**Guideline**

**Subject:** The Ethical and Legal Issues in Relation to the Use of Human Tissue and Test Results in Australia

**Approval Date:** October 2003, February 2010

**Review Date:** July 2014

**Review By:** BPPQ

**Number:** 4/2003

---

**Executive Summary**

**The Rights of the Patient.**

**Generally**

- Pathology services provided with respect for the patient’s autonomy and privacy.

**Specifically**

- Right to privacy. Privacy Act 1988 (Cth) as amended 2001
- Right to pathology services in accord with informed consent.
- Right to pathology services in accord with accepted standards. NATA / RCPA / NPAAC / Common Law?
- Right to results of pathology service. RCPA Guideline 2/2001 & Privacy Act (Cth) 1988

**The Obligations and Rights of the Pathologist.**

**Generally**

- Obligation to provide pathology services ethically. AMA Code of Ethics http://www.ama.com.au
- RCPA Policy Statements http://www.rcpa.edu.au
- Obligation to provide pathology services legally. Multitude of legislative and common law requirements.
- Obligation to provide pathology services in accord with accepted standards. NATA / RCPA / NPAAC / Common Law / Others.
- Right to retain and use tissue for diagnostic purposes, quality assurance, teaching and research subject to patient consent / HREC approval / NPAAC

**Specifically**

- Obligation to maintain patient privacy. Privacy Act (Cth) 1988 as amended 2001
- Obligation and right to retain results / health information. NATA / RCPA / NPAAC / Insurer requirements / Others.
- Obligation to disclose results / health information. RCPA Guideline 2/2001 & Privacy Act (Cth) 1988
• Obligation and right to retain and dispose of tissue. NATA / RCPA / NPAAC / Insurer
requirements / Others.
• Right to use tissue for quality assurance purposes. NPAAC
• Obligation to obtain HREC approval / patient consent for conducting research, teaching and
some quality assurance activities. NH&MRC

Guideline

The fundamental objective of the practice of pathology is to promote the welfare of patients in
terms of maintenance or restoration of health.

Fellows engaged in the practice of pathology should be guided by the same ethical
considerations as practitioners in other areas of medicine. For these purposes the college
follows the code of ethics of the Australian Medical Association.

In the ethical practice of pathology, special consideration must be given to the requirement for
technical competence, the pathologist’s relationship to other physicians and the pathologist’s
responsibility to the patient.

The underlying principles which suggest a priority in values for the pathologist are:

1. Integrity
2. Respect for persons
3. Beneficence
4. Justice

Integrity
Pathology is the medical speciality which most clearly demonstrates the scientific basis of
medicine. The conscientious practitioner will therefore maintain knowledge and technical
excellence and take responsibility for accuracy and honesty in the reporting of results in such a
way as to encourage the responsible use of such clinical information. This is the heart of the
service to patients.

Respect for persons
A guiding ethical principle for pathologists is respect for persons – respect for their welfare,
rights, beliefs, perceptions, customs and cultural heritage. This applies to patients, professional,
technical, operational and administrative staff as well as medical colleagues.

Beneficence
Beneficence requires that the skills of the pathologist as for all physicians be directed towards
the good of their patients and the avoidance of harm through the diagnostic procedures for
which they are responsible. It also includes issues of respect for the human body and body
parts as well as protection of privacy of individuals.

Justice
The principles of Natural Justice should be adopted in all interactions. This means that when
making a decision, the pathologist has to accumulate information on competing viewpoints
before making an even handed decision. The Pathologist often has to decide on a balance
between burdens and benefits and what is required by law or in the public interest.

Helpful checklists have been established for pathologists by the Royal College of Pathologists
(UK) www.repath.org/index.php

Page ID=9 (Good Medical Practice in Pathology) and the
The RCPA has developed a number of relevant policy statements in the area of professional ethics. (http://documents.rcpa.edu.au) These include:

1. Provision of Second Opinions with Particular Reference to Histopathology, Cytology and Specimens for Morphological Examination;
2. Guidelines for Pathology Service Providers and their Non-Medically Qualified Employees – Release of Results to Patients;
3. RCPA Human Tissue Workshop Principles and Guidelines;
4. Autopsies and the Use of Tissues Removed from Autopsies
5. Ethical Responsibilities of Pathologists in relation to Test Utility
6. Patenting Human Genes
7. Patient Consent for Observational Research
8. Privacy Principles
9. The Role of the Pathologist

A guiding principle with the use of tissue is that consent for autopsies and the intended disposal of organs and tissues at autopsy and surgery should occur in a way that recognises the autonomy of the next of kin or patient but also has regard to public benefit.

