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A SOLIDARITY-BASED APPROACH TO THE GOVERNANCE OF RESEARCH BIOBANKS

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ABSTRACT

New opportunities for large-scale data linkage and data-mining have rendered biobanks one of the core resources of medical research in the twenty-first century. At the same time, research biobanking has been seen to pose particular ethical and legal challenges pertaining to, for example, data protection, and the minimisation of other risks for participants. These measures have in turn led to heavy administrative, logistical, and financial costs and attracted criticism for unduly impeding disease research. Based on a newly formulated approach to solidarity, we propose an approach to governance that recognises people's willingness to participate in a public research biobank, and poses stronger emphasis on harm mitigation. We argue that such a model avoids some of the pitfalls of previous approaches. It also allows moving beyond overly restrictive and burdensome, exclusively autonomy-based governance towards governance that is reflective of people's willingness to accept costs to assist others.

Keywords: solidarity, research biobanks, health governance, risk.

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I. INTRODUCTION: RISK SOCIETY AND BIOBANKS

Giandomenico Majone famously spoke of a shift from the positive to the 'regulatory state', where de-centralised and private actors increasingly replace public rulemaking and administration. In the UK context specifically, the shift towards replacing public by private ownership, in tandem with an increasing number and role of quasi-independent regulatory bodies in the 1980s and 1990s, is often seen as marking the emergence of the regulatory state.[1] This does not mean, however, that governmental control as such is waning: as Moran points out, from the vantage point of the early years in the new millennium, we see 'massive government controls over social and economic life' in British society.[2] It is not the extent or intensity of governmental control as such that has changed, but the mode by which this control is exercised.[3]

Closely interlinked with the emergence of regulatory governance is the notion of risk. A common reference in this context is to Ulrich Beck's work on *The Risk Society*, in which industrial society is described to have created an unprecedented scope and number of potential and actual dangers that need to be anticipated, quantified, and managed.[4] The advent of risk thinking, in turn, has been regarded by some scholars as a highly useful governance tool: the concept of risk, so it has been argued, renders uncertainty manageable and thus reduces complexity. In this understanding, it is not primarily risk that is the substrate to be governed (ie, the governance *of* risk), but it is primarily with the help of risk that governance is effective (ie, governing *through* risk).[5]

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[1] G Majone, 'From the Positive to the Regulatory State – Causes and Consequences from Changes in the Modes of Governance' (1997) 17 J Public Policy 139–67; RAW Rhodes, *Understanding Governance* (Open University Press, Buckingham, 1997); RAW Rhodes, 'Understanding Governance: Ten Years On' (2007) 28 Organization Stud 1243–64; R Baldwin, M Cave, and M Lodge, *Understanding Regulation: Theory, Strategy, and Practice* (Oxford University Press, Oxford 2011).

[2] M Moran, 'The Rise of the Regulatory State in Britain' (2001) 54 Parl Aff 19.

[3] JS Wright, 'The Regulatory State and the UK Labour Government's Re-regulation of Provision in the English National Health Service' (2009) 3 Regul Gov 334–59.

[4] U Beck, *Risk Society: Towards a New Modernity* (Sage, London 1992).

[5] AE Clarke and others, 'Biomedicalization: Technoscientific Transformations of Health, Illness, and US Biomedicine' (2003) 68 Am Sociol Rev 161–94; RV Ericson and A Doyle (eds), *Risk and Morality* (University of Toronto Press, Toronto 2003); N Rose, *Powers of Freedom. Reframing Political Thought* (Cambridge University Press, Cambridge 1999); N Rose, *The Politics of Life Itself: Biomedicine, Power and Subjectivity in the Twenty-First Century* (Princeton University Press, Princeton, NJ 2006); H Gottweis, *Governing Molecules: The Discursive Politics of Genetic Engineering in Europe and the United States* (MIT Press, Cambridge, MA 1998). See also NBM Power *The Audit Society* (Oxford University Press, Oxford 1997), and C

It is in the context of governing through risk that research biobanks are particularly interesting. On the one hand, biobank governance is about the governance *of* risk: legal provisions and governance frameworks in biobanking clearly aim at minimising risks such as access to identifiable information by unauthorised parties, discrimination, or the accidental loss of data. Research biobanks are, on the other hand, also part of a rhetoric and public imagery of managing risks to public health. By funding and participating in biobank-based research, so the dominant narrative goes, we work towards the development of treatments and thus help minimise the risk of disease and death. By promoting research biobanks as a tool to reduce the risk of disease in the population, they become part of a system of governance *through* risk.

Why have biobanks come to be seen as playing such a central role in medical research in the last two decades? The systematic collection of biological samples and data, together with disease and/or other phenotypic information, is almost as old as clinical medicine itself. What is arguably novel about the nature and role of research biobanks since the late 1990s is (i) the large scale of collections, (ii) the systematic approach to sample and data collection and data generation, and (iii) the possibility of automatisation of data collection and comparison, the purpose of which is not clinical diagnosis anymore but research. While traditional small-scale collections continue to exist (eg, collections of tumour tissue in hospitals' pathology departments), many newer biobanks contain samples and data from hundreds of thousands of participants, and virtually unlimited opportunities for data linkage and data-mining. Unsurprisingly, these 'new' biobanks,[6] and networks of biobanks, where large amounts of samples and datasets can be mined to discover new patterns (eg, genetic markers correlating with a particular disease phenotype) have been seen to pose ethical and legal challenges. Particularly prominent in this context have been concerns such as data protection, confidentiality, and privacy; genetic discrimination; and return on investment (including access to findings).

When we look at the way in which such ethical challenges are usually discussed in the literature, it becomes apparent that often, the implicit or

Hood, H Rothstein, and R Baldwin, *The Government of Risk: Understanding Risk Regulation Regimes* (Oxford University Press, Oxford 2001).

