Section 1- Background

Before analysing the “consent to tissue banking” debate, it is necessary to explain what is meant by “tissue banking” in this context, why tissue banking is considered important and what challenges it presents. More specifically, it is necessary to explain why the debate about consent to tissue banking has arisen and why its resolution is a social imperative.

1.1 Description of tissue banking research

1.1.1 What is a tissue bank?

The phrase “tissue bank” can refer to any collection of human tissue stored in any physical form for any purpose. Tissue can be stored in the form of whole organs, tissue masses, paraffin blocks, microscope slides, cell cultures, blood samples (containing cells), serum or other body fluids not containing cells, gene chips, protein chips and DNA/RNA suspensions. These are used for a variety of activities (1)(19.1-19.37) including research (the subject of this thesis); diagnosis (eg. pathology laboratory collections); transplantation (eg. collections of heart valves, corneas, bone); transfusion (eg. blood banks); reproductive therapy (eg. embryo banks); education (eg. anatomy and pathology “museums”) and forensics (eg. DNA collections for identification). Table 1 summarises the activities encompassed under the heading of “tissue banking.” Almost all universities, research facilities, hospitals and pathology laboratories have some version of these “collections,” “repositories” or “banks”, as they are variously called, of human tissue.
### Table 1: Activities encompassed by the term “tissue banking”

<table>
<thead>
<tr>
<th>Scientific research (the subject of this analysis)</th>
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<tr>
<td>Education</td>
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<td>Diagnosis</td>
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<td>Medical diagnosis of living patient (clinical/diagnostic pathology) or deceased person (autopsy specimen collections)</td>
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<td>Genetic registers/ population genetic screening collections</td>
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<td>Newborn screening collections (Guthrie cards)</td>
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<td>Transplantation/ therapy</td>
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<td>Assisted reproductive technology (ART) banks eg. embryo banks</td>
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<td>Non-ART repositories (skin, bone marrow, cord blood, bone)</td>
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<tr>
<td>Blood banks</td>
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<td>Non-medical testing eg. law enforcement, insurance, employment</td>
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### 1.1.2 What is “tissue banking research”?

Banked tissue is a resource rather than a specific research method, and can be used for any kind of research including requiring human tissue. Nonetheless, research utilising tissue banks tends to be carried out according a fairly stereotyped research method. Rather than being manipulated as a disease model, tissue is screened for the presence of abnormalities in its genes, proteins, cytological/histological appearance or micro-organisms. The pattern of abnormalities is then correlated with the aetiology, prognosis or treatment responsiveness of a disease. This method, which can be thought of as “laboratory-based epidemiology,” is outlined in the following steps and illustrated in Figure 1.
Step 1: Tissue is collected, either specifically for research or for other purposes;
Step 2: Rather than being discarded, tissue then becomes part of a research collection, and is stored in a tissue bank;
Step 3: Laboratory techniques are used to examine specific physical features of the tissue, such as its histological (tissue-level) or cytological (cell-level) appearance, or its genetic, immunological, microbiological or biochemical profile;
Step 4: These findings are then correlated with environmental and clinical features such as exposure to putative aetiological agents, disease prognosis and treatment responsiveness. The existence of many samples (ie. a “bank”) enables epidemiologically-sound correlations to be made. Long-term storage of tissues, and linkage to personal (demographic, behavioural and health) information is required for these associations to be made.

There are several different kinds of laboratory-based epidemiological research, with different purposes, but all aim to establish the association between a particular histological, cytological, immunological, microbiological, genetic, protein or biochemical profile and the risk (aetiology), natural history or treatment responsiveness of a disease (or adverse drug reaction) with a view to developing new, targeted diagnostic and therapeutic tools (2). Genetic association studies are particularly prevalent following the mapping of the human genome. For genetic associations, there are several types of studies with different aims:

1) Studies aimed at establishing that there is a genetic component to the disease risk/progression/treatment responsiveness.

2) Studies aimed at determining the mode of genetic transmission and what the genetic component of a disease looks like (oligogenic, polygenic, etc).
3) Studies aimed at establishing the relative size of a genetic effect in relation to other sources of variation including the effects of the physical environment (e.g. intrauterine environment, chemical or physical exposures) as well as the effects of particular behaviours and psychological profiles.

4) Studies aimed at identifying the gene(s) responsible for the genetic component of disease risk, natural history or treatment responsiveness. Linkage studies are used to identify the gene sequences associated with the inherited diseases. Association studies are used to find correlations between the disease and a genetic change where there is no obvious pattern of inheritance. Population association studies (retrospective case-control or prospective cohort studies) focus on population frequencies, and compare the frequency of specific alleles in affected cases against those in unaffected controls (3). Association is usually with a susceptibility locus, which increases the probability of contracting the disease, or exhibiting a particular natural history or treatment responsiveness, but is not necessary or sufficient for this.

All of these laboratory-based epidemiological studies require multiple samples. These can consist of collections from families (nuclear families, affected relative pairs, extended pedigrees or twins) or from unrelated populations. Most tissue banking research takes the form of association studies using collections comprised of samples from unrelated donors.

Below are three actual examples of association studies looking, in turn, for markers of disease risk (study A), natural history (study B) and treatment responsiveness (study C). Blood was banked for studies A and B, and tumour samples were banked for Study C. In study A, the tissue abnormality of interest was a genetic mutation. In studies B and C the abnormalities were the presence of an antibody to a virus, and the presence of a receptor protein on the surface of cells respectively. Studies B and C illustrate the point that genes are not the only molecules of interest in laboratory-based epidemiology.
Study A:

Aim: Epilepsy researchers wished to determine whether there is an association between a polymorphism (mutation) in the promoter region of the interleukin 1 (Il-1) gene and a certain form of epilepsy. In general terms, the study aimed to identify the gene(s) responsible for the genetic component of disease risk.

Method: A genetic cohort study was carried out to assess the association. Blood samples containing blood cells which, in turn, contain the patient’s genome including the Il-1 gene were taken from patients and controls (4).

Study B:

Aim: Hepatitis researchers wished to determine the association between the presence of a particular hepatitis virus, and the progression of hepatitis to cirrhosis (chronic liver scarring) and to liver carcinoma. In general terms, the study aimed to identify the association between viral infection and the natural history/prognosis of a disease.

Method: Blood samples containing antibodies to the virus were taken from patients with hepatitis and from controls (5).

Study C:

Aim: Cancer researchers wished to establish the association between the presence of estrogen receptors on breast cancer cells and responsiveness of hormonal therapy. In general terms, this study aimed to identify the proteins responsible for the genetic component of treatment responsiveness.

Method: Tumour samples expressing estrogen receptors and control tumour samples not expressing receptors were collected from material removed at surgery (which was carried out for diagnosis or treatment) (6).
Figure 1: Laboratory-based epidemiology research using tissue banks

Sample removed for diagnosis and/or treatment → Sample sent to pathology laboratory where it is examined → 

Sample stored in a tissue bank/collection along with other similar specimens → 

Sample discarded or stored for further diagnostic tests → 

Tissues examined for specific abnormalities or patterns using techniques such as tissue micro-arrays. → 

Epidemiological analyses carried out physical findings correlated with: 
-Cause (e.g. exposures) 
-Patient prognosis 
-Patient treatment responsiveness, etc.
1.2 The promise of tissue banking research

1.2.1 Why is tissue banking research considered to be important?

Research utilising banked tissue is perceived to be an essential strand of medical research in the post-genomic era (1, 7-10). Laboratory techniques such as tissue microarrays, laser capture microscopy and adaptations of mass spectrometry, together with new information technology tools give tissue banking research its power. Whilst the above techniques can be applied to single samples, banking of many specimens enables the consistency of findings to be confirmed. This, in turn, greatly enhances the power of this research by enabling epidemiologically-sound correlations to be made. As illustrated above, storage over time enables laboratory findings to be correlated with disease progression and patient response to treatment, as well as enabling as-yet undiscovered techniques to be applied in the future to current samples.

This statement by Oosterhuis is a typical illustration of the enthusiasm for tissue banking techniques and their clinical (diagnostic and therapeutic) applications:

It has never been more rewarding to collect and store leftover tissues from diagnostic and therapeutic procedures in tumour banks. Scientific and technical advances in genomics, proteomics and bioinformatics make it possible to do extensive analyses of very small tissue samples, and many assays can even be done on formalin-fixed and paraffin-embedded tissue. We are beginning to diagnose and treat cancer by identifying markers and critical biological targets in tumours. Information technology techniques, including telemedicine, are available to optimize the management and accessibility of stored samples (7)(P73).
Similarly, this statement by Qualman et al exemplifies the belief that tissue banking research will lead to new clinical techniques (in this case, diagnostic tests).

It is estimated that by the year 2005, as much as 10% of clinical laboratory tests will be based on RNA or DNA analysis. These efforts will only be successful with the logical application of tumour banking and its associated informatics systems as the translational bridge linking new molecular information to its clinical significance (8)(p1115).

Qualman’s use of the phrase “translational bridge” illustrates the popular idea that the results of tissue banking research, as distinct from “basic science” research, are able to be translated directly into clinical (diagnostic and therapeutic) applications. This is an increasingly popular and well-funded form of research, the promises of which have been used to justify massive multi-national research endeavours such as the human genome project and, more recently, the field of proteomics which aims to identify the proteins produced by abnormal genes, since this is the level at which many diagnostic and therapeutic tools are targeted.

1.2.2 Why do people want to make use of tissue archives?

Many “research collections” consist of archival material which was not collected specifically for research. Many diagnostic pathology laboratories, for example, have stores of diagnostic material collected over several decades. These are argued by researchers to have unique value, and to enable research that would be significantly delayed, if not impossible, were these collections to be discarded (1).
The perceived importance of accessing these archives is captured in this excerpt from the Australian Law Reform Commission (ALRC) report (“ALRC96”) of an inquiry into the protection of genetic information in Australia:

In the post genome sequencing era, the ability to easily and extensively access the staggering amount of medical and biological information locked up within tissue archives is paramount—molecular pathology could play a pivotal role in unlocking the bases of multiple disease types, including infectious diseases, cancer and developmental disorders (1)(19.23).

The need to access archival material is particularly critical in the study of rare disorders for which few samples are available, but also applies to common disorders (such as breast cancer) with many physical subtypes, each of which is rare. Furthermore, with the advent of new therapies, it may now be impossible to find samples of untreated disease. These are important for assessing the tissue-level effects of therapy.
1.3 Concerns raised by tissue banking research

Despite all of the enthusiasm described above, tissue banking research is also the subject of much controversy, which has arisen in part as a result of a series of media exposures of “scandalous” retention of organs from post-mortem examinations, together with increasing concerns about information privacy. These triggers have resulted in an extensive debate in the academic literature and an active period of legislative reform. The dominant themes of, and conceptually restricted nature of, this discourse is the subject of this thesis. This section will outline the wide variety of challenges (technical, professional and ethical, regulatory and conceptual) that face scientists wishing to engage in scientifically, morally and legally-sound tissue banking research.

1.3.1 Organisational and technical concerns raised by tissue banking research

Organisational challenges relate to the administrative and interpersonal problems that arise in the course of tissue banking research. These include: lack of incentives to share tissue outside of the clinical department in which it was collected, or the laboratory in which diagnosis was carried out. This reflects competition for resources between different types of researchers (for example, medical oncologists and surgical researchers), as well as competition between those wanting to use tissue for diagnostic purposes and those wanting to use it for research purposes; lack of communication between researchers and surgeons carrying out late-stage palliative procedures which are only aimed at relieving symptoms and are not sent to pathology laboratories; and costs involved in banking (10).

Technical challenges relate to difficulties in isolating the tissue of interest and applying laboratory techniques. These challenges include: reduction in availability of specimens due to earlier detection and fewer surgical resections (8); difficulty identifying, selecting
and banking normal tissue from areas adjacent to the diseased material (eg. normal tissue surrounding a resected tumour) (10); cellular degradation (11); lack of appropriate information systems to support tissue banking (“pathobioinformatics” or “data mining” tools) and inadequate training of pathologists in the use of these tools (10); technical difficulties associated with multi-institutional specimen banks (standardisation of collection methods, coding and dissemination of patient information, etc.) (11) and difficulties with patient tracking to allow prognostic correlations.

1.3.2 Ethical concerns raised by tissue banking research

Ethical concerns raised by tissue banking relate to confidentiality, ownership and commercialisation, sacredness of tissue, scientific validity and consent. Each of these will now be outlined.

Confidentiality

In order to make epidemiologically-sound correlations between a physical profile and disease aetiology, prognosis or treatment-responsiveness, samples need to be linked to personal information about the tissue donor including family history, environmental exposures, lifestyle/behaviour, disease progression and response to treatment. Linkage studies require collections of tissue taken from multiple family members and information about which members suffer from the disorder. Association studies require large collections of samples from people with a given condition, combined with detailed medical histories. Genetic epidemiology studies require access to very large population collections as well as detailed medical histories. Pharmacogenetic studies require clinical records and genetic information (1).

This means that, if tissue banks are to be maximally utilised, samples cannot be completely anonymised. At best, they can be de-identified (coded) to reduce the risk of inappropriate disclosure of personal health information. Coding, however, is not
foolproof, and there is always the risk of inadvertent disclosure of personal information. This, in turn, places subjects at risk of discrimination or distress if stigmatising information is disclosed to insurers, employers or family members or the general community. Moreover, disclosure of genetic information about a research participant also discloses genetic information about the donor’s family and ethnic group.

Unlike many other types of research (e.g., pharmaceutical trials), tissue banking research does not pose a risk of physical harm to research subjects. Loss of confidentiality is, therefore, the most serious risk posed by tissue banking research. The powerful techniques used in laboratory-based epidemiology which are the main selling points for tissue banking research cause concern relating to the sheer volume of sensitive personal information that can be generated from tiny amounts of tissue in very short times. So whilst tissue banking research used to be considered “risk free,” there is increasing recognition that this is not the case (9, 12, 13).

As a result of this recognition, along with the surfacing of more general concerns about the protection of genetic and other personal information, significant legal activity aimed at protecting privacy and confidentiality has arisen, both within the health sector and more generally. The Australian Law Reform Commission recently conducted an inquiry into the “Protection of Genetic Information in Australia.” The resulting 1200-page report (ALRC96), released in 2003, devoted several sections to the concerns raised by tissue banks and other types of research databases (1). Several recent legislative amendments also reflect the perceived importance of health privacy. In New South Wales the Health Records and Information Privacy Act came into force in 2004. This Act was accompanied by Statutory Guidelines specifically directed at the maintenance of privacy and confidentiality in medical research. According to this Act, human tissue is considered to be a type of health information and tissue banking research is, therefore, subject to all of the requirements of the Act unless specific exemptions (as set out in the Statutory Guidelines) apply.
Ownership and commercialization

The issue of tissue ownership and the commercial application of tissue research is complex (14-16). At present in Australia tissue cannot be bought or sold, and it cannot be owned unless it has been modified in some way (eg. in a laboratory). It is not clear, however, what level of “processing” confers property rights (17). In the United States, the Moore case established on appeal that the patient does not own tissue that has been removed. In the US, however, processed tissue has been bought and sold as a commodity, raising concerns about exploitation. This issue has not yet arisen in Australia, but similar commercial activity would not be illegal here.

Legislators have considered the possibility of changing the ownership status of tissue as a way of enhancing the control that people have over their bodies. To date, however, this approach has been rejected in favour of more stringent privacy legislation and, as a result, more stringent consent requirements (1).

Sacredness and aesthetics

Certain individuals and cultural groups have specific sensitivities about the removal, retention and use of human tissue. To some, human tissue has specific sacred or aesthetic significance and cannot simply be considered to be surgical or post-mortem waste. Some cultures (eg. Islam and Judaism) believe that it is important to bury people with their organs intact and have complex views on organ and tissue donation (18-20). These concerns are closely related to the unease that people feel about tissue ownership and the commodification of the human body (21).

Scientific validity

Despite the enthusiasm for tissue banking research as described in section 1.2, there is increasing recognition that research, even if well-funded and unimpeded, does not always deliver on its promises. There is also increasing concern about the existence of science which is methodologically unsound. Research that fails to meet the criteria of validity and
utility is unethical, even with the most rigorous mechanisms in place for protection of research subjects. Furthermore, failure to inform tissue donors that research has of unknown benefits would render any consent uninformed and, therefore, invalid.

Some laboratory epidemiological studies are weakened by small numbers of samples, widely heterogeneous collections, and the problem of bias towards cases from which spare tissue can be obtained (22). Moreover, there are some concerns about the epistemological inferences underpinning this kind of laboratory-based (particularly genetic) epidemiology (23-26). Most laboratory-based epidemiological studies, for example, are confined to the study of genes, but there is increasing recognition that the intervening DNA sequences (so-called “junk”) are likely to be important in terms of regulatory and other functions and should not be neglected (27).

Consent

Informed consent for the use of tissue in research is generally believed to be crucial, a belief typified by claims such as this one by Qualman:

Informed consent is the factor by which all tissues are qualified or disqualified for use by a potential researcher (8)(p1118).

There are two main reasons for concerns about inadequate consent to tissue banking research: firstly, tissue banking research poses the risk of loss of confidentiality; consent is a way of ensuring that research participants are aware of, and willing to take on, this risk (28-30). Secondly, unlike other forms of research, in which contact between researchers and subjects ceases after completion of a pre-defined project, tissue banks (by definition) store tissues for long periods and use the tissue in a number of different projects. It is generally thought that donors should be made aware, through informed consent, of the types of research that will be carried out and given the opportunity to choose whether or not to consent to a specific type of research (31). It is conceivable, for example, that a cancer patient may be willing to donate his tumour sample for research
into new treatments, but not for research into development of a screening test where no treatment is possible and a positive result will only cause distress and possible discrimination.

Others argue that stringent consent is potentially problematic, and a debate has arisen in the bioethical and legal literature about 1) the need for ongoing, project-specific consent and 2) the need to recontact patients whose tissue is currently stored in archives. The nature of this “consent to tissue banking” debate is the subject of this thesis, and conceptualisation of these issues will be revisited.

1.3.3 Regulatory concerns raised by tissue banking research

Policy makers have responded with much enthusiasm to the ethical challenges raised by tissue banking. Numerous national research agencies, health ethics bodies and health law organisations have produced myriad analyses and guidelines in the public domain. Overseas, bodies involved in tissue banking regulation include the American Association of Tissue Banks, the US Department of Health and Human Services, the US National Bioethics Advisory Commission, the British Association of Tissue Banks, the UK Medical Research Council, the European Commission and the Council of Europe (30, 31). In Australia, the Australian Law Reform Commission (ALRC) has produced a massive (1200 page) examination of the issues of privacy, confidentiality, consent, scientific value, legal constraints, relationship to other branches of science and future potential of genetics and tissue banking. In the process, the ALRC has drawn on the expertise of many stakeholder groups from law, philosophy, religion, science, medical practice and consumer groups. This reflects their mandate to construct a broadly representative, pluralistic document which is even-handed in its respect for public sensibilities and the demands of scientific progress. Legislation of relevance to tissue banking include new privacy legislation (Health Records and Information Privacy Act (2004)) and recent amendments to the Human Tissue Act (1983), the Anatomy Act and
the Coroners Act. Whilst such a response is necessary and well-intended, it has occurred in a way that has led to a new set of regulatory challenges. In order to identify the consent requirements for setting up and permitting access to even the simplest tissue bank, a clinician or researcher in New South Wales would need to be cognisant of:

1) **Common Law** relating to assault and confidentiality;

2) **Legislation** such as the *Privacy Act 1988* (Cth); *Privacy and Personal Information Act 1998* (NSW); *Health Records and Information Privacy Act 2004* (NSW); and *Human Tissue Act 1983* (NSW);

3) **National guidelines** such as the NH&MRC National Statement on the Ethical Conduct of Research involving Humans;

4) **Organisational policies** such as the Royal College of Pathologists of Australia (RCPA) policy statement on the secondary use of human tissue samples collected for diagnostic purposes, the Guidelines for Human DNA Banking from the Human Genetics Society of Australasia and the National Pathology Accreditation Advisory Council Guidelines for the Retention of Laboratory and Diagnostic Material;

5) **NSW Health Department policies** such as the Information Privacy Code of Practice and Requirements Of The Human Tissue Act 1983 In Relation To Research Utilising Human Tissue: Guidance For Human Research Ethics Committees;

Despite the existence of all these documents, individual ethics committees are left to generate their own policies, and at least one institution in NSW has deemed it necessary to get outside assistance in interpreting the legal and ethical requirements for tissue banking research.
1.4 Conceptual challenges to resolving the ethical concerns raised by tissue banking

The organisational, professional and regulatory concerns will not be discussed further since the ethical concerns, particularly consent, are the subject of this thesis. Each of the ethical issues described above is the subject of ongoing debate in the academic (ethical and legal) literature and in the public sphere (eg. as part of law reform processes). In relation to confidentiality, there is a debate about the meaning and appropriateness of privacy in the health care context. In relation to ownership, there are debates about the implications of commodification of the body and the commercial nature of research. There are also debates about the ontological, aesthetic and religious significance of human tissue. In relation to consent, there is a debate (which is the subject of this thesis) about whether archival materials can be accessed without consent, and about the need for project-specific consent. These debates each confront specific and separate issues, but all are part of a larger “tissue banking ethics” discourse. This discourse (and therefore all the associated debates) is mired in a more general conceptual difficulty which make discussion and resolution of the specific issues far more difficult.

As mentioned previously, the phrases “tissue bank” and “tissue banking research” are blanket terms that refer to several different practices, each of which raises specific ethical issues and is associated with specific regulatory requirements. The various activities that fall under the heading of “tissue banking” (Table 1) and the various types of laboratory-based epidemiology that fall under the banner of “tissue banking research” have already been discussed. Appendix A presents a taxonomy of tissue banking research which further breaks down the various activities that fall under this broad heading.

Such a breakdown is necessary because unless one is specific about the details of a given research bank, it is extremely difficult to make sense of the ethical issues that are relevant to a particular situation. For example; it may be considered ethical to use archival stores, collected prior to legislative amendments without recontacting patients, but it may not be
considered ethical to apply the same standards to tissue collected today; material stored in the form of whole organs and reproductive tissue raise more aesthetic and religious concerns than do non-reproductive tissue and tissue stored in other forms; and fully anonymised tissue poses far less risk of loss of confidentiality than do identified or coded tissues.

