

Preface and report:

‘Access to the UK Biobank Resource: Concepts of the Public Interest and the Public Good’

Part 1. Background information on the commissioned report

Introduction

The purpose of the UK Biobank project is to provide a resource for research with the aim of improving the prevention, diagnosis and treatment of illness and promoting health throughout society. The resource is expected to contain health and lifestyle data and biological samples from 500,000 individuals aged 40-69 at time of enrolment.

Participants will grant access to their health records, provide some biological samples (e.g. blood and urine) and information about their lifestyle. The cohort will be followed up for decades, capturing all major health episodes and eventual death. The consent obtained at enrolment will allow the resource (data and samples) to be accessed and used for research projects in the future that fall within the purpose of the project.

The UK Biobank Ethics and Governance Council (EGC) is an independent monitoring body that advises on the ethical framework under which UK Biobank operates. A key function of the EGC is to keep under review applications for access to the resource with regard to the interests of research participants and in accordance with UK Biobank’s Intellectual Property and Access Policy.

In 2007 the EGC commissioned a report which aimed to provide a conceptual analysis of the terms the ‘public interest’ and ‘public good’. The final commissioned report is attached below.

Why we commissioned this research

The terms the ‘public interest’ and ‘public good’ are often used in the context of UK Biobank, including the early drafts of the project’s Intellectual Property and Access policy which describe UK Biobank as being ‘a managed resource for the public good’. However, the application of these terms to the management of resources like UK Biobank is unclear.

The EGC wanted to inform itself of how these phrases might be interpreted in the context of UK Biobank and how they might apply to access decision-making. Ultimately the EGC would like to develop a framework of principles to guide its future advice and decision-making with respect to access requests to the UK Biobank resource. The conceptual analysis was commissioned in order to inform, and provide a theoretical base for, the development of this framework.

Research aims

The research was commissioned with the following aims, to:

- provide a conceptual analysis of the ‘public interest’ and ‘public good’ as they might be applied to UK Biobank access decision-making
- deal with the notions of enhancement of the public good, threats to the public good and public interest and safeguarding the public good and public interest
- be based on a literature search in the moral and political philosophy scholarly literature and in relevant policy documents
- conclude with a summary and critical analysis of the issues emerging.

Research outcomes

The report is attached at Part 2 of this paper. It should be noted that the conclusions are those of the authors and not necessarily those of the EGC. In the interests of transparency the EGC has chosen to publish the full report.

In order to extract the most value from the report the EGC has produced a document which summarises the findings of the report in the context of their application to the EGC's activities. This is available separately on the EGC's website. This summary is a 'living' document and will be revised over time to take account of new thinking by the Council on its interpretations of 'public interest' and 'public good' (e.g. in response to other commissioned work or future experiences).

Part 2. The commissioned report

Access to the UK Biobank Resource: Concepts of the Public Interest and the Public Good

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Summary

In this Report, we discuss how the concepts of 'public interest' and 'public good' might be applied to decisions regarding access to the UK Biobank. The Report is in two parts. Part One is a scholarly analysis of concepts of 'public interest' and 'public good'. We review the relevant moral and political literature to identify themes of public and individual 'good' and 'interest', and to locate mainstream normative theories which may be of use to the modern-day understanding and practical use of these concepts. We conclude that aggregate ideas of interest may lead to the disempowerment of vulnerable groups; and therefore recommend that interest should be considered as referring to procedural frameworks providing political security, and public goods as the necessary features for the enjoyment of rights. These goods are divided into generic freedom (procedural goods) and generic wellbeing (substantive goods), and are necessary for agents to flourish within a community of human rights. They are neither beneficial nor disadvantageous in regard to any specific individual member of a corporate public body, but are generic and equitable in regard to all its members. According to this view, we argue that consent and trust are important public goods specific to the policies of UK Biobank.

In Part Two, we apply this theory to how UK Biobank should develop its access policies with regard to consent and trust. First, we look at current practises in various national biobanks, and we identify emergent issues of interest and good which may bear upon the future expected roles of UK Biobank. Three issues come to the fore in this analysis: compliance with the Human Rights Act 1998, procedures of consent, and managing intellectual property rights. In the final part of the Report, we discuss the threats to public good and public interest in the context of UK Biobank's access policy, and suggest the necessary safeguards and various strategies to enhance ethical practice. In regard to UK Biobank's policies on access, securing procedures of consent and trust provide the opportunities necessary for agents to fully participate in the biobank, both directly and indirectly as members of the public. We conclude that measures which prioritise a non-paternalistic understanding of consent and promote trust in government institutions are central to an ethical UK Biobank access policy.

Introduction

The UK Biobank's aims are to become a major resource to support research that will improve the prevention, diagnosis and treatment of illness, and to promote health throughout society for public benefit. It will eventually contain health and lifestyle data and biological samples from 500,000 voluntary participants in the age range 40 to 69 years.¹

Accessing samples and data will be subject to the (current draft) *Intellectual Property and Access Policy*, in which it is stated that the UK Biobank (UKB) is to be managed for the 'public good'.² Access applications will (normally) be considered by the Ethics and Governance Council (EGC) in advance of a decision being made by the Board of Directors of the UK Biobank. In this regard, the EGC will prioritise the protection of participants and ensure that commitments made to them – including acting within the scope of their consents – are honored.³ This raises a concern, that in strengthening principles of participants' consent, it places participants in a position of potential conflict with other – public-wide – interests. Central to the UKB's access policy, therefore, is the balancing of personal autonomy and 'the public', the latter expressed in terms of 'public interest' or 'good'. This raises a wide range of ethical issues regarding the 'fundamental dependence on altruism and trust from those who donate their biosamples and health data; and the corresponding duties which rest on genetic database creators and custodians to honour these commitments from donors'.⁴

In the first part of this Report, we will present a conceptual analysis of 'public interest' and 'public good' in the context of 'the self' and 'the public'. This background analysis will be used to identify the key theoretical points that may be used by the EGC in decisions regarding access – including competing claims – to the Biobank's samples and data. In Part Two, we will look at how the UKB should take account of 'public good' and 'public interest' in a practical way, and how its access policies may reflect its commitment to public benefit and honour its duties to those individuals that have contributed to the resource.

PART ONE: THE PHILOSOPHICAL GROUNDING OF PUBLIC INTEREST AND PUBLIC GOOD

1. The 'Self' and 'The Public'

Understanding the self/public debate is dependent on the grounding of terms that refer to the various *interests* and *goods*. The terms 'interest' and 'good' are ethically weighted depending on their deployment and context of use; and when reflected in norms or rules, they are often intertwined with concepts such as 'welfare', and positive (to act in a certain

¹ See website: <http://www.ukbiobank.ac.uk/>.

² UK Biobank Policy on Intellectual Property ("IP") and Access. Draft, 11 January 2005. p. 2. (hereafter 'Access Policy'). Previously available at: <http://www.ukbiobank.ac.uk/docs/UKBiobankIPandAccesspolicyfirstpublicdraft11.1.5final2.pdf> Please contact the Secretariat of the EGC to access this document.

³ Priority will be given to the implications of granting access to 'Protected Material', which includes any application for access to (reversibly-anonymised) data relating to individual participants' health, lifestyle and environment, biological samples and data derived from sample analyses or to re-contact participants. For applications requests for less sensitive data, decisions will be made by the Directors and reported to the EGC. In addition, the EGC, along with the Science Committee, will advise the Board of Directors, and assist to identify and articulate appropriate principles and policies, and assists in overseeing their effective implementation. A further responsibility of the EGC is to keep under review applications for access to the resource, and thereby refine the Access Policy in regard to ensuring compliance with legal and regulatory requirements, establishing a framework for assessing claims to access those parts of the resource that are limited in availability (particularly depletable samples), and to manage intellectual property rights in the resource and the results that flow from it.

⁴ Campbell, A. 2007. The Ethical Challenges of Genetic Databases: Safeguarding Altruism and Trust. *King's Law Journal* 18: 227-245; p. 228.

way) and negative (to refrain from acting in a certain way) responsibility to fellow citizens.⁵ The concepts have been used to evince normative and descriptive theories defining, in both egoistic and communitarian terms, 'what is good for me', or 'in my interests';⁶ and this inconsistency has contributed, at different times, to (un)persuasive, (un)convincing, and confused interpretations in applied ethics. The terms are often used in conjunction with one another, and sometimes treated as synonymous. However, while there is an underlying definitional relationship reflected in both terms regarding the individual's connection to the community, we shall propose that there is a difference between them, and one which is reflected in the history of use and theoretical development of the two concepts. As we shall see, ideas of community assume a prominent place in the ethical governance of biobanks, where the '*self-public will*' becomes a reflection of motivation to participate in such projects. This consequently defines the safeguards that are developed to protect and promote the individual *and* public in terms of 'interest' and 'good'. For now, we must be content to define the limits of a general conception of 'the public', since this will give us clues as to the solutions to such questions to be considered in the following sections.

An examination of the literature illustrates that underlying the concept of 'the public' is a discrete definition of the *range* of inclusiveness and the *strength* of any relational ties. Our first task is therefore to establish a democratic-centric political theory of 'the public' that will ground our discussion in Part Two.

A basic assumption that may be made when one is talking about 'the public' is that one is referring to a collection of individuals, who may or may not be congruous in their collective goals. In this way, many writers conceive of this idea of independent decision-making as a multi-layered concept of autonomy, and they readily evoke ideas of sovereign agents with powers of self-determination and governance.⁷ This may lead to two roughly opposing views: for Jeremy Bentham the coming together of individuals represented '...a fictitious *body*, composed of the individual persons who are considered as constituting as it were its *members*'.⁸ Thus, the ties of 'community' were merely the happenstance of many autonomous wills being in the same place and time. (This is not quite the end of the story for Bentham, as he did believe, as we shall see below, that the sum of individual interests could equate to a collective political will).

By contrast, John Dewey, among other writers, saw the social and political value in creating a stronger sense of community. Dewey described 'the public' as coming into existence as a result of 'Indirect, extensive, enduring and serious consequences of conjoint and interacting behaviour'.⁹ Thus, according to Dewey, the public was a collection of independent selves, each with their own – but a common – interest in controlling matters like 'sanitation, public health, [and] healthful and adequate housing ...and so on'.¹⁰ As autonomous individuals going about our lives, we 'join, assemble, foregather, [and] combine',¹¹ and therefore it is normal that we become located within 'communities', described by de Graza as being connected through '...habitual relations or mutual

⁵ On welfare, see: Gewirth, A. 1996. *The Community of Rights*. Chicago. Chicago University Press. esp. Chapter Four; and on positive and negative rights and duties, see: Gewirth, A. 1978. *Reason and Morality*. Chicago. Chicago University Press. esp. Chapter Four.

⁶ Rawls relates this to social cooperation, which when seen from a single standpoint, is what each participant (individuals, families, associations or government) recognises as being to their 'rational advantage' in what they are trying to achieve; Rawls, J. 2005. *Political Liberalism*. Expanded Edition. New York. Columbia University Press. p. 16.

⁷ O'Neill, O. 2002. *Autonomy and Trust in Bioethics*. Cambridge. Cambridge University Press. esp. Chapter Two.

⁸ Bentham, J. 1996. *An Introduction to the Principles of Morals and Legislation*. Burns, J. and Hart, H. eds., with a new introduction by Rosen, F., and an Interpretive Essay by Hart, H. Oxford. Oxford University Press. p. 12

⁹ Dewey, J. 1927. *The Public and Its Problems*. New York. Henry Holt & Co. p. 126.

¹⁰ *Ibid.* p. 124.

¹¹ *Ibid.* p. 11.

communications [which are] ...so many and all-embracing as to give the people a culture'¹² (or other shared will).¹³ The public exists, according to de Grazia, in the *political relations* which people in the community have;¹⁴ thus, according to these communitarian descriptions of society, communities themselves exist (since there is often to be found more than one) within wider 'societal' networks of directly and indirectly interacting groups. Thus, 'the public' refers to '...a group of people where the unit of the group is determined by its organisation under a common public authority...[and] the interests [or good] of all other people'.¹⁵

Dewey's (and others') definition of 'the public' evokes confidence in a person's democratic competence – or a 'sense of justice' –¹⁶ to participate responsibly in the government of society. This fundamental democratic idea confirms that, as free and equal persons, we all have a sense of justice and a conception of the good. As autonomous agents, we are capable of making our own decisions and having our own opinions, which may be at odds with others around us. Such self-interest therefore refers to private wants, preferences, and choices; and equates to what any agent claims is good or in their interests as a function of some positive attribution to their purposes (i.e. the motivating reason of why any agent pursues any purpose).¹⁷ However, we are agents that have 'public' lives, and in this sense, 'public' evinces not what any individual wants or chooses, but a benefit for an as yet undisclosed number of people, all of whom likewise have private, as well as public lives. Public is therefore about the 'socially valuable' aspects of our lives, which may not be beneficial or advantageous to any particular individual.¹⁸ Our rational choices with regard to others are informed by egoistic, altruistic and benevolent motivations based on private virtues, available information and understating and self-designated purposes.¹⁹ It is therefore disingenuous to attempt to remove 'the public' from democratic political purpose; and one may reject Bentham's prior definition (if it is to be taken seriously), which makes an unpersuasive case for disregarding any meaningful distinction between a fictitious 'public' and private autonomous utilities.

Therefore, in the following, our definition of 'the public' refers to the interests or goods that are associated with the multitude of people that comprises a political democratic state, i.e. what effects 'the public' *qua* members of the public²⁰ (and indeed, 'the public' may

¹² de Grazia, A. 1962. *Political Behavior; New, Revised Edition of The Elements of Political Science, Volume One*. New York. The Free Press. p. 116.

¹³ Ferdinand Tönnies contrasted a social order which – being based upon consensus of wills – rests on harmony and is developed and ennobled by folk-law, mores, and religion; and an order which – being based upon a union of rational wills – rests on convention and agreement, is safeguarded by political legislation, and finds its ideological justification in public opinion; see: Tönnies, F. 1955. *Community and Association*. Loomis, C. trans. and ed. London. Routledge & Kegan Paul Ltd. pp. 38-39.