[6] R Tutton, 'Person, Property, and Gift' in O Corrigan and R Tutton (eds), *Genetic Databases: Socio-Ethical Issues in the Collection and Use of DNA* (Routledge, New York 2004) 19–39; H Gottweis and AR Petersen, *Biobanks: Governance in Comparative Perspective* (Routledge, London 2008); J Kaye and others, *Ethical, Legal, and Social Issues Arising from the Use of GWAS in Medical Research* (Wellcome Trust, London 2009); European Commission, Expert Group on Dealing with Ethical and Regulatory Challenges of International Biobank Research, *Biobanks for Europe: A Challenge for Governance* (Brussels 2012).

explicit point of reference is the prevention or minimisation of risk. In this paper, we present an approach towards biobanks governance that rests on our understanding of solidarity that we presented in a report commissioned by the Nuffield Council on Bioethics in 2011.[7] Against this background, we propose (i) a shift from an exclusive or dominant focus on autonomy (whose function is also preventing litigation for the biobank) towards a stronger emphasis on people's willingness to engage in activities that benefit others and (ii) an increasing importance of harm mitigation strategies to complement strategies of risk prevention within biobank governance frameworks. These shifts include a reframing of the relationship between participants and biobanks in the sense that solidarity becomes an important dominant frame of and in this relationship.

We will first introduce our understanding of solidarity, and discuss how this applies to the governance of research biobanks in general. We will then describe how the two shifts could play out in practice, and conclude by specifying how our suggested changes to biobanks governance resonate with results from ongoing debates to address the challenges in research biobanking.

II. A MULTI-TIERED CONCEPTION OF SOLIDARITY

In previous publications, we have outlined the core elements of our understanding of solidarity.[8] In our report, we brought together several strands of thinking about solidarity in different bodies of literature[9] and proposed a definition specific enough to facilitate new

[7] B Prainsack and A Buyx, *Solidarity: Reflections on an Emerging Concept in Bioethics* (Nuffield Council on Bioethics, London 2011).

[8] B Prainsack and A Buyx, 'Solidarity in Contemporary Bioethics' (2012) 26 Bioethics 343–50. A Buyx and B Prainsack, 'Lifestyle-related Diseases and Individual Responsibility through the Prism of Solidarity' (2012) 7 Clinical Ethics 79–85. B Prainsack and A Buyx, 'Understanding Solidarity (With a Little Help from your Friends): A Response to Dawson and Verweij' (2012) 5 Public Health Ethics 206–210.

[9] The report's findings rest on an extensive literature analysis (chapter 3). We referenced both books and articles on the topic from the last two decades, such as, eg, J Dean, *Solidarity of Strangers: Feminism after Identity Politics* (University of California Press, Berkeley 1996); RT Meulen, W Arts and R Muffels (eds), *Solidarity in Health and Social Care in Europe* (Kluwer, Dordrecht 2010); S Sternø, *Solidarity in Europe: The History of an Idea* (Cambridge University Press, Cambridge 2004); S Scholz. *Political Solidarity* (University of Pennsylvania Press, University Park, PA 2008); K Hinrichs 'The Impact of German Health Insurance Reforms on Redistribution and the Culture of Solidarity' (1995) 20 J Health Polit Policy Law 653–87; S Boshammer and M Kayß, 'Review Essay: The Philosopher's Guide to the Galaxy of Welfare Theory: Recent English and German literature on Solidarity and the Welfare State' (1998) 1 Ethical Theory Moral Pract 375–85; M Trappenburg.

thinking about bioethical problems, and which can be fruitfully applied to issues of governance in different policy fields. We did not attempt to offer a normative justification of solidarity, namely to answer the question of why we need solidarity in the first place. Nor should our definition be seen as an attempt to reinvent the wheel; in fact, it contains elements of several existing definitions in the literature. However, during our analysis of bioethical and bioethics-related literature, we found that there was often a lack of clarity when the concept of solidarity was invoked; particularly where it was discussed in relation to its practical application in policy and governance.[10] Our 2011 Report offers an overview of the different uses of solidarity, and of how solidarity overlaps with other concepts (such as charity, reciprocity, altruism, or empathy). Underpinned by this analysis, we developed an account of solidarity capturing core elements of existing definitions, whilst at the same time trying to distil those elements that distinguish solidarity at its point of gravity from other, related concepts.

In its simplest form, our definition of solidarity signifies 'manifestations of people's willingness to carry costs (financial, social, emotional, or otherwise) to assist others'.[13] Solidarity in our account is neither primarily a political concept nor a moral value; we take it to be a practice, or a set of practices, and these can be apparent at any or every one of the three levels of institutionalisation:

(1) At the interpersonal level, or tier 1, manifestations of the willingness to carry costs to assist others[11] are typically articulations of individuals who act in this way because they consider themselves similar to these others *in a relevant respect*. Facing similar risks, having shared the same experience, or working towards the same goal, are frequent 'causes' of solidarity.
(2) When practices of accepting costs to assist others, between individuals, become so widespread that they become, or have in the past become, shared practices in a given group or community, then we encounter what we call tier 2 solidarity. Examples of

'Lifestyle Solidarity in the Healthcare System' (2000) 8 Health Care Anal 65–75; RE Ashcroft, AV Campbell and S Jones, 'Solidarity, Society and the Welfare State in the United Kingdom' (2000) 8 Health Care Anal 377–94; R Chadwick and K Berg, 'Solidarity and Equity: New Ethical Frameworks for Genetic Databases' (2001) 2 Nat Rev Genet 318–21; M Häyry, 'Precaution and Solidarity', (2005) 14 Cambridge Q Healthcare Ethics 199–206.

[10] Prainsack and Buyx, above, n 7.