Research by Pathologists
Research falls into the category of procedures or processes carried out in addition to those that would normally be performed in the diagnostic process. For any procedure that could be recognised as research, (even the collation of already held data) consent should be obtained from the patient or alternatively a waiver from the Institutional Human Research Ethics Committee. The details concerning this and research in general, have been detailed by the National Health & Medical Research Council (NHMRC) (www.nhmrc.gov.au/issues/researchethics.htm) In particular readers are referred to Section 15 “Use of Human Tissue Samples.”

The Guidelines under Section 95 of the Privacy Act (http://nhmrc.gov.au/publications/pdf/e26.pdf) which apply to both public and private sector researchers, describe the criteria that the Human Research Ethics Committee (HREC) must consider when deciding whether the need for consent may be waived.

Human Research Ethics Committees’ approval should be obtained when performing procedures or processes for research purposes. Organisations such as Universities, Hospitals, Foundations and Institutes have such committees, from which members should obtain the consent. Often the committee will stipulate that a written patient consent form has to be signed giving the patient the right to withdraw from the research at any stage.

Consent
Consent should be informed, written and specific to the purpose to which a specimen is to be used. In some situations where for example specimens have been archived, stored in banks or are in excess to requirements for clinical purposes, this will be difficult. Consent should be obtained for any procedure that may lead to harm, benefit or an injustice to the donor. A waiver from the Human Research Ethics Committee may be sought in these situations. Readers are referred to RCPA Policy 10/2000 Patient Consent for Observational Research and case studies (http://documents.rcpa.edu.au).
Situations where consent may be of particular relevance are:

1. The specimen is surplus to diagnostic requirements and would otherwise be destroyed as it is of no use to the owner.
2. The specimen has been donated specifically for research and the donor is agreeable to its use.
3. The use of the specimen either in a diagnostic laboratory or a research facility could lead to significant profits for an organisation or individual.

RELEVANT LAW

All Pathologists have to practice their specialty within the confines of the law, both Statutory and Case law. Until tissue or another specimen reaches the laboratory, the legal owner of the pathology sample is the patient. However, once the Pathologist has applied his or her skill to the sample, it becomes the property of the Pathologist [Doodeward v Spence (1908) 6 CLR 408.] The issue of ownership of pathology results is not clear; however the result will probably be the property of the patient who paid for it, following comments made by Justices Dawson and Toohey in the case of Breen v Williams (1996) 186 CLR 71.

With the amendments to the Privacy Act 1988 in December 2001 (http://www.privacy.gov.au/health/index.html) further significant legal restrictions have been imposed and must be adhered to. The overriding principle of privacy laws in Australia is that information concerning a patient should only be passed to another party if it is necessary as part of the primary purpose for which the information was collected or a directly related secondary purpose of treatment. The Privacy Act recognises that persons may use and disclose information where there is consent, or if there is no consent

- For a directly related purpose;
- Where it is required or authorised by law;
- Where the research exemption applies; or
- If one of a number of less relevant exemptions under national Privacy Principal (NPP) 2 applies, but not otherwise. See RCPA Guidelines on the National Privacy Principles 5/2002.

Both the practising bench Pathologist and the Proprietor of a large private pathology firm should recognise that the new privacy obligations will not diminish their existing obligation under law. For example, the privacy regime does not diminish the obligation for pathologists to sign and submit an APP application (http://www.hic.gov.au/providers/resources/forms/mc/pathologists/path_app_docs.pdf) to the minister and to abide by the provisions in that application, be they ethical or otherwise, nor does it diminish the obligation for owners of pathology enterprises to sign an APA application (http://www.hic.gov.au/providers/resources/forms/mc/pathologists/path_apa_docs.pdf) and to fulfil the requirements of the Approved Pathology Collections Centre Scheme (www.health.gov.au/haf/branch/dtb/pathlcc02.pdf). This is because they are required to do so under the Health Insurance Act.
FREQUENTLY ASKED QUESTIONS

Questions are as follows:

1. **What are patient’s rights concerning human tissue or other specimens?** There has to be respect for patient's autonomy and privacy. Adequate informed consent has to be obtained. Informed consent has to be obtained for both standard & diagnostic procedures and where no relevant exemptions apply for any research performed.

