The furore over the retention of organs at postmortem examination, without adequate consent, has led to a reassessment of the justification for, and circumstances surrounding, the retention of any human material after postmortem examinations and operations. This brings into focus the large amount of human material stored in various archives and museums, much of which is not identifiable and was accumulated many years ago, under unknown circumstances. Such anonymous archival material could be disposed of, used for teaching, used for research, or remain in storage. We argue that there are no ethical grounds for disposing of the material, or for storing it in the absence of a teaching or research rationale. Nevertheless, with stringent safeguards, it can be used even in the absence of consent in research and teaching. Regulations are required to control the storage of all such human material, along the lines of regulations governing anatomy body bequests.

The use of human tissue has been integral to medical research and teaching for many years, and it has frequently been argued that this is essential for the continued flourishing of both areas.1 The removal of tissues and organs from dead bodies has traditionally occurred, however, in an ethical vacuum. Until the 1960s this may have been acceptable by the standards (and possibly legislation) of the time. Changes in the public’s awareness of medical procedures have, however, brought the practice into the spotlight and have resulted in widespread scrutiny. This has been especially true where the practice continued into the 1990s, and has led to a plethora of inquiries over the retention of body parts and organs from postmortem examinations.8 In this sense material can be considered to be archival, material which has died and also for their family, the role of and tissues, such as respect for the person who has died and also for their family, the role of understanding and informed consent, and a diversity of cultural pressures. The significance of a gift relationship, with emphasis on the donation of organs and tissues rather than on taking and retaining them, has also been underlined.11–13

It is living people who are principally affected by what is done to cadavers and body parts, hence the general assumption that it is their consent that is crucial.1 Consider the following: if internal organs are removed from a cadaver, following appropriate consent by the person prior to death and/or living relatives at the time of death, the integrity of that cadaver has been retained. The wishes and expectations of those involved have been respected. Conversely, when consent has not been given, the cadaver has been desecrated. Biologically, the two cadavers are identical, but there is a symbolic difference between the two. These considerations lead to an emphasis upon showing respect for human material, as well as to what Walker4 has termed reticence: “doing no more than what can be justified in advance on reasonable and decent criteria for the benefit of science, justice, and society”.

Unfortunately, such principles appear to have been neglected by the manner in which organs, body parts, and tissues have been retained following postmortem examinations and operations. In recent reports, the greatest attention has been paid to stored body parts of relatively recent acquisition, and with protocols for obtaining body parts today. This is understandable, but surprisingly limited attention has been paid to archival material, an enormous amount of which is in existence, and which in some cases has been collected since the end of the nineteenth century. Many of these collections constitute the backbone of medical education and research, and yet the ethical issues involved in their continued usage have been barely explored.

**NATURE OF ARCHIVAL MATERIAL**

The term “archival” is generally considered to cover the long term preservation of tissue or organs,8 although it may also be used in a more specific sense to refer to pathological archives of histological slides, such as stained blood and bone marrow films for haematological examination.4 In this sense material can be considered to be archival once the decision has been taken to retain it for future reference, meaning that it is retained beyond the period necessary to establish the cause of death or is surplus to requirements for medical diagnosis.14 Pathological archives of this nature are considered essential for quality control and assurance, allowing review of...
diagnoses and for establishing the natural history of diseases. They have played a role in identifying new varieties of tumours, informing decisions concerning therapy and evaluating the effectiveness of various medicines. Pathological archives have a clearly defined focus, that of enhancing medical understanding, and so their storage is governed by the reasons for their initial retention.

