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A reflection on the morality of ownership of genetic material

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2011-11-23
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A REFLECTION ON THE MORALITY OF OWNERSHIP OF GENETIC MATERIAL

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A research report submitted to the Faculty of Health Sciences, University of the Witwatersrand, Johannesburg, in partial fulfillment of the requirements for the degree of Master of Science in Medicine in the field of Bioethics and Health Law.

This work has been approved by the aforementioned university for the degree of MSc (Med) Bioethics and Health Law.

Johannesburg, 2011

Declaration

I Candice Lee De Carvalho (candidate number) 0209366M declare the following information concerning my research report titled:

A Reflection on the Morality of Ownership of Genetic Material

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- I am aware that plagiarism (the use of someone else's work without their permission and/or without acknowledging the original source) is wrong.
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Abstract

The question of ownership of genetic material is highly relevant to medical ethics at this point in our history. What has become a major debate is how DNA can, and if it ought to be commoditised; and how and if individuals can keep their genetic information private, or whether it ought to be shared with all.

In this research report I question whether genetic information is exceptional when compared with other medical or health-related information. The Kantian view of commoditisation of the body and human dignity is given along with some of the most prominent views on self-ownership.

Patenting and genetic biobanking have received much attention in recent years, I focus on these issues and moral questions that surround these practices.

The idea of genetic information as a common and natural 'resource' is discussed. If it is indeed a common heritage for all, how ought individuals, populations, researchers and funders to relate to genetic information? I briefly examine what some communities and cultures may have to say about genetic information and I attempt to tie all these varying perspectives together.

I find that it is not ownership per *se* that is often the subject of dispute, but how those who happen to have control over that information share it. I present a possible maxim to guide the sharing of genetic information with others; that patenting does not necessarily amount to an affront to human dignity in the Kantian sense and that inter-cultural perspectives on genetic information may differ significantly. I conclude that how genetic material is shared, or not shared and why seems to depend more on the population in question at any given time and its social, political and economic structures than on the question of ownership per se.

Acknowledgements

I would like to thank all who assisted and supported me in the completion of this study.

I gratefully acknowledge my supervisor, Professor Donna Knapp van Bogaert for her assistance and inspiration.

A special word of thanks to my family, friends and colleagues who encouraged me throughout.

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Ethics waiver

The method or inquiry I use in this research thesis is not subject to the problems of confidentiality or informed consent as no human participants are involved. Ethical issues which are appropriate to this research include 1) a careful analysis of facts while remembering that facts may change in the light of new knowledge, 2) the obligation of fairness – to ensure that I give the oppositional position equal consideration to my own, 3) the duty to ensure I reference my sources properly and completely to avoid any thought of plagiarism, 4) the obligation to keep an open mind, and 5) the duty to continue to learn. I have therefore applied for a waiver of ethical review. Please see Appendix I.

Preface

The body is a source of instrumental value to others in the following ways: organs, tissues, gametic materials and cells provide what sometimes can be life-saving benefits to patients and benefits to physicians and researchers, in addition. For this reason, society has approved (with some debate) the acquisition of these in various ways. This may be through gifts and donations, such as of blood, marrow, organs and sperm and through the sale of hair, sperm and blood (Campbell 1992:36). However, what has become a major debate is how DNA can, and if it ought to be commoditised; and how and if individuals can keep their genetic information private, or whether it ought to be shared with all.

The rise of genetic research and information has transformed how scientists study, diagnose and analyse disease. Molecular-level information and would have been unthinkable 100 years ago. From the time that Watson and Crick discovered the structure of DNA in 1953, the race was on to discover the genetic code. This was achieved in 2003, and now the function of every part of the genome is the main concern of those wanting to advance genetic breakthroughs even further. This revolution in medicine – molecular genetics – has not only transformed the way that diseases are diagnosed, but also how they are treated.

Researchers and the public alike have been captured by the possibilities offered by this genetic information and wander how it can be exploited and protected. Human genetic information is relevant to forensics, human development, genealogy and history, as well as some other fields.

Considering the vast number of topics and ethical dilemmas introduced by this relatively new field of study, this research report has been limited to the question of genetic information ownership of DNA in the context of patenting and biobanking. Captivating and possibly enlightening to the subject in question is human rights, questions of what constitutes the self and personhood and political philosophy of self-ownership. These, however, have been limited due to length restrictions on the research report. I find these topics fascinating, however, and I intend to pursue these at a later stage.

In section 1 of this research report first I will present an overview of the rise of genetic manipulation and advancements in molecular technologies. I will briefly provide context as to some of the uses of genetic information and how genetic information, as it pertains to this report, is viewed. The instrumental value of genetic information is outlined as well as some of the fears that people may have concerning the use and privacy thereof. This will lead me to the idea that genetic information is exceptional in the context of health information and I will also present arguments against this notion.

How genetic information is organized is addressed as well as further discussion on some of the social pressures around it are discussed, specifically in terms of family duties and relationships. The Kantian view of commoditisation of the body and human dignity is given along with some of the most prominent views on self-ownership.

As part of section 1, genetic patenting will be discussed. Some of the moral arguments for and against the practice will be outlined.

In section 2 of this report I will discuss another of the major issues that is rising around the ownership of genetic information, biobanking. In this report I will outline what biobanking is and how some practical issues tie in with moral ones. I will discuss some moral arguments for and against biobanking.

I will attempt to apply ideas of community, sharing, gifting and common heritage to the problem of genetic ownership and I will offer some concluding remarks drawn from my summation of the key authors that will be outlined.

Introduction

In 1972, scientists first isolated a DNA segment from a virus and combined it with a piece of bacterial DNA. This gene, when placed into a plasmid and introduced again into a bacterium, functioned normally. The biotechnology of recombinant DNA resulted in the birth of genetic engineering. There is a current explosion of scientific technology and developments in the field of genetics. This includes the sequencing of over 15,000 genes that have been identified to be associated with human heritable diseases or phenotype variations (Collins and McKusick 2001: 540-544).[1]

Variations of particular individuals may be identified by way of their genetic markers ("DNA fingerprinting") whilst other family members may be disease-free. This technology-explosion has brought great benefit to many individuals as prior knowledge of predisposition to a particular disease has enabled medical science to intervene, in as much as it is possible, to preempt or treat the disease.

Biotechnological advances in human genome mapping, so-called predictability or susceptibility testing, heritage testing, biobanking, pharmacogenomics, reproductive technologies and novel diagnostic techniques have transformed access to genetic information. Along

[1] Gene variants or mutations do not always result in disease. For example, one of the most recent discoveries is of three new genetic loci that have been identified with involvement in subtle and quantitative variation of human eye colour (Liu 2010).

with this accessibility come complicated ethical questions of access to- and storage of- information, security thereof, privacy, consent and ownership.

Section 1

1. Genetic information

Genetic medicine involves statistical evidence of expressed genetic characteristics of diseases in various family members for determining patterns of inheritance and probabilities of risk recurrences. Although once seen through the lens of clinical practice ethics, as many of its applications were specific to health care, ethics of genetics are evolving.

Genetic information broadly refers to all of the currently known genetic data for all living organisms. It can also refer to the genetic composition of one individual and their families. At the same time, there are ethical issues which are raised which concern many aspects of this explosion of technologically-driven knowledge, specifically that of genetic information. This is because genetic information holds the ability to identify uniquely each human individual (Rothenberg and Terry 2002: 196-197).

Many individuals express concern that a positive finding on a genetic screening test will result in discrimination and stigmatisation because they are out of the norm. This response though is only applicable outside of the doctor-counselor-patient sphere as genetic counseling

[2]is an integral part of genetic medical practice. Another concern raised is that the release of genetic information may result in an individual's loss for example the inability to get insurance, or employment if genetic information crosses into the public domain (Orentlicher 1990: 1005).

Nowadays, genetic information is used not only in the doctor's office, but also beyond. For example, genetic information in a variety of forms is found in courts of law as a way of proving or disproving paternity, determining immigration status[3], in criminal cases involving genetic materials[4], by the military for soldier identification purposes, and by insurance companies. As an example of one of the problems arising from knowing an individual's genetic information, the latter may provide a good example.

Since insurance companies base their profits on good risk assessments, it is quite possible that genetic information will make it

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[2] Genetic counselors are specifically trained to help an individual or his / her family to comprehend the medical facts, including the diagnosis, appreciate the ways in which heredity contributes to the disorder and available management, the risk of reoccurrence, the availability of management, the options available for managing reoccurrence, and the provision of varieties of courses of actions aimed at providing the patient with the best possible information upon which he or she can make a decision. In considering the history of genetic medical practice, counseling has always played an enormous part as it has been documented that there are emotional (Lerman, 2002: 784) and practical issues (Liao, 2011:308) in that type of practice which require an enormous amount of psychological support and logistical effort.

[3] See interesting article by David Stipp in the *Wall Street Journal* July 9, 1990: "Genetic testing mark some people as undesirable."

[4] The UK owns the largest database of DNA samples in the world. The UK's National DNA Database (NDNAD) is used to show suspects guilty or innocent by comparing their DNA profiles (10 Short Tandem Repeat markets plus amelogenin for sex identification) with the millions on 'file'. Collecting criminal records, as a standardised practice began in 1896 in the UK, and those records are available today (Human Genetics Commission, 2009 Report). The use of DNA has been a revolutionary innovation to forensic investigation, but some have complained that the retention of DNA profiles on the NDNAD constitutes an intrusion into personal privacy; and that it produces unfair discrimination. There are justifiable reasons, focused on the 'greater good' for keeping population DNA samples, but these must be weighed against individual freedoms and dignity.

possible to discriminate between individuals based on their genetic characteristics that place them into a higher risk category. Already insurance companies discriminate between particular people based upon the place they happen to live (e.g. high-risk versus low risk neighborhoods). Such discrimination based on risk also may extend to other areas such as those concerning race, gender, belief system, etc. (O'Neill 1997:1087-1093). The way in which genetic information can be used to discriminate is a pause for concern for it is unclear how insurers will account for this information e.g. as a harm or help when coverage is needed. Genetic information may involve other family members. Thus, we might consider a problem arising when one insured individual has disclosed his genetic information indicating e.g. a high risk of colon cancer to his insurance company and another family member (also insured by and thus known to the same company) has not undergone genetic testing nor knows of his risk (Orentlicher 1990:1005).

