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An analysis of the whether propriety concepts, specifically conditional contribution, can resolve current ethical and legal dilemmas; specifically focusing on medical research using contributed material.

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ABSTRACT

Title: *An analysis of the whether propriety concepts, specifically conditional contribution, can resolve current ethical and legal dilemmas; specifically focusing on medical research using contributed material.*

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This paper will analyze how a model based upon propriety concepts, specifically the conditional gift, could be utilised to address the current limitations of the legal safeguards that have traditionally been used to protect individuals’ contributing to medical research. The paper outlines three benefits of using the concept of the propriety right in the form of a conditional gift to reform medical research. Firstly the conditional nature of consent embodied in the conditional gift, secondly the persistent nature of rights held in immovable and movable contributed material and finally, the ability to use conditional contribution to distribute the rights of researchers and the participant as well as to ensure that beneficial medical research can continue.

The essay will conclude by showing that the conditional gift model may not the *only* way to reform current legal safeguards; yet it may be one of the best candidates for the role.

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Introduction

The thesis explores whether a conditional contribution model could be used to frame the rights and duties that arise when a participant contributes their bodily substances and personal health information (contributed material) to a research project. The conditional contribution model is rooted in the common law conceptualisation of the propriety concept of a conditional gift. Yet, to move away from associating the conditional contribution with property rights, the thesis shows how the concept can be tailored to fit within the context of medical research. The thesis is that the conditional contribution model outlined has a number of benefits which make it a good candidate for the challenging role of reforming medical research using contributed material in Canada; especially in light of recent innovative large-scale research project.

To support this thesis, the essay will have three sections which consider the central attributes of rights held in movable or immovable objects when structured upon the basis of a conditional gift. The three benefits are, firstly ‘Conditional rights’, secondly ‘Persistent rights’ and finally ‘Distributive rights’.

For each of the three attributes three issues will be addressed. Firstly, how this attribute has traditionally been utilised by common law judges to structure the interests of the different parties to a transfer. For example, ‘Persistent rights’ refers to how conditions attached to an item of property have traditionally bound third parties that has received the property irrespectively of their knowledge. Secondly, how this attribute could be specifically tailored to apply to the context of medical research. In particular, how a statute based upon the conditional gift model could be
drafted to address the unique relationship that arises within the context of medical research. Finally, the section will consider how this attribute of the conditional gift could provide additional benefits beyond the traditional rights that are used to protect participants in medical research.

The conclusion of the thesis will acknowledge that the conditional contribution model would not be a panacea. It would still be necessary to use the long-established methods for protecting participants; namely the right to informed concern and privacy rights in unity with the conditional contribution model. In addition, the wider systemic reform of medical research advocated in this essay would require a wide-scale acceptance by researchers and policy-makers that changes are required. Nonetheless, it will be submitted that the conditional contribution model has several attributes which could be used to structure the rights and duties that arise within the context of medical research.

It is also important to note from the outset that the conditional contribution model outlined in this essay does not seek to reform the common law rules concerning conditional gifts or ownership of body parts or substances.¹ This essay does not seek to make any conclusion as to who will ultimately own bodily substances once removed from the human body. Instead, the paper seeks to highlight that it is possible to utilise the advantages of propriety rights, in particular

¹ The common law rules surrounding ownership rights in bodily substances are unsettled and controversial. For example, the common law authorities seemingly suggest that the contributor of bodily substances or body parts is the initial owner however they can be estopped from relying upon their right to ownership if there is an application of human skill by a third party: R. v. Kelly/R. v. Lindsay [1998] 3 All E.R. 741, (CA); Magnusson (1983) 36 Current Legal Problems 193, at p. 259. In addition the common law rules concerning conditional gifts are unsettled therefore this essay does not seek to reform these rules given the current state of flux and disagreement about the future direction the general common law ought to take: See Ziff, Principles of Property law (2006) 6th Ed
the conditional gift, within the context of medical research to frame the rights and duties of the different parties.

The need to extend current legal protection, such as informed consent and privacy rights, may be especially important in light of new medical research projects occurring over longitudinal periods, concerning thousands of participants, transfers to multiple parties, permanent linkages with other databases and the particular research projects are unknown at the start of the project. In these innovative large-scale health studies, there is often less of a personal relationship between a participant and researcher than compared to traditional medical research projects.

The result of these innovative projects is that researchers organising such

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2 The innovative research project that I considered to consider the potential risks that may arise is the Ontario Health Study as controlled by the Canadian Partnership for Tomorrow; “Who are we”, *The Canadian Partnership for Tomorrow* (6 August 2010) Canadian Partnership Against Cancer. The website describes itself as ‘an independent organization funded by the federal government to accelerate action on cancer control for all Canadians. We are a partnership of cancer experts, charitable organizations, governments, patients and survivors, determined to bring change to the cancer control domain…The Partnership evolved from the Canadian Strategy for Cancer Control – a volunteer-driven coalition working to counteract the growing burden of cancer on Canadian society.’ online: http://www.partnershipagainstcancer.ca/Who


4 *Ibid. Information Booklet* at page 5 The Study is organised by the ‘Canadian Partnership for Tomorrow’ and has currently recruited over 8,184 participants and aims to recruit 100,000 individuals. The project is part of one of the ‘largest ever Canada and one of the most far-reaching population studies in the world to date.’

5 The results of the OHS will be shared and compared across Canada, around the world and transferred to private parties ‘Canadian Partnership for Tomorrow Annual Report’ (Winter 2009) Canadian Partnership Against Cancer. online: http://www.partnershipagainstcancer.ca/sites/default/files/documents/CPAC_ProgressRep08Eng_W.pdf at pages 5 and 8-14

6 Supra. fn. 3 *Information Booklet* at p6 OHS will also be a permanent linkage with the Ontario Ministry of Health and London-Term Care (OMHLC) and/or the participant’s doctor

7 Supra. fn. 3 *Information booklet*, at page 6; Participants concerns were revealed in the Saskatchewan Health, Consultation paper on protection of personal health information (1998), online: http://www.health.gov.sk.ca/ph_br_health_leg_phiq/default.htm. Saskatchewan 63% of respondents agreed “to receive informed consent health professionals would need to provide details of every anticipated use of information.” In Ontario the majority of individuals would agree to the use of their personal information for research purposes as long as consent was obtained first.
projects may be perceived to be under a less onerous duty of care to the participants. This is evident in the consent form used in the Ontario Health Study which only provided a very general description of the uses of a participant’s transferred material.\textsuperscript{8} Similarly, it did not provide specific information of the third parties which may receive the contributed material.\textsuperscript{9} The Participant Information Booklet did state that the research subjects can ‘follow the Study’s progress on the website.’\textsuperscript{10} However, almost two years after the launch, there is no specific information on the research projects currently being completed. This uninformative approach makes it difficult to claim that this large-scale Health Study and other similar international projects are adhering to the strict national and international requirements to satisfy the duty of researchers to ensure participants give fully enlightened consent.\textsuperscript{11}

Nonetheless, the limited disclosure provided by such Studies may be regarded as legitimate because a Research Ethics Board (REB) can rely upon Article 2 of the Canadian \textit{Tri-Council Policy Statement on the Ethical Conduct of Research involving Humans (TCPS)}\textsuperscript{12} to decide that fully informed consent is not \textit{ethically necessary} when certain assumptions are made by the REB. The result is that the researcher is

\begin{itemize}
\item \textsuperscript{8} Supra. fn. 3 Information booklet, at page 6
\item \textsuperscript{9} Supra. fn. 3 Information booklet, at page 10
\item \textsuperscript{10} Supra. fn. 3 Information booklet, at page 7
\item \textsuperscript{11} The Nuremberg Code. From Trials of War Criminals before the Nuremberg Military Tribunals under Control Council Law No. 10. Nuremberg, October 1946/April 1949.
\end{itemize}
under less onerous disclosure duties to ensure participants given fully informed consent. This thesis attempts to show that instead of accepting that researchers are under a less onerous duty of care, a more ethically and legally justifiable approach would be to consider whether a new model is required to address the challenges posed by innovative research projects.

The conditional contribution aims to be that model. It accepts that it may be necessary to alter or waive the requirements of informed consent to ensure beneficial medical research can continue. Yet, it acknowledges that where a REB does dilute the requirements of informed consent upon the basis of certain assumptions, those assumptions ought to be subject to scrutiny. Moreover, that when those assumptions materialise to be incorrect or lead to harm to participants, then there ought to be redress to acknowledge the fact that REB has taken a risk with the participant’s rights and that risk has caused legal recognisable harm. To achieve this end, the essay will show how the conditional contribution model can use the assumptions of the REB as a basis for conditions upon which the use of the contribution is demarcated. Prior to delineating the conditions, the essay will explain how the conditions could be enforced through providing participants with Conditional and Persistent rights in their contributed material as part of holistic reform of medical research. It will be shown that although other legal remedies could achieve similar results, the conditional contribution framework may be one of the most effective and reflective ways to address the current difficulties with medical research using contributed material.

\[13 \text{ Infra Section 1.3. The difficulties conditional rights could address page Error! Bookmark not defined.}\]
1. Conditional rights

A conditional gift embodies two elements which are intertwined into a distinct legal concept. The first is the *donation* aspect embodied in the ‘gift’ element. A gift requires three distinct legal requirements are satisfied; namely an intention to donate, acceptance by the recipient and a sufficient act of delivery.\(^\text{14}\) An intention to donate has to be ‘manifest and expressed with certainty’ and the condition attached to the transfer ought ‘not to retain it [the transferred item] in the transferor’s hand for any purpose, fiduciary or otherwise.’ \(^\text{15}\) The resulting relationship is a unilateral endowment of the utility, possession and ownership rights held in the transferred gift. \(^\text{16}\) The ability to donate all rights in an item reveals the charitable and benevolent nature of a gift. The transferor gives up all rights purely for the benefit of another individual, a group or the wider public benefit.

Yet, a conditional gift has a distinct and significant additional aspect, namely the benevolent transfer of the contributed material is ‘conditional’ upon certain express or implied conditions. Rather than an absolute intention to benevolently donate, the conditions transform the gift because there is an element of reciprocity, conditionality and restrictiveness. The gift becomes conditional upon good faith reliance that the conditions will be respected. To ascertain any implied conditions, courts adopt a ‘common sense’ approach considering the wider context in which the gift was made.\(^\text{17}\) For example, when A places a dollar into a box labelled ‘Charity’

\(^{14}\) Ziff *Supra*. Principles at fn. 1

\(^{15}\) Nolan v Nolan & Anor [2003] V.S.C 121


held by B there is an implied condition that B will use the dollar for charitable purposes.\textsuperscript{18} The conditional nature of the gift allows the transfer to be more specifically tailored to reflect the particular context in which the transfer was made.

The need to add conditions suggests that the contributor has felt that the relationship is not sufficiently close to allow a unilateral transfer. Rather, additional steps have been taken to ensure that the recipient, firstly, appreciates the conditions attached to the use of the gift and secondly, that they can enforce their conditions when the conditions are breached. The second result is achieved because a breach of the conditions allows the transferor to request the return of the gift.\textsuperscript{19} This is evident in a case where a recipient sold an estate delivered to the recipient for the purpose of building a Temple and the transferor could reclaim the land from the fraudulent transferee when the land was sold inconsistently with the conditions.\textsuperscript{20}

Yet, there may be a point where an individual loses a right held in an item. Indeed, even the very right to ownership is relative to others who may have a greater right to ownership.\textsuperscript{21} This is illustrated in the adverse possession rules which allow a third party to claim a right to ownership better that the original

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\textsuperscript{18} Re Gillingham Bus Disaster Fund [1959] \textit{Campbell v. MacKenzie}, [2003] AJ. No. 1472, 46 R.F.L. (5th) 321 (Alta. Prov. Ct.) An Entertainment Centre gifted by one party in a relationship with the recipient may have the implied condition that the gift is only for the couple together if they remain in the relationship and when the relationship breaks down the Centre may be returned to the donor.


\textsuperscript{21} Rodger Smith, \textit{Property Law} (2006) (5\textsuperscript{th} Ed.) (Oxford University Press (OUP)) page 44
\end{flushright}
owner where they detrimentally rely upon the owner giving up that right in the item for at least a decade.\textsuperscript{22} Similarly, the rules concerning finders would allow a finder, A, who finds property belonging to B, but C has subsequently seized the possession, to recover the item from C.\textsuperscript{23} Yet, they may not be able to assert their right again B, the person to whom the property belongs. The ability of rights held in an item to be lost when another relies upon shows that there is an \textit{estoppel} at a certain point. In the conditional gift cases, an estoppels will arise when there is reliance by the transferor upon the gift.\textsuperscript{24} There is limited authority on the issue, but generally considerable reliance is required before a transferee can claim a greater right to possession than the contributor of the transferred item. For example, an adverse possession requires over a decade of reliance by the possessor of the property to claim a greater right to the original owner. The considerable reliance required before a right may crystallises reflects the fact that rights held in movable and immovable objects are particularly precious and are not easily lost to another third party recipient.

In summary, the central characteristics of conditional gifts are the benevolent intention to donate with the additional need to create conditions to ensure the contributor’s rights are respected. The fatal result of the conditions not being respected emphasises the importance of respecting the good faith that the transferor has placed in the recipient to ensure that the gift is cherished and used.

\textsuperscript{22} \textit{Asher v Whitlock} (1865) LR 1 QB 1
\textsuperscript{23} \textit{Armoury v Delamirie} (1722) 1 Stra 505 (93 ER 664)
for the ultimate purpose for which it was delivered. Yet, there is also a possibility a
interest held in the item being lost when another detrimentally relies upon receiving
a right in the item.

