

## BIO-OWNERSHIP

BIO-OWNERSHIP: PROPERTY THEORY AND OUR SEPARATED  
BIOSPECIMEN

By: RYAN MOSOFF, B.A.

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AUTHOR: Ryan Mosoff, B.A (Wilfrid Laurier University)

SUPERVISOR: Dr. Stefan Sciaraffa

SECOND READER: Dr. Claudia Emerson

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## Lay abstract

As medical and information technologies advance the uses of our human tissues follow. These advancements have led to legal cases that show the gaps in our understanding of how to control the biospecimen we have separated from our bodies. I argue for the utility of property theory and law for control of these tissues. Property theory does not come without its downsides though. In order to combat the issues that come about through regulating our biospecimen-use through property law, I argue for the importance of liability rules. These legal protections will both limit and strengthen property law's applicability in this context. In the end I conclude that the limited-property framework is the best legal regime we currently have to regulate our separated human tissues.

## Abstract

As medical and information technologies advance the uses of our human tissues follow. These advancements lead to legal cases that show the gaps in our understanding of how to control the biospecimen we have separated from our bodies. Such cases offer us glimpses into the normative difficulties that the control of separated biospecimen bring up in modern liberal democratic societies. I argue for the utility of property theory and law for control of these tissues as a means to combat the normative issues that arise out of tissue use. Property theory does not come without its downsides though. In order to deal with the issues that come about through regulating our biospecimen-use through property law, I argue for the importance of liability rules. Tort law and fiduciary obligations in particular offer valuable legal protections that can both limit and strengthen property law's applicability in context of biospecimen use. In the end I conclude that the limited-property framework is the best legal regime we currently have to regulate our separated human tissues.

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Declaration of academic achievement

This M.A. thesis was completed by Ryan Mosoff under the supervision of Dr. Stefan Sciaraffa and Dr. Claudia Emerson in the Philosophy department at McMaster University.

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## Introduction

Individuals often visit doctors, nurses, research scientists and other medical professionals for a variety of reasons including health-related inquiries, participation in research ventures, voluntary tissue donation, among others. Often the individuals in question are asked to give up parts of their body for examination. The purpose of this examination could be for their own benefit (e.g. in the case of their family doctor diagnosing an illness) or the benefit of others (e.g. in the case of clinical research). Sometimes the examination depletes the excised tissue to the point where further use is impossible. However, this is not always the case. After a research scientist has completed their study or a doctor has done their analysis, the vials of blood or swabs of saliva these medical professionals have gathered may have further uses.

The information collected from various datasets is incredibly important in modern society. Which websites people visit, their spending habits, and their economic and medical information are just a few examples of useful datasets that governments and private companies collect. Excised human biospecimen is no exception to this list. The potential benefit of the use of these human tissues is not contained within the interests of the individual who offered them. The more private and public organizations know about the physiology of individual humans the more possibilities are open for scientific and economic growth. Without data, these possibilities are less likely to be realized. Public and private corporations can clearly benefit from the dissemination of human tissues for use by people other than those who conducted the original excision.

Some find this idea uncomfortable. They protest when told their blood, saliva, or hair is being tested in government or private facilities - asking something to the effect of, “what gives them the right?” People feel a genuine attachment to their body and this often translates to parts of their body once removed. Some care deeply about the use of their excised tissue. However, the situation becomes contentious when these individuals are told their biospecimens are being used without their consent. There exist some laws that regulate the use of human biospecimen, however in their discussion of the use of excised human tissues in biobanking, Timothy Caulfield and Blake Murdoch have argued that these regulations are currently an inadequate means of controlling excised biospecimen. They have shown that the law is unsettled when it comes to ownership of human tissues and the role of individual consent. In addition to an unclear regulatory environment, Caulfield and Murdoch argue that there continues to be a live debate in the public on relevant issues that surround excised biospecimen such as perceived rights of control, public trust and commercialization, and privacy and discrimination concerns.<sup>1</sup>

We find ourselves in a difficult situation. In the right hands excised human tissues can be valuable and put to good use as individual or public goods. However, these tissues come from individuals with interests and rights of their own. As Alta Charo puts it, we have a debate that is “about the proper balance between respect for persons and the collective

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<sup>1</sup> Timothy Caulfield and Blake Murdoch, “Genes, Cells, and Biobanks: Yes, There’s Still a Consent Problem,” *PLOS Biology* 15, no. 7 (July 25, 2017): e2002654.

interest in promoting research involving human tissue.”<sup>2</sup> In what follows I argue that a well thought out legal regime which supplements property rules with liability rules would be well-suited to account for and balance the competing values and interests in the context of separated biospecimen. Property law alone cannot sufficiently deal with the normative concerns in the context of human tissue use. This is why liability rules are necessary. Together, this regime is referred to as the limited-property framework. In addition to showing how the limited-property framework is beneficial in regulating human tissue use, I provide a broad analysis of how such a regime should be applied to specific case-types.

### **1. Preliminary Assumptions and Context**

To begin, the questions my thesis aims to answer are situated within Canadian, United States and United Kingdom case law and scientific research. I do believe that the arguments in this thesis can be applied more generally because they ultimately rest on widely accepted values of equal concern for the flourishing of all individuals.

Aside from the political context that my argument fits in, I will also be limiting the kinds of arguments I will entertain. Specifically, I will be including the kinds of supernatural arguments that some spiritual or religious individuals might make in support of ownership of their excised biospecimen within the general category of individuals’ connection with their tissues. That is not to say that these individuals’ concerns are moot. Only that while they might believe their connection to their tissues is metaphysical in origin, it is relatively uncontroversial to point out that there is no scientific evidence for this connection. I am not arguing that they do not have a deep psychological connection to their tissues. There are other cases of non-religious or spiritual individuals who claim to have strong cultural ties to their tissues. As I will argue in a chapter 2, these instances denote a special kind of valuing and constitutes a genuine and important interest for their ownership of those tissues. However, when I deal with arguments that take metaphysical evidence to constitute an individual’s right to hold ownership over their excised biospecimen, I will not be considering their rights as given to them by a God as constituting a valid form of justification *per se*.

In addition to these points, it will be important to clearly understand the distinction between clinical/diagnostic practice and research. In clinical practice, some individual visits a doctor or medical professional for an ailment and thereby expects to be treated for that ailment. The doctor or medical professional may then be required to take tests and ask for the patient to voluntarily give up portions of their human tissue. When a patient offers these tissues, it is usually under the assumption that they will be used for their own benefit. It is not immediately apparent that the tissues will be used to benefit others (unless explicitly stated). In responding to the patient’s concerns, the doctor or medical professional has various fiduciary duties to their patient. We expect that the professionals in these cases act in certain ways and do their best to ensure the success of the treatments for their patient’s ailments. On the other hand, we can examine medical research. In these cases, a research participant might voluntarily offer up their human tissues for a given study

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<sup>2</sup> R. Alta Charo, “Body of Research — Ownership and Use of Human Tissue,” *New England Journal of Medicine* 355, no. 15 (October 12, 2006): 1517–19.

in exchange for some small benefit for their participation. That being the case, the direct benefit of the study may not apply to that participant. While some studies do aim to benefit the ailments of their participants through the creation of new techniques or medicines, this is not necessarily the case with all medical studies. My argument deals directly with these two professional circumstances where individuals voluntarily give up their tissues in some capacity for some benefit and is important to note that fiduciary responsibilities are owed to those individuals by the professionals who deal with them. Individuals in these circumstances have certain expectations of the professionals they deal with, and these expectations will be key to my discussion.

A final point of clarification I will make before moving on is to spell out the specifics of the kind of data I will be referring to in my paper. The term ‘data’ as it is used in the field of scientific research can refer to a wide array of research substances. These substances can be physical or intellectual. Since data is such a broad term, I could not possibly account for all forms of data in this thesis. So, I have chosen just one subset of scientific research data, namely physical separated human biospecimen/tissues - I will use the terms ‘biospecimen’ and ‘tissues’ interchangeably. I will not be dealing with intellectual data in my argument, which I believe is the more contentious data-type. Undoubtedly who owns a tissue-set will influence who should have rights to data derived from that tissue-set. I do not have space to deal with the intricacies of assigning ownership rights to intellectual data derived from tissues, and so I must leave these concerns to other writers.

## **2. Chapter breakdown**

My argument in the following three chapters proceeds as follows. Throughout each chapter I examine different case-types. Each case-type is comprised of a basic set of conditions. If the facts of a case align with the conditions of a case-type we can determine that case to be an example of that case-type. After explicating and examining a case-type I will determine what the main normative considerations are that justify our assigning ownership rights to one party within the case-type or another. We will then have a clear picture of who is normatively justified in claiming ownership rights by default in a given case-type.

I begin in chapter one by introducing the first case-type – the diagnostic case-type. Alongside my explication of this case-type I examine the utility of property rules and their applicability (or inapplicability) to our whole bodies and separated tissues. In diagnostic cases the issue of informed and ongoing consent is of particular importance, and I end that chapter with a discussion of what implications the application of property theory to human tissues has for the consent practice. In chapter two I propose two additional case-types, the research case-type and the hybrid case-type. I offer a similar analysis to what was offered in the previous chapter. The possibility of commercial exploitation becomes apparent when dealing with research and hybrid case-types. In examining what commercial exploitation means in the context of separated biospecimen use, I argue that liability rules are important to protect the individual from harm. Finally, chapter three follows the formula set out in chapters one and two, offering two additional case-types: the bailment case-type and the biobank case-type. In this chapter I discuss the normative difficulties of protecting privacy concerns in bailment and biobank-type cases, and how liability rules can help alleviate

these concerns. After this lengthy review of different case-types, I conclude that the limited-property framework offers a clear way to regulate human tissue use that also sufficiently deals with the unwanted normative implications of property theory. A summary of each case-type can be found in **Table (i)** below.

<b>Case-type</b>	<b>Characteristics</b>	<b>Default Property Rights Upon Separation</b>
Diagnostic	(1) informed consent must be gained from the individual offering their tissues <i>at least</i> before separation. (2) the tissues must be excised for the <i>main</i> purpose of providing a diagnosis of the health of the individual who offered them.	Source individual gains control and income rights. Certain rights are then transferred to relevant parties under terms agreeable to the source individual.
Research	(1) an individual consensually offers their tissues for medical research purposes. (2) those tissues are used for the <i>main</i> purpose of completing the research endeavor. (3) the research endeavor itself is ethically sound.	Research institution gains control and income rights.
Hybrid	(1) an individual consensually offers their tissues for diagnostic purposes. (2) those tissues are used for the <i>main</i> purpose of diagnosing their ailment. (3) the tissues are then used for ethically sound research purposes.	Source individual gains control and income rights. Certain rights are then transferred to relevant parties under terms agreeable to the source individual.
Bailment	(1) informed consent must be gained from source individuals before excision or separation (which includes determining the purposes and conditions of bailment). (2) excised or separated tissues must then in fact be secured by medical professionals or organizations for the agreed upon purposes.	Source individual gains control and income rights. (Transfer of rights is specified on page 49).
Biobank	(1) an individual consensually offers their excised biospecimen to either a government or private institution. (2) those tissues may <i>possibly</i> be used for a weak diagnostic purpose for the benefit of the individual.	Source individual gains control and income rights. Certain rights are then transferred to relevant parties under terms agreeable to the source individual.

**Table (i):** Summary of case-types and default property rights assignments

Bibliography

- Caulfield, Timothy, and Blake Murdoch. “Genes, Cells, and Biobanks: Yes, There’s Still a Consent Problem.” *PLOS Biology* 15, no. 7 (July 25, 2017): e2002654.
- Charo, R. Alta. “Body of Research — Ownership and Use of Human Tissue.” *New England Journal of Medicine* 355, no. 15 (October 12, 2006): 1517–19.

## Chapter 1: Property Theory and the Diagnostic Case-type

After seeing her doctor and receiving a blood test requisition Samantha attends LifeLabs, a private Canadian company that owns medical test centers in Ontario, British Columbia, and Saskatchewan. The requisition asks for Samantha's blood samples to be drawn and tested. She consents to the procedure under the supposition that her tissues are being taken for the purposes of diagnosis. Though some LifeLabs facilities have infrastructure available to test her blood samples at the test center, the facility she visits does not. Her biospecimen is therefore couriered to a nearby hospital or medical laboratory for testing. Samantha's test results are made available to her and her doctor online.<sup>3</sup>

The drawing and testing of Samantha's tissues in her case is a routine procedure than many individuals undergo when seeking medical care. Though the procedure is fairly mundane, this does not make it uncomplicated. A few questions arise:

- What if she has a change of heart and asks for the tissues to be returned to her? Does Samantha have a right to make such a request at any time?
- If LifeLabs would like to sell the excess or remainder of the tissues after tests are complete, do they have a right to do so?

Samantha's case is one example of a larger set of cases that deal with the diagnosis of human tissues. I will refer to this set of cases as the diagnostic case-type, which covers most of the interactions individuals have with medical professionals. Whether it be a visit to their family doctor, a professional working in a specialized medical field, an emergency doctor, or any number of other interactions, individuals have their biospecimen voluntarily excised quite often. Diagnosis covers a broad range of medical practices, and therefore deals with a large set of uses of separated biospecimen. Undoubtedly, specific circumstances and contexts will warrant a more nuanced analysis.

In Samantha's diagnostic-type case, the individual testing the tissues is not the doctor who ordered the biospecimen-testing requisition. This means that the tissues will pass through different hands before the benefit for which the individual offered them is realized. In diagnostic case-types there are two key facts that must be present: (1) informed consent must be gained from the individual offering their tissues *at least* before separation, and (2) the tissues must be excised for the *main* purpose of providing a diagnosis of the health of the individual who offered them. These stipulations are important in order to clarify the kinds of normative considerations we are dealing with. If (1) is not present in Samantha's case, we could be dealing with a case of assault or battery, where Samantha is harmed because she had not given consent for someone to touch her body. However, this is not a harm that arises out of the misuse of her tissues, it arises at the point of separation. On the other hand (2) is important to differentiate diagnostic-type cases from other cases. Samantha's case falls within the diagnostic case-type because her tissues are being used for the *main* purpose of diagnosing her illness.

In what follows I will argue that conceiving of Samantha's tissues as property-objects will offer us answers to the questions posed above. Property law is a valuable tool to fairly regulate the use of separated human tissues. Biospecimen is normatively meaningful in different ways depending on the context within which they are being used as well as the

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<sup>3</sup> LifeLabs Medical Laboratories, "Home | LifeLabs," Life Labs, 2018, <http://www.lifelabs.com/>.



people using them. I will argue that conceiving of the procedures within which biospecimen is excised and used in terms of ownership and property theory will help us actualize and adjudicate between the various competing interests and values different people and groups have in liberal democratic societies. Property theory offers part of the conceptual framework and property law offers the tools to implement that framework.

## 1. Ownership and Property Theory

The ‘bundle of rights’ theory of ownership is a popular theoretical framework for property rights. On this account ownership over a thing is constituted by bundling together a set of entitlements. An often cited example of such entitlements would be Tony Honoré’s ‘incidents of ownership’ that “are each constitutive of, but not necessary to, the concept of ownership.”<sup>4</sup> Honoré’s standard incidents are:

- 1) “the right to possess: to have exclusive physical control of a thing, or to have such control as the nature of the thing admits.
- 2) the right to use: the [right to] personal use and enjoyment of the thing owned.
- 3) the right to manage: the right to decide how and by whom the thing owned shall be used.
- 4) the right to income: [the right] to use or occupy a thing ... [or] forgoing personal use of a thing and allowing others to use it for reward.
- 5) the right to capital: the power to alienate the thing and the liberty to consume, waste, or destroy the whole or part of it.
- 6) the right to security: [the right to] look forward to remaining owner indefinitely if he so chooses and he remains solvent.
- 7) the incident of transmissibility: the interest can be transmitted to the holder’s successors and so on *ad infinitum*.
- 8) the right of absence of term: [the right] to continue in the enjoyment of [ownership] forever.
- 9) the duty to prevent harm: uses harmful to other members of society are forbidden.
- 10) liability to execution: liability of the owner’s interest to be taken away from him for debt, either by execution of a judgment or on insolvency.
- 11) the incident of residuary: the existence of B’s lesser interest in a thing is clearly consistent with A’s owning it.”<sup>5</sup>

### 1.1 Income and control rights

Appealing to the bundle of rights theory of ownership and Honoré’s incidents, Jesse Wall has offered a compelling and useful analysis of property law as it applies to human tissues. He argues that the point of ownership in the law is to adjudicate conflicting parties’ claims of entitlement towards an object. Honoré’s incidents of ownership represent a bundle of entitlements that an individual can claim against another in situations of conflict. Accordingly, Wall argues that we must bundle these entitlements together into four specific

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<sup>4</sup> Jesse Wall, “The Legal Status of Body Parts: A Framework,” *Oxford Journal of Legal Studies*, no. 4 (2011): 785.

<sup>5</sup> Geoffrey M. Hodgson, “Editorial Introduction to ‘Ownership’ by A. M. Honoré (1961),” *Journal of Institutional Economics* 9, no. 02 (June 2013): 231–44.

categories – control rights, income rights, derivative rights and structural necessities. The relevant bundles for my discussion here are control and income rights.<sup>6</sup> Wall states that control rights act as “the primary arbitrator over what is to be done with a thing.”<sup>7</sup> The bundle of control rights can be made up of any of the incidents that would facilitate that fact, such as the right to possess, the right to use, or the right to manage.<sup>8</sup>

Wall’s second category of bundled rights are income rights, the content of which is conditional on circumstances surrounding the benefit to be gained through relinquishing a control right in an object, usually determined by market value. Income rights are thereby concerned solely with Honoré’s right to income. Wall gives the example of the sale of a pint of blood to summarize his discussion of incidents of entitlements and bundled categories: “to sell a pint of your blood ... is to relinquish your possession, use and manage interests (control rights) in the blood in exchange for income (an external benefit).”<sup>9</sup> Income rights permit putting a ‘price-tag’ on the object in the transaction of control rights between parties.