[11] It should be noted that our notion of assisting others does not imply that those assisting others are therefore acting in the public interest. One of us regards the question of what and who is acting in the public interest as one that needs to be answered specifically for every case; therefore, we refrain from using the notion of public (or collective) interest altogether.

such more institutionalised solidarity-based practices are informal groups and arrangements that are not (yet) consolidated by contractual or legal arrangements.

(3) If such communal practices, in turn, solidify further into contractual relationships or hard law, then we have an instance of tier 3 solidarity, the most institutionalised and least flexible version of solidarity. Welfare societies all have such elements of tier 3 solidarity, namely solidaristic arrangements that are enacted and enforced by law (eg, solidaristic health insurance systems with compulsory contributions; pension systems, etc.).

This definition does not claim to describe actual historical developments; instead, it seeks to provide an idealised and simplified version of how solidarity manifests itself in practices of individuals and groups, and legal practices. Although many instances of tier 3 solidarity will have been preceded by 'lower' tiers in the past in this way, so that solidarity emerges 'bottom up' rather than being imposed 'top down', our model is not meant to preclude the latter scenario in principle. Laws in the spirit of solidarity can indeed 'enforce' (ie, foster, or give rise to) solidaristic practices that have not existed previously. However, if such a law contradicted commonly shared values, it would risk not being observed, and/or be circumvented; the practices that it would give rise to would then be something else than solidaristic.

It is also important to note that the different tiers of solidarity are not mutually exclusive; in any given context solidarity may contain elements of practices from any or all tiers, and the boundaries between them is often fluid. However, the points of gravity in every tier are different, and so are the configurations and stakes (eg, arrangements in tier 3 are much more difficult to undo than in tier 1, etc.)

III. A SOLIDARITY-CONSISTENT MODEL FOR BIOBANK GOVERNANCE

A. The Value of the Solidarity Model

We believe that the concept of solidarity is suited to reflect a core feature of research biobanks, namely that their success hinges on the willingness of participants to donate time, bodily materials, data,[12] and information to contribute to research that assists and benefits others. In this sense,

[12] We use the term 'data' to signify the (digital or analogue) representation of the biological matter (eg, the succession of nucleotides in a DNA sequence), whereas 'information' pertains to data that have become meaningful in a particular respect (an annotated DNA sequence, or the interpretation of a DNA sequence in a functional context). See BC Parry, *Trading the Genome: Investigating the Commodification of Bio-information* (University of Columbia

research biobanks can be understood as entailing and encouraging practices of solidarity. We also believe that the current regulatory framework for the governance of research biobanks, which is oriented towards protecting individual autonomy and preventing risks, does not sufficiently reflect many people's willingness to assist others. This willingness to assist others, as empirical research has shown, is part of the motivation of many participants in biobank-based research.[13] We believe that this phenomenon should be acknowledged more explicitly and solidarity should underpin the relationship between participant and biobank, alongside autonomy. A governance approach that explicitly draws on solidarity also captures and responds to several areas of unease about existing biobanks governance arrangements and their consequences on a practical level.

What goals and aims does a model of biobank governance follow that are consistent with the understanding of solidarity that we have described? Our approach to understanding solidarity rests on seeing people's willingness to accept costs to assist others. A biobank reflective of that would pursue assisting others as its main research goal; that is, the main activity of the biobank would always have to be research aiming to improve health of individuals or populations (or comparable, other-directed goals). In addition, transparency towards participants is required about how the goal of improving the health of individuals and populations relates to commercial goals.

B. The Limits of the Solidarity Model

Our solidarity-based framework is unlikely to be suitable for a research biobank for which profit-making is its main or overarching objective. This excludes exclusively commercial research biobanks from the scope of initiatives to which our framework is applicable. Research-biobanks suitable for our framework—most typically, publicly funded biobanks—typically prioritise research serving pressing health needs over research that generates surplus economic value.

Press, New York 2004); G Pálsson and B Prainsack, 'Genomic Stuff: Governing the (Im)matter of Life' (2011) 5 Int J Commons 259–83.

[13] D Pullman and others, 'Personal Privacy, Public Benefits, and Biobanks: A Conjoint Analysis of Policy Priorities and Public Perceptions' (2012) 14 Genet Med 229–35; L Johnsson and others, 'Hypothetical and Factual Willingness to Participate in Biobank Research' (2010) 18 Eur J Hum Genet 1261–4; R Tutton, 'Constructing Participation in Genetic Databases: Citizenship, Governance, and Ambivalence' (2007) 32 Sci Technol Hum Values 172–95. See also M Levitt and S Weldon, 'A Well Placed Trust? Public Perceptions of the Governance of DNA Databases' (2005) 15 Crit Public Health 311–21; G Williams and D Schroeder, 'Human Genetic Banking: Altruism, Benefit and Consent' (2004) 23 New Genet Soc 89–103.

It should be noted here that expecting biobanks (for them to be suitable for our model) to pursue the improvement of health as an important goal is not the same as assuming altruism to be the core motivation of biobank participants; the difference between solidarity- and altruism-based models is that the first assume research participants to be other-directed, whereas our solidarity-based model combines other- and self-directedness as motivations for participation. Self-directedness would entail, for example, that individuals do also consider how research participation would benefit them, either directly—if they suffer from the particular disease that a biobank researches, or indirectly by benefiting family members, friends, or by satisfying a need to contribute to society.

C. Shifts Necessitated by a Solidarity Model

What would a solidarity-based approach mean for the regulatory governance of research biobanks? An approach consistent with solidarity necessitates two shifts in the framing of the relationship between participant and biobanks, and a reconceptualisation of several main governance elements, including the terms under which research participants participate in biobank-based research; policies of (re-)consenting and communicating findings to participants, and stronger emphasis on harm mitigation strategies within governance frameworks for research biobanks. These shifts respond to critical debates that have been increasing over the last few years. We will discuss each of them in turn.