1.1. Structuring conditional rights to reflect the context of medical research
The good faith and expectation balanced with concern, restriction and conditionality
which is a central attribute of a conditional gift seems to most adequately reflect the
relationship that arises within the context of a transfer of contributed material to
medical research. This is because the conditional gift could be structured to reflect
the trust and good faith reliance the participant has in the researcher. Yet, the
conditions attached to the transfer could be structured to reflect the concerns
participants have and provide a basis upon which to restrict the use of the transfer.

The paramount issue that ought to be considered when deciding the
conditions that ought to be attached to the gift is when the transferor can request
that the contribution is withdrawn. The general approach adopted in the TCPS is
that the participant can withdraw from a research project at any stage. The TCPS
guidance which suggests participants ought to always retain the right to withdraw.25
This is reflected in the decision of Washington University v Catalona.26 In the
case, despite only some consent form stating that the participant could withdraw
from the Study, the Eighth Circuit of the American Court of Appeal held that all
participants did maintain the right to withdraw by requesting the destruction of

25 TCPS, Supra, Art.2.4(d) ‘an assurance that prospective subjects are free not to participant, have the
right to withdraw at any time without prejudice to pre-existing entitlements, and will be given
continuing and meaningful opportunities for deciding whether or not to continue.’
their contributed material.\textsuperscript{27} At a minimum, the \textit{Catalona} case reveals, that there is an implied condition that the participant will be able to request the destruction of the material and thus from the project.

However, a medical researcher may expend considerable funds and time completing a research project. Indeed, in \textit{Catalona}, it was noted it would not be possible to destroy or recall any research results already obtained.\textsuperscript{28} Indeed, many research projects have to limit the participant’s right to withdraw because of the need to ensure that the research project continues. For example, although the Ontario Health Study allows participants to withdraw from the ongoing duty to provide information and samples to the Study, the consent form states that participants cannot withdraw material already contributed. Nor can participants terminate the permanent link the Study has with the Ontario Minister of Health and/or the participant’s physician until 2059.\textsuperscript{29}

The conditional gift model could reflect the need to not overly restrict researchers with overly wide withdrawal rights as well as ensure that participant’s fundamental rights to withdraw are protected. This could be achieved by holding that once a research project has commenced the participant cannot withdraw unless one of the conditions is breached. The case-law concerning a conditional gift suggests that where a transferor does attach conditions to a contribution and those conditions are not complied, then the gift will fail and the participant can reclaim

\textsuperscript{27} \textit{Ibid} at para 22
\textsuperscript{28} \textit{Ibid} para 8
\textsuperscript{29} OHS PARTICIPANT Information Booklet” \textit{The Ontario Health Study} (6 August 2010) online: http://www.ontariohealthstudy.ca/common/pages/UserFile.aspx?fileId=6457
their contribution.\textsuperscript{30} This would make the right to request the destruction of the material conditional upon a condition being breached. This approach would acknowledge the fact that the participant may not be able to withdraw where researchers have invested considerable time and expense on a research project. Nonetheless, the participant maintains the right against the research to withdraw the gift when the researcher fails to respect the conditions the participant has attached to the contributed material.

This approach may balance researcher’s concern of a mass withdrawal leading to considerable fund expended on a project being wasted. Thus, where the researcher follows the conditions there ought to be no need to be concerned of mass withdrawals of participants. However, if the conditions are breached, then the participant could reclaim their fundamental right held in the gift. This would give participant the authority that they may lose when they allow a researcher to remove contributed material from their body and use, store and disclose their personal information.\textsuperscript{31}

Indeed, it may be the fatality of a breach of the conditions which is one of the central benefits of the gift. The conditional gift model could provide an incentive to researcher’s to respect the conditions attached to the gift; this is because the participant could claim the right to remove their contribution where the conditions

\textsuperscript{30} Ziff, Principles at Supra fns.1
are breached. This may be a more appropriate centre ground between allowing the researcher to use the material without the participants freely withdrawing, yet it also acknowledges that the contribution was conditional upon certain safeguards being adhered to.

In addition, it is important to acknowledge that there may be instances where this right to withdraw may be completely lost. The conditional gift model may be able to recognise this through utilising the concept of an *estoppel*. For example, when the researchers relies upon the conditional transfer to publish research which is used by a number of other public bodies to provide remedial treatment, it may be impossible to the participant to withdraw from the project because the results have already been culminated, published and used. In addition, anonymised material could provide a researcher with an *estoppel* from a claim to withdraw the contributed material.

A conditional gift could be structured to acknowledge that it may be possible

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32 Supra, conditions attached to the gift outlined at page 2
33 Although certain studies have shown that participants do believe that they maintain a ongoing link with their material irrespectively of anonymisation; Asai Atushi et al., "Attitudes of the Japanese public and doctors towards use of archived information and samples without informed consent: Preliminary findings based on focus group interviews" (2002) 3 BMC Medical Ethics 1 at 9; For example, a group study on Japanese individuals using anonymous information revealed that certain participants wished to give their informed consent and be given the right to withdraw irrespectively of the fact that the material had been made anonymous. It was concluded that the participants ‘might have felt that they could have been wronged by a study that used archived medical records and samples without their own prior permission, even if the information and samples were dealt with anonymously. It follows that they might say something like ‘information about me is an aspect of myself, just as is the physical space that I live in and someone looking through it has intruded upon me as surely as if he or she had entered my home.’ D J. Willison et al., "Patient consent preferences for research uses of information in electronic medical records: interview and survey data" (2003) 326 British Medical Journal at 373; Similar values were held by a participant in an Ontario Health Study. The participant stated that ‘I think [that] you need to give conscious consent to having any data, any personal data used, whether you are identified or not. That's certainly a right. That's your information; it's your medical history. Whether it's identified or not, you should control it.’ If such an approach was accepted it may require that anonymisation doesn't necessitate any estoppels or vitiation of rights.
to withdraw because the concept recognises the fact that the held in the contributed material are relative, not absolute. The point at which the right to withdraw may be lost may depend upon the extent of time and reliance the researcher places on the contribution. At the very least, it ought to recognise that once a Study is completed and published it may be impossible for the participant to withdraw from that project. For example, the consent form could state 'that information already used towards a completed, or substantially complete research project, cannot be withdrawn once that information has been compiled and published.' This would encourage researchers to regularly culminate data and publish results to ensure that participants are aware of its uses.

Another benefit of the conditional gift is that it may allow the participant to state a successive condition delineating an alternative use of the gift when one of the terms is not complied with. This will allow the contributed material to continued to be used for the public benefit rather than allowing it to be completely withdrawn by the participant. For example, where a research project breaches a condition attached to the contributed material, the participant could request that the material is transferred to another research project rather than request its complete withdrawal.\(^{34}\) This would provide additional safeguards to address concerns that the public benefit of medical research may be undermined if participants start claiming the right to withdraw from a particular project. An alternative option is that the participant could be given the option to accept the breach and allow the research to continue when they are unconcerned.

\(^{34}\) Ziff Principles fn.1 Supra at page 222
Although, the common law conception of a conditional gift has not recognised compensation for a breach of the conditions, it could be possible to incorporate a condition allowing for limited compensation and/or an apology rather than requiring that the donation is returned. In addition, although the courts have not considered the issue, arguably the loss flowing from the condition would include harm the contributor suffers because of the breach. For example, the English High Court recently held that a breach of a condition attached to a bailment of a sperm could lead to compensation for psychological harm the participants may suffer as a result of the breaching the condition. Other cases have allowed compensation to family members for in-consensual uses of a relative’s human body. These additional measures may address the limitation of withdrawal being the participant’s only remedy. This possibility will be considered further in the final part of the essay.

1.2. The current difficulty that conditional rights could address

35 Yearworth v. North Bristol NHS Trust [2009] EWCA Civ 37 [2009] All ER (D) 33 (Feb) at para 48 Although this was not within the context of medical research and the High Court did note that the US District Court decision in Catalana was distinguishable because the case concerned an absolute gift. The High Court decision was partially overruled by the Court of Appeal because it suggested that there was an implied condition that the participants could withdraw from the project.

36 The usual basis of damages is mental distress and anguish caused to the relatives. See, for example, Gonzales v. Metro Dade City Health Trust (1995) 651 So. 2d 673, (Supreme Court of Florida), where it was held that an action for mental anguish based on negligent handling of a dead body could be brought by relatives of the deceased if physical injury could be proved or the defendant’s conduct was wilful or wanton; Mackey v. U.S. (1993) 8 F. 3d 826, (United States Court of Appeals), noted in [1995] Med L.Rev. 222. In England, negligently inflicted mental distress is irrecoverable unless part of a “pain and suffering” claim arising out of physical injury: Alcock v. Chief Constable of South Yorkshire Police [1991] 4 All E.R. 907, (HL). If, on the other hand, the defendant interfered with the body with the intention of causing harm to the plaintiff, then the rule in Wilkinson v. Downton [1897] 2 Q.B. 57 would apply and an action would lie for any recognised psychiatric injury: see further, (1996) 4 Med. L. Rev. 216, where it is argued that a negligence action would only succeed if the plaintiff satisfied the Alcock rules for recovery of damages for psychiatric injury as a “secondary victim”. On this basis, the deceased’s relatives would need to “witness” the mishandling of the body in order to succeed: cf. Owens v. Liverpool Corporation [1938] 4 All E.R. 727, (CA), where a claim for psychiatric injury by relatives of a deceased who witnessed an accident involving the hearse carrying the body was upheld.
Utilising the concept of conditional rights would ensure that participants in medical research could ensure that their contributed material is handled with care. This right has traditionally been protected by the right to informed consent. However, there are a number of difficulties with relying upon the traditional conception of informed consent to protect participants in medical research. The conditional gift model could remedy these limitations.

The right to informed consent is often seen as a weak right. It lacks the ‘bite’ to create a significant difference to a researcher’s behaviour because it can often be breached without any repercussions. This is for two central reasons. Firstly, the right to informed consent may not place a researcher under an ongoing duty to ensure the safe custodianship of the material. Thus, the participant lacks the ability to maintain ongoing control.37 Secondly, to make a legal claim upon the basis of a breach of the right to informed consent it requires proving the necessary factual and legal causative link of the breach to the harm suffered. This necessitates that the participant must show that if all the information had been disclosed, the participant would have decided not to participate and thus avoided any harm that eventuates. This hurdle may be difficult for the participant to overcome.38

The need to maintain an ongoing link with the research project could be achieved by rooting the participant’s rights in the possession of the contributed material. Indeed, where the possession of the material is the reason why the

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38 Stapleton, Occam’s razor reveals an orthodox basis for Chester v Afshar L.Q.R. 2006, 122(Jul), 426-448
researcher has to obtain the participants informed consent and protect their privacy.

then it is the material which ought to be the focus of the conditions that govern the requisite rights between the parties. The conditional rights model would acknowledge that this is the case by attaching the conditions to the contributed material. It would thus embellish the need to respect the contributed material rather than focusing on providing general disclosure of possible uses of the contributed material at the start of the research project. Ongoing disclosure can also alleviate inevitable difficulties which arise because of natural benefits and burdens in society which make it difficult to remove all ulterior constraints on informed consent.39

However, others may argue that the conditional gift model could equally be achieved via drafting contractual conditions in a consent form which lead to compensation where they are breached. Yet, adopting a purely contractual approach does not seem to reflect the nature of the relationship that arises in the context of medical research. Contracts tend to suggest a need to enter binding agreements because the parties are not willing to rely upon the pre-existing relationship of the contractee as a substitute for ‘consideration.’ Consideration exists where ‘the promisor [has] obtained a benefit in consequence of making the promise’40 or ‘the

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39 This issue touches on a number of problems. The fact that participants are simply unable to not appreciate all the risks because of limitations in human reasoning capacity, see for example evident in Wisstub and Verden Jones, Biomedical Experimentation involving elderly subjects 1998 Health Law Canada which indicates that 20-40% of persons possessing decisional capacity do not understand one or more important aspect of the research. Finally, it has been pointed out that the different position of the participant vis-a-vis the researcher make it difficult for the researcher to appreciate the context in which the participant makes her decision, see for example Dodds, S., 2000, “Choice and Control in Feminist Bioethics,” in Relational Autonomy: Feminist Perspectives on Autonomy, Agency, and the Social Self, C. Mackenzie and N. Stoljar, eds., New York: Oxford University Press.

40 “[c]onsideration means something which is of value in the eye of the law, moving from the plaintiff: it may be some benefit to the [defendant] or some detriment to the [plaintiff]”(Thomas v. Thomas
promisee [has] suffered a detriment on the basis of (or in reliance on) the promise.’

Within the context of a contract requiring a physical transfer of an item, it is the transferor’s benefit or burden on the recipient which provides the justification for keeping the promise. This is because ‘it gives the party seeking to enforce the promise a compelling justification because he or she has given some enforceable agreed exchange for that promise.’ In addition ‘at the remedial end, [considerations] provides the basis for determining the extent of liability on the promise.’ Yet, when a conditional gift is made there may be no consideration. The implication of a party to a transfer deciding not to require consideration is that they assume that they do not need to have a justification or remedial calculator to effectively enforce the promise.

In the context of medical research there is often no consideration because the participant (promisor) may receive no benefit and the recipient (promisee) may in fact gain, rather than lose, as a result of taking possession of the contributed material. Thus, the nature of the relationship creates an expectation that there is no need to take gain considerable because there is a sense of expectation, faith and confidence that the recipient will respect the express and implied conditions. The sense of trust may arise due to the professional position of the recipient which creates an expectation that they will appreciate and abide by the gift. For example, a doctor may receive a piece of property from a patient in the expectation that this

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(1842), 2 Q.B. 851 at 859, 114 E.R. 330 at 333, per Patteson J); similarly, "valuable consideration in the sense of the law may consist either in some right, interest, profit or benefit accruing to one party, or some forbearance, detriment, loss or responsibility given, suffered or undertaken by the other"(Currie v. Misa (1875), L.R. 10 Exch. 153 at 162, per Lush J.)