Wall argues that each category of ownership functions in a different way in regards to varying context and interests, and so ownership should be understood as a spectrum or as being made up of smaller bundles of entitlements within the larger bundle of ‘ownership’.<sup>10</sup> I adopt Wall’s framework for income and control rights when it comes to human tissue control. The entitlements that make up these bundle categories are what cause most issues when dealing with human tissue use. As I will argue more extensively below, with clearly delineated control and income rights over human tissues we can answer the questions I raised above in Samantha’s diagnostic case.

### *1.2 Two approaches to justifying income and control rights*

While the bundle of rights theory of ownership is useful as a way of delineating an owner’s legal relationship to the things they own and to others, it presupposes a justification for assigning the ownership entitlements that make up those bundles. There are two general justificatory techniques: one stemming from a natural rights perspective and the other from a positive rights perspective. The natural rights justification for ownership states that one expresses oneself as a person through the control of one’s property. The natural rights tradition follows the work of theorists such as John Locke, holding that individuals’ rights of control and income over their property are justified outside of a legal social setting. The main aspect of Locke’s view on property is that one ‘mixes one’s labor’ with objects in the world and thereby creates a right of control over those objects. Property on this view is seen as a normative and not simply legal relation between individual and object.<sup>11</sup>

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<sup>6</sup> Wall includes the right to security, transmissibility, and absence of term within the derivative rights bundle. For my purposes I have included these within control rights generally, as I see them linked to and derived from the right to control.

<sup>7</sup> Wall, “The Legal Status of Body Parts: A Framework,” 790.

<sup>8</sup> *Ibid.*

<sup>9</sup> *Ibid.*, 791.

<sup>10</sup> *Ibid.*

<sup>11</sup> B Björkman and S O Hansson, “Bodily Rights and Property Rights,” *Journal of Medical Ethics* 32, no. 4 (April 2006): 211, <https://doi.org/10.1136/jme.2004.011270>.

On the other hand, for the proponent of positive rights property is understood as a means of achieving one's ends. This position justifies property rights through appealing to their utility in order to bring about a certain state of affairs.<sup>12</sup> Social constructivists employ this instrumental kind of justification, arguing that property rights necessarily exist within a legal social structure. Property rights are thereby a means to promote the goal of that social structure, whether it be facilitating justice, economic productivity, the good life, etc.<sup>13</sup> I will be adopting the positive law perspective, taking the purpose of legal rights as a means to promote human flourishing in society.

### *1.3 Three means of protecting property rules*

Wall adds that in addition to justifying ownership, property rules require protection. He states that it is important to assess trespassory rules in order to protect ownership entitlements. From a legal perspective there are three ways to protect ownership entitlements in an object: property rules, liability rules, and inalienability rules. The difference between these three protections comes down to the circumstances of transfer or interference. Under property rules, transfer is controlled by the market value that determines the conditions of a voluntary transaction between parties. Under liability rules the parties do not determine the value or circumstances of transaction, the state does. Finally, under inalienability rules transfer is forbidden by the state. Property rules and liability rules both impose obligations on persons in relation to owners. However, the two kinds of rules are different in their protections.<sup>14</sup> My argument concerns both property and liability rules. Property rules protect the ownership entitlements an individual has in a particular set of separated human tissues while liability rules protect their interests in relation to the tissues outside of those entitlements.

### *1.4 The bundle of rights*

Wall presses the distinction between the concepts of ownership and property, arguing that equating the terms misrepresents what is distinctive about them. In his view, an ownership entitlement can be protected by property, liability, or inalienability rules. For Wall, the entitlement is a normative relationship one has with an object that is not linked to property law. One ought to enjoy an ownership entitlement in an object as justified by one of the two justificatory frameworks set out above.<sup>15</sup>

While Wall's position on ownership and property is useful in some respects, Björkman and Hansson state that the distinction is less important. They note that "in modern society there exist a vast number of transferable rights to different types of entities"<sup>16</sup> and thereby argue that due to the plethora of these relations, a unification under the institution of property would be helpful. They argue that a considerable benefit to the bundle view is the versatility of property as it applies to human tissues. On the bundle view an individual or group's legal rights to a human tissue can be constructed in a variety of ways depending on

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<sup>12</sup> Wall, "The Legal Status of Body Parts."

<sup>13</sup> B Björkman and S O Hansson, "Bodily Rights and Property Rights."

<sup>14</sup> Wall, "The Legal Status of Body Parts."

<sup>15</sup> *Ibid.*

<sup>16</sup> B Björkman and S O Hansson, "Bodily Rights and Property Rights."

circumstances. They argue that the main focus of this exercise should be the normative issue of determining what that bundle of rights should contain. Whether or not we refer to that bundle as ‘property’, ‘ownership’, or some other term is a secondary concern.<sup>17</sup> I agree with Björkman and Hansson’s focus on the bundle of rights and its normative justification. The bundle is what we reference when informing someone of their liberties when using a biospecimen sample, or adjudicating conflict in cases of improper human tissue use. For the sake of clarity, I will be referring to Honoré’s incidents as ownership entitlements, which are bundled together into categories of ownership protected by property rules.

## 2. Property and the Body

### 2.1 *The whole body*

How can we situate these ownership entitlements in human tissues? A good place to start might be where the tissues originate - the body of the source individual. If we are generally considered self-owners of our whole bodies then we might have a foothold to delineate rights of control and income in our whole bodies, which leads to an easier time conceiving of a transfer of those ownership rights.

Muireann Quigley takes this view by appealing to Honoré’s model of ownership.<sup>18</sup> Quigley supplements Honoré’s incidents of ownership with Wittgenstein’s concept of family resemblance, which holds that examining one characteristic of a group of characteristics will not show what the group has in common. Instead, a network of similarities is what offers insight into the nature of a group of characteristics. Quigley believes that family resemblance allows us to apply Honoré’s incidents of ownership broadly and incorporate the similarities between potential property-objects in addition to their relations to each other when assessing their appropriateness for property status. However, critics have argued without specificity any number of inappropriate uses of human tissues might come about.<sup>19</sup>

In response, Quigley states that the fear that motivates this criticism is unfounded, and that if we agree *prima facie* with self-ownership we can then shift our conversation to the specific instances of ownership of our bodies that may lead to trouble.<sup>20</sup> Quigley notes that Honoré opposed ownership of an individual’s body, stating that “a person does not either ‘own’ or ‘have’ his body or liberty.”<sup>21</sup> Though this is the case, she argues that the variety of uses of our bodies and body parts have grown and become varied such that we must rethink how we understand their treatment. She argues that if we are justified in holding a sufficient number of incidents in our bodies then we can also be self-owners of our bodies, satisfying the criteria for property.<sup>22</sup>

She examines this supposition by investigating each incident in relation to our bodies, keeping in mind the importance of its ties to the other incidents. One example is the right

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<sup>17</sup> *Ibid.*

<sup>18</sup> M. Quigley, “Property and the Body: Applying Honoré,” *Journal of Medical Ethics* 33, no. 11 (November 1, 2007): 631–34, <https://doi.org/10.1136/jme.2006.019083>.

<sup>19</sup> *Ibid.*, 632-633.

<sup>20</sup> *Ibid.*, 634.

<sup>21</sup> *Ibid.*, 632.

<sup>22</sup> *Ibid.*

to income: “With regard to the body, this occurs whenever we go to work and are paid for our labour. More controversially, this can be seen as occurring where an individual sells their body or body parts or products—for example, hair, blood, semen, kidneys.”<sup>23</sup> By establishing this framework with the other incidents Quigley concludes that we have sufficient reason to understand self-ownership in our bodies in a full sense. She states that we may justifiably refer to our bodies as our property and that this has implications for separated human tissues. She notes that while there may be perverse instantiations of her framework in the face of controlling human biospecimen through property regimes, she argues that “a society which truly values individual liberty would not shy away from such consequences.”<sup>24</sup>

I believe Quigley wrongly applies the incidents of ownership to our whole bodies in a few instances, one of which being the aforementioned right to income. She argues that we exercise this ownership right over our bodies when we work for payment or sell our body-parts. The former act misconstrues what the right to income truly is, and the latter moves too quickly.

Recall that Wall importantly explained that in exercising income rights one relinquishes control rights of an object for compensation. To say we relinquish our control rights over our whole bodies when we work for payment is a misunderstanding of the essence of ownership transfer. We maintain control of our bodies when we work, we do not lose our ability to use or manage them. It is true that we have voluntarily committed ourselves to use our bodies in certain ways when we sell our labour to an employer, however that is clearly a different act from relinquishing control rights for reward. We are able to quit work if we wish through the physical act of leaving our work environment. It might be true that this incident applies to body parts, but we cannot say that this is true as a result of the precondition of the incident applying to our whole bodies.

Aside from income rights in our whole bodies, Quigley’s application of control rights to our bodies is also troublesome. Control rights seem more obviously suited to how we use our whole bodies. We enjoy the right to use our bodies how we wish (within reason), manage those uses, and determine which parts of our body we wish to separate. These rights of control align with the liberties we protect in society more generally. There exist equivalents to control rights through constitutionally protected rights such as the right to bodily integrity and freedom of movement. Our whole inhabited bodies have a large set of legal protections through both statute and case law. There are crimes of battery and assault when dealing with non-consensual bodily invasions as well. For my purposes here, I do not wish to weigh in on whether or not control rights in our whole bodies are sufficient to establish self-ownership. The relevant question in regards to ownership rights in our whole inhabited bodies is which people in society should we allow to claim those control rights.

At first glance it seems that the only individuals who should be allowed to claim control rights in our whole bodies are ourselves. We cement the equivalent to control rights of our whole bodies in our constitutions through fundamental freedoms and protections. Both those rights and the control rights Quigley advocates are focused on the individual.

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<sup>23</sup> *Ibid*, 633.

<sup>24</sup> *Ibid*, 634.

Ostensibly, the same values that justify the constitutional rights and protections (autonomy, human dignity, or others) justify Quigley’s proposed control rights in our whole bodies. They function in the same fashion. However, the constitutional rights and protections apply to individuals only. You do not enjoy my freedom of movement right; that right only applies to me in reference to my body. The same should be said for control rights in our whole bodies. The only individual who should normatively be allowed to enjoy control rights in my whole body is myself.

One perverse instantiation of applying property law to our whole bodies would be that those entitlements could be transferred to others, allowing them ownership over our whole bodies. In reference to control rights such as the right to possess and use, Quigley argues that at different times in our lives we enjoy varying degrees of these incidents in our whole bodies. For example, when we are young we are subject to the will of our parents, or we allow others to use our bodies for enjoyment (with our consent). She argues that if there are issues with these control rights in our whole bodies we can nevertheless get around these troubling circumstances with proper regulations and safeguards. Additionally, by appealing to Wittgenstein family resemblance Quigley can surmount these perverse instantiations of apply property theory to our whole bodies – not all incidents need apply in every case. She thereby states that “the theorist who is minded to reject self-ownership because of some of the radical extensions mentioned earlier—such as the sale of organs, or slavery— can still embrace the conception of self-ownership.”<sup>25</sup>

While Quigley may be correct, I am dealing with just these radical extensions in my discussion. It is important to mark the various ways that property theory can apply to our bodies and body parts. Though I disagree with her, it might be true that we are self-owners in the ways Quigley outlines. However, the issues that arise in my discussion are with the transfer of these ownership rights. As property law applies to our whole bodies we can see that the only individuals who should morally enjoy full control rights in our inhabited bodies are ourselves, and to transmit some of those rights would be immoral. I might enjoy a control right to use and possess my whole body, however allowing others to do so would be at least objectification and at worst slavery. I am unsure how simply adding safeguards and regulation would surmount this ethical obstacle.

## 2.2 *Body parts*

While there are issues with the transmissibility of ownership incidents in our whole bodies, I argue that our body parts do not fall victim to these criticisms. Simon Douglas marks the importance of property rights’ ‘exigibility’, which refers to the number of individuals a right can be enforced against. Douglas states that property rights are exigible against all other persons: “If A has a property right, such as freehold of land, then his right would be enforceable not just against B, but all other third parties (C,D,E ... etc): If B,C,D or E walk across A’s land without A’s consent, A will have a claim against each individual.”<sup>26</sup> In addition to property rights’ exigibility against the world, Douglas mentions

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<sup>25</sup> *Ibid*, 633.

<sup>26</sup> Simon Douglas, “The Argument for Property Rights in Body Parts: Scarcity of Resources,” *Journal of Medical Ethics*, 2012, 23.

their second important characteristic; that they are tied to physical things. They are ‘thing-related’, which is key to applying property rights as they are currently understood. This is because the rules of property presuppose the existence of physical things. The kinds of rights of control that property rights offer have been determined to preside over those physical things (he argues that intellectual property rights therefore require new control rules to be created).<sup>27</sup>

Contrary to Quigley, Douglas argues that we cannot enjoy property rights over our own bodies because they are not external to us. He states that property rights require ‘separability’, where the owned thing is separate from the owner. In order for the rules of property rights to be applied to one’s body the rules must be changed in order to fit with this special set of circumstances.<sup>28</sup>

These points do not directly contradict Quigley’s position though. She advocates re-conceiving of current property law. Honoré argued that our whole bodies are not ‘things’ in a legal sense and characterizing our whole bodies as such would interfere with human freedom.<sup>29</sup> Though Quigley recognizes this statement, if we conceive of our bodies as property in the way she asks us, our whole bodies would be ‘things’ that are exigible against the world but are not separated. Even if we can surmount the conceptual obstacle of conceiving of our whole bodies as ‘things’, I believe the inseparability of our whole bodies from our sense of self is more damaging. On Quigley’s model the owner and owned would be one entity. Property law and Honoré’s incidents are well equipped to deal with circumstances where owned objects are external to both the owner and others in the world. However, in this instance that would not be the case.

Human tissues are physical things and are therefore *prima facie* amenable to being the subjects of property rights without the worrisome normative complications considered above that trouble treating whole bodies as property. The rights associated with separated human tissues as things can be exigible against the world. Additionally, human tissues can be the objects of possession, transfer, acquisition, and a number of other property-related acts.<sup>30</sup> Assigning separated biospecimen property status also does not fall victim to the inseparability critique. Owner and owned are not the same entity when it comes to separated human tissues. A criticism of self-ownership I leveled above was that ownership entitlements become redundant (from the perspective of positive law). However, these redundancies exist to a far lesser extent in the context of separated human tissues. The law protects some forms of separated biospecimen such as organ donation - and ownership rights in these contexts might be inappropriate. However, rights of control and income in separated human tissues would be beneficial towards the goal of facilitating the interactions between individuals in society in the majority of contexts. Those who enjoy property rights in separated tissues will understand their legally justified liberties to use the tissues as set out by their particular bundle of control and income rights, while at the same time setting legal obligations on others in relation to what is now considered their property.

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<sup>27</sup> *Ibid*, 23.

<sup>28</sup> *Ibid*, 24.

<sup>29</sup> Hodgson, “Editorial Introduction to ‘Ownership’ by A. M. Honoré (1961).”

<sup>30</sup> Douglas, “The Argument for Property Rights in Body Parts.”

For example, in Samantha’s diagnostic case LifeLabs might be justified in enjoying control rights such as the right to possess and manage but not income rights, thereby limiting the ways in which LifeLabs can legally use Samantha’s tissues. If LifeLabs steps outside its rights of use with Samantha’s tissues she can hold them accountable. I will deal with how we should arrive at the justification for this and other arrangements of control and income rights below. For now, I hope to make clear that separated tissues do not fall victim to the same criticisms I made of whole-bodies above. That is not to say there are no issues with assigning property rights over human tissues. However, I argue that the issues that arise with ownership of separated biospecimen are normative and not conceptual. They deal with concerns surrounding important normative considerations such as consent, privacy, and commercial exploitation. Theoretically, there is no conceptual issue with assigning ownership entitlements to human tissues.

### 3. Tissues as Property-Objects

How might we apply property rules to human tissues? Rohan Hardcastle has provided an in-depth review of different case law and statutes from a variety of countries where excised biospecimen control has come under question. He offers an argument for how human tissues are transformed into objects subject to property rights, offering three circumstances where this can take place: “(1) work or skill performed on biological materials; (2) detachment of biological materials *per se*; and (3) detachment of biological materials coupled with an intention to use such materials as property.”<sup>31</sup> Because I take (2) to be a necessary condition for considering biospecimen as property I will examine this criterion first.

#### 3.1 Separation and bodily integrity as justification for property rights in biospecimen

Hardcastle argues that detachment, or “the physical separation of biological materials from a human body,”<sup>32</sup> can transform human tissues into things that are capable of being property. Arguing in line with my position above, Hardcastle states that human bodies should not be considered ‘things’ because they are intrinsically tied to a person. He states that tissues are no longer part of the intrinsic nature of persons upon separation from the whole body – making them contenders for property rights.<sup>33</sup>

He then argues that while excised tissues are no longer part of the source individual, as an extension of the right to bodily integrity it is important to recognize their claim to own those tissues at the moment of separation. To do otherwise would be inconsistent with the right to bodily integrity.

He states that the right to bodily integrity is enforceable generally against society as it applies to our inhabited bodies, however separated biospecimen do not fall under the jurisdiction of this right. He argues that property rights allow source individuals to maintain rights over their separated tissues that they enjoy when their bodies are whole. Hardcastle believes a space exists in the current regulations of human tissues where no legal guidance

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<sup>31</sup> Rohan Hardcastle, *Law and the Human Body: Property Rights, Ownership and Control*, 1 edition (Oxford; Portland: Hart Publishing, 2009), 126.

<sup>32</sup> *Ibid*, 145.

<sup>33</sup> *Ibid*, 147.



is offered in terms of their control. Currently biological materials are available to whomever possess them. Finding mere possession insufficient, he argues that “if the creation of property rights in separated biological materials can be viewed as an extension of the right to bodily integrity, then it follows that the right should also be allocated to the source.”<sup>34</sup> If the right to bodily integrity is what forms the normative justification for establishing property rights in separated human tissues it would be inconsistent to vest property rights in anyone else.