Furthermore, lack of contextual specificity makes it impossible to ascertain what regulatory requirements may exist in a particular situation. For example; archival material collected prior to legislative amendments may have fewer legal consent requirements than materials collected today; material stored in the form of tissue blocks and slides is not subject to the same consent requirements as whole organs and material stored in other forms; tissue stored in the form of DNA or RNA pellets is not expressly included in amended human tissue legislation, so their status is unclear; identified or coded materials raise more ethical issues than anonymised materials, for which consent is not required; samples containing only diseased tissue only raise fewer ethical issues than samples containing normal tissue, since the latter contain more information about the family members of the donors; collection of regenerative tissue (eg. blood) for research is legally less problematic than is collection of non-replaceable tissues; collections of reproductive materials (eg. embryos) raise more legal issues that other types of collections; collections from post-mortem examinations have to meet different consent requirements to collections from living patients and regulations in the private sector differ slightly from those in the public sector.

The phrase “tissue bank” thus means very little on its own, and clarification is required before ethical debates can be conducted and regulation can be applied. Unless these conceptual difficulties are addressed, and the larger “tissue banking ethics” discourse is conducted in a more precise manner, specific debates such as those surrounding consent will be extremely difficult to navigate.
1.5 **Rationale for analysis and critique of the consent debate**

The major organisational, technical, ethical and regulatory challenges associated with tissue banking have now been outlined, and the conceptual weakness of the broader “tissue banking ethics” discourse has been described. It is now possible to carry out a detailed analysis and critique of one specific ethical debate: the “consent to tissue banking” debate. The remainder of this thesis will consist of a literature review of concepts relevant to the consent debate (Section 2), followed by a thematic analysis (Section 3) and a critique (Section 4) of the “consent to tissue banking” debate. Before embarking on the literature review, the reasons for choosing to analyse the consent debate— as opposed to debates about privacy, commercialisation, tissue sacredness or scientific validity— will be outlined. These are: 1) the centrality of consent to the triggers of the tissue banking discourse; 2) the relevance of consent to other aspects of tissue banking ethics; 3) the opportunities presented by the emergence of the consent debate; 4) the ongoing ambiguity of consent requirements and 5) the existence of reason for concern about the nature of the existing “consent to tissue banking” debate.

1.5.1 **The centrality of consent to the triggers of the tissue banking discourse**

There are many historical instances of public resistance to the scientific use of human tissue (32) and the status of the body as property has long been a subject of debate in legal and ethical discourse(33, 34). Perhaps surprisingly, therefore, tissue banking research went on essentially unnoticed for much of the late twentieth century. Laboratories were able to accumulate decades worth of diagnostic material, and there was little academic or public discourse about it. Autopsy specimens were automatically kept in the form of tissue blocks and stained slides, as were surgical specimens and blood samples. Consent, if obtained at all, was obtained in a blanket fashion that permitted researchers to carry out unspecified research on tissue left over after necessary diagnostic
tests were completed. There was no strong community feeling against the research use of surgical specimens. Such tissue specimens seem to have been regarded as relatively anonymous, ethically neutral (“waste” products) and epistemologically useful.

This complacency ended as a result of two social phenomena – the “tissue retention scandals” and the emergence of stringent privacy legislation – both of which relate directly to consent. The “tissue retention scandals” arose in response to the public’s discovery that organs removed at post-mortem examination were being retained and used for research. A series of such scandals, first in the UK (Bristol and Alder Hey) and then in New Zealand and Australia (Glebe), led to several inquiries and reports which in turn led to an examination of all types of tissue banking practices and the development of new legislation. Organs were often removed from children without parental knowledge, and there was an enormous amount of distress when parents discovered that their children had, unbeknownst to them, been buried without their brains or hearts. It became clear that the tissue retention scandals were not as much about undesirable research as they were about unauthorized research. Consider, for example, the title of a journal article published in the medico-legal literature:

Retained human tissues: a molecular genetics goldmine or modern grave robbing?  
(35)

Similarly, the following newspaper headlines capture the sensitivity surrounding tissue retention without consent:

“How doctors stole little kids’ hearts” (The Age 4 February 2001) and
“The body snatchers” (Ninemsn 18 March 2001).

The use of terms such as “robbing”, “stealing” and “snatching” illustrate the centrality of consent (or lack thereof) to the tissue retention scandals. The public was not against research itself; rather, they were against unauthorized research.
The tissue banking discourse has also arisen in response to increasing general concerns about privacy, and the widespread reform of privacy legislation has forced a re-thinking of research practices. Whilst it may seem that the privacy discourse is of more relevance to debates about tissue banking confidentiality than to debates about tissue banking consent, examination of the ever-increasing so-called “privacy” legislation reveals that many of the principles in the various pieces of privacy legislation set out consent requirements for the gathering, use, transfer and disclosure of personal (health) information. Furthermore, the increasing stringency of privacy legislation has caused great controversy in the scientific community, and it is the new consent requirements—rather than requirements relating to protection of confidentiality—that have been the source of this controversy, since many scientists see stringent consent as an unnecessary burden that will stifle important research. For this reason, consent has been, and continues to be the main aspect of tissue banking ethics debated in the bioethical and legal literature.

1.5.2 The relevance of consent to other aspects of tissue banking ethics

In addition to being central to triggers of the tissue banking discourse, consent is also closely related to debates about privacy, commercialisation and tissue sacredness. Whilst there may be an argument that health and genetic information should not be private, most so-called “privacy” debates are actually about the nature of consent required to warn about potential breaches of privacy. Similarly, whilst there may be arguments about whether tissue should have special moral status beyond that accorded to other types of health information, most debates in this area are about the type of consent that is needed to show respect to people with particular religious or cultural beliefs about tissue. Consent is also central to debates about commercialisation, since consent and the granting of ownership status are both ways of increasing the control that people have over their tissues; and the commercialisation debate examines whether consent is an adequate means of maintaining personal control in the absence of ownership rights.
1.5.3 The opportunity for philosophical reflection presented by the consent debate

In addition to being an ongoing problem for tissue bankers, the sudden salience of uncertainties about consent to tissue banking makes visible issues about consent that are relevant to all kinds of research, but have not been considered in sufficient detail in other research contexts. The question of how to manage consent to unspecified future tissue research, for example, is relevant to all epidemiological studies in which data may be re-analysed or research subjects re-contacted to give further information. The issue of how to gain consent for the use of potentially sacred human tissue in research is also relevant to other tissue-based research such as stem cell research. Even if these concerns are not unique to tissue banking consent (as they apply for example, to consent to other kinds of genetic or epidemiological research), the advent of a discourse about tissue banking research has brought these concerns out into the public and academic discourse, providing a valuable template for their consideration, and possibly providing an opportunity for the improvement of all consent-related policies and procedures.

1.5.4 The ongoing ambiguity of consent requirements despite extensive discourse and a call for guidance

Despite the centrality of consent to the triggers of and debates about tissue banking, as well as the proliferation of academic articles, discussion papers and guidelines about consent, there is still no clear ethical resolution or practical guidance on consent requirements. In relation to the use of archival collections, there is no clear guidance as to whether samples can ethically be used without re-contacting tissue donors. In relation to
new collections, it is not clear how project-specific consent needs to be. It is also not clear whether one-off consent (eg. at the time of surgery) is acceptable, or whether donors need to be re-contacted every time a new project is to be carried out. **Appendix B** outlines existing consent requirements and the associated ethical and legal uncertainties.

Meanwhile, Human Research Ethics Committees are expected to judge consent procedures and decide whether projects should go ahead without consent from donors. Without clear guidance, Human Research Ethics Committees are forced to make independent judgements on consent requirements, a situation that is likely to provoke concern and perhaps stunt the research endeavour as a result of defensive, highly conservative decisions being made. The combination of recent public scandals, rapid development of legislation and requests for tissue to be given to researchers in other facilities, private companies and law enforcement agencies, have led to the perception amongst ethics committees that clear guidance is needed urgently (31) and this is another reason for a detailed analysis of, and an attempt to facilitate, the “consent to tissue banking” debate.

### 1.5.5 The existence of reason for concern about the nature of the standard “consent to tissue banking” debate

The “consent to tissue banking” debate is not between two sides who differ on whether or not consent is needed. Rather, as will be illustrated in **Section 3**, it is a debate between those arguing for stringent consent, even at the expense of scientific progress, and those arguing for more lenient consent requirements that do not impede the tissue banking endeavour.

In relation to tissue archives, stringent consent involves re-contacting all people whose samples are held in tissue archives, in order to gain consent to use of these samples. More lenient consent involves using these tissues without re-contacting donors.
In relation to materials collected today, stringent consent involves gaining detailed, project-specific consent, and promising to re-contact patients for every subsequent project that uses their tissues. A consent form might say the following:

“I agree to the use of my tissues for research into the genetic basis of estrogen receptor-positive breast cancer. I agree to be re-contacted in the future regarding the possibility of consenting to other research projects using my tissue.”

More lenient consent involves the gaining of blanket, open-ended consent. A consent form might say:

“I agree to the use of my tissues for medical research. I agree to my tissue being used in the future for projects that have been approved by a Human Research Ethics Committee and a scientific review committee.”

The mere existence of an ongoing debate and regulatory ambiguity does not necessarily imply that there is anything wrong with the way in which the debate is being conducted. Indeed, such a state of affairs could be a sign of a healthy discourse when ethical issues are at stake. There is, however, reason to suspect that the current debate is problematic. General concern about the “consent to tissue banking” debate has been flagged by some scholars, who see the existing debate as anxiety-driven “rudderless” and “susceptible to premature political intercession [which could]...frame the terms of the debate for years to come and lead to unintended consequences of profound import” (9)(p62). More specifically, it appears that the current “consent to tissue banking” debate is problematic in two ways:

- Firstly, it is mired in a seemingly intractable conflict between those who want to maximise personal autonomy via stringent consent requirements, and those who want science to progress in a manner that is unconstrained by stringent consent requirements. No amount of simple re-iteration of these positions will resolve the conflict between those incommensurable goods.
Secondly, the practical outcomes being generated by the debate are all underpinned by a restricted notion of consent as an individualistic, legalistic and static activity, without any recognition that philosophical systems such as communitarianism and feminism have produced well-developed, well-justified notions of consent that have significantly different characteristics than traditional accounts of consent.

These concerns warrant examination, and are another reason for analysing the consent debate.
Section 2- Conceptualisations of consent

In Section 3, a thematic analysis of the current “consent to tissue banking” debate will be carried out. This will critique the degree of reflection on the value-level assumptions underpinning the arguments, and the degree to which alternative systems of values are considered.

In order to carry out this analysis, it is necessary to review the system of values (36) underpinning the dominant notions of autonomy and scientific progress (and therefore consent), and then to review some alternative systems of values (communitarianism and feminism) which have different conceptualisations of autonomy and scientific progress (and therefore consent).

First, the centrality of consent to modern bioethics and health law will be discussed. This will be followed by a summary of the standard bioethical criteria for consent. Challenges to standard bioethical consent will then be presented. This argument begins with an outline of practical challenges which assume that this kind of consent is desirable, but may, unfortunately, not always be possible. Value-level challenges to the necessity and/or desirability of standard bioethical consent will then be presented.

1 Notes on terminology
The phrases “system of values” and “value-level analysis” will be used extensively in this review and in subsequent parts of the thesis. A “system of values” (or “value system”) refers to a system of ideas as to what constitutes wellbeing- referred to here as ontological security and human flourishing. Liberalism, feminism and communitarianism are examples of systems of ideas which make claims about the best routes to ontological security and human flourishing. It is beyond the scope of this thesis to address meta-ethical issues such as the meaning and moral status of values, value-systems, ontological security and flourishing, or normative issues such as the relative merit of different systems of values. Indeed, one of the conclusions that will be drawn from this analysis is that systems of values can be applied fruitfully to real-world ethical problems, without having to address these meta-ethical and normative questions. ”Value-level analysis” simply refers to the process of analysing an issue or argument with reference to the systems of values.
The value-level challenge will consist of the following steps:

1) The western liberal system of values underpinning standard bioethical consent will be outlined;

2) Challenges will then be presented to
   a. individualism in general (liberal or otherwise);
   b. specifically liberal/modernist –as opposed to, for instance feminist or communitarian– conceptions of the individual, autonomy or consent and
   c. the privileging of individualism *within* a western liberal system of values.

This process will then be repeated, replacing *autonomy/ individualism* with *scientific progress*. 
2.1 Review of dominant and alternative conceptualisations of autonomy (and consent)

2.1.1 Dominant (standard bioethical) conceptualisations of autonomy (and consent)

Consent to research is a key issue in both modern bioethics and health law. In terms of the law, consent requirements make up a significant proportion of privacy, human tissue and anatomy legislation. The common law of battery or trespass prevents any physical contact with a person, however slight, without their consent (28). The tort of negligence applies if people are not adequately informed of risks before deciding to participate in research. In the bioethical sphere, The National Health and Medical Research Council (NH&MRC) National Statement on the Ethical Conduct of Research Involving Humans (National Statement) is largely concerned with the need for, and ways of achieving, consent. In the first chapter of the National Statement, the “guiding principle” for researchers is defined as respect for persons which is “expressed as regard for the welfare, rights, beliefs, perceptions, customs and cultural heritage, both individual and collective, of persons involved in research” (37)(1.2; p11). Regard for these things is primarily achieved through informed consent. Similarly, according to the National Statement, “respect for the dignity” of research participants requires that research participants are adequately advised of the risks and benefits involved in the project, that participants are made aware that the potential benefit may not accrue to them, that research ethics committees should not be overly protective in assessing risk (ie. research participants should, if capable, make independent and considered decisions about participation), and that participants are not deceived (28). Consent is itself listed as one of the “principles of ethical conduct” outlined in the first chapter of the National Statement. The remainder of the National Statement is largely concerned with requirements for, and conditions for waiver of, consent under particular circumstances including research.
involving: children and young people, persons with an intellectual or mental impairment, persons highly dependent on medical care, persons in dependent or unequal relationships, collectivities and Aboriginal and Torres Strait Islander people and deception of participants, concealment or covert observation (37).

Standard bioethical conceptualisations of consent, found in documents such as the National Statement and in most bioethics texts, encompass several criteria: including information, competence/capacity, voluntariness and the recording of consent.

**Information**
In modern bioethics and law, the term “consent” is essentially synonymous with the phrase *informed* consent. The National Statement requires: “provision to participants, at their level of comprehension, of information about the purpose, methods, demands, risks, inconveniences, discomforts, and possible outcomes of the research (including the likelihood and form of publication of research results)” (37)(1.7; p12). The Human Research Ethics Handbook notes that the manner and form of provision of information needs to be considered in addition to the type of information provided (28). Although the law only requires a person to be informed in broad terms of the nature of the intended procedure, a person who is not informed of the risks of research may be able to sue for negligence if harm arises (28). The standard of information required for consent to research is generally higher than that required for consent to therapeutic procedures.

**Competence/capacity**
Standard bioethical consent is thought to be valid only when the research subject has the *ability* to adequately understand all the relevant options and their risks (38). Competence requires an individual to 1) comprehend and retain information, 2) believe it to be accurate, and 3) balance it and make a decision based on the information (28).
Voluntariness

Standard bioethical consent needs to be voluntary, which means that there is no coercion (actual or perceived) or fraud in obtaining consent (28). Voluntary informed consent enables research to be carried out, and people to be put at risk, without this constituting exploitation (28). The ability to refuse to participate in and to withdraw from research is another of the Principles of Ethical Conduct that make up the first chapter of the National Statement, as is the requirement that consent is not “subject to any coercion, or to any inducement or influence which could impair its voluntary character” (37)(1.10; p12). Developments in contract law recognise the importance of people being able to be released from contracts and compensated for loss where advantage has knowingly been taken of the less competent party (28).

Clear means of recording consent

The National Statement requires consent to be clearly established via a signed form, return of a survey, video- or tape-recorded agreement for interview or other sufficient means (37).

2.1.2 Practical challenges to dominant (standard bioethical) conceptualizations of autonomy (and consent)

There are several practical challenges to the dominant, bioethical notion of consent. These include difficulty in: obtaining truly informed consent, evaluating and communicating harms and benefits, assessing competence and defining the role of surrogate decision-makers, obtaining truly voluntary consent and allowing complete withdrawal.
Obtaining truly informed consent

Some critics argue that consent can never be truly informed, since information can never be fully imparted or understood. Indeed, “understanding” is a complex concept involving knowledge, comprehension and information processing, as well as the possibility of non-acceptance of the truth and the holding of false belief (39). The law recognizes the limitations to understanding, and consent is not considered (legally) ineffective just because the person does not fully understand what is involved. All that is required is that the person is informed in broad terms of the nature of the procedure.

These difficulties are compounded where consent is being obtained for future events that are not yet fully elucidated so that subjects cannot possibly be informed fully. Practices such as tissue banking for future research raise the question of whether even “competent” adults who fully understand the nature of tissue banking research today can give meaningful consent, since tissues will be stored for long periods of time and will be analysed using techniques that do not even exist now. The issues raised are similar to those associated with clinical advance directives, in which patients state in advance whether they would like to be resuscitated or treated in the event of a life-threatening illness that renders them unable to communicate. These directives are highly controversial since patients often change their minds about treatment decisions, directives are often ignored by families and treating staff, and circumstances arise that could not have been predicted, let alone communicated, at the time of gaining consent (40).

The Human Research Ethics Handbook notes that, whilst consent is widely believed to inform autonomous decision-making rights of participants, there is in fact always a need for subjects to trust physicians and researchers to guide them through the decision-making process and to ensure that participants are not being asked to consent to something that would be wrong even if consent was obtained (eg. to becoming enslaved) (28). Indeed, it may only be meaningful to talk about “authorisation,” rather than “consent” in the context of tissue banking research in which patients are asked to allow,
and trust researchers to carry out appropriate research on their samples as part of currently unknown future research projects.

*Communicating harms and benefits*

Another difficulty associated with information-giving is the difficulty of communicating harms, benefits and the nature of experiences. Many people have difficulty conceptualising risk and benefit statistics (41). Even if risks and benefits are accurately understood, different people have different notions of what constitutes adequate benefit or unacceptable risk. To those suffering from a serious illness in desperate need of a cure, what would seem like a large, unacceptable risk to others, may seem small. Donors with a life-threatening cancer, for example, may be willing to incur the risk of loss of confidentiality, whereas those with more minor problems may find such risks unacceptable.

Furthermore, some groups are more susceptible to a given (accurately assessed) risk than are others because they are physically weaker, or more vulnerable to stigma or psychological damage. Aboriginal tissue donors may, for example, be at greater risk of stigmatisation should results be inappropriately disclosed, so even a small risk of disclosure is highly significant.

*Assessing competence and the role of surrogates*

It is obvious that that not all individuals have equal capacity to give informed consent. Capacity is not, however, an absolute concept. Beauchamp and Childress note the complexity of defining, setting standards, testing and drawing boundary lines when it comes to competence (39). Difficulties do not end once incompetence has been determined, since it is then necessary to choose appropriate surrogate decision-makers and to decide on the appropriate standard for surrogate decision making, of which there are at least three (each with its own shortcomings) (39): 1) substituted judgement in which the surrogate attempts to make the decision the incompetent person would have made if competent; 2) the pure autonomy standard in which the surrogate’s role is to put into practice an advance directive in order to respect a patient’s prior autonomous judgement and 3) the best interests standard in which the surrogate must determine which
of the available options is likely to provide the highest benefit. None of these are ideal or entirely practicable. It is impossible 1) to be certain of what someone would have done had they been competent; 2) to know whether an advance directive reflects the person’s more recent desires and 3) to know what is in somebody else’s best interests.

Avoiding coercion

Obtaining truly voluntary consent is difficult. Patients may feel coerced into participating in research if asked to participate by clinicians with whom the patient has a relationship that is necessarily imbalanced. A monetary sum that would not constitute inducement for someone of moderate or high socio-economic status might constitute inducement for poorer “volunteers.” A similar imbalance might apply to volunteers with varying levels of self-esteem, dependence and trust in the medical system (28). Feminist and critical psychology researchers note that some vulnerable research subjects are accustomed to “accommodating themselves to nonchoice situations in order to survive” (42)(p848). This makes it vital that the researcher take full responsibility for identifying and changing aspects of the research process that might be experienced as coercive. More subtly, in certain types of in-depth qualitative research with disadvantaged populations, the research subject may misconstrue the researcher-subject relationship as a friendship, and disclose information that they would not really want used in research (42).

As well as being difficult to achieve in practice, voluntariness is conceptually complex. There are at least three categories of influence: coercion, persuasion and manipulation (39). Moreover, in some circumstances, such as those involving clearly incompetent patients, influence (even coercion) is both necessary and desirable, so these acts cannot be rejected outright.
Enabling withdrawal

Whilst in practice it can be that volunteers can withdraw their consent and participation at any time, it may sometimes be practically impossible to withdraw information specific to a particular participant. Fully anonymised samples, for example, cannot be withdrawn should the research take a direction that is unacceptable to a specific participant. Also, withdrawal of samples may compromise the research by reducing the sample size or creating bias (since some people are more likely than others to withdraw). This may be unethical to other participants who are willing to incur risks on the basis of a particular likelihood of success (28).

2.1.3 Responses to these practical challenges

A number of suggestions have been made in order to deal with these practical challenges. In relation to tissue banking research, the need to gain consent to unspecified future research is a particular problem, since it makes it impossible to give sufficient information. Practical suggestions to overcome this difficulty include:

1) Review of all subsequent projects by an ethics committee if only open (blanket) consent is obtained. In this way, ongoing information is provided, albeit to surrogate decision-makers;
2) Clearly stated time limits for the use of the bank so that there is a limit to the amount of unspecified research that can be carried out and
3) An absolute right of withdrawal so that people can remove their samples if the research goes in directions that are unacceptable to them (43, 44).

Even if such practical safeguards and remedies are successful, however, they do not address value-level (as opposed to practical) challenges to standard bioethical consent. Those putting forth practical challenges assume that standard bioethical consent is necessary and desirable. They do not consider the possibility that this type of consent
might be inappropriate even if the practical issues are met, and do not encourage consideration of significantly different notions of consent, such as those advocated by feminist and communitarian scholars.

In order to outline value-level challenges, the western liberal underpinning of standard bioethical consent will be outlined, followed by a series of value-level challenges.

2.1.4 Systems of values underpinning standard bioethical conceptualisations of consent

**Western liberalism, or liberal individualism as the dominant system of values underpinning standard bioethical consent**

*Characteristics and dominance of liberal individualism*

The standard bioethical notion of consent is underpinned primarily by a liberal individualist system of values, which consists of a particular set of assumptions about the route to ontological security and human flourishing that privileges values such as individual choice, freedom and protection from interference. Autonomy is central to western liberalism and, in this context, refers to *individual* autonomy. Beauchamp and Childress, define liberal individualism as: “the conception that in a democratic society a certain space must be carved out within which the individual is protected and allowed to pursue personal projects” (45, 46)(p356). Respect for an autonomous agent involves respectful action, and is associated with obligations to maintain capacities for autonomous choice in others (39). Liberalism also (necessarily) encompasses a belief in the rational capacity of individuals (47).