1. Shift 1: including solidarity

The principle of informed consent was introduced in medical ethics after WWII in order to protect individuals against possible harm, such as unwanted treatment or other intrusions into one's bodily integrity.[14] This notion has arguably become overshadowed by narrow interpretations of individual autonomy, which interpret consent not only as one of its manifestations, but also as a quasi-synonym for autonomy itself.[15] Particularly in modern litigous cultures, informed consent has assumed the role of a 'stamp of approval' for medical practice and, more recently, of

[14] M Sutrop, 'Viewpoint: How to Avoid a Dichotomy Between Autonomy and Beneficience: From Liberalism to Communitarianism and Beyond' 269 (2011) J Int Med 376; See also, eg, JK Mason and GT Laurie, Law and Medical Ethics (8th edn Oxford University Press, Oxford, 2011, Ch 4), and BMA Medical Ethics Today, *The BMA Handbook of Medical Ethics and Law* (Wiley & Blackwell, London 2012); SHE Harmon, 'Semantic, Pedantic or Paradigm Shift? Recruitment, Retention and Property in Modern Population Biobanking' (2009) 16 Eur J Health Law 27–43.

[15] Eg AL McGuire and LM Beskow, 'Informed Consent in Genomics and Genetics Research' (2010) 11 Annu Rev Genomics Hum Genet 361–81; critically, O O'Neill, 'Some Limits on Informed Consent' (2003) 29 J Med Ethics 4–7; J Wilson, 'Is Respect for Autonomy Defensible?' (2007) 33 J Med Ethics 353–6.

research participants to state that they have understood the risks involved in their participation and have willingly agreed to accept them, so that they cannot hold the biobank responsible for any harm resulting from activities that were carried out as described. Consent, thus, is also a tool to manage risks, to 'tame' the uncertain and unknowable into actionable and contained tasks and objectives. As a result, significant resources are channelled into developing and implementing policies and protocols to document that participants have been informed about, and agreed to, what will be done with their samples and data. This is clearly mandated in scenarios where the risks for research participants are considerable (eg, health risks). However, in connection with contemporary biobank-based research—especially in the field of genetics and genomics—risks for participants are currently regularly very small, both in terms of the nature and the degree of risk.[16] In many instances of biobank-based research, the most significant risks for individuals are the possibility of involuntary and/or unauthorised identification, and possible scenarios of discrimination that may emerge from it. To the best of our knowledge, instances of actual discrimination based on a participant's involvement in a biobank (including large genetic research studies or cohorts) are extremely rare.[17]

Moreover, recent research has increasingly drawn attention to the very limited predictive value of—particularly current common-variant genetic—markers at the individual level, a phenomenon that insurance companies also seem to recognise.[18] And even in the cases where such results would be meaningful at the individual level, it cannot be

[16] The infringement of data protection standards and physical harm would be examples for a particular nature of risk. In the context of biobank-based research, the degree of the former is medium to low, depending on the concrete context; the risk for the latter is extremely low to absent (physical harm is never a direct result of somebody's participation in a research biobank); See also European Commission, above, n 6.

[17] Note, however, the conflict between the Havasupai Indians and Arizona State University; see A Harmon 'Havasupai Case Highlights Risks in DNA Research' (2010) *The New York Times*, available at <http://www.nytimes.com/2010/04/22/us/22dnaside.html> accessed 20 September 2012.

[18] DNA sequencing—that is, the mapping of all (protein-producing) elements of DNA rather than focusing only on certain areas that are 'flagged up', which is commonly the case, could change the limited predictive value of most genetic markers. A more comprehensive approach to DNA mapping such as DNA sequencing could show the presence of rare variants in a given individual, and the effects of these could be much larger than those of common variants. For the predictive value and actionability of incidental findings in genomic research, see the contributions to issue (2012) 14(4) Genetics Med. See also CE Nabholz and J von Overbeck, 'Gene–Environment Interactions and the Complexity of Human Genetic Diseases' (2004) 36 J Insurance Med 47–45; B Prainsack, 'What Are the Stakes? Genetic Nondiscrimination Legislation and Personal Genomics', Guest Editorial (2008) 5 Pers Med 415–8.

assumed that everybody will want to know their results ('right not to know'[19]). In addition, countries in the European Union as well as the USA, for example, have started to adopt non-discrimination legislation.[20] Thus, in many contexts of biobank-based research, the risks that participants face today are much smaller than risks encountered in other situations of disease research or clinical trials.

Focusing our efforts and resources to protect participants from these small risks leads to barriers for research. Significant resources are currently used for (re-)consenting procedures and formal risk prevention requirements (eg, obtaining new research ethics approval for a slightly modified research question, re-contacting and re-consenting participants).[21] These resources could instead be devoted to front line research, or into building platforms for the dissemination of research findings or public engagement with this field of research. The latter situation would be consistent with the solidarity-related aim to pursuing research to assist others. Moreover, there is emerging empirical evidence that biobank participants are often willing to 'let go' more than current autonomy-based governance allows.[22]

In view of this, and of the problems with procedures narrowly focussing on protecting individual autonomy, we believe that recognition of solidarity—that is, the willingness to accept costs to assist others with whom one perceives similarity in a relevant sense—should enter governance models for research biobanking.

In our model, individual autonomy remains an important guiding principle, particularly at the stage of initially informing individuals about possible risks and benefits of their participation in biobank-based research. It is, however, interpreted in such a way that it is possible for a person in her capacity as an autonomous individual to accept a certain level of risk and uncertainty (as we do in almost all realms of life). This means that, in line with proposals made by scholars such as Lunshof and others,[23] we propose that consent procedures that specify all research

[19] See G Laurie, *Genetic Privacy: A Challenge to Medico-legal Norms* (Cambridge University Press, Cambridge 2002).

[20] See, eg, D Gurwitz, 'Biomarkers: Better Donor Protection' (2011) 470/7333 Nature 175.