2. **What are Pathologists’ rights regarding the use of human tissue or other specimens?** The Pathologist as the owner’s agent has the right to carry out procedures for diagnostic purposes that he/she deems necessary and may also be used for teaching, quality assurance or for research purposes (the latter with appropriate consents, unless waived by a Human Research Ethics Committee).

3. **What consents are required from adults, guardians and parents or guardians of minors for:**
   a) **Routine Pathology Testing:** Usually consent is obtained in a written form by a surgeon in the case of tissues and in a verbal form in the case of blood or other samples being taken by the clinician doctor or the person performing the venesection.
   b) **Autopsy:** Written informed consent has to be obtained from the next of kin for an autopsy to be performed for non-coronial autopsies. For Coronial autopsies, there is also an expectation to consult with the next of kin particularly in issues relating to organ retention.
   c) **Genetic Testing:** Written informed consent has to be obtained preferably at the time of a clinical consultation with a Clinical Geneticist so that follow up consultations can be arranged should a serious condition be identified from the testing eg Huntington's Chorea. The NHMRC has a useful section regarding this [http://www.health.gov.au/nhmrc/issues/humangenetics.htm](http://www.health.gov.au/nhmrc/issues/humangenetics.htm).
   d) **Research:** Unless a relevant exemption applies written consent must be obtained. Ethics committee approval should also be obtained.
   e) **Storage of Material for possible future Research:** Unless a relevant exemption applies written informed consent with confirmation that the person consenting has fully understood the implications should be obtained. Ethics committee approval should also be obtained. Sometimes dilemmas and difficulties could arise with archival material. (See Question 2).
   f) **Screening Tests:** These fall into two categories:
      i) Routine neonatal screening tests such as a Guthrie test. Consent for this should be obtained from the mother, perhaps on a verbal basis at a later obstetric appointment.
      ii) Screening test for general disease: Consent is obtained by implication when a venesection is taken on the understanding that the person performing the venesection is agreeable to answering any medical or non medical questions. If they themselves are unable to answer the question, they will do their best to obtain the requested information.
      iii) Screening tests as part of a research protocol: Written informed consent and prior ethics committee approval.
      iv) Antenatal screening tests.
   g) **Laboratory Quality Controls, Quality Assurance, Method Development, Calculation and Review of Reference Intervals and Education Material.** These are regularly performed in the performance of normal laboratory practice. Should samples in addition to those taken for routine service requirements be needed, then informed written consent from the patient should be obtained. However, if these estimations and assays are performed on samples in excess for patient investigative needs then consent is not required. For these purposes, data/material should only be used in deidentified forms.

4. **When is Human Research Ethics Committee approval required?** This is required for any research that is being performed. It should be obtained along the NHMRC guidelines

5 **When can results of routine testing be passed on to the patient?** At the first instance, the patient should always be advised to obtain the results of testing from their requesting medical practitioner. Refer to Guideline “Guidelines for Pathology Service Providers and their Non Medically Qualified Employees-Release of Results to Patients 2/2001.” This is for three reasons:

- The clinician requested the investigation of the Pathologist to assist him in his clinical practice.
- Pathologists should be particularly aware of becoming involved in a territorial debate.
- Only the clinician knows why he/she requested the tests and the questions he/she wanted to answer in a particular situation concerning the patient and he/she is in the best position to counsel the patient on the interpretation of results. In certain instances the clinician may do this with the assistance of the Pathologist but the clinician is in the best position to convey the results to the patient, as he/she knows that individual patient.

However, Pathologists must keep in mind and comply with their obligations to provide patients with access to their personal information under the Privacy Act 1988 (Cth). The patient’s record will comprise “personal information” for the purposes of the Privacy Act.

6 **When can results of routine testing be passed on to another treating doctor other than the requester?** The usual practice should be to pass on the results to the requester but in certain circumstances eg. where the requester has referred the patient to another medical practitioner (and by implication that patient’s results) or when the requester is deceased or moved to another practice, it may be appropriate for the Pathologist to pass on the results to a different medical practitioner. The Pathologist or his/her staff should ascertain that the patient has consented to his/her records being disclosed to the relevant medical practitioner and the person to whom they are passing on the request is in fact the person they state themselves to be.

