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## **Managing access to biobanks: How can we reconcile individual privacy and public interests in genetic research?**

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### **ABSTRACT**

This article is concerned with the ultimate objectives of genetic biobanks set up to promote the public interest – being the sharing of samples and data for medical research - and the consequences for personal privacy of realising them. Our aim is to chart the values, interests and principles in play, to consider the challenges of realising biobanking objectives on a global scale, and to propose viable ways forward that ensure as far as possible that access provisions remain fit for purpose throughout the entire life of a biobank while adequately protecting the privacy interests at stake. It is argued that key features in any robust access model must include mechanisms (a) to maintain participant trust in management of the resource and to measure and respond to participants' expectations, (b) to facilitate and promote the sharing of benefits, and (c) to respond timeously and effectively to challenges as and when they arise.

### **ACCESSING BIOBANKS: THE VALUES AND INTERESTS AT STAKE**

This paper is concerned with biobanks which are expressly set up to promote the public

interest and a paradigm example of this is the publicly-funded biobank in the health sector. In this context it is submitted that the objectives of such biobanks are, quite simply, to create resources of genetic material and information and to promote access by a range of as-yet unknown parties. Although specific purposes and users will vary across biobanks, the reality is that the continued existence of such genetic biobanks can only be justified if appropriate access is given; and threats and concerns about the privacy of the individuals whose samples and data constitute the particular resource come with all kinds of access. This article explores the tensions that can arise and offers ways forward for biobank governance and regulation focussing on the role of trust, participants' expectations, benefit sharing and responsive governance mechanisms that develop and evolve with the resource itself.

This section describes the core values that we believe are at stake with the maintenance and exploitation of biobanks containing human genetic material and data. These are (a) privacy, (b) public interest(s), including the maximisation of the utility of genetic resource resources, and (c) solidarity, including the sharing of the benefits of these resources as widely as possible. We are not concerned here with the mechanisms necessary to recruit participants and to protect their interests when setting up a biobank, but rather our concern is with the interests that are in play once the resource exists and access to it is contemplated. This having been said, the core interest which is common to both the recruitment and the retention phases in biobank governance is that relating to guarantees of personal privacy protection and it is, therefore, fitting that we begin with an account of the nature of these interests.

## **Privacy**

Human genetics and biobanks have taken some of the classic privacy concerns such as fear of misuse of personal information, stigmatisation of groups, and unjustified intrusion into private life, to new heights. The conceptual complexities of privacy are well recognised, and our involvement in the *Privileged project*<sup>1</sup> has led us to believe that it is valuable to see privacy interests in four inter-related dimensions: (i) physical privacy, (ii) informational privacy, (iii) decisional privacy and (iv) proprietary privacy. Each dimension is very evident in laws and governance regimes in European states as well as in public understandings of the concept.<sup>2</sup> Each dimension is also important when mapping the privacy concerns that biobanks pose. For example, the concern of *physical privacy* in relation to biobanks arises at the recruitment stage of the biobank; this relates to gathering and storing genetic samples and not testing them without consent. Once recruitment is completed then *informational privacy* becomes relevant with respect to the information and/or samples of individuals that make up the resource. The core concern is about the possibility of misuse of

information, not least the risk of discrimination, which we define here as treating different groups differently for illogical or irrational reasons. *Decisional privacy* highlights the interest that biobank participants have in control or influence over what is done with the resource - and by implication with their data and samples. Primarily, this involves processes of decision-making in relation to access to biobanks and control of governmental or third party use, and also includes the individual choice whether or not to remain a biobank participant. Finally, *proprietary privacy* concerns ownership of genetic samples and the control of identity as it relates to our genes. Even if it is not generally recognised that individuals own their genetic samples,<sup>3</sup> proprietary-type claims might be invoked in response to concerns that arise from new technologies such as data-mining and profiling. These technological possibilities mean that different databases and data can be compared quickly and easily, creating new groups of people or profiles, and thus potentially giving way to new and unexpected possibilities of discrimination and stigma.<sup>4</sup>

These dimensions of privacy are not discrete categories and often overlap. They may intersect with other concepts such as autonomy or liberty that are well recognised and protected values in western and other countries. At this level of abstraction, however, we can use this approach to understand and characterise meaningfully the *kind* of interests that are at stake. It is important to be able to do so because at a more specific level –e.g. that of the nation state– we often find that different legal devices are used in different countries to protect the same kind of privacy interest. For example, Portugal’s Law 12/2005 establishes a property right in biological material gathered for biobanking purposes and this right remains with the person from whom the material was taken. This, however, is a relatively rare instance of proprietary privacy being protected directly through a property claim. Most other countries attempt to give control to individuals through informational privacy or decisional privacy mechanisms. For example, all EEA countries have data protection laws that protect informational privacy interests and make consent the primary control device. Similarly, all Council of Europe countries protect the right to respect for private life and the European Court of Human Rights has recognised decisional privacy as an aspect of autonomy under Article 8 of the European Convention on Human Rights.<sup>5</sup>

We must distinguish with precision the different problems arising from biobanking and the analysis and use of the data and samples that biobanks contain. As is evident from the *Privileged project*, the interpretation of privacy in constitutions, law and regulations within European countries reflect cultural differences. In some cases, for instance, access is permitted for commercial use and in others it is not, and in some cases citizens have an obligation to share biological information for medical research. With growing international collaboration between researchers, privacy concerns need to be sensitive to these different cultural issues. These cultural differences need to be

addressed but, we suggest, our framework provides a helpful basis for comparison. If we can better understand the types and range of privacy interests that are in play, and the particular legal devices that can be used to protect them, then we will have come a long way to addressing the problems themselves. The focus of this article is the privacy challenges thrown up by *access* to biobanks.

### **Privacy and access**

The issue of access to biobanks touches upon all of the different dimensions of privacy outlined above. The central question is whether access necessarily and unjustifiably compromises privacy interests or whether it can be compatible with robust privacy protection.

The right to privacy is often seen as empowerment or control of what is seen or sensed by others. This poses a problem for biobanks because once information has been handed over it has been shared to a degree and control will have been lost or certainly compromised. Moreover, onward sharing is an express aim of many biobanks that have been set up in the public interest; as such there is self-evidently a potential increase in risks to privacy. There are two main ways in which laws tend to protect against loss of control and/or harm caused by information sharing. The first of these is consent and the second is anonymisation. Each has value in the protection of privacy interests but also inherent limitations.