¹⁴ de Grazia, op. cit. note 12, pp. 120-121.

¹⁵ Rees, W. 1964. *Symposium: The Public Interest*. *Proceedings of the Aristotelian Society (Supp.)* 38: 19-38, p. 31-32.

¹⁶ Waldron, J. 2004. *Law and Disagreement*. London. Oxford University Press. Chapter Thirteen.

¹⁷ This end may not be considered good in a moral sense or as intrinsically good, as an assertoric evaluation may entail (assertoric is about purposes, so that assertorically, these purposes are good), and are not about some person's judgement or statement about purposes (so that a purpose may be good from the standpoint of some person, or that some person says or thinks 'my purposes are good'). Gewirth, 1978, op. cit. note 5, p. 45.

¹⁸ Dewey, op. cit. note 9, p. 14. These are the 'indirect consequences of transactions to such an extent that it is deemed necessary to have those consequences systematically cared for [by legal public officers]'; *ibid.* pp. 15-16.

¹⁹ Oppenheim, F. 1975. *Self-Interest and Public Interest*. *Political Theory* 3: 259-276.

²⁰ One may borrow from Bentham, who states (in reference to 'Classes of Offences') public offences as causing: 'distinct mischief which they threaten to bring upon an unassignable indefinite multitude of the whole number of individuals, of which the community is composed'; [our emphasis] Bentham, op. cit. note 8, p. 189. Such offences are to be distinguished from (among others) self-regarding offences, which are detrimental to himself, and no one else.

change according to the particular time and context in which a question is raised).²¹ As we shall demonstrate, the deployment of ‘interest’ and ‘good’ as suffixes to ‘public’ by various theorists, reflects a basic affirmation of either an all-encompassing prescription upon agency (‘the public’ does not reflect the opinions, or good or bad, for any one individual) or as a link to personal atomistic preference (it is equitable to collective interest or good).

2. The Public Interest

There are many critical and nebulous interpretations of ‘public interest’, to which Gunn commented: ‘It is never easy to write of interests: protean and all-pervasive, definable at any level of generality, multiple and conflicting even within a single individual – their coherent description strains our command of language and forces us at times into dubious metaphors’.²² Often, public interest has been deployed as a rhetorical tool; politicians and parties have ‘justly’ exercised their powers – given to them by the people – in the ‘public interest’. But these claims of ‘political standards’ – descriptive statements that something is in one’s, indeed *everyone’s* interests – have often lacked an ethical explanation. To this end, there have been many normative attempts to establish, or provide a definitive rejection, of the validity of public interest as a ‘gold standard’ in policy making.

There is a view that public interest is roughly synonymous with a definition of ‘general welfare’; the physical, social, and financial conditions under which individuals can live satisfactorily in a democratic state.²³ This signifies a prior distinction that we wish to make: since the ‘public interest’ can also refer to what *the public is interested in* (referring to the transient nature and necessity of a personifiable ‘possessor’ – *qua* ‘the public’ – of opinion).²⁴ In this Report, ‘the public interest’ refers to the enduring and intangible concept of ‘democratic political value’, which plausibly includes such sub-values as equality, happiness, security, or safety.²⁵ This reification creates a difficult conceptual problem, given that ‘the public’, as defined above, represent relationships and interactions between individuals. Whereas an account of a person’s interests must be sufficiently abstract, or relative to that person (e.g. her ‘will’), a proclamation as to what is *in the public interest* represents those (contingent) things that are relevant to everyone’s (or most peoples’) wellbeing in similar circumstances.²⁶ For example, having enough food is in everyone’s interests, although the amount or type of food may vary from person to person and depend on size, health or being pregnant.²⁷ On our account of public interest, in the example given, access to food becomes a public interest when there is a danger of it not being protected or promoted, e.g. a group is denied access by others or there is unfair distribution, or that securing enough food is for some or most individuals out of their hands. Therefore, any interest *is public* when it applies to (nearly) *everyone*, or can become an interest to *anyone*, i.e. everyone *can* be negatively affected by food shortage, and thereby requires a form of state action. In a famine, there may be people unaffected by a lack of food; but within the community, there may be a majority directly affected, and even the well-off will be affected by a breakdown in social welfare and infrastructure.

²¹ For example, the ‘public interest’ in the specific case of access to the breast cancer drug Herceptin would be for relatively less of ‘the public’ than issues of prescription charges. For a further discussion on the issue of people affected as parts of the public, see: Barry, B. 1990. *Political Argument: A Reissue with a New Introduction*. Hemel Hempstead. Harvester Wheatsheaf. p. 192.

²² Gunn, J. 1968. 1968. Jeremy Bentham and the Public Interest. *Canadian Journal of Political Science* 1: 398-413, p. 412.

²³ *Supra*. note 5.

²⁴ In the case of *X v Y* [1988] 2 All ER 648, a newspaper wanted to reveal the identity of HIV+ health professionals. The judge drew an explicit distinction between disclosure in the ‘public interest’ and disclosure which is merely ‘interesting to’ the public – the latter was not a valid reason for disclosure of the information.

²⁵ Cassinelli, C. 1958. Some Reflections on the Concept of Public Interest. *Ethics* 69: 48-61.

²⁶ Benditt, T. 1973. The Public Interest. *Philosophy and Public Affairs* 2: 291-311.

²⁷ *Ibid*.

Taking 'public interest' to signify this latter sense, it becomes a basic issue of political ethics, and permeates the governance of every decision-making public institution. Therefore, justifying the actions of such institutions requires 'discovering' the interests that each (or most) individuals possess, and then turning this into a representative policy of 'the public'. While there are many views on how this is to be achieved, it has been variously suggested that public interest corresponds either to a *commonly- (majority) held value*, because it cannot be the same for all (therefore, while we all require sustenance, we also require different amounts and types depending on circumstance);²⁸ or as a *moral imperative* defensible on the grounds of rational argumentation (the focus is in those interests that we all truly do share).²⁹ Thus, when something becomes a public interest, there is a value that is either an aggregate of individual utilities, or a sense in which it represents the substance of public community.

2.1 Utility and the Public Interest

A utilitarian view of public interest may be seen as a project of *political abstraction*; in which 'public interest lacks a neat and precise formulation, [but] it has over the years of use (and occasional abuse) acquired a pragmatic and functional definition'.³⁰ The 'public', qua Bentham, cannot be defined as a discrete entity, and the public interest becomes a matter for procedural and aggregate resolution. In this regard, policies should be enacted on the grounds of public support, and therefore the right actions reflect the common values of the majority. Furthermore, government action can be justified in the public interest if it conforms to legitimate procedures, which include fair representation and methods of vote-counting, established within a constitutional framework.³¹ Such a view lends itself readily to relativist and utilitarian thinking, whereby definitions of public interest become a prioritisation of government action to enact policies which represent an efficient path to the satisfaction of the opinions of as many citizens as possible in the current state of affairs.³²

In this respect, the ethical relativist depicts the public interest as a reflection of local traditions and values of a selected community at a particular time. This concept of 'human nature', if it can at all be a shared value, is a contextual entity which designates political values within a particular historical or cultural context.³³ However, in this regard, the public interest would always equate to what the multitude of people desired, but as such, would merely represent a transient evaluation of the needs and desires of that time; therefore individual interests are not, as Lippmann contends, 'propositions of the public interest'.³⁴ The trouble is that public interest, if measured as a statistical sum of opinion, is ephemeral, unsettled, and subject to the whims of socially dictated transition. Its content (if it there can be any meaningful one) becomes obscurantist and useless, and therefore the term becomes impractical and inoperable within the bounds of a definitional public policy.

Thus, strict utilitarian theorists have attempted to define a more concrete and lasting concept of public interest. The basic logic of utilitarianism is that there is no golden rule protecting the rights of each individual; nor is there any golden rule that any choices or wishes should be observed. If, all things considered, the consequences of allowing some act would be more productive of utility (or less productive of distress) than any other course

²⁸ As we will discuss below, this may reflect distributive ideas regarding 'common interest', to reflect all of the members of society, and 'majority interest' as an approximation of 'the many'.

²⁹ Cassinelli, op. cit. note 25.

³⁰ Sorauf, F. 1957. The Public Interest Reconsidered. *Journal of Politics* 19: 616-639.

³¹ A constitution '...sets out the framework of government, postulates how it ought to operate, and makes declarations about the purposes of the state and society and the rights and duties of citizens'. de Smith, S. 1973. *Constitutional and Administrative Law*. 2nd Edition. London. Penguin. p. 18.

³² Musgrave, R. 1962. The Public Interest: Efficiency in the Creation and Maintenance of Material Welfare. In: Friedrich, C. ed. *The Public Interest: Nomos V*. Atherton Press. New York. pp. 107-114.

³³ See the Introduction of: Rorty, R. 1989. *Contingency, Irony and Solidarity*. Cambridge. Cambridge University Press. pp. xiii-xvi, and *passim*.

³⁴ Lippmann, W. 1955. *The Public Philosophy*. New York. Mentor. p. 39.

of action, then it would be right to proceed. Jeremy Bentham attempted to fit this basic premise into the 'public interest' as a collective benefit; and therefore 'public interest' was the sum of interests of the several members who comprise the community. According to Bentham, measuring public interest was directly correlated to what was in the *individual's* interest: thus, an action that conformed to the principle of utility (in respect to the community at large) tended to 'augment the happiness of the community [which] is greater than any it has to diminish it'.³⁵ The assessment of public interest was therefore defined by procedures to count the votes of individuals, since what they regarded as most making for their own happiness (normally) would spell the greatest happiness for the greatest number.³⁶ The more happy individuals there were, the happier the community would be. The significance of the public was incidental to Bentham; the community represented a fictitious body covering a mass of individual interests, and ultimately was reducible to 'private and personal advantage'.³⁷

Underlying the utilitarian procedural move from self- to public interest is the aggregation of autonomous interests, which lends itself to *laissez faire* individualism. For Bentham, this demanded minimal, if any, state interference in the pursuance of individual interests that produced no outward conflict. He did believe, however, that limited collective ends may be teased from an understanding of self-interests, and therefore authority could be placed in aspects of security, property and equality, which were interests that were truly universal. In the extreme, 'social interests' may develop in times of 'extraordinary public danger', but even in such situations of national defence, zealous public protection through state action was to be viewed as suspect.³⁸ On a mundane level, the public interest therefore equated to individual interests deemed to belong to more or less all private persons, such as in security and allied rights. However, there was a realistic limit to the homogeneity of the public, and striving for unity may provide for 'sinister interests' incompatible with utility; to which Bentham commented that it was an 'obscure and false notion, that private interest ought to give way to public interest', and concluded: 'Take care of individuals ...and you will have done enough for the public'.³⁹

Therefore, by distilling the utilitarian argument to its basic premise – the prioritisation of private interests through democratic conceptions of process and procedure – a concept of public interest emerges as the availability of political tools to us all equally (Bentham strongly believed in Universal Suffrage). Thus, we may minimally deduce that the public interest includes those measures that ensure that we keep peace with each other in pluralistic democracies. The function of public authority is therefore to establish the frameworks necessary to calculate the multitudes of self-interests and express them as common standards of rule; beyond this is the construction of institutions necessary to enforce such rules, punish 'crimes', and thereby preserve peaceful coexistence.

2.2 The Moral Imperative and the Public Interest

In contrast to the implied-procedural definition of public interest, which merely measures the public interest, a second camp can be identified as '...a series of attempts to formulate the best possible method of serving the public interest'.⁴⁰ Like Bentham's account above, there is a strong procedural element. However, recognising that utilitarian calculations could lead to the instrumentalism, enslavement or impoverishment of some

³⁵ Bentham, op. cit. note 8, pp. 12-13.

³⁶ Gunn, op. cit. note 22.

³⁷ Bentham, J. 1843. *The Book of Political Fallacies: from Unfinished Papers of Jeremy Bentham*, Edited by a Friend (orr. publication 1824). In Bowering, J. ed. *The Works of Jeremy Bentham*, Volume II. Edinburgh. William Tait. pp. 377-487, p. 416.

³⁸ Gunn, op. cit. 22, p. 402.

³⁹ Bentham, J. 1843. *Principles of the Civil Code*. In Bowering, J. ed. *The Works of Jeremy Bentham*, Volume I. Edinburgh. William Tait. pp. 297-364, p. 321.

⁴⁰ Zarecor, W. 1959. *The Public Interests and Political Theory*. *Ethics* 69: 277-280, p. 277.

persons in the public interest, a conception of the ‘substance of public community’ has been sought that could accommodate an idea of community while equally recognising every individual as a cooperative and social entity.⁴¹ Additionally, the motivation to move away from aggregated interests as a justification of public policy may be due to the presence of certain moral ambiguities, not least because ‘majoritarian truth’ only tells us which political acts are procedurally legitimate, but neglects to take account of substantive moral justifications.

The idea of an imperative-grounded public interest can be traced to the writings of Plato, in which he describes *logos*, or *nous*, as that which enabled agents to live together in ordered communities through the coming together of the private and public realms in a shared experience of justice and social contract.⁴² Such an approach has appealed to modern Political Liberalists, Communitarians and Ethical Rationalist who have attempted to locate *nous* within the political objective of the protection of equal rights as *the public interest*, and the individual’s guaranteed participation in democratic government to secure an equitable social contract. Thus, prioritising a concept of public interest is the *raison d’état* for government authority over the wills of citizens.

Jean-Jacques Rousseau argued that the public interest was fluid, and therefore something was in the public interest if the general will willed it;⁴³ but he saw the danger of the ‘will of all’, and distinguished the mere aggregate of personal desires from judgments about the common good.⁴⁴ Rousseau, in the Republican tradition, argued that public interest should normally equate to what individuals had prescribed as good for themselves with the general good in mind;⁴⁵ thus, the ‘social compact’ (qua resulting policies of the social contract) was the general wellbeing of the whole community, and was that which was proclaimed, at that time, by a majority. Thus, the ‘*Republic or body politic*’ was created as a public (of individual subjects) personified in a sovereign and the laws of State;⁴⁶ and was grounded upon the understanding that the general will has an ‘interest’ in removing itself from crime, sickness, poverty, and the like.⁴⁷

For some, Rousseau’s ‘utopian’⁴⁸ ideas – of the right of the people to share in government – fall down on their adherence to finding a general will (much like utilitarianism and aggregate ‘wills’), because the unanimity necessary for democratic public interest – that is based on the majority principle – is unrealistic with regard to decision making.⁴⁹ What one can find in Rousseau’s project is the entrenchment of the idea that the *rational* public would find certain common values that were in their (qua everyone’s) interests to preserve. We will return to a definition of ‘public’ below (sec. 3.1).