Another issue is that genetic test kits are available via the internet, a process that outside the area of medical supervision, clinical advice and genetic counseling. For the individual, this amounts to a greater access to his or her own, and perhaps the genetic information of others.

Such massive shifts remove genetic information from traditional medical settings and place it in the public domain where it is possible that it can be coupled with non-medical, quasi-medical or other

databases. It is no surprise then that different ethical concerns have arisen in connection with genetic information, because it is or has the potential to be used for many different purposes.

Why this matters is because genetic information is seen as different from other biological tissues in that it potentially involves more "broad-ranging features of an individuals' health status" and carries implications for relatives (Skene 2002: 49, Gillet and McKergow 2007: 2094). Within the ambit of health and wellness, genetic information is being used in reproductive and fertility health, disease diagnosis and treatment, epidemiological studies, bioinformatics and pharmacogenomics[5]. The ethical problems raised by these focus more on issues of the control and protection of information, ownership viz. individual or family,[6] confidentiality and research use as well as ways to limit possible coercion. It is accepted within genetic medicine that the powerful relationship between DNA technology and information technology results in some urgent and complex questions about who ought to benefit and about how individuals, families and communities can be protected against harms.

[5] Simply put, this is the study of the effect of an individual's genotype on the body's potential response to medications.

[6] The problem becomes more complex in that although it is now possible to tell an individual that he or she will have a genetic disease or at least a predisposition towards it, that particular individual may not want to know that information, or release the information to his or her family members who may be implicated.

1.1 Genetic exceptionalism

Despite that the gifting and sale of certain parts of the body has become a (debatably) acceptable practice in some parts of society, there has been an attitude of what is termed "exceptionalism" regarding genetic information. This is most likely due to the 'mystique' around genetics, in that the concepts can be highly abstract and difficult to understand, but also in that there tends to be much suspicion about the nature and power of the contents of genetic information.

Genetic exceptionalism is an expression used to convey the idea that genetic data differs intrinsically from other personal, including medical data, because it provides information not only about the individual from whom a genetic sample is taken but also about other familial individuals (Chadwick and Thompson 1999: 84). In learning about our own genetic makeup, we also, because of the very nature of genetics know something about our families.

1.1.1 Some arguments for genetic exceptionalism

The conviction that genetic data require a greater degree of protection than do other medical or personal data is because of their unique and special nature. The arguments for classifying genetic information as exceptional are generally grounded in the belief that genetic information is uniquely sensitive information owing to its "prophetic, predictive, shared, and symbolic nature" (McGuire et al. 2008: 500). The most obvious example of this is that of the genetic

relationship between monozygotic twins. Since they share such a high percentage of their genetic makeup, if the one were to discover a deleterious mutation, it would be highly likely that the other twin would have it as well. As familial relationships move further apart (genetically), this probability decreases, but the information may nevertheless be relevant to family members and therefore affect decisions that they make about their health care, and in some cases reproductive choices.

So we see that the argument from exceptionalism has some merit. It does so because in e.g. a general practice setting a doctor conveys medical information (of any sort) to an individual patient. For example, “Mrs. Jones, I’m sorry to tell you that your tests show you are mildly hypertensive. Now let me explain what that means …you should exercise, meditate, take your medicines …”. The tests have shown that Mrs. Jones has mild hypertension. While her diagnosis and acceptance of advice may result in a change in her life-style, which may affect family members, it affects them only in that particular social-historical context; it does not carry the potential to affect future generations. Indeed, the conveyance of genetic information because its basis is genetics cannot, by its very nature be placed in the same type of doctor-patient-family frame.[7]

[7] In considering the patient as part of a larger family relationship, Family Medicine and Genetic Medicine are both specialist areas in which this consideration has always been important. The is currently a trend in other areas of medicine to also afford greater inclusion of the family and community in decision-taking but the patient still remains as the major focus.

This is because an individual receives not only information relating directly to her, but also she receives the genetic history of her family or in some cases, her extended family (husband, mother-in-law, father-in-law). This information may inform her that if e.g. she gives birth to a son that X disease may continue as a part of the family genetic linage; it may inform her that she is a genetic carrier of X and as such, she and her daughter have a potential for X disease. Thus, the argument goes, genetic information should be considered as exceptional. It is within this frame that individual consent, privacy and confidentiality classically practiced as medical ethical tenets are, as claimed by genetic exceptionalists, insufficient as parameters broaden. Genetic information thus should be offered to all family members as they have a 'right to know' (O'Neill 2001: 703-704).

UNESCO (2003) also offers an international perspective on genetic data noting,

> "a. Human genetic data have a special status because:
>
> i. they can be predictive of genetic predispositions concerning individuals;
>
> ii. may have a significant impact on the family, including offspring, extending over generations, and in some instances on the whole group to which the person concerned belongs;

iii. they may contain information the significance of which is not necessarily known at the time of the collection of the biological samples;[8]

iv. they may have cultural significance for persons or groups.

b. Due consideration should be given, and where appropriate special protection should be afforded to human genetic data and to the biological samples."

As may be discerned from part 4 of UNESCO's points is that some of the ethical concerns about genetic information include thoughts of discrimination, predictions of the future and even revelations of lineage and history which are all associated with the powerful knowledge and analysis of gene sequences (Nelkin and Lindee 2004: 150, 164). Perhaps what is of major consideration is the idea that there is a social meaning of treating people differently based on their genetic makeup that is different from the social meaning of discrimination on the basis of health or illness (Hellman 2003: 57-77). So the parameters for genetic exceptionalism further expand.

1.1.2 Some arguments against genetic exceptionalism

On the other hand, it may be argued that genetic information is neither "exceptional nor ethically different from other medical information" (Murray 1997: 63). Here I acknowledge that in the

[8] One can realize from the above quotation that the spectrum of genetic information is not confined to a single area such as issues related to individuals receiving genetic information. It extends far out to social, political, cultural and economic considerations; to populations and groups who are 'advantaged' and 'disadvantaged'. The broadness of the topic is beyond the scope of this research report but I hope in the future to explore these issues further.

earlier example of an individual who received genetic information all the information given concerned genetic problems. This is one point raised by those who argue against genetic exceptionalism, for not all information relayed to individuals concerns serious, monogenic, and incurable genetic diseases. It is asserted that other medically relevant but non-genetic information has similar qualities (although perhaps less amplified) and authors are disparaging towards ideas of genetic exceptionalism (Murray 1997: 65; Suter 2001: 668).

Murray (ibid: 63) argues that there are medical issues such as elevated cholesterol, or exposure to an infectious disease that perhaps ought to be shared with family members as well. Murray does not deny that information sharing among family members may be a duty, but reiterates that this duty is present with non-genetic conditions and therefore argues that that genetic information is not exceptional. From a public health perspective, Hodge (2004: 68-69) argues that the ethical principles of public health justify voluntary genetic testing for populations and the sharing of data for population-based purposes[9]. Thus, he argues, individual rights should not always trump the use of genetic tests or screening programs (or information derived there from) for legitimate public health purposes (ibid). So, while there is general agreement that genetic information is personal, sensitive, familial and potentially discriminatory,

[9] To envision the voluntary testing of populations to gain genetic information is difficult to imagine. Practically, at least dependent on the type of genetic information desired, in some cases it would not be necessary to gather genetic information from all members of a population, only a /or particular family members would suffice. Likewise, if others or those believed to be at risk object to genetic testing, then a key individual may be prevented from having a genetic test that he or she considers important because of familial objections.

arguments are that it may not be uniquely so (Lemmens and Austin 2001: 26; Suter 2001: 669; Gostin and Hodge 1999: 21).

Broadly, arguments for and against the idea of genetic exceptionalism have now been outlined. In the following sections, I will will look at how genetic information is organised and then I will turn to one of the most relevant topics in DNA ownership - patenting.

1.2. Organising and ownership of genetic information

De Witte and ten Have (1997: 51) suggest that two distinctions simplify a discussion of genetic information. The first, is between levels of how genetic information is generated. One level concerns "information that is expected to result from the dual process of mapping and sequencing the entire human genome". The other level concerns the information obtained as a result of sequencing an individual's genes or short pieces of sequence.

The other distinction is between genetic *material* and genetic *information*. The authors state that it is not immediately clear whether the "moral status of genetic material is the same as the moral status of genetic information". I will set aside that debate in this discussion.

Since genetics touches so intimately on an individual's life, as does any other health-related information, it is often thought of as falling into a property "paradigm" in that individuals tend to think of themselves as proprietors of their genetic material (Andrews 1986:

29; de Witter and ten Have 1997: 51; Gillert and McKergow 2007: 2095; Campbell 1992: 40).[10]

In their discussion on ownership of genetic material and information, de Witte and ten Have (1997) identify a few possible owners:

a) the individual with the particular genome;

b) the scientist or company that discovered the particular genes or nucleotide sequences;

c) humankind in general (as previously noted in the UNESCO declaration). I would add another category:

d) a group of people who happen to share an identical set of specific nucleotides for a sequence in question. These parties are in a position to claim of ownership either over their genetic material or information or both.

In this next section, I will turn to a discussion concerning the ownership of genetic information.

1.3. Discussion: The ownership of genetic information

In this section, I will first look at some of the basic principles argued for by Kant, including his approach to moral decision-making. Then I will look at Kant's views on self-ownership and I will attempt to tie these ideas to the issue of genetic ownership.