Control is exercised through consent as the original terms of the consent set the parameters for future uses of the resource. Thus, consent will be breached if a downstream use is outside the purposes outlined when consent was given. The importance of this is recognised in the OECD Guidelines on Human Biobanks and Genetic Research Databases (Annotations), which state that:

These Guidelines set out that the HBGRD should not grant access to or disclose participants' human biological materials or data to third parties for non-research purposes, except when required by law. For example, the operators of the HBGRD should not make available participants' human biological materials or data to third parties such as insurers, employers, law enforcement agencies or other civil-law agencies, for non-research purposes.<sup>6</sup>

If samples or information are to be collected with consent then it is assumed that control can be maintained by the provision, withholding or ultimate withdrawal of consent. However, the control that consent provides in the case of long-term projects such as biobanks is rather limited. Participants will typically agree to participate, refuse to do so, or withdraw once they have done so. It is an all-or-nothing affair with precious little room for negotiation or compromise. The exercise of decisional privacy must either be based on up-front trust of the biobank project at recruitment

(see further below) or it will be in response to downstream events, including breaches of privacy, when it may be too late to protect the core privacy interests at stake.

A further limitation of consent is that it has little role to play in the security of information.<sup>7</sup> This important informational privacy interest is most comprehensively protected through data protection laws, and it is important to note that consent to data processing is but one of a range of justification for data use.<sup>8</sup> Put another way, consent alone does not absolve data controllers or processors of their legal obligations to process personal data lawfully and fairly, and this means keeping them secure.

Laws also tend to recognize anonymisation as a way to protect against the harm caused by data sharing. The rationale being that if individuals are not identifiable, then their (informational) privacy interests are not in jeopardy. While we might dispute this on the richer framework of privacy developed by the *Privileged* project, we cannot discuss the merits here. There is lengthy and on-going debate about different kinds of anonymisation techniques and what is ethically and legally required,<sup>9</sup> but these do not concern us here either. Our concern is this: to what extent does anonymisation offer the necessary security to privacy protection for participants *while also* furthering the objectives of biobanks to facilitate sharing and maximising benefits?

Unlike consent, which is a reflection of an individual's wishes and desires and a manifestation of the exercise of their autonomy (concerned primarily with decisional privacy), anonymisation is a technical measure achieved by technical means (involving mostly informational privacy). In the vast majority of cases, user access to medical research biobanks will only be offered on an anonymised, aggregated basis. Can anonymisation provide sufficient safeguards for participants and also provide researchers with sufficient material to conduct valuable research?

This clearly invites further questions. What is a sufficient level of protection for participants and what is a sufficient level of access for researchers? There are advantages and disadvantages for both sides – if it is appropriate to talk of sides – in using irreversible anonymisation or reversible anonymisation.<sup>10</sup> The former might be the most secure form of privacy protection for participants in that it is designed to make identification impossible, but it might not provide researchers with rich enough datasets; moreover, irreversible anonymisation removes the possibility of going back to participants with clinically relevant data, and the jury is out as to whether there are ethical and legal duties to do so.<sup>11</sup> In most cases it has been considered appropriate to keep samples/data with some form of indirect identification to the donors (reversible anonymisation). The question then is whether we can still meaningfully about anonymous data when it is possible to identify the sample subject, albeit indirectly. Obligations under data protection law arise (and remain) whenever personal data relating to any identified or *identifiable* individual are being processed. Additionally, and more recently, it has been confirmed by the European Court of Human Rights that data

protection extends to genetic sample collections as ‘personal data’.<sup>12</sup> Thus, at least with respect to those who hold data/samples for the purposes of the biobank, reversible anonymisation will not avoid the rigours of regulation. It might be an entirely different matter when it comes to release of data/samples to users of the biobank who can receive information/materials that are suitably anonymised to absolve them of obligations under data protection law. Of course, whether this provides them with sufficient levels of information for research purposes is another matter; contracts and confidentiality clauses are the most common means used to control users in their handling of biobank data and samples. But to the extent that the goals of anonymisation and access might be irreconcilable in certain contexts, then trade-offs might be required. We return to this below but equally we need not see the options in a polarised fashion.

The value of privacy and the nature of privacy interests are often presented as individualistic concerns. Protection of individuals is self-evidently important, but to do so also serves wider social and collective –or public– interests. Indeed, the protection of privacy is itself in the public interest. Seen in this light, is it possible to reconcile individual privacy and public interests when it comes to managing access to biobanks?

### **Public interest**

It is often claimed that biobanks are set up to further the public interest, especially in the health sector and/or with public monies. Appeals to this amorphous concept are found throughout health law and practice, but the nature and scope of public interest remain illusory. What, for example, is in the public interest and what exactly constitutes public interest? Is it necessary to find out how many members of ‘the public’ must benefit from an action before it can be declared to be in the public interest? What is the degree to which the ends of individual members of society should be the ends of their society or be thwarted for those societal ends? And more specifically: what does it mean to maintain a biobank in the public interest when there are clear attendant privacy risks for participants? This last question has been raised already and brings us to the tension alluded to at the end of the last section. The concept of public interest enjoys an uneasy relationship with notions of privacy often because public interest is held out as a justification for interference with privacy or with private interests. But as we have suggested above, the appropriate protection of privacy interests is also, in itself, a public interest. The two are not, therefore, necessarily mutually exclusive. Still, a brief discussion of the essential nature of public interest claims helps to tease out the tensions and assists us in the search for options to resolves them.

Public interest may encompass contradicting attitudes. According to Häyry and Takala, for example, ‘[p]ublic interest is a diffuse matter, and respect for it can mean many things. Some of

which cannot always co-exist peacefully'.<sup>13</sup> As we have identified, it is a public interest to protect individuals' rights to privacy and confidentiality.<sup>14</sup> However, this public interest is not an absolute one and it is often met, ironically, with countervailing public interest claims that seek to limit it. Thus, there might be cases of public interest where it will be necessary to interfere with privacy in order to protect the general public, including identified or unidentified individuals or groups; as Powers has phrased it: '[a] commitment to privacy rights does not entail a commitment to absolute rights'.<sup>15</sup> This conception of public interest is one concerned exclusively with the avoidance of harm to others, and Ashcroft has exemplified the possible contradictions by writing: 'there is a public interest in the effective... administration of .... criminal justice; but there is also a public interest in restraining undue... surveillance of our personal lives'.<sup>16</sup> In the biobank context, then, access by police cannot be ruled out, indeed it should be positively contemplated and communicated to participants as a possible risk to their privacy if participating in a biobank project. That said, this *negative* conception of public interest – that is, as a justification for interfering with personal interests to avoid harm to others – is hardly unique to biobanks. The police can, and do, access personal details in a range of sources and resources on a daily basis. The point, however, is that given the fundamental human right to respect for private life, the onus is always on those who would interfere with such a human right to demonstrate just cause; and in the European context<sup>17</sup> this must meet the exacting criteria of *effectiveness*, *necessity* and *proportionality* to which we return below.