Authority has the potential to threaten individual autonomy, and different strands of liberalism allow for varying levels of authority. Anarchists claim that the state has no justified power at all. Libertarian liberalism only allows the state to act to prevent infringements of people’s right to do what they choose (46). Alternatively, the state’s
powers may extend to allow for the provision of welfare. Welfare liberalism requires the state to insure basic satisfaction of needs and provision of opportunity for each individual (47). Even in welfare liberalism, maximal individual autonomy remains the central tenet, and the purpose of welfare is to increase liberty of individuals. Moreover, welfare liberalism allows for authority only as long as individuals choose to submit to that authority.

Liberalism is clearly the dominant system of values in our society. This is reflected in the shape that the field of “bioethics” has taken. The field of “bioethics” emphasizes liberal values. A liberal value system is reflected, for example, in the strong focus of modern research ethics on autonomy of individual research subjects and on protection of individual research subjects from undesirable interference. The centrality of this liberal value system to modern bioethics is largely due to historical, and frequently paternalistic abuses of research subjects, and the gradual recognition over the course of the 19th and 20th centuries that “what it was right to do within the closed and detached world of science, was not necessarily right in the wider context of society at large” (48)(p136). The Nuremberg Code, which arose as a result of Nazi abuses of research subjects, requires a research participant to be able to exercise “free power of choice, without the intervention of any element of force, fraud, deceit, duress, over-reaching or other ulterior form of constraint or coercion” (49).

Even normative ethical theories, which are supposed to be confined to the form, rather than the content, of moral reasoning, and therefore neutral on the question of particular values, tend to have a liberal flavour. The phrase “liberal principlism” is, for example, sometimes used to describe the view of human flourishing emphasized by most principle-based ethicists. Callahan observes that principlism reflects the liberal, individualist culture from which it emerged (50). The fact that an individualistic version of autonomy is one of the four central principles of bioethics, and perhaps the dominant principle to which the other principles “seem ineluctably to lead back,” (50)(p288) demonstrates this leaning of bioethics towards western liberalism. Nonmaleficence emphasizes the (liberal) right of bodily non-interference, beneficence aims to enhance people’s ability to live
autonomous lives and justice aims to ensure than individuals have the resources to be autonomous (51). Beauchamp and Childress’ description of the derivation of the principle of autonomy is based on an individualistic notion of a good life. They see personal autonomy as an extension of political self-rule to self-governance by the individual in which the individual is free from interference and other limitations to meaningful choice(45).

Whilst there is a debate within modern bioethics about the exact meaning of and criteria for autonomy, in much of this discussion, autonomy remains confined to individual (liberal) autonomy and the various schools of thought differ only in relation to how this individualism should be expressed. There is also recognition that individual autonomy has limitations, should not be oversimplified and needs to be qualified. Beauchamp and Childress (39) make several such qualifications, but the essentially individualistic definition of autonomy is retained. They note, for example, that autonomy is compatible with the existence of authority, but that believe that autonomy and authority can co-exist as only long as individuals (italics added) choose to accept and submit to authorities. They also acknowledge that principles (including autonomy) are shared, and derived from and expressed in cultural traditions, yet they insist that these principles remain an “individual’s own principles.” They do acknowledge that the principle of autonomy can be overridden by other principles such as beneficence. We cannot, for example, make choices that endanger the public health, potentially harm innocent others, or require an unavailable resource. Even this, however, sustains an essentially individualistic definition of autonomy, in which the meaning of autonomy is still maximal freedom for, and welfare of, the individual. In this case, autonomy is simply balanced against other principles such as beneficence and justice. Finally, they acknowledge that there are clearly some situations in which individuals (eg. children and the mentally ill) are not, and cannot be autonomous, even to the extent of allowing “justifiable paternalistic interventions” on behalf of persons as individuals. Once again, however, the definition of autonomy remains essentially individualistic.
Like principle-based ethics, human rights theory is also closely allied to liberal individualism. Human rights theorists promote the provision of shelter and a recourse for individuals and groups (usually minorities) who feel themselves in conflict with or wronged by other individuals or groups (36). Freeden’s definition of rights emphasizes a particular notion of human flourishing based on the protection of the personal and social attributes of an individual, and rights are “intended to serve as a protective capsule” for these attributes (36, 52). The language of individualistic principles overlaps with the language of rights. Beauchamp and Childress note, for example, that correlative to the obligation to respect autonomy is the right to self-determination, which supports various autonomy rights including those of privacy and confidentiality (italics added) (39).

Liberal individualism is also central to the utilitarian defence of individuality and (one view of) Kantian autonomy (45). Mill argued that people should be able to shape their own lives as long as this does not prevent others from doing so (53). Kant argued that people should never be treated solely as a means to an end, without regard to that person’s own goals (54). Respect for individual autonomy flows from these recognitions (39).

Liberal individualism is even embedded even in supposedly non-normative conceptions of the cognitive structural development of moral reasoning. Kohlberg’s most “mature” stage of moral reasoning consists of principled morality coming from an autonomous self operating above communal norms (55).

Given the dominance of liberal individualism in our society and in modern bioethics, it is not surprising that the standard bioethical model of consent is underpinned by liberal individualism.
The link between liberal individualism and standard bioethical notions of consent

Individual autonomy, the key feature of western liberalism, translates directly into informed consent in the medical setting. As the Human Research Ethics Handbook states: “consent is widely believed to affirm the autonomous decisionmaking rights of prospective research participants, and their capacity to protect their own interests (italics added) (28)(E29). In their discussion of the principle of “respect for autonomy,” Beauchamp and Childress refer to the positive obligation of respectful treatment in disclosing information and fostering autonomous decision making (italics added). The modern bioethical criteria for consent are clearly recognisable in this interpretation of autonomy in practice, as are the broad characteristics of modern bioethical consent: individualism, project-specificity and legalism. The individualism of standard bioethical consent is a reflection of the western liberal privileging of individual (as opposed to, say, community or state) autonomy. The specificity of the standard bioethical consent reflects the western liberal privileging of individual choice and control. The more specific the information given to participants, the more informed their choices are and, therefore, the more control they have. The legalistic nature of standard bioethical consent (as a simple contract) reflects the western liberal notion that individuals need to be (legally) protected from exploitation by other individuals, and a legal contract is the best means of achieving such protection.

In summary, all of the major characteristics of standard bioethical consent can be traced to their underpinning liberal individualist system of values.

Other systems of values that are compatible with the standard bioethical notion of consent

Whilst western liberalism is the dominant system of values underpinning the modern bioethical conception of consent, other systems of values, such as some branches of feminism, would also advocate a consent process that is individualistic, specific and legalistic. According to some feminist scholars, for example, the goals of feminist social
and political philosophy are “to suggest morally desirable and politically feasible ways to give women the same justice, freedom and equality that men have” (56)(p306).” This would translate into informed consent processes that give women (and other disadvantaged groups) increased individual autonomy and would be compatible with standard bioethical consent with its focus on the individual (in this case a woman.) Indeed liberal feminists might aspire to an even more individualistic, legalistic type of consent than is usually applied in bioethics. Feminist scholars have also challenged definitions of competence that seem to be pretences to limit the autonomy of research subjects, or even to oppress and mask other sources of oppression (57).

2.1.5 Value-level challenges to dominant (standard bioethical) conceptualisation of consent

Given the recognition that standard bioethical consent is underpinned by a specific, liberal system of values, it is possible to mount value-level challenges to standard bioethical consent. There are three kinds of value-level challenges to the standard bioethical notion of consent:

A) Challenges to the notion that individualism (liberal or otherwise) is the route to security and flourishing;

B) Challenges to the liberal system of values, with an emphasis on challenging its individualist elements and

C) Challenges to the notion that that liberal individualism is the primary value within the modernist meta-narrative, which refers to system of values privileged in the post-Enlightenment civilisations of Europe and North America, and also endorses science, technology, capitalism, secularism, rationalism and humanism) (58).

Each of these will be considered in turn in order to illustrate the variety of ways in which value-level challenges can be mounted, and as a preface to Section 3 in which the values
underpinning the standard “consent to tissue banking” debate will be analysed and
Section 4 in which alternative systems of values will be used to build a new model of
tissue banking consent.

A) Value-level challenges to individualism in general (liberal or otherwise)

There is widespread recognition, even in traditional bioethical circles, that individual
autonomy has severe limitations. Even Beauchamp and Childress, whose “principle-
based ethics” has long been the mainstay of western liberal bioethical reasoning, open
their chapter with the following acknowledgment:

Respect for the autonomous choice of other persons runs as deep in common
morality as any principle, but little agreement exists about its nature and strength
or about specific rights of autonomy (39)(p57).

Most of the criticisms of individualism, however, come from outside standard bioethics
which is more concerned with the nuances of individual autonomy than with challenging
its fundamental validity as a route to ontological security and human flourishing.

Unbalanced individualism, with its emphasis on individual autonomy and neutrality
about questions of the good life can be seen as leading to disturbing moral relativism
(36). It also threatens social cohesion. Marx, for example, saw individualism as an
obstacle to human emancipation since individualist rights are egoistic and lead people to
see each other as obstacles to freedom leading to competition, degradation and
antagonism (59)(p143). At worst, critics of individualism argue that totalitarianism is the
consequence of a world devoid of common connections and common meanings (46).

This is disturbing to us not only because it precludes condemnation of morally abhorrent
acts, leads to egoism and may prompt totalitarianism, but because it threatens our
identity. It does this because it fails to recognize that identity is linked to social roles and
shared history (36). Hegel, for example, emphasized the centrality of our role as citizens and as participants in a common life to our sense of personhood. Indeed, these roles are partly constitutive of the persons we are (46).

On a more practical level, there is increasing dissatisfaction with the lives that individualist systems of values endorse, with its expectation, and even encouragement of social and geographic mobility, distanced personal relationships, welfare dependence, breakdowns in family life and marital fidelity, political fragmentation, etc. (45). This fragmentation is evident in the increasing dissatisfaction with medical and scientific cultures which seem ever more removed from the community and the notion of care. From a political perspective, the individualist vision is seen as being too limited because it makes it difficult to justify political arrangements since it must do so largely without reference to common purposes and ends (46). Some argue that it also excludes—or at least seriously limits the attention paid to—communal demands, group interests, education in citizenship and commitment to the general welfare such as public health, biomedical research and the protection of animals—goods which do not emerge from freely made contracts between individuals (45).

Individualism is often justified on the basis of its origins as a response to the abuses that have occurred when individuals have not been given control over their lives, and have not been protected from interference. Not all origins of individualism are, however, so obviously justifiable. Our emphasis on the individual might be at least partly the result of 1) vicious circles of isolation, since individualistic societies are characterised, and their individualism reinforced, by loss of religious an other traditions; 2) loss of local social systems; 3) loss of trust; 4) corruption of government, institutions and commerce; 5) frightening developments in science and medicine and 6) a modern preoccupation with personal authenticity (36). The increasing dissatisfaction with science and medicine, and the failure of autonomy-focused research ethics to assuage our concerns may stem from unspoken concerns about the deeper, and not always desirable, forces underpinning modern individualism and may reflect a desire to return to some of the more communal value systems that have been lost.
B) Value-level challenges to western liberal conceptions of the individual, autonomy and consent

In our society, a challenge to individualism in general is almost synonymous with a challenge to the individualist component of western liberalism. Indeed, the word “liberal” could have been inserted in front of the word “individualism” in the preceding section without changing its meaning. It is, however, useful to see individualism as being part of a broader socio-political system of values (ie. western liberalism) since there are several well-developed value-level alternatives to western liberalism (eg. communitarianism and some branches of feminism) that privilege different notions of security and flourishing, conceptualise autonomy in different ways and may, therefore, lead to interesting notions of, and approaches to, consent. Communitarian and feminist conceptions of the individual, and associated conceptions of consent, will now be outlined so that it can be shown how different conceptualisations of the individual, autonomy, ontological security and human flourishing can be translated into different models of consent.

(B1) Communitarianism

Communitarian conceptions of the individual, autonomy, ontological security and human flourishing

Communitarian theory is formed from a multiplicity of discourses with varying degrees of compatibility with liberalism. The common thread through these discourses is their philosophical and/or ideological emphasis on the importance of community for identity and flourishing. To communitarians, community security and community-level flourishing are at least as important as individual autonomy and the flourishing of individuals. Communitarians claim that modernity, with its liberal individualist focus and resulting loss of community structures, has had deleterious effects on the abilities of both individuals and communities to flourish and achieve ontological security. Indeed,
communitarians would argue that human beings are social animals “whose lives are lived out within deeply penetrating social, political and cultural institutions and practices” (p288) and that the liberal individualist values such as individual autonomy, authenticity and freedom, which may well be necessary for individuals to flourish, are actually logically secondary to community, and thus require community if they are to have any meaning (36).

Taylor argues that flourishing communities are also a prerequisite to true authenticity. In a critique of the individualistic focus of the “authenticity movement,” Taylor has emphasized that authenticity and individual development can only be established by dialogue and that the values developed in that dialogue can only be established against the background of values shared with others (36). Similarly, whilst communitarianism might seem incompatible with freedom, this is not necessarily the case because freedom might only be achievable in the context of political community that expresses the identity of its members (46). Communitarians thus situate and define the individual in a social context, thus avoiding what they see as a false separation between individuals and their community (60).

Communitarianism is associated with communal values such as connectedness, trust, solidarity, altruism and sacrifice for the common good. Attainment of the common good might justify compromise of individual autonomy because communitarians view the community as having a valid existence of its own, deserving of protection and enhancement, rather than simply being the sum of its individual parts. This might be called an ecological approach which takes the welfare of the whole as the point of departure (51). Communitarians thus propose that we shift from an emphasis on rights in to an emphasis on the common good and the community’s way of life (45). These social goods are not incompatible with liberal values and language, but communitarianism elevates different elements of a flourishing society, and refrains from pitting individual protections against community protections (60). In the medical context, for example, Glannon proposes a model for organ donation that conceives of organ donation as giving back something to the community from which one has benefited: “The idea of giving
back, as opposed to just giving, implies an obligation and accordingly should not be
confused with the idea of donation as a gift or an altruistic act. It is not generated from a
right or claim by others but instead from the idea that one shares common interests,
needs, and values with other individuals in a community” (61)(p155). More generally,
Little believes that, even in our liberal culture, it is important to see health as a
community endeavour, rather than seeing individuals as rights bearers and health
organisations as rights deliverers (36).

At a political level, communitarianism allows for far more state power than does
liberalism (even welfare liberalism). At the extreme end of the spectrum is Hobbes’
argument that government has no obligation to pay any regard at all to the liberties of its
subjects (59). Communitarianism also rejects distinctions between the public and private
sphere, and demands that society actively determine what (if anything) belongs in the
private sphere (50). In a practical sense, communitarians see the importance of
democratic participation, in which “every member of the community ought to have a part
in…discussions [of the human good, understood comprehensively], and allowed to speak
the language most congenial to their religious or secular values” (51)(p504).

Applications of communitarian conceptions of the individual, autonomy, security and
flourishing to the consent process
Unlike standard bioethical (western liberal) consent, which is well-developed,
extensively debated, and nuanced, the process of consent based upon communitarian
values has not been clearly articulated and needs to be surmised from the more general
communitarian values. There would, of course, be many variations of so-called
“communitarian consent”, and it is impossible to elucidate all of them. Nonetheless, it is
possible to infer the overall purpose and major characteristics of consent based upon
communitarian values. Of particular relevance are the communitarian notions that
individual autonomy is secondary to communal goods and that the good is best achieved
through communal processes (36).

Purposes of consent
Unlike liberalist consent, which aims to maximise individual freedom and protect individuals from undesirable interference, communitarian conceptions of consent aim to maximise the good for whole communities and, through this, for the individuals within those communities. It would also aim, through its procedures, to strengthen solidarity and involve communities in decision-making processes to the greatest extent possible. At the very least, it would aim to ensure that communities were not harmed by the research and/or consent process.

Consent procedures
Communitarian consent might involve liaison with, and acceptance of decisions made by, community representatives rather than individual research subjects. Thus it would involve a reconceptualisation of the relationships between individual research participants, communities, researchers and research ethics committees. Researchers might, for example, need to liaise with community representatives rather than individual patients/supjects. Ethics committees would also need to liaise with community representatives, rather than being isolated from research subjects. Communitarian consent would also require a reconceptualisation of the relationship between individuals and their communities, since community representatives, rather than individuals, would be making consent decisions. This community consent process has precedent in other settings. Irwig et al recommend that consent for population screening be carried out by community sampling. Community sampling provides information on the distribution of preferences among “fully informed potential screenees.” Advantages include reduced effort and increased depth of information that can be given to community representatives (62).

In general terms, the communitarian consent process would be contextual, and able to respond to the needs of particular communities rather than abstract, legalistic and rigid. In communitarian ethics, the aim is not to apply universal principles, but rather to consider the values expressed in the ways of life of real communities and generate principles in such as way that they are accepted and owned by social actors (50).
Communitarian consent would also be ongoing, rather than static. Bastian notes that the community consent process is not a single encounter, and the researcher must continue to involve and work in partnership with community representatives through the entire research process (63). Indeed, this dynamic, ongoing relationship is one of the key differences between individual and community-level consent. Whilst it is not possible to involve every individual in every step of research, it may be possible to maintain contact with community representatives throughout the life of a project. This is particularly relevant to tissue banking research, since tissues are stored for indefinite periods of time, and may be used for research that could not have been envisaged at the time at which original individual (or even community-level) consent was gained.

Communitarian consent has been used for research in non-western countries in which it has been recognized that standard bioethical (Western) research ethics guidelines do not adequately attend to the role and influence of the community. In these settings it is clear that community consent procedures precede or supersede those involving individuals (60). The latest (2002) revision of the Council of International Organisations of Medical Sciences (CIOMS)/ World Health Organisation (WHO) guidelines (64) emphasise the need to involve local communities in the research process. Dresden et al (60) have applied communitarian research ethics in Africa. To account for cultural differences, HIV researchers in Swaziland phoned, faxed and spoke to community leaders before visiting their district. They then held town hall meetings, at which community leaders and community members could hear about the research and ask questions. These meetings allowed information to be fed back to the researchers who were able to adjust their research to that community’s needs (60). Zion reports a positive outcome of community involvement in allowing an HIV drug trial study proceed. Initially, some lobbyists feared that participation in a trial would lead to unsafe sex practices and threaten the whole community. Others argued that individuals should have the right to participate in trials. Eventually, the representatives of the gay community chose not to prevent community participation in the trial, but rather to provide more information and remain involved in the research process (65). This illustrates that, paradoxically, a communitarian approach might actually increase the knowledge that the community (and, therefore the individuals
within it) have over the research endeavour, thereby indirectly increasing individual autonomy.

(B2) Feminism

Feminist conceptions of the individual, autonomy, ontological security and human flourishing

Feminism is a multi-dimensional philosophical and socio-political system, some branches of which are perfectly compatible with liberal individualism, other branches challenge the liberal notion concept that security and flourishing are best achieved through individuation. In feminist scholarship, connectedness and the maintenance of relationships have been recognized as key components of both human flourishing (66) and morality (66, 67). Not all feminist scholars endorse a replacement of “masculine” characteristics with “feminine” alternatives, for example, provides a feminist critique of the tendency of some philosophers to construe men as being preoccupied with culture, reason, the abstract, rules justice, the mind and the public domain, whilst women are grounded in nature, passion, the concrete, contexts, caring and connectedness. Such dichotomies have a dangerous impact on values and social logic (68).

In terms of human flourishing, some feminist theory privileges care-based relationships, with balance between self and other, seeing this rather than separation as the pinnacle of human development. Benhabib, for example, argues that “a critique of the ideal of the autonomous and male ego as the ideal telos of human development” is a theme requiring further elaboration (66). Nussbaum identifies several aspects of human functioning which are compatible with feminist conceptions of human flourishing. These include affiliation with other human beings, humour and play (along with separateness). Basic human functional capacities include living with and for others (along with living one’s own life) (69).
In terms of morality, some feminists reject an exclusive emphasis on individual rights and autonomy in bioethics (70). Carol Gilligan notes that women speak “in a different voice” and challenges the idea that a (feminine) care and responsibility-based morality is inferior to a (masculine) rights- or justice - based morality (67). Moral conflicts do not need to be resolved in an adversarial way. Instead, many feminist scholars stress the significance of empathy, interdependence and caring (58).

Feminist theories of morality also contain an emotional element, seeing empathy as equal in importance to rationality (70). Many philosophers who might not identify their approaches as 'feminist' argue that the quest for universal principles of morality is unlikely to succeed. Rather than searching for external sets of norms, one should instead be concerned about people’s motivations. Bernard Williams argued that, whilst we should not aim to do away with modern attempts to gain social understanding, ancient philosophers were “better off” in that they were “less determined to impose rationality through reductive theory(71)(p197).” This does not mean that ethical thought is exempt from the need to stand up to reflection, but it does follow that rational impartiality is not necessarily central to ethical reasoning and that philosophies do not need to be value-neutral in order to be valid. As Williams argues:

> We must reject any model of personal practical thought according to which all my projects, purposes and needs should be made, discursively and at once, considerations for me. I must deliberate from what I am (71)(p200).

Like communitarianism, feminist ethics also privileges experience and the importance of “rich empiricism” in assessing the morality of a particular act (72). Abstract ethical principles are not required (73) and it is necessary to have an understanding of local politics and power if ethics is to be understood (58). Benhabib believes that practical reason should be grounded in the indeterminate and pluralistic realities of real life, rather than in the constructions of legislating reason (66). Feminist scholars also challenge the
notion that scientific standards of evidence are the only way of knowing about the benefits and risks of research. Non scientifically-based desires and concerns have just as much ethical weight (74).

Bridging human flourishing and morality for many feminists is the notion that obligation and connection are the starting point of human interaction. Feminism thus values personal growth and negotiation, the aim of which is to create freedom out of connection while retaining as much as much of the connection as possible (75). This contrasts with the liberal tradition in which freedom is the starting point, and obligation is voluntarily assumed through processes such as contract.

