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# The law of gifts, conditional donation and biobanking

Cameron Stewart, Jennifer Fleming and Ian Kerridge\*

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*Tissue banks are critical to research efforts into the causes and treatment of many diseases. Biobanks are created from donated tissue but property concepts have not played a major role in understanding methods of the collection and use of tissue. Little work has been done to study the proprietary dimensions of these gifts primarily because of the influence of the res nullius rule. Instead, the primary focus of studies has been the concept of informed consent, but this has proven to be problematic. This article examines how the law of gifts can help to resolve these difficulties. It argues that the concept of conditional donation is a more useful way to understand and explain how tissue can be donated to biobanks. The article also suggests ways that conditional donation could be regulated so as to balance the needs of researchers and the concerns of donors.*

## INTRODUCTION

Biobanks are collections of human biological material utilised in translational biomedical research. These biorepositories provide collections of tissue samples for use in biomedical research. They increasingly underpin many of the recent developments in biomedicine such as the identification of biomarkers and the development of targeted therapies.

Nevertheless, biobanks face regulatory challenges in relation to issues such as consent, collection, storage, usage and access. To varying degrees these challenges reflect issues of control that traditionally have been regulated by the law of property, but interestingly, such laws have not played any major role to date in tissue bank regulation. This is reflective of the res nullius rule which states that human tissue cannot be property unless it is transformed by work and skill, with the result that donors have lacked property rights over their tissue so that the act of donating to biobanks is non-proprietary.<sup>1</sup> Consequently, the nature of the donation to biobanks has lacked a definite legal form. As a fall-back position, most discussions of tissue donation have focused on informed consent<sup>2</sup> but this is an odd fit, given that it is a doctrine concerned with the provision of negligent advice concerning treatment. It is also problematic as consent can hardly be “informed” when the future uses of tissue are unknown at the time of donation.

The property law of gifts is an alternative to the informed consent doctrine. Recent cases that have recognised property rights in “unprocessed” human tissue have created an opportunity to examine how the law of gifts can shed light on the process of donating to biobanks.<sup>3</sup>

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\* Cameron Stewart, BEc, LLB (Hons), Grad Dip Jur, Grad Dip Legal Prac, PhD, Professor and Pro Dean, Sydney Law School, University of Sydney; Jennifer Fleming, BA, MHA, PhD, Academic Postdoctoral Research Associate, Centre for Values, Ethics and the Law in Medicine, The University of Sydney; Ian Kerridge, BA, BMed (Hons), MPhil (Cantab), FRACP, FRCPA, Associate Professor and Director of the Centre for Values, Ethics and the Law in Medicine, Sydney Medical School, University of Sydney. All authors are also members of the Network for Bodies, Organs and Tissues, University of Sydney.

Correspondence to: C Stewart, Sydney Law School, University of Sydney, NSW 2006, Australia.

<sup>1</sup> *Doodeward v Spence* (1908) 6 CLR 406.

<sup>2</sup> Clayton EW et al, “Informed Consent for Genetic Research on Stored Tissue Samples” (1995) 22 JAMA 1786; Trommelmans L, Selling J and Dierickx K, “The Importance of the Values Attached to Cells for a Good Informed Consent Procedure in Cell Donation for Tissue Engineering Purposes” (2009) 10 *Cell and Tissue Banking* 293.

<sup>3</sup> Traditionally, the work and skill exception has been an exception to the res nullius rule which applies to tissue which has been transformed by a process of labour, such as a two-headed fetus preserved in a jar: *Doodeward v Spence* (1908) 6 CLR 406. In *Yearworth v North Bristol NHS Trust* [2010] QB 1, the Court of Appeal of England and Wales found that donors of sperm had property rights sufficient to support a claim in bailment against a hospital which negligently stored the sperm, even though the donors had not added work and skill to the tissue or paid for such work and skill to be performed.

This article begins with a brief overview of tissue banking practice and the problems of the informed consent model. It then examines the law of gifts to see what this law can bring to our understanding of tissue banking. It argues that the act of donation to biobanks is underpinned by very strong feelings of altruism, which could be promoted and protected by a deeper understanding of the law of gifts. It also argues that concepts of conditional donation are more useful in balancing the protection of donors and the needs of researchers. The article concludes by proposing that some conditions should be implied into gifts to biobanks to achieve this balance.