Newborn screening fits into a category of its own; in this a blood spot is obtained to test for a range of diseases. The blood, however, may be stored for many years in an identifiable form and may be used for a variety of purposes unrelated to diagnosis of any of the conditions for which it was originally obtained. While storage of blood is not the subject of this paper, it raises policy issues relating to mandatory and voluntary screening and the nature of the consent obtained and/or subsequent use.13

Much other human material (both normal and pathological) is also retained, although the reasons for this may be far less well defined, being used in a wide range of research and in the education and training of medical and allied students. Material such as this has often been stored for very long periods of time and forms the basis of museum collections, dating in some cases from the nineteenth century. We may refer to these as museum archives, with material coming from postmortem examinations, surgical operations and, in anatomy museums, from bodies bequeathed to anatomy departments.

A concept related to archival material is that of anonymity. In general this term is used to refer to unidentified specimens, that is, specimens that cannot be linked in any way to a known individual or individuals. Since the major use of archival material is in the advancement of knowledge of disease in general and specific diseases in particular, and in education, there is generally no need to link samples to known individuals. It is entirely appropriate therefore, that storage should be anonymous. A related term is anonymised, where a specimen has been rendered anonymous by removing identifiers or codes to link it to known individuals; such specimens are also termed unlinked specimens.16 17

Museum archives consist largely of anonymous archival material. Of this, older material dating from before the 1960s or early 1970s can be referred to as “historic archival” material. The year 1970 has been used as an arbitrary demarcation point in the UK by the Department of Health.10 The year 1961 may also be used, since prior to this year in the UK stipulation of non-objection to organ retention following postmortem examinations was not present.13

Since anonymous archival material has been retained and stored for well over one hundred years, the result is a sizeable source of human tissue archived in pathology repositories, anatomy departments, medical schools, and museums worldwide. As of 1999 in England, an estimated 104 300 organs, body parts, stillbirths or fetuses retained from postmortem examinations are held by pathology services. There are an additional 480 600 samples of tissue similarly stored in museums and other archives.16

Historic archival material would have been obtained in a variety of ways, and in diverse legal and ethical climates. As a result, it has no known links to its original subject, no information is available regarding whether consent was obtained, there is no indication of the intended purpose of the tissue, and little or nothing may be known about the method of acquisition of the tissue. At the University of Otago the anatomy museum has material dating from 1879, just three years after the beginnings of the medical school, through to the present day. While there is only limited evidence of consent for the pre-1970s material, all the more recent material (which by definition is not archival) has been from cadavers bequeathed to the anatomy department in terms of the local human tissue act.

OPTIONS IN THE USE OF ARCHIVAL MATERIAL

Does the storage of material like this raise ethical dilemmas? Various answers have been given. For instance, the Retained Organs Commission13 stated that “the views of family members and the historic and educational value of the collections need to be considered before decisions are taken on retention or disposal”. The emphasis here is that tissues and organs are to be treated with respect, and that whatever is done to these collections should be in line with society’s current expectations.

A somewhat different perspective emerged from the National Bioethics Advisory Commission14 in the United States, which concluded that research on already existing unidentifiable (anonymous or anonymised) specimens should not be classed as research with human subjects. Consequently, neither informed consent nor ethics review is required. This conclusion was based on the view that research using human subjects involves an intervention or interaction with a living person. Since archival and museum specimens are already in existence, there is no need for such interaction since there is no risk to the donor.15 It was the commission’s view that restrictions imposed on the use of stored anonymous tissue could seriously hinder potentially valuable research projects.

A similar stance has been expressed by Knoppers and Laberge,16 who have warned against the “sacralisation” of stored samples. Their concern stems from what they perceive to be an excessive desire to control the use of human organs and tissues in an attempt to protect privacy and autonomy. They argue that if we fail to distinguish samples from persons, we will end up encouraging reductionism rather than individual integrity.

The view of the Royal College of Physicians14 is that research on archival material is ethical even in the absence of the consent of individual patients, subject to certain provisos. These include anonymisation of the material as early as possible in the research process, an assurance that subjects are not inconvenienced in any way, and that consent is obtained if doubt surfaces about the intrusive nature of the research. These provisos do not apply to anonymous archival material, where there is no possible link to known patients or their relatives.