There has been considerably less exploration in the literature of *positive* senses of public interest, that is, of the public interest as it relates to actions that promote socially beneficial ends rather than those which avoid socially harmful outcomes. It is precisely on such a conception – however vague it may be – that much of the argument in favour of the creation and maintenance of numerous biobanks rests. It is true, for example, that the benefits of biobanks might come back to individual participants - there could be downstream opportunities for feedback of health-relevant data - but this is not normally the primary purpose. Godard et al. noted in a study of four national genome projects (UK, Iceland, Canada and Estonia) that the Estonian project is 'the only project that explicitly states that donors upon request will have access to their personal data and research results'.<sup>18</sup> This remains broadly true today of such national population-based projects, and for this reason we do not purport to explore issues of individual feedback in this paper. Rather, our concern is with the prospect of the public benefits, which is advanced to justify such projects.<sup>19</sup> Indeed, we offer the following proposition: scientifically sound, ethically robust research using biobanks is manifestly in the public interest. We would, in fact, go further and suggest that there is a positive moral obligation to promote the use of these research resources in ways that, in turn, promote the public interest. This can only happen through access. The imperative, then, is to promote access on



sound scientific, ethical and legal principles. But where does this leave privacy? And – to bring this to a central question – what precisely will it mean to promote access in the public interest? We offer some observations on the analysis thus far.

### **Reconciling privacy and other public interests**

On privacy, we would make a number of observations. We suggest that the guiding principles of necessity and proportionality can and should operate to temper access decisions in ways similar to the context of negative concepts of public interest discussed above. For example, access should not be granted to identifiable data if appropriately anonymised access can serve just as well. But it is also important to be aware that anonymity and robust privacy protection are more akin to crafts than strict science. No level of technical protection can offer an absolute guarantee of privacy and participants must understand this and be prepared to assume some level of risk. Finally, there will always be occasions for genuine and reasonable disagreement over access decisions that, for some, will fail to strike an appropriate balance between the protection of the (privacy) interests of participants and the promotion of the public interest in research. We need, therefore, mechanisms both to gauge participants' expectations as to their privacy (and, indeed, as to what counts as research in the public interest) to feed into decision-making processes. We also require mechanisms to allow participants to voice their concerns about what might be happening to their data/materials and to their privacy; the most obvious example here is the right to withdraw at any time and for any reasons without consequence and in order to protect one's information privacy; but for those who wish to remain involved and to exercise their decisional privacy other mechanisms must be devised.

On public interest, we suggest that our last point provides a valuable first piece of the puzzle: participants in a biobank could have a say in the use of the resource and could help to define and refine what it means to use it 'in the public interest'. This could include input on where to set a level of adequate privacy protection and/or where compromises on privacy might be reached. This is not to suggest that participants have a monopoly on what counts as the public interest; indeed, their own desire to protect individual privacy might stand in the way of wide-ranging uses of a resource. By the same token, it does not follow that a commitment to individual privacy is irreconcilable with the promotion of public interests. The value of including participants in helping to decide what constitutes a public interest use of the resource is a reflection of the shared commitment – between researchers and participants - to promote the biobank for precisely such uses. This is what people have signed up for in an act of social solidarity. We do not suggest that what counts as the public interest is the exclusive preserve of participants because this must be a matter for far wider debate and engagement.<sup>20</sup> Notwithstanding such efforts, no amount of involvement will cover and answer all possible questions and issues, and at the same time be accepted by everyone. Still we suggest

that what should be taken from this section is that, broadly speaking, public interest should include acts or conduct which further society's better interests as well as providing adequate protection of the general public from harm. It is therefore arguable that public interest in the context of biobanks should include genetic research for the benefit of society as a part of public health and welfare, the promotion of wider collective interests where appropriate,<sup>21</sup> and this may also include personal security and the fight against crime. More specifically, and because the value of the principle of solidarity in the context of biobanks is particularly strong,<sup>22</sup> broad engagement with publics and participants should inform the process of deciding it means to manage a biobank 'in the public interest'.

In dealing with delicate and borderline cases, or in cases where there might be tensions between competing conceptions of the public interest in access and the public interest in privacy protection, then the rule of proportionality should be applied in each individual case. Three tests are required in order to meet the rule of proportionality. The first is the *test of effectiveness*: the measure taken should constitute an effective means for the realisation of the aims or targets pursued by that measure. The second is the *test of necessity and subsidiarity*: the measure taken is necessary to achieve those aims and no alternative that is less intrusive is available. Finally, the third is *the test of fair balance*: there should be a fair balance between the aims pursued and the interests harmed.<sup>23</sup> What is 'fair' falls to be determined as much by participants in biobank projects as by any legal or administrative body. Although it might be possible to draw some clear lines in the sand about that which is, by broad consensus, *against* the public interest – for example, any research intended to prove racial superiority or inferiority, ethnic origins or sexual preferences – the reality is that this will not assist us in the vast majority of access requests. Instead it leaves us to fall back on broad principle although this is not without a measure of evidence in its support: genetic research must go on for the benefit of society<sup>24</sup> and privacy must be adequately protected. The drawing of the line in any given situation will obviously depend on a large number of variables, but some may carry more weight than others. Such variables might help tip the balance toward tighter privacy protection or, contingent upon beneficial outcomes, toward access. In the next section we explore one crucial variable that might serve this function and help to reconcile privacy and other public interests in biobanking access decisions. This is the phenomenon of benefit sharing.