7 **When can results of testing be passed on to a Researcher?** Unless a research exemption applies under NPP 2.1 (d), such results can be passed on to a researcher only if the researcher or Pathologist has previously obtained written informed consent from the patients involved and in the case of archival material, Human Research Ethics Committee consent.

8 **When can a sample be passed on to another doctor for either a second opinion or research?** Samples can be passed on to another doctor for a second opinion without obtaining consent since that opinion is simply a consultation by the first Pathologist to another Pathologist to assist in making his/her diagnosis. However, in the case of research by a Pathologist, unless a research exemption applies, informed written consent should be obtained from the patient. The researcher in addition should have obtained Human Research Ethics Committee consent.

9 **Can broad consent be obtained for a variety of research projects or research projects in the future or does specific consent for each research project have to be obtained?** A broad patient consent could be obtained in the case of the storage of tissue or other material for future projects not envisioned at the time of specimen collection. The patient’s interests are protected by the fact that the researcher must obtain Human Research Ethics Committee consent. However, the consent should not be too broad so that the patient is unaware of the types of research to which they have consented.
10 Can a patient request back their own tissues in the form of blood, slides, microorganisms, tissue blocks or whole organs? As stated in question one, the legal owner of these tissues is the owner of the laboratory. However, it is not infrequent for patients to request the return of their own tissues eg. gallstones removed at cholecystectomy. In that situation it is up to the Pathologist to decide whether to comply with the request. He/she is under no legal obligation to comply with the request. If there are no good reasons to the contrary and he/she is aware that the specimen will be stored adequately then it should be reasonable to comply with the request.

11 Can next of kin request back tissues for either a minor or a deceased in the form of blood, slides, microorganisms, tissue blocks or whole organs? The answer to this question is as per the answer to question 10.

12 How should specimens be disposed? Following appropriate pathological examination, tissue specimens should be incinerated as per NPAAC Guidelines and any local human tissue disposal legislation. Should any tissue be released to the patient, then this and the accompanying advice given to the patient should be documented. Some specimens will be required for controls, method development, reference intervals, teaching or Quality Assurance. Other material will be required for medico legal reasons such as a coronial autopsy and disposed of appropriately.

13 What should be done if on review of laboratory data or slides, a major diagnostic error is identified? The error should be brought to the notice of the original reporting Pathologist with a view to consulting the clinician regarding the implications for patient management. The electronic and hard copy report concerning that particular specimen should be modified with an appropriate accompanying comment. If the original Pathologist is non contactable then advice should be sought from the Department or Institute Head.

Summary

There are three broad underlying principles to which Pathologists should adhere:

1. Unless a relevant exemption applies, written or verbal informed patient consent, either directly or indirectly from the requesting clinician, should be obtained for all procedures.
2. Should any procedure be carried out that requires the collection of additional specimens or is additional to that required for routine service provision (ie. Research in its broadest sense) consent from the patient and the Human Research Ethics Committee should be obtained.
3. If an interaction occurs with a patient directly regarding a pathology specimen or if any extraordinary event concerning a patient or their specimen occurs, it should be documented in either the patient's clinical notes or in the laboratory records.

Additional useful resources are:
2. Ethics Law and Medical Practice Breen KJ, Plueckhahn VD, Cordner SM Allen and Unwin, Sydney, Australia, 1997
3. Royal College of Pathologists (UK)
   b) www.rcpath.org/activities/publications/consensus.pdf
   c) www.rcpath.org/worddocs/guidance.doc
   d) Consensus statement of Recommended policies for Uses of Human Tissue in Research Education and Quality Control
e) Good Medical Practice in Pathology [website]
4. Medical Research Council (UK)
   [website]
5. Canadian Association of Pathologists – Code of Ethics
   [website]
6. College of American Pathologists
   [website]
7. Retention of Laboratory Records and Diagnostic Material 2nd Ed
   [website]
8. Report into the Retention of Body Parts after Post-Mortems
   [website]

The college expresses its thanks to Sister Regis Mary of the Mater Misericordiae Hospital, Brisbane for assistance in preparing this guideline.