## **BIOBANKING AND THE INFORMED CONSENT MODEL OF DONATION**

Biobanks are important resources for expediting the discovery of genes and other biomarkers which can be correlated with the aetiology, prognosis and treatment responsiveness of numerous diseases.<sup>4</sup> Biobanks also support drug development by enabling research into the selection of drug receptors and the most efficacious and least toxic compounds for treatment.<sup>5</sup> Because of their importance as pivotal research infrastructure, it is imperative that biobanks have a solid legal foundation and a clear understanding of the legal mechanics of donation, storage and use.<sup>6</sup>

It would seem logical, given that the process of tissue donation involves the manual delivery of a physical thing (res), that the legal foundation of tissue banking be based on the passing of property rights from donors to banks, moderated through gifts, contracts and/or trusts. But that approach has not been taken, primarily because donors have not traditionally been viewed as having property rights over their tissue. Human tissue is a thing that belongs to no one or is a *res nullius*. Instead, discussion over collection, storage and usage has been based on the doctrine of informed consent.

Informed consent, in legal terms, is a doctrine concerned with the provision of information about the material risks of proposed treatment. In ethics, informed consent is concerned with respecting the patient's autonomy over interference with their bodies. Both doctrines are clearly based on an assumption of bodily integrity that is, in tissue donation, then extrapolated to apply to parts of the body that have been excised.

A strong sense of public altruism is also a core component of the culture of donation to biobanks and this has been raised as another reason for employing an informed consent model for tissue donation rather than a property transaction model.<sup>7</sup> Property rights are seen by some to be inimical to this altruistic urge. The current authors believe that this fundamentally misunderstands the nature of property rights. Property rights are used altruistically every day at birthday parties, in deceased estates and in the day-to-day workings of charities. There is no conflict between owning a property right and then wishing, altruistically, to bestow it on another. As shown below, a gift *is* a property transaction. These arguments about altruism are not really about whether donors should have property rights. They are about whether donors should be paid or receive some benefit for donating (a topic which is beyond the scope of this article).<sup>8</sup> Most of the evidence from Australia and elsewhere, however, suggests that

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<sup>4</sup> Cambon-Thomsen A, Rial-Sebbag E and Knoppers BM, "Trends in Ethical and Legal Frameworks for the Use of Human Biobanks" (2007) 30 *Eur Respir J* 373; Tutton R and Corrigan O, "Introduction: Public Participation in Genetic Databases" in Tutton R and Corrigan O (eds), *Genetic Databases: Socio-ethical Issues in the Collection and Use of DNA* (Routledge, London, 2004).

<sup>5</sup> Sawyers CL, "The Cancer Biomarker Problem" (2008) 3 *Nature* 548; Antill YC et al, "Gene Methylation in Breast Ductal Fluid from BRCA1 and BRCA2 Mutation Carriers" (2010) 19 *Cancer Epidemiology, Biomarkers and Prevention* 265; Tan DS et al, "Biomarker-driven Early Clinical Trials in Oncology: A Paradigm Shift in Drug Development" (2009) 15 *Cancer Journal* 406.

<sup>6</sup> Watson RW, Kay EW and Smith D, "Integrating Biobanks: Addressing the Practical and Ethical Issues to Deliver a Valuable Tool for Cancer Research" (2010) 10 *Nat Rev Cancer* 646.

<sup>7</sup> See discussions in Steinmann M, Sykora P and Wiesing U (eds), *Altruism Reconsidered: Exploring New Approaches to Property in Human Tissue* (Ashgate, London, 2009).

<sup>8</sup> A good starting point for that debate is National Health and Medical Research Council, *Ethics and the Exchange and Commercialisation of Products Derived from Human Tissue: Background and Issues* (2011).

donors are quite happy to donate tissue to banks without receiving any form of benefit.<sup>9</sup> The current authors believe that recognising property rights in donors would have little effect on altruism.

The problems with using an informed consent model are various but for the purpose of the present argument the main issue is that informed consent is not possible for future unspecified research, which is the *raison d'être* of tissue banking.<sup>10</sup> If informed consent is taken to be the relevant standard, tissue bank researchers either have to re-approach donors for informed consent to every new study or they have to apply a concept of “broad” consent at the time of collection which is so far removed from the informed consent doctrine that it becomes fictional.<sup>11</sup> The current authors argue that informed consent, both legally and ethically, is not appropriate as the legal foundation of tissue banking because its focus on bodily integrity means that it is ill-suited to the task of gaining permission for future unspecified research on tissue which has had nothing to do with a donor’s body for some time. A more appropriate model is the law of gifts.