⁴¹ Rawls, J. *A Theory of Justice*. 1973. Oxford. Oxford University Press. pp. 522-525.

⁴² Plato. 1998. *Republic*. Waterfield, R., a new translation by. Oxford. Oxford University Press. sec. 358e-359b & 370d, and esp. 434c-e. For discussion see: pp. xxxvi-xxxix of Waterfield’s Introduction to this edition; Niemeyer, G. 1962. *Public Interest and Private Utility*. In: Friedrich, C. ed. *The Public Interest: Nomos V*. Atherton Press. New York. pp. 1-13; and Dobbs, D. 1985. *The Justice of Socrates’ Philosopher Kings*. *American Journal of Political Science* 29: 809-826.

⁴³ Or ‘...the supreme direction of the general will’; Rousseau, J. 2003. *The Social Contract and Discourses*. Cole, G. trans. and introduced; Brumfitt, J. and Hall, J. revised, and augmented; Jimack, P. updated by. London. Everyman. p. 192. A further explanation can be found in ‘Yesterday’s law is not binding today’ and the transient nature of law, at *ibid.* p. 261.

⁴⁴ *Ibid.* p. 203. In a similar vein, Walter Lippmann defined such an interest as ‘...what men would choose if they saw clearly, thought rationally, acted disinterestedly and benevolently’; *op. cit.* note 34, p. 40. The public good is discussed further, below.

⁴⁵ Rousseau believed ‘their common interest’ to reside in *natural law* – as a ‘collection of rules, without any other proof than the good that would result from their being universally practiced’; *op. cit.* note 43, pp. 46-47. We will return to this idea of natural law below, in section 3.1, esp. *infra.* fn. 74.

⁴⁶ *Ibid.* pp. 192-193.

⁴⁷ See: *ibid.* *Discourse on the Origins of Equality*, pp. 31-126 and *passim*; and pp. 142-145.

⁴⁸ Held, D. *Models of Democracy*. 3rd edition. Cambridge. Polity Press. Chapter Three.

⁴⁹ Manin, B., Stein, E. and Mansbridge, J. 1987. *On Legitimacy and Political Deliberation*. *Political Theory* 15: 338-368, p. 352.

3. The Public Good

The public good, like interest, has a history of rhetoric used to denote the general values of society without specifying a particular group that is to benefit.⁵⁰ The result has been that the political use of the term belies an indeterminate method for the meaningful employment of the concept. In its most general sense, the public good appears to equate to the provision of a good or service; thus something that is for the public good brings about an ideal (or better) set of circumstances, whether that is peace, order, or community, or the things that provide for wellbeing, freedom, or prosperity.⁵¹ These are not necessarily (but may be) tangible 'goods', such as cheaper pharmaceuticals, and they include such things as 'electoral votes'. There is therefore a link between Rousseau's public interest(s) and an account of public good.

A central premise elicited by public good is a juxtaposition with autonomy. This idea, which first became a popular theme of political-moral thought of the Enlightenment theorists, is an attempt to locate a dichotomy between individual and collective goods in the normative foundation of government.⁵² The concept has since been redefined and adapted in light of relevant cultural and historical contexts,⁵³ and like utilitarian and relativist theories of interest, there is a recent trend to secure the public good through the conglomerate of mutual self-motivations. But it is worthwhile revisiting the early ideas of public good as a value found in community cooperation and the unequivocal rightness of the benefits of public life; and in doing so it becomes evident that underlying many Libertarian and Communitarian theories is a common understanding that locating the public good is a central premise of contemporary societies and communities. Therefore, the question is how far existing democratic systems can use political authority to take a distinctively paternalistic view of certain aspects of living, pushing autonomy into the background of permitted personal choices. In this regard, democratic states and communities have developed public institutional responses to areas of private disagreement and conflict, which purport to further the public good. It is this path that we will develop here.

3.1 Our 'Public' Lives

The definition of public good above is closely aligned to what we have previously said about 'interest' (in sec. 2.2). For example, while votes can be considered as 'goods' necessary for the political aspects of agency, it is also seemingly in one's interest to have and use such votes; that is, suffrage advances the opportunities *qua* interests that one has.⁵⁴ However, this also suggests that public good is a self-motivated goal, and therefore similar concerns as to those shown above, regarding utilitarian calculations, surface.

Because of the risk of individual rights succumbing to aggregate interests, some theorists have found it necessary to define a more concrete distinction between public good and widely-held interests. In this regard, the former has been segregated in the context of common benefits – secured by an ethical imperative – and these benefits are common in the

⁵⁰ Barry, op. cit. note 21, pp. 189-190.

⁵¹ Flathman, R. 1966. *The Public Interest: An Essay Concerning the Normative Discourse of Politics*. New York. John Wiley & Sons.

⁵² Harrison, R. 2002. *Hobbes, Locke, and Confusion's Masterpiece: An Examination of Seventeenth-Century Political Philosophy*. Cambridge. Cambridge University Press.

⁵³ Winch, P. 1972. *Man and Society in Hobbes and Rousseau*. In Cranston, M. and Peters, R. eds. *Hobbes and Rousseau: A Collection of Critical Essays*. Garden City, New York. Anchor Books. pp. 233-253.

⁵⁴ The idea that the public good may be directly evinced by public interest is suggested by Joseph Raz. He argues that securing rights to public good serves one's (and everyone's) public interest. Thus, he describes a balance of individual and group interests as, on the one hand, a system of collective rights, insofar as its object is a whole system or institution that cannot be parcelled out among individuals; while on the other hand, a set of individual rights (and duties), insofar as its subjects are individuals each of whom the system is designed to benefit; Raz, J. 1986. *The Morality of Freedom*. Oxford. Clarendon Press. pp. 207-209.

sense that they pertain equally to all members of society in conducting their public lives. Joseph Raz's description of rights recognises this concern; and he maintains that collective interests in public goods have a distributive aspect in that they can also be construed as individual rights. This is because rights are designed to benefit and protect individuals as such, and not only a collective entity; and therefore individuals are treated equally as benefactors of the public system.⁵⁵

John Rawls argued that public good evinces the public system and the character and content of justice. His project was to affirm the basic good of liberal political institutions, and distinguish between 'ideas of the good' and the 'priority of the right' as distinctive, but complementary concepts. The former represented ideas of comprehensive conceptions of the good (comprehensive philosophical, religious and moral doctrines) – that is to say moral and political conceptions of human value, personal virtue and character, which characterise the pluralism of modern democratic societies as an exercise of free human reason⁵⁶ – while the latter confirmed a narrower political conception of 'justice as fairness'. At its core, justice as fairness affirms certain basic rights and liberties, and assigns them a priority in political and social life, the basic structure of society, its institutions, and so on.⁵⁷ The 'public good', although a term not used by Rawls in *Political Liberalism*,⁵⁸ equates to this second concept; and in this regard, the meeting of political and comprehensive ideas, collectively called 'political liberalism'. This political (democratic) conception of justice, as with Rousseau, is an idea which can be shared by all citizens regarded as free and equal, and which does not presuppose any particular comprehensive doctrine.⁵⁹ Rawls further shows that it is in one's own benefit to *consent* to a constitutional regime on the grounds that the basis of freedom and justice in pluralistic democracies requires creating a contract with an external power to enforce public laws (since no one doctrine can reasonably be expected to bind all to a fair and just political community).

To reflect upon Rawls' analysis, a step back is required to look at the origins of constitutional democracy, and specifically at the evolution of the social contract. For Rawls, the public good represented that which is common to each citizen: everyone can agree that everyone is striving toward one single end, which is justice for all citizens. The question that must be asked prior to this is how can persons of good faith be wholehearted participants in a liberal constitutional democracy?

The social contract derives from the work of Thomas Hobbes.⁶⁰ Hobbes was one of the first political theorists to attempt methodically to show why individuals are rationally bound to creating models of socio-political stability. This was his idea of the social contract: a system of collectively enforced social arrangements that are *legitimate* as the objects of an agreement for the people who are subject to it. He systematically showed that securing one's wellbeing in the 'state of nature' would require a self-interest in protecting oneself (indeed, the right to self-protection was the only right in the state of nature), and this would often be at the expense of the wellbeing of others. To remove one from this primitive state, a contract between parties was necessary to refrain from such actions and thereby create a

⁵⁵ The kinds of benefit that this system secures tend to be illustrated by enduring caricatures of wellbeing and freedom, rather than a suggesting a purpose or aim to maximise overall utility; *ibid.* cf. Gewirth, 1996, *op. cit.* note 5, pp. 48-49.

⁵⁶ Rawls, *op. cit.* note 6, p. xvi.

⁵⁷ *Ibid.* p. 175.

⁵⁸ But is used by Rawls in: Prusak, B. 1998. *Politics, Religion and the Public Good: An Interview with the Philosopher John Rawls*. *Commonweal*, vol. 125, September 25th.

⁵⁹ For Rawls, political liberalism is in part derived from the prioritisation of admissible ideas of the (public) good, which respect the limits of, and serve a role within, the political conception of justice. Thus, citizens recognise the (intrinsic) public good, both as persons and as a corporate body, in maintaining a just constitutional regime, which itself creates the necessary framework for individuals to benefit as members of a pluralistic community; Rawls, *op. cit.* note 6, p. 176 & 201. See: Capps, B. 2008. *Authoritative Regulation and the Stem Cell Debate*. *Bioethics* 22: 43-55.

⁶⁰ Hobbes, T. 2005 (or. 1651). *Leviathan*. A critical edition by Rogers, G. and Schuhmann, K. London. Continuum International Publishing Group.

mutually protective (rights) community. It would be naïve to think that all would lay down their swords at the same time, and the reality of the ‘fool’ to free-ride at the expense of others made such a commitment perilous (often made at a personal cost due to the necessity of compromise).⁶¹ Such distrust meant that it was rational, not merely good sense, to delegate one’s interests into the hands of an authoritarian sovereign to oversee and enforce such contracts, even though one was knowingly sacrificing some personal freedoms and interests.⁶² Essentially, in the state of nature, there could be but one interest – to protect oneself – and the creation of a sovereign overseer, however construed, allowed the development of civil society and all its vexed interests *by consent*.

The Hobbesian argument for absolute sovereignty was seen as unacceptable by many,⁶³ thus there is an argument that in a pluralistic State, conflicting interests can only be settled through compromise and consensus for the sake of stability in the public sphere.⁶⁴ The concern with ascribing to a conciliated public good in determining private affairs, i.e. limiting what citizens may or may not do in the public and private spheres, rather than leaving it to choice and personal doctrine, is that it subjects everyone to *positive legal ordering*, and the prospect of waking up each day to rules restricting our freedom.⁶⁵ Rawls addressed this concern in *Political Liberalism*, stating that the public good is a compromise situation between the different groups for the sake of a best, and necessarily enforceable, public policy.⁶⁶ Central to this thesis is a procedural ethic that allows us all to take part in, and consent to, an authoritarian community. This is arguably a state of affairs that is better for everyone concerned than they would be in a ‘state of nature’ where this is absent, and allows for community values to transcend pure self-interests and uncovers those arguments that can justifiably determine public policy, i.e. while less advantageous to each, it leaves no one worse off than in the absence of the public good.⁶⁷ The public good therefore describes the content of policies that benefit the actor and others both directly and indirectly; and in this way, ‘public’ reflects distributive benefits.⁶⁸ Thus, political action becomes a *public* good when it effects the community in a positive and generic way, and often with long-range (extending even to future agents) and systemic impact.

‘Public good’ is not merely a reflection of political processes as *compromise-as-method*;⁶⁹ it is both procedural bargaining to create policies designed to achieve personal and group ends – and to thereby allow persons to control their futures –⁷⁰ and *compromise-as-result* in the securing of generic, *qua* necessary to each member of society, goods as required. These goods benefit us all (in one way or another) as members of a territorially circumscribed society.⁷¹ Such public goods may equate to what Alan Gewirth referred to as basic wellbeing, which comprises the natural⁷² rights to essential conditions such as life, physical integrity and mental equilibrium, without which it would be difficult or impossible to

⁶¹ *Ibid.* pp. 115-119.

⁶² *Ibid.* pp. 102-103.

⁶³ ‘As if when Men quitting the State of Nature entered into Society, they agreed that all of them but one, should be under the restraint of Laws... This is to think that Men are so foolish that they take care to avoid what Mischiefs may be done to them by *Pole-Cats*, or *Foxes*, but are content, nay think it Safety, to be devoured by *Lions*’; Locke, J. 2003 (1698). *Two Treatises of Government*. Laslett, P. ed. with an introduction by. Cambridge. Cambridge University Press. p. 328.

⁶⁴ Capps, *op cit.* note 59.

⁶⁵ F. Michelman. 2003. Constitutional Legitimation for Political Acts. *Modern Law Review* 66: 1-15.

⁶⁶ Rawls, *op. cit.* note 6, see: ‘Lecture IV: The Idea of Overlapping Consensus’.

⁶⁷ *Ibid.* pp. 421-433.

⁶⁸ Gewirth, 1978, *op. cit.* note 5, s. 4.4.

⁶⁹ Of which Rawls explains in detail; *supra.* note 6, *passim*.

⁷⁰ This includes the having of rights indicative of social and political wellbeing; see: Kalleburg, A. and Preston, L. 1975. Normative Political Analysis and the Problem of Justification: The Cognitive Status of Basic Political Norms. *Journal of Politics* 37: 650-684.

⁷¹ Buchanan, J. 1968. *The Demand and Supply of Public Goods*. Chicago. Rand McNally. p. 49.

