
Navigating tissue banking regulation: Conceptual frameworks for researchers, administrators, regulators and policy-makers

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In the “post-genomic” age of biomedical research, researchers often wish to utilise collections of human tissue. This type of research raises many ethical and legal issues and anyone wishing to use such collections is faced with an enormously complex set of regulatory requirements, many of which are still ambiguous, reflecting ongoing ethical and legal debate. Whilst there is no way of entirely avoiding such regulatory complexity and ambiguity, conceptual frameworks can assist those who wish to use, administer, authorise and generate policy on tissue banking research. Two conceptual frameworks are described here: a taxonomy of tissue banking practices, aimed at assisting those who need to ensure that tissue banks meet ethical and legal requirements; and a “syncretic” approach to policy-making, for those who wish to generate new policy, or streamline existing policy relating to tissue banking research.

THE PROMISES OF TISSUE BANKING RESEARCH

Tissue banks are thought by many scientists to be an essential resource for medical research in the post-genomic age.¹ 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. Moreover, 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 previously collected samples. Evolving 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.

Many “research collections” consist of archival material which was not collected specifically for research. Many diagnostic pathology laboratories, eg, have stores of diagnostic material collected over several decades. Researchers argue that these have unique value² and are particularly important in both the study of rare disorders for which few samples are available and for common disorders (such as breast cancer) with many physical subtypes, each of which is rare.

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¹ Oosterhuis J et al, “Tumour Banks: Well-guarded Treasures in the Interest of Patients” (2003) 3 (1) Nat Rev Cancer 73; Korn D, “Dangerous Intersections: New Proposals to Protect Genetic Privacy May Collide with the Public Interest in Fostering Medical Research” (1996) 13 (1) *Issues in Science and Technology* 55; Australian Law Reform Commission, *Essentially Yours: The Protection of Human Genetic Information in Australia* (ALRC 96) (Commonwealth of Australia, Canberra, 2003).

² Australian Law Reform Commission, n 1.

ETHICAL AND LEGAL ISSUES RAISED BY TISSUE BANKING RESEARCH

Where tissue is removed specifically, and only, for research, the ethical issues are similar to those raised by any clinical or epidemiological research for which subjects knowingly volunteer. Tissue banking research is, however, different because tissue is usually removed in the course of diagnosis or therapy, the primary purpose of which is to guide clinical practice rather than to facilitate research.

The main ethical issue surrounding tissue banking research is the need to obtain consent. For many years, the secondary use of diagnostic and therapeutic tissues in research did not cause much ethical concern. Consent for research, if obtained at all, was obtained in a “blanket” fashion, asking patients to authorise the use of their tissues for any kind of research. This approach was widely supported by researchers and was not illegal.³ The ethical requirement that consent to research be “specific” was interpreted broadly and waiver criteria for consent, such as “inconvenience” and “public interest”, were applied liberally.⁴

Recently, however, controversy has arisen about the practice of using human tissue for research purpose. This controversy is due, in part, to a series of media exposures of “scandalous”, non-consensual retention of organs from post-mortem examinations,⁵ together with increasing concerns about information – particularly genetic – privacy.⁶

There is now an extensive debate in the bioethical⁷ and law reform literature⁸ about the way in which consent to tissue banking should be obtained. Three models are commonly proposed:

- The first model, which prioritises individual autonomy,⁹ human rights¹⁰ and respect for persons,¹¹ permits the use of archival materials only when the original donors can be recontacted and asked for consent. This model also demands that individual donors be recontacted to provide consent each time a new research project using their tissue is proposed.
- The second model allows consent to be (at least partially) open-ended and allows archival tissues to be used even if the original donors cannot be contacted. This model tends to be endorsed by those who are concerned about the deleterious effects of stringent consent requirements on participant recruitment, study power (and validity of results) and workload.¹²
- A “middle ground” approach is also suggested,¹³ in which participants are given the opportunity to decide whether they would like to:
 - (a) be recontacted for every proposed research project;

³ Australian Law Reform Commission, n 1.

⁴ Australian Law Reform Commission, n 1; National Health and Medical Research Council, *National Statement on Ethical Conduct in Research Involving Humans* (Commonwealth of Australia, Canberra, 1999) (National Statement).

⁵ Walker B, “Inquiry into Matters Arising from the Post-mortem and Anatomical Practices of the Institute of Forensic Medicine” (New South Wales Government, 2001); Mason K et al, “Consent or Property? Dealing with the Body and Its Parts in the Shadow of Bristol and Alder Hey” (2001) 64 (5) MLR 710.

