



**Public Consultation on draft Access Procedures:  
Summary of responses and modifications**

UK Biobank Coordinating Centre  
1 & 2 Spectrum Way  
Adswold  
Stockport  
Cheshire SK3 0SA

Tel: 0161-475-5360  
Fax: 0161-475-5361  
E-mail: [access@ukbiobank.ac.uk](mailto:access@ukbiobank.ac.uk)

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## **Background to the Consultation**

UK Biobank's objective is to encourage the extensive and appropriate use of the UK Biobank Resource for all types of health-related research that is in the public interest by all bona fide researchers, without preferential or exclusive access for any person.

The aim of the Access Procedures is to reflect the Access Policy outlined in UK Biobank's Ethics & Governance Framework (EGF) and the undertakings given to participants when they agreed to take part. During its development, the EGF was the subject of considerable public discussion, as well as a public consultation in 2003.

The purpose of the consultation on the draft Access Procedures was to obtain the views of participants, scientists, members of the public and other interested parties on the proposed procedures for allowing access to the UK Biobank Resource.

## **The Consultation Process**

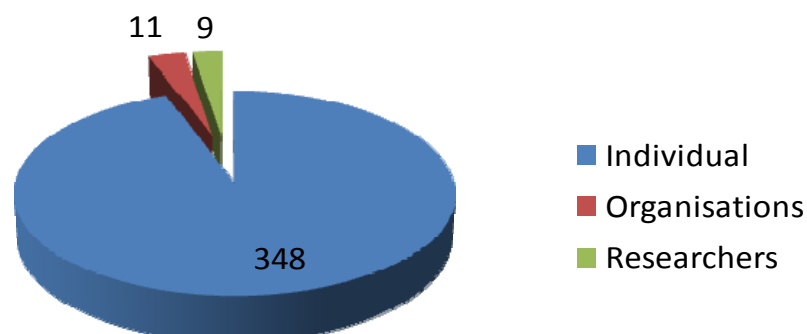
The draft Access Procedures and related consultation materials (including various illustrative scenarios) were on the UK Biobank website for review and feedback between 1 June and 6 July 2011.

UK Biobank promoted the public consultation widely:

- Plans for the consultation were highlighted in a newsletter mailed in early 2011 to all 500,000 participants (who were also encouraged to provide email addresses).
- Over 300,000 participants who had provided email addresses (either when joining the study or subsequently) were notified at the start of the consultation.
- Individuals and organisations involved with previous consultations on the EGF were informed of the consultation and asked to comment.
- More than 200 scientists, health research charities and groups involved in the biobanking and commercial research communities were also informed (including individuals or organisations that had previously been critical of UK Biobank).
- A letter "For Publication" about the consultation was sent to newspapers in the towns and cities from which UK Biobank had recruited participants.
- All recipients of the consultation materials were encouraged to forward details of them to any other person or organisation that they thought might be interested in providing comments on UK Biobank's proposals.

## Responses to the Consultation

UK Biobank received 368 responses to this public consultation. The vast majority of responses were from individuals, many of whom identified themselves as being participants (Figure 1). Nine respondents identified themselves as researchers and eleven were from organisations with an interest in health-related research.



**Figure 1: Responses to the consultation by category**

### Overview of comments received

Respondents provided comments not only about different aspects of the Access Procedures, but also about UK Biobank more generally. With the exception of respondents who indicated that they were satisfied with the draft procedures or who commented on access fees and security, no one issue generated a large number of comments. A significant number of the respondents raised more than one point.

The comments that were received have been grouped (Figure 2), although there is some overlap between the categories. Moreover, within most categories, a range of views on a number of different topics were expressed. For example, comments on “governance” covered issues related to public good, ethics review of applications, the composition of the Access Sub-Committee, and other governance-related topics.

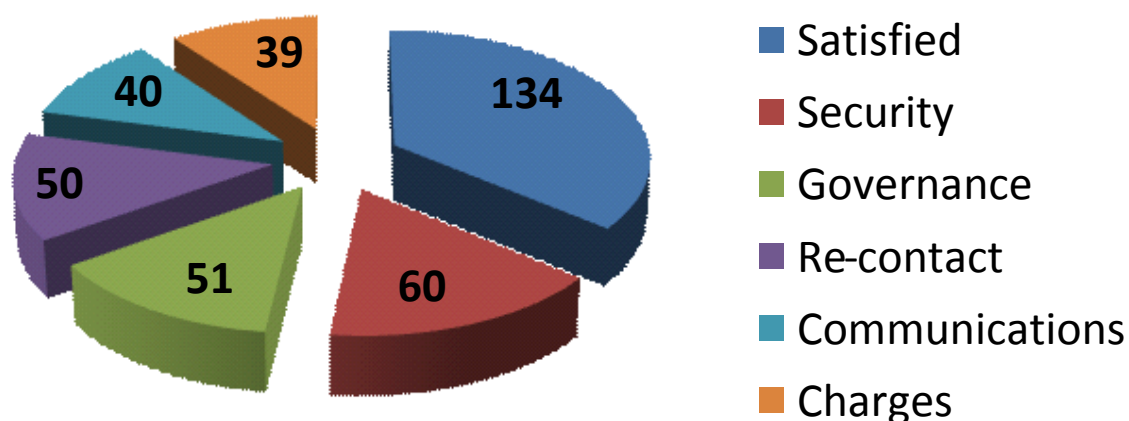
The numbers of respondents who made comments in different categories related to the access procedures themselves were:

- *Satisfied*: 134 respondents gave a clear indication that they were satisfied with the access procedures in their current form.
- *Governance*: 51 respondents raised a variety of different issues, as noted above, about the governance of access to the Resource.
- *Charges*: 39 respondents had concerns about the proposed access charges, chiefly that the fee for administration of the application process was too high for academic and charity-funded researchers or that commercial organisations should pay more for access to the Resource.