Separation is important, though I do not believe Hardcastle’s detachment principle offers us the full picture. Hardcastle rightfully fills the vacuum where the law has not yet provided answers on tissue use with property law. However, the right to bodily integrity does not clearly justify this move. It is unclear whether the normative principles that underpin the right to bodily integrity can be used to justify ownership of tissues once separated in the way Hardcastle believes they can. The right to bodily integrity is justified by the importance of non-interference by those we share physical space with. In order for me to realize my life goals I require non-interference by those around me. It is one thing to say that if I am physically restrained I cannot actualize my life plans in the ways I wish, but it is another thing to say that if my separated biospecimen is restrained I am in a similar position. Physical harm is both painful and debilitating. We guarantee people a right to be free from non-consensual bodily intrusion in order to protect them from that physical harm. Sensation does not follow with our tissues wherever they go, and so I argue that the physical detachment of tissues comes with a relevant amount of normative detachment. It is not clear that the principles that justify our claim to the right to bodily integrity serve the same purpose in reference to our separated tissues.

### *3.2 Work and skill*

Hardcastle’s argument for the utility of work and skill as a principle justifying property claims in tissues appeals to both the Lockean conception of property as well as the doctrine of specification. Specification refers to the manufacture of new objects such as the creation of wine from grapes. With a sufficient amount of work and specification done on excised biospecimen, Hardcastle argues that there would be good reasons why we should vest property rights over those tissues in the laborer. He states that the labourer need not have an intention to create a new thing under the specification doctrine, and that only two questions are relevant: “whose materials were used, and who was the maker?”<sup>35</sup> In the cases I am discussing here the answers to the latter question are often self-evident, while the former refers to the crux of the debate. Though he believes the specification doctrine is useful, Hardcastle argues that in most cases there is not a sufficient level of specification done through work and skill on biospecimen for them to be deemed a new thing. As a general principle he believes there is too much variance in the kinds of work done on biospecimen for this principle to be effective in determining and assigning ownership

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<sup>34</sup> *Ibid*, 149.

<sup>35</sup> *Ibid*, 141.

claims. Instead, he appeals to the aforementioned doctrine of separation and forthcoming doctrine of intention.<sup>36</sup>

I agree with Hardcastle's analysis. Specification should lead us to believe that through labour a worker has created a new object. If anyone is to deserve property claims in that new object it seems fitting to be the one who 'created' it. This leads to a number of individuals who would potentially have property rights claims in diagnostic and other cases-types. In regards to Samantha's case, the employee who administers the blood test, the courier who handles the tissues, the technician who tests the biospecimen, the doctor who reads the test and diagnoses any ailments, and possibly even Samantha herself all perform some sort of labor on or in relation to the tissues. If labour itself is to be a sufficient condition to vest property claims in excised biospecimen, we might run into issues in delineating who has the strongest claim. Specification only aids us slightly. If we can prove a sufficient amount of specification has been done on a set of tissues then we would be able to assign property rights to its labourers. However, what determines 'a sufficient amount of specification' is unclear. In Samantha's case, is the act of testing tissues a sufficient amount of specification? What about the couriating of the tissues between facilities? If tissues are altered slightly in the testing process, should we consider them sufficiently specified? Each of these acts is unlikely to provide sufficient specification. So, it seems correct that Hardcastle does not believe work and skill is sufficient as a doctrine to establishing property rights in human tissues in all cases. I agree that work and skill is useful as a starting-point to delineate who the relevant contenders are for property claims in a given set of human tissues, and that it might transform property-objects moving past the point of initial separation from the source, however more needs to be said about whose claim is most justified upon separation.

### *3.3 Intention*

Finally, Hardcastle supplements work and skill with intentionality, adding a person's intention to use the material as property as an important consideration when applying property rights to human tissues. Hardcastle believes that at the point of excision an individual can consent both to their tissues being excised and to those tissues being used as property. This would form an intention on their part, and this intention should be respected. In cases where an individual does not form this intention Hardcastle argues that it is unclear whether tissues can be considered property-objects under the law. However, through an appeal to the detachment principle he argues that in cases where an intention is not apparent property rights should remain with the source individual. This creates the further principle that, absent an intention by the source to establish property claims in another party, property rights of separated tissues are always assigned to sources by default. This is justified through an appeal to the right of bodily integrity, and Hardcastle argues that it continues to be true in cases where an opposing party forms an intention to use a source's tissues and detaches them without their consent, or in cases where no intention by either party is present.<sup>37</sup>

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<sup>36</sup> *Ibid.*

<sup>37</sup> *Ibid.*, 150-155.

I do not believe Hardcastle has provided sufficient justification for defaulting property rights in source individuals for similar reasons to why I criticize his appeal to the right of bodily integrity above in the detachment principle. It is not clear that the right to bodily integrity encompasses separated human tissues. However, intentions are a key normative consideration when assigning property rights to a party upon separation from a source. Tissues are in most cases separated from their sources for a reason or purpose. The intentions for tissue excision I deal with in this chapter are diagnostic intentions, however there are a variety of other purposes that tissues are used for. Transparency is beneficial to facilitate interactions between people in society. It is thereby important that all parties involved in tissue use are aware of at least the common intention to use those tissues, and that they understand and consent to the allocation of property rights as a result of the procedure at hand. What I mean by ‘common intention’ is the shared (often implicit) intent by all parties for tissue use – the purpose of excision. In diagnostic cases each individual understands that at the very least the main common intention to excise biospecimen is for diagnostic purposes. Though there may be other secondary intentions for tissue use by any of the parties involved, the main common intention should be understood by all parties. Common intentions do not ground rights-claims in every case as a general principle, however I argue that they are too important to the transactional nature of biospecimen use to ignore.

#### **4. The Importance of Value**

I add a fourth consideration to Hardcastle’s framework for delineating property rights in human tissues at the time of separation: to whom is a tissue the most valuable? Moving forward we can assess any case where human tissues are excised and used on the following grounds:

- (1) Have the human tissues been excised or detached *per se*?
- (2) Is a sufficiently specified amount of work or skill being performed on those tissues either at the point of excision or afterwards?
- (3) What are the relevant intentions to use the tissues? Is one of those intentions to use them as property?
- (4) How and to whom are the tissues most valuable?

(1) – (3) rely draw from Hardcastle’s framework explicated above. Due to my criticisms of his model I have added (4). Human tissues are valuable in a variety of ways. I argue that conceiving of human tissues as objects of value facilitates human flourishing. There are a variety of ways we regulate and protect this social fact. In addition to property laws we have laws of protecting free speech and free movement. These facilitate individuals’ ability to flourish by carving out space in society that guarantees their free actions. This point does not only apply to individuals and groups of individuals though. In order for a communal sense of the good in society to be actualized (where this ‘communal sense’ comes about through a sort of overlapping of different personal senses of the good) society requires a means to utilize objects of value. Conceiving of human tissues as objects that can be owned in both a moral and legal sense (the moral sense justifying the legal sense) facilitates people and groups’ abilities to further their goals and life plans through their chosen use of the tissues they deem valuable. This is what I take to be the main justification for property

theory's utility in regulating biospecimen use. We can understand how an individual or group values their tissues through examining their historical, cultural political, etc. situation in a society, alongside simply asking them what they feel their relation is to their tissues.

I argue that Harcastle's framework above represents three ways in which tissues' value justifies assigning a particular scheme of ownership entitlements. The detachment principle frames tissues as valuable in terms of their connection to the source, linked through the principle of bodily integrity. Through the work and skill principle we can understand tissues as objects of value to be transformed in the hands of a capable individual or group. Finally, tissues are valuable in a more subjective way in terms of their utility in furthering individual and group intentions. We can see how each of the principles justifying property right allocations above can be encompassed within the general sphere of tissue-value. I argue that if we tease out the most weighty or meaningful ways in which tissues are valuable in diagnostic and other case types we are justified not only in utilizing property law as a means to control human tissue use, but also granularly assigning property rights in separated biospecimen. The fact that tissues are valuable is what justifies us using property law to begin with, while the competing ways in which tissues are valuable offers us reasons for assigning particular arrangements of property entitlements.

At first the term 'value' as I am using it may seem vague, however over the coming chapters I hope to solidify its place in my framework through reference to cases that exemplify the importance of the concept. One way that tissues can be more or less valuable to individuals or groups is their variable sensitivity. Lisa Parker offers a useful analysis of tissue sensitivity. On her model, ordinary human tissues are "the majority of excess surgical tissue."<sup>38</sup> Alternatively, sensitive tissues are those that are outside of this category. She offers examples of sensitive tissues that she believes to be relatively uncontroversial: "large organs, particularly the heart, brain and reproductive organs; large body parts such as the head and limbs, gametes; aborted fetal tissue and genetic tissue [and] cadaveric tissue."<sup>39</sup> She notes that the classification of tissues as ordinary or sensitive is not binary but instead on a spectrum. She states where certain tissues fall on the spectrum is likely to change between cultures and over time.<sup>40</sup> Keeping this spectrum in mind, it seems clear that more sensitive tissues are likely to be more valuable.

## **5. Applying the Framework**

### *5.1 Samantha's case*

As I mentioned above, Samantha's tissues have been separated without the intention to use them as property. They will also have minor work done on them that is not sufficiently specified. So, we have examined her case in light of (1) – (3) but still have no answer as to who deserves property rights upon separation. Samantha's blood samples are ordinary tissues being used for the purpose of diagnosis. Additionally, Samantha has not expressed an intention to control or use her tissues after her ailments are diagnosed. Though this is the case, it is clear her tissues are valuable to her insofar as they are necessary for this

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<sup>38</sup> L. Parker, "Using Human Tissue: When Do We Need Consent?," *Journal of Medical Ethics* 37, no. 12 (December 1, 2011): 759.

<sup>39</sup> *Ibid*, 759.

<sup>40</sup> *Ibid*, 760.

diagnosis. LifeLabs and its employees also claim value in the tissues they test. For the business to succeed it must provide the service to all its patients. For a similar reason the doctor who will diagnose the tested tissues finds value in them. Both LifeLabs and Samantha's doctor have reputations to uphold. Mishandling the biospecimen in question would likely damage this reputation. These are only a few of the ways in which the tissues are valuable to each party.

There are good arguments for why tissues are *most* valuable to each of the relevant parties in Samantha's case. In order to use value to justify assigning ownership entitlements we must determine how we can promote the aforementioned personal and societal goods that value facilitates. In order to facilitate Samantha's moral agency and responsibility in relation to the tissues I argue it is important to assign her property rights in them upon separation.

The diagnostic procedure is focused around Samantha and her wellbeing. She thereby not only has a strong value claim in the tissues, but the common intention behind separation is for her benefit. It is clear that the normative justifications for assigning property rights to any of the parties involved weigh heavier on Samantha's side. Upon separation we should consider her the owner of her tissues. Pursuant to an agreement between her and LifeLabs before the tissues are drawn, Samantha can actualize her life plans in the way she wants. She can contemplate how she would like her tissues to be used and then determine the transfer of control and income rights in the way she believes is best. Both control and income rights are important here. Samantha may feel strongly that no one should profit off of her tissues, and if a situation arises where this is a possibility she may refrain from allowing her tissues to be taken in the first place. This is why assigning her income rights upon separation is equally as important as control rights. The value that justifies her control and income right claim is the importance of facilitating her moral agency in a procedure that is focused around her well-being. She can determine how her tissues are used through a conversation with LifeLabs in the consent process. Importantly, any issues that arise can be adjudicated through reference to the transfer of control and income rights.

### *5.2 Control and income rights*

I advocate a context-based assignment of ownership entitlements whenever we deal with separated biospecimen. However, this may end up burdensome and impractical. It is thereby useful to note the default assignment of ownership rights in separated tissues in easy cases. For diagnostic cases, I argue the default position is to assign complete ownership and income rights to sources. This is because the main way in which tissues are valuable in diagnostic case-types is for the procedure of diagnosis and treatment. That being the case, the majority of control should be vested in the source. Their well-being forms the locus of common intent for tissue use. I argue this is sufficient to ground initially assigning them property rights in their biospecimen upon separation.

Having good justification for assigning property rights in the tissues to Samantha at the point of separation allows us to answer the difficult questions posed above. How control and income rights are distributed will change Samantha's relationship to her tissues moving forward. Samantha might not care very much about control or income rights in her tissues and thereby freely consents to their full transfer to LifeLabs upon separation. On the other

hand, before excision Samantha can set out an agreement with LifeLabs – knowing that she will be awarded property rights upon excision – to maintain some control or income rights in the tissues moving forward. She will have to relinquish the right to possess and use the tissues in order for LifeLabs to offer the benefit of diagnosis to her. However, she can retain the right to manage and transmit the tissues, ensuring LifeLabs and their technicians are the only individuals who are allowed to handle her tissues. Additionally, she might maintain the right to security and capital, ensuring LifeLabs does not destroy the tissues without her knowledge or consent. LifeLabs and her doctor would act as stewards over her property, claiming limited control rights. Additionally, Samantha could maintain income rights. This would bar LifeLabs from conducting further profit-related research on her tissues. If they did such research Samantha could justifiably request compensation from profits gained.

Keeping the transactional nature of right-transfer in mind, we can now offer more direct answers to the questions posed above:

- What if she has a change of heart and asks for the tissues to be returned to her? Does Samantha have a right to make such a request at any time?

If Samantha has maintained the relevant control rights in her tissues (such as the right to manage or capital), then she can seek remedy for the misuse or damaging of her biospecimen or request they are returned to her at any time. Otherwise, she has consensually relinquished these rights and cannot hold LifeLabs accountable in these ways.

- If LifeLabs would like to sell the excess or remainder of the tissues after tests are complete, do they have a right to do so?

Samantha must determine whether or not she wishes to bar her tissues from being priced and sold. LifeLabs can create a market in the tissues if Samantha transfers income rights to them upon separation. In the following chapters I will deal with the normative considerations surrounding the potentially exploitative consequence of creating markets in tissues. For now, we have a simple answer to this question. If income rights are transferred then LifeLabs is justified in seeking profit through the sale of the tissues.

These are not the only relevant normative considerations when dealing with tissue use, and as cases become more complicated so must the framework I advocate here. However, I hope to have shown through my analysis of her case that property rules promote Samantha's ability to develop her sense of a good life. She can choose what rights of control and income each party that interacts with her tissues enjoy before excision. This also holds Samantha more accountable for the ways in which her tissues are used. While she is able to come to an agreement with each party in regards to who owns and controls her tissues, this is also a responsibility she must take seriously.

## **6. Consent**

### *6.1 The Dilemma*

Consent in medical practice offers normative circumstances that property theory is ill-equipped to deal with. Conceiving of tissues as property brings up issues in the practice of obtaining consent. Hardcastle extensively examines the Human Tissue Act of 2004, which is a UK statute that regulates the importance of informed consent (among other principles) when extracting biospecimen. It deals with setting the scope of informed consent, offering

guidance on who consent should be obtained from, what can be done once informed consent has been obtained, what excised biospecimen count as ‘relevant material’, and criminal offences that occur when tissues are used for purposes outside the consent of the source individual. The Human Tissue Act also offers exceptions to its requirements, which deal with ethical approval from regulations outside the act, uses of tissues that have not been consented to but will positively impact the health of the source individual, and other administrative exceptions. Interestingly, the act prohibits commercial dealings in human tissues and it conceives of biological materials as property upon separation.<sup>41</sup>

In my view, if we utilize property law to control human tissues there are instances where individuals’ ongoing consent is not necessary. I submit that consent is tied to control rights. It makes little sense to say that an individual can consent, or should be asked to consent, to the use of an object they have no justified ownership entitlements of control in. Control rights are thereby a necessary condition for ongoing consent rights. If this is true, there is a dichotomy between two important concerns: ownership rights (specifically those that deal with control) and informed consent. A purely property-based framework would call into question individuals’ agency in their relationships with medical professionals and institutions through its justified disregard for informed consent in some cases. In cases where an individual no longer has claim to any incidents of ownership in their excised biospecimen, their claim to be continually consented in the use of those tissues is empty. However, some might contend that this characterization, if true, leads to an unwanted outcome. If individual consent is substantially diluted, the practice of medical treatment and research may be called into question.

Take Samantha’s diagnostic-type case. Through regulating human tissues under the kind of property regime I have proposed, Samantha obtains property rights upon separation. Alongside consenting to the procedure of piercing her body and drawing her blood Samantha was informed of and consented to a particular arrangement of control and income right transfer. Recall that the framework I am arguing for presupposes this interaction before separation. Samantha will have been told that upon separation she will be the owner of her tissues, and she will be required to relinquish certain ownership entitlements in order for the procedure to take place. In cases where she maintains sufficient control-oriented incidents to form control rights in her tissues consent is not an issue, she satisfies the necessary condition. However, the aforementioned issues arise when she transfers all control rights in her tissues to LifeLabs. In this situation Samantha no longer has a property right claim to the tissues and it makes little sense to require her *ongoing* consent for tissue use outside of the original purpose. Is this problematic?

