

## Human dignity and consent in research biobanking

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Biobanking policy needs to take into account the concept of human dignity, because this concept is enshrined in both international and South African law. The accepted understanding of informed consent, which is also required by law, is inadequate for biobanking because it is often not possible to inform people of possible uses of their stored tissue.

If human dignity is understood as a multidimensional concept that corresponds to the multidimensionality of the human person, then human dignity can be said to be both (i) something that all people already have, as an inviolable worth that inheres in their potential to live meaningful lives; and (ii) something that people seek to realise through morally good behaviour in historically-situated relationships.

This understanding of human dignity can be used as both an interpretive lens and a normative vision. It is interpretive because it reveals how various attitudes to biobanking and the various proposed consent regimes – presumed, broad, and specific – might all be underpinned by appeals to human dignity. It is a normative vision because, given that all of these positions can be underpinned as morally meaningful with respect to human dignity, provision should be made for all of the possible consent regimes in law and in biobanking practice.

Nonetheless, where compromise cannot be avoided, then, at the very least, human dignity understood as the human potential to live a meaningful moral life must be protected.

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Research biobanking raises numerous ethical questions.<sup>1</sup> This article addresses the role that the concept of human dignity might play in ethical and legal reflections on the notion of informed consent in research biobanking.

Though types of biobank vary,<sup>2</sup> for the purposes of this article a biobank is defined as a collection of 'samples of human body material or derivatives thereof from which genetic information can be derived and which are, or can be, associated with related information concerning the participants. A research biobank is a biobank used for scientific research purposes,<sup>3</sup> and is distinct, therefore, from a forensic biobank. We are concerned with research biobanks in the broadest sense of the term because, regardless of whether they are population biobanks, part of clinical trials, or formed by particular disease advocacy groups, they all raise similar issues regarding the notion of informed consent.<sup>4</sup>

We first address why the concept of human dignity needs to be considered in the formulation of policy concerning consent in biobanking. Second, we briefly address why informed consent is a problem for biobanking. Third, we argue that a proper understanding of human dignity is necessarily multidimensional, so as to correspond with the multidimensionality of the human being whose worth the principle of human dignity is intended to affirm. Fourth, in light of such a multidimensional understanding, we will consider how human dignity may be appealed to by opponents of biobanking, followed by three examples of how it could be used to support three different kinds of consent that have been proposed as a solution to the problem of informed consent. Finally, we propose a solution based on a multidimensional

understanding of human dignity that takes into account the diversity of the positions analysed.

### The importance of human dignity in biobanking

The formulation of policy concerning consent in biobanking needs to consider human dignity for at least two reasons.

First, the concept of human dignity has a prominent place in international codes governing the use of human tissue. Several prominent documents uphold the importance of respect for human dignity, e.g. the United Nations' 1945 Charter, and 1948 Universal Declaration of Human Rights; UNESCO's 1997 Universal Declaration on the Human Genome and Human Rights, and the 2003 International Declaration on Human Genetic Data; and the 2009 OECD Guidelines for Human Biobanks and Genetic Research Databases.

Second, in the South African context, the 2003 National Health Act states, 'The State must, in compliance with section 7(2) of the Constitution, respect, protect, promote and fulfil the rights enshrined in the Bill of Rights, which is a cornerstone of democracy in South Africa.' Health legislation must therefore take into account section 10 in the Bill of Rights, which states, 'Everyone has inherent dignity and the right to have their dignity respected and protected.'

### The problem of informed consent in biobanking

A closer look at the Constitution and the South African National Health Act of 2003 also reveals why an analysis of informed consent

is important, and why the concept poses a particular problem for research biobanks. Both the Constitution and the National Health Act affirm what is widely accepted as standard practice for the taking of human tissue samples, and the use of human beings and their tissue in research: the participant's informed consent is required. Section 12(2)c of the Bill of Rights states that persons are 'not to be subjected to medical or scientific experiments without their informed consent'. The National Health Act states in Chapter 9, section 71(1)b that, in research with human subjects, this requires 'the written consent of the person after he or she has been informed of the objects of the research or experimentation and any possible positive or negative consequences on his or her health'.

The problem for research biobanks revolves around precisely what it means to be informed. First, in research biobanking it is usually impossible to say what research the tissue or associated data will be used for. Second, while research biobanking seldom has immediate negative consequences for a person's health, there may be other unforeseen negative consequences.

This has led to a variety of approaches to consent in biobanking, with different approaches favoured in different contexts. While developed countries favour so-called broad consent, developing countries – shown in the analysis of South African law above – tend to favour specific consent.<sup>5</sup> Before addressing the various consent regimes that have been proposed, we need to consider what is meant by human dignity.

## What does human dignity mean?

The concept of human dignity is not without its problems with regard to contemporary bioethics, and has been criticised on several fronts.<sup>6-9</sup> This pressure has led some agencies to move away from 'dignity language' in the formulation of ethical guidelines. For example, in Australia, the 2007 National Statement on Ethical Conduct in Human Research<sup>10</sup> specifically excised all earlier references to human dignity. Nevertheless, it still used the language of respect for persons, raising the question of whether avoiding the term 'human dignity' really solves the problem.