What are we to make of these differing perspectives? Since this material is anonymous there will be no next of kin to consult. Consequently, decisions will have to be taken by those in lawful possession of the material. What will be in the best interests of the human community? What will show the greatest respect to those people from whom this material was taken in the first place, in all probability without their consent?

A first option is to dispose of the tissue through burial or incineration as clinical waste. This line of action would not directly benefit any party, although it would prevent the perceived misuse or abuse of the tissue. Does the mere disposal of tissue serve any positive purpose? Since the material exists, something has to be done with it. Disposal is possible, but this is not an ethically neutral action, since it presupposes that disposal is preferable to its use for teaching and/or research purposes. We remain to be convinced that disposal as such has any merits when considered alongside a use of potential benefit to members of the human community. Even if disposal demonstrates respect for unknown patients in the past, it achieves this by accentuating the effects of the burden of illness on current and future patients.17
A second option is use of the tissue in teaching, an option intended to produce immediate educational benefit. While not all stored tissues will be suitable for teaching, it is an option that will apply to some collections. We consider that teaching is a legitimate use to which some anonymous archival material may be put. This prospect does not, however, justify the retention of tissue in the vague hope that it may serve some ill defined teaching purpose at some indefinite time in the future. The teaching rationale should be a focused one, and should be based on clearly articulated teaching goals.

A third option is for the tissue to be used in research. The justification in this case depends upon the potential usefulness of the tissue in research. This will not apply to all tissue in storage, and it has to be determined which tissue falls into this category. Nevertheless, research on appropriate tissue may lead to considerable insights into clinical conditions and benefits to patients in the future, opening up the possibility of carrying out some research under clearly circumscribed conditions. This option includes the retention of material for audit purposes.18

A fourth option is that the tissue remains in storage. Even if continued storage is of little immediate benefit, this option allows for the use of the tissue in future research projects, providing it is treated with care and respect. A sound research rationale has to include potential future benefits to science and medicine, even though precision in this area is beyond our grasp. On the other hand, the mere stockpiling of tissue, like the stockpiling of raw data, in the absence of a convincing research paradigm, is ethically unacceptable.

This is a practice that lay at the heart of a number of the controversies that led to the 1961 and 1988 policies. In this situation, the autonomy of persons and respect for their dignity are paramount.

None of these options accepts that human tissue can be kept indefinitely for no good reason, or that it can be used for ethically dubious and/or scientifically substandard research.

What emerges is that the potential scientific and clinical value of human tissue in storage should be taken into consideration when determining what can or cannot be done with it. While it is preferable to use human tissue for which specific consent has been given for its use in teaching and research, the paucity of such recently acquired human tissue emphasises the crucial teaching and research role of stored tissue.

Our argument is that ethical justification is required for retaining human tissue, and storage in the absence of a legitimate scientific use fails to satisfy this criterion.19 The parallel between this situation and that applying to human skeletal remains is compelling, since in the latter ethical justification is required for retaining skeletal remains.20 If there is even the merest hint that some stored material might be identifiable, efforts should be made to identify next of kin and obtain consent. The ethical balance should always be weighted in favour of obtaining consent if at all feasible. It is only where this is not possible, that the above conclusions apply.

END LEVEL SAFEGUARDS WHEN USING ARCHIVAL MATERIAL WITHOUT CONSENT

It is widely accepted that informed consent must be obtained for projects that involve the direct prospective involvement of human subjects. The role of consent is much more opaque, however, when it comes to research involving the use of human tissue rather than human subjects themselves. This is to be expected because a person has higher value than that attributed to his or her body parts.21 The essence of the debate over anonymous archival material is that it represents a further move away from an actual subject; indeed, the actual subject has disappeared completely from view. By contrast, where tissue can be traced back to a human person, the onus is on the researcher to demonstrate that the subject (or next of kin) approves of the use to which it will be put. Only in this manner are the autonomy of persons and respect for them safeguarded.11 19