Of most relevance to consent are the feminist conceptions of autonomy and power. Feminism is similar to communitarianism in that it rejects the idea that autonomy can exist without connection, and that we should strive to minimize interference (in the liberal tradition) or ‘false consciousness’ (in the Marxist tradition). There are, however, differences between communitarianism and feminism. Whereas communitarianism reduces the importance of individual autonomy in favour of community-based processes aimed at maximising the common good, feminism redefines autonomy as a relational process, which may take place at the individual (or community) level and may be concerned with the autonomy of individuals (or communities). In contrast to the autonomy of classic liberal theory which entails the creation of protective barriers (76), relational autonomy is seen as being nurtured through one’s relationships with others, which give one the capacity to act for oneself and govern oneself.

Relational autonomy does not require elimination of power imbalances. (75). Rather, it advocates a particular way of using power. Whereas power in the liberal tradition means getting others to do something through the threat of sanction or through force assuming conflicting interests, feminism emphasizes a “politics of persuasion” —getting others to do something through an appeal to long-run self interest, duty and empathy, assuming that on some issues common interests exist or can be created (75). The feminist notion of an ethic of care focuses on the ways in which power imbalances (which are inevitable)
can be used to the advantage of those affected by a decision. Closely related to the recognition of the inevitability of power imbalances is the emphasis that some feminist scholars place on trust. Baier argues that “morality, as anything more than a law within, itself requires trust in order to thrive (77)(p96).” Relationships of trust are not usually played out in explicit contracts between articulate adults who willingly accept vulnerability. People are often in dependency relationships characterised by gross power inequalities, and trust requires those of us in power to determine “what it is for whose care we have some discretionary responsibility (77)(p101).”

Before applying feminist theory to the consent process, it is important to note that there are many ways in which feminism (at least of the kind discussed here) and communitarianism are either linked or complement each other. Both discourses emphasise the value of community in human flourishing, the importance of the common good in ethical thinking, and the importance of collective action in the attainment of these goods.

*Applications of feminist conceptions of the individual, autonomy, security and flourishing to the consent process*

Although feminist conceptions of consent- like communitarian conceptions- are not as well developed as standard bioethical consent, several feminist scholars have developed a relational process in which, even fully competent people enter into significant, interdependent relationships with other (78). Again, there are many possible variations of so-called “feminist consent”, and it is impossible to elucidate all of them. Nonetheless, it is possible to infer the overall purpose and major characteristics of consent based upon feminist values.

*Purposes of consent*

Unlike the ideal of consent underpinned by liberal (and liberal feminist) values, which aim to ensure that a healthy separation is achieved between research subjects and researchers, consent based on some of the feminist values discussed above would aim to cement relationships and promote mutually beneficial behaviour. Feminism emphasizes
the role of the research process itself, in particular consent processes, in challenging social injustice and promoting the interests of participants. Feminist consent would aim to ensure that the effects of the consent process itself are positive, and that the consent process itself did not reproduce the injustices it was trying to fight (42). In other words, feminist consent would see one of its goals as nurturing (as opposed to just protecting) research subject autonomy.

The consent process
Research ethics based upon the values discussed above might have the following procedural characteristics:

1) It would emphasise the “intersubjective nature of the research relationship” and therefore the importance of an ongoing connection between research participants, researchers and ethics committee members. The research process should, therefore, acknowledge and cement the relationship between researcher and subject in a way that “honours the mutuality of the research relationship” (42)(p851);

2) In order to sustain this relationship, consent would need to be an ongoing, rather than static, process. This would not simply consist of asking subjects repeatedly for consent, but would involve ongoing discussions about the direction of research and the experiences and changing circumstances of research participants;

3) Like communitarian consent, feminist consent processes would not be based upon abstract consent rules, and would need to be continually adjusted so that they are appropriate for a given research context and the circumstances of (individual and community-level) research participants. Researchers would need to ground the development of consent procedures “in the messiness of everyday situations” (42)(p842). Paradis, for example, notes that when carrying out research on homeless women, researchers need to redefine ethical concepts such as consent so as to avoid perpetuation of the marginalisation, stigmatisation, and victimisation homeless women face (42);
4) Feminist consent would challenge the notion that scientific standards of evidence are the only way of knowing about research risks, and would put in place procedures for hearing and taking seriously participants’ values and concerns. Feminist Health Advocates (FHAs) see it as their role to ensure that women participating in scientific experiments understand the risks and likely benefits and have the opportunity to express their concerns (74).

5) Balancing the above criteria, which all emphasise autonomy (albeit in a relational rather than individualistic form), is the feminist recognition of a potential obligation to participate in research (75). Protection from harm may thus be relegated to a secondary position, with the primary purpose of enabling the obligation to be fulfilled. Consent processes might (carefully) remind people of their obligations, and appeal to their desire to reciprocate.

6) In keeping with the recognition of obligation, a politics of persuasion (75) might involve scientists explaining the potential benefits (rather than just the risks) of research, including enlightened self-interest and fulfilment of obligation to others to the participants and their ethics committee representatives. This would require the setting up of clear lines of communication between scientists, ethics committees and research participants.

C) Challenges to the notion that individualism is the primary good within the modernist meta-narrative: the “modernist” dilemma

So far, the value-level underpinnings of standard bioethical consent have been challenged through a challenge to individualism in general and specific communitarian and feminist challenges to liberal individualism. The third and final type of challenge does not
question the value of individualism as a social good. Instead, it challenges the notion that individualism (liberal or otherwise) is necessarily the primary social good within the modernist “meta”-level system of values, and cannot be overridden by other modernist goods (58) such as scientific and technological progress.

As will be discussed, this type of challenge is the basis of the most common arguments against stringent consent to tissue banking. These arguments do not challenge (or, indeed, even explicitly mention) individualism or the importance of autonomy. They simply assert that scientific progress is a social good that should not be impeded by anything, including individual autonomy.

This challenge, and its dominance in the “consent to tissue banking” debate highlights an interesting tension within the modernist meta-narrative between the valuing of individual freedom (specifically in the form of liberal democracy) on the one hand, and the valuing of science and technology on the other. The co-existence of liberal democracy and scientific progress in the modernist meta-narrative is clearly expressed by Cahoone who describes modernism as (italics added):

a civilization founded on scientific knowledge of the world and rational knowledge of value, which places the highest premium on individual human life and freedom, and believes that such freedom and rationality will lead to social progress through virtuous, self-controlled work, creating a better material, political, and intellectual life for all (79)(p9).

Whilst both individualism and scientific progress share a modernist origin, they come into conflict where consent is concerned. This tension arises because the sciences – particularly epidemiological sciences such as tissue banking research – make their strongest epistemological claims when their conclusions can be generalised. This requires sample sizes that are as large as possible and free of selection bias. This, in turn, requires participation of as many research subjects as possible. They are, therefore, inevitably in logical and moral conflict with other modernist values, such as individual
autonomy, that privilege the individual. This modernist dilemma is evident even in definitions of (liberal) principle-based bioethics, as illustrated in the following excerpt from ALRC96 (italics added):

The school of principlist ethics…is characterised by an assumption that scientific progress is essential for the good of humanity, coupled with a concern to protect individual and group rights that may be endangered in the course of scientific research. It seeks to establish principles that must be respected in carrying out this work (1)(6.25).

A review of dominant and alternative conceptualizations of scientific progress will now be presented, and it will be argued that notions of scientific progress can be challenged, and enriched by considering the value-level underpinnings of dominant notions of scientific progress, as well as alternative- communitarian and feminist- systems of values.
2.2 Review of dominant and alternative conceptualisations of scientific progress (and consent)

2.2.1 Dominant conceptualisations of scientific progress

In today’s Western society, scientific progress leading to increased knowledge and technological capacity is clearly privileged as a social good. The privileging of science can occur at a number of different levels. In the most extreme version, nature, studied through science, is itself seen as the source of ethics. To evolutionary ethicists, the study of nature itself is thought to “reveal to man patterns which represent the true, objective and ‘natural’ basis for his own society” (48)(p139). A slightly less extreme version of valuing scientific progress is the belief that the acquisition of knowledge must be regarded as the first duty, since the pursuit of knowledge is the best route to an ethical society. According to Bernard, science itself provides us with “a severe and restrictive ethic” which is:

…an ethics that leads to the preaching of a disdain for violence and temporal domination. An ethic of personal and political liberty since disputation, criticism and constant challenge are here not only a right but a duty. A social ethic since objective knowledge can only be established as such in the midst of a community which is aware of its norms (80)(p378).

Even if science is not used as model for society and ethics as a whole, science as a route to knowledge holds special privilege in our society—a phenomenon known as epistemological privilege—and the technological outputs of this progress are generally viewed as essential social goods. As Richards notes:
to append the word scientific to one’s evidence is to lend one’s argument weight of a special kind; to associate it with some action is to suggest a specially notable reputability (48)(p137).

This type of privileging of scientific method and progress is exemplified in the urgency with which tissue banking and its associated technologies are being pursued. The “race” to map the human genome is over, and the goal is now apply these findings to disease as quickly as possible, using thousands of samples at a time.

2.2.2 Practical challenges to dominant conceptualizations of scientific progress

Just as there are practical challenges to the achievability of standard bioethical consent, there are challenges to the notion that science can deliver the goods it promises. The genome project is a good example of science that, to date, has not lived up to expectations with for instance gene therapy being far more difficult than was previously envisaged (81).

Even if scientific endeavours such as the human genome project were to prove, over time, to be successful, there may still be value-level (as opposed to practical) challenges to standard notions of scientific progress. Value-level challenges will now be presented, beginning with identification of the systems of values underpinning dominant notions of scientific progress.
2.2.3 Systems of values underpinning dominant conceptualisations of scientific progress

Western liberalism, and the broader modernist meta-narrative as systems of values underpinning dominant notions of scientific progress

The dominant view of scientific progress described here is compatible with Western liberalism. Liberalism has historically stressed the importance, or indeed the necessity, of the maximal use of natural resources and science-derived technology for human gain (47) as well as the importance of freedom of thought, expression and discussion (59). Liberalism privileges nearly unconstrained scientific progress as a social good. Like a free-market economic system, science is thought to be best left to its own devices, with freedom to respond to opportunity and to a variety of market forces (industrial, military, etc).

2.2.4 Value-level challenges to dominant conceptualization of scientific progress

Given the recognition that dominant conceptualisations of scientific progress are underpinned to a significant extent by a liberal system of values, it is possible to mount value-level challenges to dominant notions of scientific progress. There are three kinds of value-level challenges to the dominant notions of scientific progress:

A) Challenges to the notion that scientific progress (liberal or otherwise) is the route to security and flourishing;
B) Challenges to the liberal system of values, with an emphasis on challenging the way in which it values market-driven scientific progress and
C) Challenges to the notion that that scientific progress is the primary value within the modernist meta-narrative, which also endorses, among other things, liberal individualism.

A) Value-level challenges to the privileging of scientific progress in general (liberal or otherwise)

Modern research ethics—a branch of bioethics—focuses almost exclusively on the protection of research subjects. Far less time is devoted to questions such as: “why do research at all?” And “why examine this particular health problem in this particular way?” Fields such as critical ethics, sociology and philosophy of science challenge us to go beyond standard research ethics and challenge the deeper assumptions underpinning our valuing of scientific progress in general, and our choice of research goals and methods.

Recognition of a need to challenge unconstrained scientific progress has also made its way into the legal sphere. In ALRC96 there is acknowledgment (albeit only theoretically) that a “critical ethics” is required that questions the assumption that scientific progress is necessarily for the good of humanity and criticises principlist bioethics for remaining silent on fundamental issues raised by the progress of health science (including genetics), arguing that bioethics frequently does little more than legitimise the activities of laboratories and governments. In place of the traditional concern with patients’ welfare, it seeks recognition of a wider set of responsibilities than those that professionals traditionally accept, and a wider set of interests than those typically attributed to clients and patients (1).

It is possible to challenge each of the levels at which scientific progress is privileged.
Challenges to valuing science as an epistemologically ideal or superior route to knowledge

Philosophers of science have long been interested in the epistemological nature of scientific reasoning and the status of scientific knowledge. Arguments range from that of Francis Bacon who called for a uniquely scientific path of true induction which (supposedly) transcended the influence of individuals and societies, to the constructivism of Woolgar, which claims that there is nothing unique or intrinsically special about the scientific method as a route to knowledge (82). Whilst these complex debates cannot be neatly converted into a process of scientific review, it needs to be acknowledged that science is not the only route to knowledge, is not necessarily the best route to knowledge and is certainly not a process of reasoning free from human influences. Bernard suggests that the principle of “respect for science” should remind us to make certain that the scientific bases of the problems posed to ethics committees are sound, since “whatever is not scientific is not ethical” (80)(p379). Similarly, we need to ensure that experiments putting subjects at risk are not performed unless they are the best route to the desired solutions, since this is one of the requirements for ethical treatment of research subjects.

Challenge to valuing science as a duty or social good driven by disinterested, beneficent scientists

Just as we should not uncritically see science as the source of ethics, or as the ideal route to knowledge, it is problematic to uncritically value scientific progress as a duty, and its outputs as unquestionable social goods. Research ethics only exists as a field because it has become obvious the outputs of science are capable of creating as many problems for society as they solve, that the process and outputs of science often abuse the environment viewing it simply as a source of resources for technological progress and as a “dumping ground” for the waste then generated by this technology, and that the morality and integrity of researchers, and their concern for research subjects and the wider community/environment cannot be taken for granted.
The priorities and methods chosen by scientists (e.g., to pursue tissue banking research) are not value-neutral. We cannot assume that all scientists, and scientific questions, have equal opportunity to be heard and developed (48). Hagstrom warns that scientists are driven by the desire for recognition by their fellows and that the drive to publish affects the choice of question and method (48). This is in keeping with the “Mertonian imperative” that scientific knowledge will accumulate by virtue of conformity to institutional norms and Kuhn’s description of “normal science” with its insight into the rigidity with which scientists are attached to paradigms (48). Rather than seeing science as an universalist, atemporal and asocial epistemological system of pure observation, therefore, modern sociologists and philosophers of science, prompted by people such as Merton and Kuhn, conceive of science as a complex form of social activity with goals and outputs that need to be examined and challenged (82).

More generally, unchecked science, in a society without its own universal ideology is perilous (48). Critical science theory warns us that science is not actually controlled by the wishes of humanity at all; rather, it is driven by the imperatives of technology (48). Bauman observes that technology has become a closed system—i.e., its own legitimation since it views its failings effects of its own insufficiency, and the problems it causes as demands for more science (83).

More extreme warnings are put forward by Marxist philosophers and radical sociologists of science. These scholars emphasize the influence of social forces (in this case individualist market forces) on the origins of ideas themselves (48). In its most extreme form, radical sociology views science as intrinsically oppressive, and always aimed at meeting the needs of the dominant political actors (82).

In summary, the role of scientific progress in enhancing ontological security and human flourishing can be questioned at all levels. Science cannot be equated with ethics, it cannot always be viewed as an epistemologically ideal route to knowledge and it is certainly not always a social good driven by beneficent, disinterested scientists.
B) Value-level challenges to western liberal conceptions of scientific progress

Just as western liberal notions of autonomy (ie. liberal individualism) can be challenged, western liberal notions of scientific progress are also open to criticism. Critics of the way in which scientific progress is conceptualized in a liberal society are primarily concerned with way in which liberalism has “enslaved science to the profit motive” and “prohibited its application for the good of humanity” (82). They argue that science should not necessarily be free to respond to opportunity and to market forces. Callahan notes that market values are autonomy’s “ideological twin,” so while liberal individualists devote their energy to challenging authoritarianism, they fail to take account of the fact that the power of technology, and the profit to be made from it, “can control and manipulate us even more effectively than authoritarianism…liberal individualism makes this scenario more easily possible, and this is why it is not a tolerable guide to the sensible use of medical knowledge and technology” (51)(p506). In relation to genetic (and, therefore tissue banking) research, ALRC96 recognises the (critical ethics) concern that genetic research depends on the medical-industrial complex and involves significant commercial interests. Critical ethics warns that commercial interests might compromise compliance with “ethical principles and values that are significant for the retention of an Australian ethos and society” (1). The Marxist critique of science argues that, in a liberal capitalist society here can be no meaningful distinction between pure and applied science since the value of knowledge resides in its application, and scientists are merely production workers in such a system (48).

Critics of liberalism also challenge the liberal approach to bioethics which generates procedural rather than substantive solutions to controverted ethical problems and has a has little interest in considering comprehensive notions of the human good (51, 83). In other words, bioethics assumes that the scientific questions are worth asking, and that the benefits, to a large extent, outweigh the risks. The role of bioethics is, therefore, limited to ensuring that overt and extreme exploitation do not occur, leaving the broader questions about the purposes and goals of research unanswered.
The valuing of scientific progress is not confined to liberalism. Other systems of values, such as communitarianism and feminism, are perfectly compatible with scientific progress, but these systems have different conceptions of the purpose and nature of scientific progress. Before outlining communitarian and feminist conceptions of scientific progress, it is interesting to note that even liberal philosophers have seen the need to limit scientific freedom within a liberal society. Mill, for example, who was a prominent proponent of freedom of thought and expression, and critic of censorship, believed that freedom of expression should be limited when there was risk of harm to others (59).

(B1) Communitarianism

Communitarian conceptions of scientific progress, ontological security and human flourishing

As discussed previously, communitarianism differs from even the most welfare-oriented form of liberalism in that its primary concern is the attainment of secure and flourishing communities. Scientific progress is, therefore, only a social good if it maintains or enhances community security and flourishing. Any activity (including science) needs to be examined in terms of its social meaning, implications and context, even in those cases which seem to affect individuals only (50). Communitarianism also asks that the particular community context be taken into account when assessing a potential social good. As Callahan argues, communitarianism asks that rationality be balanced by insight and sensitivity to context—an understanding of the “embedded quality of our lives”—self-knowledge and an appreciation of the religious and cultural traditions relevant to the setting (50).

In a practical sense, communitarianism asks that the public participate in all levels of scientific decision-making, including the setting of research priorities and determination of what constitutes the common good. This involvement is important because it can promote goals, bind individuals or groups together, impart a sense of competence and
responsibility and help express political or civic identity (84). Bastian believes that “a meaningful role” for the community in determining what is essential to enhance people’s health and their ability to exercise their rights is long overdue, both at a global and local level (63). This is underpinned by the assumption that the expertise of the public should lead to more appropriate decisions than the “decisions” generated by market forces or top-down imposition of priorities from governments or scientists.

In the domain of bioethics, communitarians are critical of so-called “liberal principlism.” which has “led to a systematic marginalization of religious and conservative perspectives, often treated with disdain and hostility” and which does not have “the intellectual strength or penetration” to deal effectively with the most important bioethical issues including the goals and purposes of medicine and the meaning of health or the capacity to deal effectively with the complexity of developments in information theory, bioterrorism, new natural pathogens, economic and urban life, and so on. According to Callahan, “liberal individualism’s greatest weakness is what is often thought of as its greatest strength: eschewing a public pursuit of comprehensive ways of understanding the human good and its future.” To pursue this requires an understanding of the ways in which developments affect our collective lives, shared institutions and shared values. Individual autonomy and market values (autonomy’s “ideological twin”) do not provide adequate guidance (51).

Applications of communitarian conceptions of scientific progress to the consent process

Just as communitarian notions of the individual and autonomy can translate into different consent processes, communitarian notions of scientific progress lead (albeit less directly) to a reconceptualisation of the goals and process of consent.

Since communitarianism defines social goods according to their enhancement of community security and flourishing, additional questions need to be asked when decisions are made about which research studies should go ahead. In addition to asking whether specific research studies are methodologically sound and whether research participants have given adequate consent (as individuals or as communities), it is
necessary to ask broader questions such as “why do research at all?” and “why research this?” The asking of such questions is not typically seen as being part of the consent process, and is generally left to scientists, funding bodies and scientific review committees. Communitarianism leads, however, to a broadening of the notion of consent because it recognizes that communities need to be involved in all stages of decision making, and that only local communities have the ability to evaluate potential social goals based upon the specific needs and desires of particular communities. This means that the consent process starts long before a particular study is approved by an ethics committee and presented to potential research participants (as individuals or communities.) Aspects of the research process that can be incorporated into community level consent include: 1) the way research is balanced against other social goods (eg. education, the arts); 2) the way in which research priorities are determined (ie. how the goals of research should be determined); 3) the types of research methods that are prioritised (ie. the best means of achieving defined research goals); and 4) the decision to allow particular studies to proceed.

In relation to the type of research that is prioritized, communitarian values would emphasise the need for research that satisfies shared goals and communal goods such as public health and environmental research. These goods do not emerge from freely made contracts between individual researchers, research subjects and ethics committees, and they certainly do not emerge from research driven by the medical-industrial-military complex. Consideration of the “common good” in decision-making has precedent in clinical and public health practices in, for example, compulsory reporting of certain communicable diseases (overriding individual confidentiality) and compulsory immunisation (overriding individual autonomy.) In these cases, medical confidentiality and autonomy are seen as “collaboration in a common purpose” which aims to restore, or maintain the patient’s health in a manner than preserves and promotes the common good (85).

In relation to the way in which research is balanced against other social goods, communitarianism reminds us that scientific progress is not the only important
component of flourishing communities (and, therefore, individuals). Whilst health, and therefore a certain amount of scientific progress, may be necessary for achievement of basic “ontological security,” other goods such as education and artistic expression are also important for human flourishing (36, 86).

In relation to the way in which research priorities are determined, communitarianism requires whole communities to be involved in deciding on the appropriate direction of the research endeavour. Such an approach has precedent in the allocation of health resources (87).

In relation to the decision to allow a study to proceed, communitarian processes would empower communities to make these decisions for themselves. This currently disempowered status of subjects manifests itself in the almost complete absence of research participants in the research ethics review process. It is left entirely up to ethics committees to decide whether the potential benefits of research outweigh the potential harms. This is a strangely paternalistic approach, given the emphasis we place on the principle of autonomy. Somehow our notion of autonomy only goes as far as allowing research subjects to decide whether or not to participate in studies that have been previously approved by someone else. Subjects play little, if any, role in deciding whether research should be carried out in the first place.