41 Chen-Wishart, "Consideration, practical benefit and the Emperor's new clothes"; Chapter 5 in Good Faith and Fault in Contract Law ed. Beatson & Friedmann page 14
land will be used to construct a hospital. By using the conditional gift model it can reflect the good faith and trust the participant places in the researcher. Therefore, although a contract could possibly be used to frame the relationship between a researcher and participant, it would be less reflectively of the special relationship that arises between a researcher and a participant.

On the other hand, it could be argued that participants have been too willing to rely upon researchers acting with good faith. There may be a need to adopt a more powerful contractual approach to bind researchers and require compensation for failing to respect the participant’s fundamental right. Yet, the conditional gift model also addresses this issue as well. The benefit of the conditional gift is that it does so without adopting a full contractual approach which researchers may be reluctant to accept and participants may find distasteful.

It is the conditions attached to the gift which achieve the similar effect to a contract without the need to adopt a full contractual approach. This intermediary position between a contract and a gift may address the need to give participant’s greater control of their contributed material and also respect the general belief in a public health care system that ultimately medical research ought to be built upon an altruistic donation.

A further benefit of the conditional gift model is the fatal result of the conditions failing enhances the participant’s control in the contributed material. This need for control is necessary given that, as Trudo Lemmens points out, there is deep underlying culture amongst medical researchers of participants being seen as

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42 Osstenhoff, Chambers, Smith, McInnes, Osstenhoff on Trusts page 1022
mere commodities. In addition, the apathy of researchers needs to be replaced with a ‘culture of conscience.’\textsuperscript{43} Indeed, there may a denial amongst medical researchers that a problem even exists. For example, the Editor of the British Medical Journal recently noted with despair the response of medical professionals to articles published in the journal criticising ghost writers. The Editor concluded that the responses expressed the view that the BMJ should just ‘grow up and recognise that everybody has conflicts and agendas.’\textsuperscript{44} The concept of conditional rights signified in the conditional gift model may send the symbolic and symbiotic message that participants are not mere commodities. Moreover, the wider loss of good faith to the reputation of medical community if rights are undermined will cause wider damage by making participants less willing to consent to medical research in the future.\textsuperscript{45}

Finally, it is difficult to dispute that where the possession of the material is the very reason for the duty owed to the contributor of the material; then surely the rights and duties logically \textit{ought} to be delineated upon the basis of the possession of the material instead of a right to provide informed consent to participant or a privacy right. Indeed, the conditional contribution model would provide a way to more reflective visualise the requisite rights and duties of the parties and allow legal

\textsuperscript{44} \textit{What’s your price}, BMJ 2003;327 (9 August)
\textsuperscript{45} GT Laurie and JK Mason, ‘Consent or Property? Dealing with the Body and its Parts in the Shadow of Bristol and Alder Hey’ (2001) 64 Modern Law Review 710; K Liddell and A Hall ‘Beyond Bristol and Alder Hey: The Future Regulation of Human Tissue’ (2005) 13 Medical Law Review 170–223; Clive Seale et al., "Effect of media portrayals of removal of children’s tissue on UK tumour bank" (2005) 331 BMJ: British Medical Journal. A practical example of the lack of trust is evident in Havasupai Tribe v. Ariz. Bd. of Regents 204 P.3d 1063 (Ariz. Ct. App. 2008) 220 Ariz. 214, *; 2008 Ariz. App. LEXIS 180, ***; 544 Ariz. Adv. Rep. 10. The participants from an indigenous native American tribe believed that their contributed material would be used for diabetes research to help the tribe. They were not informed of the fact their tissue would be used for research into schizophrenia. In response to the research project, the indigenous community has now successfully sought a land injunction to prevent individuals who are not members of the tribe entering the tribe’s property.
decision makers, participants and researchers to appreciate, apply and interpret the respective rights in the transferred item. This visualisation may more openly acknowledge the reality that there is a physical transfer of a sample; there is something more than just an invasion of the participant’s body because there is an actual transfer and ongoing possession of an element of the body which necessitates a unique and inspirational approach.

Therefore, it is submitted that the concept of a conditional gift may more reflectively emphasise the expectation, good faith and reliance that the participant has placed on the researcher to comply with the express or implied conditions. By emphasising the expectation that the contributed material is a ‘gift’ and thus requires that it ought to be cherished, treasured and respected it may help to ensure that participants in medical research are not seen as mere commodities; rather their contributed material is a gift which deserves respect. Furthermore, that the gift-bearer has tied powerful conditions to the gift will give the participant authority to enforce their conditional rights when the conditions are breached.

It may be possible to achieve this indirectly via the right to informed consent, privacy rights or a contract. However, the conditional gift may more naturally and truly reflects the nature of the relationship that arises in medical research concerning the transfer of contributed material. In addition, the final section will show how the concept of conditional rights based upon the assumptions

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of Research Ethic Boards (REB), could be used to reflect the concerns held by researchers that participants ought not to be given too much authority and ensure that medical research can continue for the wider public benefit.
2. Persistent rights

A distinct attribute of rights held over an item of property is that the conditions tied to the item can bind subsequent recipients irrespectively of their subjective or objective knowledge of the conditions. However, there is limited authority on whether a conditional gift will bind third parties because the case-law has quite simply not ever considered this issue. If the issue does arise, it is likely that judges would consider the common law guidance concerning analogous rights held in immovable or movable property. The following section will consider the protection of analogous rights.

The general approach of Canadian Law is a move towards the Torrens system. This approach ensures that once an interest is legally registered, the holder of the interest has an indefeasible title guaranteed by the Government (through the Land Registry). Additional attempts to limit the application of the rule of nemo dat quod non habet have been achieved through the incorporation of electronic conveying in a number of Canadian provinces. The result of registering an interest in an item is that third party recipients will be automatically bound by

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48 Law Reform Commission of Saskatchewan Final Report on Private Title Insurance online: http://sklr.sasktelwebhosting.com/TitleI.pdf at page 10-15 which provides an overview of the Canadian Land Registration system
49 The Manitoba Act; The Land Titles Act, 2000, S.S. 2000, c. L-5.1 [Saskatchewan Act]; Land Titles Act, R.S.A. 2000, c. L-4 [Alberta Act]; Land Title Act, R.S.B.C. 1996, c. 250 [B.C. Act];
the interest attached to the item and thus will be liable for failing to check the Register to ascertain whether another individual had an interest in the item.  

Yet, to prevent injustice, when a third party receives property which is subject to an unregistered interest, the holder of the interest will have three remedies. Firstly, the holder of the right can apply to the Land Registry Office or the Office of the Director of Titles to correct the Registry. The second remedy the holder of the interest has is a direct right against any recipient who receives the item when the holder of the interest did not intend that this recipient should have received the item. Due to the fact that the item was in-consensually transferred, the holder of the interest can reclaim the item from the recipient and claim compensation where they suffer loss as a result of the individual interfering with their interest in the item. This is achieved by allowing the participant to raise a rebuttable presumption that their interest will defeat the interests of third party recipients. This will make it unnecessary for the holder of the interest to satisfy on the balance of probabilities that the recipient knew or ought to have known about their interest. Rather the precise reason for the claimant’s right is their absence of consent to transfer the item to the defendant. The absence of consent provides the justification for a claim to return the item in the English and Canadian law. It is

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51 Ontario land Registry Certification of Title under the Land Registration Act at page 20 Guides online: http://www.ontario.ca/en/information_bundle/land_registration-guides/index.htm

52 Citadel General Assurance Co v Lloyds Bank Canada [1997] 3 SCR 805

53 Lambton Lumber Ltd. v. Claran Homes Ltd., [1979] O.J. No. 4124, 23 O.R. (2d) 673 (Ont. C.A.). Foskett v McKeown (2004) If the claim is based upon restitution then the court will maintain a discretion whether to award proprietary restitution, however if the claim is based upon propriety rights then the propriety remedy should automatically be allowed because of the pre-existing rights in the transferred item.

54 The first restitution decision in Kelly v Solari for money had and received was analysed upon this
unclear whether the claim is based upon propriety restitution or is simply based upon the individual holding a proprietary interest in the item (a *vindicatio*). Irrespectively of which approach is doctrinally correct, either accepts that the holder of the interest has a persistent interest which can bind subsequent recipients irrespective of their knowledge.

Where the individual cannot claim against the recipient, the final remedy that the holder of the interest has is to claim an indemnity for any loss that arises due to an error with the Registry. The individual will have to apply to the Land Registry Office or the Office of the Director of Titles to claim compensation by applying to have an oral or written Tribunal Hearing. The Hearing will consider whether the holder of the interest can claim compensation for any loss or harm.

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55 *Ibid* (*)LCBO*(1995), 24 O.R. (3d) 403, 126 D.L.R. (4th) 301 (C.A.), The founding restitution case in Canada, *Clark v Eckroyd* also focused on the plaintiff’s fault and not the defendant’s negligence. *Clark v. Eckroyd*, [1886] O.J. No. 11 [26] ‘it was negligence in relation to the plaintiffs’ own business, negligence in relation to something which would have been prudent, in respect to the plaintiffs themselves, but not of any duty they owed to the defendant’.


56 GHL Fridman ‘*Unjust Enrichment (Dis)Contented*’ Chap.3 in J W Nayers, M Mclnnes, S Pitel, Understanding Unjust Enrichment (2009) (1st Ed) p44: the current position of the Canadian Law governing the right to restitution is unclear. It may adopt a case-by-case incremental approach or a ‘resort to general notions of morality and policy that seem so popular with the Canadian courts.’ J W Nayers, ‘Introduction’ in J W Nayers, M Mclnnes, S Pitel, Understanding Unjust Enrichment; Burrows, The English law: a ten year review in J W Nayers, M Mclnnes, S Pitel, Understanding Unjust Enrichment at p22; and Lord Hoffman [1948] Ch 464, ‘This [claim] is not based upon unjust enrichment except in the most trivial sense of that expression. It is a *...vindication of a property right*."

suffered as a result of their interest not being registered and the recipients thus
being unaware of their interest in the item. The remedies available to the
individual can also be assigned to successors-in-title after the holder of the interest
has died.

Similar rules exist in regard to personal property. Federal legislation
allows security agreements to be made over personal property which will bind
recipients of the securitised item. Provincial Personal Property Security Acts also
state that once a security agreement is registered it will encumber the personal
property. Thus, both personal and real propriety interests can bind recipients
irrespectively of their knowledge. This distinguishes interests which are propriety
in nature from rights which are personal in nature; as Rodger Smith observes
‘proprietary transactions are exceptional in that they operate outside the normal
concepts of privity of contract.’

2.1. Structuring persistent rights to reflect the context of medical research
The ability of rights held in transferred items to persistently bind the recipients
could be used to bind recipients of contributed material provided for the purpose of
medical research. This could be introduced by make it compulsory for Researchers
to register all research projects on a central database in a similar way to the
registration of interests on the Land Registry system. A ‘Research Register’ could act

58 Online:
http://www.ontario.ca/en/information_bundle/land_registration/content/STEL02_165707?openNa
v=land_titles_assurance_fund_%28ltaf%29
59 Doodeward v. Spence (1908) 6 C.L.R. 406, (High Court of Australia). The result of the majority
decision was to recognise that the successor in title to the preserved remains of a still-born child had
a proprietary claim for its return from another who had taken it.
60 s 427 Bank Act (CAN) S.C. 1991, c. 46
61 (ON) Personal Property Security Act, R.S.O. 1990, c. P.10 and H. R. McLaren, Secured Transactions in
Personal Property in Canada, 2nd ed. (Toronto: Carswell, 1989), Vol. 1 at 5-93.
as way for participants and researchers to register and ascertain whether there are any conditions attached to the use or disclosure of contributed material. The Register could state whether any conditions are attached to the use of contributed material. Thus, subsequent recipients could simply ascertain the researcher from whom the contributed material came from and assess whether there are any conditions attached to the use of the material. Similarly, participants could ascertain the uses of their contributed material and ensure that any conditions attached to its use are being respected.

Where an interest is unregistered, the participant could be given a number of remedies delineated upon the basis of the remedies offered to holders of interests in property. The first remedy is a right to correct the Register by applying to the Research Registry. The second remedy could arise where a contributor to medical research discovers that their contributed material has been conveyed to a third party recipient inconsistently with any conditions attached to its use. 63 The holder of the interest in the contributed material could be offered the opportunity to withdraw. In addition, where the holder of the interest suffers harm as a result of an in-consensual transfer they ought to be able to claim compensation from the recipient. 64

To ensure that compensation is available from the recipient, it may also be beneficial to use the French model that governs biomedical research. Biomedical researchers in France ‘assume compensation for damage arising from biomedical research to the person who is suitable and that of his dependents, unless evidence

63 Supra at page 2
64 Infra page.2164 for suggestions concerning the conditions that ought to be attached.
to bear the damage is not due to his fault or that of any stakeholder. To ensure researchers can provide compensation, they are required to enter into a compulsory insurance scheme to cover costs for any damage as a result of an accident due to biomedical research.

Where the holder of the interest in the contributed material cannot claim compensation from a researcher who receives the contributed material, the final remedy contributors could resort to is compensation from a central fund administered by the government; this could be implemented upon a similar basis to the Land Title Assurance Fund and enforced by Tribunals who consider applications of participants.