## THE LAW OF GIFTS

A gift is the voluntary transfer of property. The person who transfers the property is called the donor (or grantor, disponent, transferor) and the person who receives the property is called the donee (or grantee, disponent, transferee).<sup>12</sup>

The elements of a gift are:

- the donor must have mental capacity;
- the donor must not be unduly influenced; and
- the property is intended to pass to the donee without any consideration or obligation being owed to the donor (benefaction).

Gifts can be effected in different ways depending on the nature of the property.<sup>13</sup> For example, gifts of land must be by deed (for old system land) or registered (for Torrens land); testamentary gifts must be in compliant wills under succession law; and gifts of debts and choses in action must be made in writing with written notice to the debtor. Gifts can also be made in equity via a declaration of trust or informally via the rule in *Milroy v Lord* (1862) 45 ER 1185 which requires that both the donor has done everything necessary to be done and that the property is dealt with in such a way as to make the gift binding on the donor.

Gifts can also be made conditionally, meaning that the gift is subject to conditions which might have to be satisfied prior to title passing (conditions precedent) or might have to be complied with after the passing of title to avoid forfeiture of the interest (conditions subsequent). Under conditions precedent the failure to comply with the condition will mean that the donor never enjoyed title to the property. Conversely, under conditions subsequent a breach will mean that the title will be divested

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<sup>9</sup> Huber J et al, “Two Decades’ Experience with a Prospective Biobank for Urologic Oncology: Research, Clinical Care, and the Patients’ View” (2012) 31 *Urol Oncol* 990 (1 March 2012 Epub ahead of print); Streicher SA et al, “Reasons for Participating and Genetic Information Needs Among Racially and Ethnically Diverse Biobank Participants: A Focus Group Study” (2011) 2 *J Community Genet* 153; Morrell B et al, “Cancer as Rubbish: Donation of Tumour Tissue for Research” (2011) 21 *Qualitative Health Research* 75; Kettis-Lindblad A et al, “Genetic Research and Donation of Tissue Samples to Biobanks. What do Potential Sample Donors in the Swedish General Public Think?” (2006) 16 *European Journal of Public Health* 433; Otlowski M, “Donor Perspectives on Issues Associated with Donation of Genetic Samples and Information: An Australian Viewpoint” (2007) 4 *Journal of Bioethical Inquiry* 135.

<sup>10</sup> Caulfield T, Brown R and Meslin E, “Challenging a Well Established Consent Norm? One Time Consent for Biobank Research” (2007) 4 *Journal of International Biotechnology Law* 69; Caulfield T, “Biobanks and Blanket Consent: The Proper Place of the Public Good and Public Perception Rationales” (2007) 18 *Kings Law Journal* 209. But for a defence of broad consent see Otlowski M, “Developing an Appropriate Consent Model for Biobanks: In Defence of “Broad” Consent” in Kaye J and Stranger M (eds), *Principles and Practice of Biobank Governance* (Ashgate, Aldershot, 2009); and National Health and Medical Research Council, *Biobanks Information Paper* (2010) pp 23-25.

<sup>11</sup> Hoffmann B, “Broadening Consent – and Diluting Ethics?” (2013) 35 *Journal of Medical Ethics* 125. See also Siminoff LA and Traino HM, “Consenting to Donation: An Examination of Current Practices in Informed Consent for Tissue Donation in the US” (2013) 14 *Cell and Tissue Banking* 85.

<sup>12</sup> Fisher S, *Commercial and Personal Property Law* (Butterworths, Sydney, 1997) pp 446-447.

<sup>13</sup> See Radan P and Stewart C, *Principles of Australian Equity and Trusts* (2nd ed, LexisNexis, Sydney 2013).

from the donee and returned to the donor (or to a third party described in the gift). The current authors believe that, in the tissue banking context, conditions subsequent are the most relevant type of conditional gift because most donors will usually intend to grant the tissue bank the property rights over the tissue but may then wish to have conditions placed on the bank's subsequent use.