## 6.2 *Ongoing consent*

It will be useful to examine closely what consent means and why it is important so that we can find the most appropriate solution to these unwanted normative circumstances. Though some theories of consent are justified through concerns of autonomy, O’Neill offers a different characterization. O’Neill argues that it is because we are obligated not to deceive or wrongly coerce others that informed consent is key. She thereby emphasizes that

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<sup>41</sup> Hardcastle, "Law and the Human Body."

consent must be informed, stating that “consent is a propositional attitude, given in the first instance not to another’s action, but to a proposition describing the action to be performed.”<sup>42</sup> O’Neill notes that individuals need not consent to every specific aspect of a medical procedure. Consent as a proposition includes all aspects of the practice being consented to that might be entailed or logically equivalent to the practice. She argues that in order to ensure valid informed consent, a doctor need not create a list of every possible permutation and result of a practice. Consent may still be opaque while the intricacies of a procedure are not made explicit. She states that the aim when seeking consent should be to ensure the consenting individual has not been deceived. O’Neill argues that sufficient and extendable information along with the ability to rescind one’s consent are key for that consent to be informed and ethically sound.<sup>43</sup>

On the other hand, Collin O’Neil<sup>44</sup> argues for a view that narrows the broader idea of informed consent that O’Neill puts forward. O’Neil stresses that the act of consenting is truly about waiving one’s rights to something. That being the case, for similar reasons to O’Neill, O’Neil argues that consent must be informed. One must be aware of which relevant rights one is waiving when offering consent.<sup>45</sup> For the purposes of my discussion, the relevant rights one might waive would be those pertaining to control rights, income rights, and rights freeing oneself from bodily intervention. O’Neil brings up the point that sometimes bodily interventions benefit us and other times they are instrumental to benefit others. Being sufficiently informed about this process is key to avoid exploitation. O’Neil concludes his discussion by arguing that, “explicit consent to treatment plus merely presumed consent to research does not suffice to waive the right against being intervened upon for the benefit of others, because successfully waiving this distinct right requires actually knowing that this is the right one needs to waive.”<sup>46</sup>

I agree with both O’Neill and O’Neil about the importance of informed consent at the outset. If an individual is not informed at the outset of the potential uses of their excised biospecimen then their trust is likely to be eroded. The issue is *ongoing* consent when ownership entitlements have been fully transferred. If an individual is sufficiently informed of the ownership rights they are waiving through the transfer of their human tissues to a medical professional or organization, it is difficult to see why they should be continually consented into the future. If we understand consent as a propositional attitude, it might even be sufficient to have an individual agree to full control right transfer without going into too much detail about their nuanced legal relationship with their tissues. So long as they understand that upon separation they retain a property right to their tissues, and they decide to waive and/or transferred their rights of control and income, informed consent can be present.

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<sup>42</sup> O’Neill, “Some Limits of Informed Consent,” *Journal of Medical Ethics* 29, no. 1 (February 1, 2003):5.

<sup>43</sup> *Ibid*, 4-7.

<sup>44</sup> C. O’Neil not to be confused with O. O’Neill.

<sup>45</sup> Collin O’Neil, “Consent and Rights in Comparative Effectiveness Trials,” *American Medical Association Journal of Ethics*, 2014, 6.

<sup>46</sup> *Ibid*, 6.



If Samantha transfers her right to use her tissues then that liberty belongs to LifeLabs. Conceiving of tissues as property that allows for transferable rights of control and income crystalizes the consent relationship. If Samantha would like to maintain ongoing consent for particular uses of her tissue she must make this clear at the outset. We can then examine the transfer of rights when dealing with ongoing consent. For some this may be a scary thought. I would urge these people to think carefully on my analysis of tissues' value above, and the benefits of property rules for regulating the control of those tissues.

When one offers up one's tissues to a medical professional one exercises one's moral agency and autonomy, recognizing the value one sees in one's tissues, and nevertheless relinquishing ownership entitlements. This puts more responsibility in the hands of the individual to take their relationship to their tissues seriously. If that means supplementing their relationship with medical professionals with additional contracts, so be it. In the end I argue that the individual and society are both better off with the framework I have set out, where the options to use tissues are clearly defined.

### **Conclusion**

I began by offering Samantha's diagnostic case-type. Upon posing two sets of difficult questions that arise from her case, I argued that property regimes can resolve these issues. I also showed that attempts to assign property status to our whole bodies are misguided and poorly deal with the important issue of ownership transfer. I then argued that this issue does not arise when dealing with separated biospecimen. Through an analysis of and an application of Hardcastle's framework, I showed how property regimes are useful to regulate human tissue control. I added the important point that human tissues are valuable, and that in hard cases we should determine who deserves property rights based on an analysis of both value and intention. Finally, I showed how consent will look quite different on the model I am proposing for human tissue regulation. My analysis here is missing an important piece though. There are times where property regimes might lead to unwanted normative circumstances that are not accounted for by simply referencing ownership entitlements. I believe property regimes must be supplemented by liability rules in these cases. I will examine this necessity in the next chapter.

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## **Chapter 2: Medical Research and the Importance of Liability Rules**

In this chapter I will discuss two more case-types, the research and hybrid case-types. In doing so I offer examples that fall within each case-type and apply the same limited-property framework I did in the previous chapter. In addition, I will examine a criticism of characterizing human tissues as property-objects that concerns commercial exploitation. I will show how two positions that levy this critique are flawed, and that supplementing property rules with liability rules deals with the issues those criticisms take seriously.

### **1. The Research Case-type**

Biospecimen are excised and collected for a number of medical research endeavors. In these cases, a research participant might voluntarily offer up their human tissues for a study in exchange for benefit. All scientific studies involving human participants must offer some form of benefit to the participant, though that benefit is not required to be part of the purpose of the study itself. Though some studies aim to cure the ailments of their participants through the creation of new techniques or medicines, this is not necessarily the case with all medical studies. When it is the case, the study might be said to muddle the line between clinical care and medical research. Cheung et al. have provided a test to help delineate between diagnostic and research tissue. They refer to this test as the ‘but for’ test. In the ‘but for’ test, we ask “But for study X, would this tissue (or this amount of tissue) have been excised from this individual?” If the answer to this question is ‘no’ then the tissues should be considered research tissues. Otherwise, any form of positive answer to the ‘but for’ test leads us to characterize the tissues in question as diagnostic.<sup>47</sup>

The research case-type has a few key characteristics: (1) an individual consensually offers their tissues for medical research purposes, (2) those tissues are used for the *main* purpose of completing the research endeavor, (3) the research endeavor itself is ethically sound. The possibility of commercial exploitation becomes apparent when dealing with the profits gained through research done on an individual’s excised biospecimen. Income rights will be key when dealing with these cases in addition to control rights.

While (1) and (2) are important for reasons explained in diagnostic cases, I have added (3) when dealing with the research case-type specifically. Research endeavors are less clearly ethical than diagnostic endeavors. To conduct proper scientific research, studies must most often undergo intense ethics board approval. I add this characteristic to the research case-type in order to narrow the scope of my discussion. I aim to assess the limited-property framework against the various case-types on offer. In order to do so, I believe limiting the kinds of research endeavors that are open to analysis is important. It would be inappropriate to discuss the limited-property model’s suitability against unethical research studies because those studies are unsuitable to begin with. To allow these cases into the discussion would muddy the water and make assessing whether the limited-property framework is suitable much more difficult. So, (3) is a pre-condition for assigning property rights to individuals in research-type cases.

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<sup>47</sup> Carol C. Cheung, Bella R. Martin, and Sylvia L. Asa, “Defining Diagnostic Tissue in the Era of Personalized Medicine,” *CMAJ: Canadian Medical Association Journal* 185, no. 2 (February 5, 2013)

An example of a research case involving excised biospecimen is the Havasupai tribe's case. Between 1990 and 1994 a group of researchers from Arizona State University collected DNA samples from the Havasupai people, an American Indian tribe located in the Grand Canyon in Arizona. The original intent of the tissue collection was to test for type two diabetes within the Havasupai tribe, to which the group consented. However, the researchers from Arizona State University took those DNA samples and tested them for a variety of other purposes, such as schizophrenia, migration, and inbreeding. These tests were neither disclosed to the Havasupai nor were the tribe's research participants asked to consent to the additional research use of their tissues. Acting as a sovereign entity, the Havasupai sued the researchers at Arizona State University, and they settled out-of-court with a compensation agreement of \$700,000 and the return of their DNA samples. While the Havasupai tribe's case has been publicized and debated in both the mainstream media and academic settings, the fact that the case was settled out-of-court offers little closure on the various issues it brings up.<sup>48</sup>

There is no judicial decision to look to for guidance on the ethical and legal considerations at hand here. However, I believe it is an interesting example of the research case-type. The members of the Havasupai were consented, though possibly not as robustly as would have been required. Additionally, their tissues were used for purposes outside of the main purpose of the study. Finally, there is little evidence to show the original study's design was unethical. The main purpose of the study was clear to the Havasupai. It is the fact that the researchers went outside the study's design that brings up ethical issues. While I believe these points are valid, it stands that the three circumstances of research case-types have only been minimally – yet sufficiently - satisfied. The Havasupai's case fits within the general research case-type.

## **2. Ownership in Research Case-types**

How might we recognize ownership rights in excised biospecimen in research case-types? In answering this question we must first determine the ways in which tissues are separated, and then assess to whom and how tissues are valuable.

### *2.1 Have the human tissues been excised or detached per se?*

In the case of the Havasupai, the Arizona State University researchers would have been required to excise and collect the tissues from the Havasupai research participants in order to test them. So, the precondition of separation is apparent. Should Hardcastle's detachment principle justify the Havasupai's property claim in their excised biospecimen? I do not think that the facts of this case change it sufficiently to give us good reason to believe the principle applies more strongly. Hardcastle's reliance on the right to bodily integrity to justify property claims in the sources of tissues upon separation runs into the same issues here as I mentioned in the previous chapter. So, like in diagnostic cases, separation is a precondition for property rights but not sufficient in itself to ground them.

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<sup>48</sup> Nanibaa' A. Garrison and Mildred K. Cho, "Awareness and Acceptable Practices: IRB and Researcher Reflections on the Havasupai Lawsuit," *AJOB Primary Research* 4, no. 4 (October 2013): 55–63.

## 2.2 *How and to whom are the tissues most valuable?*

Once tissues have come into their possession, research institutions can conduct a wide array of studies and analyses towards the advancement of the scientific field of medicine. That being said, these researchers will receive a benefit through the use of their participants' excised biospecimen – namely the advancement of their own career or their institution's reputation. Their motives are not solely altruistic. In the research context we can say that scientists have a general interest in the control of the human tissues they work with for both their own betterment and the betterment of the fields they work in.

A similar point can be made for researchers in the corporate field. Not all research done on human tissues is for academic purposes. Pharmaceutical companies, biotechnology companies, and other corporations like them use human tissues for research to grow their profits through the development of new drugs and technologies. While I am sure these companies will argue they offer a benefit to society by creating medical interventions, their altruistic goals fall far lower on their list of priorities in comparison to the academic research field. For commercial organizations, their interests in controlling the human tissues they collect are to turn a profit. I would like to make clear; I do not wish to portray an anti-corporate bias here. While it is important that we understand that corporations are profit-motivated, they also offer society and the international community a considerable benefit through their work. When dealing with these interests Imogen Goold notes, "Without investment from the private sector many drugs and therapeutic agents would not have been developed and would not be available for treatment."<sup>49</sup>

It is likely that factors such as rarity of tissues, importance of tissues to the human body, profitability of tissues, among others will determine the specificity of an organization's interests in a given type of biospecimen. A sensitive tissue such as a human kidney is likely more valuable to a research institution than ordinary tissue such as hair samples.<sup>50</sup> In addition to her analysis of ordinary and sensitive tissues, Parker adds two further categories in regards to research contexts with the same names: ordinary and sensitive. On her framework we can analyze tissues in both an ordinary/sensitive tissue context as well as an ordinary/sensitive research context. She states that ordinary research ventures include "investigation into the treatment or prevention of major disease such as cancer and immunological disorders" and sensitive research ventures "include research into human cloning; interspecies reproduction... embryo destruction or fetal abortion" among others.<sup>51</sup>

Parker's full framework is important to note when dealing with research organizations' interests in human tissues. If I am correct in stating that tissues' sensitivity correlates with their value, I believe it is likely that an organization undergoing an ordinary research venture with ordinary tissues will have a weaker interest in the tight control of those tissues than if it was conducting a research venture involving sensitive research and sensitive

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<sup>49</sup> Imogen Goold, "Why Does It Matter How We Regulate the Use of Human Body Parts?," *Journal of Medical Ethics* 40, no. 1 (January 2014): 6.

<sup>50</sup> On average this is likely true, but it also depends on the research being done. If a research organization is working with hair samples specifically, those hair samples are likely more valuable to them than a kidney would be.

<sup>51</sup> Parker, "Using Human Tissue: when do we need consent?" 759.

tissues because of the variability of those tissue's value. This would be true purely based on comparing the relative value in each tissue-set.

For example, organizations testing for the effects of diabetes in patients using blood samples taken from diagnostic sessions likely have less to worry about than organizations testing for markers for superior genes based on race using reproductive tissues. For these organizations, the variable sensitivity of their research in conjunction with the variable sensitivity of the tissues being used factor into the strength of the specific interests they have in the tissues, and thereby the value that they see in those tissues.

The example of the Havasupai brings up a set of interests that are specific to certain communities of individuals. These groups of individuals deserve attention for the unique views they hold, their position in relation to other individuals in society, and their historical background. In the Havasupai's case, excised biospecimen have a highly important cultural connection to their sources. A defense of this interest has been offered by Remigius Nwabueze who argues for the importance of traditional knowledge, which can refer to a variety of mental objects: "knowledge of the medicinal properties of plants and animals, knowledge relating to agriculture, folklore, art, music, dance, literature, designs, marks, names and symbols."<sup>52</sup> Nwabueze argues that modifications to traditional knowledge have direct impacts to culture and identity.<sup>53</sup>

An important characteristic of traditional knowledge is that it is most often owned by the entire community. Only in rare circumstances is traditional knowledge owned by an individual community member. It is passed down from generation to generation through community instruction and lived experience.<sup>54</sup> Indigenous communities are often the example pointed to when dealing with traditional knowledge. The identity of the individual in these communities is tied closely to the substance that makes the individual up, which is in turn tied closely to the identity of the community. If we take these connections seriously, we can see a clear interest in excised biospecimen in indigenous communities with deep and nuanced traditional knowledge. Advocating for this view, Dr. Frank Dukepoo, a Hopi geneticist, once remarked that "to us, any part of ourselves is sacred. Scientists say it's just DNA. For an Indian, it is not just DNA, it's part of a person, it is sacred, with deep religious significance. It is part of the essence of a person."<sup>55</sup>

If we take Dr. Dukepoo seriously, it is undeniable that tissues have value to indigenous people. I believe Dr. Dukepoo's sentiments track closely with those of the Havasupai as well. Indigenous communities might have scientifically interesting gene pools that provide novel research opportunities.<sup>56</sup> It is likely that the Havasupai were considered for this research study for just that purpose. The researchers likely believed they could gather and analyze a whole set of scientifically interesting data from the use of the Havasupai's

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<sup>52</sup> Remigius N. Nwabueze, *Biotechnology and the Challenge of Property: Property Rights in Dead Bodies, Body Parts, and Genetic Information, Medical Law and Ethics* (Aldershot, England ; Burlington, VT: Ashgate, 2007), 234–35.

<sup>53</sup> *Ibid.*

<sup>54</sup> *Ibid.*, 235–39.

<sup>55</sup> Nanibaa' A. Garrison, "Genomic Justice for Native Americans: Impact of the Havasupai Case on Genetic Research," *Science, Technology & Human Values* 38, no. 2 (2013): 201–23.

<sup>56</sup> Nwabueze, "Biotechnology and the Challenge of Property," 168.

biospecimen that was outside of the original study's design. Insofar as that is the case, the tissues would be valuable in a special way, one that can only be seen by those who have the relevant scientific training to 'unlock' the hidden secrets through scientific study and research.

Has a sufficient amount of specification been done to ground a property right in the case of the Havasupai? The researchers from Arizona State University conducted work through studying the Havasupai's tissues for type two diabetes. There is no doubt that they also would have had to excised the tissues, handle them with care, house them in a safe facility, among other research-related tasks. As we saw with Samantha's diagnostic case-type, this can all be considered work in some respect. However, it is debatable whether this work can be considered specified work. Some might argue that the tissues themselves aren't being molded into a new thing. They are being analyzed, however small alterations to the physical nature of the tissues being tested does not provide sufficient specification.

On the other hand, the intellectual endeavor of testing tissues in research might provide sufficient conceptual specification even though the physical tissues are not changed. How we think of the tissues has changed, and that should lead us to determine them to be sufficiently specified. It is unclear whether or not medical research involving human tissues specifies tissues to a sufficient degree to ground a property claim on the side of researchers. I surmise that the specification debate can be decided based on the facts of a given research-type case. An important point to note would be that we can differentiate between the physical tissues themselves and the intellectual objects that are created from those tissues through labour. The specification doctrine can apply to either object. In the case of the Havasupai, though we might believe on a conceptual level that the tissues have changed, or that new intellectual objects have been created as a result of tissue research, the physical nature of the tissues has not been altered greatly. Seeing as I am dealing with physical biospecimen in this thesis, I argue that the specification principle does not justify assigning property claims in this case.

Though the work and skill principle does not offer much in the way of assigning property rights in this case, recall that tissues are also valuable insofar as they can be used as tools to realize the intentions of individuals and groups, thereby facilitating interactions between individuals in society. Similarly to how I argued in diagnostic-type cases, property regimes can be beneficial towards the goal of ethically utilizing valuable tissues, in turn facilitating these interactions.

### *2.3 Default research cases*

In the average research case where a common intention is clear and the research procedure specifies in its consent process that the tissues (once separated) become property of the research institution, that is sufficient to ground a property claim *upon separation*. Recall that in diagnostic cases I argued for property rights to be allocated in the source upon separation. This was because the main common intent of the diagnostic procedure is to benefit the source individual. Affording them property rights goes furthest in facilitating interactions between individuals in society. However, in research contexts the purpose is to further science, benefit a large population or a research institution's profitability. Sources have a weaker claim to the tissues they offer in research contexts because they are

voluntarily consenting to providing tissues for a different purpose. In research-type cases individuals offer their tissues for the purpose of benefiting others. They understand this common intent between themselves and researchers beforehand as outlined in the study design and consent procedure. I therefore argue that in the majority of research-type cases common intention is sufficient to ground property rights, and after obtaining informed consent<sup>57</sup> research institutions gain those rights upon separation.