⁶ Australian Law Reform Commission, n 1.

⁷ Savulescu J, “No Consent Should be Needed for Using Leftover Body Material for Scientific Purposes. Against” (2002) 325 (7365) BMJ 648; Bauer K et al, “Ethical Issues in Tissue Banking for Research: A Brief Review of Existing Organizational Policies” (2004) 25 (2) *Theor Med Bioeth* 113; Korn, n 1; Hair J et al, “Is Research on Human Tissues at a Crossroads?” (2003) 39 *European Journal of Cancer* 2253; Ashcroft R, “The Ethics of Reusing Archived Tissue for Research” (2000) 26 (5) *Neuropathol Appl Neurobiol* 408; Furness P, “Consent to Using Human Tissue: Implied Consent should Suffice” (2003) 327 BMJ 759; Ingelfinger J et al, “Registry Research and Medical Privacy” (2004) 350 (14) *NEJM* 1452; Tu J et al, “Impracticability of Informed Consent in the Registry of the Canadian Stroke Network” (2004) 350 (14) *NEJM* 1414; Kass N et al, “The Use of Medical Records in Research: What Do Patients Want?” (2003) 31 *J Law Med Ethics* 429; Sobel M, “Ethical Issues in Molecular Pathology: Paradigms in Flux” (1999) 123 *Arch Pathol Lab Med* 1076.

⁸ Australian Law Reform Commission, n 1.

⁹ Savulescu, n 7.

¹⁰ Bauer et al, n 7; Trouet C, “New European Guidelines for the Use of Stored Human Biological Materials in Biomedical Research” (2004) 30 (1) *J Med Ethics* 99.

¹¹ National Health and Medical Research Council, *Human Research Ethics Handbook* (Commonwealth of Australia, Canberra, 2002).

¹² Hair et al, n 7; Ashcroft, n 7; Furness P, “The Human Tissue Bill: Criminal Sanctions Linked to Opaque Legislation Threaten Research” (2004) 328 BMJ 533; Ingelfinger et al, n 7; Tu et al, n 7; Kass et al, n 7; Sobel, n 7.

¹³ Australian Law Reform Commission, n 1.

- (b) be recontacted for some types of research projects; or
- (c) give open-ended consent to any research use of their tissue.

Whilst consent is the main issue causing concern, and is the basis of much of the regulation discussed in this article, there are other ethical issues surrounding tissue banking. First, there is debate about whether, and to whom, tissue-derived data can be disclosed.¹⁴ This is ethically and legally important because, whilst tissue banking research poses no direct physical risk to research subjects, there is a risk of inappropriate disclosure of personal – particularly genetic – information which has the potential to cause stigma and discrimination.¹⁵ Second, there is a debate about whether tissue can be owned and sold, since it is becoming clear that commercial uses of tissue are unacceptable to some tissue donors.¹⁶ Third, there is a debate about whether tissue is “sacred” and, therefore, different to other kinds of health information, such as medical records and genetic databases.¹⁷ Finally, there is discussion about whether the laboratory-based epidemiological techniques typically used in “tissue banking research” are well founded scientifically and whether, therefore, such research – which poses a risk to participants – is ethical.¹⁸

THE COMPLEXITY OF ETHICAL AND LEGAL REQUIREMENTS

Policy-makers have responded enthusiastically to the ethical challenges raised by tissue banking. Numerous national research agencies, health ethics bodies and health law organisations have produced analyses and guidelines. Overseas, bodies involved in tissue banking regulation include the American Association of Tissue Banks, the United States Department of Health and Human Services, the United States National Bioethics Advisory Commission, the British Association of Tissue Banks, the United Kingdom Medical Research Council, the European Commission and the Council of Europe.¹⁹ In Australia, the Australian Law Reform Commission (ALRC) has produced a comprehensive (1,200 page) report examining the issues of privacy, confidentiality, consent, scientific value, legal constraints, relationship to other branches of science and potential of genetics and tissue banking.²⁰ The report was based upon extensive community consultation and involved the unprecedented partnering of the Australian Health Ethics Committee (AHEC) with the ALRC. Recent legislative amendments of relevance to tissue banking include new privacy legislation (eg the *Health Records and Information Privacy Act 2004* (NSW)) and recent amendments to the *Human Tissue Act 1983* (NSW), the *Anatomy Act 1977* (NSW) and the *Coroners Act 1980* (NSW).