We argue that for human dignity to be of value in ethical and legal discourse, it has to be understood as a multidimensional concept. The concept becomes problematic when it is reduced to one or other feature of the human person, for example autonomy, biological life, certain capacities, sense of self-worth, creation in the image of God or evolved superiority of the species, and so on. These reductions miss the point that human dignity refers to the worth of every human person, and the human person is multidimensional. The concept of human dignity must be likewise multidimensional.<sup>11</sup>

An important part of this multidimensionality has to do with the philosophical observation that a human person both exists as a being *per se*, and as a being situated in historical time – in other words, as both an ontological and an existential reality. Consequently, human dignity is simultaneously (i) already and always present for all human beings as human beings; and (ii) not yet fully realised, as human beings are subject to the moral ambiguity of historical circumstances, in which they nonetheless seek to realise the fullness of their dignity. Human dignity is both 'already' and 'not yet'.

All human persons already have dignity because they possess a broad range of capacities, including not only the traditional notions of reason and free choice,<sup>12</sup> but also emotion, affiliation, play, imagination, and so on.<sup>13</sup> Regardless of their actual level of development, these capacities constitute an innate potential to live in a morally meaningful way<sup>14</sup> within that person's historically situated set of relationships.<sup>15</sup>

At the same time human persons, as meaning-seeking and meaning-making beings, seek to realise this 'potential' by acquiring dignity. This acquired dignity can be equated with a conscious sense of self-worth or pride,<sup>16</sup> and is strongly associated with a worth attributed to them by their social group. In both cases, it is the result of what they believe to be their own morally good behaviour.

To respect human dignity, therefore, means to protect both our inherent potential and the realised sense of self-worth that results from the development and application of our capacities in moral behaviour. Only then do we truly respect the multidimensional uniqueness of every human person as a historically situated, meaning-making and meaning-seeking moral subject in relation to all that is.

If we understand human dignity this way, then in terms of contemporary ethical and legal discourse it (i) prevents us from reducing ethics to the simplistic application of one-dimensional legalistic solutions, and (ii) encourages prudence and humility, by highlighting the tentative nature of both our individual behaviour and our collective mores (including laws) as, at best, well-intentioned attempts to realise the ultimately unattainable fullness of human dignity for ourselves and others. In other words, it invites us to proceed, but always with caution.

## Human dignity and opposition to biobanking

Three features of biobanking might lead people to refuse to participate in it, or even to actively oppose it on grounds of human dignity.

First, biobanking cannot say for certain what kinds of research may be conducted in future. Nor can it guarantee that the samples, associated information, or research results will never be used for malicious purposes. This means that participation in a biobank carries risks to a person's dignity because it may lead to information or practices (e.g. genetic discrimination, breaches of confidentiality, damage to reputation) that place additional limits on a person's potential to live a morally meaningful life.<sup>17</sup>

Second, biobanking deals with human tissue and, increasingly, human genetic material. A person may consider their genes to be an extremely intimate and integral part of their identity and dignity. For example, one may hold a religious belief that all human beings have dignity because they are created in the image of God and that therefore genes – as containing that image – are sacred and should not be tampered with (this of course is not the only position that a belief in divine creation necessarily supports). For such people, genetic research in general is always an offence to dignity.

Alternatively, people may have no problem with genetic research *per se*, but feel that research into genetic diseases may perpetuate a certain ideal of the dignity of a healthy adult person, thereby undermining the inherent dignity that all human beings have, regardless of their genetic makeup. They may oppose biobanking as an act of solidarity, in the interests of upholding the dignity of those who have incurable genetic diseases or who will never have access to the benefits of the research.

Third, people may oppose biobanking because it constitutes a kind of commercialisation of human body parts. European law, for example, specifically condemns treating human tissue as property to be traded as a violation of human dignity, arguing that it should be considered 'a gift' to the common good.<sup>5,18</sup>

Despite these objections, several possible solutions to the problem of informed consent in biobanking have also been suggested. What follows shows how each of these might be argued for on the basis of human dignity.

## Human dignity and presumed consent

Presumed consent applies where samples are banked for research because it is believed that the people from whom the samples were originally taken, e.g. for clinical purposes, would want this. It is usually accompanied by the right to opt out of the process.<sup>19</sup> In Iceland, the deCODE biobank was constituted on this basis.

A related practice is 'collective consent' where, in cultures characterised by strong group rather than individual identity, the consent of the group is sought via representatives.

In terms of human dignity, the case for presumed consent could be made as follows. Biobanking-facilitated research has the potential to significantly benefit portions of the population. Thus, participation is for the good of the dignity of everyone in the population, enhancing their chances of realising their inherent potential free of debilitating diseases. Moreover, since dignity is partly realised by living a morally meaningful life, it could be presumed that a person would want to contribute to the good of others, thereby enhancing their own sense of self-worth and public reputation as a morally good person.