France may once again provide an example of how this could be implemented in practice. This is because the French system allows compensation for harm due to the use of biomedical material from the National Office for Compensation for Medical disorders and iatrogenic nosocomial infections (Office National D’indemnisation des medicaux office) in cases of silence or explicit rejection of the insurer to make an offer. A similar approach to the French model based upon the Land Registry system could be adopted in Canada. This may be beneficial given that the French system is based upon no-fault liability which may be difficult to simply transfer into Canada. For example, a Research Ethics Board Oversight Body could be established and provide an indemnification for harm due to in-consensual

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65 Public Health Code Article L-1121
66 Public Health Code Articles L1243-3-1243-6
67 Public Health Code Articles L-1121 L1142-22 and L1243
use of contributed material.\textsuperscript{68}

There are three central benefits of utilising the Land Registration model to reform medical research. Firstly, it would provide a central resource to track medical research projects and allow participants to gain control over their contributed which they are currently lacking.\textsuperscript{69} Yet, it would also acknowledge concerns researchers may have that ‘research could not practicably be carried out’\textsuperscript{70} if there was greater disclosure about the research to participants. This is because researchers can simply provide the information provided to the REB who authorises the project\textsuperscript{71} to the Register who will place the information on a central system.

Thus, the Research Registry could provide an easy way for researchers to provide further information about a project without being impracticable. Therefore, the Register system could holistically reform medical research by giving individuals the power to track the use of their contributed material but also acknowledge the need not to overly restrict research.

\textsuperscript{68} Public Health Code Articles L1243-3-1243-6See introduction to website available at http://www.oniam.fr/dispositif.php 'You or someone you feel you have suffered a medical accident, a disease or iatrogenic nosocomial infection serious occurred on or after September 5, 2001 and wish to obtain compensation for damage resulting from the medical accident. This compensation can be paid either by the insurer of the health professional at fault in an accident, either by accident ONIAM than misconduct or nosocomial infection. To obtain this compensation, you can contact Regional Commission for conciliation and compensation place of production of a medical procedure involved removing a form application with the commission. The procedure is free and you can get compensation in less than a year.'


\textsuperscript{70} Art 2.1(iv) allows the waive or alteration of the requirements of informed consent where it would be impracticable and cert. 1 http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/revised-revisee/Default/

\textsuperscript{71} REBs have to authorise most research projects: see Hadskis, The Regulation of Human Biomedical Research in Canada in Downie, Caulfield and Flood, Canadian Health Law and Policy (2007) 3rd Ed. Lexis Nexis Butterworth’s (Canada) at page 262
The second benefit of the Registry is that it gives participants and researchers clear proof of rights in an item. Indeed, registration would serve to make visible rights which exist on the basis of legal constructions which are invisible in reality. For example, a right of way may exist, although it may not be evident when looking at the land; because the written verification is an imperative step for embellishing and maintaining the existence of the interest.

The final benefit of the Registration model is that it would serve a cautionary effect; this is because the process of registering the right would force the parties to fully contemplate the fact that they are entering into a binding agreement. It also serves as explicit consent for a Researcher as a conditional donee of the contributed material.\footnote{Birks, \textit{Fives Keys to Land law} in Land Law, Themes and Perspective, S Bright and J Dewar (Ed) Oxford University Press (1998) p483}

Thus, the introduction of a Research Registry would act to emphasize the participant’s interest in the material; indeed given that the scheme would be compulsory researchers it will ensure that all researchers are aware that they ought to check the Register when they receive contributed material from another researcher. Moreover, the model would allow researchers and participants to appreciate the binding agreement they are entering into; although a donation to medical research appears to be a gift, the recipients need to be aware that it is a conditional gift. Thus it is not freely given but is subject to binding conditions.

It may also be beneficial to utilise the ability of interests held in an item to bind recipients of the property for longitudinal periods to structure reform of medical research. This is because the longitudinal nature of propriety rights may be helpful
when considering the interests of relatives to the participant when the contributor dies. There are common law and human rights cases which suggest that relatives of individuals maintain a right in the individual bodily substances and body parts when that individual dies. The conditional gift could acknowledge the interest of relatives by offering relatives a right to withdraw when a contributor registers the fact that they wish to allow a family member to withdraw the material after they have died. Given the extent to which new research uses genetic material which reveals considerable information about family members, this approach may be beneficial because it offer relative a right to withdraw from a research project which they may not wish to have a link to.

2.2. The current difficulty that persistent rights could address
The following section will outline how the persistent nature of propriety rights could address the difficulties with current legal protections utilised to protect participants in medical research.

2.2.1. REB’s can adequately protect the concerns of participants

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74 Research involving genetic information also poses potential risks to family members of research subjects. "In the context of many forms of genetic information, this potential for harm arises not only for the individuals who have provided the information, but also for the blood relatives of such persons. This is because of the essential nature of most genetic conditions; they are passed from one generation to the next." Graeme Laurie "Genetic Databases: Assessing the Benefits and the Impact on Human and Patient Rights -- a WHO report" (2004)
The first difficulty with medical research that could be addressed through the Registration system is reform of the governance Research Ethics Boards (REBs). A central reason why REBs require reform is because most national policy statements allow a REB to ‘approve a consent procedure that does not include, or alters some of the elements of informed consent’ provided that certain requirements are met. One of these requirements is that ‘the research involves no more than a minimal risk to the research subjects’ and ‘the research is unlikely to adversely affect the rights and welfare of the subjects.’ The difficulty with relying upon REBs to ascertain whether there is a minimal risk arises because it is questionable whether a REB can sufficiently appreciate the risks posed to research subjects in innovative research projects. The new projects make it unlikely that researchers are able to inform REBs of all the uses of a participant's contributed material at the start of the project. Given that all the uses of the material are unforeseeable at the start of the project, the REB is quite simply unable to appreciate whether a minimal risk is posed.

However, it could be argued that REBs can track research projects and ‘wherever possible and appropriate’ ensure that ‘the subjects will be provided with

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75 Article 2 TCPS, USA HIPAA Authorisation: Privacy rule 45 CFR 164.512(i)(2)(ii) IRB or Privacy Board to authorize waive. The FDA regulations also allow a waive of the requirements of informed consent in certain circumstances. Art.5 of the UK Medical Research Council, Guidelines for good clinical practice in clinical trials, March 1998
76 TCPS, Supra, Art 2.1(c)(i)-(iii)
77 TCPS, Context at section G General Principles in practice, Art.1.13 Ongoing Review and Art 2.1(c)(i)-(v) Minimal risk
78 TCPS Art.1.5, 2.4 and supporting Commentary
79 See for example OHS which provides only general information about the uses of the contributed material: OHS Information Booklet at fn.2
additional pertinent information.’ In addition, REBs can ensure that participants re-consent to certain uses of their contributed material where a potential risk is foreseeable. Arguably these safeguards are sufficient to protect participants in REB approved project. However, there is considerable evidence to show that the heavy workloads of REBs has resulted in a failure by many Boards to track and control research projects. By utilising the persistent nature of interests held in an item it can allow participants to actively ascertain who has received their material and enforce any conditions attached to its use as opposed to relying upon REBs to appreciate the possible risks to each participant. Participants could thus fill the gap currently left by REBs.

2.2.2. Holistic reform of privacy statutes

The persistent nature of interests held in items could also remedy limitations with using privacy legislation to protect participants in medical research. The difficulty with relying upon privacy statutes is that privacy statutes often leave gaps in the legal protection offered to participants. In addition, there are often wide exceptions to the protections that are offered which will often provide a defence to a claim against a defendant for breaching a participant’s right to privacy. To highlight the difficulty with relying upon privacy statutes to protect participants, the following section will consider the lacunas in the Ontario Personal Health Information Privacy Act (PHIPA).

80 TCPS, Supra, Art 2.1(c)(iii)
82 PHIPA 2004 SO 2004 c3 Sch A S3
Firstly, a major lacuna in PHIPA is that ‘personal health information’ received by directly from a participant to a researcher, and not indirectly via a health information custodian, will not bind the recipient of the information. This is because the definition of a ‘health information custodian’ under the legislation does not include research institutions but is limited to mainly health care providers. Thus, the researcher will not be subject to the rules in the statute concerning the use of contributed material for medical research.

A second lacuna that exists in PHIPA is that currently neither health information custodians nor REBs are under a duty to require the re-consent of the contributor of personal health information when it is transferred to a researcher. The result is that there is a risk that the contributor’s right to informed consent will be breached because of the in-consensual use of the contributed material. Moreover, the contributor may have no remedy for the breach of their informed consent where a researcher has not been required or by the health

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83 PHIPA, Ibid. S4(2)(a)-(g) Similar definition to PIPEDA SC 2000 c5 including s4(2)(e) Donated materials as well as general information concerning health, and matters related to the health, of the providers of information.
84 PHIPA, Ibid, S44
85 PHIPA, Ibid, S3(1)-(12)
86 PHIPA, Ibid s44(5) ‘Before a health information custodian discloses personal health information to a researcher under subsection (1), the researcher shall enter into an agreement with the custodian in which the researcher agrees to comply with the conditions and restrictions, if any, that the custodian imposes relating to the use, security, disclosure, return or disposal of the information.’ Thus, the custodian only has to specify conditions concerning the disclosure of the personal health information and no conditions have to be attached concerning the consent of the participant, rather the legislation specifies that the custodian has to attach conditions concerning ‘use, security, disclosure, return or disposal of the information’ but does not mention informed consent and/or re-contacting the individual.
87 PHIPA Ibid s44(3)(d) and s44(6); a researcher who receives personal health information about an individual from a health information custodian under ‘shall, (a) comply with the conditions, if any, specified by the research ethics board in respect of the research plan’ The REB is required to consider ‘whether obtaining the consent of the individuals whose personal health information is being disclosed would be impractical’. However, the REB is under no duty to ensure conditions concerning consent are included to the research project and no mention is made of the conditions which a provider of the information may have attached to it under s19.
information custodian or REB under s44 to obtain the re-consent of the participant; this is because the researcher is likely to be able to rely upon the approval of the custodian or an REB as an estoppel to a claim for breaching the contributor’s right to informed consent.

The further lacuna in PHIPA is that a custodian can seemingly easily dispense with any conditions attached to the contributed material by relying upon a collective practice of the medical community under the ‘conditional consent’ section.88 This seemingly wide exception may extend to using administrative and economic burdens as a justification not to re-obtain the consent of the individual. Clearly, the right to informed consent is too precious to limit simply upon the basis of administrative concerns.89 Given the lacunas in PHIPA, it is unsurprising that Felthusen and Linden have concluded that the ‘legislative protection of privacy interests have not significantly advanced this area of the law.’90

The Registry system would quickly and efficiently limit the risks posed by the lacunas in PHIPA. The first lacuna to PHIPA would be remedied because participants would have a directly enforceable right against recipients of contributed material; thus, the participant could enforce the conditions attached to the contributed material irrespectively of whether the recipient received the contributed material from a health information custodian. Similarly, the participant could rely upon

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88 S19(2) PHIPA; this section allows a condition to be declared ineffective where it prohibits or restricts the recording of information ‘required by law or by established standards of professional practice or institutional practice.’

89 Caulfield, Timothy, Biobanks and Blanket Consent: The Proper Place of the Public Good and Public Perception Rationales, Source: King’s Law Journal, Volume 18, Number 2, 2007, pp. 209-226(18) (Hart Publishing)

90 A Linden, B Feldthusen, HTO 18 Intentional Torts, Privacy “Privacy” in Halsbury’s Law of Canada (2009) Supra. fn.2
interest in the material to claim an indemnity from a Fund administered by a Body within the Research Registry where they are harmed through the in-consensual use of information contributed to medical research.

The second and third lacuna to PHIPA could be also be remedied through the suggested reform because the Registry would limit the risk of harm arising due to researchers not re-obtaining the consent of participants for subsequent uses of material. This is because researchers would be under a duty to register all research projects and participants could ascertain the uses of their material via the Registry. This would allow participants to ascertain whether the use of their contributed material is occurring consistently their informed consent and with the conditions attached to the material. Thus, it would reduce the risk of a breach of the right to informed consent. In addition, the transferor of the material may be able to claim an indemnity when their right to informed consent is breached due to a REB altering the requirements of informed consent.\[^{91}\] This will be considered further when outlining the conditions that ought to be attached to the conditional gift.

However, a counter-argument that could be levelled at using the Registry model to achieve a persistent interest is that current statutory privacy laws could be reformed to provide participants with a persistent privacy right without any need to accept that a contributor has a propriety interest in a contributed material item. For example, the first lacuna could be remedied by expanding the definition of health information custodian to include researchers. The result would be that researchers would then be under a duty to enter into agreements with any subsequent

\[^{91}\] *Infra*, conditions attached to the gift outlined at page 2
researchers to ensure that researchers that receive contributed material adhere to conditions attached by the health information custodian.

The second and third lacuna to PHIPA could also be reformed by requiring researchers to provide all information about research projects to a central registry. In addition, s49 of PHIPA could be extended to require that recipients of transferred material from a researcher would be bound by the holder’s interest in the material. Furthermore, all researchers could be required to obtain compulsory insurance for harm due to the in-consensual use of material and the Privacy Commissioner could offer compensation where the insurance scheme fails to provide a remedy. Therefore, arguably all the benefits of the Land Registry system through reform of privacy laws without taking the additional steps of accepting that the contributor had a propriety interest in the material.

However, to be conceptually, doctrinally and legally correct it would be necessary for the contributor of the material to show some kind of link between the transferor and the recipient of the contributed material to act as a basis for a claim. Thus, for s49 to apply it would be necessary for a provider of personal health information to show a link between them and the recipient. Otherwise, it would be illogical to assert that a participant has a directly enforceable right because conceptually they have nothing to rely upon to link themselves to the recipient. Nonetheless, it could be argued that the contributor could rely upon agreements entered into by health information custodians on their behalf. Yet, the difficulty with this approach is that the extent to which the participant can claim against a

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92 S49 PHIPA Supra
recipient will be dependent upon the existence of agreements and sub-agreements. Moreover, there would only be an indirect claim against third party researchers that receive contributed material and there may be no directly enforceable claim against recipients.