Given the complexity of the ethical issues surrounding tissue banking research, it is not surprising that regulatory requirements are complex. For example, in New South Wales, researchers, administrators and ethics committees wishing to utilise or authorise the use of tissue collections for research may need to be cognisant of:

- the common law relating to assault and confidentiality;
- legislation such as the *Privacy Act 1988* (Cth); the *Privacy and Personal Information Act 1998* (NSW); the *Health Records and Information Privacy Act 2004* (NSW); and the *Human Tissue Act 1983* (NSW);

¹⁴ Australian Law Reform Commission, n 1; Korn, n 1; Gaze B, “Privacy and Research Involving Humans” (2003) 10 (4) JLM 410; Caulfield T, “Tissue Banking, Patient Rights and Confidentiality: Tensions in Law and Policy” (2004) 23 (1) Med Law 39; National Health and Medical Research Council, n 11.

¹⁵ Savulescu, n 7; Bauer et al, n 7; Trouet, n 10.

¹⁶ Australian Law Reform Commission, n 1; Dickenson D, “Commodification of Human Tissue: Implications for Feminist and Development Ethics” (2002) 2 (1) Developing World Bioeth 55; Zodrow J, “The Commodification of Human Body Parts: Regulating the Tissue Bank Industry” (2003) 32 (3) Southwest Univ Law Rev 407; Jack A et al, “Why Surgical Patients Do Not Donate Tissue for Commercial Research: Review of Records” (2003) 327 (7418) BMJ 262.

¹⁷ Campbell C, “Religion and the Body in Medical Research” (1998) 8 (3) Kennedy Inst Ethics J 275.

¹⁸ Zeps N, “Ethics and Logistics of Using Archival Pathology Material” (2003) 27 (2) *Cancer Forum* 108; Potter J, “Epidemiology, Cancer Genetics and Microarrays: Making Correct Inferences, Using Appropriate Designs” (2003) 19 (12) *Trends Genet* 690; Makalowski W, “Genomic Scrap Yard: How Genomes Utilize All That Junk” (2000) 259 *Genetica* 61; Jablonka E, “Epigenetic Epidemiology” (2004) 33 *Int J Epidemiol* 929.

¹⁹ Bauer et al, n 7; Trouet, n 10.

²⁰ Australian Law Reform Commission, n 1.

- National guidelines such as the NHMRC's *National Statement on the Ethical Conduct of Research Involving Humans*;
- 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";
- New South Wales 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".

ONGOING REGULATORY AMBIGUITY

Despite the enormous complexity of tissue banking regulation, there remain several areas of uncertainty. In relation to consent, eg, there is still no consensus on:

- what it is that constitutes sufficient "inconvenience" or "public interest" to warrant the use of tissue archives for research without recontacting donors; and
- what it is that constitutes "specific consent" and whether, therefore, consent obtained prospectively can be obtained once only (eg at the time of surgery) or whether consent needs to be obtained every time a new research project is initiated.

These issues were discussed at length in the ALRC's report, *Essentially Yours*, and many of its recommendations were aimed at clarifying these issues. For example:

The National Health and Medical Research Council (NHMRC) ... should amend the National Statement to provide ethical guidance on the establishment, governance and operation of human genetic research databases. The amendments (whether by means of a new chapter or otherwise) should include specific guidance on obtaining consent to unspecified future research.²¹

There is also ongoing regulatory uncertainty regarding disclosure of information, with continuing debate regarding the moral and legal implications of privacy concerns. In response to these concerns, the ALRC has recommended that consistent rules be generated on the circumstances under which tissue-derived information can be disclosed:

The Australian Health Ministers' Advisory Council, in consultation with State and Territory Attorney-General's Departments and police services, the Human Genetics Commission of Australia and the NHMRC, should develop nationally consistent rules governing the disclosure, for law enforcement purposes, of genetic samples and information held in human genetic research databases.²²

More generally, the ALRC recommended that:

AHMAC [Australian Health Ministers' Advisory Council], in consultation with the HGCA [Human Genetics Commission of Australia], the NHMRC and key professional bodies, should review the need for nationally consistent rules 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.²³

THE NEED FOR CONCEPTUAL CLARITY

Until such time as these issues are clarified, researchers wishing to establish or utilise tissue banks, research ethics committees wishing to approve the research use of tissue samples, and administrators wishing to ensure regulatory compliance need to contend with regulatory complexity and ambiguity. This is no small task and there is evidence that researchers and administrators are concerned about the ever-increasing complexity of tissue banking regulation and the ever-increasing workload associated with meeting regulatory requirements. Furness and Sullivan, eg, complain that new British legislation

²¹ Australian Law Reform Commission, n 1 at [18-1].