### **The role and value of benefit sharing**

Benefit sharing has long been a recurrent theme in international debates about access to genetic resources. However, despite its prominence in law, medical ethics and political philosophy, the concept has never been satisfactorily defined. Attempts made in academic literature envisage a wide range of roles for benefit sharing. Most pertinently, perhaps, it has been characterised as an

‘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.’<sup>25</sup> So defined, benefit sharing can be cast in three different dimensions, i.e. as an act of sharing the resource and/or its outputs with: a) the individual research participant (and his/her family), b) third parties (ie, granting access), and/or c) the community/society/future generations. The main normative problem in this context, however, concerns the status of benefit sharing, i.e. whether and to what extent it should be a (legal) duty of the research institution managing the resources to share them with others. In a rare example, the new Norwegian Act on Medical and Health Research<sup>26</sup> recognises a legitimate interest for access by researchers to data and human biological materials and goes so far as to create a legal obligation to share biological material with researchers from outside the responsible institution. We submit that the basis for supporting such an obligation lies in the close connection between benefit sharing and the promotion of public interests. Notwithstanding any legal obligation to share, there is a sound case in principle and some evidence in practice to suggest that making benefit sharing a part of best practice can help resolve tensions between public interests in access and privacy protection.

A commitment to benefit sharing can be a powerful indicator of a commitment to conduct genetic research in the public interest.<sup>27</sup> In fact, the connection between benefit sharing and public good is expressly recognised in various legal instruments. For example, Article 12(a) of the Universal Declaration on Human Genome and Human Rights (1997) states: ‘(a) Benefits from advances in biology, genetics and medicine, concerning the human genome, shall be made available to all, with due regard for the dignity and human rights of each individual.’ Article 15(1) of the UNESCO Universal Declaration on Bioethics and Human Rights 2005<sup>28</sup> provides some specific examples of the benefits that ‘should be shared with society as a whole and within the international community, in particular with developing countries.’ Such benefits include, *inter alia*, ‘special and sustainable assistance to, and acknowledgement of, the persons and groups that have taken part in the research’.

Most recently, we have the OECD Guidelines for Human Biobanks and Genetic Research Databases.<sup>29</sup> In them we read:

In recognition that the sharing of knowledge is one of the most important benefits to be derived from HBGRDs, they should endeavour to foster the exchange of information, technology and research. Information, technology and research may be carried through various means including through technology transfer, material transfer, licensing, joint development activities, etc. According to the Guidelines benefits resulting from the HBGRD activities and their applications should be shared as

much as possible among OECD and non-OECD states (with donors, communities, society as a whole).<sup>30</sup>

And, as a precursor to all of this, we have Article 27(1) of the UN Declaration on Human Rights (1948): ‘Everyone has the right freely to participate in the cultural life of the community, to enjoy the arts and to share in scientific advancement and its benefits...’.<sup>31</sup>

Each of these approaches, from the most general to the more specific, envisages benefits accruing to one or more of the three categories of actors we identify above, viz, research participants themselves, those who would access the research resource in the pursuit of new knowledge, and the wider society, whether present and future. Benefit sharing might, therefore, take different forms from simple data sharing among scientists of the research resource, to concrete financial or therapeutic benefits for participants, and beyond to the distribution of wider benefits in a social infrastructure. But as Sarah Wilson has observed: ‘with the increasing commercialization of ownership of the databases, the benefit sharing arrangements become seemingly more specific and more financially or materially oriented’.<sup>32</sup> It is, however, an overly crude conceptualisation to limit benefit sharing to a partaking of eventual profits. Our own work in public engagement has generated evidence that suggests that participants in genetic research projects do not generally expect a financial return; they do, however, expect some wider sharing of benefits within the community – be these scientific, clinical and/or commercial.<sup>33</sup>

The difficulty is that the practicalities of implementing these values rarely work. The *Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising out of their Utilization*, adopted in 2002,<sup>34</sup> is one of the most elaborated documents in the field of benefit sharing although it does not have binding force. The Guidelines have none the less been recognised as a useful first step in the implementation of relevant provisions of the Biodiversity Convention related to access to genetic resources and benefit sharing. The guidelines highlight the fact that: ‘mutually agreed terms could cover the conditions, obligations, procedures, types, timing, distribution and mechanisms of benefits to be shared. These will vary depending on what is regarded as fair and equitable in light of the circumstances.’ They provide detailed guidance for the implementation of benefit sharing arrangements and may be useful as a model to refine these arrangements in human population genetic research. But in many cases<sup>35</sup> the reason why benefit sharing models have not yet been in use is a simple technical difficulty: ‘In the absence of royalties, profits and patents ...it is difficult to apply the international principle of benefit sharing beyond the obligation to generate and widely disseminate new knowledge, and to return research results to the population databases.’<sup>36</sup>

Notwithstanding, the imperative to share has become all the more acute with the emergence of population-based genetic studies and the opportunity is very real to design these possibilities into new and emerging governance structures. The reasons to pursue a workable approach are manifold. For example, benefit sharing can create a sense of solidarity between the research community, participants and the public. As the National Bio-Ethics Committee of Italy has said:

[T]he future outlook of biobanks – whether collections or tissue banks – is to grow in scale, from local to national, and from national to European, and these changes in scale might have an effect on ethical issues and on their elaboration, in the sense of directing them towards less individualism and a new sense of solidarity. More than in the rights of the individual, and within the respect of private life, biobanks could become tools in a new form of solidarity between groups and generations, based on a voluntary sharing of samples and information, for a common resource that must be available on a basis of rules of democratic participation.<sup>37</sup>

Benefit sharing in this context can also serve to acknowledge the importance of on-going participation and support from the public in large-scale research projects from which, at least in the short term, there is little prospect of direct therapeutic benefits for the participants or the community.<sup>38</sup> It provides a degree of reciprocity on which the trust relationship between participants and researcher is based.<sup>39</sup> We have argued above that scientifically sound, ethically robust genetic research itself is in the public interests, and here we suggest that a clear commitment to benefit sharing must be a part of this. ‘Benefit’, however, should include not merely access to the results of research such as downstream therapeutic products, but also access to genetic resources themselves as necessary to realise those downstream benefits. It follows that widespread sharing of a biobank resource should be a given to maximise its utility and its service in the public interest. With this, however, will come attendant, possibly increased, risks to participant privacy.