I argue that in most research-type cases the medical institutions or individuals that run studies should gain full control rights in tissues by default. Those parties will require rights of possession, use, management and capital in order to conduct research. Additionally, where research is done involving multiple professionals or organizations, researchers will require the right to transmit their control rights to others should they deem it necessary. Once separated from the source, I see no issue with affording the full bundle of rights to excising research professionals. The same logic that applies in diagnostic cases applies here in research cases, only different facts require different results. Where the common intent for tissue excision is focused on research, property rights should be assigned to researchers.

This has implications for further research done with separated biospecimen. In cases where biospecimen has been collected for research study A, and researchers for study A have full ownership rights in those tissues by default, those researchers can apply to use the same tissues for a different research study (say study B). This must be true on the framework I am advocating because the researchers own the tissues by default once separated for the purpose of study A. I note the necessity that the researchers apply to do work with tissues in study B because as is true of all research cases, the study design must be ethical to begin with. There are many reasons why study B might be unethical as a result of the same tissues being used. For example, the potential for further research using the tissues may not have been disclosed to participants in study A, making consent in that study uninformed and invalid. In this case, we are not dealing with a situation of ongoing consent but invalid original consent. Recall from my discussion of the diagnostic case-type that original informed consent is of prime importance, ongoing consent is subject to the assignment of control rights. Alternatively, the type of research that uses a given tissue set may be ethical in study A but not B. Different study designs call for different ethics approval. Though researchers enjoy control rights in study A's tissues they cannot use them in any way they wish. However, if study B's design is ethical, meaning (among other considerations) it takes into account that tissues have been used in a previous study, researchers with the relevant control rights are justified in using the tissues for study B.

While control rights are the simpler bundle to deal with, income rights pose normative difficulty. The ability for researchers to profit from the tissues they acquire is a contentious topic. I will deal with this issue in depth with my discussion of the hybrid case-type below. For now, I submit that research institutions should gain income rights upon excision from a source. This is justified by my argument below that tissue-markets are not intrinsically exploitative and that we can sufficiently protect source individuals from harm through liability rules. While this is the case, income rights should also be dependent on approval

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<sup>57</sup> Where this consent includes the source individual being made aware of the property relationship the research institution will 'inherit' upon tissue excision.



of study design from ethics review boards as well as strict regulation. While this distribution of income and control rights is justified in easy cases, if we are dealing with a difficult case where intentions are unclear or there exists a strong value claim on one side I argue that we have good reason to reconsider and amend the default property-rights assignment. The case of the Havasupai offers us just such an exception.

### *2.3 The Havasupai exception*

How do the ways in which tissues are valuable factor into the allocation of property rights in the Havasupai's case? The intense value the Havasupai find in their tissues offer a counter-factual reason to the norm I advocate for in research cases. The Havasupai believe they have a different metaphysical relationship to their tissues than the average person. This belief can be corroborated through sociological, anthropological and historical analysis. I argue this tips the scale in their favor when allocating property rights upon separation.

If a source claims superior value in their tissues such that they believe they deserve property rights in their tissues upon separation, I argue it is their responsibility to make the case. The Havasupai have evidence to justify this claim where the average individual may not. There may be grey areas where spiritual individuals claim superior value in their tissues with little to no evidence to back up that claim. In these cases I leave the decision of control and income right assignment to research ethics boards and impartial adjudicating bodies. Should an individual find that the assignment of property rights is not to their liking they are by no means obligated to join a study. It is both their right and responsibility to only offer tissues from their body under terms they are agreeable with.

The framework I advocate requires a nuanced examination of both intent to use tissues and value seen in tissues by relevant parties. Though they are entering into a research endeavor, the Havasupai have such a strong connection to their biospecimen that to deny them ownership claims would constitute a considerable harm. In a similar fashion to diagnostic case-types, if the Havasupai retain full ownership over their tissues upon transfer then the researchers' use of those tissues might look closer to a loan. In this situation the Havasupai will have transferred the right to use, possess, and manage, but likely not the rights to transmit or capital. Essentially, the members of the Havasupai will maintain close control-related connection to their tissues, making ongoing consent necessary for use. In this situation the members of the Havasupai will likely also wish to maintain income rights for similar reasons to why they wish to maintain their control rights.

Alternatively, if the Havasupai relinquish all ownership entitlements upon excision, the researchers will have much more control over those tissues and the control/income right distribution will look like a standard research-type case. Where the Havasupai members relinquish all ownership entitlements, the only difference between this case and a standard research case is that in this special case the entitlements originate in the Havasupai members upon excision and are then transferred immediately, whereas in standard research-type cases the entitlements are assigned to the researchers upon separation.

While this might seem like a formality, I believe the fact that ownership rights should have originated with the Havasupai in this situation is important. Recall that it is because people in society require a means to use the objects they hold the most value in that leads me to argue that property regimes are the most beneficial means of regulating human tissue

use. From there I argued that rights of control and income should be assigned to those individuals upon separation. In most cases the default assignment of control and income rights aligns with the common intent of a medical procedure, whether that be diagnostic-related, research-related, or others. The point I draw out with the Havasupai exception is to show that sometimes individuals in society hold superior value in their tissues, which trumps the default property right assignments. So, according to the framework, it is important that they receive control and income rights upon separation even if they decide to relinquish and transfer those rights immediately. This is all decided beforehand in the informed consent procedure. The Havasupai are informed of the research design, purpose, etc. as well as their potential arrangement of control and income rights upon separation. They then choose which arrangement they prefer, and tissues are excised. This choice does not exist in default research cases.

In terms of the central issue of consent in this case, through the informed consent process the Havasupai consented to certain uses of their tissues, and those uses alone. It might be argued that the researchers breached the terms of the Havasupai's initial consent. The researchers acted improperly insofar as they did not disclose the possibility of other uses of the Havasupai's tissue. The Havasupai have thereby been misled in the consent process. In my view, the Havasupai were unable to truly take into consideration the value of their tissues in response to the research study that was proposed to them because they were not made aware of the possibility of other uses of their tissues. So, if the Arizona State University researchers gain full ownership entitlements of the Havasupai's tissues upon excision, they acted wrongfully not because they did not consult the participants on an ongoing basis, but because the original consent process was not fully informed. They did not act in accordance with their fiduciary duty as medical researchers.

### **3. Liability Rules**

#### *3.1 The trespass of property law*

The fiduciary duties I mention above fall under the more general class of law referred to as liability rules. Wall has argued that the application of property regimes to excised biospecimen has been inappropriate in some cases, and that in those cases property law trespasses into the jurisdiction of liability rules. Wall breaks down property law's dimensions and then argues that these dimensions do not sufficiently regulate the range of normative circumstances apparent when dealing with human tissues. He states that property is contingent insofar as the only normatively relevant consequences that appear when dealing with property are the relations between person and object. However, Wall notes other interests that arise in the control of human tissues when dealing with sensitive tissues such as reproductive tissue, or contexts such as the control of corpses of dead relatives. In these cases, Wall argues that individuals have non-contingent entitlements in the tissues or bodies under their control that can only be exercised by them.<sup>58</sup> His major critique is that property law cannot stretch itself outside its realm of expertise. He argues that it is poorly equipped to deal with the relevant normative circumstances that arise in the context of

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<sup>58</sup> Jesse Wall, "The Trespasses of Property Law," *Journal of Medical Ethics* 40, no. 1 (January 2014): 19–22.

excised biospecimen control, and it thereby trespasses where it does not belong when implemented as the sole regulatory control mechanism over separated human tissues.<sup>59</sup>

Wall points to an important deficiency of property law here. Property law is inert when dealing with some of the important normative circumstances that arise outside of control and income rights. In the Havasupai's case the harms they argued befell them as a result of the non-consensual use of their tissue stems from their believed intrinsic connection to those tissues. We require a different set of remedies for the psychological harms that the Havasupai were subject to as a result of the misuse of their tissues.

### 3.2 Tort

Tort law is an example of a set of liability rules that remedy harms outside of property-related law. An example of the kinds of torts that might be suitable to offer non-proprietary protections are nervous shock or psychiatric injury that result from the mistreatment of excised biospecimen. Nwabueze defines nervous shock as “the apprehension of a sudden terror that results in provable or recognizable psychiatric illness.”<sup>60</sup> This can be a result of malicious intent or negligence. Additionally, for this tort to award compensation it must be shown that the plaintiff has suffered a non-negligible amount of damage.<sup>61</sup>

Hardcastle has provided additional considerations to this conception in the form of three legal remedies for emotional distress. The first is the case of *Wilkinson v Downton*, where upon hearing false news about her husband, a woman fell severely ill. The principle applied in this case stated that the defendant “willfully done an act calculated to cause physical harm.”<sup>62</sup> This principle has been applied more broadly in other cases dealing with emotional distress. In addition to this test, Hardcastle examines the torts of harassment and intentional infliction of emotional distress than run similar lines of remedy to the protections of nervous shock and psychiatric injury that Nwabueze examined.<sup>63</sup> At first glance this kind of tort seems to be a good contender for protecting the interests of individuals in their excised biospecimen. For those who have a strong intuition that their human tissues are an integral part of their identity, and that the wrongful use of those tissues would cause them mental anguish, a successful psychiatric injury lawsuit would be beneficial as a remedy.

Additionally, Hardcastle offers the torts of battery or negligence, which have much clearer parameters in terms of their applicability. Battery concerns “intentional physical contact that is not generally acceptable in ordinary conduct of daily life” and negligence deals with “negligently inflicted damage to an individual's property or invasions of bodily integrity.”<sup>64</sup> These torts seem fairly straightforward in their applicability to excised biospecimen. No individual should commit a battery against another individual when retrieving excised biospecimen, negligently or otherwise. This is one of the reasons why informed consent is crucial to the excising of biospecimen. We can see how tort law is

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<sup>59</sup> *Ibid.*

<sup>60</sup> Nwabueze, "Biotechnology and the Challenge of Property," 191.

<sup>61</sup> *Ibid.*, 192–93.

<sup>62</sup> Hardcastle, "Law and the Human Body," 190.

<sup>63</sup> *Ibid.*

<sup>64</sup> *Ibid.*, 185.

beneficial when dealing with the kinds of normative circumstances that Wall pointed to when assessing property law's utility in regulating human tissue use. Tort law can aid in filling the gaps in regulation where property law offers no guidance.

### *3.3 Fiduciary obligations*

Establishing a larger and more varied set of fiduciary obligations is another useful way of protecting the important interests found in the context of excised biospecimen use. Fiduciary obligations exist in circumstances where an individual or group of individuals act in a particular role in relation to others. In situations where individuals have not relinquished all rights of control, one obligation would be to use tissues only for the purposes that the source individual has consented to. Though this is the usual process that researchers and medical professionals undertake when working with excised biospecimen, there are times when consent is not necessary. These occur when individuals who wish to do additional work with human tissues obtain permission from a Human Research Ethics Committee (HREC).<sup>65</sup> HRECs are examples of institutions that claim the legal authority to attach a set of fiduciary obligations and rights of control over a set of human tissues to an individual or group of individuals. Additionally, there exist protocols which form obligations for the proper maintenance and eventual disposal of tissues. Where control rights are shared between individuals, it is possible that a very robust and intricate set of fiduciary obligations could be created to protect the competing interests of those involved.

Fiduciary obligations have a proactive nature that acts as a boon towards the aim of protecting individual and group interests in excised biospecimen. If medical professionals and source individuals understand the obligations they owe to sources before tissue separation, both parties can feel more secure in their expectations. This is how society functions properly, when each of us understand the obligations we have to each other (whether those be legal, moral, societal, cultural, etc.) we can be reasonable in our expectations of each other's behavior in addition to feeling safe in the implicit 'contract' we hold with one another.

Hardcastle offers an example of such a fiduciary obligation – the duty of confidence. This duty is found in cases where an individual receives information about another person that can be reasonably understood as confidential. In these cases, the individual holding the information has a duty to uphold and protect that confidentiality. Hardcastle argues that as it applies to human tissues, the duty of confidence can aid with remedying privacy concerns. He makes the important point that this duty should not be applied to physical tissues directly, as the law pertains only to information, not physical objects. Nevertheless, "the duty of confidence can provide protection in relation to personal genetic information once it is extracted from separated biological material."<sup>66</sup>

In the case of the Havasupai, it might therefore be said that the researchers failed to uphold a fiduciary obligation they have to their research participants, and that the Havasupai are welcome to bring legal action against the researchers for this breach. We see

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<sup>65</sup> Loane Skene, "Legal Rights in Human Bodies, Body Parts and Tissue," *Journal of Bioethical Inquiry* 4, no. 2 (August 22, 2007): 130–31.

<sup>66</sup> Hardcastle, "Law and the Human Body," 184.

here the limits of property rules and the benefits of liability rules. Where the jurisdiction of property rules run out, it is at least beneficial and at most necessary to supplement those rules with liability rules as a means to protect and remunerate harmed parties. In addition to difficulties with consent, there are other concerns to be dealt with in research case-types such as concerns of commercial exploitation as a result of profits from research using excised biospecimen. These concerns also arise in what I will refer to as hybrid case-types, which I will examine now.

#### 4. The Hybrid Case-type

The hybrid case-type is a cross between diagnostic and research case-types. In these cases, an individual attends a medical professional and has their biospecimen excised for diagnostic purposes, however those tissues are then used for research purposes. The prime characteristics of hybrid-type cases are: (1) an individual consensually offers their tissues for diagnostic purposes, (2) those tissues are used for the *main* purpose of diagnosing their ailment, and (3) the tissues are then used for ethically sound research purposes. While the issue of consent will come up in these cases, I will focus my discussion of the hybrid case-type on commercial exploitation. Financial concerns become particularly important when the purposes of tissue use are muddled. This muddling is more likely to occur in hybrid case-types where the intent for tissue use straddles the line between diagnosis and research. There are two widely known and controversial cases that fit within the hybrid case-type: the case of Henrietta Lacks and the case of John Moore v. UCLA.

In 1951 Henrietta Lacks was diagnosed with cervical cancer at John Hopkins Hospital. Her diagnosis was determined by testing samples of her tissues, which were freely offered to her doctor. These tissues were then sent without her knowledge or consent to other researchers for testing of different characteristics - a common procedure at the time. These tests would confer no direct benefit to Lacks. The testing produced a miraculous discovery: Lacks's cancer cells were capable of surviving indefinitely under certain conditions, offering the potential for a wide variety of further research to be done through their use. While Lacks unfortunately succumbed to her cancer and passed away, her cell line lived on. Researchers gave her cell line the name 'HeLa' cells, and they have been used for a far-reaching range of scientific research projects across the globe. In some cases, these projects have gone on to make large sums of money, none of which Lacks's descendants have seen a penny of. Some have argued that the issue of compensation in this case is especially problematic seeing as her socio-economic situation was dire and she was of African American decent, putting her in an underrepresented minority population. In addition, in 2013 researchers posted the HeLa cell line data sets online, making the genetic information open to anyone with an internet connection around the world. In a response to the privacy concerns that Lacks's decedents might have due to their genetic information being so widely available, the HeLa cell line datasets will be moved to controlled-access databases.<sup>67</sup>

A legal case that has offered relevant insight for this discussion is Moore v. University of California. John Moore attended the UCLA Medical Center in 1976 for treatments for

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<sup>67</sup> Laura M. Beskow, "Lessons from HeLa Cells: The Ethics and Policy of Biospecimens," Annual Review of Genomics and Human Genetics 17 (2016): 395–417.

hairy cell leukemia. Under Dr. Golde’s recommendation, Moore consented to having his spleen removed. After this successful procedure, Moore’s condition stabilized. He then returned over the next seven years for semi-regular blood sample tests. Over these visits, Moore was asked to consent to the use of his tissues for research purposes, which he did not agree to. In 1984 Dr. Golde created a cell line developed solely through Moore’s tissues, and at least nine products had the potential to be developed as a result of this newly created cell line. Moore sued Dr. Golde, and after three appeals the California Supreme Court held that Moore did not have a right to his excised tissues, and thereby was not justified in seeking compensation. However, in their ruling they stated that “the allegations of Moore’s third amended complaint state a cause of action for breach of fiduciary duty or lack of informed consent, but not conversion.”<sup>68</sup> This justification signals a shift of thought. The original thought was that the key issue here was whether or not Moore owned his tissues and they were thereby improperly converted by Dr. Golde. The new thought that the court’s justification signals is whether Moore had a right to be informed of how his tissues were being used. In other words, in its final decision the court found this case to be an issue of informed consent and not ownership or property rights.<sup>69</sup>

We can see how Lacks and Moore’s cases both fit squarely within the hybrid case type. Both individuals had their tissues excised for diagnostic purposes, and both had their tissues used for research purposes. Although each of their tissues were used for the main purpose of diagnosing and treating their ailments, Lacks was unaware of the research done with her tissues, and Moore became aware of this fact in respect to his tissues even though he expressly forbade it. It may be useful to consult Cheung et al.’s ‘but for’ test in assessing how we should refer to Lacks and Moore’s tissues. Recall this test asks “but for study X, would this tissue (or this amount of tissue) have been excised from this individual?”<sup>70</sup> Though we answer this test in the affirmative, I believe the test leaves out the fact that these tissues were used for research. So, at the time of excision the ‘but for’ test is helpful; we should classify the tissues as diagnostic at this stage. However, after research has been conducted on the tissues we must classify them as at least partly research tissues, if not research tissues entirely.

## **5. Ownership in Hybrid Cases**

### *5.1 Have the human tissues been excised or detached per se?*

In Lacks and Moore’s cases separation is apparent. They both offered their tissues for diagnostic purposes to medical professionals. Should Hardcastle’s detachment principle justify either of their property claims in their excised biospecimen? Similarly to my points above, I do not think that the facts of this case change it sufficiently to give us good reason to believe the detachment principle justifies property claims in this case. Though this is true, it is worthwhile to note that the precondition of separation is found in both cases.

