

Access to the UK Biobank resource: Advising on the public interest and the public good

Introduction

It is the role of the UK Biobank Ethics and Governance Council (EGC) to advise and monitor UK Biobank on its management of the resource, protection of participants' interests and, overarchingly, protection and promotion of the public interest. Moreover, it is a stated objective of UK Biobank "to manage the resource for the public good".

The EGC has commissioned two independent academic papers to help it in its role in advising on "public interest" and "public good". The first paper¹ provided a conceptual analysis of these terms ('the report') while the second paper² provided a survey of public attitudes to access issues more broadly ('the survey'). The papers are not documents of the Council and they merely provide background information to assist the Council in its work. The Council has extracted elements from these papers which it feels best inform its role and below we explain what these are and how they might feed into any advice to UK Biobank or decisions taken by the Council itself.

It should be noted that this document is a living instrument, by which we mean that it will change and evolve as the EGC develops more knowledge and experience of what "public interest" and "public good" mean in the context of UK Biobank.

Broader conceptual lessons

1. The conceptual analysis report states that the public interest should not be thought of as a conglomeration or amalgam of individual interests. Further it asserts that if measured as a sum of opinion, it can lead to uncertainty, whims and "tyranny of the majority".³

EGC opinion: This has lessons for the value attached to public attitude surveys and the way they are used to inform advice and policy.

2. Equally, the report states, it is essential not to attribute countless individuals with common interests, goals or attributes when this may be on an entirely arbitrary basis. The risk here, it is suggested, is that this view of public interest might equally lead to a tyranny, this time of non-existent community values.⁴

EGC opinion: This suggests that values informing a policy cast "in the public interest" must be described and justified.

¹ 'Access to the UK Biobank Resource: Concepts of the Public Interest and the Public Good'. Authors: Benjamin Capps, Alastair V. Campbell and Ruud ter Meulen (April 2008) Available at www.egcukbiobank.org.uk/meetingsandreports. (Hereafter: Capps *et al.*)

² 'Public attitudes to third party access and benefit sharing: their application to UK Biobank (Final report)'. Authors: Andrew Webster, Nik Brown, Conor Douglas, Graham Lewis, Jane Kaye, Richard Tutton and Nick Williams (June 2008) Available at www.egcukbiobank.org.uk/meetingsandreports. (Hereafter: Webster *et al.*) The public attitude survey was conducted on members of the general public rather than a selection of UK Biobank participants. The resulting views should not therefore be seen as representative of a person who has been through UK Biobank's consent procedure.

³ Capps *et al.* p13

⁴ Capps *et al.* p14

3. The report suggests that public interest may, rather, be seen as a system to which all, or a majority of, *reasonable* individuals would approve and which promotes accepted community values and goods while not leaving individuals disproportionately or irrevocably worse off.⁵

EGC opinion: **This reflects to a certain extent the system of human rights protection.**

4. The report states that public goods are those elements of social life which are generic features of our individual and collective well-being and freedom, such as health, food and housing.⁶

EGC opinion: **Scientifically robust and ethically sound health-related genetic research can count as a public good.**

5. The report suggests that the public good has *both* substantive and procedural aspects, that is, it is both about securing the tangible good in question, and about ensuring that there are procedures for taking and justifying decisions about attaining certain public goods (potentially over other public goods).⁷

EGC opinion: **This has implications for the nature of decision-making processes which will be deployed by UK Biobank and to which the EGC may have input.**

6. EGC opinion: **As a suggestion of relevant features of a system to which all, or a majority of, *reasonable* individuals would approve, the EGC might consider:**
 - a. **The need for a fully transparent process**
 - b. **The need to articulate the reasons behind decisions**
 - c. **The need to articulate the values that inform (prioritisation) decisions**
 - d. **The need for a scientific case to justify certain choices over others**
 - e. **The need for procedures of accountability**

7. The conceptual analysis report further suggests that *consent* and *trust* are public goods in the context of UK Biobank.⁸ It has even been mooted that not to use the resource to promote public goods would be a betrayal of trust because it was on this basis that the original consent was given by participants.⁹

EGC opinion: **This emphasises the important point that it is both in the public interest to maximise the utility of the resource and to ensure that this fully respects original consents of participants and bolsters trust.**

⁵ Capps *et al.* p16

⁶ Capps *et al.* p17

⁷ Capps *et al.* p12 - 13

⁸ Capps *et al.* p16 and 25

⁹ Capps *et al.* p28

Specific applications of these concepts to UK Biobank

8. Conditions of taking part and opting out: The conceptual analysis report endorses the approach adopted by UK Biobank, and notes that the altruistic basis for participation supports both the public good and the position that participants should not receive any personal (financial) gain from their participation.¹⁰

EGC opinion: **It is noted that the Ethics and Governance Framework takes a very participant-oriented position, and it is for further consideration how this might lie with future public interest and public good arguments. This should be borne in mind as the EGC proceeds with its work.**