Thus, instead of attempting to gap-fill through technical statutes as a basis for a claim surely the best way to protect participants is to base their interest upon a binding propriety interest held in the item. This would provide a simple, logical, clear and efficient mechanism to link the contributor and the recipient. Moreover, the Land Registry already provides a clear framework that could be used for future reform therefore surely this would be the best place to start. Given, that the Land Registry model already exists as a basis for reform, it would seem commonsensical to utilise it as the basis for a central registration and indemnity system.

Nonetheless, s49 suggests that providers of personal health information could simply rely upon the statutory provision to enforce a claim. Yet, the section also states that the right to privacy is ‘subject to the exceptions and additional requirements.’ This provision could be relied upon by a researcher to claim that the consent of a REB or custodian is an estoppel to a claim.

This conclusion is supported by the case-law concerning Canadian privacy statutes suggests that the right to privacy is limited to the extent that it is ‘reasonable in the circumstances’ and it may also be limited by ‘the lawful interests of others.’ Thus, the inadvertent showing of a topless photo and the publication

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of a list that identifies a person as a carrier of a communicable disease by an internal hospital have been held to not breach a provincial statutory privacy right.\textsuperscript{95} These decisions suggest that participants in medical research could only rely upon a statutory privacy right in limited circumstances. The main reason for this is because the possessor of the right will have to show that the right to privacy has been breached\textsuperscript{96} and that the public interest in using the contributed material does not outweigh the potential harm.\textsuperscript{97} A propriety model would ensure that the participant could rely upon their interest in the material without taking the additional steps of proving that the right to privacy has been breached. In addition, the third section of this essay; will show that the conditional gift model could be utilised to limit the extent to which legal decision-makers rely upon the public interest to defeat an individual's fundamental rights over the contributed material.

2.2.3. Remedy the limitations with Common Law and Charter Privacy rights

The previous section revealed that relying upon a statutory mechanism to enforce an interest held in contributed material can be conceptually and practically difficult. On the other hand, it could be argued that the participant can maintain a link to the recipients of their contributed material by relying upon a right to privacy or personality protected by the common law\textsuperscript{98} or the \textit{Canadian Charter of Rights and
Freedoms. S7 of the Charter requires contributed material is only used in accordance with the right to life, liberty and security of the person and s8 protects contributed material from 'unreasonable search and seizure.' Thus, the common law and Charter right to privacy could be relied upon to protect participants where the statutory protection fails.

However, there are similar limitations with relying upon common law or Charter privacy rights to protect participants. These limitations suggest that achieving a persistent interest in contributed material could be more effectively achieved through utilising the propriety model.

The main difficulty with the common law right to privacy is that the Anglo-Canadian courts have been reluctant to recognize a separate common law right to privacy. In Ontario, although a number of lower court authorities suggest that a participant and the research. In addition, the Ontario Court of Appeal has recognised the tort of 'appropriation of one's personality.' This has lead to the recognition that a photographer owes a duty to individuals in the photo to not publish the photo to advertise products without the individual's consent. This has been relied upon in a number of Ontario cases inter alia Krouse v. Chrysler Canada Ltd, [1973] O.J. No. 2157, (1973), 1 O.R. (2d) 225 (Ont. C.A.), revg [1971] O.J. No. 1884, [1972] 2 O.R. 133 (Ont. H.C.J.); Athans v. Canadian Adventure Camps Ltd, [1977] O.J. No. 2417, 4 C.C.L.T. 20 (Ont. H.C.J.) (Per Henry J.)


Canadian AIDS Society v. Ontario, [1996] O.J. No. 4184, 31 O.R. (3d) 798 (Ont. C.A.), leave to appeal to S.C.C. denied (1997), 216 N.R. 159n. Within the civil context, s7 and s8 ensured that the use of medical records ought to be limited even when this may serve a wider public interest.


right to privacy does exist,\textsuperscript{103} there is limited authority from the appellate courts on the right and its scope and contents is unclear.\textsuperscript{104} Thus, the right to privacy is a malleable and unclear right which may be less apt at protecting an individual's right to protect their contributed material than a right directly held over the contributed material.

Moreover, it also seems that the right to privacy in the civil context can easily be defeated when there is a countervailing public interest consideration.\textsuperscript{105} Thus, the case-law suggests that the public interest will only be held to not require the restriction of the right where the disclosure of information causes considerable psychological stress and stigma to the individual \textit{and} the individual has been assured that such information could not be disclosed.\textsuperscript{106} The right to personality has also been limited in favour of the wider public interest. For example, in \textit{Gould Estate v. Stoddart Publishing Co}, the Ontario Court of Appeal suggested that a famous musician could not claim control of photos of him upon the basis of the right


\textsuperscript{105} \textit{Canadian AIDS Society v. Ontario} \textit{Ibid.} fn. 97

\textsuperscript{106} \textit{Canadian AIDS Society v. Ontario} \textit{Ibid.} fn. 97
personality because of the ‘public interest in knowing more about one of Canada’s musical geniuses.’\textsuperscript{107}

Nor has the \textit{Charter} right to privacy significantly advanced the Law in this area. The gradual acceptance into English Law of the right to privacy has been driven by the incorporation of the European Convention of Human Rights through the Human Rights Act which does provide a direct right to Privacy.\textsuperscript{108} Yet, in the Canadian \textit{Charter}\textsuperscript{109} there is no direct right to privacy. Rather, the \textit{Charter} only indirectly protects the right through s7 and s8. This may make it difficult for a participant in medical research to prove that a government organisation has breached one of her \textit{Charter} rights.\textsuperscript{110}

Even when a plaintiff has established a violation of her \textit{Charter} rights, the onus then shifts to the government to justify those limits pursuant to section 1.\textsuperscript{111} In assessing whether the government has discharged this burden, courts employ the test set out by the Supreme Court of Canada in \textit{R. v. Oakes}.\textsuperscript{112} In many cases, courts have exhibited a high degree of deference to governmental decisions, requiring little justification for a rights violation.\textsuperscript{113} This approach is likely to be adopted in medical

\begin{thebibliography}{99}
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\item 108 \textit{Human Rights Act} (1998) incorporating European Convention of Human Rights (Sch.1) UK
\item 109 Excluding Quebec, see Article 1053 of the \textit{Civil Code} (now Article 1457)
\item 111 Under section 1 of the \textit{Charter}, the protected rights and freedoms may be subject to such reasonable limits prescribed by law which can be demonstrably justified in a free and democratic society.
\item 112 [1986] 1 S.C.R. 103 [\textit{Oakes}]. Under this test, courts ask whether the objective is pressing and substantial, whether there is a rational connection between this objective and the legislation, whether the means chosen to achieve this objective minimally impair the right in question, and finally whether there is proportionality between the limits on the right and the objective.
\item 113 Colin Feasby, “Constitutional Questions About Canada’s New Political Finance Regime” (2007) 45 Osgoode Hall L. J. 513 at 541 Feasby condemns the “overly deferential approach favoured by the
\end{thebibliography}
research because of the ubiquitous concern of undermining the public benefit of medical research completed by public institutions. Furthermore, much of the Charter case-law, particularly the case-law concerning the use of bodily samples, has been applied within the criminal context when the individual’s right to freedom from imprisonment is at stake. Within the context of medical research, where only the contributed material is used for the purpose of medical research (rather than to conduct a criminal investigation) courts may be far less willing to hold that the individual’s right to freedom outweighs the wider public interest in a research project.

In sum, the right to privacy based upon the common law and the Charter is questionable in its scope and may be limited by countervailing rights of other and the public interest. Using the conditional gift model would serve to remedy the pitfalls that previous privacy legislation and common law and Charter rights has suffered from. It would clearly emphasise to researchers and legal decision makers that the participant has a persistent right which ought to bind third parties. By making it clear the participant’s right arises from their interest in the contributed material it would make it clear that considerable harm to the personality or privacy is not required before the right can be enforced. Instead, the participant’s rights are simply dependent upon the possession of the contributed material. Section three will also consider how the public interest in medical research could be recognised and considered through the conditional gift model.

2.2.4. Should participants be able to claim a persistent interest?

Before proceeding to consider the conditions that ought to be attached to the conditional gift is it necessary to respond to claims that providing participants with persistent rights would give them too much control. Moreover, that researchers ought to only be accountable for harm based upon the reasonable person and should not be under a duty to consider the unique position of each participant. Thus, arguably, there is simply no need to provide ongoing disclosure of the uses of contributed material and/or provide compensation or indemnification for harm caused by failing to ensure adequate disclosure.

However, common law protection of the right to informed consent and the TCPS makes requires researchers to adopt a subject-centred perspective. Thus, researchers are required to provide ‘full and frank disclosure of all information relevant to free and informed consent’ to protect against the ‘potential for physical or psychological harm’ and ensure protection of ‘cultural integrity.’ Similarly, the Nuremberg code requires that the researcher ensures that the participant is ‘situated as to be able to exercise free power of choice’ without ‘ulterior constraint’ and with ‘sufficient knowledge and comprehension of the elements of the subject matter involved as to enable him to make an understanding and enlightened decision.’ Thus, both National and International Human Rights instruments and the Anglo-Canadian common law demonstrate a widespread ethical need to adopt a

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115 TCPS, Supra, D. Context. Subject Centred Perspective page i.7 paras 1-3; Halunshka v. University of Saskatchewan (1965), 53 D.L.R (2d) 436, 52, 52 W.W.R. (Sask. C.A).
116 TCPS, Supra, Art.2.4(a)-(c) and (e
118 Article 5 Council of Europe Convention on Human Rights and Biomedicine, also provides requires free and informed consent necessitating at the very least appropriate information of the risks
subject-centred approach to ensure that informed consent is protected. To ensure that a subject-centred approach is achieved, researchers ought to consider the unique position of the participant and provide the necessary disclosure to allow participants to make an enlightened decision throughout a research project.

Nonetheless, some may argue that contributed material once removed from the participant is separate from their body and therefore the right to control the material is lost. Thus, there is simply no need to ensure ongoing consent to the uses of contributed material. Similarly, that is no need to inform a participant of a minimal risk because it is unlikely to affect their decision as to whether contribute to a research project. Thus, it is not ethically necessary to require fully informed consent when contributed material is removed from the human body and were the risk posed by the Project, as assessed by a REB, is only minimal.

However, it could be argued that it is necessary to protect an individual’s right to autonomy rather than physical integrity and thus encompasses a right to decide the uses of contributed material and to assess the risk no matter how small. Therefore, the right to autonomy in itself requires being fully informed of all risks irrespectively of whether harm may eventuate simply because of a basic right to make all decisions autonomously and freely when it concerns one’s wellbeing. This is evident from the approach of certain jurisdictions which protect the right to be fully informed *simpliciter vis-a-vis* requiring a physical and causal connection. These jurisdictions award a ‘modest solatium’ for the breach of the opaque right.\(^{120}\)

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\(^{119}\) TCPS, *Supra*, Art.2.4(a)-(c) and (e)

Yet, Anglo-Canadian Common Law has not protected this right *simpliciter* and it is unlikely that the Law will change to extend to such protections. Nonetheless, the common law has continually protected the entitlement of a participant to consent medical research no matter how small the *a priori* risk.\(^{121}\) When informed, the participant may decide not to contribute to the project and may this may thus affect the amount of individuals who will be struck down by the risk if it does eventuate. This explains why the Fifth Circuit of the American Courts held that a Drug Manufacturer was required to warn of a one-in-a-million risk that the participant may suffer polio due to a vaccination drug. This was because, ‘the patient is entitled to adequate information so that he can, given his superior knowledge of his situation, balance *the risks and benefits of a given medication himself*...the manufacturer cannot make this choice for its ultimate consumers.’\(^{122}\)

Similarly, a REB ought not to be able to alter or waive the right to informed consent when it considers it to be ethically unnecessary because the participant ought to be able to make this assessment. If this is to occur, alternative safeguards ought to be adopted to ensure that when that risk does arise alternative safeguards are provided.

Furthermore, the fact that there is a link to contributed material is evident from the fact that there is a strict requirement that consent has to be given to allow the use of personal information and blood samples by the police under s8 of the *Charter*. There would be quite simply be not need to require this consent unless one accepts that contributed material does deserve protection *even after* it is removed

\(^{121}\) ‘Even when his or her own life depends on receiving medical treatment, an adult of sound mind is *entitled to refuse* it. This reflects the autonomy of each individual and the right of self determination.’ *St. George’s Healthcare NHS Trust v S* [1999] Fam. 26 at [43] *per* Judge L.J.; *per* Butler-Sloss L.J. the claimant, a pregnant woman, had “a deep-seated aversion to medical intervention”.

\(^{122}\) *Reyes v Wyeth Laboratories*, 498 F.2d 1264 at 1276 (5th Cir. 1974)
from the body. Similarly, the TCPS and common law guidance insists that participants ought to always be given the right to withdraw contributed material from a research project. The fact that the right to withdrawal is accepted as being a fundamental right of research participants shows that the participant must maintain an ongoing link with the contributed material which justifies being able to enforce that right to withdraw. Similarly, Arden LJ has pointed out the right to informed consent is ‘reflected in the right to integrity of person contained in article II.63.2 (a) of the Charter of Fundamental of the European Union.’ The Human Rights Codes explain why the Fruits of the Poisoned Tree doctrine has been continually protected in certain jurisdiction to place a general exclusionary rule on the use of in-consensually obtained evidence, including bodily samples and even sound recordings, being used during the course of criminal proceedings.