## Human dignity and broad consent

Broad consent is where the person supplying the sample signs a once-off consent to any research that may be performed using the sample and/or associated data, at the discretion of an ethics committee. The practical advantage of this type of consent is that it speeds up the research process. Here too there is usually an option for withdrawal at any stage.<sup>20</sup>

From the perspective of dignity, the case for broad consent is similar to that for presumed consent, with the added dimension that it explicitly acknowledges the existential importance of being able to decide on morally meaningful matters for oneself. Since it acknowledges the individual as an autonomous person who would like to make informed choices on moral matters, especially insofar as these affect his or her own person, a broad consent should always be accompanied with sufficient information about what biobanking is, its uses, its risks, and so on. Though one cannot provide the specific information about what a particular individual's sample will be used

for, the idea of solidarity – a belief that one can contribute to the good of others – plays a role. Nonetheless, depending on the person's belief regarding the implications of biobanks for dignity, they may also consider it an act of solidarity not to participate (see above).

## Human dignity and specific consent

Specific consent means that a person should give consent for each use of their sample as and when the need arises. They should therefore also be adequately informed of each use to ensure that the sample is not used for research of which they would not approve.<sup>9</sup>

If presumed consent emphasises the principle of beneficence and hence the good of maximising the dignity-as-inherent-potential of human beings in general, then specific consent tends to emphasise the realised dignity of the autonomous individual above all else. As such, no 'good cause' can override the individual's right to choose whether to support it, or to decide how to dispose of parts of their body. Ironically, this is the most restrictive position, in that it prohibits research without specific consent and therefore perhaps has more in common with those who reject biobanking as entirely immoral than with those who see it as force for good. In other words, specific consent very strongly defends the dignity of the human person insofar as this is realised in a person's existential meaning-making and moral opinions, such that should a person be happy to support research into cancer but not into stem-cells, that choice should rest entirely with them.

## Human dignity as interpretive lens and normative vision

As seen above, human dignity is used to underpin a rejection of biobanking, a paternalistic presumed consent, a possibly legalistic broad consent, and a seemingly individualistic specific consent. The fact that it has been employed in different arguments does not, however, mean that it is useless.<sup>6</sup> On the contrary, human dignity is very valuable as a concept that refers to the worth of every human being as a meaning-seeking and -giving, multidimensional, moral person embedded in a world in which disvalues are so ubiquitous that almost no moral behaviour can be perfectly good.

A multidimensional understanding of human dignity that captures the multidimensionality of the human person enables one to affirm that all of the above 'solutions' to the consent issues in biobanking are, in their way, trying to do good and avoid evil. They all attempt to grapple with the problem that every ethics committee must face: respect and protect the dignity of research participants; and further the dignity of those who potentially benefit from the research.<sup>21</sup> These solutions all depend on the anthropological, philosophical and sometimes religious presuppositions of their proposers. Therefore, as much as all proposers might be trying to serve the normative vision of a world in which human dignity can be fully realised, they cannot be expected to come up with perfect, 'one-size-fits-all' solutions.

For this reason, a broad, multidimensional understanding of human dignity is vital in the day-to-day practice of biobanks. How people are shown respect can vary, but that they are shown respect, and feel that they have been shown respect, are vital.<sup>22</sup> For some, this may mean not feeling compelled to participate; for others, being left alone after they have given their sample; or even feeling that they are actively participating in decisions regarding their samples and in the

ongoing successes of genetic research in general. All of these ways of engaging with biobanking will be existentially meaningful to the people who choose them.

Therefore, human dignity, the worth of each individual, may best be respected by policies that accommodate as many of these positions as possible. There is no reason, for example, why people should not feel proud of contributing to biobanking, such that giving their consent is actually a formal expression of their commitment to the common good. The consent is required, but it is assumed it will be given. At the same time, there is no reason why people who are happy to commit their samples to the process, but who are unconcerned about the details and may indeed see repeated contacts as a nuisance,<sup>23</sup> should not be allowed to sign a broad consent. Nor is there any reason, from the perspective of dignity, why people who want to give specific consent at every opportunity should not be able to. They may find this more 'active' participation to be particularly meaningful and even fulfilling,<sup>2</sup> and may ultimately prove to be the best spokespeople for biobanking. Moreover, they may be more willing to link their biological data with biographical information, making them important for longitudinal studies.

Finally, a multidimensional understanding of human dignity shows that sometimes the only solution is a compromise – albeit always with an awareness of the necessary gravity for those who may be compromised. Thus, though policy-makers may believe that biobanks may significantly benefit the public, they cannot make those who don't believe this, believe it. At best, they can ensure that a person's potential to live a meaningful life (his or her inherent dignity) is not compromised, and this should be done by, at the very least, making it possible to opt out.

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