[21] P Taylor, 'Personal Genomes: When Consent Gets in the Way' (2008) 456 Nature 32–3. M Taylor, *Genetic Data and the Law: A Critical Perspective on Privacy Protection* (Cambridge University Press, Cambridge 2012).

[22] J Kaye and others, 'From Patients to Partners: Participant-centric Initiatives in Biomedical Research' (2012) 13 Nat Rev Genet 371–6.

[23] J Lunshof and others, 'From Genetic Privacy to Open Consent' (2008) 9 Nat Rev Genet 406–11. In this paper, Lunshof and others discuss the open consent framework used by the Personal Genome Project in Harvard (<http://www.personalgenomes.org/>). The authors' point of departure is that contemporary large-scale genetics and genomics research studies can

carried out with donations are not necessarily more desirable than more broad or even open consent models.[24] In broad consent models, participants agree to be part of a research endeavour guided by a range of *values* and *goals*, rather than being told what exactly will happen with their samples and data.[25] Also in our model, commitments to such values and goals need to be communicated to potential participants at the point of signing up; and if these values and goals should change significantly (eg, if a dataset collected for medical research will be used exclusively for behaviour genetics), participants would need to have the opportunity to opt out. They would not, however, need to be given the choice to opt out of new research projects as long as they are consistent with the stated goals of the biobank at the time when participants signed up. When exactly the point has been reached that values and goals that a biobank is committed to have changed significantly will depend on the way in which these values and goals are specified; this will need to be determined on a case-by-case basis. Research biobanks that have trusted intermediary and/or custodian arrangements in place can entrust these with making this decision. We explicitly do not recommend that research ethics bodies will be entrusted with this task, not only because of the additional work load on research ethics bodies, but also because they may not be familiar enough with the research biobank to accurately assess the extent to which a commitment to a particular value has changed in practice.

In summary, the relationship between participant and biobank in a model recognisant of solidarity is understood to be a reflection of the fact that the participant is willing to assume some costs to help others, and in turn trusts the biobanks to hold up its end of the bargain. The latter is codified in a 'mission statement' or some other insight into the 'value system' of a biobank that has to be a mandatory part of any participation agreement at the point when participants sign up.[26] It would ensure that potential participants, at the stage of recruitment, are informed in detail about the mission of a particular biobank, its funding and governance structures, and what it hopes to achieve.

This interpretation of the relationship between the participant and the biobanks entails a shift from a dominant or exclusive focus on individual autonomy (and the related efforts to respect and protect it through governance) towards including a recognition that the participation of

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no longer reliably promise privacy and confidentiality to their participants and thus need to rethink what they ask participants to consent to.

[24] B Hoffmann, 'Broadening Consent – and Diluting Ethics?' (2009) 35 J Med Ethics 125–9.

[25] See also Harmon, above, n 14.

[26] Ibid.

many participants in research-biobanks can be understood as a solidaristic practice. For example, the participant would accept costs by ceding some of the benefits she may have in an exclusively autonomy-based approach, such as more control over the future use of the data; or being informed individually about incidental findings that may be relevant but not clinically actionable (see below). In a solidarity-based model, while it would be desirable for participants to have all these opportunities, it would in principle be acceptable to ask them to consent to not having them. There are already successful biobanks where the relationship between participant and biobanks resonates with our approach, such as UK Biobank—without, however, explicitly mobilising the concept of solidarity.[27]

2. Shift 2: towards more emphasis on harm mitigation

The shift towards rendering solidarity one of the core concepts framing the governance of research biobanks also leads to changes on a more practical level. As mentioned above, informed consent procedures are effectively aimed at preventing and minimising risk. That is, despite the refinement that biobank procedures have undergone in recent years, most instruments are still designed to inform participants about the risks inherent in participating in order to protect their autonomy and to protect the biobank. This could perpetuate the implicit expectation that once participants are duly informed of as many risks as possible and of all efforts in place to prevent these risks from materialising, they will be 'safe'—which they never are. An exclusive focus on risk prevention can, at its best, reduce risks and make participants feel secure. At its worst, it can foster a mistaken expectation of participation being completely risk-free.

As explained above, our solidarity-focused framework allows for an open acknowledgement that there might always be some risks. It explicitly includes the option for participants to accept these as a cost of helping others. In order to reflect such willingness of participants to accept costs in biobank-based research, we suggest curtailing the current strong emphasis on risk prevention in benefit of a shift towards more emphasis on devising strategies for harm mitigation in cases where actual harm occurs. (By 'actual harm' we mean instances of, for example, discrimination against a person whose data and samples are stored in a biobank by an insurer or employer). The difference between risk and harm here is that a risk is something that has not (yet) materialised, that is, it is something that is considered prospectively. Harm, on the other hand, is something that has already materialised and is thus considered retrospectively. Stronger emphasis on the latter

[27] See Laurie, above, n 19.

would mean that we increase the scope for action *after* an undesirable event has taken place (eg, by making available funds to compensate affected individuals for the harm that they suffered), instead of focusing all our resources on preventing the happening of the undesirable event before it has taken place.

The funds that would become available if biobanks—following a solidarity-based model—had shorter and less administration-heavy consent procedures (eg, by having shorter consent and information documents and/or using online portals, by not needing to re-contact participants if their donations will be used for novel research, by easing the requirements for research ethics approval, etc), could be used for substantive research activities, public engagement initiatives, or similar health- and education-related activities. The slightly larger probability that participants will face negative consequences resulting from their participation is a cost that those signing up would declare to be willing to carry. And those who would actually be affected by harm would be compensated by newly created mechanisms (see below).

IV. PRACTICAL APPLICATION: PROPOSED CHANGES TO BIOBANKS GOVERNANCE

A biobank governance model that includes the recognition of solidarity entails specific characteristics.

