the **Australian Society** *for* **Medical Research**

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Mr Bret Walker SC,
Attn: Ms Nichole Nobel
Executive Officer
Level 20 Goodsell Building
8-12 Chifley Square
Sydney 2000

Dear Mr Walker,

Re: Inquiry into matters arising from the post mortem and anatomical examination practices of the Institute of Forensic Medicine

Background

The mission of the Australian Society of Medical Research (ASMR) is "To foster excellence in Australian health and medical research, and to promote community understanding and support for health and medical research in Australia".

ASMR is the peak body representing medical researchers. ASMR was established in 1961 and is incorporated as a limited liability company. It has a core membership of 1,100 medical research scientists and affiliation agreements with 44 specialist societies and medical colleges representing a further 18,000 members. Through association with 13 disease related foundations and patient support groups and eight supporting pharmaceutical and biomedical companies, ASMR represents 113,500 Australians.

The goals of ASMR and the activities through which they are achieved are:

Public advocacy
The annual ASMR Medical Research Week ®, presents the results of health and medical research to the general public and encourages the involvement of politicians, the corporate sector and community groups in supporting the health and medical research effort in Australia.

Political advocacy
The ASMR continues to play an major role in lobbying Government to provide adequate and sustained funding for health and medical research and is represented on key bodies such as NHMRC, NSW Cancer Council, Research Australia, etc.

Provision of scientific forums
The ASMR National Scientific conference is held annually to highlight quality, multidisciplinary medical research. Other regular forums focus on specific issues such as commercialisation. ASMR is the principal organiser of the Australian Health and Medical Research Congress to be held in 2002.

Encouragement of younger scientists and career development
ASMR actively fosters involvement of students in medical research especially through forums and Awards. ASMR promotes the need for career development opportunities in health and medical research including career stability and professional development.

Terms of Reference

While the terms of reference are focussed on specific investigations concerning the Institute of Forensic Medicine at Glebe, the core questions under investigation and the outcome of this inquiry will likely have larger public impact. This is likely to have specific impact on issues of informed consent and/or authorisation for use of human tissue in medical research. Therefore, we comment both specifically and more generally.

Autopsy and Tissue Removal

Autopsy may occur as statutory requirement, after consent or upon request. While a legal requirement in some instances, and necessary to establish cause of death, to the general public and to next of kin, autopsy is a grossly invasive process. The public does not seek, or require, the same level of informed consent about autopsy as is required for experimental medical interventions. Thus, the general public and next of kin are frequently not specifically aware that following autopsy not all body tissues are returned to their normal positions or indeed may not be located in the cadaver at the time of burial or cremation. For example, tissues may still be undergoing fixing, embedding or examination at the time of burial or cremation. These tissues would not normally be subsequently returned to the next of kin. However, examination of these tissues may be crucial to establishing the cause of death.

Those tissues that are needed to establish cause of death must therefore be removed at autopsy. Moreover, cause of death may involve precipitating disease rather than the actual event. The public has accepted that investigation of the underlying cause of death is appropriate.

Tissue samples, have been used by coroners and clinicians to provide the knowledge into the causes of death or disease that may have an impact beyond the examination of the specific individual body or patient concerned. These uses could be classified as research. In addition, various jurisdictions have also allowed the retention of tissues or organs for specific use in medical research or the teaching of pathology.

Moreover, the public has endorsed the compulsory removal of some tissues at autopsy such as pituitaries for public therapeutic purposes as highlighted in the Human Tissue Transplants Report No 7. While the collection of such tissues has now ceased due to the realisation of concerns about Creutzfeldt-Jacob Disease, treatment of dwarfism and infertility was undertaken using extracts prepared from these tissues.

Surgical Tissue Removal

At surgery, tissues are removed and subjected to pathological examination and may be retained or discarded. This examination may occur during surgery or later and these tissues are not returned to the patient.

Current Consent Mechanisms for Obtaining Post-Mortem Tissue for Research

The evolving ethical standards on Informed Consent have led to a situation where for most researchers seeking to obtain tissues post-mortem, prospective consent from the deceased or retrospective consent from the next of kin is now required. Such consent typically makes both the tissue and medical records of the deceased available and represents current best practice.