⁷² On the natural-law and positive-law approaches, see: Beyleveld, D. and Brownsword, R. 1994. *Law as a Moral Judgement*. Sheffield, Sheffield Academic Press. esp. Chapter One and *passim*.

achieve, or have a reasonable chance of achieving, any purposes;⁷³ and basic freedoms, such as distributive and aggregative levels of 'justice', 'equality', 'crime control' and programmes of health care.⁷⁴ This may include tangible goods like food and housing; intangible goods, such as political security; and goods on demand, such as health care and legal representation. These goods are public, in the sense that they are generic (according to our definition of 'public', and which signifies those goods which are necessary for everyone, but which become an interest when denied to some). Thus, they are objects which on occasion require positive action by public institutions, and which cannot be sacrificed for an aggregate public benefit.⁷⁵

Thus procedural ethics includes the measures necessary to promote such 'common' goods (and negotiate the problem of 'free-riders'),⁷⁶ and the framework necessary to enable and support the equal having of such goods.⁷⁷ Policies that reflect the public good therefore both relate to certain goals that are in meaning consistent with community values (and not necessarily those which are identified and secured either by an aggregate or general will), and provide the mechanisms necessary for the consenting to, and thereby legitimate implementation of these values in society.

4. Interim Conclusion

The concept of 'public interest' has been central to many socio-political theories, but its usefulness as a guide to policy making has been damaged by an inability to remove it from transitional uncertainty and ephemera. The concern for the ethical rationalist is that the concept may personify moral subjectivity, and therefore bias and political uncertainty, if it is limited to a utilitarian calculus. The problem, as they see it, is that the defining focus is on process of government and aggregated opinions; and therefore politics is only about counting goals, one-by-one, and politicising those held by a majority.⁷⁸ The resulting 'public' policies become a majoritarian ethic, and any 'value element' is equated with voter (self-centred) choice, based on a preference for one's own interests.⁷⁹ Therefore, without a grounding ethic (which signifies a more concrete content than a 'pleasure over pain' calculus), the 'tyranny of the majority' risks overriding the interests of minorities.⁸⁰ While there is no evaluation of intensity or importance of the various interests, it is possible that

⁷³ Gewirth, 1978, op. cit. note 5, p. 53.

⁷⁴ This idea is most clearly reflected in natural law ideas of human rights. For Rousseau, '...respecting [natural] law is that, if it is to be a law, not only the wills of those it obliges must be sensible of their submission to it; but also, to be natural, it must come directly from the voice of nature'; op. cit. note 43, p. 46. This law was derived from: 'Two principles prior to reason ...our own welfare and preservation [and] ...seeing any other sensible being, and particularly our own species, suffer pain or death'; *ibid.* p. 47. Modern ideas of natural law – that law is naturally connected to morality, as opposed to being entirely separate (positive law) – focuses on the nature of agency (for rational beings to purposively follow moral prescriptions) rather than any particular religious doctrine; Beyleveld and Brownsword, op. cit. note 72.

⁷⁵ These may equate to what Rawls called 'basic liberties', which have 'an absolute weight with regard to reasons of public good'; Rawls, op. cit. note 6, p. 294.

⁷⁶ Harrison, op. cit. note 52, pp. 119-124.

⁷⁷ Gewirth, 1978, op. cit. note 5, p. 312-322.

⁷⁸ This may equate to Rousseau's 'General Will', which represents what the body politic (community of citizens) would unanimously do if they were selecting general laws and were choosing/voting with full information, good reasoning, unclouded judgment, public spirit, and attempting to discern the common (for everyone) good; *supra.* note 43, p. 192.

⁷⁹ Capps, op. cit. note 59.

⁸⁰ For the relativist, 'the majority' may be replaced by 'cultural norms', with the same results for opposition minorities; see: Nussbaum, M. 1993. *Non-Relative Virtues: An Aristotelian Approach*. In Nussbaum, M., and Sen, A. eds. *The Quality of Life*. Oxford. Oxford University press. pp. 242-269. In response to the Relativist claims, it is likely that the transient nature of consensus and agreement makes it impossible, or at least difficult, to gauge future and global interests beyond a case-by-case analysis, reopening the concerns of a 'cultural', *qua* majoritarian, ethic.

popular or more controversial interests (for example, only those reported in popular media) will be prioritised at a particular time, leaving unpopular or minority interests unexpressed. Understood in these terms, public interest originates little moral depth, and there is no way to assess the advantage of a 'shared', 'real', 'enlightened' or 'long-range' public policy.⁸¹ While there may be value in utilitarian procedural mechanisms to reach a *political point of view*, upon exit from the strict criteria of the calculation (if such a calculation is at all possible), procedural safeguards that protect individual rights must exist, and this all but destroys any purely utilitarian ethic.⁸² Despite Bentham emphasising universal suffrage, a utilitarian political system would not feasibly allow each agent to protect her interests in the face of public opinion.

The problem for ethical rationalists (and liberalists), conversely, is justifying prescriptive – some claim arbitrary – deductions about the rights every individual has, and ascribing to countless individuals common goals and aspirations. What is it that unites all human rights as public interest? How should society prioritise interests in full employment, the redistribution of wealth, or equal access to health care at point of demand? For critics, these nebulous interests do not sufficiently encompass the different needs and claims that we all have as individuals, thus making the existence of any natural rights a fallacy.⁸³

A similar argument may be directed at ideas of 'the public good'. As a descriptive value that is common to public unity, it represents a conception of 'good' beyond individual claims to material gains and limitless freedom. The problem is that like 'interest', this may be abstracted too far for the realities of policy, and thereby become a tyrannical project to locate nonexistent community values; and we still are left with the question of the conflict between various private moralities as comprehensive doctrines. If policy is to reflect a moral imperative as a standard, then it risks representing merely a 'superior good'; and this leads to, at best, paternalistic measures or, at worse, dictatorial authorities, on the grounds that no one is the best judge of their own interests.

Where does this leave us with regard to public interests and public good? A person's interests are (roughly) advanced when her opportunities to get what she wants are increased. The state advances these interests for everyone and without actively discriminating, by providing internal law and order; providing adequate 'goods', such as health, food and housing; and by installing public institutions that bear positive duties to society in providing these goods.⁸⁴ These goods are recognisably public in the sense that they are generic features of everyone's wellbeing and freedom. Individuals have a right to lay claim to these goods, and to demand, in some cases, duties to provide them. The *public good* therefore represents both the possession of goods which are necessary for a stable and flourishing social life in regard to a *corporate public body*, such as food, housing, clean water and healthcare which are necessary for a minimum level of wellbeing; and procedural aspects which justify governmental policies which prioritise the general welfare (i.e. generic freedom) over individualistic interests. It is therefore disingenuous to entirely separate interests from goods (although their particular natures should not be conflated). For example, having access to clean water is a public good, and while there is equal access to this resource, there is no *public* interest in redistribution; should the circumstances change, for example, during a drought, then plausibly, a public interest materialises for the government to take action, which may require the infringement of the rights of those who control that resource (i.e. to equitably redistribute the available water).

⁸¹ Sorauf, op. cit. note 30, pp. 620-621.

⁸² Capps, op. cit. note 59.

⁸³ Bentham, J. 2002. Nonsense Upon Stilts, or Pandora's Box Opened, or The French Declaration of Rights Prefixed to the Constitution of 1791 Laid Open and Exposed - With a Comparative Sketch of What has been done on the same Subject in the Constitution of 1795, and a Sample of Citizen Sieyès. In: Schofield, P., Pease-Watkin, C. and Blamires, C., eds. The Collected Works of Jeremy Bentham: Rights, Representation, and Reform - Nonsense Upon Stilts and Other Writings on the French Revolution, Oxford: Clarendon Press. pp. 318-401.

⁸⁴ Supra. Sec. 3.

Public policy should therefore not leave anyone dispositionally and irrevocably worse off, and it must advance the *collective* welfare of the public – as agents within communities, and communities within societies – in the long-term, rather than focus on the individual and occurrent welfare of any of its members. This may even extend to *future* agents, since the nature of community permits the conceptualisation of the past, present and future relationships between individuals. Policies should include rules of process for the recognition of and action to remove public harms (i.e. threats and risks to human rights infringements), and likewise mandate for the achievement of long-term goals (i.e. the fulfilment of certain duties), such as equal health care or a sustainable and nurturing environment. Fundamentally, public policy should aid the removal, rather than creation, of barriers to the enjoyment of generic goods. The task of institutions that operate in the public sphere is therefore to facilitate certain procedures that promote ongoing participation and partnership, such as independent ethical oversight, openness, transparency and accountability.⁸⁵ They must act with impunity from recriminations and accusations of bias, and must work to foster, rather than damage, public unity. In this way, ‘public’ refers to our – or everyone’s, including bodies and ‘institutions’ – conduct within a community, our civic duties, the restrictions in our actions, and responsibilities to others. Public policy is a collective decision made by a beneficent overseer, or government, which represents the community, rather than any one’s self-interest, inclination, opinion, or ideal.

It remains a concern that institutional action does not in fact ‘correspond to’, ‘promote’, ‘defend’, or ‘represent’ the public ‘interest’, since rarely will an interest motivate all citizens, and there will often be controversial issues which array parts of society against others. However, an assessment of ‘public interest’, if restricted to the more simply held (uncontroversial) interests, may indicate the societal norms which bind society. For example, while it is not clear whether embarking on a given ‘just war’ is in everyone’s interest, providing adequate health care is (although questions of rationing, for example, may become an interest for a specific group). Importantly, however, this provides a means to pry the ‘public interest’, such as social contractual agreements, from ‘special interests’ belonging to an individual or relatively small group;⁸⁶ thus public interests are distinguished from, and allow us to locate, actions which are advantageous to one person and disadvantageous to another.⁸⁷ As a pragmatic political phenomenon, the concept of public interest has the ability to direct attention towards often ignored group interests, such as equality and opportunity, and it locates the ethical standards which apply to every member of the community.

Conversely, issues of public good tend to push personal interest into the rear echelons of political decision-making. The purpose of just politics is therefore to somehow link the myriad of interests to ideas of ‘public good’ – which is plausibly defined as the moral good of tangible goods, political participation, justice, fairness, impartiality and liberty –,⁸⁸ and therefore create a robust criterion for political decision-making based on procedural processes that may offer a solution to complex disagreements. In this case, while consent may be the content of (i.e. is a good), *and* the procedural means to protect certain interests, it may be overridden in some ‘public’ circumstances. The *real* public good is, however, about ensuring that (every)one is in a position to *trust* that this is done openly, fairly and without discrimination, and that one is protected from public actions which are ‘sinister’ or obscure.

Thus, it is a public interest to provide the necessary procedures and institutions to settle disputes in an orderly and fair manner, and which provide an equitable respect for the way that differences divide us. Furthermore, we all require certain generic goods as political equals. There are two such goods which are important to UK Biobank: consent and trust.

⁸⁵ Campbell, op. cit. note 4.

⁸⁶ And which is often arrayed against; Braybrooke, D. 1962. *The Public Interest: The Present and Future of the Concept*. In Friedrich, C. ed. *Nomos V: The Public Interest*. New York. pp. 130-131.

⁸⁷ Cassinelli, op. cit. note 25.

⁸⁸ Blackstone, W. 1973. *Political Philosophy: An Introduction*. New York. Thomas Y. Crowell Co. p. 139.

One ethical standard is the ability to *consent* to actions taken in regard to one's interests. This standard is equally necessary for all agents (i.e. disregarding consent would plausibly harm any agent), and ensuring the procedural validation of consent *is* a public interest.

Consent, when linked to procedural justice, also becomes a public good (i.e. consent, so conceived, represents a requirement for generic freedom, and consequently generic rights), and enables one to interact with public institutions. This is further made possible through the maintenance of trust-relationships with such institutions. If seen as above reproach, a society is possible in which all persons affected (i.e. are in such relationships) can participate to make their wishes effective in the determination of public policy. This is true for public institutions such as UK Biobank, as well as government itself. While such participation must inevitably rely on majority (democratic) decision-making, the policies thus sanctioned cannot overstep the having of generic goods. Thus, while the government may dictate how such institutions operate, they cannot normally advocate for some to lose their 'rights' through participation. Fundamentally, participants cannot be disenfranchised to the extent that they are unable to challenge policies through approved procedural means, or to participate in the ongoing scrutiny and electoral approval of government policies. Society must be careful that 'public interest' is not used for 'sinister' interests that foster conflict or create further divides by denying or depriving some of necessary goods, but at the same time it must encourage private creativity without being paternalistically overbearing.

5. Summary

In Part One, we discussed in depth the concepts of public good and public interest. We argued that the aggregation of private wills does not equate to a public interest. Instead the public interest referred to the interests which were held by everyone, and which are not disadvantageous or advantageous to anyone in particular. We identified that such interests could plausibly indicate an advantage in having procedural systems which have the effect of empowering individuals to flourish (i.e. to give them opportunities and the means to protect their rights), and to allow government action to sometimes override individual freedom.

Now, the public interest may be identified as a system to which all reasonable individuals would approve. This system, as described by Rawls, is 'Justice and fairness', and which affirms basic rights on an equitable basis. Thus, the public interest, in its most general sense, could be located in systems that advocate the generic enjoyment of certain goods, and to which we all have a justifiable (and general) claim.

What are these goods? Gewirth argued that all agents have an equal claim to the preconditions of purposeful action, the so-called generic goods of freedom and wellbeing. Two such goods become important with regard to UK Biobank: trust and consent. The reason why these goods are important in this respect is that they provide for social cohesiveness, and they are necessary to enable citizens to flourish within a community. If one doesn't trust the institutions which serve the community, then plausibly, there will be a breakdown in the public interest of procedural justice. Likewise, consent, as a procedural guarantee against, and permission for, certain actions, would be lost if it was disregarded through institutional 'public' measures. In essence, without these goods, society would begin to fragment, and there would be no 'public' to speak of. However, it is also the case that social cohesiveness and community can benefit from balancing such goods with other benefits which may take priority in the public sphere.

In Part Two we discuss how these goods can be developed within the bounds of UKB policies.