A final point is that if we accept the Land Registry ought to exist to provide Persistent rights to owners of interests held in immovable property, and that the Government ought to expend funds to provide this service, then surely, similar protection ought to be offered to individuals over items which are associated with their right to bodily integrity; namely their body parts, substances, biotechnical

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125 TCPS, Supra, Art.2.4(d) The TCPS states that the consent forms ought to include ‘an assurance that prospective subjects are free not to participant, have the right to withdraw at any time without prejudice to pre-existing entitlements, and will be given continuing and meaningful opportunities for deciding whether or not to continue.’
126 White v. Paul Davidson & Taylor [2005] PNLR 15 CA at paras. 41 & 42
127 Silverthorne Lumber Co v US (1920)
material and their personal information attached to that material. At the moment, the legal system suggests that society ought to provide greater protection to landowners vis-a-vis individuals attempting to control their own contributed material. Surely, a just legal system ought to provide equal Persistent rights to both classes of individuals. In addition, failing to acknowledge a Persistent Right underplays the fact that there is an actual transfer and ongoing possession of an element of another individual which may necessitate additional safeguards and protections.

The inevitable conclusion from analysing the Policy codes, International Common Law and National and International Human Rights norms is that participants do maintain an interest in contributed material. This shows that the use of contributed material is worthy of a Persistent Rights triggering duties of disclosure, protection and in some cases compensation, to the person who provided the material. Thus, the preponderance of legal jurisprudence suggests that participants ought to be given a Persistent Right in their contributed material.

Nonetheless, as noted in the Introduction, the TCPS does allow the right to informed consent to use contributed material to be diluted when certain requirements are met. In addition, it may be unfair upon researchers when they expend considerable time and funds on a project for all the participants to withdraw and the funds to be waster. Thus, there is a need to balance the rights of participants and researchers and also acknowledge the wider public benefit in medical research. The final part of the essay will consider how the conditional contribution model, based upon the research being conditional upon the assumption of REBs, could ensure an adequate balancing between the public interest in medical interest and
the, sometimes countervailing, rights or participants and researcher.
3. Aspect of conditional transfer: distributive rights

Rights held in immovable (real property) and movable (personal property) objects can be tailored to reflect the wider context in which the object exists. This is achieved by distributing or sharing the rights held in a single object between different parties and/or to serve different purposes.\textsuperscript{129} For example, the utility of personal property can be shared between many individuals by attaching conditions to a single item. For example, a chattel, such as a computer, could have conditions attached to allow X, a Public Authority, to own the chattel, Y, a Library, to act as the custodian of it, Z, a member of the public, to have a right to use it in accordance with certain rules and A, the police, to have a right to inspect it.

Nonetheless, the common law rules governing a conditional gift also recognise that there are limits on the conditions that can be tied to a gift. In the context of medical research, a likely reason to void a condition is upon the basis of public policy of undermining invaluable medical research.\textsuperscript{130} Yet, there is only a limited range of circumstances in which public policy has been relied upon to vitiate a conditions attached to a conditional gift. A condition inciting an act prohibited by law, \textsuperscript{131} restraining marriage or custody of children,\textsuperscript{132} prevents vesting for a perpetual period\textsuperscript{133} preventing the beneficiaries instituting any litigation to enforce

\textsuperscript{129} Jackson, \textit{Principles of Property Law}, Chapters 2 and 3, especially pp39-45 and 67-78

\textsuperscript{130} Moore v. Regents of the University of California 793 P. 2d (1990) 479, (Supreme Court of California). See, generally, B.M. Dickens, "Living Tissue and Organ Donors and Property Law: More on Moore", (1992) 8 Journal of Contemporary Health Law and Policy 73. There has been a huge volume of American legal literature on the \textit{Moore} decision.

\textsuperscript{131} Re Piper, [1946] 2 All E.R. 503 (K.B.)


\textsuperscript{133} Re Spritzer’s Will Trusts, [1939] 2 All E.R. 266 (Ch.)
the gift is void\textsuperscript{134} or is discriminatory highlight the limited range of circumstances when the Public Interest has vitiated conditions.\textsuperscript{135} Although a case did void a condition requiring the use of Aboriginal land for the public benefit,\textsuperscript{136} this case is likely to be overruled if considered again in light of recent litigation concerning aboriginal law rights.\textsuperscript{137}

Nonetheless, new heads of public policy can be created with changing times and may be used by judges to void conditions created to protect participants.\textsuperscript{138} Furthermore, the effect of a condition being void is based upon a very technical and complicated set of rules. The effect will depend upon whether the condition was drafted as condition subsequent or precedent, whether the civil law or common law approach is adopted and whether the gift is only \textit{malum prohibitum} (conflicts with law or public policy), as opposed to \textit{malum in se} (inherently wrong or immoral).\textsuperscript{139} Nevertheless, these complications could be avoided by simply stating in the statute the effect of a condition being voided; indeed the Ontario Law Commission has recommended that this reform occurs.\textsuperscript{140}

The fact that there are far more limited circumstances in which the gift will fail due to the public interest compared to the general flexible balancing that occurs when considering privacy rights may adopt a fairer approach in the context of

\textsuperscript{135} \textit{Morris v. Morris} (1986), 34 A.C.W.S. (2d) 211, 5 Ont. Lawyers Wkly. No. 38 at 21 (Ont. H.C.J.)
\textsuperscript{136} \textit{St Mary’s Indian Band v Chadwick} (1995) 10B.C.L.R (3d) 249
\textsuperscript{137} \textit{Rio Tinto Alcan Inc. v. Carrier Sekina Tribal Council} 2009 BCCA 67; \textit{Haida Nation v. British Columbia (Minister of Forests)}, 2004 SCC 73; \textit{Taku River Tlingit First Nation v. British Columbia (Project Assessment Director)}, 2004 SCC 73; \textit{Mikisew Cree First Nation v. Canada (Minister of Canadian Heritage)}, 2005 SCC 69; All these cases have held that there is a duty to consult aboriginal communities when using Crown Land which may be subject to rights of indigenous communities.
\textsuperscript{138} \textit{Nagle v Nagle}
\textsuperscript{139} \textit{Ziff, Principles} 248
\textsuperscript{140} \textit{OLRC Report on Basic principles of Land Law} (1996) at 64
medical research. This is because there may be more incentive to protect a participant’s rights because they have altruistically and benevolently given up their contributed material for the public benefit. The need to protect participants is heightened within the context of medical research because the longer-term consequence of in-consensual research will be distrust of medical research and reluctance to participate in the future.

The risk is of damaging medical research is evident from the Alder Hey and Bristol scandals.\textsuperscript{141} The United States of America case of \textit{Havasupai Tribe v. Ariz. Bd. of Regents} also reveals the devastating effects of failing to ensure that appropriate consent is obtained.\textsuperscript{142} The \textit{TCPS} also states that ‘researchers have sometimes treated groups of merely as sources as data’ and ‘such conduct has harmed the participant communities and spoiled future research opportunity.’ \textsuperscript{143} The \textit{TCPS} guidance is a reminder of the wider potential harm of failing to respond; namely a distrust of medical research and in the worse cases, such as the \textit{Havasupai Tribe}, the complete alienation of communities in need of medical assistance. Given the need to ensure medical research can continue the rights of participants that allow medical research to occur need to be protected. To recognize this fact, the Public Interest ought to only trump an individual’s rights in a limited range of circumstances.

3.1. Structuring distributive rights to reflect the context of medical research


\textsuperscript{143} Section 6 Research involving Aboriginal Peoples at 6.1
Having addressed the difficulty of the conditions causing the gift to fail, it is necessary to outline the conditions that ought to be included. The consent form outlining the conditions attached to the gift could be tailored to reflect the concerns of participants, researchers and ensure the wider public benefit in medical research continues.

3.1.1 Concerns of participants
Participants appear to have three key concerns. Firstly, there is a concern with the generalised purposes specified in consent forms and a loss of control over material contributed to medical research. Secondly, participants may fear economic, psychological or social harm due to the subsequent use, transfer or disclosure of their contributed material to third parties. Thirdly, participants have a particular fear that contributed material will be used for commercial purposes and/or used, disclosed or conveyed to third parties. A similar concern is that participants may wish to ensure that their contributed material is primarily used for the research projects which do not limit the public benefit of the project by allowing commercial parties to patent valuable medical findings and divert profits

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144 Due to word limits, this essay can only touch upon the possible concerns that participants may have. Caulfield,
145 Supra Ontario Health Study fn. 7, Saskatchewan Health, Consultation paper on protection of personal health information
146 Ibid. 2
away from public institutions.150 For example, the case of *Greenberg* reveals that many individuals simply wish to ensure that their information and specimens are used primarily for the public benefit.151 To address the concerns of participants, three categories of conditions that 'benefit' the participant could be outlined.

3.1.1.1. Ensuring control, disclosure and compensation for harm
To address the first two concerns the conditional gift could state that the rights in the transferred item will be persistent and thus will bind the initial researcher and recipient of the contributed material. The researcher and recipient also ought to be subject to conditions to provide ongoing disclosure about the research project to allow the participant to appreciate any research being completed using their samples.152 Compensation could also be awarded if disclosure is not provided to participants about a future project using their contributed material and they are harmed as a result of the use of material in that project. Disclosure could be via the central Registry system as outlined in the second part of this essay.

*Prima facie* it would be difficult to ensure greater disclosure by using a

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151 *Greenberg v Miami's Children Hospital* [2003] 264 F Supp.2d, 16 Fla.L.Weekly Fed. D 417, 121 A.L.R 5th 687; The contributors suffering from Caravan disease prime motivation was not to have an interest in commercialisation; rather it is to ensure that their understanding at the start of the research project is adhered to namely to find a cure for Caravan disease which would benefit the community that participated in the project and the wider community.

152 Saskatchewan Health, Consultation paper on protection of personal health information (1998), online: <http://www.health.gov.sk.ca/ph_br_health_leg_phiq/default>
propriety concept or the conditional gift. This is because the primary remedy for breaching a condition is the return of the gift. However, participants in medical research may not wish to demand the return of the gift; rather their primary intention in contributing was to ensure that the wider public interest in medical research is advanced. Yet, a simple remedy to this pitfall is specifying a gift over when the initial condition fails. \(^{153}\) Thus a condition could state that the contribution can be conveyed to another research public project where the gift fails. Alternatively, although compensation is not generally awarded for breach of a condition, a Statute introducing the gift could allow for compensation from a researcher or indemnification from a central fund where the conditions fail. This could be a nominal amount to limit concerns of researchers of indeterminate liability.

It could be argued that greater disclosure is unnecessary and could be costly if compensation is awarded for a failure to disclosure a research project. However, there is an important for requiring greater disclosure throughout the project. This is because a researcher can reduce the risk of incidence of harm by providing greater disclosure. Indeed, in a large scale health study this may make a significant difference. For example, if 1 in 1,000 will suffer some psychological harm in the future due to the Study and a Study recruits 100,000 then 100 participants will be harmed by the Study (Even assuming 1 in 10,000 may suffer harm then 10 will be harmed by the Study). Assuming that all participants had been informed of the purposes of their contributed material then some may have withdrawn, for example

\(^{153}\) *Kotsar v Shattock* (1981) V.R.13 (S.C Fii Ct.)
10%. Then the incidence of harm would be 90 and 9 individuals. Thus, the breach of
the obligation to provide greater disclosure may make a measurable difference to
the total incidence of harm.

Thus, by failing to provide disclosure the researcher is increasing the risk of
the total incidence of harms arising. Similarly, a million people take a drug which
has a 1 in 10,000 risk of causing Cancer. Thus, 100 people will suffer cancer as a
result of the drug. If the manufacturer had informed the consumer of the risk there
may have been a 5% decrease in the total number of sales; thus only 95 individuals
would have suffered the risk.\textsuperscript{154} Thus, on a deterrence basis, it is better to disclosure
all uses of the material on an ongoing basis because it will ultimately lead to less
individuals being harmed by the research.

\textbf{3.1.1.2. Commercial parties: disclosure and compensation for harm}

The third concern could also be addressed through open disclosure of commercial
parties that receive contributed material on an ongoing basis. In addition, where it is
expected that commercial parties will receive contributed material, a condition
ought to clearly acknowledge this fact. A condition could also agree to provide
additional safeguards when commercial entities collaborate with public research
projects, such additional privacy safeguards and the opportunity to re-consent. The
conditional gift model may be helpful in controlling uses by commercial parties
because a right held in an item could be used as a basis for a claim to return the item

\textsuperscript{154} Davis \textit{v} Wyeth Laboratories, 399 F.2d 121 (9th Cir. 1968) Ninth Circuit held that the manufacturer
of the Polio vaccine should have warned the patient that the vaccine carried a one-in-one-million
chance of infecting the patient with polio. This warning was held to be legally required even though
this level of risk was much lower than the general risk of polio from not taking the vaccine (at
pp.129-130).
where one of conditions concerning uses by commercial parties is breached. By breaching the condition the participant could reclaim the gift for a breach of the conditions. In addition, as noted above it is possible to include conditions stating a gift over and possibly compensation due to a breach of a condition.

It may also be able to divide any claim for compensation upon a basis which reflects the fact that the transferor’s consent has been breached; a medical researcher may have expended considerable funds completing research using the contribution and the concern of all parties that the public benefit is progressed. Thus, the conditions could allow for the sharing of compensation upon the basis of the particularly facts of a case. Compensation could also be subject to statutory limit to address fears of the withdrawal of private funding from research projects.