### *5.2 How and to whom are the tissues most valuable?*

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<sup>68</sup> Maureen S. Dorney, “Moore v. The Regents of the University of California: Balancing the Need for Biotechnology Innovation against the Right of Informed Consent,” *High Tech. LJ* 5 (1989): 333.(342)

<sup>69</sup> *Ibid.*

<sup>70</sup> Cheung, Martin, and Asa, “Defining Diagnostic Tissue in the Era of Personalized Medicine,” 136.

In Lacks's case her tissues went on to make vast amounts of money, and her genetic information might be made public. Though she has passed on, her family can find great value in their mother's tissues as a result of the profitability of research done on them. Moore has a similar interest in his tissues. He saw the financial gain that was achieved through work done on tissues separated from him, which shapes how he values those tissues. In addition to their patients' interests, the medical researchers in both cases find value in the diagnostic tissues they transformed into research tissues. In Lacks's case in particular, the value has been multiplied and spread globally.

It is clear that work is being done on both Lacks and Moore's tissues. Has that work provided a sufficient amount of specification to ground a property right? Excising, handling, housing, and other research-related tasks might all be considered work. However, it is debatable whether this work can be considered specified work. Some might argue that the tissues themselves aren't being molded into a new thing. They are being analyzed, however small alterations to the physical nature of the tissues being tested does not provide sufficient specification. On the other hand, the intellectual endeavor of testing tissues in research might provide sufficient conceptual specification. How we think of the tissues has changed, and that might lead us to determine them to be sufficiently specified.

Like I argued in research cases, it is unclear whether or not medical research involving human tissues specifies tissues to a sufficient degree to ground a property claim on the side of researchers. Here, like in research cases, it is important to recall the difference between physical and intellectual objects. Like I argued above, the specification doctrine can apply to both types of objects, but I am dealing with physical objects in particular here. I surmise that the specification debate can be decided based on the facts of a given hybrid-type case. In Lacks and Moore's cases it is unclear whether the work that the researchers performed on the tissues can be considered sufficiently specified to ground a property claim on their part.

Both Lacks and Moore's original intentions to offer their tissues were for diagnostic purposes. We can thereby ascribe to them the kinds of intentions that I outlined in my discussion of the diagnostic case-type. Lacks and Moore's cases are similar to the Havasupai's case, as both of their tissues were used for means outside of those they had offered them for. However, it can be argued Lacks and Moore's cases of unintended tissue use are more nefarious. The Havasupai consented to a research endeavor using tissues excised from them to begin with. Neither Lacks nor Moore consented to such an endeavor. They both thought they were offering their tissues for diagnostic procedures. The fact that medical professionals used the biospecimen for an entirely different procedure altogether is clearly problematic. However, this fact does not aid us in ascribing either Lacks or Moore property rights *upon excision*.

Hybrid cases are interesting in this regard. While straightforward hybrid cases make the intention to use diagnostic tissues for research purposes clear, controversial hybrid cases are a result of the unintended use of diagnostic tissues for research purposes (like in Lacks and Moore's cases). Seeing as hybrid cases are a synthesis of diagnostic and research case-types, and that intentions lead us to assign property rights to different parties depending on if we are dealing with a diagnostic or research case-type, how should we adjudicate these rivaling intentions?

### *5.3 Default hybrid cases*

I argue that in both straightforward and controversial hybrid case-types whether or not the intent to use diagnostic tissues for research purposes is made clear to sources, those individuals should acquire property rights upon separation. This is because the diagnostic procedure is the primary intent of hybrid cases, making the research procedure secondary. We can arrive at this conclusion by applying Cheung et al.'s 'but for' test. 'But for' the research aspect of hybrid cases would tissues be excised? Yes, the diagnosis is primary. Though these cases are not as clear-cut as purely diagnostic cases, the same logic applies. The source is the primary focus of the excision of tissues, the initial common intent of the procedure is to diagnose and treat their ailment. That source should be assigned property rights in a similar fashion to standard diagnostic-type cases. Like in diagnostic cases, in hybrid cases individuals attend medical professionals to have their tissues separated and examined for the main purpose of their benefit. The further research to be done is supplementary. But for the diagnostic procedure those individuals would not have tissues excised from them, whereas the biospecimen would be excised but for the research procedure. Like in diagnostic cases we can find a common intention to focus primarily on the wellbeing of sources, I argue this is sufficient to assign them full control and income rights in their tissues upon separation.

### *5.4 Control and income rights*

The court in the Moore case decided not to deal with the property and ownership issue in response to the lawsuit. However, I believe if both Lacks and Moore were made aware of the status of their ownership relationship to their tissues upon excision the circumstances in both cases would be less difficult to navigate. As I have mentioned in my analysis of the past two case-types, control rights should be determined before the point of excision. Rights to ongoing consent are then a result of how those control rights are assigned.

Control rights are not the main source of grievance in these cases though. The research institutions went on to gain financially from the use of the tissues they excised. It might be the case that control rights are settled, however in situations where financial considerations are present income rights are equally important. It might be the case that Lacks and Moore hand over full control rights to their tissues but remain entitled to a share of the financial profit gained through the use of their tissues. A question we might ask in reference to income rights in particular is whether or not those rights are in fact inalienable. Should we allow individuals to relinquish or transfer income rights in the first place?

## **6. Financial Exploitation**

Up until this point I have assumed that sources enjoy the liberty to do so. However, if alienating income rights in their tissues leads to the financial exploitation of sources as people, should we ever allow them to transfer income rights? Is it exploitative not to compensate these individuals for the use of their tissues? To answer that question, we require a nuanced discussion of what it would mean to say the situation is financially exploitative.



Stephen Wilkinson elucidates the ways in which biospecimen and the sources that offer them can be commercially exploited. Though Wilkinson does not believe financial inducement is a means through which people are exploited in medical research, he does entertain the possibility that the tissues themselves can be exploited through commercialization. Academic researchers or biotechnology companies might use human tissues for profit and not only to promote the public good. For example, “a researcher (or other tissue gatherer) could simply sell a physical tissue collection, or part of it, for profit [or] tissue banks could sell services to researchers, such as limited access to a tissue collection, or the provision of data about a tissue collection.”<sup>71</sup> In addition to these examples, Wilkinson situates his discussion outside the context of informed consent. Consent has its own set of relevant issues that he agrees are important, however he is concerned with the thought that the human body or parts of the human body should not be used for financial profit as such. This involves characterizing human tissues as mere commodities capable of being sold, which can be immoral.<sup>72</sup>

Wilkinson notes that this act has been described as ‘objectifying’ human tissues in a negative way. He references Nussbaum to explain why objectification is wrong: “Treating things as objects is not objectification, since [...] objectification is making into a thing, treating *as* a thing, something that is not really a thing.”<sup>73</sup> However, he argues this line of reasoning runs up against issues when applied to human tissues because human tissues *are* objects. If objectifying is wrong because it is the immoral act of treating something as an object that is not an object, excised biospecimen do not seem to fit the category of objectification. Human tissues are objects. However, Wilkinson argues that human tissues can fit this category because objectification also applies to treating things as *mere* objects. He believes treating body parts as mere objects is immoral because this kind of objectification disregards the intimate relationship humans have with their body parts. Wilkinson argues that where valid consent has been achieved, objectification can occur if a party does something with human tissues that can harm the source individual of those tissues. He argues that this can happen through a variety of ways, two of which being adverse societal implications of the commodification of an individuals’ tissues or risks to privacy concerns due to identifying markers attached to tissues.<sup>74</sup>

If property frameworks allow for commercial exploitation, this may be a reason to limit their use or abandon them altogether. Alpinar-Sencan et al. continue this conversation with an appeal to human dignity. They argue that buying and selling human tissues is an affront to dignity. They state that human dignity is often used as a means to explain why certain acts that treat humans in particular ways are immoral. They consider selling organs as such an act. By selling an organ one puts a price on and thereby calculates the value of that organ. They argue that the social element of dignity “appears when dignity constitutes an

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<sup>71</sup> Stephen Wilkinson, “Biomedical Research and the Commercial Exploitation of Human Tissue,” *Genomics, Society and Policy* 1, no. 1 (February 2005): 32, <https://doi.org/10.1186/1746-5354-1-1-27>.

<sup>72</sup> *Ibid.*

<sup>73</sup> *Ibid.*, 35.

<sup>74</sup> *Ibid.*

idea about how people would like to be perceived and treated by others.”<sup>75</sup> This aspect of dignity comes out in the social attitudes attached to transactions between people. On Alpinar-Sencan et al.’s account human worth is incomparable and unconditional. People cannot gain or lose dignity, they can only have their dignity violated by the attitudes of others. In the case of organ trading, the action of putting a price on an individual’s organ violates their dignity as it symbolizes the perception that people can have price-tags. Alpinar-Sencan et al. argue that the individual who sells their organ is perceived by themselves and others to have had their dignity violated. Where there are social relations of a certain kind there exists a social account of human dignity. In general, if the perceived violation of human dignity is allowed to come about through the commodification of human tissues, there will be a degradation of the perceived value of source individuals.<sup>76</sup> Bringing Alpinar-Sencan et al. and Wilkinson’s critiques together we can see a clear issue in the commodification of excised biospecimen that a purely property-based framework does not account for.

## 7. Supplementing Property Regimes

### 7.1 Semiotic objections to tissue markets

Will characterizing human tissues as property allow for markets in human tissues that treats people solely as a means to profit without compensation? Recall that there are two main reasons why commercializing tissues might be considered unethical: (1) Wilkinson’s analysis that treating tissues as *mere* objects is objectification of the wrong kind, and (2) Alpinar-Sencan et al.’s argument that commercializing human tissues puts a price-tag on humans that leads to the perception (by both themselves and society) of a loss of dignity. I believe both of these difficulties can be solved through reconceiving tissue-markets in a new way and supplementing that new conception with liability rules. Jason Brennan and Peter M. Jaworski have argued against the notion that markets signal disrespect. They state that these criticisms of markets are ‘semiotic objections’, which hold that:

to allow a market in some good or service X is a form of communication that expresses the wrong attitude toward X or expresses an attitude that is incompatible with the intrinsic dignity of X, or would show disrespect or irreverence for some practice, custom, belief, or relationship with which X is associated.<sup>77</sup>

Brennan and Jaworski’s central thesis is that markets are not intrinsically immoral or exploitative, and that “if you may do it for free, then you may do it for money.”<sup>78</sup> Their thesis is based on the principle of possession, which holds that whether or not objects should be deemed immoral to trade should depend on whether or not they are immoral to own or possess. Clear examples of objects that should never be owned are child pornography or nuclear weapons. Markets in child pornography or nuclear weapons only amplify the wrongness of the possession of such objects. They argue that to show that

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<sup>75</sup> Zümürüt Alpinar-Şencan, Holger Baumann, and Nikola Biller-Andorno, “Does Organ Selling Violate Human Dignity?,” *Monash Bioethics Review* 34, no. 3–4 (November 2017): 198.

<sup>76</sup> *Ibid.*

<sup>77</sup> Jason Brennan and Peter Jaworski, eds., *Markets without Limits: Moral Virtues and Commercial Interests* (New York ; London: Routledge, Taylor & Francis Group, 2016), 47.

<sup>78</sup> *Ibid.*, 10.

markets are inherently immoral in some circumstances one must show that it is ethical to possess an object but not to create a market in its trade. In these discussions they mention it is important to set aside circumstances where markets are incidentally wrong, such as situations where individuals have promised not to sell an object or they have pre-existing duties not to sell the object. Their focus is on the market itself and its inherent morality in normal circumstances. Their argument is that markets do not inherently change the moral status of either the transfer of or ownership of objects. If it is morally permissible to own and give away an object for free, it is morally permissible to commercialize it.<sup>79</sup>

### 7.2 *A rebuttal*

I believe Brennan and Jaworski have offered us a reasonable response to Wilkinson and Alpinar-Sencan et al.'s objections. We allow individuals to give away their tissues without pricing them. I do not think those who criticize commercializing tissues would also criticize the very process through which those tissues are excised. Individuals consensually offering up their excised biospecimen for diagnostic or research purposes are not acting immorally, and *prima facie* neither are the medical professionals who extract these tissues. In addition, through my analysis of the previous case-types we have seen that it is not immoral for these medical professionals to claim property and/or ownership rights in these tissues, and so the principle of possession should lead us to assume they are morally justified in their ownership claims if those claims are the consequences of an ethical transaction. So, Wilkinson's mere commodity objection does not hold much weight here. We now have a situation where both possession and the market are shown not to be inherently immoral. If Wilkinson believes we are wrong to commercialize excised biospecimen because they should not be considered *mere* objects, I argue he must first contend with the issue of possession, and then the issue of the immorality of tissue-markets. If it is wrong to objectify human tissues then it must be wrong to possess them as objects, however this is not straightforwardly the case.

A similar point can be made for Alpinar-Sencan et al.'s wrong currency-type objection. The fact that putting a price-tag on human tissues signals a loss of dignity to the individual or to society is a contingent matter. This is not an inherent issue with the market itself, but a contingent issue with societal attitudes. It might be the case that if society was only slightly different, then commodifying human tissues might not signal disrespect to human dignity in the way Alpinar-Sencan et al. argue it does. In fact, this contingent social fact might change if markets are introduced and regulated. The individual good of allowing people to exercise their autonomy and control their excised biospecimen in accordance with the value they see in them, as well as the social good of the advances in biotechnology and medical practice that would likely come about through such a change would, in my view, likely change public perception about markets in human tissues. If this was to take place Alpinar-Sencan et al.'s objection becomes much less damaging.

### 7.3 *Importance of liability rules*

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<sup>79</sup> *Ibid.*

If my rebuttal to commercial exploitation arguments is not satisfactory I do not believe that makes property regimes unsuitable for the regulation of human tissue use. Instead, I argue we have found another place for liability rules to aid the contracts that people will enter into with their newfound property rights. Whether or not tissue-markets are exploitative, it would still be important to properly regulate markets in human tissues. Like other markets, legislative intervention would be important to uphold principles of justice and to reduce widening inequality. Legal rules such as the principle of unjust enrichment could aid in this endeavor.

Nwabueze offers the test for unjust enrichment, which comes in three parts: “a. the defendant was enriched; b. at the expense of the plaintiff; and c. it is unjust for the defendant to retain the benefit.”<sup>80</sup> If an individual or group of individuals believe their biospecimen have been unjustly enriched by those who have control over them, they have this legal remedy to appeal to in their defense. When dealing with the commodification of human tissues or the results of work done through human tissues, an unjust enrichment lawsuit seems to be a useful legal tool. Additionally, unjust enrichment need not necessarily recognize human tissues as property-objects. By its definition, a plaintiff need only prove the unjust enrichment of the defendant. In a case such as this, if the plaintiff could prove that the defendant used their tissues for unjust personal gain they could protect themselves and seek damages. Interestingly, the law of unjust enrichment recognizes the value of human tissues without treating them as property-objects. I argue that a successful unjust enrichment lawsuit would show that the defendant unjustly usurped the value of the plaintiffs excised biospecimen for their own purposes. The main point to keep in mind is that markets in human tissues are not inherently immoral. Though this is the case, contingencies must be taken into consideration and proper regulatory safeguards put in place.

What does this mean for the transfer of income rights? I believe that the result of my analysis here shows that income rights can be fully transferred to medical professionals upon excision, they are not inalienable. Though this is one outcome of excising biospecimen, it is not the only result of tissue-transfer. There may be good reasons why a source should maintain some form of income rights in their excised biospecimen, however this should be justified.

In both Lacks and Moore’s cases it seems clear that the possibility that profitable research would be done with their tissues should have been disclosed to them. This would put them into an informed position where they would be able to decide whether or not they want their tissues excised. They might have negotiated and made clear they do not want their tissues used for research purposes, or that if research done on their tissues became profitable they should receive compensation. However, it is not clear that they should maintain income rights in their tissues forever. Hardcastle’s work and skill principle is important here. The researchers had to conduct work on the tissues, and to say this does not relevantly transform the situation and the value of the tissues is to mistake a key point of the discussion.

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<sup>80</sup> Nwabueze, "Biotechnology and the Challenge of Property," 220.

Yes, Lacks and Moore were misinformed and had their consent breached, however this does not necessarily translate into a transfer of ownership entitlements. Surely, they could have (and in Moore's case did) sought legal remedy for the misconduct of the medical professionals that excised their tissues, and this would be where the limits of the limited-property framework do the heavy lifting. The clear delineation of ownership entitlements at the point of excision is important and is why the limited-property framework is so beneficial. Unfortunately, Lacks and Moore did not have this framework to appeal to. I believe in order to protect against others falling to their misfortune we should implement the framework in the future.

### **Conclusion**

In this chapter I have added two further case-types to the discussion – the research case-type and the hybrid case-type. Through analysing examples that fall within each case-type I have shown further evidence for why the limited-property framework for human tissue control is so beneficial. In addition, I examined in detail the criticism of commercial exploitation often levied against arguments for property regime control of excised biospecimen. I then showed how two main positions within this critique are flawed, and how supplementing property rules with liability rules will deal with the issues that might arise as a result of the commercialization of human tissues. I will continue with my analysis of various case-types in the following chapter.

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### **Chapter 3: Additional Case-Types**

While the majority of separated biospecimen uses fall within diagnostic, research, or hybrid case-types, human tissues are used for other means as well. In this chapter I will examine two other case-types that cover additional instances of human tissue use. Though they are less prevalent in society this should not cause them to be dismissed. They bring up important issues that have implications for the more common case-types. I believe examining these case-types will offer a more complete picture of the limited-property framework's applicability, and therefore strengthen the case for its implementation into the future.

#### **1. The Bailment Case-type**

The bailment case-type refers to situations where an individual or group of individuals offer their tissues to a medical professional or organization to hold on to for safe keeping. The tissues are often under bailment for a specified period of time, or until the source individual requests the tissues to be returned. In these cases, it is important to be clear on what entitlements are in fact being transferred. Bailment by definition refers to the transfer of objects without changing ownership. So, in bailment-type cases source individuals wish to retain the majority of ownership entitlements in their tissues, though they cannot claim full control rights. These cases might deal with mistreatment of the excised biospecimen under bailment, and are primarily concerned with control rights. Two important legal cases fall within the bailment case-type, one from the UK and one from Canada.