PART TWO: PUBLIC INTEREST, PUBLIC GOOD AND THE OPERATION OF UK BIOBANK

1. Outline and Proposal for the Use of Public Interest and Public Good Regarding Access Decisions of UK Biobank

In Part One, we discussed in some detail the moral grounding of public interest and public good. We concluded that a person's interests are advanced by state action which provides for certain public goods. These goods are generically necessary for everyone's wellbeing and freedom. The public interest is therefore political guarantees, such as representation and institutional integrity (i.e. procedural frameworks which identify public concerns and allow opinions to be aired before policies are made), and the public good characterises those things that are necessary for a stable and flourishing social life. The having of such goods can be justifiably prioritised (when necessary) over individualistic interests. Furthermore, systems of interests and goods promote trust and accountability in the political machinery.

How does this reflect practically upon UK Biobank's (UKB) policies? Public goods are acquired and protected by the having of certain rights.⁸⁹ Earlier, we described Gewirth's argument that public goods equate to those things necessary for basic wellbeing, and without which it would be difficult or impossible to achieve, or have a reasonable chance of achieving, any purposes (such as food and housing, and procedural consent);⁹⁰ and basic freedoms, such as distributive and aggregative levels of 'justice', 'equality', and 'crime control'. It is highly plausible that such rights are given voice in the various human rights acts and conventions;⁹¹ although the exact derivation of them is more debatable.⁹² The most important rights in regard to UKB are those related to procedural justice, and specifically the prioritisation of *consent* (both as necessary for basic freedom and a procedural good), and *trust* that such institutions will avoid causing direct harm (or negative wellbeing) to participants.

If this link between rights (as a means to secure generic goods) and interests can be kept intact, then principles of content (what are the important rights and how should they be deployed) and principles of procedure (how does government implement and preserve them in policy, and inform and involve the public in policy making) become central to public policies,⁹³ and in this regard, provide the rules which honour, and in some cases, override consent.

In practical discourse, consent functions as a justificatory reason: on the one hand, *A*'s actions violate *B*'s rights without *B*'s consent (thus consent is a justificatory cover in relation

⁸⁹ Part One of this Report (P1), sec. 3.1.

⁹⁰ Gewirth, 1978, op. cit. note 5, p. 53.

⁹¹ Such rights are made visible in human rights law, and as such, UK law is dominated by human rights jurisprudence stemming from the *European Convention on Human Rights and Fundamental Freedoms* 1950; see: Beyleveld, D. 1995. The Concept of a Human Right and Incorporation of the European Convention on Human Rights. *Public Law Winter*: 577-598. For reasons given below, UKB, although a *private charity*, may be subject to the *Human Rights Act* 1998, in the sense that it plausibly acts *in the place* of a public body. Furthermore, it would be 'in the spirit of the law', or at least judicious (pending upon a future legal challenge), to take human rights seriously in regard to its policies. This is something like the rules and principles of law that Dworkin applies to 'Hard Cases', in which Judges are likely to use human rights (or other prevailing legal basis) in such cases regardless of a body's status; Dworkin, R. 1977. *Taking Rights Seriously*. New Impression with a Reply to Critics. London. Duckworth. Chapter Four.

⁹² Many human rights theorists cover common ground when deriving human rights, and many of the more popular accounts of rights, such as those of Gewirth, Feinberg and Dworkin, have similar origins and purposes; Capps, B. 2003. *UK and European Policy in Stem Cell Research: Proposals for the Ethical Grounding of Future Regulation*. Ph.D. Thesis. University of Bristol, UK.

⁹³ Lasswell, H. 1962. The Public Interest: Proposing Principles of Content and Procedure. In Friedrich, C. ed. *Nomos V: The Public Interest*. New York. pp. 54-79, at pp. 61-63.

to *A*'s actions and serves as a protection for *B*'s rights); on the other hand, *B*'s consent may strengthen what *A* can justifiably do. Therefore, in practice, the government and its institutions will take negative and positive action regarding interest (either critically or paternalistically) when it is sufficiently important to do so *and* on the grounds of what agents have or have not consented to. There may be cases when consent can be legitimately overridden (i.e. there may be a *rule* which society has indirectly consented to, such as reporting of infectious diseases without consent), and at other times, consent may be virtually absolute (in prohibiting what *A* wants to do), and violations will become complaints under human rights law.⁹⁴ Deciding political actions under an umbrella of consent is associated with mechanisms that encourage agents to trust that their consents will be normally honoured. The bounds of such consent will be guided by rules which promote interests directly, and as such apply to all agents under existing human rights law (i.e. that every agents' consent will or will not be honoured under *X* circumstances), or is limited to sectional interest (in effect, laws which define the limits of consent with regard to a given section or group of the community).⁹⁵ Where government actions become effective and justifiable under human rights law will be decided at a point at which toleration (of individual freedom) impinges upon certain upper and lower limits of enacted regulations.⁹⁶ For example, upper limits on permissible inequality, and lower limits with regard to basic education or degrading treatment.

Before discussing such upper and lower limits in regard to UKB, we will first discuss the context of UKB's operation. From this applied analysis, detailed provisions for accessing the UK Biobank resources, and which can be reflected in existing policy documents to aid decision-making, will be discussed in the final section.

2. Current Practice and Emergent Issues of Public Interest and Public Good

UK Biobank is one of a number of resources established with a purpose to collect and store biological and genetic data which may contribute to a national 'public' benefit.⁹⁷ Each has its own governance framework and operates to specific ethical standards and cultural principles. The following is a descriptive assessment of the access policies of established banks of biological material and genetic and health data. Our purpose is to call attention to the lessons that can be learnt from their experiences, successes and failures; and these can be then used to illustrate the complexities and solutions to applying ethics and research governance policies.

There are a number of issues that can be identified and may be applicable to the UKB's access policies, which must be interpreted in light of the (changing) environment and circumstances in which it will be expected to operate. These issues relate to the risk of harm to participants, of which Nömpfer has identified three possible types – physical, psychological and informational.⁹⁸ For our focus on access policies, the second and third types are most

⁹⁴ The procedural function of consent is an immensely complex area, and is beyond the scope of this Report. We therefore suggest the UK Biobank considers commissioning a further Report to look at the nature of consent under UK and European human rights jurisprudence.

⁹⁵ Rees, *op. cit.* note 15, pp. 32-36.

⁹⁶ Lasswell, *op. cit.* note 93, pp. 74-75.

⁹⁷ There are a number of public and private biobanks being established around the world. In this Report, we will be concentrating on public and pseudo-public (i.e. UKB) biobanks. One of the major concerns for private biobanks is that many of their procedures, including those for consent, are often shrouded in secrecy. Some private biobanks, for example, consider key documents such as consent forms proprietary; and if companies go bankrupt, critics contend, tissue and DNA samples might be sold. In 2002, for example, a court in Japan auctioned off a human cell collection that a scientific society had used as collateral on a loan; Kaiser, J. 2002. Biobanks: Private Biobanks Spark Ethical Concerns. *Science* 298: 1160.

⁹⁸ Nömpfer, A. 2005. Open Consent – A New Form of Informed Consent for Population Genetic Databases. PhD. Thesis. University of Tartu, Estonia. Available at: <http://www.utlib.ee/ekollekt/diss/dok/2005/b17285835/nomper.pdf>, p. 39ff.

significant, since psychological harm refers to being exposed to unwanted information and the use of data for purposes that one may find offensive, and informational harm refers to a 'violation of personal integrity' as a consequence of research projects.⁹⁹ In this regard, issues of access may arise as a result of (1) the conditions of taking part; (2) future situations of conflict that may arise as attitudes to the distribution of limited and protected public resources; and (3) access demands from external forces.

2.1 The Conditions of Taking Part and Opting Out

The conditions of consent established in the biobank governance frameworks can have significant implications for the motivation to take part in such initiatives, and illustrate to various levels, the elevation of either private or public benefit. For most bio- and gene banks, the process of enrolling participants (or 'donors', depending on, among other conditions, whether it is a one-off deposit, or participation is prolonged or somehow encouraged) begins with obtaining consent of one type or another. 'Valid' consent for each bank may include many pertinent and noteworthy factors, such as the conditions of agreement, e.g. facilities which enable participants to opt-out at various stages, and the level of information given regarding purposes, risks and benefits. The conclusions of these dialogues are normally the identification of willing participants – based on altruistic or personal benefit – who trust that the conditions of their consent will not be betrayed.

In this regard, the Estonian Gene Bank represents a balance between personal and public benefit, by allowing patients and their doctors to access their details at any time free of charge, and allowing participants to order the destruction of their donated samples.¹⁰⁰ However, the Icelandic Health Sector Database has raised significant questions with regard to standards of consent, since 'participation' was presumed and therefore explicit consent was not required. (In addition, the deceased would be included regardless of the concerns for living relatives.) There were provisions for individuals to opt-out unconditionally in the first 6-months, if they objected to their 'participation'.¹⁰¹

The UKB differs from both of these banks. Like the Icelandic bank, it is designated solely as a resource to study future health and illness. Campbell identified that the key motivation for participation in UKB was a combination of self-interest and altruism,¹⁰² but with little for participants to directly gain, the impetus was primarily driven through a manifestation of the solidarity principle.¹⁰³ One of the themes that underlie this was trust in those who oversee genetic databases of this type to ensure that the altruistic commitment is respected and honoured in the way in which such databases operate and are allowed to be used.¹⁰⁴ Thus, consent – which is active and generic in the case of UKB – is provided on the assurance that confidentiality and privacy rights will be prioritised over all other issues (including an active right to withdraw at any time). Participants will also 'take part' in the UKB through 'active engagement'. Furthermore, UKB (through the EGC) has publicly expressed the grounds on which research access requests will be ethically vetted,¹⁰⁵ and therefore has underscored its intention to protect participants from discrimination (through the resistance of the use of the resource for undisclosed purposes) and sensationalisation (avoiding the 'unethical' use of the resource for certain research enquires, e.g. questionable

⁹⁹ Ibid.

¹⁰⁰ See: Estonian Gene Bank: www.geenivaramu.ee.

¹⁰¹ See: Rose, H. 2001. *The Commodification of Bioinformatics: The Icelandic Health Sector Database*. London. The Wellcome Trust.

¹⁰² A similar conclusion was found in the Swedish Biobank experience; see: Kettis-Lindblad, A., Ring, L., Viberth, E. and Hansson, M. 2002. Genetic Research and Donation of Tissue Samples to Biobanks: What do Potential Sample Donors in the Swedish General Public Think? *European Journal of Public Health* 16: 433-440.

¹⁰³ Campbell, op. cit. note 4. p. 235

¹⁰⁴ Ibid.

¹⁰⁵ UK Biobank Ethics and Governance Framework. Version 2.0, July 2006. sec. II B. 1. p. 14.

research into ‘genes for...’;¹⁰⁶ and the careful management of tabloid reporting). The impermissibility for conditions to be attached by the participants themselves – but which are stated upfront by in the UKB’s policies to validate the *generic* consent given – uphold the altruistic understanding of *public interest*, i.e. that no individual participant can gain or influence who gains from their participation. UKB is thereby entrusted to defend the participants’ rights according to the stated policies, and which the participants have consented to.

2.2 Attitudes to the Distribution of Limited and Protected Resources

The second issue concerns the *balance* of public and private benefit. A (temporary) exclusive license is granted to deCode Genetics to use the data from the Icelandic Health Sector Database for commercial (private) purposes. This has raised serious complaints – especially in light of the conditions of presumptive consent – as a sell-out of *public resources* and the establishment of a monopoly. A similar concern was raised with regard to the Estonian Gene Bank, since although the data and samples are the property of the Estonian state, a US company called EGen had a 25-year exclusive licence for commercial utilisation of the database. This contract was terminated by mutual agreement in 2004.¹⁰⁷ Private co-investors are currently being sought.

The concern is that if biobanks are truly to be seen as a resource to benefit ‘the public’, then links to private enterprise (with perhaps conflicting goals), funding, and control, is questionable. The solution taken by UKB is to ensure that the separation from (and links to) industry are transparent, and that its research intentions are unambiguous. Thus, UKB is confirmed as a *private charitable trust*, with no visible influence or monopoly coming from private business. Funding is provided from *public bodies* and self-financing initiatives (e.g. charging for access).¹⁰⁸ The concern is, however, that even though samples and data will be stewarded by the UKB – and in this way the use and access to data and samples can be strictly controlled – the link to ‘other’ interests, whether they are industry (because they will, not objectionably, be granted use of it) or the current (indirect) *government* funding, and therefore government policies (declared or not), are not entirely severed.

This is particularly evident in the conditions of access of UKB, which are in line with current rules on Intellectual Property Rights (IPR) and protected material. In the case of IPRs, current UK and European laws permit temporary monopolies to control the use of inventions, including in the broad field of genetics. IPRs are one of the corner stones of the biotech-industry, allowing companies to recoup the costs of expensive research and development programmes while ensuring the investment needed to produce the therapeutic and diagnostic products of the future. They are widely accepted as a political and scientific means of striking a reasonable balance between the rights of inventors and the public interest. However, for the public healthcare sector there is a danger that IPRs may generate disproportionate claims from private right-holders, leading to undue restrictions and charges in licences and constraints upon further research and the distribution of benefits.¹⁰⁹ The

¹⁰⁶ Capps, B, and Nutt, D. Forthcoming, 2007. Cannabis and Psychosis: The Environmental Trigger. In: Nature or Nurture or Neither? Genetics in the Post-Genome Era. Proceedings of a Conference organised by the Galton Institute, London, 2006. London. The Galton Institute.

¹⁰⁷ Press Release from the Estonian Gene Bank. 2004. Genome Project Ends Cooperation with Current Financier. 27 December at: <http://www.geenivaramu.ee/index.php?lang=eng&show=uudised&id=172&PHPSESSID=07b67176bd44d4c7345cbfcc4cf783d0>. Accessed April 2007. This case differed from Iceland, however, since the Estonian government held 100% of the shares of EGen (through a Foundation).

¹⁰⁸ The first seven years will be funded jointly by the Medical Research Council, Department of Health, and The Wellcome Trust, after which funding will be entirely based on access charges and licenses.