A recent example illustrates this well from the realm of open access; this is the phenomenon of encouraging sharing of scientific knowledge or resources with little or no expectation of return. While sound in principle, the privacy implications of such a policy remain unclear. A publication in 2008 demonstrated that it was possible to identify individuals whose genomic data had been included in a cohort of anonymised genetic profiles made available to researchers over the internet.<sup>40</sup> Although this was only possible if the genetic profile of the individual in question was already known to those seeking to make the association, this revelation nonetheless led international organisations such as the Wellcome Trust and the US National Institutes of Health to shut down their

‘open’ systems of sharing data among researchers.

What should we make of this? Well, it implies that even if we accept that benefit sharing is an important aspect of a positive commitment to the public interests in genetic and genomic research, the practice of sharing – to include the practice of granting access to a genetic resource – will probably be accompanied by increased privacy risks. While it is clear that such risks must be minimised wherever possible, it is impossible to eliminate them completely; moreover, a *de minimis* approach to privacy risks might not be possible or desirable when considered against particular public interests in access and sharing. Then again, this might not be what is expected by participants who may be willing to trade-off elements of privacy in order to be a part of a project that is run determinedly in the public interest and in the governance of which they have a say. Matters are complicated by the fact that it is currently impossible to know what future access requests will look like or what privacy risks they will bring. Agreements about downstream benefit sharing are obviously even further removed. The task, then, is to devise governance systems that can meet the challenges as and when they arise. In the next section we offer some insights on the core challenges as we currently see them, before finally moving to propose ways forward to meet such challenges through governance arrangements.

## **CHALLENGES OF ACCESS & SHARING IN THE GLOBAL ENVIRONMENT**

### **Trust**

The establishment and maintenance of trust in a biobank and its operation is arguably amongst the most fundamental challenge that we face. It is self-evident that participants must trust that their privacy interests will be adequately protected, although as we have suggested above, the realities of the risks must be fully understood and these will invariably change over time. Arguably, the most dangerous approach to take is to raise expectations too high with regard to privacy protection, for example, by suggesting that absolute anonymity can be guaranteed or by failing to alert participants to likely challenges to privacy protection over time.

Another feature of trust, which is often overlooked, is the trust of participants, the public and the research community that the research resource will be optimally managed to promote both the private and public interests at stake. Once again, this has implications for privacy in that trade offs might have to be negotiated and accepted if a full range of research ends are to be realised and a wide degree of benefit sharing is thought to be acceptable. For example, in order for biobanks situated around the globe to deliver their benefits, sharing of material and data will have to occur on an international scale. No one biobank, whatever its size, has the capacity to answer the wealth of research questions that will be generated. Only by pooling resources do we have a collective chance of arriving at meaningful answers. Thus international access is inevitable. Furthermore, if we accept

that international cooperation is the only route to success then there is a strong moral imperative that international sharing of benefits should also follow. This, however, might have a paradoxically negative effect on trust in biobanks. For example, a public attitudes survey that was recently commissioned with respect to the UK Biobank resource – which aims to recruit 500,000 participants from around the United Kingdom and which will openly encourage international access – found significantly lower levels of confidence in international transfers of data or materials among the UK citizens who took part in the survey.<sup>41</sup> What is not clear is what lies at the root of this level of concern or mistrust. Moreover, it might not be an answer –for participants at least– that the Data Protection Act 1998 does not allow international transfers of data to countries which do not enjoy equivalent levels of privacy protection. Eurobarometer (Data Protection: 2008) did report, however, that the highest levels of trust (82%) among European citizens lay with medical services and doctors.

A final point about trust brings all of these elements together. At the present time we simply do not know who will seek to access biobanks, nationally or internationally, for which purposes, ends or objectives. While it is true that projects that benefit from detailed governance arrangements have tried to set some parameters, inevitably these remain broadly defined. For example, UK Biobank states in its Ethics and Governance Framework that its purpose is to encourage ‘health-related research’.<sup>42</sup> But will this permit access for the creation of embryonic material through somatic-cell nuclear transfer?<sup>43</sup> If it does, is this something that participants and publics would have contemplated or will tolerate? Challenges such as these will inevitably confront biobanks around the globe. It becomes a matter of trust, then, for all of us to know that such challenges are being appropriately met.

### **Mapping and measuring expectations over time**

It is a further challenge of large-scale population-based biobanks that they will not yield their benefits for a very long time. A common approach is to seek to build the research resource of genetic material and data and to follow participants over time until instances of disease emerge. The objective is to better understand gene/environment interactions comparing baseline data from recruitment with changes in health monitored through records and over time. But it will take many decades before statistically significant numbers of disease instances arise. For example, in a cohort of 500,000 it will take between 30-40 years before there are 10,000 instances of lung disease and around 25 years before there are equivalent instances of Parkinson’s disease.<sup>44</sup> In the interim, attitudes towards privacy, the public interest, benefit sharing and medical research might change dramatically.<sup>45</sup> Scientific and technical threats and opportunities will arise and the core governance challenge is how to devise a mechanism that remains fit for purpose over time while also mapping

and measuring public and participants' expectations with respect to privacy and the uses of the resource more generally.

These realities of research and access have significant implications for our traditional approaches to research governance.<sup>46</sup> The most obvious of these is the impact on the role of consent. Informed consent had become of primary importance in recent years, for reasons that need no rehearsal here. We have suggested above that its limitations are revealed in the context of biobanks: how can a prospective participant be sufficiently informed about the range of uncertainty detailed above? The simple answer is that she cannot be. As a result, we cannot rely on informed consent as the ethical or legal basis upon which participation is legitimated. Rather, it is argued, participation is on the basis of broad consent to participate in the project with all that this entails. The attendant obligation on the part of the project researchers and managers is, however, to provide adequate information about the development and uses of the resources as and when these occur. It might even be argued that this is a more robust consent mechanism since it casts consent as an ongoing process and not a one-off event. Participants are at liberty to withdraw from biobanks that are set up on this basis at any time and for any reasons; but threats to their privacy may remain if samples or data have been distributed beyond their control or that of the biobankers. For those participants who remain, appropriate mechanisms must be devised that can adequately assess changing threats to privacy as well as applications to use biobank resources cast under the broad rubric of public interest.