The case of *Yearworth v. North Bristol NHS Trust* from the UK is a noteworthy example of a bailment-type case. In the *Yearworth* case, six men who had been diagnosed with cancer were to undergo a chemotherapy treatment, which have the possible side-effect of causing infertility. With the aim of securing the reproductive capabilities into the future, the men gave samples of their sperm to a hospital to be stored. Due to an insufficient amount of nitrogen in the storage containers at the hospital, the sperm was destroyed. The men claimed that the loss of their sperm lead them to suffer moderate mental anguish, and consequently they sued the hospital. During the lawsuit, the hospital staff agreed that they had a duty to protect the samples obtained from the six men, however they argued that the destruction of the sperm could not be a case of negligence. This is because the loss of the sperm was neither a personal harm to the men, nor a case of destruction of their property. The original court sided with the hospital and did not award the men damages. However, the men appealed that court's decision and won. The reasoning the appellate court reversed the original court's decision was that it recognized each man's possessory title over their sperm, constituting ownership. In addition, the appellate court argued that in holding the property of each man (their sperm) in trust, the hospital was liable for the mistreatment of those men's' property, as well as any mental anguish that mistreatment caused. In reaching their decision the appellate court argued that ownership can be understood in this case based on a contextual analysis. For a variety of reasons, the court granted ownership of their

sperm to the men based on the context in which they entered into a relationship with the hospital.<sup>81</sup>

In addition to the Yearworth case, there is a Canadian case with similar facts. The case of *Lam v University of British Columbia* is another example of reproductive tissues and the classification of property. This was a class action lawsuit brought against the University of British Columbia, whose representative was Howard Lam. In this case the class of men deposited their sperm to be kept in a freezer at the university. In a similar fashion to the Yearworth case, the freezer malfunctioned and the sperm was destroyed. In this case the Warehouse Receipt Act was applied and the question of whether sperm is considered property was answered. The court found that sperm is property as it applied to the Warehouse Receipt Act. The justification for this decision was that the sperm could also be understood as ‘goods’ under the same act. The court applied a framework to determine that each member of the class “had ample rights in relation to his own sperm specimen that invested him with ownership of the specimen sufficient to be defined as ‘property’.” However, it is important to note that the court stated that their decision to classify sperm as goods and property would only apply to the Warehouse Receipt Act.<sup>82</sup> Though this would limit the applicability of the court’s decision to the specific act, it is clearly relevant as an example of a bailment case. Interestingly, the court in this case referenced the Yearworth case in its reasoning for its decision.

After examining these two cases we can find a few important characteristics of bailment case-types: (1) informed consent must be gained from source individuals before excision or separation (which includes determining the purposes and conditions of bailment), and (2) excised or separated tissues must then in fact be secured by medical professionals or organizations for the agreed upon purposes. In addition, though it is usually the case in bailment case-types that source individuals offer up sensitive tissues, this need not always be true. So long as the two conditions are satisfied, any kind of tissue can be offered for bailment.

We can clearly see how both the Yearworth and Lam cases fit within the bailment case-type. Each has a class of individuals who have offered their tissues to medical professionals for safe keeping. It also happens to be the case that the tissues in question are sensitive in type. Additionally, it seems clear that each party in both cases understood their roles in relation to each other and to the biospecimen in question. The men offered their tissues for the purpose of safe-keeping, and the hospitals accepted the responsibility of stewardship. In both cases the hospitals failed to uphold their responsibility and were charged by a court of law to compensate the men who they had harmed through their negligence. Interestingly, considerations of ownership and property arise in both cases. I believe the shift towards a property model in these cases invites an assessment of the limited-property framework’s applicability to bailment case-types.

## **2. Applying Property Rules to the Bailment Case-type**

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<sup>81</sup> Luke David Rostill, “The Ownership That Wasn’t Meant to Be: Yearworth and Property Rights in Human Tissue,” *Journal of Medical Ethics* 40, no. 1 (January 2014): 14–18.

<sup>82</sup> *Lam v University of British Columbia*, No. CA041447 (Court of Appeal for British Columbia January 6, 2015).



### *2.1 Have the human tissues been excised or detached per se?*

In bailment cases the separation precondition is satisfied when biospecimen is excised, however individuals may bail tissues that need no excision *per se*. The tissues must be separated from their source, though this does not necessarily require the professional skill of another individual.

### *2.2 How and to whom are the tissues valuable?*

The men in both cases have weighty interests in the safe protection of their reproductive tissues. It is the fact that the tissues are valuable to these men that brought them to find a bailment relationship with another party to begin with. The situation they found themselves in in regards to their health made it such that should they wish to reproduce in the future they must save their reproductive tissues. The court in the Yearworth case recognized the mental anguish that the men went through as a result of the destruction of their sensitive tissues. If this is genuine mental anguish, their emotional response to the destruction of their stored tissues signals their interests and value seen in their tissues. On the other hand, the hospitals and medical professionals also have interests in the tissues they have been charged with safe-keeping. These interests are similar to the kinds of interests I previously discussed in other case-types dealing with an institution's reputational risk in regards to their stewardship over tissues in their possession. The medical professionals in question hold fiduciary roles as bailees of the men's tissues. Insofar as they take these roles seriously, the tissues they have been entrusted with are valuable to them as the objects over which they are stewards.

The common intention for use of the tissues in these cases is to store them - if this can even be called a 'use'. In fact, it is usually the expressed intent of the source individuals bailing their tissues that the biospecimen is not used for any other purpose. Other uses might frustrate the goal of securing the tissues' safety for later use by the source. Though the intention may or may not be present to deem the tissues property, the courts in both the Yearworth case and the Lam case characterized the biospecimen in question as such. Moving forward with bailment cases, this precedent should not be overlooked. While it might be improper to attribute the intention to classify the men's tissues as property to either the men themselves or the medical professionals acting as bailees, the decision of the courts to do so will be taken into consideration as precedent law in future cases. So, while the intent to use the tissues as property may not be present in the cases at hand, it is likely to be present moving into the future with similar bailment-type cases.

### *2.3 Control and income rights*

The bailment case-type refers to a specific kind of ownership entitlement transfer between source individual and medical professional/organization, and it is due to this fact that I believe it is appropriate to narrow down and examine the specific incidents of ownership that each party can claim in these cases as opposed to the general 'control' or 'income' bundles I have been referring to. I refrained from completely specifying these incidents in the previous case-types because the variables that might confound such an analysis are immense. Instead, I found it more appropriate to examine the implications of general bundles of ownership incidents in those case-types, referencing the kinds of control

incidents that may or may not be transferred, thereby allowing for each party to determine what the specific ownership entitlement transfer should look like depending on their relationship and context. However, bailment cases are less prevalent and more specific. I believe it would be useful to offer a granular analysis of the ownership transaction in these cases in order to offer more guidance in regards to the property framework's application.

We have good reason to set aside income rights in bailment case-types in their general form - unless otherwise stated by a source. It seems to me counter-intuitive to suggest that in a bailment relationship the bailee should retain income rights to the bailed tissues. This would undoubtedly lead to conflicts of interest between the value seen in the tissues by source individuals and the value sought in those tissues by medical professionals. This leaves control rights. Which incidents that make up the bundle of control rights should be transferred to bailees in bailment case types? Here is a breakdown of what I argue is an appropriate arrangement:

*Bailor* (source individuals)

- (2) the right to use
- (3) the right to manage
- (4) the right to income
- (5) the right to capital
- (6) the right to security
- (7) the incident of transmissibility
- (8) the right of absence of term
- (11) the incident of residuary

*Bailee* (medical professional/organization)

- (1) the right to possess
- (9) the duty to prevent harm
- (10) liability to execution

The majority of ownership incidents belong to the bailor (or source individual) in bailment-type cases. In order for the common intention of the transaction to be realized the Bailee must claim the right to possess. However, this is truly the only positive incident that medical professionals or organizations acting in a bailee capacity have claim to. I argue that these kinds of bailment contracts are aimed at benefiting the bailor, and so in a similar fashion to diagnostic case-types, source individuals have the strongest claim to the majority of control and income rights. That a source maintains these rights is truly what gives the bailment case-type its name.

In the process of fulfilling their obligations as bailees medical professionals may wish to manage or transfer the tissues. For example, a storage unit may be faulty and the institution bailing may wish to transfer the tissues to another facility. In my view these acts should be subject to the ongoing consent of the bailor. Bailors may have other wishes for their tissues, and because the main ownership claim resides on their side any control-related undertakings by the bailor should be subject to their ongoing consent. The other two

incidents that bailees have claim to reference their obligations in regard to their position as bailees.

Privacy interests are important to consider here if identifying markers are attached to excised biospecimen. It is likely that tissues will not be completely anonymized and de-identified due to the fact that those same tissues must be returned to their source individuals. In fact, for pragmatic reasons complete de-identification would be counter-productive to the bailment process itself, for the bailed biospecimen must eventually be returned to their owners. In the Yearworth and Lam cases, it is clear that the medical professionals acting as bailees harmed the men through the negligent treatment of their tissues thereby transgressing their duty to prevent harm. However, should identifiable information surface about these individuals as a result of the misplacement of their tissue samples a further harm might befall them. I will examine the issues this might bring up more closely below. Finally, it is clear that bailees have a liability to execution in bailment case-types. If any reproductive tissue remained in the Yearworth and Lam cases, I argue that alongside compensation for their losses, the remaining tissues should be returned to the injured parties thereby terminating the medical professionals' ownership entitlements.

Supplementing these incidents of ownership with liability rules is clearly beneficial here. In both the Yearworth and Lam cases the courts established both property rights in the men's human tissues and awarded them compensation for the harms inflicted on them as a result of the mistreatment of their tissues. I therefore argue that the courts' reasoning and decisions in these cases so closely resemble an application of the limited-property framework that they are in fact examples of how well the framework applies to human tissues.

### **3. The Biobank Case-type**

Biobanks do not fall squarely within any of the aforementioned case-types, and so they deserve their own category of cases. In biobank-type cases, individuals offer their tissues to an organization that will provide some small benefit to them or to society but will then own or hold their tissues indefinitely. Biobanks are "a collection of samples of body material which is connected with genetic data and/or health data from patients or donors (in general: associated personal data)."<sup>83</sup> This might make biobanks seem like a specific kind of bailment relationship. I separate biobank and bailment case-types in my analysis because as I will explain below, the relationship between biobank and source individual is different than between bailee and source individual.

There are different sized biobanks depending on the kinds of tissues that are being collected. Some biobanks will collect tissues from a large population (These can be government run, or private organizations such as '23 and Me' or 'AncestryDNA'), whereas disease-related biobanks might collect a smaller range of tissues from specific groups of individuals. Some private organizations provide a certain biobank-type service referred to

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<sup>83</sup> Christian Lenk, Judit Sándor, and Bert Gordijn, eds., *Biobanks and Tissue Research*, vol. 8, *The International Library of Ethics, Law and Technology* (Dordrecht: Springer Netherlands, 2011), 9.

as ‘direct-to-consumer (DTC) genetic testing’, “DTC genetic testing companies offer genetic tests independent of a physician.”<sup>84</sup> In their analysis of DTC genetic testing companies, Allyse et al. offer the history of the practice of DTC genetic testing. Originally these companies would offer sub-par results to those who request their services, in addition to selling individual’s data for secondary uses. Now the Food and Drug Administration (FDA) of the US regulates these companies and limits the uses of individual genetic information. The FDA ensures quality controls and safeguards are in place to protect consumers. Whether or not these companies are undertaking medical diagnosis is currently a debated topic though, “it is not yet clear what ethical or legal responsibilities DTC companies may have to ensure that medical results are not only communicated to customers but are understood and acted on appropriately.”<sup>85</sup> Nevertheless, many individuals are taking advantage of the services that private DTC genetic testing companies offer.

I believe it will be important to proactively delineate ownership rights over banked biospecimen before an inevitable and controversial court case arises. Aside from commercial biobanks, there exist government run biobanks as well. An example of such an institution is the UK’s biobank, which holds itself as “a major national and international health resource, and a registered charity in its own right, with the aim of improving the prevention, diagnosis and treatment of a wide range of serious and life-threatening illnesses.”<sup>86</sup> In addition to collecting excised biospecimen for analysis, volunteers for the UK Biobank’s research have worn 24 hour monitors and undergone other medical studies to supply data and support the institution’s research efforts.<sup>87</sup> The main goal of the UK Biobank seems to be to support the public good.

In general, most biobanks’ interests lie in their protection, stewardship and use of the tissues within their possession. Acting as a sort of intermediary between individuals and research groups, biobanks have a unique relationship with the tissues under their possession. It might be the case that a biobank would conduct research themselves like in the case of the UK biobank, however it is more likely that they would offer tissues or data to scientific organizations doing research – sometimes at a price. In addition to maintaining the biospecimen they collect, biobanks also have an interest in the protection of the sources who offer their human tissues to the bank. If source individuals’ tissues have identifying markers that link back to them, biobanks might be said to have an obligation to protect the privacy of those individuals through tight security conditions.

So, there are two relevant considerations to examine in biobank cases: (1) an individual consensually offers their excised biospecimen to either a government or private institution, and (2) those tissues may *possibly* be used for a weak diagnostic purpose for the benefit of the individual. (2) is clearly optional and is most likely to occur in cases of DTC genetic

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<sup>84</sup> Megan A. Allyse et al., “Direct-to-Consumer Testing 2.0: Emerging Models of Direct-to-Consumer Genetic Testing,” *Mayo Clinic Proceedings* 93, no. 1 (January 1, 2018): 114.

<sup>85</sup> *Ibid.*, 119.

<sup>86</sup> UK Biobank, “About UK Biobank,” About UK Biobank (blog), March 21, 2018. <http://www.ukbiobank.ac.uk/about-biobank-uk/>.

<sup>87</sup> *Ibid.*

testing companies. I deliberately mention a *weak* diagnostic purpose in (2). This is because in the biobanking cases current technology is not capable of offering robust diagnostic results. It is possible that one day genetic testing technology and techniques will be so advanced that medical professionals will be capable of diagnosing a wide range of maladies from simply examining one's genetic information. If so, (2) will require slight amendment. However, for now the emphasis on DTC genetic testing companies' weak diagnostic capabilities is important. Additionally, institutions need not refer to themselves as biobanks in order for the framework to apply to them. So long as the interactions and contracts between individuals and institutions fit closely enough to these characteristics, I argue the limited-property framework can be applied.

Timothy Caulfield and Blake Murdoch argue that informed consent is a serious issue in the new age of genetic research and biobanking. They state that “despite decades of debate and a huge amount of public and private investment in biobanking, there is still a great deal of ambiguity and uncertainty regarding the issues associated with participant control of specimens and health information.”<sup>88</sup> In the face of this issue Caulfield and Murdoch advocate for a proper framework for consent. They cite empirical research that has shown mixed public perception of broad consent procedures. In response to this research, Caulfield and Murdoch examine a few important factors that should be taken into consideration when creating a new and more robust informed consent framework.<sup>89</sup>

The first factor is the perceived rights of control that some individuals believe they have over their biospecimen. These individuals wish to maintain rights of control for various reasons, including but not limited to wishing to be compensated for financial gain as a result of using their tissues or concerns with controversial research being conducted with their tissues. Social controversy tends to weigh heavily on the minds of individuals who offer their tissues to medical professionals, whether the statements that drive that controversy are justified or not.<sup>90</sup>

A second factor that Caulfield and Murdoch examine is the trust that the public has in research institutions. This trust is apparent but to a lesser degree when dealing with commercial endeavors. However, they note that “the inevitability of increased industry involvement creates the potential to erode public trust and to intensify the challenges associated with consent and sample ownership.”<sup>91</sup> It is due to this point that they advocate disclosures of commercial endeavors in the consent process. Without clear disclosure of commercial intent, it is likely that public trust will be damaged. In addition to concerns regarding commercialization of tissues, Caulfield and Murdoch examine concerns of privacy that the public has shown in regards to the data that is gleaned from their tissues. Some individuals worry about loss of control over their data or improper uses of that data.

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<sup>88</sup> Caulfield, Timothy, and Blake Murdoch. “Genes, Cells, and Biobanks: Yes, There’s Still a Consent Problem.” *PLOS Biology* 15, no. 7 (July 25, 2017): e2002654. 2.

<sup>89</sup> *Ibid.*

<sup>90</sup> *Ibid.*

<sup>91</sup> *Ibid.*, 4.

This contributes to the public's wariness of offering up their tissues without a robust consent procedure.<sup>92</sup>

#### **4. Ownership Rights in Biobank-type Cases**

Supplementing my examination of commercial and government-run biobanks with Caulfield and Murdoch's analysis of the public's perception of biobanks will offer us a clearer picture of how human tissues are valuable to individuals and groups of individuals in biobank case-types. The majority of tissues biobanks gather and examine are not sensitive. Current DTC genetic testing companies such as 23andMe ask consumers for saliva, an ordinary tissue-type. However, while the tissues themselves are not sensitive, the information gleaned from those tissues may be. These companies examine the genetic coding that makes us unique. If a company is testing for genetic markers associated with hair or eye color the results of their work likely would not have sensitive personal or social consequences. On the other hand, if a company or institution used genetic testing for the purpose of determining risk of hereditary diseases, or deficiencies based on race, these results would clearly have both personal and social consequences. Depending on the additional research purposes the tissues will be used for aside from the agreed upon testing, both individuals' and DTC genetic testing companies and government-run biobanks' interests will vary and they will thereby find more or less value in biospecimen.