¹⁰⁹ The UK Biobank’s Draft Policy goes somewhat to limit this by stating: ‘[the access agreement] will prevent the licensee using any future patents based on the licensed material to restrict research use of such material by UK Biobank or its users’; supra. note 2. This, of course, only refers to biological material and (presumably) data of which the Biobank owns; it does not stop users from filing patents

upshot could be unacceptable barriers against public access to medicines and diagnoses, curtailing the public healthcare sector's – including UKB's – ability to fulfil its primary role and commitment to public good, and restricting its own ability to generate healthcare products.

2.3 Forced Access

One of the fears for participants of large-scale biobanks is the use of mandated policies to release data for originally unspecified purposes for reasons of *public safety*, and which are motivated by either the securing of 'public goods' on the grounds of derogatable 'autonomy' rights or the assessment of the aggregate good based on utilitarian calculations.¹¹⁰ This concern is highlighted by the threat of terrorism being used by some to justify extreme intrusions into personal liberty (indeed, many find such a justification acceptable for the identification of perpetrators of any crime).¹¹¹ Others have argued that a DNA bank (possibly expanded from the samples contained in UKB) could be used for public benefit to identify victims of crime and major accidents, and to control pandemic disease.¹¹²

There is ample evidence that enforced access to biobanks by third parties is a realistic possibility. In 1999, a New Zealand Court permitted the police to obtain stored Guthrie cards of two suspected murder victims.¹¹³ Similarly, in 2003, a research biobank was used by police to identify the killer of Swedish Minister of Foreign Affairs.¹¹⁴ In this latter example, access was achieved via an existing loophole in the law. However, in January 2006, lawmakers temporarily changed the existing law (for an 18 month period) to allow access to biobanks in order to identify bodies of Swedish citizens killed in the Asian tsunami.¹¹⁵

However beneficial to criminal and identification proceedings access to biobank databases may have been in these cases, they demonstrate just how easy it is to obtain a special authorisation or the adoption of legislation in order to gain access to, and thus misuse (or not use for stated purposes), biobanks. A number of biobanks therefore expressly prohibit such forensic use by third parties. For example, the Estonia Gene Bank expressly prohibits the use of genetic data for 'civil or criminal proceeding or for surveillance'.¹¹⁶ This statutory restriction unequivocally separates the operation of the biobank from any other political priorities.

UKB has declared that it will resist any such claims by the police or other third party (and therefore is well aware that forced access is a realistic possibility), and as a matter of policy discloses to potential participants that overseas government authorities have in the past forced data to be released. In the UK, in recent years, the authorities have carried out certain activities that could be perceived as impinging on civil liberties.¹¹⁷ A case heard in

on their own discoveries stemming from this material (and where the real profits are going to be made).

¹¹⁰ Besson, S. 2005. *The Morality of Conflict*. Oxford. Hart Publishing.

¹¹¹ Head, M. 2004. *The Global 'War on Terrorism': Democratic Rights Under Attack*. In: Brownsword, R. ed. *Global Governance and the Quest for Justice: Volume Four Human Rights*. Oxford. Hart Publishing. pp. 11-32.

¹¹² Hansard Commons Debates. 2001. Title: *Coalition Against International Terrorism*. 4th October. Volume 372; Part No. 27.

¹¹³ Elkin, K. and Jones, G. 2000. *Guthrie Cards: Legal and Ethical Issues*. *New Zealand Bioethics Journal* 1: 22-26.

¹¹⁴ Hansson, S and Björkman, B. 2006. *Bioethics in Sweden*. *Cambridge Quarterly of Healthcare Ethics* 15: 285-293.

¹¹⁵ Anon. 2005. *Swedish Biobank Data Used to Identify Tsunami Victims*. *Nature* 433: 564.

¹¹⁶ *Human Genes Research Act 2000*; RT I 2000, 104, 685; § 16.

¹¹⁷ Article 8 of the *Human Rights Act* provides for everyone to have 'the right to respect for his private and family life, his home and his correspondence'. There is an exemption that allows for interference with the exercise of this right by a public authority; *infra*. note 118. Furthermore, personal information and samples are protected in the UK by the *Data Protection Act 1998* and the *Human Tissue Act 2004*, both of which contain exceptions that allow the police to access personal data and samples for the purposes of investigating crime. Public interest in medical law is most commonly associated with

the House of Lords tested whether the storage of biometric information on the UK National DNA Database (NDNAD) from two individuals, who were not convicted of any crime, was covered by Article 8 on the Right to Respect for Private and Family Life of the Human Rights Act.¹¹⁸ It was held that the mere storage (as against the dissemination) of private information was potentially within its scope, whereas the storage of DNA that would enable only identification (but not enable other information about a person to be gleaned from it) was not. However, even if the storage of DNA samples fell under the scope of Article 8, the purposes of law enforcement for which the samples in this particular case were stored amounted to a justification. It would therefore seem that in UK law it was permissible to infringe people's rights if this was done in order to protect the rights of others. Likewise, Sweden has strong privacy laws and traditions, but convicting an assassin was sufficient to sweep them away. Furthermore, there is evidence that public opinion and pressure to allow access can be favourable for the purposes of crime prevention, detection and investigation purposes.¹¹⁹

The concerns raised in this regard are serious for UKB, since, as noted in the Access Policy, a court order can force data to be released; and it would be further difficult to deny access, regardless of its adherence to protection of participants, if the weight of public opinion demanded it. The UKB should also monitor the surreptitious access to data through collaborations between biomedical researchers and criminal forensic scientists, and from the trend to promote international collaboration, and trans-national data and sample sharing. The concern is, on the one hand that volunteers have not consented to such uses, since, for example, 'crime prevention' or 'forensic identification' is not an express purpose of the UKB.¹²⁰ On the other hand, how far can the idea of 'public interest' be stretched within the bounds of the initial consent? Therefore, a careful analysis of the benefits of evermore complex research projects and collaborations should be considered. Furthermore, the degree to which enforced access is permitted with regard to catastrophic disasters and criminal behaviour requires urgent assessment, especially in the context of communities which are (reportedly) in such a heightened status of risk. To this end, how much potential public objection can be applied to the UK Biobank when it perceivably contributes to public threats, or unsympathetically adheres to policy and obstructs accident investigations?

the public and private interests in maintaining confidentiality and disclosure, such as in regard to commutable diseases. See: Kennedy, I. and Grubb, A. 2000. *Medical Law*. 3rd Edition. London. Butterworths. pp. 1090-1125.

¹¹⁸ *R (S & Marper) v Constable of South Yorkshire Police* [2004] 1 WLR 2196; for discussion see: Roberts, A. and Taylor, N. 2005. Privacy and the DNA Database. *European Human Rights Law Review* 10: 373-392. The case concerned whether the retention of fingerprints and DNA samples by the police of suspects who were charged but not convicted is compatible with Articles 8 and 14 of the ECHR. 4 out of 5 Law Lords found there was no interference with Article 8(1) 'Everyone has the right to respect for his private and family life, his home and his correspondence'. One found that there was some interference but that it was proportionate and justified under Article 8(2):

'There shall be no interference by a public authority with the exercise of this right except such as is in accordance with the law and is necessary in a democratic society in the interests of national security, public safety or the economic well-being of the country, for the prevention of disorder or crime, for the protection of health or morals, or for the protection of the rights and freedoms of others'.

The Law Lords also found there was no interference under Article 14 (the Right to Non-Discrimination).

¹¹⁹ Korts, K., Weldon, S. and Gudmundsdottir, M. 2003. Genetic Databases and Public Attitudes: A Comparison of Estonia, UK and Iceland. *TRAMES* 7: 4.

¹²⁰ Gostin, L. 2001. Health Information: Reconciling Personal Privacy with the Public Good of Human Health. *Health Care Analysis* 9: 321-335.

3. Threats, Safeguards and Enhancement in UK Biobank Access Policies: Using Public Interest and Public Good Effectively?

How can this conceptual analysis be used to create a framework for meaningful discussion of the ethical issues that emerge when individual and public interests are in potential positions of mutual support and conflict, and when 'goods' are enhanced or threatened by affirmative action?

In this final Part of the Report, we will apply the theoretical models of 'public good' and 'public interest' discussed in Part One, to the justifications of the UK Biobank's existing policies, and suggest how they perhaps ought to be developed further. Three issues come to the fore in this analysis: compliance with the Human Rights Act 1998, consent and trust, and managing intellectual property rights. These key issues are relevant to UKB's Access Policy and current practices discussed at the beginning of Part Two. In the draft Access Policy, priority is given to governing access on the grounds of 'public good'. In the policy, these are stated as (sequentially discussed in this Report, below): (3.1) ensuring compliance with legal and regulatory requirements; (3.2) protecting participants and honouring the commitments made to them and acting within the scope of their consents, which includes prioritising access to those parts of the resource that are limited in availability (particularly depletable samples); and (3.3) managing intellectual property rights in the resource and the results that flow from it.

The assessment of how 'public interests' and 'public good' can be employed within the terms of the policies developed by UKB involves contextualising them in the motivation of UK-based participation in the biobank initiative, and what is clearly ruled out by the Ethics and Governance Framework, which is based on principles of ethics agreed by the Board and the EGC in 2006. While the content of existing policy documents was dependent upon, among other issues, a prior critical assessment of the purpose of the UKB, our part-retrospective analysis will concentrate upon how it may best achieve its stated goals, and how its deployment of these policies can be optimised.

3.1 Compliance with Legal and Regulatory Requirements of the Human Rights Act

While it is important for UKB to show that its conduct is above reproach with regard to safeguarding the interests of persons falling within its domain of responsibility, its protective actions towards participants' rights are defined by compliance with statutory and constitutional legal requirements. On the one hand, these legal entailments may allow UKB to be infiltrated by enforced access, but on the other hand, they are also fundamental to the protection of participants.

The Human Rights Act 1998 covers all *public* bodies, and is firmly focussed on protecting rights concerning privacy, personal integrity, self-determination and non-discrimination. As a *private charitable trust*, it is not certain whether UKB comes under the Act. The Act covers private bodies 'of whose functions are of a public nature'.¹²¹ Examples

¹²¹ See section 6 of the Act. In *Aston v Wallbank* [2004] 1 AC 546, Lord Nicholls said that: 'Factors to be taken into account include the extent to which in carrying out the relevant function the body is publicly funded, or is exercising statutory powers, or is taking the place of central government or local authorities, or is providing a public service'. This issue has been recently addressed to ensure that individuals are not excluded from claiming their rights for the reason that a public service, or part of it, is delivered from outside of formal governmental bodies; 'Public Authorities 'What's in a name?', Human Rights News, Issue 2, November 1999, p.1. In this regard, The House of Commons Joint Committee on Human Rights recently stated:

'...during the last three years, there has been little evidence of progress towards an approach that gives effect to what we consider to have been Parliament's original intention to bring rights home for everyone, including those who receive public services delivered by private bodies. In view of the continuing trend towards the outsourcing of public services and the continuing failure to fill the gap in human rights protection, we consider that it has now become a matter of some urgency to consider what action is necessary to bring about a solution';

of private bodies subject to the Human Rights Act (currently confirmed in various legal cases) include privatised utilities that exercise public functions (e.g. Railtrack) and professional associations in their regulatory capacities (e.g. The Law Society). Charities may also count as public authorities if they provide services that would otherwise be delivered by a public body.¹²² There is apparently no clear test.

A second question concerns 'the spirit of the law'. According to Dworkin, 'Hard Cases' are where arguments exist as to the best understanding of the law.¹²³ In this sense, 'Does the person who skates on thin ice have a legitimate grievance when the point at which he falls in is not specifically marked so as to give him forewarning?';¹²⁴ or can a defendant who acts to avoid human rights law realistically (or, for his part, hope to) predict whether that activity would be considered as a breach of duty under the Act (or consider that a court will see it that way)? For Dworkin, it is more likely that the Judges will rely on prevailing law (in the case of the UK, the Human Rights Act) regardless of a body's status; and especially when there is uncertainty.

It does occur to us that the exercise of public functions is the test used to bring certain bodies under the remit of the Act. How the exact borders of that are patrolled is not clear; but put another way, it is fairly clear that the UKB is not performing a private function – it is collecting samples and data *from the public*, storing both, and allowing access by public and private bodies on the ground of *public* good. While it is not clear as to the status of UKB under the Act,¹²⁵ and (in light of suggestions that the private-public separation may be narrowed),¹²⁶ it may be pertinent to assume that its actions may be challenged under human rights law in the future. Indeed, human rights have now become so entrenched in UK law,¹²⁷ it may be argued that the continued private-public divide should be removed altogether.¹²⁸

The Act makes it unlawful for a public authority to act (or fail to act) in a way that is incompatible with the Articles. Assuming then that UKB may come under the Act, like all other public bodies, it will have a positive obligation to ensure that respect for human rights is at the core of its day to day work, and therefore must act in a way that positively reinforces the principles of the Human Rights Act. This will cover all aspects of the Biobank's activities, including drafting rules and regulations, its administrative procedures, processes of decision making, and policy implementation.

A welcome result of coming under the ambit of the Human Rights Act is that legal challenges to UKB's access policies must be referred to full judicial review; thus placing any

2007. The Meaning of Public Authority Under the Human Rights Act. Ninth Report of Session 2006-07. Report, together with formal minutes, minutes of evidence and appendices. HL Paper 77, HC 410. London. The Stationary Offices Limited. para. 11.

¹²² UK Biobank is jointly funded by a number of institutions which are classified under the Human Rights Act 1998 as public bodies. Furthermore, it may be argued that UKB is carrying out a duty that the Department of Health (or some other government institution) would normally do. Research Ethics Committees, who will vet individual projects prior to application to UK Biobank, are also firmly within the public realm. Additionally, UKB is situated within, and works closely with, UK Universities, which are another entity whose 'public' status is in question. However, 'Factors such as delegation from, or supervision by, a State body, public funding, the public interest in the relevant function or service being provided and the pursuit of the public interest as opposed to a pure commercial interest in profit are not in themselves likely to establish public authority status'; *Ibid.* para. 16. Interestingly (or worryingly) guidance for would-be public authorities on their status is limited to taking 'specialist legal advice' (*ibid.* para 27), and (as the question has not been solved at the highest of Courts) this is far from comprehensive or authoritative as advice goes!