A. The Participation Agreement

Specific consent has been the subject of significant critique in the context of research biobanking, and alternative models have been proposed.[28] Prominent reasons for why broad consent models have been regarded as ethically suitable for biobank-based research include that such research is carried out to satisfy a universal need, namely health; and that broad consent is no less suitable to express individual autonomy than specific consent is (as long as people are fully aware that they are giving broad consent).[29] We agree with authors who contend that broad consent has a commensurable yet problematic relationship with autonomy, because individuals giving broad consent cannot know, in terms of concrete scenarios, what it is that they are consenting to.[30] In

[28] Eg, Harmon, above, n 14.
[29] MG Hansson and others, 'Should Donors be Allowed to Give Broad Consent to Give Consent to Future Biobank Research?' (2006) 7 Lancet Oncol 266–9.
[30] T Caulfield and J Kaye, 'Broad Consent in Biobanking: Reflections on Seemingly Insurmountable Dilemmas' 10 (2009) Med L Int 85–100; A Bhan, 'Use of Blanket Consent for Retrospective Research in Academic Institutions: Need for Scrutiny and Integrating Safeguards' (2010) 7 Indian J Med Ethics 51–3.

our model, participants' autonomy is expressed, in full, at the time of signing up to the biobank; after that, the expression of their autonomy is to some degree compromised.[31] This compromise of ways to express individual autonomy—after a conscious and deliberate decision to allow this limit to their autonomy on the side of the participant—is in line with our proposed two shifts (to include solidarity alongside autonomy, and to emphasise harm mitigation alongside risk prevention). We see it as a manifestation of somebody's willingness to accept costs to help others if they willingly allow a limit to their expression of autonomy for the sake of a project that is carried out for the benefit of others or all. (It should be noted here that this framework of broad consent is already applied across a wide range of biobanks, yet with different justifications than the one that we provide.) It is, of course, of utmost importance in this context that this initial agreement takes place without any force, clear manipulation, or undue incentives.[32] The value of *veracity*, as promoted by the bioethicist Jeantine Lunshof and colleagues,[33] thus plays an important role in guiding the participation agreement in our model. Veracity means telling (potential) participants as much as one knows but also admit that it is impossible to know everything. We thus propose the introduction of a participation agreement as the contractual basis for the relationship between the participant and the biobank, reflective of both solidarity and autonomy, and guided by veracity. This should have the following elements:

- A mission statement, detailing the 'value system' and overarching goals of the research biobank. For a biobank to be consistent with a solidarity model, these would be research efforts aiming to improve the health of individuals or populations;
- information about the research questions and contexts that the biobank supports at the time of recruitment, with an explicit statement that these might change in the future (in a way consistent with the overall goal of other-related health research);
- information on commercial strategies and interests. As empirical research has shown, the commercialisation of body substances and personal data is an important concern for potential research

[31] There is a certain analogy here to the way sovereign states gave up a portion of their national sovereignty when they become members of the European Union (EU). The EU can, in certain specific areas, take decisions that can be binding for certain member states even if they have not supported the decision.

[32] See, for example, G Tyldum, 'Ethics or Access? Balancing Informed Consent Against the Application of Institutional, Economic or Emotional Pressures in Recruiting Respondents for Research' (2012) 15 Int J Social Res Methodol 199–210.

[33] Lunshof, above, n 23.

participants to consider,[34] and the initial disclosure should highlight current arrangements and policies of the biobank in this regard, and an assessment of how this could change in the future;
- statement of future use: the participation agreement should include a statement that the biobank—and thus the samples and data of the participant—may be used to serve research that cannot yet be envisaged, and that appropriate research ethics approval will be obtained wherever laws and regulations require this.
- re-contacting and feedback: participants should be informed what kind of data and information (including incidental findings) they will have access to, and how (eg, will they be contacted individually? Will they need to obtain this information proactively, eg by logging into a secure website, or getting only aggregate data on a publicly available website? Or will no data and information be available to them? The latter scenario, albeit not desirable, is not in principle incompatible with our approach, as long as participants are told that they will not have access to this information);
- a list of risks and benefits insofar as they can currently be foreseen, with an explicit note that this list may not be exhaustive.

Many of these elements of the participation agreement that we propose are not new; for example, UK Biobank already includes a kind of 'mission statement' in the materials handed to potential participants.[35] Moreover, many of the governance changes we suggest in this article on the basis of our solidarity model resonate well with ongoing initiatives in, for example, 'reflexive' or 'proportionate' governance.[36] What sets our model apart from previous approaches is its justificatory foundation in our understanding of solidarity; its resulting conceptual framing; and the stronger emphasis on harm mitigation. With regard to consent procedures, for example, we are not suggesting a wholly new way of organising consent procedures; instead, we are proposing to reframe the objectives that participation agreements serve.

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[34] For an overview, see K Hoeyer, 'The Ethics of Research Biobanking: A Critical Review of the Literature' (2008) 25 Biotechnol Genetic Eng Rev 429–52; CM Gere and BC Parry 'The Flesh Made Word: Banking the Body in the Age of Information' (2006) 1 BioSocieties 83–98; BC Parry, *Trading the Genome: Investigating the commodification of Bio-information* (University of Columbia Press, New York 2004).

[35] See Laurie, above, n 19, and Harmon, above, n 14.

[36] Again see G Laurie, 'Reflexive Governance in Biobanking: on the Value of Policy Led Approaches and the Need to Recognise the Limits of Law' (2011) Hum Genetics 130, 3, 347–356; and Academy of Medical Sciences, 'A New Pathway for the Regulation and Governance of Health Research' (2011) available at <http://www.acmedsci.ac.uk/p47prid88.html> accessed 11 June 2012.