## **MANAGING EXPECTATIONS AND BENEFITS FROM RESEARCH**

Thus the position is this: we simply do not know what the privacy challenges will be nor, indeed, what benefits will emerge from biobanks. We have seen elsewhere<sup>47</sup> that many countries use systems of 'prior checking' to authorise particular data flows, and we are all now very familiar with the role of research ethics committees in approving medical research projects. The problem with each of these processes is that they occur *before* the research is carried out, and – importantly with biobanks – long *before* access is granted. The personnel involved suffer (axiomatically) from a lack of informedness about the future; they too have to trust that the project will be managed appropriately. Arguably such faith is not enough, nor is the fact that legal sanctions already exist if breaches of privacy protection occur. This is too little, too late for participants and might well signal the demise of a biobank and the loss of important future public interests.

Furthermore, there is little sense in trying to second-guess the science or indeed the social sensitivities at some point in the future. Just as it is difficult, if not impossible, to define categorically what we mean by 'privacy' or 'public interest', so too will our notions change with circumstances and we need access mechanisms that can accommodate such changes. While we can



have an up-front commitment to the promotion and protection of privacy and the public interest, the specifics of how to ensure this elude us until the resources exist, access is considered and given, and benefits are realised. The easy cases – today – may be those where there is clear consensus on the privacy risks or the limited public benefits – such as access by insurers or research on race – but for the most part we cannot be and should not be categorical. This means a period of uncertainty for both participants and researchers and a raft of attendant obligations over time to keep participants on board and the genetic resources viable. One clear example is the on-going commitment to keep people informed; another, we would suggest, is provided by robust benefit sharing and this is borne out in part by empirical evidence. Privacy clearly remains a central concern but trade offs are, and will be, necessary and these will become increasingly important as potential benefits come closer to within our reach.

The objective is to devise governance mechanisms that take account of these uncertainties, that can respond to developments as and when they occur, that can ensure participants are informed on an on-going basis, and that can also help to measure and manage expectations over time.

We suggest that a model such as that adopted by UK Biobank might be useful in meeting this challenge. This project is founded on a model of broad consent and trust. Participants agree ‘to participate in UK Biobank’ and the obligations of the researchers to participants are laid out in the Ethics and Governance Framework. It includes commitments to keep participants informed and to require some degree of benefit sharing from those who access the resource. Importantly, the entire project is overseen by an independent Ethics and Governance Council which monitors UK Biobank’s conformity with its Ethics and Governance Framework and which has the interests of participants as paramount in its objectives. It also advises on the use of the resource in the public interest, whatever that may turn out to be.<sup>48</sup>

The value of this approach, we would submit, is that it is designed to develop as the resource develops. It is primed to be responsive to new and as-yet unforeseen threats to privacy and participants’ interests and it has a specific aim to operate to promote the public interest. Its limits, however, are also considerable. The Council has no basis in law and has no formal sanction over UK Biobank. It is a creature of the funders not of the law. Furthermore, the commitment to benefit sharing is currently under-developed in the Framework and many have argued that far more should be expected of it.<sup>49</sup> None the less, as a responsive and forward-looking mechanism it is a good start.

And what is the role of law in all of this? Whether or not a legal basis for biobanking should be established at the national or international level is a matter of considerable debate.<sup>50</sup> In favour of legal intervention are factors such as legal certainty and the prospect of effective sanctions. Against is the need to avoid further regulatory burden and the fact that many governance mechanisms can work perfectly well without express legal provision. The UK Biobank is an example of this. It must

also be remembered that current data protection laws exist as much to facilitate responsible data sharing as to protect privacy.<sup>51</sup> Beyond this, it is not obvious that matters of access should be further legally prescribed especially when the considerable benefits of access will only be realised through open international sharing. The watchword here must be flexibility, at least from the researcher perspective. The same is true – to some extent – when it comes to protecting participants’ and public interests because social mores necessarily change over time and law may ossify regulatory perspectives that become all-too-soon out-of-date. For these reasons we advocate a responsive model such as that typified by UK Biobank.<sup>52</sup>

We cannot possibly hope to answer all the questions about privacy and public interest that currently surround the development of biobanks. Indeed, it would be fruitless even to try. But, as we have suggested here, we can identify what is at stake within a broad conceptual framework of privacy even if we do not know what specific future threats will be. We propose that this framework and acceptance of future uncertainty allow us to begin to devise mechanisms that will provide answers over time. Only time itself will tell if they prove to be the right answers.

## **CONCLUSIONS**

This article has argued that to maintain a biobank ‘in the public interest’ means to protect individuals’ rights to privacy and confidentiality, to promote access to the resource on sound scientific, ethical and legal principles, and to commit to benefit sharing. We conclude as follows: (a) international cooperation, which is imperative to obtain meaningful answers from large-scale (publicly-funded) biobanks in the health sector, will require global access to genetic resources in the future; but this does not necessarily mean that international legal intervention is required, (b) scientific developments and uncertainty regarding future uses of genetic resources challenge traditional protection mechanisms (such as ‘informed consent’ and ‘prior checking’), while attitudes towards privacy, the public interest and benefit sharing are fluid and contingent over time; accordingly, a responsive and flexible governance mechanism is needed to address these changes as and when they arise, (c) expectations about privacy must be realistic and monitored and managed carefully throughout the life of the biobank; the notion of public interest may be used both to consider access requests and to assess changing threats to privacy, (d) as no technical protection measures can offer absolute guarantees of privacy and much uncertainty surrounds what counts as research in the public interest, the relationship between participants and researchers is largely based on trust; nonetheless, participation in biobanking should be recognised as an act of social solidarity and a shared commitment to promote public interest research. This should entail a more interactive dynamic between participants and researchers than has occurred to date. Accordingly, our core

message is that governance systems for biobanks must be devised that can meet emerging challenges adequately and timeously while also mapping and measuring public and participants' expectations with respect to privacy and the uses of the resource more generally.

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<sup>1</sup> <http://www.privileged.group.shef.ac.uk/> See also D Townend, MJ Taylor, J Wright and D Wickins-Drazilova, 'Privacy and Access: Privacy Interests in Biobanking: A Preliminary View on a European Perspective,' in J Kaye and M Stranger (eds), *Principles and Practice in Biobank Governance* (Ashgate, 2009), pp. 137-160.

<sup>2</sup> Anita Allen identifies these four dimensions of genetic privacy in her paper 'Genetic Privacy: Emerging Concepts and Values' in MA Rothstein (ed), *Genetic Secrets: Protecting Privacy and Confidentiality in the Genetic Era*, (Yale University Press, 1997) There are many more accounts of privacy and recently several privacy scholars have argued that privacy is a cluster concept. See for instance and Judith Wagner de Cew *In Pursuit of Privacy*, (Ithaca and London: Cornell University Press, 1997). Beate Rössler, *The Value of Privacy*, (Cambridge, Polity Press 2005).