9. Consent and trust and informing participants: The report suggests that the importance of all of these factors should be stressed and the specific recommendation is made that UK Biobank should be wary of close ties with bodies raising potential conflicts of interests, such as industry, or by overstating private, as opposed to public, interests.¹¹

EGC opinion: **This does not preclude collaborations but “transactions must be above reproach and in line with stated public interests”¹². This is a useful measure for the EGC in advising UK Biobank on any future collaborations.**

10. Human Rights Act 1998:¹³

EGC opinion: **The relevance of human rights to UK Biobank and the EGC should be borne in mind and the commitment of both bodies should be confirmed, involving, for example, participants in on-going communication and dialogue.**

11. Understandings and expectations of participants: The public attitudes survey points to a potential slippage for a minority of respondents themselves from ‘participant’ to ‘participant-patient’ (where some form of individual clinical benefit might be expected).¹⁴

EGC opinion: **While UK Biobank’s consent materials are explicit on the point that personal benefit should not be expected, and that the benefits will instead be for future generations, it would be a valuable exercise to explore in more detail participants’ expectations and understandings of their future involvement in the project, including those relating to personal benefit.**

12. Differences between age groups: The public attitudes survey involved two age groups, 18 – 30 and 40 – 69. The Council was keen to know whether different sectors of the public might have different attitudes towards access to a resource like UK Biobank. In the majority of circumstances the survey found no clear statistical significance between the opinions of the two age groups.¹⁵ No firm conclusions can therefore be drawn about any differences in opinion that might exist between the two groups.

¹⁰ Capps *et al.* p19

¹¹ Capps *et al.* p25

¹² Capps *et al.* p29

¹³ Capps *et al.* p23

¹⁴ Webster *et al.* p43 and 48

¹⁵ Webster *et al.* p44

EGC opinion: **The Council remains open, however, to the likelihood that different sectors of the public have different attitudes toward biobanks and, moreover, that these might change over time.**

13. Security of information: The public attitudes survey highlighted that respondents had more concerns over security of information held by biobanks rather than matters of anonymity and consent. The authors suggest that security is likely to be a key decisive consideration for potential participants.¹⁶

EGC opinion: **The EGC and UK Biobank have responded to these findings in a number of ways. UK Biobank provides regular biannual reports to the Council describing recent activities in relation to its data management and security systems strategy and UK Biobank acted on the EGC's recommendation to place more information about its security measures on its website. Security of information should be an area of ongoing vigilance for UK Biobank and the EGC.**

14. Judging applications: The conceptual analysis report states that "It will be necessary to judge all potential projects on a combined evaluation 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."¹⁷

The results of the public attitudes survey shows widespread support for UK Biobank and its current policies on access and intellectual property. In particular there was very strong support for the range of restrictions carried within the access policy¹⁸ and especially the importance of the role of the EGC in advising UK Biobank on matters such as direct access to biological samples.¹⁹

15. Attitudes towards distribution of limited resources: The conceptual analysis report makes the point that there is concern in some quarters about the involvement of private enterprise in genetic research and it highlights that intellectual property rights (IPRs) can be used to ill-effect.²⁰

EGC opinion: **This raises the important point for the EGC that IPRs are supposed to exist to promote public good (new innovation through reward) and that it must be vigilant that the UK Biobank access and IP policy is designed to promote the overarching public good.**

16. Intellectual Property Rights:

EGC opinion: **Both reports confirm that it is important that UK Biobank develop a clear, transparent, robust and reasonable access and intellectual property policy that is fit for purpose both to protect participant interests and to be sufficiently detailed, clear and fair for prospective researchers and users. By the same token, UK Biobank must reserve flexibility for itself to respond to new and changing circumstances.**

¹⁶ Webster *et al.* p43

¹⁷ Capps *et al.* p32

¹⁸ The study reflected on the content of the draft Intellectual Property and Access Policy (January 2005). This policy is currently under revision and the latest version was not available on the UK Biobank website at the time of writing. The principles which inform access to UK Biobank are contained in the Ethics and Governance Framework, available here: <http://www.ukbiobank.ac.uk/ethics/egf.php>

¹⁹ Webster *et al.* p43

²⁰ Capps *et al.* p20

17. Benefit sharing: The public attitudes survey found that a fees-for-access arrangement was seen as reasonable by the majority of the respondents within the focus groups once the practical implications of sliding scales of profit sharing arrangements or similar schemes had been discussed. There was however support for profit sharing where UK Biobank has made a material contribution to the intellectual property behind the new products or processes.²¹

EGC opinion: The EGC will be mindful of this in its discussions with UK Biobank regarding its access and intellectual property procedures. The Council intends to look in more detail at the practicalities of a profit sharing model (e.g. What are the pros and cons of such an approach? How would 'material contribution' be defined? What issues are at stake in determining a definition of a 'material contribution'? What factors should be considered by UK Biobank in deciding whether such a policy should be adopted?).