[10] There is an additional layer of ownership and intuitive value of genetic material as a "treasure" in communities where ancestry and heritage is a major part of the community's sense of worth and well-being (Gillert and McKergow 2007:2094). In cases where screening tests show that a person has a sequence variant that will likely lead to a particular disease in the future, the knowledge of genetic sequences is predictive and so there is possibly even another layer of value that is assigned to genetic material.

Immanuel Kant, believing autonomy to be fundamental to morality, re-engaged the concept and the duty to act autonomously and this became the cornerstone of Kantian thought. He (1996: 150) writes,

"Autonomy of the will is the sole principle of all moral laws and of duties in keeping with them."

In this passage, we can see that Kant does not hold autonomy to degrees of competence, freedom from outside influence, or other relational aspects. For Kant, autonomy is intrinsic to living in accordance to our duty which binds us to respect the intrinsic value, worth, and dignity of other human beings.

1.3.1. The intrinsic value of human beings

Kant (1996: 154) argues that all people have unconditional worth and the capacity to determine his or her own destiny because of their status as rational beings writing,

> *"The capacity to set oneself an end - any end whatsoever - is what characterizes humanity (as distinguished from animality). Hence there is also bound up with the end of humanity in our own person the rational will, and so the duty, to make ourselves worthy of humanity by culture in general, by procuring or promoting the capacity to realize all*

sorts of possible ends, so far as this is to be found in a human being himself."

Kant (ibid: 436) argued that these qualities are the basis of freedom and equality - the very bedrock of dignity and the reason why persons are deserving of respect,

"The lawgiving itself, which determines all worth, must for that very reason have a dignity, that is, an unconditional, incomparable worth; and the word respect alone provides a becoming expression for the estimate of it that a rational being must give. Autonomy is therefore the ground of the dignity of human nature and of every rational nature."

Our humanity concerns, 'that collection of features that make us distinctively human, and these include capacities to engage in self-directed rational behavior and to adopt and pursue our own ends, and any other capacities necessarily connected with these' (Robert 2010). Since humanity has unconditional worth, Kant's moral formula requires regard for that worth and that is why Kant denied that persons or their actions could be owned. If they could, then they could be thought of as analogous to property, which a person can do with what she wishes, whether that be sell it, misuse it, give it away, change it or destroy it (Kant 1999: xxxiii).

1.3.2. The categorical imperative

"Humanity is free and exercises that freedom through moral action (Kant 1996: 25)."

For Kant, to act morally is to act on some principle or maxim and therefore he believed that morality is a matter of following absolute rules that do not depend on our having specific desires, but rather depend on reason (Rachels, 1999: 123). Our duties are derived from a categorical rule, which Kant (1996: 18) calls the Categorical Imperative:

"Act only according to the maxim by which you can at the same time will that it should become a universal law."

By applying this moral rule, a person makes moral decisions based on reason alone. The first formulation of the categorical imperative forbids actions that cannot also be stated as universal norms without generating a contradiction (Kant 1996:150). The second formulation states that one should:

> *"Act in such as way that you treat humanity, whether in your own person or in the person of any other, always at the same time as an end and never merely as a means to an end."*

These formulations can be used as a guide in a moral decision-making procedure. The procedural steps according to Johnson (2010) are as follows: First, formulate a maxim that enshrines your reason for acting as you propose. Second, recast that maxim as a universal law of nature governing all rational agents, and so as holding that all must, by natural law, act as you yourself propose to act in these circumstances. Third, [the contradiction in conception test] consider whether your maxim is even conceivable in a world governed by this law of nature. If it is, then, fourth, ask yourself whether you would, or could, rationally will to act on your maxim in such a world. If you could, then your action is morally permissible.

If the proposed maxim passes the test of all four steps then the action is morally permissible. By combining these formulations, then, it is clear that a person has a perfect duty not to use treat the humanity in themselves, nor in others, as a mere means, but always as an end in itself.

1.3.3. Kant and duty

Kant argues that the only good act is one that is motivated by duty. Being motivated by moral duties is the very expression of "good will", which according to Kant, is the only thing that is good without qualification. When deliberating about what actions ought to be taken therefore, the question of relevant duty is more important than other motivations, however praiseworthy and admirable they may be. Kant held that every person has moral duties towards both

themselves and others. In fact, these “self-regarding” duties include the duty to refrain from committing suicide (Kant 1997:38), engaging in voluntary servitude (Kant 1996:66, 104), and failing to develop one’s own talents (ibid 1997: 38, 39). To this list, we may add more contemporary notions such as the duty not to sell one’s organs (ibid 1996: 177), engage in self-mutilation (ibid 1996: 177), and to prostitute oneself (ibid 1996: 65).

Kant condemns removing or destroying parts of the body discussing the trade of the body in specific saying, as quoted in de Witte and ten Have (1997: 54)

“… A human being is not entitled to sell his limbs for money, even if he were offered 10 000 thalers for a single finger.”

Kant therefore defends bodily integrity (the right of freedom from assault); bodily independence, being one’s own master and condemns assaults on the freedom and property of others. Kant’s notion of autonomy, though remains linked to morality as opposed to other conceptions.

In contemporary times, the term autonomy has shifted to a different meaning from the original position of Kant. For example, we often come across terms such as ‘the autonomous self’, ‘autonomous agents’, ‘autonomous individuals’ (Hill 1992: 76-96). Indeed, what is currently termed ‘patient autonomy’ is now often confined to a patient’s (or research participant’s) agreement; that he or she, having

been dutifully informed of procedures, processes, research, etc, freely chooses to accept or reject the treatment, procedure, or research terms. Of course, the other party, be he or she a doctor or researcher, has an obligation not to commence any action until the patient has agreed to the proposal on hand.

While a doctor may even encourage her patient to consider the morality of autonomy in respect for his or her dignity and worth the patient may not internalise this. One reason why this may be so is that it is more commonplace now in medical and research practice to abide by the rules and regulations attached to the ritual of the informed consent process. In doing so, the doctor provides the required and sufficient ethical and legal justification that he has "recognised someone's autonomy".

This may be understandable as there are many controls in place in the form of laws and regulations, which inevitably have reshaped the doctor-patient relationship and with it the concept of autonomy.

Viewing Kant's thoughts - or what we interpret as his thoughts - in current times and circumstances is quite difficult. In the following section, I will try to unpack an example of a few contemporary writers as they present their readings of Kant in the context of self-ownership.

1.3.4. Some views on Kant and the idea of self-ownership

Kant's views on self-ownership are underpinned not by a principle of self-ownership but with the principle of end, a privilege of man by way of his humanity. Taylor (2004: 71) explains Kant's position writing,

> *"In MM [Metaphysics of Morals], Kant asserts that someone can be his own master but cannot be the owner of himself (cannot dispose of himself as he pleases) - still less can he dispose of others as he please - since he is accountable to the humanity in his own person."*

The reason for Kant's rejection of self-ownership, so construed, is not difficult to discern: if self-ownership implies a liberty to "dispose of oneself as one pleases," then it is inconsistent with his second formulation of the categorical imperative. Self-ownership, however, is sometimes thought of as an adequate interpretation of Kant (Nozick 1974: 31; Mack 1990: 521; Taylor 2004: 67).

Nozick (1974) borrows from Kant to argue that as humans with inherent value and dignity we ought to have the right to freedom, and from Locke to argue that we ought to have the right of to private property. But Nozick offers only minor references to Kant's writings and uses a brief description of the second formulation of the categorical Imperative (that people are ends in themselves) as one of his moral justifications for self-ownership.

Where Kant and Nozick agree is that a person should never be treated merely as a means to an end. On the issue of how a person should treat themselves, Nozick believes that that is a matter of personal liberty and that the person should be able to make their decisions without outside interference. Kant, in fact shares that belief. He sees voluntariness and freedom from interference as essential to autonomy. Where they disagree is on the matter of respecting oneself and what that respect means. Kant's believes that people have a duty to respect themselves as much as they do to respect others. Nozick believes that it is wrong for others to treat one as an object for their use, but fails to describe why it is permissible to treat oneself as an object. The principle of self-ownership prohibits violence or intrusion by others but permits such against oneself.

Self-mutilation, suicide, euthanasia and prostitution are permissible according to Taylors' (2004) thesis of self-ownership, but not everyone who believes that they ought to have rights of control over themselves, as would be granted by the principle of self-ownership, also believe that an act such as suicide ought to be morally permissible. Therefore, the right of exclusion (sometimes referred to as bodily integrity) may be a right conferred, not by the principle of self-ownership, but possibly by some other right or principle.

By the same token, the principle of self-ownership affirms the intuition that one ought to be protected from enslavement or

confiscation of body parts, but the same people who have this intuition do not necessarily agree that the corresponding right is moral, for example that voluntary enslavement or organ selling is right. So then, libertarians who see the principle of self-ownership as self evident due to its powerful intuitive nature have to deal with the problem of conflicting moral intuitions as they arise.

Taylor (2004: 67-69) urges libertarians to keep on in their search for a principled reason to justify self-ownership. He attempts to develop and defend a Kantian idea of self-ownership, which he describes as a perfect duty of physical non-interference which is consistent with Kant's description. He (ibid) states that it is because we have this right that it flows logically that we own ourselves. Taylor, to make his point, analyses physical coercion and paternalism. Through the application of Kant's categorical imperative, he argues that since neither can be universalised they cannot be adopted as a maxim. Since both physical coercion and paternalism are prohibited both by the principle of self-ownership and rejected by Kant, Taylor attempts to use his findings to link Kant to the principle of self-ownership. What is missing from Taylor's analysis is a description of why it is the principle of self-ownership rather than the humanity formula of individuals as ends that is the foundational basis of why coercion and paternalism are wrong.