The ambiguity of consent in the context of cadavers and body parts has been addressed recently by various legal writers. Mason and Laurie22 accept that a consent model is to be preferred to a property model, and yet they recognise that the consent model retains aspects of the language of the property model. For them, relatives of the deceased can either assent or dissent to invasion of the dead body, but cannot consent under the terms of the 1961 UK Human Tissue Act. They also argue that relatives should have interim property rights over the cadaver pending disposal of the body. Skene23 takes this further by contending that, while people should have an autonomy right to permit or prohibit their bodies and body parts being used for research, teaching, or therapy, they should not have proprietary rights (of ownership and control) in relation to the parts removed with their consent. That should reside with the person or institution holding them, who in turn should use them for appropriate medical or scientific purposes under ethical scrutiny.

This tentative move from a fully consent based ethics towards one acknowledging some property interests is of particular relevance for anonymous archival human material. In this situation, any property interests in the human material take precedence over consent which is lacking. This is a compromise situation, and those in possession of the material have compelling ethical obligations to use it in ways that will be of value in teaching, research, or diagnostic audit.

Archival material has already been obtained and so there is no additional hazard to the research subject from physical intervention.14 By definition, anonymous archival material has no links with an original subject, and so no harm can be done to a subject. It is for this reason that we reject the assertion that a wrong is being performed by invading the subject’s privacy and by treating them as a means to an end.24 Any such harms are no more than postulated ones, which have to be balanced against the harms and wrongs to science, medicine, and society if research on this type of archival material is seriously hindered.

Should identifiable tissue be anonymised once the immediate uses for which it was collected have been fulfilled? The assumption here is that the material was first collected with consent in order to undertake specified procedures on it. In our view, anonymisation can only be justified if the initial consent encompassed the possibility of subsequent anonymisation for further teaching or research purposes. While the nature of the research procedures cannot be spelled out in detail, broad directions should be given. In particular, any likelihood that it could be used for commercial purposes or that it could be linked to identifiable data would have to be stated. It is our view that no allowance should be made for commercial use of tissue unless consent was obtained when collected. If appropriate consent for future uses has not been included in the consent obtained for recently acquired tissue, the tissue cannot be used in further ways. To do so is to override the dimensions of the consent provided, and show lack of respect for those providing this consent.

An analogy is that provided by epidemiological data. It can be argued that, just as data (about the liver, say) are impersonal, a liver or liver slice is impersonal when it cannot in any way be traced to an identifiable individual. It is a source of information akin to that of epidemiological data. Confidentiality must be protected, and the research must be...
of sufficient importance to outweigh any perceived "wrongs" pertaining to the use of this material. This is an interesting analogy, but it breaks down on two counts. Epidemiological data should not be obtained without consent; the lack of consent with anonymous archival tissue reflects an historic situation rather than an accepted contemporary protocol. Secondly, treating human tissue as epidemiological data is problematic since it is more than this. Once epidemiological data have been collected, new information can only be gleaned from that data by reassessing it. By contrast, human tissue is a raw material from which considerable new information can be garnered by using additional techniques and investigatory procedures. In other words, stored human tissue has the capability of giving rise to new knowledge and concepts, thereby placing it in a different category from that of epidemiological data. Additionally, the use of human tissue is a privilege that must be respected. Consequently, the use of human tissue in research requires more stringent restrictions and controls than those applied to the use of epidemiological data.

The availability of, and subsequent study of, archival material will be a compromise, and care needs to be taken to ensure that its use never leads to a diminution in the respect shown the human body and its parts. Routinely, it is preferable to err on the side of altruism, with its emphasis on a gift relationship, and hence for consent for the use of all newly acquired human tissue. This is not possible with anonymous archival material, since it is not possible to go back to any donors for consent. There were no voluntary anonymous archival material, since it is not possible to go back to any donors for consent. There were no voluntary donors, and that is regrettable. Nevertheless, archival samples should be treated with the same care and respect as if they had been donated, and as if they had been gifts. This is possible if those in charge of the material act as its custodians rather than its owners, with responsibility for safe storage of the samples, for its appropriate use, and for the quality of the research carried out on it.