<sup>3</sup> See, for example, R Hardcastle, *Law and the Human Body: Property rights, Ownership and Control* (Oxford, Hart Publishing, 2007) and D Dickenson, *Property in the Body: Feminist Perspectives* (Cambridge, Cambridge University Press, 2007).

<sup>4</sup> HT Tavani, 'Genomic research and data-mining technology: Implications for personal privacy and informed consent' (2004) 6 *Ethics and Informational Technology* 15-28.

<sup>5</sup> *Pretty v United Kingdom* (2002) 35 EHRR 1.

<sup>6</sup> Organization for Economic Cooperation and Development, *OECD Guidelines on Human Biobanks and Genetic Research Databases* (2009), Annotations, para 63.

<sup>7</sup> AL Caplan, 'What No One Knows Cannot Hurt You: The Limits of Informed Consent in the Emerging World of Biobanking' in JH Solbakk, S Holm and B Hofmann (eds) *The Ethics of Research Biobanking* (Springer, 2009).

<sup>8</sup> The Dutch Code for Proper Secondary Use of Human Tissue of the Dutch Federation of Biomedical Scientific Societies allows secondary use of coded biological material if there is no objection from the donor, provided that the system of no objection is based on sufficient information and a low threshold of objection. Such use of tissue without consent must also serve the general interest of obtaining new scientific results, thus cannot have purely commercial purpose.

<sup>9</sup> BS Elger and AL Caplan, 'Consent and anonymization in research involving biobanks: Differing terms and norms present serious barriers to an international framework' (2006) 7(7) *EMBO Reports* 661-666.

<sup>10</sup> On the difficulties of being clear about what 'anonymisation' might mean in its various forms, see BM Knoppers and M Saginur, 'The Babel of genetic data terminology' (2005) 23(8) *Nature Biotechnology* 925-7.

<sup>11</sup> A Boggio, 'Informing participants about research results' in B Elger, N Biller-Andorno, A Mauron, and A Capron (eds.), *Ethical and Regulatory Aspects of Human Genetic Databases* (Ashgate 2008), C Johnston and J Kaye, 'Does the UK Biobank have a legal obligation to feedback individual findings to participants?' (2004) 12(3) *Medical Law Review* 239-267, BM Knoppers and L Kharaboyan, "'Deconstructing" biobank communication of results' (2009) 6(3) *SCRIPTed* 677-684, and compare F Miller et al, 'Duty to disclose what? Querying the putative obligation to return research results to participants' (2008) 34 *Journal of Medical Ethics* 210-213.

<sup>12</sup> The European Court of Human Rights has confirmed that genetic samples as also 'personal data' for the purposes of the ECHR and its interpretation of the European Data Protection Directive, see *S and Marper v United Kingdom* (2009) 48 EHRR 50.

<sup>13</sup> M Häyry and T Takala, 'American principles, European values and the mezzanine rules of ethical genetic databanking', in M Häyry, R Chadwick, V Árnason and G Árnason (eds.) *The Ethics and*

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*Governance of Human Genetic Databases* (Cambridge University Press, 2007), p. 21.

<sup>14</sup> Public interest is different from interests of the public or communities or groups, large or small, which are part of the public. Interests of the such groups are more likely to infringe individual rights to privacy, confidentiality, and dignity.

<sup>15</sup> M Powers, 'Privacy and the Control of Genetic Information' in MS Frankel and AS Teich (eds.), *The Genetic Frontier: Ethics, Law and Policy* (1994), American Association for the Advancement of Science, Washington, DC, p. 82 and G Laurie, *Genetic Privacy, A Challenge to Medico-Legal Norms* (Cambridge University Press, 2002), p. 279.

<sup>16</sup> RE Ashcroft, *Ethical, Legal and Social Issues Facing the West London Database Project: A Review of the Literature* (2001) NHS Executive London Regular Office Research and Development Office, London, p. 5.

<sup>17</sup> *S. and Marper v The United Kingdom* (2009), n 11 above.

<sup>18</sup> B Godard, J Marshall, C Laberge and BM Knoppers, 'Strategies for Consulting with the Community: The cases of four large-scale genetic databases' (2004) 10 *Science and Engineering Ethics* 457-477, p.461.

<sup>19</sup> We acknowledge the very wide diversity of biobanks that exists and in particular the important distinction between banks concerned with particular diseases and those which are established as a general research resource.

<sup>20</sup> See generally this Special Issue, P O'Leary and RL Zimmern, 'Genes for Health' (2010) *Public Health Genomics*, Issue 13(4).

<sup>21</sup> G Laurie, *Genetic Privacy*, supra note 14, at p. 279. Nevertheless, we should be very careful when we speak of collective interests. Such interests may lead us to interests of the public or groups in society, especially in non-liberal communities, who are willing to stigmatise groups, either because of their origin, race and ethnicity, or because of their culture, behavioural preferences and views. Hence we should try to limit the meaning of Public Interest in order to safeguard the individual rights to privacy and confidentiality. It is important to guarantee that people will not be discriminated on the basis of their genetic profile and one's right to full medical insurance will not be lessened.

<sup>22</sup> S Harmon, 'A (New) Ethic for Global Health Policy' (2006) 14(4) *Health Care Analysis* 215-236.

<sup>23</sup> Cf. J Schwarze, *European Administrative Law*, Revised 1st Ed. (Sweet & Maxwell, London, 2006); W Wade & Ch Forsyth, *Administrative Law*, 8<sup>th</sup> ed. (Oxford University Press, 2002), p.328; *R. v International Board of Agriculture Produce ex p. E.D. & F. Man (sugar) Ltd.* [1986] 2 All E.R. 115; O Koch, *Der Grundsatz der Verhältnismäßigkeit in der Rechtsprechung des Gerichtshofs der Europäischen Gemeinschaften* (2003) (Duncker & Humblot, 2003), p.199 et seq.; JH Jans, 'Proportionality revisited', (2000) 27(3) *Legal Issues of European Integration* 239-265 and FG Jacobs, 'Recent Developments in the Principle of Proportionality in European Community Law' in E Ellis (ed.) *The Principle of Proportionality in the Laws of Europe* (Hart Legal Publishers, 1999), p.1-22.