In addition, as mentioned earlier, we also have a right of exclusion because of the principle of ends. Taylor's (ibid) analysis implies that

man is to be treated as an end because he owns himself, which is seems, as I understand it, to be a distortion of Kant's thesis.

Attas (2000: 13, 14) provides a different perspective. He explains that the matter of informed consent is at the crux of the self-ownership debate. This is because, he argues, consent is central to the notion of self-ownership. The difference though is that consent is not always central to treating oneself as an end (ibid: 7). Attas explains that the right to be treated as an end is intuitively confused with the right of consent. Moreover, since consent (in contemporary times) is central to self-ownership, the right to be treated as an end is confused with the right of self-ownership (ibid: 15). In this way, he asserts, Kantian thought is mistakenly invoked to justify self-ownership.

1.3.5. Kant, self-ownership of genetic information and exceptionalism

Despite the strong intuition that a person is the owner of themselves, there is little principled moral argumentation to prove that people are indeed in possession of rights of self-ownership. In spite of this, there is strong legal, legal-ethical arguments that uphold individual liberty, freedom, autonomy and dignity aimed to protect the individual from intrusions on or into her body (bodily integrity). The intuition of the validity of self-ownership, also fortified in the act of giving, and libertarian approaches centres around many of these same ideals. In the end, there seems to be an overlap between the arguments for

and against body-ownership, self-ownership as well as limited self-ownership.

The critical differences between them are on issues of dignity (in the Kantian sense), especially where harms towards oneself are concerned. These are considered an infringement of respect for the humanity in oneself and are therefore prohibited. These are, in specific, the disposal of- and trade in- the body or its parts.

Kant argues that people ought to be treated as ends in themselves. They are ends in themselves because they are rational beings who have inherent worth and dignity. Because of their intrinsic value, they are deserving of respect at all times. This respect is to be applied by a person towards his or her self as well as towards others. In doing so, some of the principles of individual liberty are protected by the principle of ends. On the other hand, freedoms that constitute an indignity towards self and others, such as commoditisation of the body, are prohibited.

It is difficult to imagine just how Kant, should he be present in today's world, would view ownership of genetic information and the exceptionalism debate.

If we were create a maxim that said, "One should always offer to disclose one's genetic information to family members or relevant others" I would consider this right and appropriate, and I think Kant

would agree as I would be demonstrating my duty to respect myself and for others. It shows Kant's concept of autonomy as the principle of morality.

On the other hand, if we were to create a maxim that said, "One should always disclose one's genetic information." I would hesitate to act on this maxim. We can agree that self-ownership or autonomy conceived as the individualistic "I, me or mine" while still involving a part of human dignity may point to taking actions such as such as voluntary slavery and self-mutilation which would place us in a position of being the sovereign and final arbiter over ourselves. I do not think that was Kant's intention.

Moreover, and in a different perspective, the concept of sharing or providing one's genetic information per se may not be the real issue at hand. I tend to consider genetic information exceptional inasmuch as it is unique and still in its infancy as part of the rapidly evolving field of genetic science and technology (where I consider the precautionary principle to have some merit). On the other hand, I recognise that the benefits that can (at least purportedly) be gained by its use may outweigh my concerns. What to me is probably the most important consideration is the moral issue of to whom, why and how this genetic information will be used. And for an answer to that, I think we must wait for history to tell the tale.

Now that some of the basic concepts regarding genetic ownership have been discussed, I will turn to the issue of patenting.

1.4. The patenting of genetic information

Genetic information is fraught with issues of intellectual property rights. A person's genetic material is, in a way, seen as "raw" material. It requires expertise, effort and spend to discover, extract it from the material and to analyse it. This issue is particularly relevant to patenting and biobanking of genes and nucleotide sequences. Despite this, an individual nevertheless may an interest in controlling the privacy of their genetic information.

Patenting is "considered impossible for the discovery of things that exist in nature" (de Witte and ten Have 1997:56). Inventions, on the other hand are seen as products of human ingenuity and therefore where human constructions allow for the discovery of new aspects of things which are found in nature, those are patentable.[11] This dimension of ownership, patenting, has made it possible for DNA to be owned in the same way that an inanimate object is owned, in the case where DNA is synthesised or modified. It has also made it possible for genetic information to be owned, in the case where the methods to discover or understand that information have been invented. The system of patenting is intended to promote innovation, by stimulating resources for research and development and rewarding those who invest in such. This can be at odds with the

[11] The precedent for patenting of human genes began with the case of Diamond vs. Chakrabarty in the 1980's. The US supreme court ruled that man-made, living organisms could be patented. When biotechnology corporations began to applying for patents they used this reasoning, in combination with the long-standing precedent that chemical compounds can be patented. In the US, genes without known function were patented, later this changed genes with known function only with the assumption that the patent was justified by the knowledge that the patent would serve a public good (Macer 1991:183-200)

instinct that science may develop more rapidly with open access to information and resources.

Gene patents were soon challenged by individuals and pathologists and laboratories who wanted to perform molecular diagnostic or screening tests on patented genes and could only do so if they paid a licence or royalty to the patent holders. It was also challenged by researchers who were unable to study genes and sequences, and if they were, the cost of research was inordinately high.

A well-known example is that of Myriad Genetics, which was awarded several patents for the breast cancer susceptibility genes BRACA1 BRACA2. The patent covered sequences, mutation and screening methods for these. Up until this was lifted in 2010,[12] Myriad Genetics was the only company that was licensed to perform BRACA1/2 testing (a screen of a panel of five common rearrangements), which costed in the region of $3,120 - a cost that would have to be paid around the globe for this test. The European Patent Office objected to these patents and was later able to have the BRACA1 patent revoked in Europe (Adam 2002: 357; Matthijs 2006: 97; Cassier 2005: 658).

Questions of human dignity come into play when trying to understand the ethics of DNA ownership and patenting. A DNA patent does not mean DNA ownership, in fact it means that a patent holder has exclusive rights over that sequence, set of sequences or mutation - the right to prevent others from using it for a set period of time. This

[12] A complaint lodged against Myriad Genetics in 2009 sought to invalidate all patents held by the organisation for naturally-occurring genes and diagnostic methods to isolate and screen these. Patent laws have, since this one was granted, evolved. The judge in this case ruled that the 'informational quality of DNA is unique among chemical compounds' and therefore ruled that the patents for the genes be lifted. When Myriad appealed, the US government held it's decision (Ledford 2010, Schwartz and Pollack 2010)

said, however, since patenting sets genetic material up as a commodity, the dignity concern nevertheless stands. Some argue that buying and selling of genetic material may erode human dignity, while others argue that humans do not deserve special status when compared to other animals and therefore patenting is not an affront to human dignity (non-human animals' and organisms' genes and sequences may be patented[13]). Still others argue that despite the fact that humans should not be commoditised, buying and selling of DNA does not amount to this, since a person cannot be reduced to a single piece of code and the suggestion that parts of a genome or even the entire genome represent a person is in itself is an assault on human dignity.

Another argument for gene patenting may be that the system may promotes human health through the development of diagnostics and therapies. This benefit can be weighed against the risk of diminishing human dignity (Schulman 2010: xx). In this way, patents may be morally acceptable, and if they are, they may also be regulated to strike a balance between risks and benefits. The regulatory bar for patentability of genes and sequences needs to be set at a particularly fine level. Too low and the rewards of the system in terms of human well-being would be low. Researchers or organisations who have contributed relatively little to the understanding of a gene or sequences would benefit greatly in that they would have an inordinate amount of control over those sequences. On the other hand, if the bar of patentability is too high, then those who have invested millions in research will not be guaranteed protection of their money. Research wouldn't make

[13] In 1980 the first genetically engineered bacterium was patented (the organism is not found in nature and was deemed by the courts to be "made by the hand of man") and in 1988 the first mammal was patented – a genetically altered mouse that is used in cancer research (Dhal 2001:A32).

business sense and valuable input may be lost. The process of weighing human health benefits are therefore an important consideration to the debate.

Besides human health and well-being, the issue of accessibility is also raised (Schulman 2010). As the patenting system currently stands, the consumer is at the end of a 'retail-line' and therefore carries high costs for products and services. Although patents may promote the development of life-saving discoveries and technologies, the people that are intended to benefit may not be able to afford them. Even if subsidised by government, these may be too costly for a health-care system to bear. In this case, government may be forced focus on technologies and therapies that are of more general use to the public (maximising public utility), but then some life-saving technologies and therapies may be abandoned.

Some feel that the patenting system retards research (Dhal 2001:A33). He argues that people who are trying to patent do not talk to other scientists about their research, and worse, do not publish. "This whole rich culture of biomedical research, this culture of cooperation and communication, is now being strangled". The fact that patenting also affects research 'down the line' from discoveries that may have been made at the beginning of learning about a new aspect of the human genome also seems unfair. "There is no research exemption under patent law, but in practice patents are not enforced against researchers who use the information for noncommercial purposes". This may hamper researchers' institutions decisions to research particular diseases or parts of the genome for which they will not be able to benefit commercially. Dhal concludes by saying: " it depends on whether or not you think the patent system

and its claims to be able to attract money and investment and capital and people into some areas to solve problems speeds up or slows down medical process", in reference to whether people will choose to be for or against patenting. I would add to this that in addition to speed of research outcomes, it depends on whether people will be able to access the outcomes of this timely research.

1.4.1. Patenting and human dignity

Let us consider the patenting of genetic sequences and let us assume that the patent system operates in a democratic society. In this society, we will also assume that patenting is accepted by all its members, or at least the majority. Let us further assume that it maximises a public good in that it promotes human health and well-being. Moreover, this good is distributed evenly so that most, if not all, people who need or desire it can access it. For the individual living in this ideal world, patenting does not diminish his capacity to set himself an end; it does not diminish his rational will or his freedom. Finally, it does not diminish his autonomy. If this is true, then patenting does not diminish human dignity, in the sense described by Kant. If this line of reasoning is correct, then it may mean that certain parts of a body can be bought and sold, in specific DNA material and/or information, while the body at the same time retains respect. This respect is dependent, however, on the cultural, political and economic milieu in which an individual exists. This idea is discussed in further detail in later paragraphs.

