Dear Doctor

The *Non-Coronial Post-Mortem Examinations Code of Practice 2007* (the 2007 Code) was gazetted on 24 August 2007 (*Special Gazette No. 170*) and by virtue of clause 2 came into operation on 1 September 2007.

The 2007 Code replaces the *Non-Coronial Post-Mortem Examinations Code of Practice 2002* (the 2002 Code), which has been repealed by clause 21 of the 2007 Code.

A copy of the 2007 Code can be accessed at –


The following advice provides general background information, details the changes incorporated in the 2007 Code and the rationale behind the amendments.

Sections 32A and 32B of the *Human Tissue and Transplant Act 1982* (see Attachment 1) provide for the issuing and regulation of codes of practice by the Executive Director, Public Health (the EDPH) for the purpose of facilitating the operation of any of the provisions of this Act.

The 2002 Code, which has been in operation since 1 August 2002, was issued under those provisions and forms part of the law governing the authorisation of post-mortem examinations and, as such, is enforceable by the EDPH in accordance with the provision of section 32B of the Act.

In 2002 - 2003, the Auditor General reviewed “The Regulation of Human Organ and Tissue Removal” and reported the outcomes as part of the “First Public Sector Performance Report for 2004” which was tabled in Parliament in May 2004. The outcomes of that review are reproduced hereunder for your information.

“The Regulation of Human Organ and Tissue Removal

During the 1990s there was significant public concern regarding the unauthorised removal and retention of human organs. Since then considerable change has occurred to parts of the regulatory environment and both the Coroner and the Department of Health have changed their processes to keep the next of kin better informed.
The examination looked at controls over coronial and non-coronial post-mortems, donation of organs and tissue for transplant, scientific, medical or teaching purposes and donation and use of whole bodies by University Schools of Anatomy.

The key findings were:

- The regulation of human organ and tissue removal is generally well managed. No instances of unauthorised removal of human tissue were found.
- The Non-Coronial Post-Mortem Examinations Code of Practice, introduced in 2002, combined with the introduction of post-mortem coordinators, gives reasonable assurance that informed consent is provided by the next of kin before any non-coronial post-mortem is authorised.
- The Anatomy Act 1930 is not consistent with contemporary medical practice.

The Auditor General’s findings in relation to the 2002 Code are highlighted above. As will be noted no concerns were raised in regard to its operation and no amendments were recommended as a result of that review.

However, notwithstanding the outcomes of the Auditor General’s review, clause 23 of the 2002 Code required the EDPH to review the operational effectiveness of that Code and report the outcomes and any recommendations to the Minister.

That review has now been carried out with regard to –

- the Auditor General’s findings;
- the “2004 Operational Review of the Code” presented by the then Deputy Director General, Health Care (now Chief Medical Officer) to the EDPH in accordance with clause 21 of the 2002 Code; and

Whilst no major operational concerns were raised in any of those reports a number of matters, as set out below, of ‘administrative’ concern to pathologists and hospital post-mortem co-ordinators were identified as requiring attention:

(i) the definition of “tissue” in clause 4 of the 2002 Code has been amended so that it only covered the removal and retention of “organs” as defined in The National Code of Ethical Autopsy Practice (the National Code) as endorsed by the Australian Health Ministers’ Advisory Council;

**Reason:** The National Code separates organs, defined as “a visibly recognisable functional unit of the body (e.g. liver, heart, brain), whole or substantial parts of such a unit or other body parts”, to that of specimens, blocks and slides which it defines as “small samples required for testing by microscopic examination”.

The 2002 Code used the term “tissue”, as defined in section 3(1) of the Act as “....an organ or part of the human body or a substance extracted from or from a part of, the human body”.

Therefore, the 2002 Code required records of all organs and other tissue retained for therapeutic, medical, teaching or scientific purposes (as allowed by section 28(2) of the Act) to be kept and reported on.
The NHMRC Australian Health Ethics Committee report, *Organs retained at autopsy – Ethical and Practical Issues* (August 2001), excluded from the discussion tissue blocks and slides, histology slides, retained small tissue samples in formalin and samples of bodily fluids.

Concern has been expressed from the outset by post-mortem coordinators that the definition of "tissue" in the 2002 Code was too broad and that it would be clearer to all, including the public, to simply collect data on whole organs and substantial parts of organs retained for diagnostic and non-diagnostic purposes.