3.1.1.3. Commercial parties: account of profit claim
There is also the controversial issue of whether participants can claim a interest in commercialisation, such as a account of profits claim or a propriety interest in the creation of a patent right, as a result of their contributed material being used in breach of their informed consent which leads to considerable economic gains. The general stance that is adopted by policy-makers and the case-law is that individuals ought not to be able to claim an interest in commercialisation for a number of reasons. These include avoiding the controversial of who owns contributed material once removed from the body and a fear that allow contributors

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155 Smagkuj P, Tissue donors use their influence in deal over gene patent terms. Nature: 407: 821: PXE International has generated funding by negotiating intellectual-property agreements with commercial researchers. This has allowed private institutions to support the work of the non-profit blood and tissue bank investigate the rare disease PXE whilst ensuring that funds are re-diverted back to the public benefit
156 For example, Australian Law Commission You and Yours, Ownership Supra fn.37
157 Moore, Supra fn.130
to claim economic rights may undermine the motivation of private and public institutions to complete research which may advance scientific knowledge.¹⁵⁸

A conditional gift model could reflect these concerns because it is a propriety concept which courts are less prepared to assume will lead to an interest in the economic gains reaped from the gift; this is because the primary remedy for a breach of the conditions is the return of the gift and the case-law has not accepted the proposition that transferors can claim restitution for the misuse of the gift. Thus, the result of a breach of the conditions would be that the participant would be able to withdraw and possibly compensation for harm due to a breach of the condition; however it would not necessarily lead to a claim for an economic interest in the conditional gift.

Nonetheless, there may be instances where it is recognised that participants ought to be allowed a right to profits in their contributed material. It is beyond the scope of this short thesis to fully consider all the instances where this may be the case; it would necessitate a wide consultation with participants, researchers, ethical and privacy experts, the legal community and policy-makers. Yet, if there is a decision to allow participants to claim an interest in commercialisation then the conditional gift model could be used to implement this approach. The conditional gift model be less problematic than utilising other concepts rooted in the Law of Property to delineate the rights and duties of the parties; this is because traditionally one of the bundle of rights that is often held in an item of personal or

real property is the right to profits from its use.\textsuperscript{159} Thus, the Australian Law Commission Report into the use of Human Tissue concluded that ‘Property rights include rights to the income and the capital of an object. Allowing individuals to seek financial returns on the use of their tissue would enable them to share in the profits that are sometimes made from treatments that result from research.’\textsuperscript{160}

Yet, as noted above, the case-law concerning the conditional gift model suggests that the primary remedy is normally to reclaim the gift and not necessarily a claim for an interest in commercialisation.\textsuperscript{161} This would ensure that the fear of indeterminate liability could be restrictively contained.\textsuperscript{162} This approach may be beneficial within the context of medical research where researchers may fear indeterminate claims and participants are not primarily motivated by economic gain. This could be recognised in the conditional gift model by only allowing an interest in commercialisation in a limited range of circumstances based upon specified conditions which could only be gradually extended beyond the recognised categories. These circumstances may include where there is an intentional

\begin{footnotesize}
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\item \textsuperscript{159} A Honore, ‘Ownership’ in A Guest (ed), Oxford Essays in Jurisprudence (1961) Clarendon Press, Oxford at 133; Foskett v McKeown [2003] UKHL[119]-[120] Re Diplock (1948) Ch. 465 This right in the item allows the right-holder to trace their interest into the hands of the recipient to claim against them for interfering with their right held in the material. A right in unjust enrichment, for example an intentional misrepresentation or undue influence can lead to a similar claim. However, a right held in the item as a basis of a claim is that the common law suggests that there is no need to show an unjust factor to claim restitution of the unintended gain. Rather, as Lord Millett submitted in McKeown, it is ‘the transmission of a plaintiff’s property rights from one asset to its traceable proceeds is part of our law of property, not of the law of unjust enrichment’.
\item \textsuperscript{160} Ibid at Chapter 20 sub section 20
\item \textsuperscript{161} Supra page 2
\item \textsuperscript{162} Kit Barker, “Unjust Enrichment: Containing the Beast” OJLS (1995) Thus Kit Barker points out ‘it may still be possible to justify a restitutionary response by reference to corrective justice, even when the plaintiff has suffered no loss by virtue of the defendant’s wrong...this still requires us, of course, to identify those rights which deserve such a high degree of protection. It comes to us as no surprise, perhaps, that property (and analogous) rights currently feature at the head of this list.’ Yet, the author concludes that it is ‘more controversial’ whether a ‘restitutionary response’ extends to harm ‘such as rights to reputation and to privacy.’
\end{itemize}
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misrepresentation or undue influence induces participant and/or the contribution provided is peculiarly valuable to medical science.\textsuperscript{163} Therefore, by utilising the conditional gift model, which is unique compared to other propriety rights because of its remedial consequences, it may limit the extent to which recognising a propriety interest in contributed material would necessarily trigger an account of profits claims. Instead a claim would only arise in certain pre-recognised situations.

3.1.2. Concerns of medical researchers

However, it is also important to acknowledge the legitimate concerns that medical researchers may have. A suitable basis to acknowledge the concerns of researchers may be the guidance given by the \textit{TCPS} which indirectly governs most medical research in Canada. By using the \textit{TCPS} as a basis for reform, it may make researchers more willing to accept the conditional gift model because it would simply be reifying requirements which already bind most research projects.

The Policy Statements recognises that there may be circumstances where it is unnecessary to satisfy the stringent requirements of informed consent when a number of requirements are satisfied which are outlined in Article 2.1.\textsuperscript{164} These requirements are based upon a REB making a number of assumptions when

\begin{footnotesize}
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\item The case of \textit{Moore} may represent a case where it the law ought to have recognised the participant's significant contribution to the project. Firstly, the research project was actively misrepresented to the plaintiff. The defendant doctors informed Moore 'that he had reason to fear for his life, and that the proposed splenectomy operation ... was necessary to slow down the progress of his disease' when in fact the removal was 'not intended to have ... any relation to [Moore's] medical ... care.' Rather, the aim was to use Moore's rare tissue to create an intellectual property right for primarily for commercial gain. Where there is an intentional misrepresentation, it is difficult to conclude that the participant did consent to the contribution. As a result, it seems justifiable that the transfer either ought to be returned, or where this is impossible, the participant can follow the gift to claim its equivalent value from the recipient. A second fact in the \textit{Moore} case that may justify a claim is that the plaintiff's tissue was particularly valuable nature of the Claimant's contributed material which he was unaware of at the time of consenting; even though the researcher knew of the potential profits. Page 3
\item \textit{TCPS}, \textit{Supra} fn.2. Art 2.1 (c) (i)-(iii) PHIPA s44 fn.82
\end{enumerate}
\end{footnotesize}
deciding whether to allow research to occur which may alter or waive the requirements of full and informed consent because it is not ethically necessary due to the nature of the research project. These assumptions could form the basis of the conditions delineated in the gift. Therefore a condition could state that there may be instances where the participant will not be given the opportunity to re-consent to a research project that occurs in the future or that there is insufficient information to offer full and frank disclosure, however this will only be when a number of assumptions are satisfied.

The first assumption that a REB makes is that the research involves no more than a ‘minimal risk to the research subjects’ and the research ‘is unlikely to adverse affect the rights and welfare of the subjects.’ The TCPS makes it clear that wellbeing includes ‘bodily to psychological to cultural integrity’ and that a subject-centred perspective ought to be adopted. The reason why not ensuring fully informed consent is not ethically problematic is because the risk posed to the participant and their legal rights is so small that the participant is unlikely to be harmed. Yet, were that risk of harm does occur; there are three normative justifications for requiring researchers and a public fund to bear the burden for the minimal risk. These reasons are based upon logic, a benefit-burden analysis and a rights-based analysis.

Firstly, logically when it is the REB and researcher who is assessing the risk and then assumes the risk is only minimal, and not the participant, then it will seem that correlatively they ought to bear the burden for any harm if it does eventuate.

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165 TCPS Art.1.5, 2.4 and supporting Commentary
166 TCPS, Supra, C. Guiding Ethical Principles para 2
Given that a third party has assumed the risk, logically the risk-taker should bear the burden for that risk and not the individual who has been lead into the risky situation because of that third parties act. For example, a teacher will assess whether it is safe for a group of children to cross the road. If a child is harmed when the teacher incorrectly assesses the risk then surely that teacher ought to be responsible for that risk no matter how small it was.\textsuperscript{167}

Secondly, if the participant is not compensated for psychological or physical harm suffered due to a research project, then that individual will have to bear the burden of the risk of harm posed by a project when the ultimate beneficiary of the agreement was wider society. The unjust implication of this is that it makes a small group of people bear the burden for entirety of society who gains from scientific advancement.\textsuperscript{168} Similarly, research institutions will gain interests in patent rights and possible large profits rather than the participants.\textsuperscript{169} A more just and fair approach would be that the wider society and the research institution that benefit from the research, ought to bear some of the burden when they are the ultimate beneficiary.

Finally, as noted above,\textsuperscript{170} the preponderance of national and international jurisprudence is that the Law ought to protect the right to informed consent to the

\begin{footnotes}
\footnote{\textit{Carmarthenshire County Council v Lewis} [1955] 1 All ER 565}
\footnote{\textit{Supra}, Information Pamphlet fn.3; For example, the benefits of the large-scale Health Studies are shared amongst Society because it aims to gather research over considerable periods of time to appreciate the links between lifestyle and cancer.}
\footnote{\textit{Lemmens, Leopards in the Temple, Supra} fn.43; for example, Pfizer's cholesterol-lowering drug Lipitor had sales of $9.2 billion in 2003; 36 one tenth of the estimated total market for that drug category.}
\footnote{\textit{Supra}.}
\end{footnotes}
invasion of bodily integrity. Moreover, within the context of medical treatment\textsuperscript{171} and medical research\textsuperscript{172} the common law has refused to accept that this right can be waived or altered in any circumstances. Given that the common law protects this right, irrespectively of statements in National Policy Codes, there is a normative rights-based justification for providing additional protection to ensure that each individual can protect their right to protection from invasion of the human body.

Thus, where a participant is harmed by a research project where the requirements of informed consent have been altered or waived because a REB has assumed that there is only a minimal risk, it would then be justifiable to provide compensation when this minimal risk does materialise. This is not to suggest that compensation could be claimed directly from the REB. Instead, as noted above, there ought to be a statutory framework to allow compensation from the researcher or a method for claiming indemnification from a public fund\textsuperscript{173}. Where a participant can show harm arising due to the research project, then compensation could ensure that the participant does not bear the burden for society when they have altruistically participated. For example, compensation could be available where a participant suffers mental distress due to the publication of a Study using an individual’s contributed material when the participant was not informed of the Study and now wishes to withdraw and it is impossible to do so. In such instances, it is submitted that the REB and the researcher took a risk with the participant’s health and having

\textsuperscript{171} Chester v Afshar [2004] UKHL 41; [2005] 1 A.C. 134 (UK); Chappel v Hart (1998) 195 CLR 232 (Australia)
\textsuperscript{173} Outlines the implementation of a Indemnity scheme in a similar way to Land Registry System
assumed that risk, they ought to be required to provide a safety-net to compensate the individual for failing to give that the individual the right to determine whether their contributed material could be used for a research project.

The second requirement in Article 2 is that the REB has to conclude that ‘the research could not practicably\textsuperscript{174} be carried out without a waive or alteration.’ To ensure that this assumption is respected throughout the research project, a condition could require that the researcher ought to be under an ongoing duty to disclose to an REB and/or participants exactly why the researcher cannot be carried out without diluting the requirements of informed consent. This could be achieved by publishing further information on the Research Register. Surely, this limited additional duty of disclosure is the very least researchers ought to do where they do decide to proceed with a research project where they will not be seeking the fully informed consent of the participant. A participant could be given the ability to enforce this condition by complaining to the research, the REB and final the Research Register.

The third assumption that is made by REBs is that ‘wherever possible and appropriate, the subjects will be provided with additional pertinent information.’\textsuperscript{175} This assumption has already been considered above when considering the requirement that the purposes of the research and third party recipients ought to be disclosed to the participant.\textsuperscript{176} The fact that the \textit{TCPS} requires further disclosure when research occurs which does not fully adhere to the requirements of informed consent.

\textsuperscript{174} http://www.pre.ethics.gc.ca/eng/policy-politique/initiatives/revised-revisee/Default/
\textsuperscript{175} \textit{TCPS, Supra}, Art 2.1(c)(i)-(iii)
\textsuperscript{176} \textit{Supra}, pages 2 and 2; Page 25 considers how greater disclosure could be achieved via the Research Registry and page 41 considers the normative reason for requiring greater disclosure.
consent, reinforces the need to ensure that there is adequate and ongoing disclosure of the uses of a participant’s contributed material. Where further disclosure is not provided and this leads to research occurring which the participant is unaware of and this leads to harm,\textsuperscript{177} then compensation ought to be available for the failure to disclose a project that the participant has lost the opportunity to withdraw from.

By basing the rights of the participant on the assumptions made by REBs when they alter or waive the requirements of informed consent it provides a normative basis for the conditions attached to the gift. By clearly stating in the conditions attached to the conditional gift the assumptions underlying the research project and offering limited compensation or indemnification where those assumptions lead to harm or are incorrect, it can ensure that medical research can continue without overly burdening participants or researchers.

3.2.3. The wider public benefit in medical research.
As noted above, it is important that the conditional gift also ensures that the public benefit of medical research continues without overly restricting the participant’s rights.\textsuperscript{178} Prima facie, any propriety concept would fail in this regard because propriety rights appear to give all rights to the owner. For example, Charo claims, ‘generally, calling something “property” will enhance the owner’s interests considerably, especially with regard to prohibiting others from using it.’\textsuperscript{179}

However, the right to ownership is subject to numerous exceptions; similarly the bundle of rights that exist in an item can be shared by the owner to ensure the

\textsuperscript{177} For example the mental distress example provided on the previous page
\textsuperscript{178} See page Error! Bookmark not defined.
\textsuperscript{179} RA Charo, Body of Research- Ownership of Human Tissue, NEJM (2006) page 2
greatest utility for the property. This is evident is Knoppers conception of a conditional gift of DNA. Knoppers claims that the rights of participants ought to be delineated to ensure that the information that can be gleaned from DNA for medical research to ensure the greatest wider benefit to society. In a public health care system this could be achieved by requiring that commercial returns are re-diverted back into the health care sector. Knoppers concludes that this model would preclude “individual percentages of future royalties”; rather the health care infrastructure that made the research possible ought to receive the economic benefits from the DNA.