1.5. Kinship and genetic information

Each person possesses the genetic code within the cells of his/ her body. If we agreed that the genetic *material* belongs to that individual, we have not solved the problem of genetic *information.* This is

because a piece of DNA code holds sensitive information about that person's health, genealogy and even future health status. Since the DNA code is inherited from parents, the information contained in the DNA material may be of interest to the individual's family, or others. This means that a molecular test performed on one individual provides information about other individuals as well. For example, the individual tested may have a disorder, the knowledge of which could be of use to family members or even others.

In Beauchamp and Childress' many editions of their book Principles of Biomedical Ethics, there is an example of a father, who, although his tissue match is compatible and his kidney needed by his daughter, does not wish to donate it.

A somewhat similar discussion may come about in the area of sharing genetic information when the individual tested does not wish to share that information. In such a case, the ethical debate involves the individual's desire for his / her autonomous choice (involving privacy or confidentiality) weighed against the possible duty of information disclosure. This is because that particular genetic information could potentially save another person's life, put another way, non-disclosure could potentially lead to harm. So there could be an argument made that the duty to disclosure information should outweigh an individual's autonomous choice.

1.5.1. The duty to disclose genetic information

First, it is important to place this discussion in its particular context. Genetic medicine by definition involves families as opposed to single individual family members. Respect for a patient's autonomous

choice, under which we can place the notions of e.g. privacy and confidentiality represent critical bioethical notions.

Those arguing for disclosure lobby for a 'joint account model' whereby the traditional model of confidentiality is spread over all 'account holders' and hold that, at least, where there is serious potential harm, that is preventable, that families and even health care workers have a duty to disclose genetic information to all family members. Parker and Lucassen (2004:165) state,

> *"Whereas on the personal account model the default position is an assumption of confidentiality, on the joint account model it is assumed that information should be available to all account holders unless there are good reasons to do otherwise*."

If individuals have the duty to disclose genetic information pertinent to family members, could they ever be forced to undergo genetic tests? If there are enough benefits to enough people, this possibly could be argued for. The nature of the test is a consideration: if the molecular test is for a specific mutation, that variant may or may not be shared across family members. Before the tests are done, it is not known whether or not that variant is shared, and therefore if it is necessary to disclose. If the test is a linkage test looking for a pattern of variants, the results of one person need to be compared to others' results, and therefore are only relevant in the context of a number of family members. These kinds of tests are not as common

as one's identifying mutations in known genes, however. Liao (2009: 306) argues that genetic information is only shared in a 'weaker way among family members and does not necessarily lead to the actual manifestation of particular diseases" and therefore does not agree with adopting a system in which genetic information is shared among family members by default. Is genetic information familial in nature? Or is this another case of genetic exceptionalism?

The example of Duchenne muscular dystrophy is given by Liao: since spontaneous mutations (not a mutation passed from one generation to another) account for one in three cases, the probability that the disease is familial in nature is only two-thirds. He also points out that some familial relations are genetically stronger for example, monozygotic twins, and others are weak, like that between a parent and child. He also points out that some genes are particularly penetrant while others are not. Penetrance is the proportion of individuals carrying a particular trait (that actually have the disease), that is how likely it is that a person with a variant will develop the disease. Environment and gene-gene interactions can still influence whether a single gene disorder will result in the disease phenotype, and so penetrance is variable. The bottom line is that most cases will not be exceptional enough to override confidentiality and therefore the idea that genetic information is 'familial in nature does not seem to provide sufficient ground for why we should move towards a system in which by default we would share our genetic information with our relatives" (Liao 2009: 309).

In summary, the question of ownership of genetic material is highly relevant to medical ethics at this point in our history. It is not ownership per se, however, that is often the subject of dispute, but how those who happen to have control over that information share it.

What is there to say that genetic information is different from other kinds of personal data, information that is not under dispute and a source of great debate? Genetic information has implications for relatives; the results of genetic tests may speak to broad-ranging features of a person's health status; genetic information can be 'prophetic'; genetic information can be closely shared among populations. On the other hand there are other kinds of medical data that share some of these qualities, that have implications for families; are used to discriminate against others for economic gain. The very same features of genetic information pull individuals in two directions from an ethical perspective – towards sharing and towards higher individual control and secrecy. Perhaps the locus of decision making, ownership and control ought to shift slightly off the individual.

Kant places an emphasis on how people see themselves - as mere objects versus human beings with intrinsic worth and deserving of respect? He shows that it is wrong to commoditise the body and argues that human dignity is the benchmark of proper conduct towards oneself and others. If that treatment is respectful then it is morally acceptable. Kant might have argued that people indeed

have a duty to offer to share information that is important to other peoples' health and well-being.

In the case of patenting those who desire the information are able to fulfill that desire through the legal system. A patent can only be granted for human or man-made inventions, the utility of which is sufficiently described by the patentee. Although the patentee has exclusive use of that invention for a limited period, the patent does not amount to ownership per se. Arguments for patenting include that idea that it promotes research and development and therefore human health and well-being. Arguments against include that the system of patenting sets DNA up as a commodity to be traded and this erodes human dignity. Also, that it erodes the culture of sharing information among researchers.

On the human dignity front, those for patenting argue that it simply does not erode human dignity as a person (the object of that dignity) cannot be reduced to a strand of sequence. In addition, it can be argued that if patenting does not diminish an individual's rational will, freedom or autonomy then it does not amount to an affront to human dignity, in the Kantian sense. Those against patenting could argue that patenting is wrong because it amounts to commoditisation of the body, which Kant argued is always wrong with no exceptions.

If the patent protects research that provides high value to society, that is, the researchers show sufficient utility of their invention, and if

governments offer some small subsidisation for the end product produced from patenting, it seems that patenting would offer more benefits to society than not. Since a patent does not amount to ownership of someone else's body and since it can be argued that it does not diminish people's autonomy, there are some strong arguments in favour of the system.

On the issue of sharing genetic information with kin, there are some extreme views. Some philosophers are moving for the generation of an entirely new system of decision-making, shifting the 'limelight' off the individual and onto the family, and in some specific cases, the community. They argue that genetic information is by nature shared. The inordinate focus on the individual is therefore inappropriate and people need to begin shifting their mindsets, realising that others may have information pertinent to them that they may benefit greatly from knowing. If such a system were to be introduced, it would have to be moderated to include only diseases and tests for which this would be appropriate, argue those on the other side of the 'fence'. Some genetic diseases are characterised by spontaneous mutations or variable penetrance, cases where the shared nature of DNA is not sufficiently exceptional to override confidentiality, or to place a duty to share on the individual. The matter requires practical consideration to protect individuals in an appropriate way, combined with a fine layer of sensitivity and compassion for the broader context in which that individual may find himself.

Section 2

2.1. Biobanking and human heritage

Genetic Biobanking involves the storage of (i) tissue samples and/or genetic information *and* (ii) personal information, such as health care data (disease histories, treatments received), lifestyle information (nutrition, exercise, wealth, family background) and sometimes genealogy, or certain other sorts of identifying data (Williams 2005:57). Biobank repositories of DNA samples are used in many different ways. When combined with health-history data these can play a crucial role in researching complex genetic disorders. The strategic importance of biobanking for future studies is also of paramount importance to scientific progress. The success of biobanks hinges on public participation as 'thousands of individuals are needed for detecting genetic loci with low effect sizes and for testing models of gene-gene and gene-environment interactions (Melas 2010:93). The Swedish Act on Biobanks defines the concept 'biobank' as 'biological material from one or several human beings collected and stored indefinitely or for a specified time and whose origin can be traced to the human or humans from whom it originates' (Melas 2010:93). People tend to donate samples to biobanks with the benevolent concern for future patients, wanting research to be furthered in the future, however, individuals are also afraid of having their privacy invaded or being discriminated against and so there is a tension between wanting to donate to research and wanting to protect information (donor motivations and other fears are discussed in more detail below). Another incentive to participation is some form of benefit sharing for the individual participant, such as monetary reward or relevance to the individuals' health status or, for

example if they knew someone who has the disease being studied (ibid 2010:98). Mistrust with regards to genetic biobanks, when contrasted with other databases, such as collections of questionnaires, include mistrust for how genetic samples could be used, say for instance, in cloning experiments. Privacy is another concern; people are afraid because DNA can be used to identify a person more readily than say an anonymised questionnaire, even if the samples are anonymised. Potential participants are also concerned that the samples in the biobank may not be used for the reason that is stated in the consent form (ibid 2010:97). These perspectives are highly individual-focussed. Individual autonomy, consent, privacy are the main issues. Williams (2005:50) is critical of discussions that are focused only within this narrow frame. Since biobanks are by nature collaborative and collectively-focused projects, Williams states that it is 'very odd' that a bioethical focus is placed on informed consent and confidentiality. Scientific validity of research, likely benefits of research ought to be considered with as much emphasis and argues that scientific validity of research is also a moral demand (Williams 2005:56).

2.2. Conditions of storage

The privacy conditions under which storage of samples may take place are variable: a) anonymous: biological materials are collected without identifiers, and it is therefore impossible to link the samples to their sources, b) anonymised: although the samples originally had identifiers, these are irreversibly removed from the samples and it is

therefore impossible to link the samples to their sources, c) identifiable: for research purposes the samples are unlinked to their sources but they may at a later stage be linked through the use of a code, d) identified: the samples have identifiers such as a name, patient number, pedigree location and these are available to the researchers (Godard 2003:590). The extent to which patient identity can be determined determines part of the risk and benefit to the subject. It is also important to note that even anonymised samples can be identified using DNA identification techniques and the individuals' sample, by matching if it is really necessary to do so.