FURTHER CONSIDERATIONS

Consternation over the removal of organs from cadavers without consent revolves principally around certain organs, notably, the heart and brain. The retention of small tissue samples does not appear to have the same cultural and emotional significance as retention of larger tissue specimens or whole organs. A brain, a kidney, or a limb, for instance, are perceived quite differently from a blood sample or a bone sliver. We argue that stringent consent is required for the removal of a brain, and far less, if any, for the removal of sebaceous glands or a mucous membrane lining the mouth.

Here we are in line with a number of others who suggest that tissue blocks and histology slides might be excluded from a definition of human material, since they contain small amounts of tissue and much of the tissue has been replaced with paraffin wax or chemicals. Additionally, postmortem examination involves fragmentation of organs to varying degrees, in accordance with good medical practice.

This reflects a gradation of biological value from tissues vital to the continued existence of an individual, through to those of little significance for human functioning. Unless a line of demarcation is placed along this continuum, it becomes impossible to make any ethically relevant distinction between, say, retention of the brain and retention of hair. Clinically, there appears to be a gap of major clinical significance between essential but replaceable organs (hearts, kidneys) and nonessential organs (spleen, appendix). This tends to correspond to a symbolically significant gap, although the basis for giving this ethical weight is far from clear. Our suggestion is that whatever organs are essential for the functioning of human persons during life serve as a benchmark for the significance to be bestowed upon them at death. While this does not settle issues of consent, it provides a guide to its stringency.

General as these considerations are, they also apply to the treatment of anonymous archival material in museums, since this reflects society's or an individual's attitudes towards that material. Given the considerable distance between archival material and actual living persons, any symbolism attached to it will be far less than in the case of identifiable remains although it will not have disappeared completely. While respect for human material should be universal, regulations governing its retention and use should be most demanding for brains and hearts, and least demanding for tissue blocks and histology slides.

Archival material will have emanated from postmortem examinations, surgical operations, and bodies bequeathed to anatomy departments. Of these three sources, the only one covered by regulations will be the bequeathed bodies. Generally, the control exercised in this latter situation is far more stringent and overarching than that exercised in any of the other areas discussed. In the case of bequeathed bodies, informed consent is central and the control over them continues as long as they are held by anatomy departments—for example, Human Tissue Act 1961 or Anatomy Act 1984 in the UK; Human Tissue Act 1964 in New Zealand. This includes retention in museums. By contrast, other historic archival material is under no legal jurisdiction (neither is identifiable tissue obtained with consent).

Neither the lack of informed consent for the acquisition of anonymous archival material, nor regarding the material as property, is sufficient reason for allowing museum collections to remain unregulated. Regulations are urgently required to control the storage of all such human material, and these should take note of those currently in place for governing bodies bequeathed to anatomy departments. Along these lines we envisage the following:

- registration and licensing of collections, with external monitoring and accreditation
- all collections to be included, although time may be required to determine the fate of smaller collections
- all collections would be brought under the same regulatory framework, thereby eliminating any distinction between pathology and anatomy collections; in this way, a one tier oversight of all body parts could be provided, covering human material obtained at postmortem examination and operation, as well as anonymous archival material
- appointment of licensed staff with expertise in medical and/or allied biomedical disciplines to exercise curatorial responsibilities for collections
- all collections to have detailed records of all human specimens and body parts in their collections (although tissue blocks, slides, and plastinated slices could be excluded)
- all collections would have their own ethics committees to oversee approval of research projects, teaching usage, and diagnostic audits; these committees would themselves be appropriately accredited.

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Stored human tissue: an ethical perspective on the fate of anonymous, archival material

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