²² Australian Law Reform Commission, n 1 at [18-4].

²³ Australian Law Reform Commission, n 1 at [19-2].

is “opaque”, “impractical” and “punitive”.²⁴ Policy-makers, too, are challenged by the need to comprehend existing policy in order to respond sensibly to calls for additions or amendment.

Whilst the complexity and ambiguity of existing regulation cannot be eliminated, the tasks of applying and creating regulation can be simplified by ensuring that the terminology and concepts are as clear as possible. The remainder of this article will present two conceptual frameworks which may assist researchers wishing to establish or utilise tissue banks, research ethics committees wishing to approve the research use of tissue samples, administrators wishing to ensure regulatory compliance, and policy-makers wishing to amend or develop tissue banking regulations. The first is a “taxonomic” approach to tissue banking regulation and the second is a “syncretic” approach to policy-making.

CONCEPTUAL FRAMEWORK I: MANAGING COMPLEXITY THROUGH A “TAXONOMIC” APPROACH TO MEETING REGULATORY REQUIREMENTS

The complexity of existing tissue banking regulation relates at least partly to the fact that tissue banks are heterogenous entities. Categorisation of types of tissue collections under a series of headings (ie a taxonomy of tissue banking activities) helps to identify the specific ethical issues and legal requirements of relevance to a particular collection. Some of the questions that need to be asked are:

- Why is there a collection?
- Whose tissue is it?
- What kind of research is it?
- What “tissues” are being used?
- Can tissue donors be (re)identified? and
- Where is the tissue being stored, who “owns” it and who is using it?

Why is there a collection?

The first step in navigating through human tissue regulation is to determine the purpose of the collection. Primary purposes for collecting tissue include clinical diagnosis and therapy, research, transplantation/transfusion, forensics, insurance/employment screening and public health surveillance. The following lists the ethically and legally relevant purposes of collecting tissue:

1. **Education;**
2. **Diagnosis** (called “human tissue collections” in *Essentially Yours*):
 - archival collections;
 - new collections:
 - medical diagnosis of living patient (clinical/diagnostic pathology) or deceased person (autopsy specimen collections);
 - genetic registers/population genetic screening collections;
 - newborn screening collections (Guthrie cards);
3. **Transplantation/therapy** (called “tissue banks” or “tissue repositories” in *Essentially Yours*; a subset of “human tissue collections”):
 - assisted reproductive technology (ART) banks (eg embryo banks);
 - non-ART repositories (skin, bone marrow, cord blood, bone);
 - blood banks;
4. **Public health surveillance;**
5. **Law enforcement;** and
6. **Insurance/employment screening.**

Human tissue collections are given a number of names, including “tissue banks”, “tissue collections”, “tissue repositories” and “genetic databases”. Sometimes these terms are used to refer to

²⁴ Furness, n 12.

collections with specific purposes. In *Essentially Yours*, the ALRC distinguishes between “human tissue collections”, which are specimens that were collected for clinical, rather than research, purposes, and “research databases”, which exist primarily for research purposes. Tissue collections are further divided into collections of diagnostic specimens, including newborn screening cards, and collections to be used for transplantation or transfusion (referred to as “tissue banks” or “tissue repositories”).²⁵ At other times, the phrases are used more broadly. The National Statement, for example, refers simply to “human tissue samples” and does not distinguish between the various subtypes.²⁶

Linguistic consistency is not the only reason for determining the purpose of the collection. Regulatory requirements differ significantly according to the purpose of a collection. Standards of consent, eg, need to be much higher if tissue is removed solely for research purposes than if tissue is removed for diagnostic and therapeutic purposes. In the former case, inadequate consent would constitute assault.²⁷ In the latter case, as discussed above, ethical and legal requirements are far less clear-cut. Within the category of “diagnostic” collections, there are (previously collected) archival collections and (prospectively collected) new collections. Archival collections raise different issues to new collections, since it is not always possible or feasible to recontact donors who may have died or moved. Also, archival collections are not necessarily subject to recent legislative amendments, such as amendments to the *Human Tissue Act 1983* (NSW).

