

Reconfiguring tissue banking consent through enrichment of a restricted debate

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DECLARATION

I hereby declare that this submission is my own work and that, to the best of my knowledge and belief, it contains no material previously published or written by another person nor material which to a substantial extent has been accepted for the award of any other degree or diploma of a University or other institute of higher learning.

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Abbreviations

ALRC	Australian Law Reform Commission
FHA	Feminist Health Advocate
HREC	Human Research Ethics Committee
National Statement	National Statement on the Ethical Conduct of Research Involving Humans
NH&MRC	National Health and Medical Research Council

Introduction

Tissue banks are thought to be an essential resource for medical research in the post-genomic age. Collections of tissue, usually removed in the course of diagnostic or therapeutic procedures, enable laboratory-based epidemiological studies to be carried out, linking abnormalities in the tissue to disease aetiology, prognosis and treatment responsiveness. There are, however, a number of technical, regulatory and ethical concerns that challenge those wishing to engage in tissue banking research.

It is becoming increasingly apparent that tissue banking research is not without risk of harms, even though there is no direct physical risk to donors. This is because, in order to be most useful, banked specimens need to be linked to personal information about tissue donors and this poses the risk of inadvertent disclosure of personal— particularly genetic— information to those who might exploit such information (eg. insurance companies and employers). Furthermore, the long-term storage of specimens, and the impossibility of predicting all potential types of research programs for which they might be useful, raises the possibility that future projects will be carried out that are unacceptable to some (past) tissue donors.

The ethical principles of autonomy and respect for persons demand that research subjects be informed of such risks and of the nature of the research, and that they participate willingly. On the other hand, there is a desire for science to progress unhindered by stringent consent requirements. For these reasons, a debate has emerged in the academic (bioethical and biomedical) literature and in the legal (law reform) sphere over what would constitute adequate consent. Despite an extensive discourse, it is still unclear whether it is permissible to carry out research on archival tissue that was originally taken for diagnostic purposes and whether project-specific (as opposed to open-ended) consent is required for research on tissue collected today. This lack of clarity is of concern to researchers, ethics committees and research subjects, all of whom recognise the importance of tissue banking research, yet fear that current consent procedures may be

ethically or legally inadequate. Thus it is important that the consent dilemma be resolved as quickly and definitively as possible.

Ongoing controversy and regulatory ambiguity are appropriate when morally contentious issues are at stake, and their existence does not, on its own, signal any flaws in the discourse process. There are, however, two reasons to suspect that the current “consent to tissue banking” debate, as portrayed in the academic literature and law reform documentation, is problematic. Firstly, the debate appears to be mired in an intractable conflict between those who want to maximise personal autonomy through stringent consent requirements, and those who want the scientific endeavour to progress in a manner that is unconstrained by what are viewed as arduous consent procedures. Secondly, the possible practical options (consent models) being generated by the debate are all limited because they are underpinned by a restricted notion of consent as an individualistic, legalistic and static activity, without consideration of any alternative conceptualisations of consent.

Through a thematic analysis of the current “consent to tissue banking” debate in the academic and law reform literature (Section 3), this thesis shows that debate is essentially occurring between those who see individual autonomy (and stringent consent) as being of primary importance, and those who see unimpeded, market-driven scientific progress as the more important social good, which should not be impeded by unnecessarily stringent consent. Thematic analysis also confirms the existence of the two problems described above, and a failure of those engaged in the debate to reflect on, and challenge, the value-level assumptions underpinning their arguments and those of their opponents. It is argued that this lack of reflection accounts for the two problems:

- Firstly, it precludes recognition of the cause of— and, therefore, ways of resolving—the intractable conflict at the centre of the debate. Value-level reflection shows that this is a result of the logical and moral conflict *within* western liberalism, between two modernist goods: individual freedom and scientific progress.

- Secondly, it precludes the generation of varied conceptions of consent. Value-level reflection shows that the current range of consent models is restricted to procedures which are individualistic, abstract, static and legalistic, since they are underpinned by western liberal notions of autonomy and scientific progress. This recognition paves the way to consideration of alternative notions of autonomy, scientific progress and, therefore, consent, such as those derived from communitarian and feminist systems of values.

A conceptually enriched model of tissue banking consent is then developed (Section 4). This model incorporates dominant (liberal) conceptions of autonomy and scientific progress as well as alternative notions of autonomy and scientific progress espoused by communitarian and feminist systems of values. It is argued that this conceptually-enriched model provides a practical solution to the two problems associated with the standard “consent to tissue banking” debate. In relation to the philosophically intractable conflict— or what is termed the “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 can be accommodated. More specifically, it stimulates the construction of a model that 1) involves communities, as opposed to merely 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.

This outcome has interesting philosophical as well as practical implications. It shows that despite apparently unresolved, and possibly irresolvable, normative-level conflicts between the two modernist elements of western liberalism (autonomy and scientific progress), and between liberal, feminist and communitarian systems of values, a multi-

perspectival, inclusive, model-building approach provides a practical solution that circumvents these normative-level conflicts.