Yet Knoppers model seems to use the conditional gift model without actually utilising the central aspect of the model. It is the ability to share rights in a single thing, it is not the ability to remove the rights from one individual and distribute that right amongst lots of other individuals without providing any rights to the initial transferor. The approach of Knoppers reflects a belief that medical research is inherently beneficial to the wider community and thus justifies the trumping of the fundamental rights of the transferor. Similarly, recent litigation from the United States reveals that courts are often unwilling to protect participants through using the common law concept of propriety rights because of a perceived fear that it will undermine the public benefit of medical research projects.

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However, a failure to recognise the rights of the participants will only result in reluctance to participant which will reduce the overall benefit of medical research.\textsuperscript{183} It also ought to be noted that and there is a need to ensure the public interest in protecting the reputation of medical research.\textsuperscript{184} Any reform of this area of law would need to convey a clear message\textsuperscript{185} that the participant’s rights ought not to be trumped because of the public interest because in fact this may undermine participant’s rights, ruin the reputation of medical research\textsuperscript{186} and demean the gift the participant has made.

By using the conditional gift it may convey the necessary clear message. The conditional gift framework could embellish the rights of participants because it does not it could allow the participant to maintain their rights in the item. These rights are maintained irrespectively of the rights of other individuals or the public interest in the research project. Yet, as noted above, an exception to this rule is that the public interest can be relied upon to void a condition in the gift.\textsuperscript{187} The effect of voiding the condition may be that the gift fails and that it is returned to the beneficiary or that the gift becomes absolute and the researcher gains the right to possess the gift without the condition attached. The first remedy may be beneficial for participants because it would ensure they could where there legitimate

\textsuperscript{183} Supra pages Error! Bookmark not defined.-2; Havasupai Tribe v. Ariz. Bd. of Regents and GT Laurie and JK Mason, ‘Consent or Property? Dealing with the Body and its Parts in the Shadow of Bristol and Alder Hey’ (2001) and
\textsuperscript{184} Supra fn.45
\textsuperscript{185} The property model has not been adopted by any Commonwealth jurisdictions yet; Australian Law commission report: ‘Ownership of Samples’ ALRC Report 96 ‘Essentially Yours: The Protection of Human Genetic Information in Australia’ – Chap 20 online:
\textsuperscript{186} See for example the Nancy Olivier controversy and the book M Shuchman, The Drug Trial (2006) Random House (Canada) online review: http://www.bmj.com/content/331/7508/115.1.extract
\textsuperscript{187} Supra page.2
expectations of the research project are undermined, at least they retain the right to withdraw. Thus reform could allow for the withdrawal from the project where the public interest does require the voiding of a condition.

In addition, an underlying interpretative principle could list factors that ought to be considered when interpreting whether to void a condition could be provided to courts. For example, where a condition is breached, rather than simply accepting the public interest can void the conditional interest, the breach of the condition ought to lead to a remedy if it causes harm; thus a limited amount in indemnification from the researcher or a public fund could be offered where harm arises due to the vitiation of a condition due to public policy reasons.

The principle could also state that the public policy test in the context of medical research requires a unique approach to recognise the unique concerns in medical research. The conditions could clearly state that the rights of participants ought not to be trumped in the wider public benefit. This is because the participant has given up their time, potentially harmful information, bodily substances and certain rights, in good faith reliance upon the researcher; as result of this altruistic act it deserves safeguards beyond that provided by traditional tort and privacy rights. In addition, that the wider public benefit in ensuring the continued good reputation of medical research requires protection of participants as well as researchers. The conditional gift model would publicize the need to respect the rights of participants to ensure altruistic donation is not eroded.

3.3. The current difficulty that distributive rights could address

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188 TCPS at Research in Emergency Situations page 42 2.12 and page 86 Article 2.1. A.6
189 TCPS Section 3 Privacy and Confidentiality page 3.1
It could be argued that it is unnecessary to use a conditional contribution to reflect the rights of multiple parties and acknowledge the wider public benefit of medical research. This is because the right to privacy and Charter rights already allow consideration of countervailing rights of other individuals\textsuperscript{190} and the wider public interest in a legitimate countervailing aim of the Government.\textsuperscript{191}

Nevertheless, unlike the right to privacy, the conditional contribution model would not require the weighing of the right to private life against conflicting rights and the public interest. Instead, the bundle of rights held in the item are shared between the parties and are not weighed against each other. In addition, the conditional contribution model could provide for less limited circumstances where the public benefit could be relied upon to defeat a participant’s right to privacy.\textsuperscript{192}

Thus, each individual possesses that right which they hold onto irrespectively of the rights of others. Yet, as noted above there is an exception where public policy requires that a condition is voided. Yet, it was suggested that in these instances an alternative remedy ought to be offered. Therefore, the conditional gift could thus ensure a move away from the complications of showing that the right to privacy is implicated and there is no pressing countervailing public benefit which justifies the infringement before an individual can claim any remedy. Instead, the voiding of a

\textsuperscript{190} For example the right to freedom of expression s2 (b) of the Canadian Charter of Rights and Freedoms (Charter) can be weighed against another individual’s right to privacy over their personal health information.

\textsuperscript{191} Supra fns.98-113 and s44 PHIPA: Factors a REB ought to consider when assessing whether to agree to the use of personal health information are the ‘public interest’ in the research and the ‘public interest’ in protecting the individual’s right to privacy.

\textsuperscript{192} For example, see Gould Estate v. Stoddart Publishing Co Supra fn.107 or The Constitutional Law Group Supra fn.110
condition which the participant has legitimately relied upon can lead to limited indemnification if that condition is voided.\textsuperscript{193}

In addition, it could also be argued that the conditional contribution aims to protect a different interest to that protected by the right to privacy. The right to privacy aims to protect one’s private space and the right to personality aims to protect one’s image.\textsuperscript{194} Yet a right in contributed material aims to protect a different type of right; it is the right to protect one’s body from invasion without free and informed consent. When free and informed consent is limited because of certain assumptions made by a third party quasi-government body (REB), a just legal system ought to require safeguards which directly fill this gap in the legal system and do not leave it to other rights, such as privacy, to serve this purpose. Especially when it is questionable whether these rights even exist and when they will be trumped in the wider public interest.\textsuperscript{195}

Nevertheless, it could be argued that a similar outcome to the conditional gift model could be achieved by simply having conditions in a consent form stating the requisite rights of the different parties to the agreement. Similarly that the consent form could achieve the same results as the conditional contribution model without the need to accept a quasi-propriety interest in contributed material.

However, the difficulty with relying upon the initial consent form to delineate the requisite rights and duties of the parties is that the duty of care is dependent upon the individual being a party to the agreement. Therefore, third party recipients

\textsuperscript{193} Supra page 2
\textsuperscript{194} Supra fn.2
\textsuperscript{195} Supra page 2
may not be bound to respect the multiple interests in a single item because they were not a party to the initial agreement. Although it is true that the parties to the agreement could be under a duty to bind third parties, the parties to the agreement could only enforce those rights against the parties to the agreement. Thus, they may be able to claim compensation against a party who fails to bind a third party by the conditions, yet they would be unable to directly enforce those rights against the party that actually breached the duty. This is unlikely the persistent nature of rights held in an item of real or personal property which ensures an ongoing link with individuals who have an interest in the item which will bind third parties when the necessary formalities are undertaken.

Furthermore, although consent forms and statutes could be reformed to share the rights of parties in the material, the conditional gift framework may be best placed to install this model. This is because, as the first part of this essay aimed to show, it reflectively and openly acknowledges the fact that the participant’s contribution is conditional upon certain conditions which are often based upon the assumptions made by a REB. This adopts a more accountable, open and honest approach than consent forms which suggest that the research is conditional upon the participant’s informed consent. This is misleading when in fact in many research projects a participant’s right to informed consent is limited because the REB alters or waives the strict legal requirements because it is not ethically necessary due to certain assumptions made by the REB about the research project. The conditional

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196 See for example, a trustee is strictly liable for all breaches of the trust
197 Supra page 2 considering Persistent rights in property.
198 Supra section ‘1. Conditional rights’
gift model openly and transparently acknowledges this limitation and thus adopts a more truthful approach. This gives the conditional gift model greater legitimacy because it transparently acknowledges to the fact that their informed consent is limited, yet this is only because certain assumptions mean truly informed consent is not ethically necessary.

In addition, the conditional contribution model ensures that participants do not lose the right to give informed consent to the use of their contributed material. Instead, alternative remedies, such as the right to withdraw or limited indemnification, can be offered. It may be argued that this protection is unnecessary; that the public benefit in medical research requires the balancing and not the sharing of rights in an item and that transparency will simply cause greater confusion. Even if these fears are true, surely it is quite simply wrong to allow a participant’s right to informed consent to be implied and altered without any remedy; truly ethical medical research may require an acknowledgement that the right to informed consent is too fundamental to leave unprotected.

\[199\] The claim that further options confuses participants is somewhat misplaced; it may also be misguided to assume medical research always serves the public benefit. Many research projects do not lead to significant scientific advancement.
CONCLUSION

This essay has attempted to show that attributes associated with propriety rights, in particularly a conditional gift, could be effectively utilised to protect participants in medical research. Three core benefits of this conceptualisation were identified. Firstly, the conditional gift makes it clear that the participant’s contribution is conditional upon certain safeguards being met. This approach more openly reflects the nature of the relationship that arises in medical research using contributed material. Secondly, the persistent nature of rights in personal and real property could also be utilised to ensure that conditions attached to the material bind third parties and allow participants to ascertain the uses of their contributed material for longitudinal periods using a central database. Finally, the ability of a conditional gift to distribute the utility of an item could be used to ensure that the concerns of participants and researchers and the wider public benefit in medical research are recognised.

However, it is important to note that there are those that may claim the conditional gift is problematic because it could be analogised to an item of property. It could be claimed that this leads to difficult questions about whether the contributed material is property owed at the time it is removed and/or questions about when a participant losses all rights in the contributed material at a certain point when the consent form is signed.\textsuperscript{200} Yet, using the conditional contribution

\textsuperscript{200} McInerney v McDonald CSC at 25 J LaForest and R A Charo, Body of Research Supra fn.179
does not necessitate the reification of the transfer into common law property. Instead, this essay simply seeks to point out that the benefit of certain aspects of a propriety rights (the conditional gift) could be utilised to ensure contributed material is used more consistently with the participants consent and provide participants with the ability to enforce their rights effectively when they are limited by a research or REB. Indeed, the aim of the using the term ‘conditional contribution’ is to attempt to move away from associating propriety rights with absolute ownership; instead a conditional gift allows ownership rights to be shared between others through carefully considered conditions.

Furthermore, rather than simply ignoring the fact that there are multiple transfers of contributed material to numerous researchers and the requirements of informed consent may be altered or waived by a REB, the conditional contribution model provides a more legally justifiable way to acknowledge this fact and countenance it in a holistic and targeted way. This approach is justifiable because, as Radin points out, there is a need for a just legal system to provide a way to protect fundamental rights including providing mechanisms to utilise their inherent value to allow human flourishing for the individual and society.201

Where it is accepted that the purpose of a legal system is to attain human flourishing, 202 the conditional contribution model allows this to be achieved on an individual and collective basis. Individually, the model provides a safety net to

201 Radin, Margaret Jane, In regard to Property Law, Radin has published the article "Market-Inalienability" (1987) 100 Harvard Law Review 8 June pp. 1849-1937 which focuses on how rights in property may also be structured by policy-makers to prevent human flourishing.
protect individuals from harm due to risks and assumptions made by researchers and REBs. It thus allows individuals to attain human flourishing by satisfying the benevolent and altruistic desire to help others by contributing to collective research projects whilst ensuring that they are not harmed when supporting this wider public good. Collectively, the model ensures society can complete medical research to advance scientific knowledge to allow human beings to flourish collectively through discovery and progression. This is achieved by acknowledging that rights in the contribution can be lost through an estoppel, that the right to withdraw from a project may be conditional upon a breach of a condition and only allowing for limited interests in commercialisation. These restrictive conditions allow researchers to utilise the contributed material to be used collectively for the wider benefit of society.

In summary, the use of the conditional gift to structure a new model of conditional contribution openly acknowledges the necessary limitations with current research projects, yet it provides suitable alternative safeguards to ensure that fundamental rights are not breached and neglected. Reform would also require a deeper cultural change amongst the research community to allow them to accept that systemic change is necessary. This is a necessary pre-requisite for the conditional contribution model to allow the attainment of individual and collective

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203 Supra pages 2-2; Charter s. 7 and s.8 TCPS, Art.2.4(d) and Article 5 Council of Europe Convention on Human Rights and Biomedicine
204 McArthur v. Zaduk Supra fn.24
205 Supra, conditions attached to the gift are based upon REB’s assumptions about the research project as outlined at page 2 and Supra, result of a failure of conditions is the right to withdraw considered at page 2
206 Supra, Section ‘Commercial parties: An interest in commercialisation’ page Error! Bookmark not defined.
human flourishing. It may be possible to achieve similar results through statutory reform or possibly widening or reforming the right to privacy. Yet, if we are to consider the best way to achieve holistic and wide-scale reform of medical research, then surely the conditional gift model is one of, if not, the best candidate for this challenging role.