B. Consent and Feedback

Wherever possible in light of available resources and data security concerns, research biobanks should make as much data and information as possible accessible not only to individual participants but to the public (eg, internet platforms, online data archives, etc).[37] However, within our model, it would be possible for participants to knowingly forego the service of being directly contacted about findings in order to 'free up' these resources. For findings that can have a significant impact on health, however, we strongly recommend that biobanks encourage participants to obtain this information (again, the initial contact could be made electronically, and the findings themselves would be conveyed by a medical specialist or a genetic counselor). Where incidental findings are clinically actionable, the biobank should have some system in place to enable participants to access this information.[38]

With regard to the question of what kinds of results would be regularly fed back to participants, our approach does not prescribe particular policies. It does, however, oblige biobanks to communicate to potential participants openly whether and why results will be fed back, and what harm may result from either having or not having results fed back to them. This means that the policy of not feeding back even clinically relevant, actionable findings to individual participants would *in principle* be compatible with our approach as long as (a) the consequences of the finding for the health of the person are not significant, and (b) the possible consequences of this mechanism are communicated to potential participants at the time of signing the agreement. It seems likely that such policies would provide significant disincentives to research participation unless a compelling reason and rationale for this approach is provided by the biobank. (One possible rationale for this kind of policy could be that—as it is the case with UK Biobank, for example, a project is supported by public funding and feeding back findings to individual participants would come at the cost of research that could reap tangible benefits.)

In summary, arrangements pertaining to participants' access to data and findings in research biobanks, in our model, will be made with a view to the best way to spend resources in order to reach the mission/goal of the biobank, not *primarily* to foster individual benefit. For publicly funded research biobanks with notoriously limited resources in

[37] K Saha and JB Hurlbut, 'Research Ethics: Treat Donors as Partners in Biobanks Research' (2011) 478 Nature 312–13.

[38] For details of how such a system could look, see SM Wolf and others, 'Managing Incidental Findings and research Results in Genomic Research Involving Biobanks and Archived Data Sets' (2012) 14 Genet Med 361–84.

particular, it would be acceptable that participants who are interested in seeing data and information generated by the biobank (beyond those that we would recommend to be fed back in any case) need to take the initiative of accessing the data via online platforms or other repositories, without this service being provided to them proactively and individually by the biobank.

Wherever appropriate, the participation agreement should also state the willingness of participants to be re-contacted if further details should be needed for subsequent research (eg, more detailed phenotypic or lifestyle information, or more details about medical or family histories), although participants would, of course, never be obliged to provide these. Wherever reasonably possible, communication between the biobank and participants should take place by electronic means. Participants would also give their consent to other archived data held in separate repositories to be used in connection with the data stored in their biobank, if used in compliance with relevant confidentiality and data protection standards.[39] In many countries, this can currently be done without the consent of the participant, yet a participation agreement would include such information explicitly for the sake of honouring the principle of veracity on the part of the biobank, and the solidarity of the participant.

C. Compensation

As scenarios of potential harm depend on the concrete circumstances of participation in biobank-based research (eg, what kind of samples, data, and information are stored in the biobank? Are they coded or anonymised,[40] and who can access them?), harm mitigation strategies would best be considered, in general terms, at the time of devising the participation agreement, and be determined in detail when such harm actually materialises. Every biobank should have a committee that can meet on an ad-hoc basis and has the authority to make binding decisions on harm mitigation on behalf of the biobank (eg, whether and in what form to compensate the person affected by harm). A certain proportion of research and/or infrastructure funding that a biobank receives could go into a dedicated fund to compensate participants in the case that

[39] The ongoing debate about Electronic Health Records is particularly relevant in this context. For an overview, see IS Kohane, 'Using Electronic Health Records to Drive Discovery in Disease Genomics' (2011) 12 Nat Rev Genet 417–28.

[40] 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 EMBO Rep 661–6.

they suffer harm resulting from their participation in the biobank, if such instances ever arise. This should be underwritten by the funder.[41]

V. CONCLUDING REMARKS: WHAT SOLIDARITY CAN CONTRIBUTE

Solidarity underpins the described model for biobank governance in several ways: first, and corresponding with tier 1 solidarity (solidarity at the interpersonal level, [*see above*], we acknowledge that people are regularly willing to accept costs (the risk of harm and the inconvenience of participation) to assist others. The main objective of the participation agreement as described above, and the process in which it is embedded, is designed to give the potential biobank participant sufficient time and knowledge (not only information) for deciding whether or not she wants to participate. As mentioned, it is an inherent part of the agreement process to communicate that such participation includes risks and to assess whether these risks are acceptable to the individual in the light of the values and possible benefits that the biobank stands for, as detailed in the mission statement. However, the aim of this process is *not* to introduce more measures to minimise these risks further. Instead, by signing the participation agreement, a participant confirms that she is willing to carry certain potential costs should they arise in order to contribute to the goal of assisting others. This also entails that participants agree to the scenario of their samples and data being used for purposes other than envisaged originally (if consistent with the overall values and goals of the biobank).

In addition to harm mitigation strategies as described above, biobanks that benefit from this kind of participation and trust from the participant should put trust models in place, eg, via a governance board or trusted intermediaries. These would have the explicit objective to enforce prioritisation models for access to biomaterials and data favouring research serving pressing health needs over research that will achieve the highest profits,[42] thus ensuring the overall goal remains assistance of others. Such trusted intermediaries should have real decision making power rather than merely advisory functions.

Tier 2 solidarity [*see above*], that is, solidified solidarity practices which are expressed in terms of communal commitments, would manifest themselves in biobank governance arrangements that envisage research participants as partners in research to whom the biobank owes respect and veracity. The trust afforded by participants to the biobank

[41] See also I van Hoeyveghen, *Risk in the Making. Travels in Life Insurance and Genetics* (Amsterdam University Press, Amsterdam 2007).
[42] We are grateful to Klaus Hoeyer for this suggestion.

commits the latter to a kind of conduct that renders them worthy of trust. (Instead of a sentiment that can be deliberately built, we see trust as a continuously developing property of a cluster of practices.)

