for ancillary testing and/or second opinions may improve this situation if approved.

Biobanks external to pathology practices depend for funding on philanthropy, industry sponsored clinical trials government infrastructure grants, research grants and some service cost recovery. Where archival biospecimen retrieval, ancillary processing, pathologist review +/- supplementary testing is required for research purposes, the direct and indirect costs (including the administrative burden of storage facility searching, verifying consent and other documentation and data integrity) must be factored into the research funding model and be allocated to the entity that incurs those costs; be it a diagnostic pathology service or stand alone or networked biobanks. The funding model should include allocations for quality and accreditation of the facility and contingency funding for unexpected outcomes such as termination of the research or closure of the laboratory/biobank.

Well executed biobanking requires dedicated human resources including diagnostic pathologists, whose work is traditionally reimbursed via case-based episodes. Models for reimbursement of pathologist workload related to biobanking are essential. All pathology trainees should have access to relevant education and practical experience in biobanking. Health information and bioinformatics experts are integral to the set up and maintenance of biobanks. Ideally there would be a member of the pathology staff given managerial carriage of the biobanking function within the laboratory/ organisation organisational structure. Scientists trained in biobanking would take day-to-day responsibility for operational aspects of the biobank. This would be backed up by administrative staff and systems, appropriate governance and audit practices

3. Quality and Technical aspects

There should be accreditation processes for all biobanks aligned to diagnostic laboratory NPAAC standards and international standards. Stand alone biobanks should operate under an appropriate quality assurance and accreditation framework including external quality assurance program participation.

All biobanks (including diagnostic pathology archives) should have procedures for ensuring the quality and ongoing integrity of biospecimens and security associated patient information.

Factors requiring standardisation include:

- Data collection at the time of patient sampling
- Biospecimen sampling, processing and reporting
Procedures for Macroscopic cut-up of histopathology specimens (see RCPA Macroscopic Cut-up Manual), standardised units and terminology in pathology requesting and reporting (see RCPA PUTS and PITUS projects) and Structured reporting protocols (see RCPA Structured reporting protocols) should be used wherever possible. The pathologist is responsible for biospecimen sampling for patient care and

is in the best position to prioritise patient care and retention of biospecimens for future diagnostic or therapeutic purposes over research interests.

The uniform use of RCPA Structured Reporting protocols facilitates the collection of diagnostic information critical to the value of a banked biospecimen. The capture of critical diagnostic elements in discrete data fields for electronic transmission between diagnostic pathology laboratories and cancer registries as well as researchers reduces errors and saves time currently spent re-entering diagnostic information. The QUPP-funded PITUS project is aimed at developing data transmission standards to support this functionality.

- Biospecimen identification, transport and storage
Biospecimens should receive a unique identifier that is linked, preferably electronically, to the uniform diagnostic data set. The use of specimen tracking systems for transportation, location within the laboratory, archival storage and inventory management is strongly supported. Biospecimen transportation and storage environmental conditions should be continuously monitored and protected by alarm systems and back up and emergency procedures.

Pathology laboratories have ongoing problems with long term storage of biospecimens, mandated by NPAAC yet not specifically funded. Maintaining paraffin-embedded specimens in an appropriate environment is an increasingly costly exercise. The value of archived diagnostic biospecimens needs to be appreciated and appropriate provision made for their retention for future diagnostic use and research.

- Data management and security
The linkages to patient data (outlined above) should be managed via deidentification/reidentification programs to protect patient privacy.

Summary and Recommendations

1. Pathologists and pathology practices are best placed to guide the process of aligning biobanking with diagnostic laboratory services and research interests.
2. There should be appropriate governance arrangements and quality systems for pathology laboratory based and external biobanks including the involvement of pathologists in regulatory compliance and ethical conduct.
3. There should be National standards for all aspects of biobanking.
4. The RCPA should work with the peak representative bodies of health and medical researchers to secure sources of sustainable funding for biobanking.
5. Pathology trainees and pathologists should have access to relevant training in biobanking and a trained scientific and administrative workforce is necessary to operationally support biobanking activities.