The remainder of this taxonomy focuses on research collections (which may or may not have been collected primarily for research and which may be archives or prospective collections).

Whose tissue is it?

The tissue source is an important factor in determining relevant ethical and legal requirements. First, legislation and policy differ according to whether material is removed from a living donor or during post-mortem examinations. Second, tissue banks, by definition, reflect communities – be they disease communities (eg bowel cancer patients), geographic communities (eg the population served by a particular hospital) or ethnic communities (eg Ashkenazi Jews). Particular communities may have specific concerns about the types of research that might be carried out. The following lists the aspects of the tissue source that need to be taken into account:

1. **(Living) status of the “donor” at time of collection of data +/-material:**
 - living and still alive;
 - living and now deceased;
 - deceased (coronial post-mortem; non-coronial post-mortem).
2. **Cultural/religious/ethnic/racial background of donors (specifically in terms of likely attitudes to tissue banking):**
 - heterogenous backgrounds;
 - specific background (Aboriginal/Torres Strait Islanders; Hindu; Muslim; Buddhist; Jewish, etc)

What kind of research is it?

Once the purpose of the collection has been determined, it is necessary to establish what kind of research is being carried out. The simplicity of phrases such as “tissue bank”, “tissue repository”, “tissue collection” and “genetic database” belies the fact that these phrases can be used to refer to myriad research practices, each of which raises unique ethical and legal issues and, therefore, requires the application of different regulations.

Strictly speaking, banked tissue is a resource rather than a specific research method, and can be used for any kind of research requiring human tissue. Nonetheless, research utilising tissue banks typically employs epidemiological techniques in the laboratory. Thus, rather than being manipulated as a disease model, tissue is screened for the presence of abnormalities in its genes, proteins,

²⁵ Australian Law Reform Commission, n 1.

²⁶ National Health and Medical Research Council, n 4.

²⁷ Australian Law Reform Commission, n 1.

cytological/histological appearance or micro-organisms. The pattern of abnormalities is then correlated with the aetiology, prognosis or treatment responsiveness of a disease in a method that might be called “laboratory-based epidemiology”. A number of different research practices may fall under the heading of laboratory-based epidemiology. Relevant characteristics of research practice include the following:

1. Type of (epidemiological) correlation being sought:

- correlation between tissue abnormality and disease aetiology;
- correlation between tissue abnormality and disease progression/natural history;
- correlation between tissue abnormality and treatment responsiveness.

2. Type of tissue marker being examined:

- genes/chromosomes (autosomal or sex-linked) (adapted from *Essentially Yours*):
 - studies aimed at establishing that there is a genetic component to the disease risk/progression/treatment responsiveness;
 - studies aimed at determining mode of genetic transmission and what the genetic component of a disease looks like (oligogenic, polygenic, etc);
 - studies aimed at establishing relative size of genetic effect in relation to other sources of variation, including effects of the physical environment (eg intrauterine environment, chemical or physical exposures) as well as effects of particular behaviours and psychological profiles;
 - studies (linkage and association) aimed at identifying gene(s) responsible for genetic component of disease risk, natural history or treatment responsiveness.
- proteins;
- microorganisms (or antibodies to microorganisms);
- cytological/ histological features.

Each research practice generates different kinds of results (ie personal information) and requires access to different types of personal information, thus posing different risks and perhaps warranting different consent and confidentiality-maintenance procedures. Studies aimed at correlating tissue abnormalities with racial background may, eg, be more ethically and legally contentious than studies correlating tissue abnormalities with poor treatment responsiveness. Examination of genes may raise more concern than would measurements of environmental exposures. Family genetic studies (requiring detailed family histories) raise different concerns to population-level studies.

What “tissues” are being used?

In addition to engaging in various types of laboratory epidemiology, tissue banks use different types of tissue, ranging from whole organs to DNA pellets. Table 3 summarises the types of materials that may be stored in (research) tissue banks. These distinctions are important because ethical and legal requirements differ according to tissue type. Material stored in the form of tissue blocks and slides, eg, is not subject to the same consent requirements as material stored in other forms. And tissue stored in the form of DNA or RNA pellets is not expressly included in amended human tissue legislation, so its status is unclear. It is also important to establish whether normal tissue is stored alongside diseased tissue, since normal tissue has more power to identify abnormalities that are not directly relevant to the disease under examination and, therefore, to predict diseases of which the donor is unaware and to identify abnormalities present in genetic relatives and future offspring of the tissue donor.