¹²³ Dworkin, *op. cit.* note 91.

¹²⁴ Freeman, M. 2001. *Lloyd's Introduction to Jurisprudence*. 7th edition. London. Sweet & Maxwell Ltd. p. 1392.

¹²⁵ House of Common Joint Committee, note 121, Chapter Three, esp. paras. 67-69.

¹²⁶ *Ibid.* para. 112 & Chapter Four, esp. para 142.

¹²⁷ Beyleveld, *op. cit.* note 91.

¹²⁸ In the Preamble of the Universal Declaration on Human Rights 1948, arguably the document on which all modern human rights instruments are based, it is stated that 'every individual and every organ of society ...shall strive ... to promote respect for these rights and freedoms' (our emphasis).

formal policy decisions in the public realm.¹²⁹ By bringing questions of human rights to the fore, arbitration by independent Judges in regard to *both* UKB's policies and the Government's demands will be initiated. This would mean that criticisms of UKB will be aired in public courts; exposing unjustified policies (on the part of UKB) and challenges (on the part of government authorities) at the highest level.

It should be emphasised that the UKB's current policies, implicitly, and perhaps unintentionally, already reflect a commitment to human rights law. In this regard, one of its major achievements is to take a clear and open approach to ethical approval of its own practices and future research priorities by creating the EGE. Furthermore, its policies, which prioritise consent and ensure ongoing dialogue with participants, and 'vigorous' resistance to access by third parties (firmly placing any intention of forced access in the public sphere), are to be commended as installing trust.

A further step may be to publicly affirm its commitment to human rights as a means to secure public good, which already includes the positive affirmation of trust in procedural justice by the honouring (and protection) of participants' consent. By confirming its commitment to human rights, UKB not only accepts the prominent place that rights have in UK law in protecting – without prejudice – public interests, but also has at its disposal a means of securing equitable public goods for participants. The primary goal in this regard will be to back conditions of consent with the threat of legal prosecution under the Human Rights Act (and other laws). Any potential difficulties that this raises (i.e. that UKB wants to make samples available for a previously unspecified purpose) can be achieved by involving participants in ongoing dialogue; and if done properly, this will install trust in political (and UKB's) procedure.

Finally, enforced access may also promote public goods, as defined as elements of social cohesiveness.¹³⁰ For example, in the Asian tsunami disaster, third party access allowed authorities to identify victims, and also allowed family and friends to know the fate of their relatives and to mourn the dead. This brings many benefits to the community, and which there may be few objections from participants (if asked). Concerns may be expressed if such access became common and was non-consensual, such as the routine identification of crime suspects (it would also create problems if participants were regularly contacted via UKB for third party access). This plausibly would have the opposite effect by leading to distrust, and thereby social degeneration, in the intrusive actions of government institutions.

3.2 Consent and Trust in Access to the UK Biobank

It appears to us that there are two linked public goods to consider when protecting participants and prioritising access to those parts of the resource that are limited in availability. These are consent and trust.

Consent is popularly considered as essential – and even the touchstone – for any ethically acceptable medical practice;¹³¹ and has been a significant focus in the establishment of large-scale biobanks. In medical ethics, consent may take many forms, including informed, active (which the UKB currently favours), express and tacit; but in the context of biobanks, the type of consent used can highlight a number of moral and operative concerns.¹³² One of these concerns is placing trust that participants consent will be

¹²⁹ This is a common criticism levelled at the Human Fertilisation and Embryology Authority, which is seen by some to operate in a secretive and undemocratic way; see: Capps, Benjamin. 2007.

Bioethics, Procedural Ethics, and Misrepresentation in the Stem Cell Debate. In: Gunning, J. and Holm, S. eds. Ethics, Law and Society, Volume 3. Aldershot. Ashgate Publishing Ltd. pp. 25-38.

¹³⁰ See supra. P1, sec. 1, noting the comments of Dewey regarding common interests.

¹³¹ O'Neill, O. 2004. Informed Consent and Public Health. Philosophical Transactions of the Royal Society of London, B 359: 1133-1136.

¹³² Standard for justificatory purposes, a supposed consent must meet (at least) the following conditions: (i) it must be given by a "subject of consent", that is one who has the developed capacity, the present competence, and the relevant standing to consent; (ii) it must satisfy the conditions for a valid consent, namely by being given as a matter of unforced choice, with relevant knowledge and

honoured.¹³³ However consent is rightly conceived, it cannot be held to be valid if it turns out that participants ‘consent’ to something that they were not informed about from the outset.¹³⁴

In a detailed analysis of concepts of consent in genetic databases, Campbell finds a persuasive solution in Onora O’Neill’s description of consent as a feature of autonomous control; that the participants are enabled to have as much (or little) information regarding their consent as they decide is necessary.¹³⁵ While such a strategy favours the protection of participants, the implicit availability of autonomous permissions and conditions of opt-out as suggested by O’Neill, raises specific complexities in light of ‘public good’ and ‘public interest’; and for some, this raises the problem of the central reliance on consent in biobank protocols. The possible conflict may therefore be seen in two senses: one, that despite UKB’s commitment to benefiting the public good – and even in cases of ‘extraordinary public danger’ –, it has a prior role in protecting participants; and two, it may be undesirable to subjugate the public benefit to the extent that the participants *control* the resource.

Solving this problem may require shifting emphasis from autonomy, because it is inapplicable whenever the benefits to be provided are public – and not directly private – goods.¹³⁶ This is plausibly the approach taken by the Icelandic Health Sector Database in its no-consent/opt out strategy. If a participant’s data is included without her explicit say so, it seems unlikely that further permissions would be sought for any other current and future reasons. A second example may be the unrestricted (or non-consensual) access to the database by third parties. Thus donors (who are necessarily no longer ‘participants’) lack *any* control over the resource.

One way to interpret this approach is to firmly embed it in utilitarian logic:¹³⁷ the collective benefit (‘happiness’) befalling the public removes any requirement for individual consent, regardless of how unhappy they may be about it. In this regard, policies will be obligating society (and any powers we have of controlling our genetic and biological selves) to a majoritarian (democratic) will; and without question concerns regarding the protection of minority interests surface.¹³⁸ However, if we allow for this utilitarian solution, a more complex complaint may arise, since the non-consensual use of personal data would lead to the general undermining of trust and public confidence in public authorities, which for some would be the greater ‘public’ danger.¹³⁹ This latter Benthamite view would oppose dominant government control, since it may spell the ‘sinister interests’ that he wished to avoid.¹⁴⁰ This ‘calculation’ may mean that protecting procedural frameworks of political participation (which represent self-interests) would be at serious risk from the actions of a paternalistic and

understanding, and in circumstances of emotional calm; (iii) it must be signalled distinctly and unequivocally; and, (iv) it must have scope that is sufficient to cover the act for which justification is sought; Beyleveld, D. and Brownsword, R. 2007. *Consent in the Law*. Oxford. Hart Publishing. pp. 7-12, and *passim*.

¹³³ The concept of proportionality becomes important in this regard, i.e. that infringements of any rights should be proportional to the risks and benefits resulting from this infringement. Concern are raised about whether it is appropriate to infringe human rights for the sake of utility or whether the undeclared uses of UKB (i.e. not included in the original consent or expressed as a purpose) are compatible with the Human Rights Act.

¹³⁴ Beyleveld and Brownsword, *op. cit.* note 132, p. 130.

¹³⁵ Campbell, *op. cit.* note 4; O’Neill, O. 2003. Some Limits of Informed Consent. *Journal of Medical Ethics* 29: 4-7.

¹³⁶ Chadwick, R. and Berg, K. 2001. Solidarity and Equity: New Ethical Frameworks for Genetics Databases. *Nature Reviews Genetics* 2: 318-321.

¹³⁷ *Supra*. P1, sec. 2.1.

¹³⁸ *Supra*. P1, sec. 4.

¹³⁹ Since 1995, the NDNAD has quickly developed to hold the genetic profiles of over two million people. The DNA was taken without consent from a sizeable collection of the population; see: Williams, R. and Johnson, P. 2004. ‘Wonderment and Dread’: Representations of DNA in Ethical Disputes About Forensic DNA Databases. *New Genetics and Society* 23: 205-223. Tony Bair ‘...eulogised the DNA Database as a crime-busting tool. He called for the National DNA Database to be expanded to include every citizen’; Jeffries, S. 2006. *Suspect Nation*. *The Guardian*, 28 October.

¹⁴⁰ *Supra*. P1, sec. 2.1.

authoritarian government. The threat that this ‘tyranny of the majority’ represents would directly jeopardise – potentially on transient and reactive grounds – the primary status of the individual as a participating decision-maker, and would plausibly erode trust in government procedures (if they exist at all) to the detriment of community.

A possible second explanation may be found by linking personal consent to the ‘consent of the political-public will’. For Hobbes, consent was used to mean a mere coincidence of judgement or will.¹⁴¹ John Locke took this idea of a public consent two stages further: the first stage, as with Hobbes, is a natural ‘rational’ event in which everyone consents to ‘one body politic’.¹⁴² In the second stage, majority agreement becomes the decision-maker (since *unanimous* agreement ‘is next impossible ever to be had’).¹⁴³ Finally, in the third stage (which is presented as a natural progression), the people consent together to form a political ‘society’ with a common will to establish a democratic government that serves (or ‘preserves’) the public good.¹⁴⁴ Thus, implicit in Locke’s account is a utilitarian ethic in search of political resolution in locating majoritarian – intentionally constructed – agreement for the securing of public good as an expression of a single (qua everyone’s) will.

However, Lockian proceduralism is more sophisticated than the idea of utilitarian procedures discussed earlier; and significantly, trust becomes important: government (and by implication public bodies) are given discretion in deploying their duties, but they are entrusted with using their power for the public good.¹⁴⁵ To ensure that the public’s trust is not betrayed, government is tied down by rules, but it can act without prescription to and sometime against them in certain circumstances. Therefore, the problem for Locke, as it is with public authorities today, is how far this prerogative – ‘the power of doing public good without a rule’ –¹⁴⁶ can be stretched in the name of public good.

Locke’s account of consent encapsulates a sense of common will that may bind the ‘communities’ of a biobank’s participants and general public, and unite all in securing certain values;¹⁴⁷ but can we define what these values are? And who is to be the judge of the public good? Plausibly, harm prevention or personal and social safety are common values (or in Lockean terms, laws of nature prescribing measures to preserve ourselves and others), and therefore there may be grounds to secure them through paternalistic – governmental – measures.¹⁴⁸ Here we face a problem: that interests and goods of the public are not easily distinguished from the *common good* or *good for all*.¹⁴⁹ While it may be in the public interest to be protected from certain ‘public threats’, how far can this proceed before the value of trust in public authorities is dangerously eroded? Furthermore, how ‘extraordinary’ does the public threat have to be before an over-zealous government may justifiably undermine basic democratic protections? The question therefore is not one of resolving issues through transient head-counts, but a more fundamental evaluation of tangible human values such as freedom and liberty.¹⁵⁰

Both Hobbes and Locke turn to an idea of natural law to be the final arbiter in deciding the public good, thus locating the *logos* firmly in human rights. For Hobbes, our private wills *become* those of the sovereign, and therefore all political judgements are governmental and therefore public (and individual rights are subject to the will of the sovereign). This likewise applies to Locke: we consent to government and are thereby obedient to it. For Locke,

¹⁴¹ Harrison, op. cit. note 52, p. 119.

¹⁴² Locke, op. cit. note 63, sec 95; This equates to the Rawlsian idea of ‘overlapping consensus’ in which the basic conditions of democracy are laid down; see: Capps, op. cit. note 59.

¹⁴³ Locke, op. cit. note 63, sec. 98.

¹⁴⁴ Harrison, op. cit. note 52, p. 211.

¹⁴⁵ Locke, op. cit. note 63, sec. 159-160.

¹⁴⁶ Ibid. sec. 214.

¹⁴⁷ Supra. P1, sec. 1.

¹⁴⁸ Capps, op. cit. note 59.

¹⁴⁹ Supra. P1, sec. 2; Ashcroft, R. 2004. From Public Interest to Political Justice. Cambridge Quarterly of Healthcare Ethics 13: 20-27.

¹⁵⁰ Williams, G. and Schroeder, D. 2004. Human Genetic Banking: Altruism, Benefit and Consent. New Genetics and Society 23: 89-103.

however, the prerogative of government power is subject to trust, and if this trust is not properly used, then the people have a right to take it back.¹⁵¹

In this regard, Williams and Schroeder state: '[g]iven the predominance of commercial interests ...the grave danger exists that sample collections will be selectively exploited – worse still, exploited on terms set by commercial partners'.¹⁵² The solution for Chadwick and Berg is to ensure that humanitarian initiatives are prioritised which promote equitable benefits to society.¹⁵³ This echoes what we said previously regarding consent as an artefact of 'public good'.

Campbell argues that enrolment in the UK Biobank (because of its non-incentive condition of participation) is motivated by some altruistic sense of solidarity and commitment to the health of future generations. This major and long term commitment 'must depend both on a strong motivation to assist the project and a high level of trust in the organisation carrying it out'.¹⁵⁴ Therefore, to fail to use the resource for community benefit would be a betrayal of trust.¹⁵⁵ Campbell identifies three measures as essential for safeguarding trust:

- (1) Genuine participation and partnership requiring sophisticated and ongoing communication measures to create awareness of the ongoing development of the project by participants and to allow their input of future aims (but not in creating a form of control by participants);
- (2) Independent scrutiny to resist external pressures (for example commercial) to dilute the requirements of ethical governance and to maximise public reporting. Their role in access decisions is paramount since permission to use the resource contains ethical and well as scientific questions;
- (3) Public openness and accountability which ensures that decisions regarding the balance between personal privacy and public goods are met. Accountability makes it clear that the motivations of the stewards of UKB, through politicians and law-makers, to project scientists, are aware and respect the gift that participants have made, and that their consent and integrity are full appreciated and protected.