2.3. Confidentiality

Coding methods and anonimysation standards go a long way to maintaining the confidentiality of subjects' information. Information ought not to be provided to third parties unless designated by the subject in writing (Anonomous 1996:471). The code can be kept either by third party private institutions or by government so as to protect the best interests of the individuals who provided samples. New forms of encryption to protect the information gathered from research may also be used to protect the research and thereby protect individuals (Godard 2003:591).

2.4. Consent requirements

Although there seems to be varied approaches to the structure and nature of consent, most countries and institutions agree that there

ought to be written consent in some form; that there ought to be special considerations for vulnerable populations; and that there ought to be some oversight in the form of a ethics review committee to ensure that there is an acceptable balance between risks and benefits of the research. Consent requirements can depend on the study (for example prospective or retrospective) and on the category of privacy (anonymous or identifiable). It is a difficult task, because at the time of collection it may be difficult to foresee the different ways that a sample may be useful for research. The scope of consent therefore varies. Several elements are generally disclosed to research participants: the purpose of the research, it's limitations and outcomes, its risks and benefits, the types of information that could result from genetic research, communication of results, or means of maintaining confidentiality (Godard 2003: 594). The Nuffield Council of Bioethics (1995) has set out special rules for the storage and uses of samples procured from vulnerable populations. If the patient is lucid, their consent should be required and sought, but if the patient cannot give consent, then their best interests should be decided by the family and/ or health care workers. In general, the idea of generic or blanket consent may be a solution but may pose too many risks to the participant if their identity is known. Group consent may have to be given in the case where a population is being studied. The Human Genome Diversity Project supports the principle that the group and individual consent should be required for research in these cases. The culturally appropriate authorities ought to be consulted and give their consent to the research. Some have argued that there

may be conflicts between the individuals and the authorities, and between the national laws of a country regarding research and the opinion of the cultural authorities (Lahteenmaki 2000: 1135; Godard 2003: 595). Regulations of consent become particularly difficult when samples are banked prior to consent (as is sometimes the case with archived specimens). Sometimes consent was obtained but does not necessarily meet modern standards of consent and does not cover novel research methods and aims. It would be prohibitively expensive to discard these samples or to try and get new consent for them. In this case, making samples anonymous may help protect individuals and it may also decrease the chance of bias (in the case where a portion of the samples cannot be used because consent may not be gotten). The British Medical Research Council Working Group's position is that for 'old collections, samples should be used for new research purposes as long as ethics committee approval is obtained' (Gobard 2003:595, Anonymous 1999).

2.5. Quality assurance

Along with the confidentiality of the samples and the research, the long-term conservation of genetic material should also be a condition of biobanking (Anonymous 1994; Knoppers 1998: 401). If samples are not adequately stored the investment in the research is wasted (money that could have gone to other public benefits) and the participants, who may have been expecting positive research outcomes will be disappointed. Quality control procedures include systems for storage, coding and registration as well as methods used

to study and interpret data obtained from the materials. Standards of conservation, regeneration, and even distribution ought to be assessed.

2.6. Ownership of banked samples

The general consensus is that information belongs to 'the researcher or team that creates it and the individual who may have been a subject of the research has no legal entitlements to that research (Godard 2003:S97). The British MRC Working Group on Collections of Human Tissue and Biological Samples for Use in Research states that the funding body owns the collection, while the researcher is the custodian of the collection, with the responsibility over and control over access to it and over maintaining confidentiality of the samples and information (Anonymous 2001). The guiding principle is that if competent persons make gifts, those gifts belong to the recipient, so if a person donates a sample for genetic research, those who collect that sample own it. This again touches on issues of patenting. By distinguishing between inventions (patentable by law) and discoveries (unpatentable by law) ownership is assigned accordingly.

2.7. The community approach: benefit sharing

Schroeder (2007:207) offers a definition for benefit sharing, 'the action of giving a portion of advantages/profits derived from the use of human genetic resources to the resource providers in order to achieve justice in exchange with particular emphasis on the clear

provision of benefits to those who may lack reasonable access to resulting products and services".

Who profits from genetic databases? There is a tension between the need for a public good and pursuing commercial imperatives that will allow the databasing to be sustainable. Originally, research participants would donate according to the 'gift model'. This donation was done for purely altruistic reasons (Hunter 1999:1753), however, public opinion is shifting with a skepticism that has set in about the motives of private enterprises. "While public sentiment towards the project was generally favourable…respondents suggested that it was not only the making of a profit that was the issue, but also what was done with the profit" (Hunter 1999:1754). Generally donors in the UK felt that the database should be publicly owned, and did not necessarily feel that this was because they were or were not the owners of their genetic material, but that they see themselves as part of a broader public enterprise. They simply want the commercial benefits of the project to have a broader, more charitable impact. If money went back into 'cheaper drugs' or back into the National Health Service or related charities, respondents would feel more comfortable and willing to donate. Basic moral issues of justice and fairness and concerns over greed seem to be the main motivators. Donors, who have now accepted the inevitable commercial aspects of research, are now seeking reciprocal benefits to participate. These may either be personal, but not necessarily, for the UK group. They are more interested in the money going towards public or

communitarian projects. Fairness seems to be key, and therefore researchers need to be committed to sharing profits. Godard (2003:s98) notes that other kinds of benefits that could be returned to the community include technology transfer, local training and joint ventures and reimbursement of costs.

Schroeder (2007: 207) notes the grim reality that in the poorest areas such as Sub-Saharan Africa where there are those in most urgent need of research outcomes there is the likelihood that they won't receive it. Schroeder speculates that since these populations are poorer they won't receive agreed-upon benefits in the same way as populations in industrialised countries would.

Although there are various new models of benefit sharing (Hunter 1999:1753), Godard (2003: s98) warns that benefits need to be based on honesty, legality and appropriateness. He says that 'money is one kind of benefit that demands particular mention: paying a community for participating may raise special concerns about legality and coercion', he also notes that the appropriateness of the scale of benefit is important, "an enormous benefit may make the process of informed consent meaningless by making it effectively impossible for a community to say no".

Is the very idea of wanting a benefit wrong? Benefit sharing models have arisen to try and deal with the shifting motivations for participating in research. As already mentioned, in the UK, altruism

governs organ and tissue donation (Rapport and Maggs 2002: 495). Richard Titmuss in 1970 observed that blood donors were motivated by altruism and described this in his influential work: The Gift Relationship: From Human Blood To Social Policy'. Titmuss denounces a market-driven system in blood donation, the four main points of which Le Grand (1997: 33-39) highlights as: a) a wasteful system, where there are wastages and surpluses, b) inefficiencies and bureaucracy, c) exploitation of the poor, d) a market in blood which is 'degrading to society', where motivations of altruism are replaced with self-interest and personal gain (Rapport and Maggs 2002: 496). Although there is very little agreement about what altruism is and what motivates true selflessness and even if it operates outside of close kin groups, the debate continues (Nagel 1970: 112; Krasner and Ullmann 1973: 98-105; Trivers 1971:32; Rapport and Maggs 2002: 497). The intricacies of altruism will not be discussed in this research report as the topic is enormous and would require a lot more space. However, the question of motivation to participate in research is a pertinent one. Are notions of care, compassion, empathy, selflessness, sacrifice dying in the context of research benefit sharing? It is my intuition that it is not. On the one hand, if corporations are benefiting (and it is my understanding that they stand to benefit substantially from research) then it seems fair that they should offer something back to those who made that research possible. Secondly, it is interesting to note that, as mentioned, communities seem to be interested in receiving benefits for the group or for other organisations that do good for society, not

necessarily for themselves. Of course this changes from individual to individual, and probably even from case to case (some people may be more compassionate towards certain research topics than others), but the shift from 'pure' donation to benefit-sharing seems to be quite subtle and sensitive. There may be others who disagree and state that big corporations are simply wiping their conscience clean and benefit to a much greater degree than the populations or individuals who contributed to the research, and that may be so, especially if one considers the enormous power differential between participants and researchers in regions where the populations are particularly vulnerable. Titmuss' research showed that people gave blood out of social obligation, not for personal gain. This reasoning for blood donation stands, with 41% of people surveyed in New Zealand stating that they would no longer donate blood if a profit could be made (Howden-Chapman 1996: 1131; Oakley 1996: 1114).

Perhaps the key is not scrutinise individual motivations for participating in research but to ask if a particular kind of benefit is degrading to society as a whole, if people feel that they are being "bought out" or if they maintain their sense of worth and agency within the process of research and benefit-sharing. These questions will be difficult to answer using a blanket approach, but will depend on the values held by people in different communities. Cultural values will likely dictate what benefits are desired by a particular community. In a perfect world, this will always be true. Sadly in a world of greed, poverty and desperation the moral underpinnings of

benefit sharing – justice and fairness, respect and duty may become warped in to a system that, like may others, favours the most powerful.

Christensen (2009:101) argues that 'good reasons for everyone to participate in this type of research [biobanking] can be found in the principles and values that characterise modern societies and that many of us for granted'. Biobank research could also contribute to the kind of society that provides the individual with the opportunity to realise 'his understanding of the good life'. If this is the case and biobanking promotes values and benefits that everyone supports, Chritensen argues that researchers would not even be obliged to obtain consent for biobank research. He argues on behalf of researchers and states that if such can secure 'good health and prosperity for ourselves and future generations, the issue of whether it ought to be a duty to contribute to the realization of this common good becomes highly relevant' (ibid:111). The cultural approach will be discussed in greater detail is paragraphs below. The issue of balancing individual opportunity to raise objections to biobanking and research and to decline to participate in research with the general desire of a community and the good that could result, for all, from this research is pertinent.