When establishing a research bank, it is important to know whether the stored material is regenerative or non-regenerative since, eg, non-regenerative tissues cannot be obtained purely for research purposes. It is also important to identify the use of any morally contentious tissue types, such as fetal material or embryonic stem cells, since the legal requirements and ethical implications are significantly different. Ethically and legally relevant types of material used in tissue banking research are listed below:

1. Storage forms of information/material:

- database (computer or paper records containing data)
 - type of information stored:
 - genetic;
 - biochemical;
 - immunological;
 - microbiological data;
 - standardised clinical data;
 - genealogical data;
 - health information;
 - lifestyle information;
 - environmental information.
- tissue (in addition to data)
 - storage form of tissue:
 - genetic (DNA/RNA) sample;
 - tissue slide;
 - tissue block;
 - freshly frozen and refrigerated tissue;
 - alcohol-fixed tissue (eg for RNA preservation);
 - formalin-fixed tissue.
- whole organ.

2. Normal/diseased tissue:

- diseased tissue only;
- normal as well as diseased tissue (potential germ-line information).

3. Regenerative potential of the stored data +/- material:

- non-regenerative;
- regenerative:
 - reproductive tissue (ova/semen);
 - embryonic/fetal;
 - blood (whole blood;
 - packed cells;
 - plasma);
 - other regenerative tissue.

4. Moral status of tissue:

- not typically morally contentious (eg a breast tumour bank);
- morally contentious (eg embryonic or fetal material).

Can tissue donors be (re)identified?

Identified or coded (and potentially identifiable) materials raise more ethical issues than anonymised materials. This is because inappropriate disclosure of personal information is the main risk to participants in tissue banking research. And while anonymising tissue diminishes ethical and legal concerns, the use of anonymised tissue significantly reduces the power of research studies since tissue abnormalities cannot be correlated with disease progression or treatment responsiveness (which require medical records to be revisited over time). It is also important to bear in mind that donors can sometimes be identified indirectly from the results of a study, particularly if donors come from a

specific ethnic community, or have a rare – particularly heritable – disease. Table 4 lists the possible identifiability of tissues. Relevant aspects of identifiability include the following:

1. “Direct” identifiability of data +/- material:

- de-identified/anonymous (donor cannot be identified; identified; coded);
- identifiable (donor can only be identified by breaking a code);
- identified (donor is readily identifiable).

2. Potential for indirect identification of tissue donors:

- low (eg a common disease with samples drawn from a large population);
- high (eg banking of samples from a small ethnic community; banking of samples from a family with a rare, heritable disease).

Where is the tissue being stored, who “owns” it and who is using it?

It is necessary to establish whether a particular tissue bank is in a public or private facility, since different privacy legislation applies. The type of laboratory (eg a diagnostic pathology laboratory or health authority laboratory) is also relevant because different quality control requirements apply. The ownership status of the bank and the tissues themselves also need to be considered, particularly when researchers from other institutions (including overseas centres and commercial laboratories) request access to tissue. Ethically and legally relevant institutional and organisational characteristics include the following:

1. Primary custodian of data +/- material:

- diagnostic pathology laboratory;
- research laboratory;
- health authority (eg newborn screening);
- teaching collection.

2. Single/multiple users of data +/- material:

- single researcher recipient;
- multiple researcher recipients in same institution;
- multiple researcher recipients across institutions.

3. Public/ private sector “custodian” and/or user of collection:

- public (State; Commonwealth);
- private.

4. Reward for donation:

- donor unpaid;
- donor paid.

5. Owner of data +/- material:

- unstated;
- donor;
- bank/facility owner.

6. Intended method of disposal and/or return:

- store indefinitely;
- store until none left;
- discard;
- return to donor;
- unspecified.

The value of a taxonomic approach to navigating tissue banking regulation

The taxonomy described above brings the complexity of tissue banking, and associated regulations, into clear view and elucidates many of the issues that need to be considered by researchers, research ethics committees and administrators wishing to ensure regulatory compliance. This taxonomy is not, however, able to reduce the complexity of existing tissue banking policy. Nor can it assist with the rational development of new tissue banking policy. For these tasks, a further conceptual tool is required. Such a tool is described in the following section.