In most situations, the conditions in gifts will be expressly made either orally or in writing. However, the common law also allows for conditions to be implied by the nature and circumstances surrounding the gift. For example, gifts between people engaged to be married have an implied condition that the gift is made in contemplation of marriage.<sup>14</sup> This means that any gift will have to be returned if marriage does not eventuate.<sup>15</sup>

Conditional gifts are subject to a number of rules including the following:

- *The rule against restraints on alienation* which states that a gift cannot be made absolutely and then have conditions placed upon it. An example of this comes from *Brandon v Robinson* (1811) 34 ER 379, where there was a gift of a life estate held under a trust but a condition was placed on the life estate to make it non-transferable. This restraint was void because the life interest naturally included a power to alienate, which was offended by the condition subsequent. Contrastingly, a gift of property which has conditions built into the bundle of property rights avoids the rule. Such a *determinable estate* is considered to end naturally on the breach of the condition.<sup>16</sup> The difference between a condition subsequent that offends the rule and a determinable condition which does not relate purely to the form and wording of the disposition.<sup>17</sup>
- *The rule against perpetuities* that states that conditional interests must vest within the perpetuity period of a life in being plus 21 years. This means that conditional interests (such as that created by divesting a donee) that vest outside this time are void. However, the rule has been abolished or largely modified in most Australian jurisdictions.
- *The rule against conditions that breach public policy* which applies to conditional gifts that forbid marriage,<sup>18</sup> encourage divorce,<sup>19</sup> force parents and children to separate,<sup>20</sup> or support immoral sexual services or meretricious sexual relations.<sup>21</sup> Conversely, conditional gifts based on partial restraints on marriage,<sup>22</sup> or on religious or racial discrimination, are not against public policy.<sup>23</sup>

## APPLYING THE LAW OF GIFTS TO TISSUE BANKING

While there are no Australian cases that have applied the law of gifts to tissue banking, gift law was considered in the United States case of *Washington University v Catalona* 490 F 3d 667 (2007).<sup>24</sup> This case concerned a researcher who had recruited several thousand participants to provide tissue to his

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<sup>14</sup> Fisher, n 12, p 487.

<sup>15</sup> *Jacobs v Davis* [1917] 2 KB 532; *Gomes v De Nobrega* (unrep, NSWSC, 1990, Young J).

<sup>16</sup> *Hood v Oglender* (1865) 55 ER 733 at 737.

<sup>17</sup> *Re Scientific Investment Pension Plan Trusts* [1999] Ch 53. See the discussion in Radan and Stewart, n 13, pp 393-394, about the form of words that can be employed.

<sup>18</sup> *Lloyd v Lloyd* (1852) 61 ER 338; *Re Johnson's Will Trusts* [1967] 1 All ER 553.

<sup>19</sup> *Trustees of Church Property of the Diocese of Newcastle v Ebbeck* (1960) 104 CLR 394; *Ramsay v Trustees Executors & Agency Co Ltd* (1948) 77 CLR 321; *Ellaway v Lawson* [2006] QSC 170; *Jones v Krawczyk* [2011] NSWSC 139.

<sup>20</sup> *Re Boulter* [1922] 1 Ch 75; *Penfold v Perpetual Trustee Co Ltd* [2002] NSWSC 648.

<sup>21</sup> *Upfill v Wright* [1911] 1 KB 506; *Pearce v Brooks* (1866) LR 1 Exch 213; *Girardy v Richardson* (1793) 170 ER 265; *Andrews v Parker* [1973] Qd R 93; *Seidler v Schallhofer* [1982] 2 NSWLR 80; *Ashton v Pratt (No 2)* [2012] NSWSC 3.

<sup>22</sup> *Lloyd v Lloyd* (1852) 61 ER 338; *Jenner v Turner* (1880) 16 Ch D 188; *Re Tuck's Settlement* [1978] Ch 49.

<sup>23</sup> *Re Tegg* [1936] 2 All ER 878; *Blathwayt v Cawley (Baron)* [1976] AC 397; *Kay v South Eastern Sydney Area Health Service* [2003] NSWSC 292. But see the discussion in Komesaroff P, Kerridge I, Stewart C, Samuel G, Lipworth W and Jordens C, "Racially Conditional Donation: The Example of Umbilical Cord Blood" (2012) 19 JLM 517.

<sup>24</sup> Other related cases are *Moore v Regents of the University of California* 793 P 2d 479 (1990) where a patient failed to establish a claim for conversion of his spleen when it was used to create a cell line (although he was successful in bringing a claim for breach of fiduciary duty against his doctor due to the doctor's undisclosed financial conflict of interest); and *Greenberg v Miami Children's Hospital Research Institute* 264 F Supp 2d 1064 (2003) where donors to a tissue bank failed to

tissue bank for the study of prostate cancer. The researcher left the university and moved to a competitor institution. He tried to take the tissue bank with him. The majority of the participants wished for the tissue bank to remain under the researcher's control. They argued that the terms of their donation included the right to demand that the tissue could only be used for research conducted by the particular researcher. Washington University stated that the donors had donated the tissue to the university and that it owned all the tissue in the bank.