Involvement of communities in assessment of risks and benefits may, at first glance, seem unnecessary since modern research studies are only considered ethical if they exhibit “ equipoise”—that is, if the outcome is truly unknown, such that researchers have no reason to suspect that subjects will be disadvantaged by the research. In keeping with this, research needs to be stopped if one treatment becomes evidently better than another. Similarly, modern research projects are only considered ethical if potential harms to research subjects are unknown, and research is stopped as soon as harms become evident. A slightly different notion of equipoise is put forth by Freedman, which justifies research that would clear up honest, professional disagreement within the medical community, even if one arm seems likely to be more beneficial than another (88). Whatever definition
of equipoise is chosen, the need remains for a significant degree of uncertainty as to the best treatment. Given these subtleties, it can be argued that communities would not have much to offer in this stage of the research ethics process, since anybody can assess whether a study truly exhibits “equipoise,” and put a stop to any study that does not. The situation is, however, more complicated than this. As Kerridge, McPhee and Saul note: “Whereas the horrors of Nuremberg and Tuskegee invited spontaneous moral outrage, the dilemmas posed by research today demand ethical reflection and creative thinking about experimental methodology” (89)(p9). There are, therefore, several subtle reasons why communities may wish to be involved in this stage of the decision process:

1) It is not always possible to achieve equipoise, and there may be arguments for proceeding with certain types of research even in its absence. Certain disease communities, for example, may be willing to subject themselves to greater risks than would be allowed by some ethics committees. Some AIDS activists have argued that the pace of scientific research should accelerate, even at the expense of various ethical constraints (89). Indeed, some activists believe that research should be bypassed altogether, and that treatments should be made available to everyone irrespective of harms that might ensue.

2) On the other hand, some communities may be unwilling to expose themselves to the potential harms of a study even if the risks are deemed acceptable by ethics committees, there are likely benefits, and the study would be stopped should harms become evident. These groups might argue, for example, that randomized trials are inherently unethical since they sacrifice the individual for the good of society. Avins argues that the medical community should develop and use less morally problematic techniques for gaining reliable knowledge (90).

3) Certain communities may wish to have a say in the types of studies that are (and are not) carried out, irrespective of the presence or absence of equipoise in the study design. People with a stigmatising genetic disorder, for example, may not
want research to be carried out on diagnostic tests until a treatment is available for their disease.

4) Communities may be aware of indirect harms that would not be immediately evident to ethics committees. Certain communities may, for example, have a particular sensitivity to the use of human tissue in research, so what would be considered the harmless use of surgical waste to one community may represent an unacceptable threat to another community. In a similar way, a population of Jehovah’s Witnesses may be unwilling to participate in otherwise safe and potentially beneficial trials of a blood-based therapy.

It makes particular sense to involve communities in the research ethics process when it is recognized that, in the presence of equipoise, research projects are generally not set up to benefit individuals, but to benefit the community at large. Community involvement in study approval makes it easier to remain conscious of this fact, which is likely to be obscured if emphasis is placed exclusively on consent given by individual research subjects. In an attempt to “sell” the trial to participants, it may be impossible to avoid giving the erroneous impression that the trial has been set up for their benefit.

In practice, the communitarian approach might put systems in place that enable scientific review committees to justify a particular project to community representatives before potential subjects (individuals or community representatives) are approached regarding participation.

There is empirical evidence that this kind of community involvement in study approval is desirable to the public. A qualitative study in the UK showed that the public wants to be involved in healthcare decision making at the system and program levels. They do not want the ultimate responsibility for decisions (eg. via citizen juries), but they do want the guarantee that their contribution will be heard, and that decisions will be explained to them. Interestingly, according to this study, the public did not wish to be involved at the individual (patient) level of decision-making except to set general criteria for how this
level of decision-making would be carried out (84). In the research setting this would translate into direct public involvement in all aspects of the research process with the exception of one-on-one interactions between researchers and individual research subjects. The significance of this is that, even if individual autonomy is retained and individual research participants provide consent for themselves, there are still many roles that communities can play, including the setting of general criteria for the ways in which individual participants are treated.

Communitarian values might underpin an even more radical reconceptualisation of the relationship between researchers, ethics committees, funding bodies and research subjects whereby research subjects (as communities) become the owners of the research endeavour. This communitarian approach has been applied successfully outside the healthcare setting through the Graeme “village” bank system which was initiated by Dr Muhammad Yunus in Bangladesh in 1976. These banks provide small loans to groups of poor people (especially women) in order for them to engage in projects that enhance their standard of living. The process includes non-conventional, poor borrowers who would not be given loans by traditional banks. Importantly, it also differs from traditional banking in that the borrowers own most of the shares in the bank. The processes are unique in that borrowers discuss and attempt to solve their own social problems. The goal is self-determination and empowerment (91, 92). A similar model could be applied to research ethics whereby communities of research subjects would be the “owners” of the research endeavour. Community participation can, therefore, take several forms, ranging from 1) at one extreme, communities simply being informed of the immutable laws underpinning top-down decisions and being placated when they are unhappy to 2) full partnership (with shared responsibility) to 3) delegated power and, finally to 4) citizen control of the governance of programmes for which perhaps only the budget is externally determined (84). Indeed, there are already large-scale research projects that are “owned” by participants, such as Iceland’s De-Code genetic database.
Feminist conceptions of scientific progress, ontological security and human flourishing

Like feminist conceptions of the individual and autonomy, feminist conceptions of scientific progress are varied. Some branches of feminism emphasise the importance of unimpeded scientific progress as the provider of tools to free women from the oppression of biology (93). The call for obstetric anaesthesia, for example, was part of early feminist movements in the late 19th and early 20th centuries. Indeed, women campaigned for the routine use of anaesthetics before the medical profession considered them adequately tested (94). This notion has much in common with the more general modernist take on scientific progress, and will not be considered further here. Other branches of feminism, on the other hand, are deeply opposed to certain types of science, in terms of its goals, professional organisation, research ethics processes and research methodology. Technology is seen as a means for the continued oppression of women (95). More specific feminist conceptions of scientific progress, ontological security and human flourishing will now be discussed.

In relation to the goals of science, and the research questions asked, feminist scholars have identified the tendency of some branches of science (eg. primatology and brain physiology) to caricature, through metaphor, women, the female body (eg. passive egg vs. active sperm) (96) and female relationships. At the very least, feminism demands that researchers avoid “pejorative and pathologising” questions that can contribute to stigmatisation, victim blaming and stereotypes. Like communitarianism, feminism demands that the effects of science on the wellbeing of individuals and communities (particularly vulnerable communities) should be considered at least as important as other benefits of scientific progress. Many of today’s feminist scholars have an interest in the effects of increasing genetic knowledge on society and on vulnerable communities and individuals. There is, for example a concern that women will be forced to utilise prenatal genetic testing, and genetic enhancement techniques, so that they can produce “perfect” children.
In relation to the professional organisation of science feminist scholars have opposed the tendency to exclude women from active participation in science (82). Some feminists have identified a masculine bias in the goals, organisation and processes of science claiming that science is, among other things, patriarchal, authoritarian, deterministic, detached, destructive and oppressive (82). As a solution, some feminists simply advocate a science that is free of bias and thus more accessible to women whilst others advocate replacement of what they see as a masculine bias in the goals and methods of research with a feminine bias, characterised by wholism, interaction and complexity (48)(p137). In other words, feminism demands that science acknowledges and balances the masculine nature of its metaphors, questions and methods. This might be augmented by increasing the number of women involved in science and its review processes in order to enable a “‘feminine’ perception of the world to find its place in science” (96)(p11).

In relation to research and research ethics processes, feminism underscores the importance of ensuring that research does not reproduce injustice in its methods. This includes recognising that disadvantaged research subjects may, in subtle ways, be captive to the research institutions (42) and ensuring that vulnerable people are not coerced into participating in research, harmed by research or excluded from it. Feminism also challenges the idea that scientific evidence is the only way of measuring risks and benefits; concerns and desires stemming from values are just as valid (74). Feminism also overlaps with communitarianism in its endorsement of participatory methods in which the community collaborates in all phases of the research endeavour, and in its emphasis on the need to consider specific community contexts in determining the way in which research should proceed.

More generally, feminist scholarship makes the observation that research, in its goals, organisation and processes, is ”always political,” whether it uncritically reflects the status quo or explicitly challenges it (97). Research does not occur outside of the phenomena it studies; rather, it is the creator of social phenomena (97) and certain research goals and processes can hide, prop up and even justify existing exploitative social systems. Traditional quantitative research, for example, studies individual traits
without reference to social context or hidden assumptions about the nature of terms used and problems identified (42). As a solution, feminism asks that research be designed in such a way that exploitative social systems are made visible. Different questions need to be asked including those that will shed light on the aspects of lives that have been ignored or distorted by traditional research. Feminist psychologists, for example, focus on issues of concern to marginalised communities, seek solutions to community problems and explicate the role of social structures (as opposed to individuals’ intrapsychic experience) in oppression (42). Feminism asks that researchers take a stand on such issues and ensure that they are studied, even if this reduces the chance of research being funded and even if it reduces researcher objectivity by encouraging researchers to take an involved, rather than disinterested stance on the issues they are studying. Indeed, feminism might redefine unacceptable bias as the tendency to ask questions and interpret results that reinforce unwarranted stereotypes of marginalised communities being studied (42). In other words, what is portrayed as researcher objectivity might actually reflect and disguise the researcher’s investment in an oppressive status quo (42). Qualitative methods, which capture the nuance and complexity of issues, allow information to be gathered from many sources (eg. stories) and reveal (inevitable) researcher bias, may be encouraged. Even if traditional quantitative methods are retained, the results need to be analysed in a politicised and critical way (42).

Taking this further, some feminist scholars argue that it is not enough to make exploitation visible, and that research itself should be a tool for empowerment and “manifest a liberatory potential in its purpose, planning, methods and outcomes” (42)(p841). Research should be set up, carried out and published in ways that “gives voice” to marginalised groups who might also “own” the results. Both research participants and the communities they represent should, according to this view, be left better able to address their own needs than they were before the research was carried out. In relation to research participants, this means that informed consent is not enough of a justification for putting research subjects at risk or utilising their expertise, and contrasts with the standard bioethical notion that no inducements should be offered to research participants. It may, for example, be possible to use groups formed in the course of
research for other (political) purposes, or to use qualitative methods that empower research subjects by validating their “expert” knowledge. This requires a shift in the goals of the research ethics process from ensuring that consent is inducement-free, and that harm is avoided, to an “active investment” in the well-being of marginalised individuals and communities (42).

*Application of feminist conceptions of scientific progress, security and flourishing to the consent process*

A feminist view of scientific progress can lead to reconceptualisation of the goals and processes of consent. Many of the elements of this overlap with the communitarian reconceptualisation of scientific progress and consent, such as the use of community fora and extension of the consent process to encompass the setting of research priorities and approval of particular studies (97). Specific “feminist” elements might include the following:

1) the need to acknowledge the researchers’ accountability to the community being studied as part of the consent process. Consent would not simply be an authorisation of research and academic publication of results, but would embody an agreement of reciprocity whereby communities would directly reap rewards, both during and after research, in exchange for their participation. This differs from both liberalism and communitarianism in that feminism allows for research to be overtly aimed at benefiting the research participants.

2) direct acknowledgment by researchers of the potentially detrimental effects of the research relationship and unavoidable power imbalances (42);

3) effort to involve marginalised communities (as opposed to more powerful communities) in the consent process so that the research is accountable to the most vulnerable groups. This is in keeping with the feminist principle that radical change can
result only from bringing the knowledge and interest of those most marginalised to the centre of an analysis (42);

4) the recognition that certain groups may, in some way be “captive” to the research institution, and efforts must be made to minimise coercion and ensure that participation is voluntary;

5) the incorporation of language and concepts in informed consent which acknowledge that values, and not just scientific evidence, determine the risks and benefits of research (74).

C) Challenges to the notion that scientific progress is the primary good within the modernist meta-narrative: the “modernist” dilemma

So far, the value-level underpinning of standard conceptions of scientific progress has been challenged through (A) a challenge to scientific progress in general and (B) specific communitarian and feminist challenges to liberal notions of scientific progress. The third and final type of challenge does not question the value of scientific progress as a social good. Instead, it challenges the notion that scientific progress (liberal or otherwise) is necessarily the primary social good within the modernist “meta”-level system of values, and cannot be overridden by other modernist goods such as individual autonomy (58).

As will be discussed, this type of challenge is the basis of the most common arguments in favour of stringent consent to tissue banking. These arguments do not challenge (or, indeed, even explicitly mention) scientific progress. They simply assert that individual autonomy is a social good that should not be impeded by anything, including scientific progress.

As discussed previously, this challenge, and its dominance in the “consent to tissue banking” debate highlights an interesting tension within the modernist meta-narrative between the valuing of individual freedom (specifically in the form of liberal democracy) on the one hand, and the valuing of science and technology on the other.
2.3 Summary of review

This section has examined a variety of conceptualisations of autonomy, scientific progress and consent. It has been shown that 1) Dominant notions of autonomy, scientific progress and consent are in many ways justified, but are also susceptible to both practical and value-level challenges; 2) Dominant notions of both autonomy and scientific progress are underpinned to a significant extent by a Western liberal system of values; 3) Communitarianism and some branches of feminism provide alternative frameworks for conceptualising autonomy, scientific progress and, therefore, consent and 4) despite both being components of the modernist meta-narrative, autonomy and scientific progress come into direct conflict in the setting of epidemiological research which requires individual trust and sacrifice — concepts in conflict with the individual autonomy — in order for science to progress.
Section 3- Thematic analysis of the “consent to tissue banking”
debate and statement of the problem

3.1 Rationale for the thematic analysis and critique

In Section 1, the ethical challenges associated with tissue banking research (confidentiality, commercialisation, sacredness, aesthetics, scientific validity and consent) were outlined, as was the emergence of a bioethical, legal and public discourse surrounding these issues. Reasons were given for analysing the consent-related component of this discourse (ie. the “consent to tissue banking” debate). To reiterate, these reasons were: 1) the centrality of consent to the two main triggers of the tissue banking discourse (ie. tissue retention scandals and new privacy legislation); 2) the relevance of consent to other aspects of tissue banking ethics; 3) the opportunity presented by emergence of the “consent to tissue banking” discourse for philosophical re-conceptualisation of consent and invigoration of debates about consent; 4) the ongoing ambiguity of consent requirements despite extensive discourse and a call for guidance and 5) the evidence of reason for concern about the nature of the standard “consent to tissue banking” debate because of i) the apparently intractable conflict between those who want to maximise autonomy via stringent consent requirements, and those who want scientific progress to progress in a manner that is unconstrained by stringent consent requirements and ii) the restricted (individualistic, abstract, legalistic, static) models of consent being generated. These concerns, therefore, warrant confirmation and examination, and are the subject of this analysis.

In Section 2 dominant (liberal) and alternative (communitarian and feminist) notions of autonomy, scientific progress and consent were reviewed. These will be used as benchmarks for a critique of the standard “consent to tissue banking” debate.
The critique will be based upon a textual analysis of the bioethical and law reform literature. The purposes of this analysis are:

1) To confirm the existence of intractability (3.3.1);
2) To confirm the existence of conceptual/practical restriction of the debate (3.3.2) and
3) To test the hypothesis that the intractability and conceptual/practical restriction can be explained by the consequences of a failure to reflect on the systems of values underpinning the arguments on both sides of the debate (3.3.3).
3.2 Method of thematic analysis

Both the academic (bioethical and biomedical) and law reform discourses were examined. Analysis of the academic (bioethical and biomedical) discourse consisted of a thematic analysis of 21 articles on tissue banking ethics published in peer reviewed bioethics and biomedical journals. Medline, Philosopher’s Index and Science Direct databases were used for the search. Search terms included “tissue”, “bank”, “repository”, “collection” combined with “ethics”, “consent”, “autonomy”, “community,” “science,” “progress”, “liberal”, “communitarian” and “feminist.” Articles were chosen on the basis of their relevance to the “consent to tissue banking” debate. Importantly, articles were not chosen on the basis of their having a particular “take” on tissue banking consent or scientific progress. The articles should, therefore, reflect the breadth (or lack thereof) of academic conceptualisations of consent. There was a significant amount of thematic overlap amongst these articles, suggesting that analysis of 21 articles was more than adequate to achieve thematic saturation.

Analysis of the law reform discourse was based upon the report of the Australian Law Reform Commission’s (ALRC) Inquiry into the Protection of Human Genetic Information in Australia (the Inquiry). The 1200-page report, ALRC96, is entitled “Essentially Yours. The Protection of Human Genetic Information in Australia.” (ALRC96) Four chapters in this report are devoted specifically to issues surrounding the genetic databases and tissue banks:

- Chapter 8: Privacy of Genetic Samples
- Chapter 18: Human Genetic Research Databases
- Chapter 19: Human Tissue Collections
- Chapter 20: Ownership of Samples and the Human Tissue Acts.

Widespread community participation was one of the key terms of reference of the inquiry, so it has been assumed that the report reflects the public discourse of consent to
tissue banking. It is acknowledged, however, that the ALRC had limited space in its report, and was obligated to address specific terms of reference. These terms of reference had an unmistakably liberal foundation, and included an examination of matters relating to (italics added):

(a) whether, and to what extent, a regulatory framework is required—

(i) to protect the privacy of human genetic samples and information; and

(ii) to provide protection from inappropriate discriminatory use of human genetic samples and information…

Nonetheless, ALRC96 provides insight into the way in which tissue banking consent is being conceptualised, at least by those engaged in law reform and outside the academic literature.
3.3 Results of thematic analysis

3.3.1 Confirmation of an intractable conflict between autonomy and scientific progress

In order to assess whether the standard “consent to tissue banking” debate is, in fact, mired in an intractable conflict, the main arguments for and against stringent consent were analysed. Less common arguments (generally mentioned in only one article) are summarised in Appendix C).

(A) Common arguments in favour of stringent consent in the academic literature and law reform documentation

The common arguments in favour of stringent consent can be categorised under the following headings:

1) Individual autonomy

Autonomy is the main principle espoused as an argument in favour of stringent consent. Individual consent is seen as a key route to respecting the principle of (individual) autonomy, according to which “each mature person [is] the author of his or her own life” (29)(p649). Even where the benefits are clear, and harms are minimal, it is argued that morality should not be enforced, and that people should be able to decide what is done with their organs and tissues. (29)
2) **Respect for (individual) persons**

Informed consent is seen as one of the ways of ensuring that human beings (as individuals) are respected, and not used as means to another person’s end. The Human Research Ethics Handbook states that, whilst consent is not legally required for use of archival materials, the National Statement’s emphasis on respect for persons makes it “preferable” to obtain specific consent, even though researchers can “probably lawfully” use stored tissue for research without seeking specific consent of the person “whose tissue it is” (28)(L36).

3) **Rights of the individual**

Informed consent serves as a safeguard for individuals’ rights and welfare, by providing them the opportunity to understand an intervention, its scope and its implications, before they decide whether to agree to it (30). Trouet, for example, refers to the “right to a private life” which includes freedom to make fundamental decisions over one’s life (self-determination), and believes that even the use of anonymised samples should require consent because people may not want their tissue used for certain types of research or for commercial gain even if there is no risk of loss of confidentiality. A risk evaluation is, therefore, not the sole element to take into consideration when deciding whether human subject research is ethical (31, 98).

**(B) Common arguments against stringent consent in the academic literature and law reform documentation**

The main arguments against stringent consent relate to the desire to encourage scientific progress or, more accurately, the desire not to impede the research endeavour with stringent consent requirements. Most arguments against stringent consent focus on the detrimental effects that strict informed consent would have on the research endeavour. Korn, for example, notes the “deep concern” among scientists who work with human
tissue samples who fear that the restrictions called for in many informed consent proposals would “severely burden, if not fatally, encumber, this entire class of promising research” (9)(p55). Concerns about the effect of stringent consent relate to both the unmanageable workload that stringent consent requirements would create, and to the effects of consent on research methodology.

1) Unmanageable workload

Researchers complain that an enormous amount of work and bureaucracy would be involved with obtaining consent that is specific to individual research projects. For example, a submission to the ALRC Inquiry warned that: “Major human genetic research databases may not be able to operate effectively without the ability to seek broad and durable consent to the use of genetic samples and information in research, given the cost and time involved in obtaining specific consent from large numbers of donors” (1)(18.58). Similarly, the Human Genetics Society of Australia argued that to obtain informed consent every time a tissue sample is collected in routine hospital work would be impractical (1). Whilst those carrying out clinical trials might be able to meet strict consent requirements without being paralysed by the workload, this may not translate to tissue research, given the number of diagnostic tests carried out (99). Where attempts have been made to implement specific consent, it seems to be fraught with practical difficulties. A Leeds study showed that a laboratory could trace only 48% of surgical consent forms, and 40% of these were not complete (100). Similar challenges would apply to the need to re-contact all patients who have material stored in pathology archives (101). Dr Nikolajs Zeps submitted to the ALRC Inquiry that obtaining consent for each and every use of archival tissue would be a logistical problem that would effectively stymie the function of routine pathology (1). Furness and Sullivan warn that one possible outcome is that residual specimens, which could be used for the good of society, will be incinerated “not because the patients wish it but because of bureaucracy” (102)(p533).
2) Harms to research methodology

Rigorous consent requirements may lead to decreased participation in research, with subsequent weakening of the epidemiological power of studies. Decreased participation of certain subsets of patients may also lead to selection bias. Ingelfinger and Drazen give the example of the city of Hamburg, which had a cancer registry that included data on all cases of cancer for more than 50 years. After the introduction of laws requiring informed consent in two regions, no more than 70 percent of potential cases were included in the registry, and the situation deteriorated to the point that data were no longer made available, since they were deemed incomplete. A trust registry, set up to rectify the situation was not successful (103). A similar problem occurred in Canada when a stroke registry attempted to gain written informed consent and this resulted in not only reduced numbers, but also an “authorisation bias” and limited generalisability of results (104). Consent to research might also reduce the rate at which people submit to screening tests. A submissions to the ALRC from the New South Wales Legal Aid Commission expressed concern that, should the community become aware that newborn screening (Guthrie) cards are retained indefinitely, “there may be some drop off in participation in this vital preventative health care program” (1)(19.66).

Decreased participation may result not only from well-founded fear of the consequences of storage and research use of tissue, but simply from confusion and intimidation resulting from a complex informed consent process. In reference to the US, Korn complains that the draft consent forms that have been circulated in response to new privacy legislation (HIPAA Act) are lengthly and complex and would likely be confusing and intimidating to anxious patients about to undergo surgery. This, Korn warns, “might well encourage them to forbid any research at all on their specimens—a reaction so well known in the epidemiology community that researchers have dubbed ‘uninformed denial” (9)(p59). Refusals on the basis of values, or because of fear, are not the only problems. Selection bias may also arise because extremely sick patients are unable to give consent (105).
There is also a concern that increasing regulatory burdens may tempt researchers to anonymise material in order to avoid arduous consent procedures (106). This leads to the risk of replication of samples, and the inability to re-contact patients should important information come to light in the course of the research. More importantly for the research endeavour, anonymisation means that patient information is not available, so physical patterns cannot be linked to exposure to aetiological agents that were not asked about prior to anonymisation, nor can they be correlated with prognosis or treatment responsiveness.