CONCEPTUAL FRAMEWORK II: REDUCING COMPLEXITY THROUGH A “SYNCRETIC” APPROACH TO POLICY MAKING

Given the complexity of the ethical and legal issues raised by tissue banking, it is likely that some degree of regulatory complexity and ambiguity is inevitable. However, at least some of the complexity and ambiguity of existing regulation stems from potentially contestable socio-political forces, rather than from necessity.

Both privacy legislation (in New South Wales) and amended human tissue legislation, eg, set out rules for gaining consent to the collection, use and transfer of, and disclosure of information derived from, human tissue samples. There is also evidence of overlap within documents. The National Statement, eg, has separate sections devoted to the “use of human tissue samples”, “epidemiological research” and “human genetic research”. Many of the requirements in the “human tissue” chapter are also present in the epidemiology and/or genetics chapters, both of which also apply to the use of human tissue in epidemiology and genetics respectively.²⁸

Such overlap is not necessarily incoherent (as long as definitions and rules are consistent), is explicable given the natural history of, and socio-political forces impacting on, policy development²⁹ and may assist with navigation through documents. But it also has drawbacks. Most obviously, overlap adds to the length and number of documents. There are also several more subtle drawbacks, all of which stem from the creation of separate policy for a phenomenon (in this case tissue banking) that is arguably not entirely new, and may, to a significant extent, be covered by existing regulation such as regulation of epidemiological and genetic research.

The consequences of failure to recognise and take into account this overlap (here called “regulatory asyncretism”) include:

- consumption of time in repetitive policy-making that could be better spent developing new policy for the aspects of tissue banking research that are truly unique (eg the sacredness of particular kinds of tissues to particular communities);
- discouragement of rethinking of existing policy, asking, eg, why existing regulation for epidemiological and genetic research does not clearly account for the issues raised by tissue banking which overlaps extensively with these other practices;
- exacerbation of the arguably erroneous impression that the issues raised by tissue banking research are new; and
- creation of a climate that may encourage unwarranted apprehension.

Whilst the use of tissue (as opposed to other forms of epidemiological data) may well pose new threats, it is important to realise that many of the issues raised by tissue banking research, including the need to access archival materials and the need to obtain consent to unspecified future research, are not new since they apply to any kind of epidemiological research in which data, in any form, are stored.

²⁸ National Health and Medical Research Council, n 4.

²⁹ Rosenbrock R et al, “The Normalization of AIDS in Western European Countries” (2000) 50 (11) Soc Sci Med 1607; Gordon I et al, “Perspectives on Policy Analysis” in Hill M (ed), *The Policy Process: A Reader* (Harvester Wheatsheaf, Hertfordshire, 1993); Smith G et al, “The Artificial Debate Between Rationalist and Incrementalist Models of Decision Making” in Hill, n 29.

An alternative – “syncretic” – approach to making (and amending) tissue banking policy

As mentioned, some degree of regulatory overlap is inevitable, given the separate evolution of various pieces of legislation. It is, however, possible to at least attempt to streamline existing repetitious regulation and to ensure that the creation of new repetitious regulation is kept to a minimum. This can be achieved through a process here called “policy syncretism”. A “syncretic” approach seeks epistemological, ontological, ethical and regulatory commonalities between emerging and existing phenomena, and endorses the creation of new policy only where there is undoubtedly something new about an emerging phenomenon. A syncretic approach to developing policy for tissue banking research would therefore involve:

- identifying what, if any, ethical issues are specific to tissue banking. It may, eg, be argued that the storage of whole organs and blocks of tissue raises ethical and legal issues that are not relevant to other kinds of epidemiological or genetic research;
- creating new policy (only) when new issues are raised; and
- carrying out a detailed critique of existing (epidemiological, genetic and general research ethics) policy to determine whether laboratory epidemiology can be incorporated into these and, if it cannot be incorporated, seeing this as a sign that *all* policy may need to be refined.

These steps are conceptually challenging and potentially time-consuming, but these short-term costs are likely to result in long-term gains, particularly the creation of more explicable, streamlined and manageable regulation of tissue banking. Such regulation is likely to maximise the compliance of stakeholders as well as increasing the confidence and decreasing the resentment of those involved in tissue banking research.

FURTHER APPLICABILITY

This article has outlined two conceptual frameworks for managing and reducing the complexity of tissue banking regulation. Whilst these frameworks could be of relevance to stakeholders in tissue banking research, they could also be applied to other complex practices.