18. Access by international researchers: The public attitudes survey highlighted concerns amongst some respondents regarding access by international researchers.²²

EGC opinion: UK Biobank's participant information leaflet is explicit about the fact that international researchers will be able to apply for access, meaning that potential participants can decide, prior to giving any consent, whether or not they agree to this condition of participation. Notwithstanding, the Council considers it important to investigate participants' expectations regarding who will have access to the resource and has recommended that UK Biobank tests these expectations through a systematic post-visit survey.

The Council considers it necessary for UK Biobank to publish information that explains to participants which researchers have been granted or denied access and with respect to which kinds of proposal. This is an integral part of the project's commitment to maintain ongoing engagement with participants. This will allow participants to see the range of researchers who have access the resource and, for a participant who is, or has become, uncomfortable with the idea of access by international parties they may consider their right to withdraw from the project.

19. Forced access: UK Biobank has undertaken to resist requests for forced access, e.g. from the police.²³ The point is made in the conceptual analysis report that *undue* resistance may, in some circumstances, actually be seen in itself to be **counter** to the public interest, e.g. access in the advent of catastrophic disasters, terrorism or accident investigation.²⁴

EGC opinion: This may be important to bear in mind should any instance of forced access arise.

The public attitudes survey found that UK Biobank's current policy to vigorously resist access by the police or other law enforcement agencies was in broad terms supported by respondents but that there was also some ambivalence.²⁵ However,

²¹ Webster *et al.* p50

²² Webster *et al.* p50

²³ UK Biobank Ethics and Governance Framework (October 2007) Section II.B.1 p13

²⁴ Capps *et al.* p21

²⁵ Webster *et al.* p42

the authors also state that access by the police was seen as 'acutely problematic' in terms of the bank's public credibility.²⁶

EGC opinion: The Council's reading of the public attitudes survey is that there were counterposed views within the focus groups but that several respondents felt that if the police gained access this would have an impact on participants' willingness to continue their involvement with the project. Police or other law enforcement agencies can in practice access data held by UK Biobank if they have a court order. This is true of all medical research studies and UK Biobank is not unusual in this regard. The Council is satisfied that the participant information leaflet makes specific and sufficient reference to access by the police.

20. Re-contact: The public attitudes survey found that just over a third of respondents agreed that third parties should be allowed to contact individual participants in the future.²⁷ The authors suggest that this outcome might become a concern for UK Biobank in the future.

EGC opinion: When considering the issue of re-contact it is important to explore the purpose of re-contact. First, participants might be re-contacted by UK Biobank as part of its routine follow-up strategy (i.e. to collect more samples or information). Second, participants might be re-contacted by UK Biobank and asked if they are willing to give consent to be contacted by researchers directly (i.e. to be involved in separate research studies). In both cases UK Biobank will be the first point of contact and participants are free to decline further involvement.

UK Biobank's consent form specifically asks participants to agree to being re-contacted. The Council considers this to be sufficiently clear that potential participants who disagree on principle with being re-contacted can exercise their right to decline participation at the point of the initial invite.²⁸ For those who agree to participate in the knowledge that re-contact is a possibility, any future involvement (with UK Biobank or other researchers) is entirely voluntary. The Council endorses this policy as it gives participants a choice over their future involvement.

Notwithstanding, even if consent has been provided it is possible that the process of being re-contacted may be burdensome for participants, for example, there may be concern over the levels of re-contact or the reason for re-contact might raise anxiety (e.g. if the participant perceives that this is an indication of ill health). The Council is responsible for monitoring the rates of all re-contact in order to assure itself that participants are not being overburdened. The outcomes of the survey will be borne in mind as the process by which this monitoring occurs is developed with UK Biobank in due course.

21. International collaboration: The authors of the public attitudes survey suggest that the matter of the internationalisation of biobanking is an issue that UK Biobank and the EGC will need to prioritise in order to maximise the scientific returns from UK Biobank while still retaining public support.²⁹

²⁶ Webster *et al.* p47

²⁷ Webster *et al.* p41-42 and 47

²⁸ On average 90% of those invited decline to participate.

²⁹ Webster *et al.* p51

EGC opinion: **This highlights the importance of the EGC's continuing, active involvement with harmonisation initiatives such as the Public Population Project on Genomics, an international consortium that aims to promote collaboration between researchers in the field of population genomics.**

22. Developments in the external landscape: The authors of the public attitudes survey asserts that the work of UK Biobank and the EGC may be susceptible to a range of developments including those within the scientific and the healthcare information environment. Genetic ID systems and the growing market in online diagnostics are cited as two examples of areas that might impact on UK Biobank and/or on the motives of potential participants.³⁰

EGC opinion: **This highlights the need for the Council to keep abreast of developments in the broader scientific and policy arena and to consider the implications of such developments for the work of UK Biobank.**

³⁰ Webster *et al.* p51