(C) Substantiation of intractability

The above summary of common arguments shows that the debate is occurring primarily between those who prioritise individual liberty, framed as a call for individual autonomy, respect for persons and human rights, and those who prioritise the benefits of scientific progress, framed as a warning about the deleterious effects of stringent consent on the research endeavour. There are major problems with this limited way of conceptualising the debate:

Firstly, the stakeholders in the debate are “talking past” each other. Those arguing for autonomy barely mention scientific progress, except perhaps in passing. Similarly, those arguing for unimpeded scientific progress barely mention autonomy. Since the arguments fail to directly address those of their opponents, the dilemma cannot be resolved.

More significantly, even if the debate could be made more direct, such that those in favour of autonomy recognise and attempt to address the fact that it conflicts with scientific progress, and vice versa, resolution is unlikely because the two goods—autonomy and scientific progress—are incommensurable. There is no clear way of weighing up the importance of scientific progress against the importance of consent. Indeed, this is a common criticism of any ethical debate conducted at the level of
principles (39) without reference to the way in which these principles were derived. Unless someone can offer a clear justification for a hierarchy of principles, in which autonomy surpasses scientific progress, or vice versa, this debate will not be resolved.

At best a simple “middle ground” compromise will be reached, through a consent procedure that is stringent enough to placate those concerned about autonomy, and lenient enough to placate those concerned about scientific progress. So far, however, even this simple compromise has not been possible. The advent of any degree of consent-intensifying legislation has been met, around the world, with dismay and resistance by those in favour of unencumbered scientific progress. Furthermore, despite an extensive discourse and legislative development, in Australia at least, no clear guidelines are available on accessing archives and gaining consent to unspecified future research (see Appendix B). There is, therefore, little evidence that this conflict has been addressed, or is likely to be addressed in a satisfactory manner in its current form, and the initial observation of intractability seems to be valid.

3.3.2 Substantiation of conceptual/ practical restriction to western liberal-based, standard bioethical notions of consent

In order to assess whether the standard “consent to tissue banking” debate is conceptually limited and therefore restricted in the outcomes it is generating, an analysis was carried out of the models of consent being that have resulted from the debate.

(A) Models of consent commonly proposed by those in favour of stringent consent

In relation to tissue archives, those in favour of stringent consent endorse a process of re-contacting all individuals whose samples are held in tissue archives, in order to gain consent to use of these samples in research.
In relation to materials collected today, those in favour of stringent consent endorse a process of gaining detailed, project-specific initial consent, as well as re-contacting individual donors for consent to every subsequent use of their tissues. A consent form would read:

“I agree to the use of my tissues for research into the genetic basis of oestrogen receptor-positive breast cancer. I agree to be re-contacted in the future regarding the possibility of consenting to other research projects using my tissue.”

This is in keeping with one of the models considered by the ALRC, which requires specific consent to be obtained from the individual each time a tissue sample is to be used for a research study, as well as approval of the research by an HREC.

Some people in favour of stringent consent are willing to endorse a graded consent form, which allows patients to authorise unspecified future research without further permission.

(B) Solutions commonly proposed by those against stringent consent

In relation to tissue archives, those against stringent consent argue that these materials should be used without re-contacting donors, as long as HRECs approve the project.

In relation to materials collected today, those against stringent consent argue for obtaining blanket, open-ended initial consent, followed by HREC review (but no recontacting of donors) for subsequent uses. A consent form in this case might read:

“I agree to the use of my tissues for medical research. I agree to my tissue being used in the future for projects that have been approved by a Human Research Ethics Committee and a scientific review committee.”
The ALRC Inquiry considered two of these “lenient” options for managing consent:

1) Allow the collection and storage of clinical samples for research without consent and require approval by an HREC if the sample is to be used subsequently for research. The HREC will require de-identification in nearly all cases to protect the privacy of the individuals whose genetic material is to be used; and
2) Require general consent for research use to be obtained at the time the tissue sample is obtained and require approval by an HREC if the sample is to be used subsequently for research. The HREC will require de-identification in nearly all cases (1)(19.75).

(C) Substantiation of conceptual/practical restriction to western liberal-based, standard bioethical consent

In all of these proposed solutions, consent refers to an act that:

1) Occurs between researchers and individual research subjects, rather than communities;

2) Is defined in the abstract, rather than adjusted in different contexts. For some donor groups, blanket consent, or authorisation may be acceptable. Other donor groups may have specific reasons for needing recurrent, project-specific consent. The current models are presented as mutually exclusive options;

3) Is static rather than ongoing. If the model of recurrent HREC review is chosen, the contact with research subjects is a one-off event. Even if the option of recurrent, project-specific consent from tissue donors is chosen, it is likely that, for practical reasons, these interactions would be short and superficial since there would not be the time or resources to fully explain the new research project to every individual tissue donor and
4) Is legalistic and defensive rather than allowing for recognition of mutual benefit and more sophisticated types of contractual arrangement. If subsequent projects are reviewed by HRECs, then decisions about risk and benefit are being made on behalf of, rather than in partnership with, tissue donors. If recurrent, project-specific consent is obtained from tissue donors, this will almost certainly be a simple process of information-delivery to donors, followed by receipt of consent from them. There is unlikely to be enough time, or concepts in place, to find out what donors want from the tissue bank, what their specific concerns are, and what contractual obligations they would like researchers to adhere to in exchange for their consent.

As discussed in the review of conceptualisations of consent (see Section 2), these are all features of “standard bioethical” consent underpinned by a western liberal system of values.

(D) Further confirmation of restriction to a western liberal system of values

This restriction to western liberal/standard bioethical notions of consent was then substantiated by a deeper thematic analysis, which examined whether any of the articles or reported ALRC submissions conceptualised consent in a way that was not individualistic, abstract, static and/or legalistic.
Only two of the 21 articles reviewed conceptualised consent in a different way from the traditional conception described in Section 2.1.1.

1) In reference to the UK Biobank, Tutton (2)(p285) suggested that participants should have an influence in “setting up,” “managing,” or “shaping the direction” of future research at UK Biobank. He also recommended the inclusion of donor representatives in the Ethics and Governance Council and other management bodies as a way of securing public trust and support.

2) Winickoff (107) suggested a new form of agreement (among the medical institution, the researcher and the donor community modelled on the “charitable trust” in which the recipient of tissue has a responsibility to act as a trustee, or steward (rather than broker), of the tissue in order to ensure protection of the contribution. In this model, the general public acts as the beneficiary. Winikoff saw one of the advantages of this model as its promoting of donor participation in research governance whereby the donor group has advisory role.

These articles with alternative models of consent were then analysed to assess the ways in which autonomy and scientific progress were conceptualised, with particular attention to the use of non-liberal (eg. communitarian, feminist) notions of autonomy, scientific progress and their relationship to ontological security and human flourishing.

As hypothesised, the two alternative models of consent were underpinned by non-liberal notions of autonomy and scientific progress. In relation to notions of autonomy, Tutton (2) argues that trust as necessary to ensure long-term support for tissue banking research. This is consistent with feminist conceptualisations of consent, with their emphasis on building trusting relationships rather than simply protecting individuals from exploitative researchers. Winikoff (107) refers to the notion of “group autonomy”—as opposed to mere individual autonomy. This is consistent with the communitarian notion of
community consent. Winikoff also recognised the existence of groups defined on the basis of ethnicity, disease, geographic region or health care institution, and saw the patient population of a medical centre as the appropriate community to have a role in governance of the trust. These are consistent with the types of stakeholder— and perhaps vulnerable— communities that play a role in both communitarian and feminist notions of consent. This model was also endorsed due to its likely stimulation of altruism in tissue banking research, a notion that is consistent with both communitarian and feminist conceptions of consent.

In relation to conceptions of scientific progress, Winikoff refers to “social implications” and “need to consider benefits to the community” as well as need to “maximise scientific value,” and notes that consent forms that waive property rights are unethical “under circumstances in which communities will realise little benefit.” This is consistent with both communitarian and feminist values, in which the common good needs to be carefully assessed, since scientific progress cannot be simply be assumed to be a social good. It is also consistent with the feminist notion that communities should benefit directly from their involvement in research projects.

The other articles, which only considered standard bioethical models of consent consisted almost entirely of the standard arguments summarised in Section 3.3.1, favouring either individual autonomy or market-driven scientific progress, both of which are liberal concepts. Several of these articles made passing reference to non-liberal ways of conceptualising autonomy or scientific progress, but these were not translated into non-liberal models of consent.

In relation to autonomy, van Diest refers to the notion of “solidarity” which takes priority over self-determination (98)(p649). Regidor recognises that in certain circumstances justice and beneficence may override autonomy (108)(p1977). Similarly, McLean believes that that consent should be of secondary importance to limitation of harm (109)(p1423). Savulescu refers to a “duty of easy rescue” which says that people should
donate if risk to them is minimal, but still believes that “morality should not be enforced” (29)(p651).

In relation to scientific progress, Trouet acknowledges that freedom of scientific research may be overridden and is not so broad as to counter any possible hampering of research (31). Regidor refers to need to rectify misconceptions about “the assumption of a deterministic model of disease causation” and about the “illogicality of the notion in the declaration of Helsinki that only research that offers some benefit to study subjects is justified” (108)(p1975). Ashcroft refers to need to gain data on what factors drive the regulation of research and for the research community to make people aware of the costs and benefits of research so that autonomy and progress can be balanced (101). McLean notes that intention behind use of tissue should play a part in the ethics and lawfulness of its use (109)(p1423).

None of these ideas were developed to a level at which they could be translated into practice.

*Western liberal restriction in law reform documentation*

The ALRC document is an excellent exemplar of the dominance of liberal values in our society. Even bearing in mind the liberal essence of the terms of reference, and the impossibility of including all community submissions in the final document, it is clear that the Inquiry was underpinned by a highly restricted set of liberal ideals because it did not make use of the opportunities for consideration of non-liberal inherent in:

1) The presence of one permissive term of reference— namely to “reflect the balance of ethical considerations relevant to the collection and uses of human genetic samples and information in Australia;”

2) The unprecedented partnering of the Australian Health Ethics Committee (AHEC) with the ALRC, with the explicit purpose of enriching philosophical reflection and
3) An introductory chapter (Chapter 6) devoted to an explication of the full breadth of ethical perspectives including critical ethics and civic ethics.

There is some indirect evidence in ALRC96 that non-individualistic notions of consent might have been considered as an option. Chapter 20, for example, considered a property approach as a potential alternative to extension of privacy legislation. In many ways, a property approach is consistent with a liberal individualistic value system in that it is a means of protecting privacy and a means by which individuals can retain ongoing control and reserve the right to seek financial returns. On the other hand, certain variants of a property approach would be compatible with, and even conducive to, less individualistic goals. They may, for example, allow for sharing or transfer of control of samples. Other property approaches focus on the concept of custodianship whereby tissue banks would be able to hold and use tissue as a custodian. The Inquiry, however, rejected the property approach in favour of more stringent, and necessarily individualistic, privacy legislation. Most of the other recommendations in the Inquiry were strongly individualistic and focussed on protection of individuals (or groups of individuals) from exploitation.

Many other aspects of the report reflect a liberal individualist bias. This was evident even in the title of the report: *Essentially Yours: The Protection of Human Genetic Information in Australia*. The authors made it clear that the choice of the phrase “essentially yours” was not accidental: “… the inquiry wished to use a title that clearly signified some of the central tenets of this inquiry: that fundamental human dignity requires that individuals have a high level of control over their own genetic material, and the information derived from that material; and that human genetic information is personal, sensitive and deserving of a high level of legal protection …” (1)(1.30). Liberal individualism was also explicitly endorsed by the inquiry, not least in its uncritical endorsement of multiple ethical perspectives (ethical pluralism being a key element of socio-political liberalism).
The liberal bias might be obscured by frequent references to the need for “balance” and the presence of statements such as:

justice in this complex area is not susceptible to a simple vindication of individual rights. Rather, this is an area in which strong, competing, and even directly conflicting, interests often will arise in practice (1.31).

And

The creative ambiguity inherent in the word ‘essentially’… imports the suggestion that it would be misguided to become pre-occupied with absolutes, while ignoring competing interests in this area (1.33).

And

The ethical principle of mutuality recognises that the principle of individual autonomy is optimised when the strength of civil society is maximised (6.47).

Closer inspection reveals that even this “balance” is framed within a liberal individualist value system. “Balance” refers here to the need to balance the needs of one group against another. Protection, an essentially liberal individualist concept, is still the key goal.

Other evidence for the liberal individualistic stance is revealed in the problems identified, and the practical solutions submitted to, and chosen by, the ALRC. Chapter 8 was devoted to a discussion of whether the Commonwealth Privacy Act should be amended to include human tissue in its definition of personal information (NSW legislation already does this). The current situation, in which samples are not covered by the Act was seen as providing inadequate protection in the collection, transfer and allowing of access to tissue samples containing personal information (eg. by genetic relatives). Amendment of the Act was seen to be necessary, on the basis that “Bodily samples constitute such an immediate source of personal information (a ‘virtual medical record’) that they demand similar comprehensive privacy protection” (8.100). Chapter 18 discussed the regulation of “research databases” (information and samples collected specifically for research purposes). Increased privacy protection was considered necessary, including the use of a gene trustee, to “protect the privacy of samples and information held in databases” (18.6).
A similar liberal bias is evident in notions of scientific progress. As is the case with autonomy, there were suggestions that scientific progress could, and should be conceptualised in non market-driven, liberal ways. In chapter 4, for example, the Inquiry acknowledged that scientific progress (“the march of science”) is occurring rapidly in response to many forces, and that government bodies such as Biotechnology Australia are aware of “the driving imperative” of managing risks before “reaping the broader benefits” (4.10).

The Inquiry also notes public ambivalence towards scientific progress, observing that

there is some general fear about uncontrolled or ‘mad science’, the spectre of eugenics, threats of biological warfare, reports of xenotransplantation (transplants from one species to another), the loss of privacy, and the increased possibilities for genetic discrimination (4.12).

Finally, the Inquiry notes that law reform in times of rapid scientific change needs to:

be sensitive to the dynamic environment in which medical, scientific and technological developments are taking place in the field of human genetics. That environment includes extensive debate about the impact of developing knowledge of genetic information on how we see ourselves as individuals, as family members and as citizens. The values that inform and found the ethics of our society are likely to be challenged by such new developments. Remaining open to these challenges is an essential part of this dynamic environment (4.21).

Despite all this reflection, the ALRC doesn’t act on these issues and the “liberal” notion of science as a market-driven social good remains essentially unchallenged. Although several regulatory mechanisms are recommended by the Inquiry, these bodies and processes are likely, in the fashion of liberal bioethics, to provide procedural rather than substantive” solutions to controverted ethical problems, rather than questioning
comprehensive notions of the human good (51, 83). The role of these regulatory bodies is likely to be limited to ensuring that overt and extreme exploitation does not occur, leaving the broader questions about the purposes and goals of research unanswered.

Ultimately, the Inquiry generated 144 recommendations. Not surprisingly, given its mandate and the fact that it did not utilise opportunities for non-liberal ways of proceeding, these recommendations emphasised protection of genetic privacy and property through, for example, establishment of a Human Genetics Commission of Australia, strengthening the roles of research ethics committees and the development of protective legislation including laws on information privacy, control of human tissue and prevention of discrimination.

3.3.3 Confirmation of failure to reflect (explicitly) on values

In order to assess whether those engaging in the standard “consent to tissue banking” debate engage in value-level reflection, the debate was analysed for evidence of reflection on the systems of values underpinning the arguments.

It should be noted that it is not necessary for ethical debates to be conducted at the level of values, so reflection on values is not always required. In many cases, assumptions can be made about the values underpinning an argument. Furthermore, value-level reflection might not be appropriate when the aim is to develop pragmatic solutions. In this case, however, reflection is warranted. For one thing, no acceptable pragmatic solution has been generated despite an extensive discourse and period of legislative amendment. Furthermore, as has been shown, the debate over consent to tissue banking is 1) apparently intractable and 2) generating restricted models of consent. In situations such as this, value-level reflection is important because it can explain both of these problems.
Lack of reflection can account for intractability because it precludes recognition of the cause of, and therefore a way out of, the “modernist dilemma” at the centre of the debate which, as discussed previously, is a result of the logical and moral conflict between those who primarily value scientific progress, and expect research subjects to willingly put themselves at risk for the common good, and those who primarily value individual freedom and the unencumbered pursuit of individual goals and

Lack of reflection can also preclude the consideration of alternative conceptions of autonomy, scientific progress and, therefore, consent, such as those derived from communitarian and feminist systems of values. The resulting range of consent models is restricted to procedures that are all individualistic, abstract, static and legalistic, since they are all underpinned by western liberal notions of autonomy and scientific progress.

Furthermore, as will be illustrated in Section 4, value-level reflection is the first step in resolving these problems.

Hence the literature review on tissue banking consent was examined for evidence of value level reflection and, more specifically, for evidence of recognition of the intractable conflict or conceptual/ practical restriction inherent in the debate.

Substantiation of a lack of value-level reflection in the academic literature and law reform documentation

Of the 21 articles reviewed, only one made clear reference to the value-level assumptions underpinning the arguments. Regidor referred to “an ethical conflict… between the value of knowledge in itself and as a means to improve the quality of human life, and the rights to autonomy and personal privacy” (108)(p1976). Other articles made, at most, passing reference to values. Winikoff referred to the “competing values” of fairness to donors,
maintaining access to research materials and incentives for innovation (107)(p1182).
McLean referred to “conflicting ideologies” in a general sense (109)(p1423), and
Ashcroft recognised that “two ethical factors are in tension” (101)(p410).
3.4 Summary of the problem and a proposed solution

This thematic analysis of the literature has confirmed that there are two major problems with the “consent to tissue banking” debate. Firstly, the debate is mired in an intractable conflict between those who want to maximise personal autonomy via stringent consent requirements, and those who want science to progress in a manner that is unconstrained by stringent consent requirements. Secondly, the models of consent being generated by the debate are all underpinned by a restricted notion of consent as an individualistic, legalistic and static activity, without consideration of alternative conceptualisations of autonomy, scientific progress and, therefore, of consent.

The analysis has also confirmed a failure of those on both sides of the debate to reflect upon, and challenge the value-level assumptions underpinning their arguments and those of their opponents. It has been argued that this lack of value-level reflection accounts for the two identified problems.

As discussed in Section 1, tissue banks are an important resource for laboratory-based epidemiology research. Consent is central to the ongoing controversy about tissue banking. Clarifying consent requirements, and satisfying the public that consent processes are adequate, are the main challenges facing those wishing to utilise tissue banks for research. For these reasons, it is necessary to address the identified problems with the standard “consent to tissue banking” debate. In the next section, the approach of “value-level enrichment” of the consent debate will be illustrated, followed by an analysis of the effectiveness of this approach in modifying the form of the debate so that it is no longer intractable, and the practical options generated so that they are no longer restricted to standard bioethical models of consent.
Section 4-Value-level enrichment of the “consent to tissue banking” debate

In the previous section a thematic analysis of the existing “consent to tissue banking” debate was performed and it was the hypotheses that the debate 1) is mired in an intractable conflict; 2) is generating highly restricted models of tissue banking consent and 3) lacks value-level reflection, were substantiated.

Although lack of reflection seems to be the primary cause of the two major problems (intractability and restricted outcomes), value-level reflection alone will not solve them. Reflection does, however, is pave the way for further remedies to be applied. There are several ways of proceeding once the dominance of western values has been identified. A more sophisticated version of western liberalism could be applied to tissue banking consent, which might allay the conflict and generate a richer range of consent models. Alternatively, liberalism could be replaced with another system of values, such as communitarianism, feminism, Marxism or social contractarianism which might also allay, or at least bypass, the conflict and generate a different (and perhaps more acceptable) range of consent models.

Here a different approach will be illustrated. A “conceptually enriched” model of tissue banking consent is developed which incorporates dominant (western liberal) conceptions of autonomy, scientific progress and consent as well as alternative notions of autonomy, scientific progress and consent espoused by communitarian and feminist systems of values. This model is intended to accommodate, and work within, a liberal society rather than replace it with radical communitarian or feminist alternatives.

It needs to be noted that it was beyond the scope of this thesis to examine existing research ethics committee practices in detail. Aspects of this proposed framework may already be in place in some institutions. Even if this is the case, it is hoped that this
conceptual framework would provide a useful means for institutions to place their practices in a philosophical context, thus reinforcing the importance of practices that may have evolved for other reasons.

In Section 2, liberal, communitarian and feminist conceptions of autonomy, scientific progress and, through these, consent were outlined. Tissue banking consent will first be viewed through each of these lenses individually (4.1) and then an enriched model will be developed incorporating liberal, communitarian and feminist values (4.2). Finally, this model will be critiqued in terms of its effectiveness in resolving the currently intractable conflict at the centre of the debate and generating a more universally acceptable model of tissue banking consent which can withstand a series of practical and value-level challenges (4.3).
4.1 Application of communitarian and feminist consent to tissue banking

4.1.1 Application of “communitarian consent” to tissue banking

The goals and procedures that might characterise communitarian conceptions of consent were described in Section 2. These were based upon communitarian notions of autonomy and scientific progress and included community representation, new lines of communication, ongoing engagement, contextual sensitivity and reconceptualising management/ownership of the research endeavour. Here, the main features of communitarian consent are applied to tissue banking.

Community representation

Individual tissue banks, or clusters of banks, might identify relevant stakeholder communities such as disease communities (e.g. advocacy or support groups), geographical communities (e.g. the population served by a particular pathology facility), ethnic communities (e.g. Aboriginal and Torres Strait Islander tissue donors) or other groups such as war veterans. Researchers and clinicians might also be considered to be relevant stakeholder communities in the tissue banking endeavour. It would then be necessary to establish who represents these communities, how the representation will take place and what authority the representatives will have. The role of community representatives would need to be decided by individual communities, but might include:

1) Gathering, reporting and translating information from scientists, ethics committees and tissue bank administrators. By translating this information in ways suitable to specific communities, individual understanding and autonomy would (perhaps paradoxically) be enhanced.

2) Information delivery on behalf of communities to scientists, ethics committees and tissue bank administrators. Community representatives would act as “experts” on the goals, needs and concerns of their particular community. Community representatives
would provide information on what kinds of research projects would truly enhance the "common good" and whether particular studies should proceed. In this way, consent would be expanded beyond the recruitment of subjects for tissue bank-based projects that have already been authorised by ethics committees. Representatives would also provide guidance on what research ethics procedures (eg. consent models) are appropriate in a particular research setting. Community representatives would also alert researchers and ethics committees to specific desires, needs or beliefs their community might have. As discussed previously, it is possible that a community of cancer patients might be in favour of research into disease aetiology and treatment, but not into the development of predictive tools until treatment is available. Alternatively, a community might not want any tissue banking research at all. There may, for example, be an ethic or religious community that considers tissue to be sacred and objects to any scientific storage of, or research using, human tissue. Community representatives would also be able to better assess the risks that a particular group is willing to take on, rather then leaving this decision up to ethics committees.