2.8. Is DNA the common heritage for all?

When the human genome was first sequenced, the United Nations Educational, Scientific and Cultural Organisation (UNESCO) declared the Human Genome the heritage of humanity. This declaration provided that the heritage shall not, in its natural state, give 'rise to financial gains' and, second, that 'countries establish an international framework to make the benefits from genome research available to all' (Bovenberg 2006:1). The UNESCO declaration was based on international law precedents. Bovenberg looks at these precedents to determine if they do indeed bar the private appropriation of common heritage. He revisits the framework presented by Grotius (*Mare Liberum*) to determine whether international law precedent bars private appropriation of a common heritage and then he looks at Pardo who wrote a framework for dealing with the exploitation of the mineral resources of the ocean floor. Bovenberg intended to analyse whether the standard set by Pardo for the use of these minerals could serve as a model for an international framework for sharing the benefits of current genome research.

Grotius wrote a defense of the Free Seas, which ended up protecting the ocean from any single state dominance for over three decades. However, when manganese nodules were discovered scattered across the seabed in 1873, and technological advances opened up opportunities for further prospecting and exploitation of the resources on the ocean floor, the US was tempted to try and claim ownership of this natural resource. A private US company in fact did claim

exclusive mining rights to a section of the Pacific and so greed prevailed. Avid Pardo thus delivered an address to the United Nations General Assembly to propose that the resources of the 'deep seabed be declared the common heritage of mankind' (Bovenberg 2006:3). This is precisely what inspired the UN to propose similarly with regards to the human genome. In addition to the stipulations already mentioned, UNESCO also advised that an international body be established to make the benefits of the research on the genome available to all. This is the process that was used to govern the minerals of the ocean floor. The rationale behind the findings and writings of Grotius and Pardo were seated in understanding of property per se. Grotius was influenced by Cicero and Horace, stating that in the beginning there was no 'particular right and nothing was private property' however this shifted when people began to use consumables, and this gradually evolved to property ownership in immovable things such as fields, with occupation and maintenance by occupants who could then become owners. Grotius also recognised that although some property was technically owned by a particular state, it was free for all to use. For example, Grotius observed that the land of Athens belonged to the Athenians but the same land was split among individual owners (Bovenberg 2006: 8). Grotius observed that work and effort had a role to play in the appropriation of goods from natural resources, so that the fisherman who catches a fish using his own hooks and nets rightfully owns that fish even though the open seas belong to everyone. Diligent 'labour and industry' thus allowed private appropriation of some common

resources. He also advocated for fair competition and was against monopoly of industry, as was the case with the Portuguese (under Spanish rule at the time) who claimed the right to exclude all foreigners from navigating the Pacific and Indian Oceans. Trying to apply the common heritage principle later proposed by Pardo in practice involves a deeply involved managerial body that governs the use and exploitation of the resource. Pardo 'required a properly established international regime to assure peaceful use, orderly exploitation in the interests of mankind, with particular regards to the needs of poor countries, and freedom of research, with the results available to all' (Bovenberg 2006: 12). The issue of the resource in the ocean, which was under scrutiny by Pardo, divided the industrialised countries in the North from the South, however a new convention was set up to govern the distribution and mining of the seas. It 'took almost twenty-five years to negotiate' (*ibid:* 19).

In dealing with the human genome, the UNESCO Declaration similarly calls for the establishment of a legal framework to make the benefits of the genome research available to all. Bovenberg's analysis of the precedents set by Grotius and Pardo show that the principle of general heritage does not per se render 'a good incapable of private appropriation provided that such appropriation does not impair its common use'. He also warns that in establishing an international framework for the exploitation of the human genome 'and the sharing of any benefits by way of a global fund or trust' the lesson from Pardo is that such a framework may be prone to

‘excessive, unbalanced and counter-productive regulation’. He states ‘a more plausible way to ensure benefit-sharing could be the introduction of a tissue tax. Such a system would distribute benefits of genome projects to the entire world community in an efficient and expeditious manner’ (i*bid:* 21).

2.9. Biobanks the common heritage of all?

The “general heritage” principle and the proposed lessons learned by Bovenberg can be applied to genetic biobanks as well. If these are applied, in general this would mean two things: Firstly, biobanks would belong to all people. This would *not mean that some could not profit from them*, but rather that all would have the equal opportunity to profit from them. On this point, it is interesting to note that governing body set up to manage the mining and exploitation of the seabed was not permitted to exclude poorer regions (the South) from using technologies developed by the industrialised North to generate wealth from the Ocean, despite that they did not contribute to those technologies. Secondly, biobanks would have to be strictly managed by a regulatory board with representatives from different countries and even cultures. Pardo described a committee with various layers, legislation that overrides the laws of any one country and a highly deliberative approach to all decisions. It is assumed that this process would ensure that various cultures and countries would be equally represented and that there would be a sense of democracy and fairness governing the exploitation of biobanks as a ‘natural resource’.

These views of DNA as a common, natural resource lead us to interesting questions of how this resource ought to be apportioned, or exchanged. Below I will outline some interesting views on the nature of information exchange.

2.10. Relationships and information exchange: selling, gifting, sharing

Belk (2007:611) in his paper 'Why Not Share Rather Than Own' states that 'sharing is an alternative form of distribution to commodity exchange and gift giving'. How much sharing do people in Western communities do? Outside of families, the concept of sharing is a relatively rare one. Belk uses the example of how too few people share rides to work, despite that commuting is highly stressful and damaging to the environment. He also notes that sharing in the family seems to be on the decline, with fewer families that have a 'family car' or a 'family television'. Anecdotal as this may be, the idea of a [Western] world with less sharing rings true. Sharing donates something as ours and therefore the costs and benefits of having use of some thing are split in as many ways as there are individuals sharing. Shared items may be concrete, the park bench, or more abstract such as 'knowledge, responsibility, power'.

There are a number of interesting papers describing the difference between a gift and a commodity, most of which place these on opposite ends of a continuum, for example: egoism-altruism or

stinginess-generosity. Gift exchange is based on reciprocity, driven by societal obligations to give and reciprocate (Mauss 1967, Belk 2007:128). Interestingly, Gregory (1997) highlights that gifts entail encumbrances or debts (which ties into the idea of reciprocity), but nevertheless establishes qualitative relationships between people. They are also attached to ideas of tradition and sometimes even love.

Commodities establish quantitative relationships between people and although they also result in indebtedness, transactions are balanced with 'no lingering indebtedness and no residual feelings of friendship'. The reciprocal relationship in commodity exchange is one where there is either balanced giving and getting or non-balanced exchange in which one party wants to get more than they give (Belk 2007: 127; Frow 2007: 117; Miller 2001: 91-115).

Sharing belongs in a class of its own, according to the author. It involves income pooling and resource sharing and Belk offers the prototype of the family as an example, despite some of the exceptions already mentioned. He also offers the example of the pregnant and breastfeeding mother who literally shares her body with her baby. This exchange could never be thought of selling (a mother would not charge for these services later in life) and the author argues that it would not be though of as a gift either. The exchange is an example of sharing. He stands by his understanding of the exchange, despite that women can choose whether to share (through

contraceptive choices or fertilization technologies) and that these forms of sharing can be outsourced to a wet nurse, or a surrogate.

Belk says that sharing is a culturally learned behavior. In the West, children learn first to own and later to share, but Australian Aborigines apparently learn to share first and then later to become more aware of possessiveness. In nomadic societies, possessions are a burden and sharing things such as food and weapons is important for survival. China and Japan are other cultures that value sharing, with the *Zhanguang* concept in China and the lucky hole-in-one golfer who has to buy gifts for the whole club in Japan. Africans too seem to share this cultural value, with those who are wealthy sharing their wealth with family and extended family (Belk 2007:130).

Sharing can either be a good thing or a bad thing for a community. People can feel that they have enough or more than enough, or not enough and this can create feelings of envy or enhance feelings of community and closeness. Belk says that they more connected we feel to something, that is, the more of our *self* we feel is connected to something, the more we will want to hold on to that thing and the less likely we will be to share it. Another inhibitor to sharing is materialism. If happiness and pleasure is, for a person, highly tied into a possession, that person is likely to want to keep that for himself and less likely to want to share. Yet another impediment to sharing is the perception or actuality of scarce resources. There are, however, a few incentives and examples of sharing that span cultures. The

example of the academic community and research sharing is given. If the Human Genome Project was privatised, the great subsequent breakthroughs in biology and medicine would not have been possible (at least not as quickly, with as many accessible outcomes). The example of the internet is given as well – information, music and other goods are found freely. In fact the kind of sharing that happens over the internet has been characterised as gifting – 'the gift economy' (Pinchot 1995; Coyne 2005: 103, 149). However, Belk (ibid 132) insists that these are sharing exchanges and not gifts. The sharing economy over the internet may be the equivalent to the return to the tribal community for Westerners (ibid:133). Belk notes that by sharing people can leverage their lifestyles beyond possibilities if they chose not to share. In other words, sharing is better for everyone and provides benefits that could not have been had for individuals had they not chosen to share.