Our solidarity-based approach does not prescribe particular arrangements with regard to intellectual property (IP). As a general rule, the value of veracity guiding the participation agreement (and process) necessitates that IP aspects are explicitly discussed with potential volunteers. Included in these discussions should be aspects pertaining to individual ownership of samples, data, and information, and also policies pertaining to who will have access to samples, data and information will be granted, and for what purposes. Particularly important in this context would be arrangements limiting the free flow of data and information (patents, etc).

Good examples of arrangements reflecting Tier 2 solidarity, such as data-sharing arrangements and open access publishing standards, do already exist.[43] In fact, we suggest that data-sharing becomes a contractual obligation of researchers in research biobanks based on the solidarity model. If that is the case, the practice would become an instance of Tier 3 solidarity (where communal arrangements have solidified further into legal arrangements). The same holds for legal obligations for making data accessible to others in the public domain, and/or to use open access solutions for the publication of findings.[44] We believe that these would be sensible additions to the governance changes suggested above that would enhance the commitment of any research biobank to assisting others.[45]

We have laid out a number of suggestions for governance of research biobanks recognisant of solidarity in this article. These include, on the

[43] Ie, granting of access to datasets to other researchers; see D Dobbs, Free Science One Paper at a Time (11 May 2011). Wired. Available at <http://m.wired.com/wiredscience/2011/05/free-science-one-paper-at-a-time-2/all/1> accessed 3 May 2012.

[44] See also S Leonelli and R Bastow, 'Sustaining Digital Infrastructures' (2010) 11 EMBO Rep 730–4.

[45] H Widdows and C Mullen, The Governance of Genetic Information (Cambridge University Press, Cambridge 2010). The proposed model for the governance of solidarity-based research biobanks resonates with evidence from empirical research. For example, CM Simon and others, 'Active Choice but Not Too Active: Public Perspectives on Biobank Consent Models' (2011) 13 Genet Med 821–31, recently found in a survey and focus-group-based study involving close to 800 respondents from biobank-based research studies in the USA that '[m]any individuals want to make an active and informed choice at the point of being approached for biobank participation but are prepared to consent broadly to future research use and to forego additional choices as a result'. See also G Haddow and others, 'Tackling Community Concerns about Commercialisation and Genetic Research: A Aodest Interdisciplinary Proposal' (2007) 64 Social Sci Med 272–82.

conceptual level, a reframing of the relationship between participants and biobanks as informed by both solidarity and autonomy, instead of by a dominant or exclusive focus on protecting autonomy of the participant; a shift towards more harm mitigation; and a commitment to veracity. They also include a number of accompanying arrangements at the practical level ranging from a participation agreement to the use of trusted intermediaries to the role of data sharing with other researchers. We anticipate this model to have a number of advantages: first, our model would very likely reduce administrative costs for research biobanks. This could be achieved by making use of broad consent models, by replacing the specifications of the research for which participants' donations will be used by a statement of the core values and missions of a biobank, and by narrowing the scope of cases of new research in need of research ethics approval. In summary, rather than focusing efforts on reducing risks, more resources could be channelled into substantive research activities and education. In addition, our proposal that biobanks establish dedicated funds for compensation of affected individuals may prove a cost-effective and relatively non-bureaucratic mode of harm mitigation. We also hope that research biobanks based on our solidarity-informed model will invest into interactive platforms for participants, researchers, and members of the public to access data and information generated by or with the help of the biobank. This will support transparency and a commitment to veracity, but will likely also render biobanks better prepared for the new era of ever more data-rich medicine.

Secondly, and on a more conceptual level, our proposal is in line with recent strands of thinking about autonomy and the instrument of consent. As described above, a strong or exclusive focus on protecting patient autonomy through the use of specific consent as a legal instrument has led to ever greater efforts to minimise risks and communicate these efforts to participants, to restrictions on even small changes of research goals, and to administrative burden that results from an ongoing commitment to full information at every stage of research. Whilst there is no question that in-depth information of research participants and their giving consent prior to signing up is an essential element of a research partnership, there seems to be a growing understanding both in the academic literature as well as in policy circles that the current situation may have pushed the autonomy-dominated model slightly too far. What is more, there is also some recognition and an emerging body of empirical evidence that in fact, once being properly asked and informed, people actually *are* willing to 'let go' more than current autonomy-based governance allows. They are prepared to assume the

relatively small costs this might demand, particularly when these costs help generate benefits and assistance to others.[46]

In summary, the concept of solidarity that we have applied to biobanks governance in this article provides a conceptual framework to move beyond overly restrictive and burdensome autonomy-focused governance towards what we believe is a better approach that is reflective of people's willingness to assume costs to assist others. We believe that this is resonant with ongoing initiatives towards more reflexive governance of biobanks.[47] Our model is committed to veracity and mutual respect between the participant and the biobank including the goals and values that it represents. It can be part of openness and veracity that individuals are told that their data and material will be used for purposes that cannot be foreseen. As long as individuals are free to decide whether or not to get involved in a biobank using such arrangements, such an open interaction between institutions and individuals is preferable to agreements organised to fit audit requirements and avoid litigation. As such, the model suggested here could be applied in other areas of regulatory governance, for example where wider use of administrative data for research and policy purposes is considered, or in health and safety regulation.

Our model will not—and is not designed to—change the situation that research biobanks are vehicles for governance through risk, but it is meant to help overcome the shortcomings of a governmentality whose main point of reference is the governance *of* risk. While an emphasis on the governance of risk remains of utmost importance in areas where the degree and nature of risk faced by people and groups is significant, in the context of low-risk endeavours, we will only be able to realise the full potential of our tools and platforms to improve health and well-being when risk ceases to structure our discussions and strategies of governance.

[46] CM Simon and others, ibid.
[47] See Laurie, above, n 24.