<sup>24</sup> Eurobarometer results show relatively high levels of support for gene banking to facilitate research, especially in a number of Eastern European countries, with less than average support in the southern European countries.

<sup>25</sup> D Schroeder, 'Benefit sharing: it's time for a definition' (2007) 33 *J Med Ethics* 205-209.

<sup>26</sup> ACT 2008-06-20 no. 44: The Act on Medical and Health Research Act with few exceptions replaced the Personal Data Act, the Personal Health Data Filing System Act, and the Biobank Act in relation to medical and health research.

<sup>27</sup> In the field of human genetic research, HUGO's 1996 Statement on the Principled Conduct of Genetic Research was a pioneer. This was later developed more fully into the HUGO Statement on Benefit Sharing (2000).

<sup>28</sup> UNESCO Universal Declaration on Bioethics and Human rights. 2005, available at: [http://portal.unesco.org/shs/en/file\\_download.php/46133e1f4691e4c6e57566763d474a4dBioethicsDeclaration\\_EN.pdf](http://portal.unesco.org/shs/en/file_download.php/46133e1f4691e4c6e57566763d474a4dBioethicsDeclaration_EN.pdf)

<sup>29</sup> OECD Guidelines for Human Biobanks and Genetic Research Databases (2009) setting out principles and best practices.

<sup>30</sup> The *OECD Guidelines for the Licensing of Genetic Inventions* (2006) provide guidance so as to ensure that

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licensing and transferring agreements as well as joint development activities are carried out in a balanced manner and are based on economically rational practices that help eliminate high transaction costs and that serve the interests of society.

<sup>31</sup> And similarly, Article 15 of International Covenant on Economic, Social and Cultural Rights (1966).

<sup>32</sup> S Wilson, 'Population Biobanks and Social Justice: Commercial or Communitarian Models?' (2004) 1(2) TRAMES 80-89.

<sup>33</sup> G Haddow, G Laurie, S Cunningham-Burley and KG Hunter 'Tackling Community Concerns about Commercialisation and Genetic Research: A Modest Interdisciplinary Proposal' (2007) 64 *Soc Sci & Med* 272.

<sup>34</sup> Conference of the Parties to the Convention on Biological Diversity at its sixth meeting, held in The Hague in April 2002 adopted the Bonn Guidelines on Access to Genetic Resources and Fair and Equitable Sharing of the Benefits Arising Out of Their Utilization.

<sup>35</sup> In Norway the recent *Act on Medical and Health Research* recognises a legitimate interest for access by researchers to data and human biological materials; it creates a legal obligation to share biological material with researchers from outside the responsible institution.

<sup>36</sup> BM Knoppers, Ma'n H Abdul-Rahman and K Bédard, 'Genomic databases and international collaboration' (2007) 18 *King's Law Journal* 291-312.

<sup>37</sup> NBC 'Biobanks and Research on Human Biological Material' (2006) NBC p.6 (available at [http://www.governo.it/bioetica/eng/pdf/Biobanche\\_9\\_giugno\\_2006.pdf](http://www.governo.it/bioetica/eng/pdf/Biobanche_9_giugno_2006.pdf))

<sup>38</sup> The Indigenous People Basic Law of Taiwan, Article 21, contains a requirement that academic research in the area of indigenous people shall consult with the indigenous people and obtain their consent to participation. The indigenous people could share related benefits.

<sup>39</sup> G Laurie and K Hunter, 'Benefit-sharing and Public Trust in Genetic Research' in G Árnason, S Nordal and V Árnason (eds.), *Blood and Data* (University of Iceland Press, 2004), 323-331.

<sup>40</sup> Homer et al, 'Resolving individuals contributing trace amounts of DNA to highly complex mixtures using high-density SNP genotyping microarrays' (2008) *Public Library of Science Genetics* J 4:e1000167.

<sup>41</sup> See A Webster et al, 'Public attitudes to third party access and benefit sharing: their application to UK Biobank (June 2008).

<sup>42</sup> The Ethics and Governance Framework is available here: <http://www.ukbiobank.ac.uk/ethics/egf.php>

<sup>43</sup> DA Jones and C MacKellar, 'Consent for biobank tissue in somatic-cell nuclear transfer' (2009) 374 *Lancet* 861-3 and G Laurie, 'Role of the UK Biobank Ethics and Governance Council' (2009) 374 *Lancet* 1676.

<sup>44</sup> UK Biobank Protocol, p.14, available here: <http://www.ukbiobank.ac.uk/docs/UKBProtocolfinal.pdf>

<sup>45</sup> The three-yearly Eurobarometer reports on Europeans and Biotechnology indicate that trust in this field is slowly growing, with the exception of GM products.

<sup>46</sup> For discussion of limitation of traditional approaches see C Heeney et al, 'Assessing the privacy risks of data sharing in genomics' (2010) *Public Health Genomics*, available in e-publication format ahead of print here:

<http://content.karger.com/ProdukteDB/produkte.asp?Aktion=JournalHome&ProduktNr=224224>

<sup>47</sup> Reference needed to Knut Ruyter's Paper in this collection.

<sup>48</sup> See further M Richards, A Hunt and G Laurie, 'UK Biobank Ethics and Governance Council: An Exercise in Added Value' in J Kaye and M Stranger (eds), *Principles and Practice in Biobank Governance* (Ashgate, 2009).

<sup>49</sup> DE Winickoff, 'Partnership in UK Biobank: A third way for genomic property?' (2007) 35(3) *Journal of Law, Medicine and Ethics*, 440-456. Compare KG Hunter and G Laurie, 'Involving Publics in Biobank Governance: Moving Beyond Existing Approaches', in H Widdows and C Mullen (eds), *The Governance of Genetic Information: Who Decides?* (Cambridge University Press, 2009).

<sup>50</sup> For comment on legal aspects see G Fobelets and H Nys, 'Evolution in Research Biobanks and its Legal Consequences' in K Dierickx and P Borry (eds), *New Challenges for Biobanks: Ethics, Law and*

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*Governance* (Insentia, 2009).

<sup>51</sup> J Kaye, 'Biobanking Networks: What are the Governance Challenges?' in Kaye and Stranger, n 48 above.

<sup>52</sup> We do not address issues here such as the nature and appropriateness of the broad consent model because this is beyond the remit of this current article.