Determining a common intention in biobank cases is difficult. The field is new and uses of biospecimen in biobanks can be varied. In government run biobanks a clear common intention between sources and biobank institutions would be to further research for public benefit. On the other hand, a common intention can be found in commercial biobanks such as 23andMe to offer a benefit to sources in the form of genetic information. In these commercial biobanks there may also be an explicit intent to use the biospecimen gained from sources (and the information that accompanies that biospecimen) for private, profit-driven medical research. Because it seems that both of these biobanking endeavors are research-focused, we might decide to assign default ownership entitlements alongside research case-types. Though this intention exists in biobank cases, it is not clear that it is a *common* intention. In DTC genetic testing cases sources are consumers of a service, it is not clear they intent to allow the tissues they offer to be used for research purposes. The way tissues are used and valued is relevantly different in biobank cases from standard research cases, and thereby require a different default ownership framework. Though sometimes the case-types will overlap, biobanks' potential uses with biospecimen are more varied. In research cases those potential uses are more focused and clearly outlined to sources before tissue separation.

##### *4.1 Control and income rights*

For biobank cases I argue that default control and income rights should reside in the source individual initially, and then be transferred to biobanking institutions based on a contract between source and institution. This is more straightforwardly the case in relationships with commercial DTC biobanks like 23andMe. Recall that the reason

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<sup>92</sup> *Ibid.*

common intentions are so important is that they facilitate the interactions between people in society. I have argued that ensuring the smooth actualization of these common intentions is key to empower people in regards to their control of the objects they find value in in society. In commercial biobanking relationships the initial common intent to use tissues is to offer sources the agreed upon benefit. That being the case, like in diagnostic cases the focus of the common intention being on the source is important, and for similar reasons I argue that sources should initially gain full control and income rights. While this common intention is clear in commercial biobank relationships, it is not as clear in cases of government-run biobanks. These public biobanks are not profit-driven and are primarily research focused. In these situations, the common intention between source and institution seems more like a research case-type, where sources know of the intention to use their tissues for research purposes and offer them for that purpose.

There is a different reason why sources are most justified in claiming ownership rights in their tissues upon separation. This has to do with the way in which most biobanks operate. Most biobanks have sources send their saliva in a tube through the mail to the biobank institution. It seems clear that assigning ownership entitlements in that saliva upon separation from the source to biobanking institutions would be counter-productive. There are too many confounding variables to allow this ownership assignment to take place – it would be practically impossible. Each time some individual spits their saliva into a tube with the intention to send that biospecimen to a biobank we would be required to characterize those tissues as the biobank's property. Ostensibly this would mean that biobanks would constantly be gaining property rights in tissues they do not even know exist. What if an individual begins the biobank process by depositing their saliva in one of the tubes, but has second thoughts? Must they now treat the biospecimen in their hands as property of the biobank? These are the kinds of situations we would run up against should we assign property rights in tissues in biobank type-cases to biobanking institutions *upon separation*. The goal of assigning property rights over tissues is to facilitate the interactions between individuals in society. If we are to set the default property rights in initially separated biospecimen in biobanking institutions we will frustrate interactions between individuals, not facilitate them. I argue that it is the reality of the biobanking process that forces us to assign control and income rights to the individual upon separation as a default in biobanking cases. Undoubtedly some of these rights will have to be transferred, which should be subject to a contract between the individual and biobanking institution.

These contracts might even be contentious. For example, on the 23andMe website under their terms of service the company makes clear that their consumers waive intellectual property rights:

You understand that by providing any sample, having your Genetic Information processed, accessing your Genetic Information, or providing Self-Reported Information, you acquire no rights in any research or commercial products that may be developed by 23andMe or its collaborating partners. You specifically understand that you will not

receive compensation for any research or commercial products that include or result from your Genetic Information or Self-Reported Information.<sup>93</sup>

While this is part of the contract between consumer and private organization, because after close analysis an individual is justified in income rights to the tissues that they offer to biobanking organizations, their waiving that right in a contract would be their choice. Sources will have to take their relationship to their tissues seriously, and ask themselves whether or not the benefit to be gained from offering their tissues to biobanking institutions is worth giving up their income rights. This is highly contextual and dependent on each individual. Clearly delineating ownership entitlements in the forms of both control and income rights aids each party in understanding the legal jurisdiction they can act in.

## 5. Privacy Concerns

As for the limited nature of the limited-property framework, liability rules would surely supplement the interactions between parties. Unsurprisingly, commercial companies wish to distance themselves from potential fiduciary obligations. 23andMe does just this in their terms of service: “23andMe does not assume any fiduciary or similar obligations to you as a result of you using the Services. 23andMe is not a trustee of your Genetic Information or other Personal Information.”<sup>94</sup> A consumer signing this contract may not completely abdicate 23andMe from their fiduciary responsibilities to their customers. In fact, it would be beneficial to have an intricate set of fiduciary obligations and liability rules set in place before this technology and practice get out of hand.

Caulfield and Murdoch showed us the tumultuous public perception of biobanks. Commercial companies like 23andMe’s attempt to distance themselves from their duties to their consumers may exacerbate this perception. One pressing issue in contemporary society is information privacy and confidentiality. The source may have genetic markers or other intrinsic characteristics residing in the excised biospecimen, and/or extrinsic characteristics such as identifying information on packaging labels. Both these and other variables have the potential to disrupt a source individual’s privacy interests if misused.

In his book *Who Owns You?* dealing with ownership of genetic information and intellectual property, David Koepsell mentions people’s privacy interests in their bodies and personas. He cites the growing trend in countries such as the United States and Britain towards using biometric information for security purposes. An example of this would be genetic ‘fingerprinting’ as a highly effect technique, where people are identified through reference to their genetic code. Koepsell contrasts the few legal roadblocks for the use of genetic markers as identifying tools with the varied rights of privacy and control over one’s image or likeness. Others cannot profit off of one’s image, and they must ask for permission before they can use one’s likeness for their own purposes. Koepsell submits that it might be the case that we should be paying as close attention to our genetic privacy as we do our

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<sup>93</sup> 23andMe, “DNA Genetic Testing & Analysis - 23andMe Canada,” 2018, <https://www.23andme.com/en-ca/about/tos/>.

<sup>94</sup> 23andMe.



likeness. For instance, the Genetic Information Nondiscrimination Act in the United States forbids the use of genetic information in hiring or firing decisions, among other purposes.<sup>95</sup>

While Koepsell's analysis does not directly speak to the property debate, I think it is relevant for my discussion here. Many individuals would think twice about attending their publicly funded family doctor and offering blood to that doctor if they knew it might be used against them by their state as they try to re-enter the country from a trip, if they are prosecuted for a crime, or any other number of means. A criticism of the property framework is that a corollary of full ownership transfer of human tissues might lead to unjust breaches of privacy.

In addition to these important privacy concerns that come along with characterizing human tissues as property, there are additional legal concerns. Remigius Nwabueze outlines four categories of privacy that have been identified by Prosser and Keeton:

- (a) Appropriation of a plaintiff's name, likeness or personality for the defendant's benefit or advantage...
- (b) Intrusion upon the plaintiff's solitude or seclusion...
- (c) Public disclosure of private facts [requiring] 1. The disclosure must be public; 2. The facts publicly disclosed must be private; 3. The disclosure must be one that is highly offensive to a reasonable person of ordinary sensibilities...
- (d) Putting the plaintiff in a false light in the public eye...<sup>96</sup>

Where (a) would apply to the discussion that Koepsell offered, and it is difficult to see how (b) would be a relevant consideration when dealing with ownership of human tissues, (c) and (d) point to a different kind of privacy concern that an individual might have in response to a third parties' use of their excised biospecimen. This concern is related to the publicization of personal information gleaned from the work done with excised biospecimen. It is not clear what should be done with the information gleaned through an analysis of an individual's DNA. This information could be damaging to the individual's reputation or mental health. Incidental findings (information gathered from the examination of an object outside the purpose of the endeavor) could create important normative consequences. If upon examining a patient's blood sample a medical researcher finds out the patient is at a high risk of Alzheimer's disease, does the researcher have a duty to disclose this information? Before a procedure starts source individuals can be asked whether or not they want to be told about incidental findings to begin with or kept in the dark, however the reality of incidental findings is that the broad range of specific factors that might be discovered cannot be succinctly expressed in an informed consent process.

The privacy of the individual is not bound to the intimate relationship between them and their medical professional either. An individual's medical history, if publicized, could have detrimental effects on their social relationships with their family, friends, or employer. If an employer finds out their employee has terminal cancer this fact is likely to weigh

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<sup>95</sup> David Koepsell, *Who Owns You: The Corporate Gold Rush to Patent Your Genes*, 1 edition (Chichester, West Sussex, U.K. ; Malden, MA: Wiley-Blackwell, 2009).

<sup>96</sup> Nwabueze, "Biotechnology and the Challenge of Property," 207–9.

negatively on their decisions to offer the employee long-term projects or promotions to higher positions. If property regimes are to transfer full control rights over human tissues upon the transaction between individual and medical professional, there may remain a link to the individual in the form of privacy concerns. It is not clear that property rules are equipped to protect these relevant normative interests.

If an individual's privacy interests have been disregarded through the negligent conduct of a medical professional, that individual should be able to seek compensation for the breach. Additionally, in a proactive sense the individual should trust that the medical professional understands and promises to uphold their fiduciary obligations. This trust can only be fostered through transparent contracts between individuals and biobanking organizations. Private DTC genetic testing companies like 23andMe's attempt to distance themselves from both their ethical and legal obligations to their consumers may be unjustified and seen as a degradation of this trust. If we take the importance of liability rules in the context of biobanking case-types seriously, we can see their utility when dealing with privacy concerns in this context.

I believe this is all evidence for the conclusion that the limited-property framework is beneficial to regulating excised biospecimen use in biobank case-types. Whether the institutions in question are privately or publicly owned, their responsibilities to the individuals whom they are receiving biospecimen from are unclear at this time. Properly regulating these interactions through delineating ownership rights and liability rules will go a long way towards both protecting the interests of relevant parties and facilitating their actualization of the value they see in the human tissues under their control.

## **Conclusion**

In this chapter I have examined two case-types that cover instances of human tissue use outside of diagnostic and research settings. They are the bailment case-type and the biobank case-type. Like the previous cases, I examined examples of these case-types in order to offer a more complete picture of the limited-property framework's applicability. In reference to the biobank case-type specifically I examined privacy concerns. In doing so I re-iterated the importance of liability rules when dealing with information gleaned from both tissues and the tissue excising process.

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## Conclusion

I have shown the utility of the limited-property framework in regulating the use of separated human tissues through my analysis of the aforementioned case-types. A common thread between each case-type is that ownership rights are assigned based on the weightiest value found in the use of tissues. For example, in diagnostic case-types sources are most justified in being assigned property rights in their tissues by default upon separation due to the importance of upholding the common intention for the diagnostic procedure. A similar point is true in research case-types, where the common intention is to do research with excised biospecimen, and so I argued that research institutions should receive property rights in tissues upon separation. I also showed that the facts of any given case might shift us away from the default of a given case-type. The case of the Havasupai was a counterfactual research-type case. The value found in the Havasupai's tissues is so immense I argued that we are normatively required to assign them property rights in their tissues in their case, even though by default control and income rights should be assigned to the research institution. Throughout each of the examples I have offered in this thesis I have shown how we might analyse to whom and how tissues are valuable, weigh the countervailing reasons for valuing tissues, and assign ownership rights as a result of this analysis. The limited-property framework I suggest here can therefore be applied more broadly to other case-types that both exist currently and evolve in the future through advancement in medical practice and technology.

### 1. Canadian Statutes

There are case-types that should not have the limited-property framework applied to them though. I have purposely left out highly regulated medical practices such as tissue donation in my argument. This is because donated tissue is an already regulated practice. In Canada there are statutes dealing with the regulation of human tissues.

One central federal regulation that deals with the control of excised biospecimen in Canada is the Safety of Human Cells, Tissues and Organs for Transplantation Regulations. These regulations are enabled by the Food and Drugs Act. They deal with the transplantation, importation and registration of certain human tissues. The tissues that these regulations apply to are “organs and minimally manipulated cells and tissues.”<sup>97</sup> That being said, there is a considerable list of human tissues that these regulations do not deal with, including but not limited to: cells, tissues and organs for non-homologous or autologous use, heart valves and dura mater, medical devices containing cells, and blood components, products or whole blood. Additionally, any cells or tissues that are regulated under the Assisted Human Reproduction Act (explained below) are not subject to these regulations. The regulations delineate the steps that must be taken to apply for and register transplant tissues, cancellation of requests, storage, distribution, and record keeping.<sup>98</sup> These regulations thereby set the Canadian federal context for transplanting human tissues and organs.

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<sup>97</sup> Legislative Services Branch, “Safety of Human Cells, Tissues and Organs for Transplantation Regulations,” February 11, 2015, <http://laws-lois.justice.gc.ca/eng/regulations/SOR-2007-118/>.

<sup>98</sup> *Ibid.*

Another federal statute that deals with control of excised biospecimen is the Assisted Human Reproduction Act. The purpose of this act is to regulate assisted human reproduction (AHR) technologies and research. It protects the rights of individuals who undergo AHR or who perform AHR, and prohibits acts such as producing a human clone, altering the genome of an in vitro embryo, or transplanting reproductive tissues of non-humans into humans. While this statute's purpose is not directly related to the control of human tissues, it is indirectly related. It clearly delineates certain limits to how human tissues (excised or otherwise) can be used, as well as the punitive measures in place for when someone has proven to have transgressed those limits. It deals with controlling specific tissues in specific ways.<sup>99</sup>

Aside from federal law, most Canadian provinces have their own means of controlling human tissues, though they focus on tissues excised for the purpose of transplanting. Two of these acts are British Columbia's Human Tissue Gift Act and Ontario's Human Tissue Gift Amendment Act (or the Trillium Gift of Life Network).<sup>100</sup> Provincial transplant law supplements and specifies the federal regulations already in place. It may be worthwhile to recall that the federal regulation on transplant tissues is enabled by the Food and Drugs Act of Canada and is bound by that act. On the other hand, neither Ontario nor British Columbia's provincial legislation makes any mention in regard to the authority of the federal Safety of Human Cells, Tissues and Organs for Transplantation Regulations. This legislative situation may lead to conflicts in fringe cases of transplant procedures.

I believe applying property rules where a vacuum does not exist in the law will frustrate interactions between people in society, not foster them. That is not to say that if in the future the limited-property framework proves beneficial enough to encompass or succeed these statutes that it should not be implemented as a matter of legal principle. I wish to make clear here that for now the limited-property framework should fit within its legal jurisdiction. It is because of this that I have left certain case-types out of my analysis.

## 2. Liability Rules

In addition to property theory's importance and utility towards regulating biospecimen use in society, I argued that it cannot not trespass where it does not belong. Liability rules cover situations where property rules do not, such as tort and fiduciary obligations. An individual can hold a medical professional who misuses their tissues not only on property-related grounds but also on liability-related grounds. Such a lawsuit might charge the medical professional for transgressing a fiduciary obligation in reference to the use of a source's tissues. Therefore, I argued that fiduciary obligations supplement and enhance property rules, creating the 'limited' nature of the limited-property framework.

Liability rules set important duties in reference to three particular contexts: breaches of consent, commercial exploitation, and breaches of privacy. Interestingly, I argued that each of these unwanted normative consequences become less harmful once we take an

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<sup>99</sup> Legislative Services Branch, "Assisted Human Reproduction Act," September 30, 2012, <http://laws-lois.justice.gc.ca/eng/acts/a-13.4/>.

<sup>100</sup> Government of Ontario, "Human Tissue Gift Amendment Act," Text, Ontario.ca, July 24, 2014, <https://www.ontario.ca/laws/view>; "Human Tissue Gift Act," accessed March 1, 2018, [http://www.bclaws.ca/civix/document/id/complete/statreg/96211\\_01](http://www.bclaws.ca/civix/document/id/complete/statreg/96211_01).

individual's relationship to their tissues more seriously. I argued that many of the issues in these contexts can be explained away through granularly assigning each of the incidents of ownership in the control and income right bundles to a specific party, and then tracing the transaction of those incidents amongst parties. However, there may be additional concerns even after these incidents have been assigned and transferred, and in these cases I argued that liability rules can protect from any further issue.

### 3. Moving Forward

Situations of contentious tissues use are becoming more prevalent as tissues are drawn from sources in more situations for different purposes. Recently, Canadian immigration officials have used DNA information gained from ancestry websites to determine migrant's nationality.<sup>101</sup> Depending on the context of tissue separation and we can determine who has ownership claims in those tissues before this situation gets out of hand. This is just one way in which the limited-property framework I have argued for in my thesis will be beneficial moving forward. However, the framework is limited in important ways, one of which being its implications for intellectual property and data. While I believe a granular approach to control and income rights has implications for data gained from research done on tissues, it is not clear that these ownership entitlements encompass this new intellectual data. Who has income rights claims will tell us who is justified in seeking monetary value in exchange for tissues or data gleaned from tissues, but it does not extend to assigning full intellectual property rights. Income rights cannot be the same as intellectual property rights. Data ownership is a wholly different issue that comes with important normative consequences. Though the limited-property framework for human biospecimen use has implications for intellectual property, I leave it to others to flesh out how these implications play out.

If implemented, the limited-property framework both facilitates the interactions people in society have with each other in regard to their biospecimen as well as holds them more accountable for the transactions they volunteer into. More emphasis is placed on the informed consent process, but in doing so ongoing consent becomes less important. The transaction of biospecimen ownership becomes a contract where people can negotiate the terms before hand. Much like other commodities in liberal democratic societies, regulation sets the boundaries for these contracts and the market sets the value. People have more liberty to use their tissues in the ways they see fit and can feel safe knowing certain base interests of theirs are protected through liability rules. In the end I argue that the benefits to allowing property law into our medical practices in regard to our human tissue use far outweigh the drawbacks.

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<sup>101</sup> Ashifa Kassam, "Canada Uses DNA and Ancestry Sites to Check Migrants' Identity," *The Guardian*, July 2018, sec. World news, <http://www.theguardian.com/world/2018/jul/30/canada-uses-dna-and-ancestry-sites-to-check-migrants-identity>.

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