Also, the "approved consent forms" (as defined in clause 4 of the 2007 Code) include words along the following lines –

> "I understand that as a normal part of the post-mortem examination tissue samples and/or fluids must be taken and that those samples and/or fluids must be held indefinitely for laboratory investigations and other lawful purposes."

In view of the above the definition of “tissue” in the 2007 Code has been changed to –

> “tissue”, for the purposes of the Code, means a whole or a substantial part of a visibly recognised functional unit of the body such as the brain, heart and liver, but does not include the small tissue samples that are required to be taken for testing by microscopic examination as part of every non-coronial post-mortem examination”.

(ii) clause 19(f) of the 2002 Code has been amended to delete the words –

> “(and a percentage breakdown of the method of disposal which was used)”.

**Reason:** A percentage breakdown of the method of disposal was not found to be useful information to report on annually under clause 19 of the 2002 Code and therefore has been excluded from paragraph (f) of clause 19 of the 2007 Code.

(iii) clause 12(d) of the 2002 Code has been amended to state that a copy of the signed consent form need only be made available at the request of the “senior available next of kin”

**Reason:** Clause 12(d) of the 2002 Code required a post-mortem co-ordinator to give a copy of the “approved consent form” to the senior available next of kin after it has been endorsed by the “designated officer”. Often it was not possible for a copy to be physically given to the senior available next of kin as they had usually left the hospital by the time the authorisation has been secured, also, it was not unusual for the senior available next of kin to have indicated that they did not want further contact with the hospital on the matter. Therefore, clause 12(d) of the 2007 Code has been amended so that a copy of the endorsed consent form is only provided if requested by the senior available next of kin.

Also, further changes have been made to the 2002 Code to reflect current reporting practices under the Code and general administrative and minor drafting changes since the Code was initially introduced, that include -

(i) the definition of the “Chief Medical Officer” was inserted in clause 4 of the 2007 Code.

**Reason:** To reflect that the responsibility for day to day administration now resides with the Chief Medical Officer.
(ii) amendment of the definition “disposal” and “disposed of” in clause 4 of the 2007 Code to reflect current ‘best practice’ arrangements as provided for by *The National Code of Ethical Autopsy Practice*.

**Reason:** The current definition allows incineration of retained tissue by the hospital or its contractor. *The National Code of Ethical Autopsy Practice* specifically states that such tissue “….should not be disposed of through ordinary hospital waste processes”. It is therefore intended that the definition be reworded to reflect the position set out in *The National Code of Ethical Autopsy Practice*, that being –

“ "disposal" and "disposed of" in relation to tissue includes disposal of retained tissue by –

(i) returning the tissue to the body;

(ii) returning the tissue to a funeral director nominated by the family, or

(iii) by respectful disposal of the tissue by the hospital by cremation or burial; “.

(iii) amendment of clause 5 to highlight the need for hospitals undertaking non-coronial post mortem examinations to provide appropriate training and funding to ensure that the requirements under the 2007 Code are met.

**Reason:** General administrative update to the preamble to clause 5 which sets the requirements that need to be fulfilled by hospitals that carry out non-coronial post-mortem examinations.

(iv) various amendments to clause 19 of the 2007 Code to update the reporting arrangements and change in the definition of “tissue”.

**Reason:** General administrative changes to reflect the reporting requirements under the 2007 Code as opposed to the 2002 Code.

(v) to exclude the clauses requiring the Deputy Director, Health Care (now Chief Medical Officer) to review the Code and report to the EDHP and for the EDPH to report to the Minister on that review.

**Reason:** The 2002 Code has been operating effectively since it was brought into operation in August 2002. The 2007 Code will continue the requirement for post-mortem co-ordinators to report annually (clause 19) to the Chief Medical Officer and for that officer to report (clause 20) to the EDPH on, amongst other matters, the “….operation and effectiveness of the Code…” It is considered that those reporting arrangement will be sufficient to ensure that the Code is subject to annual review by the EDPH and, as necessary, amended accordingly in accordance with the requirements of section 32A of the Act.

(vi) to provide for the repeal of the 2002 Code (new clause 21).

**Reason:** Self explanatory.

Should you wish to clarify any matters relevant to this advice please contact Russell Tonkin, Policy Officer, Department of Health on 9222 2350 or Trevor Davies, Principal Project Officer (Legislation), Health Protection Group, Department of Health on 9222 4037.