If, however, the apparent cause of death would routinely mandate an autopsy and the organ of interest would have been removed for pathological examination, then the situation arises where a researcher is required to obtain consent to study tissues which society has already taken for examination. Some of our members have expressed concerns that seeking retrospective consent may flag even more concerns from the public and next of kin. This is because the seeking of retrospective consent highlights aspects of the autopsy process of which they may not have been fully aware.

For example, in the area of SIDS research and respiratory control, we are of the understanding that relatives of nearly all children who have died of SIDS over the past few years have already been contacted by researchers requesting permission of use of retained lung tissue. Should a second researcher wish to access this tissue or another tissue they would need to contact all of the relatives again. These requests also highlight or bring to awareness the coronial and pathological retention of tissue.

In view of the potential benefits and nature of retained tissue, it has been argued that if consent is to be sought, a series of options should be able to be provided by the next of kin. Thus, one could consent to current and future research by all ethically approved studies; consent to the specific request only; or not to provide consent. We would welcome recommendations to this effect from your Inquiry.

Medical researchers acknowledge the public's changing views on informed consent and do not seek an enforced paternalistic approach, rather, they desire a clear and transparent process by which they can approach the next of kin and clearly explain the purpose and benefits of a proposed study and seek informed consent.

Current Consent Mechanisms for Obtaining Post-Surgery Tissue for Research

A very similar situation exists for obtaining tissue for research after surgical resection.

Many pathologists consider that the tissue samples retained for examination are part of their professional resource for which they have a duty to use to elucidate the cause of disease. Further study by the pathologist would therefore normally be undertaken without further consent, beyond that for the original surgery.

There is a difference between the use of tissue for diagnostic purposes and for research purposes. The former is of direct benefit to the patient while the latter may or may not. Surgically obtained tissue can be archived for later use of direct benefit to the diagnosis and treatment of the patient. Human

Ethics committees commonly approve the use of such material for research purposes provided it has no health implication for the "owner" of the tissue (however, most research projects have potential implications), but are otherwise very reluctant to give approval. This is at least in part due to the sensitivity and privacy issues relating to the identification of disease or susceptibility to disease that the researchers may be obliged to communicate to the individual. If other researchers wish to access these materials for use in research programs, most ethics committees would require these researchers to seek the retrospective consent of the next of kin.

Current ethical practice would involve prospective consent being obtained by one researcher, who then may be unable to provide these materials to other researchers without them subsequently gaining retrospective consent from next of kin.

Therapeutic and Other Uses of Human Tissue

In view of the above and your request to consider advances in current understanding of the therapeutic use of human tissue or new approaches to its use, the ASMR submits that use of retained human tissue in research is an area of high social priority.

The current inquiry has resulted in the Institute of Forensic Medicine ceasing to supply tissues for which prospective consent has already been obtained. This is impeding research projects which have met best practice criteria for ethical consent.

For almost all medical research, appropriate control tissue samples are essential. Given that it is impossible to gain prospective consent for control tissue, the only practicable way in which such material can be gained is by retrospective consent being gained for cadavers that would be the subject of coronial autopsy. For example, to understand changes to brains caused by mental illness that resulted in suicide requires comparison to brains of age-matched individuals who have died of other causes such as the result of accident.

Medical researchers consider that appropriate ethical consent for such materials should be obtained. What is imperative for the public to gain the benefits of this research is that the mechanisms through which consent is gained and tissues subsequently collected are not blocked or impeded by the outcomes of this review.

Specific Practices at the Institute of Forensic Medicine

The ASMR has no knowledge of the specific details that fall under the subject of this investigation, but considers that the terms of reference will allow the inquiry to reach conclusions to address the terms of reference.

Summary

The ASMR notes, and we have discussed above, that several of these conclusions of this investigation will be subjective in nature and will pertain to current public and medical standards for enquiry into the manner and cause of death. These issues raised are larger than those that pertain solely to the Institute of Forensic Medicine and the recommendations of this Inquiry will impact more broadly the uses and benefits gained from post-mortem and anatomical examination practices.

We urge you to consider the impact of any recommendations that you may make on the ability of medical research to contribute to the reduction of morbidity and mortality in our community.

Yours sincerely,

Professor Peter R Schofield (PhD DSc)
President Elect