If our account of trust holds, then policies which demand informed consent should inform participants of the likely uses and access to their data. Participants are therefore empowered to give and withdraw consent in an ongoing relationship with UKB. (We here do not specify the exact type of consent to be offered, except that it should be *procedural* in the sense that participants are aware of the consent they have given and it is not given under circumstances of fraud or non-disclosure).¹⁵⁶ Participants who freely give data to a biobank to further public interests do not truly consent if it turns out that the institution is essentially serving private or third party interests. Resistance to non-consensual and forced access therefore seems justified for two reasons. Firstly, on the grounds that there is a realistic threat to basic rights and physical integrity. If we relinquish (fully) our rights to control access to our genetic data and body parts easily, there is a risk that others may benefit or exploit them without our consent, and there is a risk that this may develop to the extent that commodification will ensue. This process may lead to social relations being reduced to an exchange relation; thus the interests and goods of the individual, such as political and social freedom, health and wellbeing, will come second to monetary interests, leading to an inevitable disregard of human rights and the encouragement of exploitive practices. Secondly, this represents a public stand against paternalistic and authoritarian

¹⁵¹ Locke, op. cit. note 63, sec. 240.

¹⁵² Williams & Schroeder, op. cit. note 150, p. 100.

¹⁵³ Chadwick & Berg, op. cit. note 136.

¹⁵⁴ Campbell, op. cit. note 4. p. 241.

¹⁵⁵ Ibid.

¹⁵⁶ See: Kaye, J. 2004. Abandoning Informed Consent: The Case of Genetic Research in Population Collections. In: Tutton, R. and Corrigan, O. eds. Genetic Databases: Socio-Ethical Issues in the Collection and Use of DNA. London. Routledge. pp. 117-138.

actions in anything but the most extreme of cases,¹⁵⁷ since it is likely that they would lead to the erosion in trust in the fundamental value of democratic procedures and the ability for government institutions to protect public goods.¹⁵⁸

To reiterate, willingness to participate often entails a large degree of trust that the future of the biobank's resources will remain as stated from the outset. In respecting the participants' (or donors') consents, and to build community cohesiveness through trust-relationships, biobanks should also resist any close ties with potential conflicting interests, such as industry, or by overstating private, and not public, interests. This does not mean that UKB should not work with industry to promote public goods, but transactions should be conducted above reproach in line with the stated public interests.

3.3 Managing Intellectual Property Rights

Public interest and public good are central to the ethical management of intellectual property rights (IPRs) in the resource and the results that flow from it. On the one hand, IPRs may lead to a public good because it encourages and provides incentives for biomedical research, and therefore, for example, better health care. On the other hand, it also *limits* access and provides the means for researchers and developers to secure *exclusive* financial benefits. There is, therefore, a move to reform of the rules for incentivising research and maximising the means (and minimising the cost) of disseminating benefits to decimate the global disease burden.¹⁵⁹ According to Pogge, it *is possible* to manage IPRs in a way that research benefits remain in the public sphere and are not restricted by private patents.¹⁶⁰

Existing rules for incentivising biomedical research are morally deeply problematic. On the one hand, the need for industries to recoup their research-and-development investments is seen as an indirect benefit to the public, because without it, there would be little interest in assuming the costs of drug development. A free-market system would discourage innovative biomedical research, and therefore a temporary monopoly is justified because the inventor firm can recoup research and overhead expenses plus some of the cost of its other research efforts that failed to bear fruit. On the other hand, the present regime is not the lesser evil to the plight of the poor who cannot access expensive and protected medications;¹⁶¹ patents also operate to set a profit-maximising monopoly on products well above, and often very far above, the marginal costs of production.

But does this market solution benefit the public good i.e. provide the goods which benefit all without discrimination (therefore in the public interest)? Thomas Pogge is clear that such a system contributes to the ill health and poverty experienced by the majority of the world's population, and to this end proposes a radical overhaul of the current patent system. Realising that forcing lower prices on biomedical products is bound to fail – not least because differential pricing of products will create underground markets in supply and demand – Pogge makes a convincing argument for a *Public-Good Strategy*. This strategy's

¹⁵⁷ We do not here define 'extreme' or 'extraordinary', although we are currently led to believe that such cases may become more 'common' due to the current political environment and media interest; see: Cash, H., Hoyle, J. and Sutton, A. 2003. Development Under Extreme Conditions: Forensic Bioinformatics in the Wake of the World Trade Centre Disaster. Pacific Symposium on Biocomputing 8: 638-653; Lawler, A. 2001. Terrorism: Massive DNA Identification Effort Gets Underway. Science 294: 278.

¹⁵⁸ Supra. P1, sec. 3.1.

¹⁵⁹ Pogge, M. 2006. Human Rights and Global Health: A Research Program. In Selgelid, M., Battin, M. and Smith, C. eds. Ethics and Infectious Diseases. Oxford. Blackwell. pp. 285-306.

¹⁶⁰ A related issue concerns an individual's rights to directly benefit from their contribution to the Biobank, and questions of state and private ownership of biotechnological inventions developed from donated material. Due to space, we cannot consider these issues here; see: Beylveled, D. and Brownsword, R. 2001. Human Dignity in Bioethics and Biolaw. Oxford. Oxford University Press. Chapter Eight.

¹⁶¹ Pogge, op. cit. note 159.

complexities are beyond this current Report. However, the basic argument is that by allowing pharmaceutical innovators the option to forego the conventional patent and to claim instead an alternative patent that would reward them, out of public funds, in proportion to the health impact of their invention, drug development would be driven towards the disease burden that is affecting the majority of people in poverty globally.

The Public-Good Strategy raises interesting issues with regard to the future patenting activities of UKB. Firstly, the current draft of *Policy on Intellectual Property and Access* suggests no new reforms to the current situation.¹⁶² Therefore, there is a question as to whether UKB's policies are only about how, within the current system, it intends to manage IPRs, or whether it has any role at all in the future guidance of moral strategies of patent regimes?

Secondly, should UK Biobank attempt to control future biomedical developments to ensure that they do contribute to the public good through its patent rules? As stated by UKB, it is possible that the requirement for remittance (which will eventually be the sole source of funding for UKB) could lead to financial players – rather than other users such as universities or charitable research institutions – dominating IPSs.¹⁶³

The answer to both questions partly resides in formulating a careful balance between discouraging researchers from using the resource because its patent rules are too restrictive or overly-penalise research innovation, and keeping UKB research and resulting developments in the public domain or at an accessible (fair) price. At present, UKB says nothing on this latter question, unless the data is produced *by* UKB, because IPRs will vest with the investigator. The UKB's provisions that limit patents on *materials* are partly relevant here.¹⁶⁴ However, this is unlikely to make significant inroads into the just distribution of wealth stemming from patents. An intriguing possibility is for UKB to assert IPRs under the terms of 'standard agreement'.¹⁶⁵ While UKB will not (normally) assert IPRs *on research* using the resource, this policy leaves open the possibility, in exceptional circumstances, that UKB may assert such rights. The difficulty here is assessing in which projects IPR claims will be made by UKB; and these must be made up front in the contract. Since IPRs are so important to industry, it is likely that many researchers will be put off by blanket claims to the *possible* IPRs deriving from research. These leads to further possible solutions, such as to prioritise access by public institutions, like universities, and allow patents to vest with them, or to charge higher premium and to limit IPRs for private business.¹⁶⁶ Any meaningful reforms in this regard are likely to come from outside UKB, but the goal of UKB in this regard is to ensure that any penalties for private business are not so over burdensome that they go elsewhere; and this may be partly achieved by proving that UKB is a unique and significant resource which provides a scientific and ethical service that is worth such concessions.

Answering these questions fully would require a two pronged strategy: one, theoretical study regarding how morality is connected to the law (and used in practice in UK law), since IPRs are essentially legal constructions,¹⁶⁷ and two, an empirical assessment of the actual requirements for industry to have IPRs and the real benefits that this has to the public (currently, opinion is often based on the industry's own assessment of its needs of special economic and legal status). Much of what the UKB can do, will reside in following UK, European, and TRIPS patent law.¹⁶⁸ Unfortunately, answers to both are beyond the scope of this present Report.

¹⁶² Access Policy, op cit. note 2, sec. 5.

¹⁶³ Williams and Schroeder, op. cit. note 150.

¹⁶⁴ Access Policy, op. cit note 2, sec. 5.

¹⁶⁵ Ibid. sec. 5.1.

¹⁶⁶ As suggested by the UKB's Ethics framework, op. cit. note 105, sec. 3.

¹⁶⁷ See: Beyleveld, D. and Brownsword, R. 1993. *Mice, Morality and Patents*. London. Common Law Institute of Intellectual Property.

¹⁶⁸ Ashcroft, R. 2005. *Access to Essential Medicines: A Hobbsian Social Contract Approach*. *Developing World Bioethics* 5: 121-141.

However, in the sense in which we have described ‘public good’ and ‘public interest’, and in context of an ethical patent strategy, there would (within the bounds of the law) be grounds to restrict access on the grounds of future IPRs. Thus, we would argue that the ‘standard agreement’ may be used less often than suggested. Within a utilitarian construction, if it could be proved that IPRs benefited most, then IPRs would be perfectly justified. However, for reasons given above (in sec. 4), we are sceptical that the starting premise is morally acceptable. Therefore, it could be defensible to discourage or to at least limit access to those with the primary intention for private benefit – unless they were willing to give up or share IPRs –, since it would not be conducive to the free availability of public goods; indeed, such goods, if priced too high, would become ‘private’ to a wealthy few.

We think that the rules that UK Biobank have created do serve a research benefit to the public, but that its tendency towards silence (or acquiescence) on matters of IPRs may cast doubts on its commitment to actual public benefits. In being seen to grant patents for industry unquestionably, for example, the benefits may be seen to be willingly given into the hands of ‘big business’ (and government sponsored private institutions) rather than remaining in the public sphere. On the one hand, it is possible that selling data from the resource to private interests, however construed, may be seen by the public as being detrimental to the sense of community that it is trying to foster (i.e. being a resource for the public good).¹⁶⁹ On the other hand, not only does UKB require an income, some granting of patents may also be in the public interest, because the common good is supported by the development and availability of the products of private research. A possible way to *guarantee* such benefits would be to have policies which state the role of private industry in regard to patent permissions and ensured access to the products.

4. Conclusions

In the final analysis, the optimal rules for accessing UK Biobank resources will be a careful balance between safeguarding the interests of participants and maximising public interest and the public good. If concepts of ‘public interest’ and ‘public good’ are to be useful in assessing competing claims for accessing the Biobank resources, they will need to be given specific definitions and accompanied by an explanation of how they are to be understood as compatible or incompatible with the interests of individuals in specific contexts. We therefore conclude that trust and consent can be prioritised through non-paternalistic measures that involve positive frameworks to involve participants *in* policy decisions, rather than protect them *from* the consequences of them.

It can be deduced from the existing terms of the UK Biobank’s Ethics and Governance Framework that a balance between individual and public interests is sought, but that the former are prioritised. However, it would be important to know whether the public would actually welcome a change in priority if the need allegedly arises for reasons of national security or other ‘public interest’, to grant access for non-health related purposes. This would have to be a publicised policy change, which could presumably follow a re-contacting of participants to determine their view of such a broadening of purpose. As we have stated earlier, the public interest and good arising from projects like Biobank depend crucially on the maintenance of trust in public institutions. This would be eroded if Biobank were forced to give in to ad hoc demands to override the terms of the original consent for transient (and debatable) benefits.

Any decisions regarding access prioritisation clearly must include both ethical and scientific considerations. In the case of the former, trust would be severely compromised if specific research projects led to harm either to individuals or to the society at large. The more intriguing question, however, is whether priority of access can be determined by forecasting which projects are most likely to result in maximising good outcomes. Some critics have claimed that biobanks are fundamentally useless because of unattainable goals

¹⁶⁹ See P1, sec. 1, noting Dewey’s definition of community.

(such as 'personalised' medicine).¹⁷⁰ Others disagree,¹⁷¹ and UK Biobank has itself stated what it envisages as the chief beneficial outcomes likely to emerge over the years from the project. However, judging the merits of specific applications (especially when they are competing for the same resource) will be an arduous and (arguably), somewhat subjective task. It will be necessary to judge all potential projects on a combined evaluative factor of their contribution to public good (i.e. contributing to the development of therapies useful in the public sphere), their scientific merit, and any risk of harmful social outcomes, such as sensationalised claims to effectiveness or discrimination against particular groups.

Finally, there is the intriguing possibility of using IPRs as a leverage towards public good.¹⁷² It is already known from public research leading up to the decision to fund Biobank, that the public are most uneasy about the use of an altruistic resource of this kind for purely private profit. While participants are made fully aware that commercial advantage may be gained from their samples and data (and also that they themselves will derive no financial advantage), there is no doubt that they have accepted this because of the belief that such commercial gain will also help to drive a gain to health for future generations. Thus we suggest that the EGC explore further the idea of an IPR policy which seeks to tie patents to clear public benefit outcomes.

In conclusion, we have argued in this paper that the EGC can encourage UK Biobank to be innovative in its approach to the concepts of public interest and public good as it spells out the details of its IPRs and access policy. There is a danger that policies will disproportionately focus on the negative effects of access, and therefore protecting the rights of participants comes to the fore. However, it is also possible that UKB can positively promote a more cohesive community by allowing, for example, third party access in limited cases and by clearly defining the benefits to the public of limited IPRs. The key elements of such an innovative approach are maintaining public trust in the enterprise as a whole, creating a trusting relationship between participants and 'the public' through ongoing dialogue, being open to changes in access policy, if these can be demonstrated to promote the public good, and articulating a clear set of criteria for prioritising access and granting IPRs.

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¹⁷⁰ Hagen, P. 2003. Biobank Reveals Ethics Framework. The Scientist Daily News (online), 24 September; Anon. 2004. £62m Biobank May not be Worth It. The Daily Telegraph, 6 September.

¹⁷¹ Collins, F. 2004. The Case for a US Prospective Cohort Study of Genes and Environment. Nature 429: 475-477.

¹⁷² Supra. sec. 3.3.