3) If the community deems it appropriate, the community representatives could act as surrogate consent-givers. This could be of particular use in gaining consent to the research use of pathology archives, as it may be a way of avoiding the (probably impossible) effort to trace all donors. Community-level consent would be preferable to a simple waiver of consent requirements on the grounds of "impracticability." This approach would work particularly well for communities such as Indigenous groups, in which group-level decision-making is the norm, but could also be applied to other communities. The opportunity could also be given to people, via community representatives, to give open-ended (non specific) consent if they chose to do so (the limiting factor here is likely to be the law, which now requires consent to be "specific").
**New lines of communication**

In order for the above processes to be possible, direct lines of communication would be needed between community representatives, scientists, ethics committees and tissue bank administrators. Community representatives would liaise with scientists who would need to explain the goals of a particular research project and how these might be relevant to certain communities. Similarly, ethics committees would need to explain their reasoning about risks and benefits to community representatives.

**Ongoing engagement**

One of the main reasons for engaging with community representatives, rather than individuals, is that community representatives can remain involved with tissue banks for as long as they exist. This is particularly important in the tissue banking context, since consent to unspecified future research is one of the main challenges.

**Contextual sensitivity**

Consent procedures would not be defined in the abstract. Rather than generating nationally consistent guidelines on matters such as access to archival material—which seems to be the goal of much law reform—systems would be established to enable each community to determine what degree and type of consent is needed for their particular bank.

**Reconceptualising ownership of the research endeavour**

Communitarian values might underpin an even more radical reconceptualisation of the relationship between tissue bank researchers, ethics committees and tissue donors. Using the Grameen Bank model, tissue donors might become the "owners" of tissue banks, with researchers and ethics committees acting as consultants. Like those participating in the Grameen system, research subjects are relatively disempowered and are not usually offered a "share" in the system in which they are being asked to participate. A model of research ethics based upon the Grameen system could, to some extent, address this imbalance.
This is similar to the “charitable trust” model endorsed by Winikoff (107) and described in Section 3.3.2). Donors, or their representatives, would be directly involved in running the banks and may, therefore, be less fearful of distant exploitation.

Indeed, tissue banking provides a perfect template for such reconceptualisation. We can imagine a situation in which groups of people with particular genetic disorders (bowel cancer, say, due to specific genetic susceptibilities) would form, or cement an existing "disease community" which would claim “ownership” of a colorectal tissue bank in the local teaching hospital’s department of surgery.

4.1.2 Application of “feminist consent” to tissue banking

The goals and procedures that might characterise so-called “feminist” consent were described in the literature review. These were based upon feminist notions of autonomy and scientific progress which emphasise relationships, relational autonomy, politics of persuasion, consideration of the effects of the research process and outcomes on individual participants and communities, cultural safety, effort to involve marginalised communities and contextual flexibility. Here, the main features will be applied to tissue banking.

*Processes to cement relationships and enable relational autonomy*

“Feminist consent” would require substantial, and ongoing, relationships to be developed between research subjects (as individuals or communities), scientists, ethics committees and tissue bank administrators. In this context, relational autonomy could be achieved such that even fully competent tissue donors would establish a relationship of interdependence with researchers.

*Processes for a politics of persuasion*

Scientists, ethics committees and tissue bank administrators might explain the benefits of the tissue banking endeavour in general, as well as specific projects, to potential donors or their community representatives. The feminist recognition of a potential obligation to
participate in research may also carefully be put into practice through a “politics of persuasion” while recognising the potential for pressure on vulnerable populations.

Consideration of the effects of the research process and outcomes on communities
HRECs would consider more than the wellbeing of individual research participants. The effect of research, and research ethics, processes on whole communities, particularly vulnerable communities, would be key elements in HREC decision-making. Even if, for example, an aboriginal individual was prepared to donate tissue, the research might pose a significant risk of stigma to the community, and may, therefore, be deemed inappropriate at the community level.

Furthermore, in keeping with the feminist notion that scientific evidence should not be privileged, HRECs would need to take seriously concerns that are not necessarily supported by scientific evidence. There may, for example, be little evidence that information from a tissue bank will be inappropriately disclosed, but a community or individual’s fears about this should still be taken seriously.

Taking this even further, the research process itself might need to strengthen, rather than just avoid harming, the community. An advisory group set up for a tissue bank may, for example, be used to fulfil other advocacy or support roles than are not directly related to the tissue bank.

Ensuring “cultural safety”
Particular care would be needed in dealing with communities who may rely on the institution wishing to establish a tissue bank. A community of war veterans, for example, may find it particularly difficult to refuse access to archival tissue, when they rely increasingly on the local hospital, which runs the tissue bank, for health care.

Effort to involve marginalised communities
While it might be tempting to only set up tissue banks whose donors are easily accessible and unlikely to have cultural objections to the use of tissue in research, it is important to ensure that more “difficult” communities are not excluded from the benefits of tissue banking research.

**Contextual flexibility**

Like communitarian consent, feminist consent procedures would not be defined in the abstract. Rather than generating “nationally consistent guidelines” on matters such as access to archival material, systems would be established to enable each individual or community to determine what degree and type of consent is needed.
4.2 An enriched model of consent to tissue banking

The task now is to develop a model for consent to tissue banking that incorporates both dominant and alternative systems of values. Table 3 summarises the features of western liberal, communitarian and feminist consent.

Table 3 Comparison of characteristics of western liberal, communitarian and feminist consent

<table>
<thead>
<tr>
<th></th>
<th>Western liberalism (standard bioethical consent)</th>
<th>Communitarianism</th>
<th>Feminism</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Goal of consent</strong></td>
<td>Maintenance of individual autonomy and fulfilment of medico-legal requirements</td>
<td>Solidarity; enhancement of common good and strengthening of communities</td>
<td>Strengthening of relationships, cultural safety and fulfilment of reciprocal obligation</td>
</tr>
<tr>
<td><strong>Degree of Individualism in consent process</strong></td>
<td>Individual consent</td>
<td>Community-level consent (delegated)</td>
<td>Individual consent with a stronger relational aspect, and/ or community level consent</td>
</tr>
<tr>
<td><strong>Direction of information flow</strong></td>
<td>Unidirectional: researchers provide information to passive recipients</td>
<td>Bidirectional, responsive: communities both receive and ask for information</td>
<td>Bidirectional, responsive: two-way relationship and discussion</td>
</tr>
<tr>
<td><strong>Timing of consent</strong></td>
<td>a) Static b) Occurring after research goals set and specific projects approved</td>
<td>a) Ongoing, dynamic b) Occurring at all stages of the research endeavour</td>
<td>a) Ongoing, dynamic b) Occurring at all stages of the research endeavour</td>
</tr>
<tr>
<td><strong>Contextuality of consent process</strong></td>
<td>Abstract, pre-defined criteria for adequate consent</td>
<td>Contextually specific (processes determined according to particular community)</td>
<td>Contextual (processes determined according to particular relationships and vulnerability of population)</td>
</tr>
<tr>
<td><strong>Specificity of consent</strong></td>
<td>Project-specific information required</td>
<td>Flexible, negotiated</td>
<td>Scope for some degree of trust, flexible, negotiated</td>
</tr>
</tbody>
</table>
The goal is to generate a rich picture of tissue banking consent that incorporates as many of these characteristics as possible, rather than weighing them against each other and choosing one. In terms of western liberalism and its alternatives, the aim of such a model is to preserve as much autonomy and scientific progress as possible, whilst at the same time trying to make the process more participatory, dynamic, flexible, responsive, negotiated, etc. The procedural nature of the new model opens the door to meaningful discourse at the level of values and allows for context-specific decisions to be made, rather than generating abstract rules. Whilst it would be naïve to assume that discussion at this level is capable of resolving all conflicts, it does pave the way for increased empathy towards other positions and reflection on the weaknesses of one’s own position, and may lead to more willing acquiescence in the face of irresolvable conflicts.

This model relates to the local governance of tissue banks. Ideally, it would be situated within a broader reconsideration of state and national-level regulation. Moreover, consent (the subject of this thesis) is not the only issue that will be managed through these processes. Careful consideration also needs to be given to procedures for maintaining confidentiality and managing commercial arrangements.

It should be noted that these suggestions are essentially agnostic on the question of how detailed consent should be for any given tissue bank. Instead, processes are outlined such that these decisions can be made at the local level, taking specific contextual needs into account.

The main features of the model are: establishment of an advisory board to oversee the bank; development of a clear administrative structure reporting to the board; formation of, and ongoing involvement with, community stakeholder groups and formal sharing of research results with these stakeholder groups.
1) Establishment of an Advisory Board

An Advisory Board should be established to oversee the running of any tissue bank. This could consist of, for example, a patient, a consumer group representative, a clinician, a pathologist, a researcher, an administrator, a HREC member, a migrant/ cultural representative and a health department representative. The advisory board should develop and regularly review policies for the administration of the bank and ongoing quality control.

2) Administrative structure

An administrative structure, reporting to the Board, should be developed for the management of the tissue bank, emphasising the following elements:

a. **Training** of all tissue banking administrators, scientific reviewers and laboratory scientists in human research ethics.

b. **Ongoing liaison** with **community stakeholder groups**. These groups should be formed or re-convened whenever new projects arise or particular sensitivities are likely to be arise in relation to specific projects. The community may be variously defined according to the particular task or problem. They should review existing administrative processes and should, in collaboration with the Advisory Board, refine these according to their specific needs or the issues raised by specific projects. These groups should retain their contact with the tissue bank, and be informed of ongoing research projects, as well as any changes in the direction of research or commercial arrangements. They should work closely with HRECs in making decisions about the uses to which tissue banks may be put. Ideally, the process would extend beyond simply “informing” group members of the bank’s activities. The groups would, instead, “own” the process, with HRECs and scientific reviewers acting as consultants. The scientists would be required to justify the research on the basis of its likely benefits as well as its potential risks.
Community stakeholder groups may comprise people with specific
diseases, or people from specific cultural groups (eg. veterans, religious
groups.) The groups should represent the pluralist make-up of the broader
community in which the tissue bank is situated. Clear discursive processes
should be established for the running of such community stakeholder
groups, noting that there is likely to be disagreement both between and
within groups. Where consensus cannot be reached, acquiescence should
be the goal. This would require discourse processes that make it possible
for all “voices” to be heard, recognising that lay people consumers have
their own areas of expertise. Representatives of a local bowel cancer
support group would, for example, know whether their members wanted
research to be carried out on genetic screening tests. Special attention
would need to be paid to disempowered groups (eg. migrants, indigenous
populations) whose social discourses may be incommensurable with that
of other groups, particularly in relation to the sacredness of human tissue.

Importantly, these groups would decide for themselves what consent
requirements were appropriate in their local context, and would also give
consent on behalf of the groups they represent when it is not feasible to
ask every individual to consent. They would consider, for example:

- what procedures should be put in place for obtaining consent to
  new collections, and subsequent research use of such collections
  eg.
    - “Blanket” consent followed by HREC approval of
      individual projects
      - Pre-operative
      - Post-operative
      - Two-stage pre and post-operative “blanket consent
o Routine banking with opt-out procedures (including steps to ensure that patients are aware of the types of research being carried out and their option to withdraw.)

o Specific consent for each project utilising the stored tissue.

- whether attempts should be made to re-contact the donors of archival material and what efforts these attempts should entail.

This approach precludes the need for institutions to generate “one-size-fits-all” policies and procedures for consent to tissue banking research. These procedures should be flexible, and developed in ongoing collaboration with the community stakeholder groups and the Advisory Board, and should include consideration of issues such as those outlined in box 1.

Whilst consent has been the subject of this thesis and, therefore, the focus of this model, stakeholder groups also need to consider other issues and procedures, including

i. Maintenance of donor confidentiality if samples are to remain identifiable;

ii. Disclosure of research results to donors and/or families

iii. Disclosure of health information to external bodies such as law enforcement agencies;

iv. Sharing of samples and data with other research facilities (public and private)

v. Commercial arrangements.

3) **Ongoing formal research and quality control** should be carried out including qualitative research into the values of various local stakeholder groups. This will provide empirical evidence for any regulatory procedures undertaken.
4) **Formal sharing of results** with an audience extending beyond the community stakeholder groups eg. through a tissue bank newsletter.
Box 1: Issues to consider in development of consent procedures

In any situation
- Have the appropriate community stakeholder group/s been convened to deal with the specific issues raised in this situation? Are there any particularly vulnerable groups whose concerns need to be considered separately?
- What are the regulatory (legal and ethical) requirements for this activity?
  - What kind of bank is it (i.e. where does it fit into the taxonomy of tissue banking activities in Appendix A)?
  - What ethical/ legal consent requirements will apply to this kind of bank? (See Section 3 and Appendix B for consent requirements.
  - How have these requirements been accounted for?

For establishment of new collections/ addition of samples to existing collections
- What consent procedures have been/ will be used?
  - Have donors been informed of (in addition to standard questions on consent forms):
    - The scientific basis and likely benefits of tissue banking research?
    - The likely risks of the research (including any steps that will be taken to maintain confidentiality)?
    - Other researchers or external bodies who may have access to their tissue?
  - Whether material will be commercially developed?
  - How/ when the material will be disposed of?

For subsequent use of existing collections (including archives) for new research projects and sharing of resources with other researchers
- What consent has been gained? How specific was it, and would it incorporate the proposed new research project?

For access to archival collections
- Have attempts been made to contact donors?
- If not, has the desirability and feasibility of such contact been formally assessed (e.g. are the donors alive or dead)?
- If retrospective consent is not feasible, has a community stakeholder group been convened to decide on the importance of the project and, if appropriate, give consent on behalf of the people whose interests they represent? Appropriateness will depend upon:
  - What research is being proposed;
  - What relationship this research has to the original purpose of the bank
  - What relationship this research has to the original consent (if any was gained)
4.3 Critique of this conceptually enriched model

4.3.1 Effectiveness in resolving the previously intractable conflict at the centre of the debate

This model does not directly address the “modernist”/liberal conflict between the privileging of autonomy and the privileging of scientific progress. It does, however, seem that this tension largely disappears when this model is applied. This could be because the model challenges both a naïve privileging of autonomy, by allowing consent requirements—either stringent or lenient—to be determined according to local need. It also challenges a naïve privileging of scientific progress by putting in place systems for scientific review and justification of science to research participants.

Even if the tension remains, value-level reflection, and careful navigation of the resulting discourse could enable stakeholders to recognise that both autonomy and scientific progress are components of a modernist system of values, all of which aim for societal progress, increased security and human flourishing, rather than being entirely opposed. This might encourage empathy and acquiescence, even where value-level conflict is intractable.

4.3.2 Effectiveness in generating an effective, acceptable model for tissue banking consent

The utility of this conceptually-enriched model can only be assessed once it is in place, and its implications (both positive and negative) become evident. Nonetheless, it is possible to say that the new model seems to provide useful insights into the ways in which consent in general, and tissue banking consent in particular, can be conceptualised and carried out. Our choices are no longer limited to standard bioethical (individualistic, static, legalistic) consent in either more or less stringent forms. Moreover, it does this by
balancing, rather than sacrificing, the western liberal notions of autonomy and scientific progress underpinning the current options.

Like the standard bioethical model, this multi-perspectival model is open to both practical and value-level challenges.

(A) Practical challenges

On a practical level, it could be argued that, whilst this model might be desirable, it is not possible to achieve in practice. Policy theorists warn that due to practical and psychosocial limitations we cannot propound any values and expect that systems will be in place to put them into practice (110). Clinical practice guidelines provide an illustration of the difficulties of changing social practice, particularly at the micro-management level. A medical activity as simple as doctors washing their hands has not been uniformly implemented despite educational campaigns and clear evidence of benefit. Explanations of such non-compliance are complex and include lack of knowledge, lack of reinforcement, negative peer pressure and structural and power factors. Still, doctors do not wash their hands as often as they should when they are on general ward duty (111).

It could be argued that this conceptually enriched model, incorporating feminist and communitarian values, is not feasible in a society that retains a strongly liberal value system. The fact that communitarian and feminist procedures have worked in the developing countries does not necessarily translate into local applicability.

More specifically, practical challenges to communitarian consent begin with the difficulty in defining community and identifying relevant and “legitimate” communities. (60). Little shows how the term “community” can be used to refer to:

- A group towards whom political entities have particular responsibilities;
- Associations, such as the army and industries;
• A group capable of congregating, engaging in discourse and expressing views;
• Members of a trade group or profession;
• Interest groups (36).

Dresden et al note that it is difficult for researchers to empirically validate the existence of a community, and that it may be necessary to collaborate with self-identified members of a community to generate a working definition of what constitutes community for a particular research project (60).

Defining and identifying a community is just the first step. It is then necessary to identify community representatives who are acceptable to community members and to scientists with whom they will liaise. Then there is the need to determine the role/s of community representatives and manage communication difficulties within and between different "discourse communities" whose language and goals might be incommensurable (112).

Disease communities are probably the most easily recognisable stakeholder groups in relation to tissue banking research yet even these groups are fraught with difficulties relating to membership criteria, the purpose (and limitations) of the group, group leadership and representation, and the management of intra-group pluralism and disagreements.

Similar practical challenges would apply to feminist procedures. Who, for example, should be relating in applications of “relational autonomy,”? and how should “vulnerable” communities be identified?

(B) Response to practical challenges

The existence of practical challenges does not mean that efforts to change practice are futile. Firstly, the intellectual exercise itself has value, particularly because people involved in the regulation of “everyday” pursuits such as tissue banking are not political scientists and may not be familiar with even the limited range of alternative systems of values at their disposal. To these researchers and policymakers even the small number of
new options might provide significant shifts in thinking about what may be possible, and
(110). Moreover, there is value in considering options that seem radical, or even
impossible, from a practical point of view, since this both opens our eyes to possibilities
and helps us to see what is (110).

Secondly, the existence of practical difficulties does not mean that all efforts are futile.
Rather, it means that changes need to be well-resourced, carefully carried out and
concentrated where the need is greatest and change is most likely. Doctors may not wash
their hands on general wards, but they do “scrub up” before surgery. Similarly, it may be
possible to implement alternative approaches in situations where they are most needed
and most likely to work.

(C) Value-level challenges

It could be argued that, even if it were possible to put this model into practice (ie.
communities could be defined, representatives could be accepted and their roles defined.
etc) this is not the model should be endorsed.

It cannot, for example, be assumed that this “enriched” model is superior to standard
bioethical consent and the options that are being considered in the standard “consent to
tissue banking” debate. Rather than attempting value-level enrichment, it could be
claimed that, in out current stongly liberal and litigious society, a legalistic and defensive
approach should be taken, and the most stringent consent procedures possible should be
put in place. It could also be argued that we should choose between the two modernist
values (individualism and scientific progress), rather than trying to accommodate both.
Finally, it could be argued that a more radical ideological alternative (eg. radical
communitarianism or Marxism) should replace, rather than enrich, the liberal status quo.

Furthermore, communitarianism and feminism have their own dangers. As a system of
values, communitarianism is criticised on the basis that it ignores the very good reasons
that we have developed a dominant liberal system, including repeated abuses of power
and evidence of the dangers of group psychology. At worst, a naïve, unbalanced communitarianism can be just as relativistic as naïve liberalism, and has the potential to be used to justify morally reprehensible actions such as infecting mentally retarded children with hepatitis for the good of the wider “community,” which is the type of justification that was used by the Nazis for some of their “communitarian” activities. It is impossible to deny the dangers of group psychology and those who will use any means to achieve power, and we need to “avoid the communitarian impasse that can lead to a perversion of Rousseau’s adoption of the ‘common will,’ with its potentially disastrous lapse into totalitarianism” (113)(p54). Beauchamp and Childress distinguish between moderate and militant forms of communitarianism, and criticise the latter for on the basis that it inappropriately: “is hostile to rights, sees liberalism as “born of antagonism to all tradition” and aims to perpetuate and even impose on individuals conceptions of virtue and the good life that limit the rights conferred by liberal societies” (45)(p365). Similar criticisms would apply to feminist attempts to do away with liberal individualism and liberal notions of scientific progress. It is conceivable, for example, that a “politics of persuasion” could easily slide into a process of coercion of vulnerable populations. An exclusive focus on instinct, emotion and contextual flexibility could lead to an excessively relativist stance, on the basis of which acts that would seem unethical to most people could be justified on cultural or temporal grounds.

(D) Response to value-level challenges

While it is beyond the scope of this thesis to consider all the philosophical assumptions underpinning this values-based approach, and its advantages over other approaches, there are reasons to suppose that an enriched, multi-perspectival model may be superior to approaches based upon, even a sophisticated version of, a single system of values.

Even setting aside the dangers of each system of values, it is unlikely that any single system of values, no matter how sophisticated, will be entirely satisfactory. Welfare liberalism, for example, is a version of liberalism that attempts to account for the recognition that some notion of communal good is needed for a secure and flourishing
society. Even the most welfare-focused version of liberalism, however, will be underpinned by the primacy of individual choice over community good. Similarly, even the most autonomy-focused version of communitarianism will be underpinned by the notion that autonomy is of secondary importance to, if not derived from, community. Moreover, it does not open up new ways of conceptualising fundamental notions such as autonomy in the way, for example, feminism does (in reconceptualising autonomy as a state or process of relating, rather than individuating.)

There are also arguments in favour of trying to retain liberal values, rather than replacing them. Callahan, a proponent of communitarianism, believes that “liberal principlism is, in excessively large doses, a poor ideological basis for bioethics” yet acknowledges that it is too much a valuable part of our culture to simply throw out in favour of an alternative system of values, even communitarianism. Instead, he claims, the challenge is to put them in tension with each other, understanding that sometimes one will be chosen over another, and at other times a compromise “blend” will be appropriate (51).