In the case of providing DNA for biobanking and research, Belk may insist that sharing is key. Sharing might be the way to go about thinking of DNA. Everyone pools their resources for the common good of all, and individuals benefit more (by way of greater health care as an example) than they ever could if they tried to gain this outcome on their own. Currently DNA is being treated as a commodity and in some cases a gift. I believe it ought to continue to be seen as a gift. Putting to one side that gift-giving denotes primary ownership, or at least possession, by the giver, the system of gifting DNA may solve some of the issues of DNA demand. Gifts are

reciprocal; people tend to expect something in return for a gift. The return may or may not be money and is usually of similar value to the original gift. Gifting is seen as something generous, a good thing to do and a good reflection on the giver. A society that gives could be a society that endures. So why not share? Sharing does not necessarily carry with it reciprocity. Big, powerful corporations can just take what is shared and run – there is no obligation put onto others, as is with the gift. At the beginning of this section, the definition of a gift was given – something that carries with it obligation, something that demands reciprocity. Gifts entail debts. Those who contribute to society by giving that society access to their DNA give a good gift indeed. They don't necessarily want money in return, (what is given in return can be specified through the process of giving by the researchers), but they do go into the exchange knowing that it will be reciprocated in some way. Those who receive this gift on behalf of society understand that they are morally obliged to give something in return; they carry a debt. Gift giving also does not bring with it the morally difficult issues of commoditization - issues of dignity and respect. A person who trades in DNA and a corporation that trades in DNA may be accused of commodifying this natural resource in a way that is not fair, nor respectful of humanity. They also do not have an obligation to society other than to pay the market price. With commodity exchange, one party is usually out to get more than he gives, as already mentioned. In the context of global DNA research there are simply too many major power differentials for this to work. Gift giving seems to be the most

reasonable way to think of the exchange relationship in the context of research in general and biobanking research in particular.

2.11. Shifting lens: the cultural approach

Some of the issues addressed within a discussion about genetic ownership are addressed within a framework that is not necessarily accepted by all cultures. Indigenous groups may not conceive of personhood, ownership, health care and individuality in the same way as typically 'western' thinkers would. Gillet and McKergow (2007: 2093) suggests that perhaps the 'conceptual lens' through which the issue is viewed ought to be shifted to one that is more appropriate to 'indigenous' thoughts about genes and DNA and uses New Zealand as an example. Culturally influenced conceptualisations can transform ethical considerations involved in genetic information and property disputes. "Culture" is not about songs and ornaments, it is about activities, ideas, relationships, belonging. Central to a sense of self, what one does, how one thinks. It 'permeates our lives, often in ways of which we are unaware' (Wepa 2005:38). It is thus with respect for these differences between people, and how they fundamentally shape one's outlook on life that an approach to ethics in each culture ought to be shaped.

With genetic research and medicine being more widely used and accepted, issues of genetic biobanking, ownership, pharmacogenomics (personalised medicine) are entering the domain

of public health from an ethical and policy perspective. These bioethical issues need to take into account the social and cultural contexts of different countries and regions. Gillet and McKergow (2007:2093) argue that genetic research and medicine 'traces, represents and embodies relationships inherent in the spiritual connections between a place and its people, touches areas of human life which are seen as being of fundamental importance in most cultures, and therefore requires special attention to safeguard the relevant sensitivities'. Perhaps the concept of ownership itself is completely inappropriate as applied to genetics in such cultures. If such is seen as sacred, 'indigenous' fears may be fueled by genetic information, research and manipulation. For some cultures, the removal and dissection of aspects of their 'being' will require respect for tradition. To the Maori of New Zealand, there is a sense of sanctity or spiritual significance attached to the process of life, including a sense of interconnectedness. They believe that information is 'a part of them' and when they give it away 'they are giving themselves away'. Knowledge, with its power to be communicated backwards and forwards in time has a 'beauty and power'. The way the 'self' is seen may differ from society to society, and strict protocols are to be followed if research is to take place. In Maori culture genetic information is deeply related to the group who 'are the current representatives of their lineage' and access to this information is not within the 'domain of the individual' (Gillet and McKergow 2007:2096).

In non-western cultures, questions such as ‘are individuals entitled to donate genetic material without the consent of their kin?’ could transform the way that genetic ownership is conceived. Whereas privacy, individual freedom, self-governance, technology, individualism, economic wealth and efficiency are key to many Western ideals of life, other cultures may differ dramatically, and in some cases be completely opposite. Since ethical aspects of genetics ‘touch on fundamental issues central to the beliefs and practices of a culture’ and since genes connect us to our ancestors they embody aspects of our identities, argue Gillet and McKergow (2007:2102).

In summary, participation in biobanking research is a prerequisite for producing knowledge and insight needed to benefit both individuals and populations. Although it is a ‘public’ exercise, it could provide the individual with a ‘good’ that is possibly not attainable otherwise. At the same time, it raises questions in regards to the relationship between individuals, societies and communities and researchers. Each of these stakeholders may have different needs and desires. Since medical research has been the subject of abuse and even scandal and since people may be weary about genetic research itself (have moral objections to the research) and finally, since people are suspicious of the privacy of the information that they provide for research there may be a sense of reticence when it comes to participation in research. Outside of western cultures, there may be additional disincentives to participation such as the idea that genetic

information is sacred and ought to be sheltered from the probing fingers of researchers who may not understand protocol both in collecting samples and disseminating information once the research is finished. Incentives to participate include ‘altruistic’ motivations, the possibility of returned benefits of research outcomes and the possibility of sharing in non-research outcomes (rewards not directly derived from the research).

The main ethical issues that arise out of biobanking include individual autonomy, consent (and group consent), privacy and confidentiality, the scientific validity of the research and attention to pragmatic details such as storage conditions and collection best practices. There are three possibilities for ‘who’ owns the biobanked material and information: the researcher, the funding body, or the public. If biobanked samples are the common heritage of all, as the human genome has been declared, some of the lessons from how the seabed as a common heritage has been managed can be learned.: everyone ought to have the equal opportunity to benefit from the resource and a neutral representative body ought to manage this process.

If biobanks are seen as a common resource, then what ought the relationship of the public and the researchers to the resource be? I offer the suggestion that it is a gift relationship. I also argue that it ought to be such for the following reasons:

a) Gifts are reciprocal and demand exchange. They incur indebtedness on to the receiver;

b) Gifting is seen as a good thing, a generous society seems like a society that we would want to live in;

c) What is given as a gift in return to the original giver (by way of gift exchange) can be determined at the outset of research. Examples of return gifts could be: investment back into the community, whether into the national health system or social justice projects, technology transfer to the community and local training;

d) Gifting is not commoditisation and therefore does not necessarily bring with it the morally difficult questions of trading in the body.

In terms of ownership, gifting implies ownership by the giver, but that ownership is transferred to the receiver. This brings up interesting questions of rights of property ownership and ownership structures, however, it is beyond the scope of this report to go into the various conceptions of ownership of property.

Final thought on cultural approach

Section 3

Concluding Remarks

The question of ownership of genetic material is highly relevant to medical and non-medical ethics at this time. With issues such as genetic counseling and family dynamics, patenting and biobanking rising on the radar of the public, in corporations and among researchers, the question of who owns genetic material is frequently asked.

Genetic information has implications for relatives and for populations in which an individual finds himself. By its very nature genetic material is shared, although the 'proportion of sharing' is not always as high as some have emphasised. Therefore when and why that material ought to be shared with the family is of debate. It would seem that the proposed maxim "one should always offer to disclose one's genetic information to family members or relevant others" could be used to guide us on this moral journey.

Kant was against the idea of self-ownership as he argued that it is an affront to human dignity and the principle of respecting oneself as an end. He therefore would probably reject the idea of genetic self-ownership. With regards to patenting, however, I move that under some circumstances the practice is not an affront to human dignity and therefore morally permissible.

From these conclusions, we begin to see that there are a few arguments for shifting the locus of decision making from the individual. The quote from Knoppers and Chadwick (2005: 75), on genetic research and biobanking research sums up this trend perfectly,

> "[genetic research] has been accompanied by a shift in the emphasis towards the ethical principles of reciprocity, mutuality, solidarity, citizenry and universality".

In terms of biobanking, my research shows that there is a reticence to participation in research and disincentives (among others) include the fear of stigmatisation. Since public participation in biobanking is of the essence, we therefore see that the age-old tension between the individual and the 'greater good' once again arises. I look at the idea of biobanks as a common heritage of all and question what the relationship between participants, researchers and funders with that resource is. Is it based on ownership? I argue that the underlying exchange ought to be a gift orientated.

In this research report I take an interest in what could be varying cultural approaches to the ownership of genetic material and find that inter-cultural perspectives may differ significantly, but that many cultures, especially non-western cultures, value sharing and some emphasise the community as the 'locus' of decision-making. It seems that this bodes well for population-based genetic research. If

that is the case, and people of various cultures are willing to participate, I argue that researchers and funders must emphasise their reciprocal duty in exchange of the gift of genetic material they receive from participants.

The gift exchange does, by definition imply that that the original giver is the owner of the gift, and that that ownership shifts to the receiver. Despite this, it does not seem that the question of ownership per se is most important to the gift-giver but rather the question of fairness and reciprocity and sometimes of tradition and cultural appropriateness.

In conclusion, the bioethical focus in relation to genetic material and its ownership is opening from the individual to a broader population. How genetic material is shared, or not shared and why seems to depend more on the population in question at any given time and its social, political and economic structures than on the question of ownership per se.

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Appendix I

Ethics Clearance Certificate

University
of the Witwatersrand,
Johannesburg

Human Research Ethics Committee (Medical)
(formerly Committee for Research on Human Subjects (Medical)

Secretariat: Research Office, Room SH10005, 10th floor, Senate House • Telephone: +27 11 717-1234 • Fax: +27 11 339-5708
Private Bag 3, Wits 2050, South Africa

Ref: W-CJ-090722-3
22/07/2009

TO WHOM IT MAY CONCERN:

Waiver: This certifies that the following research does not require clearance from the Human Research Ethics Committee (Medical).

Investigator: **Candice de Carvalho Student no 0209366M**

Project title: **Reflections on the morality of ownership of genetic material.**

Reason: This study is an analysis of literature in the public domain. There are no humans involved.

UNIVERSITY OF THE WITWATERSRAND
PROF PE CLEATON-JONES
HREC (MEDICAL)
2009 -07- 22
JOHANNESBURG

Professor Peter Cleaton-Jones
Chair: Human Research Ethics Committee (Medical)

copy: Anisa Keshav, Research Office, Senate House, Wits