Both at trial and on appeal it was found that the tissue was the property of the university and the transfer of the tissue from the donor met the required legal elements of voluntary gifts. It was also found that the gifts were made on the condition that the participants could withdraw their tissue from the study (and in some cases have it destroyed). However, this did not equate with a right to control who researched upon the tissue or a right to decide where it could be stored.

The case illustrates the importance of express consent to donation and how what is written down in consent forms may be used to discern the terms of the gift. The court also relied on surrounding circumstances, such as the practices of the researcher (particularly how he would often destroy samples in his research), as further evidence that the donors had intended to give the university property rights equating to ownership.

In the Australian context, there is now case law that is sympathetic to the idea that property rights can be enjoyed by donors prior to the addition of work and skill, as discussed in the English decision of *Yearworth*.<sup>25</sup> This recognition opens the door to using the law of gifts in tissue donation. As the analysis above shows, one possibility is that donors could donate their tissue absolutely and unconditionally so there are no conditions attached to the use of the tissue. Such an absolute gift would solve the problem of unspecified research which plagues the informed consent model, as future researchers would be absolute owners and would not need to go back and seek express consent every time a new research project sought to use the tissue.

It is more likely, however, that in most donations there will be some conditional limitations on gifts of tissue, as was the case in *Catalona*. There are also good policy reasons for implying conditions into tissue donations as implied conditions could be used to foster public confidence in tissue banking and also reduce the problems encountered by an informed consent approach.

For example, research in Australia and overseas has shown that there is support for broad consent to donation as long as research is approved by a human research (institutional) ethics committee and that appropriate measures are taken to protect personal information.<sup>26</sup> Such conditions could be implied into gifts by the common law (in the same way that it implied conditions in gifts made in contemplation of marriage). Alternatively, such implied terms could be introduced quickly and clearly by amendments to human tissue legislation. Introducing such implied terms through legislation would also protect the implied conditions from the operation of the common law rules discussed above, such as the rule against restraints on alienation and the rule against perpetuities.

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bring claims for informed consent, fiduciary duty, unjust enrichment, fraudulent concealment of the patent application, conversion and misappropriation of trade secrets, when a tissue bank researcher took their samples and then went on to take out a patent on the genetic test for their disease. The court refused to recognise that the donors had any property rights in their tissue.

<sup>25</sup> *Bazley v Wesley Monash IVF Pty Ltd* [2011] 2 Qd R 207; [2010] QSC 118; *Re Edwards* (2011) 81 NSWLR 198; [2011] NSWSC 478; *Re H (No 2)* [2012] SASC 177; *Re Section 22 of the Human Tissue and Transplant Act 1982 (WA)*; *Ex parte C* [2013] WASC 3.

<sup>26</sup> Simon CM et al, "Active Choice but Not Too Active: Public Perspectives on Biobank Consent Models" (2011) 13 *Genetics in Medicine* 821; Fleming J, "Issues with Tissues: Perspective of Tissue Bank Donors and the Public Towards Biobanks and Related Genetic Research" in Stranger M (ed), *Human Biotechnology and Public Trust: Trends, Perceptions and Regulation* (Centre for Law and Genetics, University of Tasmania, Hobart, 2007); Kettis-Lindblad A et al, "Perceptions of Potential Donors in the Swedish Public Towards Information and Consent Procedures in Relation to Use of Human Tissue Samples in Biobanks: A Population Based Study" (2007) 35 *Scandinavian Journal of Public Health* 148; Williams C, "Australian Attitudes to DNA Sample Banks and Genetic Screening" (2005) 21 *Current Medical Research and Opinions* 1773; Kaphingst KA et al, "Views of Female Breast Cancer Patients Who Donated Biologic Samples Regarding Storage and Use of Samples for Genetic Research" (2006) 69 *Clinical Genetics* 393.

## **CONCLUSION**

The law of gifts is a useful but underused resource for understanding the mechanics of tissue donation to biobanks. The new property approaches have opened the door to the law of gifts and will allow us to import its structures into biobanking. The law on gifts is flexible and recognises both the altruistic urge and also the desire to maintain control over the future uses of property, which are two key drivers of concern in the tissue bank context. Conditional donations could be employed in the biobanking context to allow future unspecified research but on the basis that certain conditions be met. Should the gift approach be adopted, it would be in the public interest for a number of basic conditions to be implied automatically, particularly the conditions that future research must be approved by a human research ethics committee, properly constituted under the NHMRC regulations, and that the biobank must maintain protections for the personal information of the donors.