Even if it turns out to be impossible to devise a system that encompasses all of the chosen systems of values, and intractable conflicts remain, or the application of some systems of values turns out to be more strongly justifiable than others, the discursive process of acknowledging the value-level underpinnings of all arguments and considering alternative (valid) systems of values can still be worked into the process of considering how consent should occur and may be beneficial. Whilst it is naïve to think that this process will resolve all conflicts, it may lead to greater willingness of one party to acquiesce in order to protect a higher order good such as social cohesion. Acquiescence requires both empathy for validity (and shared origins) of alternative systems of values, and the recognition that higher order goods are shared. As Finnis claims in relation to his “basic values”, this process enables us to analytically unravel even ‘peculiar’ conventions, norms, institutions and orders of preference (114).
4.3.3 Summary of critique

Management of practical and value-level challenges would necessarily consume much of the time devoted to the operation of this enriched model of consent to tissue banking. Steps would need to be taken to ensure that "ethical" communities are formed which repeatedly interrogates its own values, includes open-minded people from many disciplines, is committed to varied processes of ethical examination and is both deconstructive and creative (112). If this is not possible, it may be necessary to form separate banks where community discourses are irrevocably incommensurable (eg. an aboriginal community bank may need to be managed separately.) This is difficult, but not impossible. There is precedent for, for example, consideration of the common good in decisions about public health care (eg. banning smoking in public places.) There is no reason that such precedents could be transferred, at least to some extent, into the research setting.
Section 5- Conclusion and further work

This thesis has confirmed, through thematic analysis, the existence of two problems with the “consent to tissue banking” debate as portrayed in the academic and law reform literature. Firstly, the debate is mired in an intractable conflict between those who want to maximise personal autonomy via stringent consent requirements, and those who want science to progress in a manner that is unconstrained by stringent consent requirements. Secondly, the possible practical options being generated by the debate are all underpinned by a restricted notion of consent as an individualistic, legalistic and static activity, without consideration of alternative conceptualisations of autonomy, scientific progress and, therefore, of consent.

The thematic analysis also confirmed the hypothesis that there is a failure, on the part of those on both sides of the debate, to reflect on, and challenge the value-level assumptions underpinning their arguments and those of their opponents. It was then argued that this lack of reflection can account for the two problems. Firstly, it precludes recognition of the cause of the intractable conflict at the centre of the debate- the “modernist dilemma”- which is a result of the logical and moral conflict between those who primarily value scientific progress, and expect research subjects to willingly put themselves at risk for the common good, and those who primarily value individual freedom and the unencumbered pursuit of individual goals. Secondly, it precludes the consideration of alternative conceptions of autonomy, scientific progress and, therefore, consent, such as those derived from communitarian and feminist systems of values. The resulting range of consent models is restricted to procedures that are all individualistic, abstract, static and legalistic, since they are all underpinned by western liberal notions of autonomy and scientific progress.

It was then argued that the debate, and its outcomes, could be improved by identifying the dominant system of values (western liberalism), considering alternative systems of
values (communitarianism and feminism) and generating a conceptually enriched model that incorporates liberal, communitarian and feminist notions of consent.

This approach was shown to address the two problems with the existing debate. In relation to the philosophically intractable conflict—or “modernist dilemma”—between those privileging autonomy and those privileging scientific progress, it shows how the two apparently conflicting “modernist” goods can both be accommodated at a practical level, thus making the “consent to tissue banking” debate more tractable and fruitful. In relation to the restricted range of consent models being generated by the current debate, it provides new insights into the ways in which consent might be obtained, such that a broader range of community values are accounted for. More specifically, it stimulates the construction of a model that 1) involves communities, as opposed to just individuals in all stages of the scientific process; 2) is flexible and able to adapt consent procedures to specific contexts, rather than predefining procedures in abstract terms; and 3) is transactional and relational rather than static and legalistic.

Practical and value-level challenges to this conceptually-enriched model were outlined. Ultimately, however, the model would need to be empirically tested. Further philosophical work is also required to explore the interesting observation that, at a practical level, systems of values are not mutually exclusive, despite the fact that they are often seen as being in conflict in both descriptive and normative political philosophy (eg. the individualism of liberalism is seen as being in conflict with the communitarian hierarchy of values.) Indeed, the disagreements seem to “disappear” when a system is based upon a “rich,” inclusive notion of security and flourishing. We do not need to “legislate on a hierarchy of values(115)” and are not forced to choose, for example, between individual autonomy and community involvement. Just as interesting, and in need of further exploration, is the fact that in all the systems other than libertarian liberalism, some form of “community” emerges. Whilst western liberalism is dominant, it is also obvious that we live in, and need communities. It should not be necessary for
communitarians and feminists to point this out, and it would be interesting to explore the basis of liberalism’s “blind spot” in relation to community.
References

74. Cannold L. There is no evidence to suggest..." Changing the way we judge information for disclosure in the informed consent process. Hypatia 1997;12(2):165-184.


Kerridge I, McPhee J, Saul P. CCEB: Module 10 Ethical & legal issues in human experimentation: Clinical Unit in Ethics and Health Law, University of Newcastle; 2000.

Avins A. Can unequal be more fair? Ethics, subject allocation and randomized clinical trials. Journal of Medical Ethics 1998;24:401-408.


van Diest P. No consent should be needed for using leftover body material for scientific purposes. For. BMJ 2002;325(7365):648-51.


Appendices

Appendix A: A taxonomy of tissue banking research

<table>
<thead>
<tr>
<th>Type of genetic epidemiology research (determining type of samples and personal information required)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Linkage studies</strong> to identify the gene sequences associated with inherited diseases (requiring collections of tissue taken from family members and information about which members suffer from the disorder).</td>
</tr>
<tr>
<td><strong>Association studies</strong> to find correlations between a disease and a genetic change where there is no obvious pattern of inheritance (requiring large collections of samples from people with a given condition, combined with detailed medical histories).</td>
</tr>
<tr>
<td><strong>Genetic epidemiology studies</strong> of the interaction between genes and environment (requiring access to very large population collections as well as detailed medical histories).</td>
</tr>
<tr>
<td><strong>Pharmacogenetic studies</strong> to determine if there is a genetic basis for certain adverse reactions to drugs (requiring clinical records and genetic information.).</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Timing of collection</th>
</tr>
</thead>
<tbody>
<tr>
<td>Archival collections (already collected)</td>
</tr>
<tr>
<td>Prospective collection (to be collected)</td>
</tr>
</tbody>
</table>
### Storage forms of information/material

(The issues raised by tissue banking research cannot be separated from the issues raised by research utilising non-tissue databases, so these databases are also included here.)

<table>
<thead>
<tr>
<th>Database (computer or paper records containing data only; no physical material collected)</th>
<th>Type of information stored:</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ]</td>
<td>Genetic, biochemical, immunological, microbiological data</td>
</tr>
<tr>
<td>[ ]</td>
<td>Standardised clinical data</td>
</tr>
<tr>
<td>[ ]</td>
<td>Genealogical data</td>
</tr>
<tr>
<td>[ ]</td>
<td>Health information</td>
</tr>
<tr>
<td>[ ]</td>
<td>Lifestyle information</td>
</tr>
<tr>
<td>[ ]</td>
<td>Environmental information</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>Tissue (in addition to data)</th>
<th>Storage form of tissue</th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ]</td>
<td>Genetic (DNA/RNA) sample</td>
</tr>
<tr>
<td>[ ]</td>
<td>Tissue slide</td>
</tr>
<tr>
<td>[ ]</td>
<td>Tissue Block</td>
</tr>
<tr>
<td>[ ]</td>
<td>Freshly-frozen and refrigerated tissue</td>
</tr>
<tr>
<td>[ ]</td>
<td>Alcohol-fixed tissue (eg. for RNA preservation)</td>
</tr>
<tr>
<td>[ ]</td>
<td>Formalin-fixed tissue</td>
</tr>
</tbody>
</table>

### Normal/ diseased tissue

<p>| | |</p>
<table>
<thead>
<tr>
<th></th>
<th></th>
</tr>
</thead>
<tbody>
<tr>
<td>[ ]</td>
<td>Diseased tissue only</td>
</tr>
<tr>
<td>[ ]</td>
<td>Normal as well as diseased tissue (potential germ-line information)</td>
</tr>
</tbody>
</table>
### Regenerative potential of the stored data +/- material

<table>
<thead>
<tr>
<th>Regenerative potential</th>
<th>Non-regenerative</th>
<th>Regenerative</th>
</tr>
</thead>
<tbody>
<tr>
<td>Reproductive tissue (ova/semen)</td>
<td></td>
<td>Reproductive tissue (ova/semen)</td>
</tr>
<tr>
<td>Embryonic/ foetal</td>
<td></td>
<td>Embryonic/ foetal</td>
</tr>
<tr>
<td>Blood</td>
<td></td>
<td>Blood</td>
</tr>
<tr>
<td>Whole blood</td>
<td></td>
<td>Whole blood</td>
</tr>
<tr>
<td>Packed cells</td>
<td></td>
<td>Packed cells</td>
</tr>
<tr>
<td>Plasma</td>
<td></td>
<td>Plasma</td>
</tr>
<tr>
<td>Other regenerative tissue</td>
<td></td>
<td>Other regenerative tissue</td>
</tr>
</tbody>
</table>

### (Living) status of the “donor” at time of collection of data +/- material

<table>
<thead>
<tr>
<th>(Living) status</th>
<th>Living and still alive</th>
<th>Living and now deceased</th>
<th>Deceased</th>
</tr>
</thead>
<tbody>
<tr>
<td>Coronial postmortem</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Non coronial postmortem</td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### Identifiability of data +/- material

<table>
<thead>
<tr>
<th>Identifiability</th>
<th>De-identified/ anonymous</th>
<th>Identified</th>
<th>Coded</th>
</tr>
</thead>
</table>

### Primary custodian of data +/- material

<table>
<thead>
<tr>
<th>Primary custodian</th>
<th>Diagnostic pathology laboratory</th>
<th>Research laboratory</th>
<th>Health authority (e.g. newborn screening)</th>
<th>Teaching collection</th>
</tr>
</thead>
</table>

### Single/ multiple researcher recipients (users of tissue)

<table>
<thead>
<tr>
<th>Single/ multiple researcher recipients</th>
<th>Single researcher recipient</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Multiple researcher recipients in same institution</td>
</tr>
<tr>
<td></td>
<td>Multiple researcher recipients across institutions</td>
</tr>
</tbody>
</table>
### Public/private sector “custodian” and/or user of collection

<table>
<thead>
<tr>
<th>Public</th>
<th>Private</th>
</tr>
</thead>
<tbody>
<tr>
<td>New South Wales</td>
<td>Commonwealth agency</td>
</tr>
</tbody>
</table>

### Reward for donation

<table>
<thead>
<tr>
<th>Donor unpaid</th>
<th>Donor paid</th>
</tr>
</thead>
</table>

### Owner of data +/- material

<table>
<thead>
<tr>
<th>Unstated</th>
<th>Donor</th>
<th>Bank owners</th>
</tr>
</thead>
</table>

### Cultural background of donors (specifically in terms of tissue banking issues)

<table>
<thead>
<tr>
<th>Unknown</th>
<th>Mixed</th>
<th>Aboriginal/Torres Strait Islanders</th>
<th>Islamic</th>
<th>Buddhist</th>
<th>Jewish</th>
</tr>
</thead>
</table>

### Intended method of disposal and/or return

<table>
<thead>
<tr>
<th>Discard</th>
<th>Return to donor</th>
<th>Unspecified</th>
</tr>
</thead>
</table>
Appendix B: The current status of consent requirements

There are two areas of uncertainty regarding the regulatory requirements for consent to tissue banking research. These relate to 1) archival collections and 2) new collections of tissue.

1) Consent to the research use of archival materials

First, there is the question of the nature of consent required for the use of archival stores of human tissue. This is tissue that has been removed in the past, usually for diagnostic or therapeutic purposes, and has subsequently been stored in pathology laboratories. Most diagnostic and research facilities have such archives. There are, for example, tumour banks that have been accumulated in good faith over 25 years or more. Consent to conduct research on these tissues may not have been obtained at the time they were removed. At best, consent would have consisted of a “tick the box” option on a surgical consent form, asking for permission for tissue removed at surgery to be used in research. This consent would have been non-specific in relation to the types of research that would be carried out, and the length of time for which the tissue would be stored.

Until 2003, when the Human Tissue Act 1983 (NSW) was amended, this practice was legal in New South Wales, since informed consent to retain clinical samples for research purposes was considered to be implied in consent to collection for clinical purposes. In November 2003, the Act was amended to require specific consent to the research use of tissues removed in the course of medical diagnosis or treatment. The changes were not retrospective, so specific consent is not required for the research use of tissues removed (from living patients) prior to November 2003. There are, however, concerns about the morality of utilising these archival collections. Indeed, there has long been an ethical, if not legal requirement for specific consent to be gained. This requirement (in the National Statement) was, however, usually waived for the research use of archival collections.

According to the National Statement’s waiver criteria, a Human Research Ethics Committee (HREC) may take into account: “…the extent to which it is impossible or difficult or intrusive to obtain specific consent…” (NS 15.8) (37). It also takes into
account the nature of the clinical condition for which the tissue was originally given, the possibility of deidentifying or anonymising the material, the extent of risk to privacy or wellbeing and the possibility of commercial exploitation. The Human Research Ethics Handbook (E94-95) provides some guidance on interpretation of this waiver criterion, noting that:

In some situations it will be impossible, or extremely difficult, for researchers to obtain the consent of the original donors for the use of stored tissue samples. Tissue from an archaeological site is an obvious example. This provision would also apply where the samples may have been stored for a long time and the donors are untraceable or have died, or it may be excessively difficult for other reasons to trace the donors. Where such a situation arises, an HREC may approve the use of these samples…(28).

Interpretation is still, however, called for in relation to these waiver criteria, and the recent legislative amendments suggest that the ease with which consent requirements used to be waived may no longer be acceptable. The Australian Law Reform Commission (ALRC) Inquiry made several recommendations relating to waiver of consent in general, and access to archival material in particular. Of particular relevance to tissue collections, the Inquiry recommended that nationally consistent rules be developed in relation to the collection, storage, use and disclosure of and access to other human tissue collections, including collections of pathology samples and banked tissue (Recommendation 19-2) (1).

Until such time as these guidelines are in place, the legal and ethical requirements will require interpretation, and this uncertainty leads to practical difficulties, as illustrated by this scenario:

A colorectal surgery research department wishes to access tumour samples stored in pathology archives. Samples have been collected and stored for over 25 years. Only “blanket” consent to research was obtained at the time of (diagnostic) collection, which was in keeping with the ethical and legal requirements at the time. The researchers now wish to convert this pathology archive into a research
collection. The bank will retain identifiers (coded) in order to enable clinico-pathological correlations to be drawn.

Researchers are thus faced with these questions: Can research be carried out on this material under previous blanket consent, given before the implications of genomic research became clear? Or should new consent be sought for gene-based research? If new consent is needed, what should be done with specimens taken from those who can no longer give consent, including those who have died?

2) Consent for establishing and utilising a new tissue collection for research purposes

Recent amendments to the Human Tissue Act state that, as of 1 November 2003, consent should be obtained for the use of residual pathology material for research. Tissue stored in the form of blocks and slides is exempt from these requirements, but otherwise consent is mandatory under NSW law, and cannot be waived. The Act does not, however, state how specific this consent needs to be. Even if it is deemed that “specific” consent should be obtained, there remains lack of clarity around the meaning of “specific,” particularly in relation to unspecified future research. The ALRC Inquiry recognised that it is not always feasible to gain specific consent to research, and that, despite the National Statement’s call for “specificity”, current practice tends to involve the seeking of broad initial consent, followed by HREC approval for subsequent projects. This is not necessarily a breach of the National Statement, since the National Statement contains certain waiver criteria (s15.8) including the provision that subsequent consent may be waived if it is thought that “the original consent given by the donor is in the spirit of the new research”(28). Nonetheless, controversy has arisen around the question of whether blanket consent followed by HREC review is adequate. This deficiency in guidance and inconsistency between guidance and practice were explored at length in the ALRC Inquiry. The Inquiry recommended that the NH&MRC develop nationally consistent guidelines on consent to genetic research (Recommendations 15-4 and 16-2) (1).
Meanwhile, researchers and HRECs need to interpret the Act and the National Statement in terms of how specific consent needs to be. This scenario illustrates the difficulty caused by the uncertainly:

_A cancer research group based at a teaching hospital wishes to set up a prospective tissue collection of all lung cancer samples removed at surgery or post-mortem. The goal of the research is to correlate the genetic profile of such cancers with prognosis and treatment responsiveness. There are currently no samples stored, so the collection will be entirely new (ie. no archival pathology material will be accessed.) The bank will retain (coded) identifiers in order to enable clinico-pathological correlations to be drawn._

Researchers are thus faced with these questions: Should present and future consent be blanket or specific? If specific research is mandated, how will consent for changed research priorities be negotiated?
Appendix C: Infrequent arguments for and against stringent consent

Infrequent arguments in favour of stringent consent:

Respect for communities
Savulescu argues that consent should be sought because there can be strong cultural grounds for rejecting research. What is waste to one culture, might have special significance to another eg. the sacredness placed on brain and placental tissues by Moari people. Seeking consent allows sensitivity to be shown towards cultural values (29); 2)

Non-maleficence
The relative leniency towards informed consent in the past has been justified on the basis that there is minimal risk to tissue donors. “Genomic age” research is, however, opening up possibilities and risks that have not previously been relevant to research in which human subjects are not physically present. New laboratory techniques have now “changed the calculus of risk” such that information gained can now “profoundly affect the lives” of tissue donors and their relatives (9) These risks relate not to physical harm to the donor, but to the harms associated with loss of privacy and confidentiality. These risks are greatest when samples are identified or coded (as codes are not foolproof) but even anonymised samples may raise concerns including fear of stigmatisation of a group, commercial use of cells or tissues and opposition to certain kinds of research (31). Waiver criteria for consent are qualified by consideration of the “possibility that the research could affect the patients’ interests in any way,” and it is generally thought that the likelihood of such negative effects is increasing. It is, therefore, no longer clear that consent can be waived, or that blanket consent and expedited ethics committee review is appropriate, even for anonymised samples. Rather than doing away with the research (and, therefore, the risk), informed consent provides an ethical means of subjecting people to possible harm. Savulsecu, for example, argues that by giving consent, an
individual voluntarily takes on the risk and, if he or she is rational, will ensure risk is minimised to a reasonable level (29).

Trust: Trouet claims that consent should be gained even for the use of anonymised materials partly because this enhances trust, which is violated if people discover that their tissue is being used without their consent (31). Similarly, Savulescu argues that consent should be sought because doing so promotes public confidence in medicine and research (29).

Beneficence: Consent might be justified on the basis that if patients give consent, they can then be given reports of research results that may be important for them or their family. It also enables researchers to gain further clinical or lifestyle-related information from patients should this become necessary in the course of research, thus providing benefit to the community through the facilitation of research (29).

Empirical desirability and/or feasibility of stringent consent
Empirical research was presented as an implicit argument for stringent consent. In a US study, for example, the specific consent process itself was empirically tested and reported to be manageable from a practical point-of-view. In terms of feasibility of re-contacting patients, a Swedish study found that most patients were contactable 11 years after initial collection (only 85 of 1494 individuals had died, moved abroad or had unknown address), leading the researchers to report that it is feasible to obtain individual consent for genetic research many years after blood was donated (116). Some empirical studies into donors’ attitudes have also been used in support of stringent consent requirements. US researchers reported that two thirds of respondents believed that consent should be required for research using clinically derived samples that retain personal identifiers. One in eight believed that consent should even be required for the research use of anonymised samples (117). The US National Action Plan on Breast Cancer (NAPBC) subcommittee charged with developing informed consent principles and procedures held a series of focus groups, and reported that “the public had little understanding of specimen banking and that they felt they had a right to know how their tissue would be used” (118). The
NAPBC thus judged the consents currently used in routine clinical practice (often a sentence embedded in the surgical consent form) to be inadequate (118). The National Cancer Institute states that: “there is an emerging consensus that informed consent should be obtained for research use of identifiable specimens collected during routine medical care. Most believe that the consent for the collection, storage and research use of tissue should be explicit and separate from the routine surgical consent” (119). A US survey of 602 people with a serious genetic or chronic medical disorder (or family history thereof) found that the majority of participants are not willing to have their medical records used for research without their knowledge or permission (105). The ALRC Inquiry received a number of submissions from groups claiming an empirical basis for requiring specific and/or retrospective informed consent. Women’s Health Victoria submitted that: “The thought that parts of our human tissue may be stored in a bank or laboratory, for some other research, without our knowledge, is abhorrent to some and feels like a violation” (1). The Androgen Insensitivity Syndrome Support Group Australia submitted that community attitudes frowned upon subsequent re-use for research purposes without specific consent (1).

**Infrequent arguments against stringent consent:**

**Non-maleficence**
Patients could suffer psychological harm from being re-contacted (120) or given misleading prognostic information on the basis of data from a consent-based (and therefore potentially selection-biased) bank (104).

**Autonomy**
Detailed consent forms may be incomprehensible and preclude the gaining of informed consent (104, 121).
Challenges to the notion that research poses a real risk
Even if samples are identifiable, it can be argued that the risk of disclosure and discrimination is less likely or significant than commonly thought (98).

Challenges to the notion that the right to self-determination applies
It is argued that autonomy and self-determination are not relevant to procedures involving leftover diagnostic or therapeutic material that would otherwise be discarded. As van Diest argues: “Every day we lose millions of cells from our skin, we excrete stools and urine, and we cut our hair and nails- and rarely do we show any signs of wanting to keep these body elements under our control (98).”

Empirical desirability of less stringent consent
Empirical research was occasionally presented as an implicit argument against stringent consent. There were several reports showing that people are satisfied with “open” consent along with HREC review of subsequent projects. In ALRC96 it was reported that this is the view of many medical professionals and scientists in Australia (ref ALRC96). The ALRC also reported results of a survey of HRECs it conducted, which demonstrated that most requests to waive consent and allow access to information or material were approved (1). Wendler and Emanuel reported that as long as initial consent is gained to the research use of clinically-derived samples, subjects did not seem to be any more demanding of subsequent consent than they would have been for subsequent use of research-derived samples. Moreover, subjects did not think it was necessary to specify which kind of research would be performed when obtaining biological samples initially, since this may render strict consent forms unnecessarily specific, and “may complicate the consent process without offering options that subjects find ethically meaningful” (117). Similarly, a Swedish study reported that, of patients whose blood had been taken for genetic risk factor research 11 years previously, the majority (93%) were willing to allow academic research on hereditary (genetic research) of cardiovascular diseases, provided that the ethics committee has given approval. Of these, a minority (22.3%) wanted to be informed about, and give new consent for, each new genetic project. Interestingly, figures were similar for academic and commercial research (116). It is
important to note, however, that these people had initially donated their blood for research, rather than diagnostic, purposes, which may put them in a category of particularly altruistic or research-oriented people.