- *Access*: 27 respondents commented on access to the Resource, with institutions and researchers asking how competing applications might be managed.

With respect to the more general comments about UK Biobank that were received, the numbers of respondents who made comments in different categories were:

- *Security*: 60 respondents had questions about UK Biobank’s security systems and its commitment to keeping participant information confidential.
- *Re-contact*: 50 respondents expressed an interest in, or offered advice on, approaches to the re-contact of participants. Participants wanted to know how this would happen and what checks would be in place to protect confidentiality.
- *Communications*: 40 respondents made comments about various issues that were related to communications. In particular, there was a keen interest in being kept informed about the ways in which the Resource was being used.
- *Overseas/commercial researchers*: 19 respondents made comments about uses of the Resource by overseas or commercial researchers.
- *Contentious uses*: 16 respondents raised concerns about potentially contentious uses of the Resource (including by the tobacco industry).
- *Other responses*: 38 participants commented on their baseline assessment visit and 15 people provided information about recent changes in their health.



**Figure 2: Six most common categories of response to the consultation**

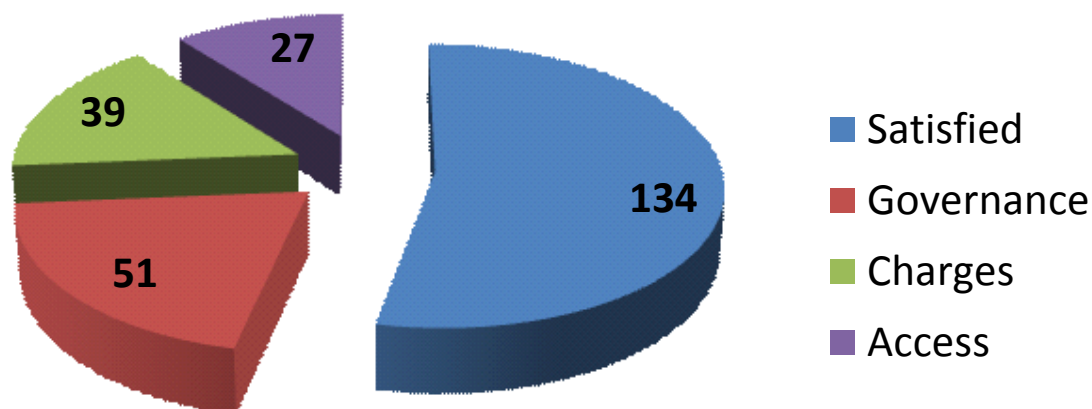
## Detail of comments within categories

There follows a more detailed analysis of the responses received by UK Biobank during the consultation process. These have been divided into comments of direct relevance to the Access Procedures and those more generally about UK Biobank.

For each category of comments, UK Biobank has provided an indication of what changes have been made to the procedures in response to the comments and/or has provided further information addressing the particular issues raised.

## Comments specifically on the Access Procedures

As indicated by Figure 3, a little over half of the comments that were related directly to the draft procedures provided support for what was being proposed.



**Figure 3: Comments relating specifically to the Access Procedures**

**(1) Satisfied:** 134 respondents gave a clear indication that they were satisfied with the draft access procedures.

- Very few expressed surprise at the proposed nature of access, particularly with regard to use of the Resource by researchers from overseas and from industry.
- 9 respondents were critical about the complexity of the access procedures or the accompanying materials. In addition, one organisation and one individual felt that a more detailed discussion about access should have taken place during the recruitment phase.

*UK Biobank response:* The aim was to achieve a balance between including enough detail in the procedures and the consultation documents for researchers who want to use the Resource and others who wish to consider how access is managed, while making them accessible to as many people as possible. The procedures reflect the policy that was contained within the Ethics & Governance Framework, as well as the undertakings given to participants when they agreed to take part, which derived from extensive consultation prior to the start of the project.

**(2) Governance:** 50 respondents raised a variety of different issues about the governance of access to the Resource.

- 2 organisations expressed views on the governance framework for the access procedures, with one indicating that it was not clear whereas the other stated that “the governance framework is transparent”.
- 4 organisations and 3 individuals suggested that the Access Sub-Committee might benefit from ethics and legal expertise. In addition, 1 organisation and 1 researcher asked about the independence of the Sub-Committee.
- 7 respondents raised questions about the need for ethics review of applications, and arrangements for seeking ethics advice on particular applications. Comments about “public good” or “public interest” were made nearly 20 times.
- One organisation had concerns about the impact of poor quality research using the Resource and the extent to which applications should be vetted.
- Some concern was raised about the potential for commercial exploitation of the Resource and how this might be addressed. One organisation said UK Biobank could give further consideration to “benefit sharing”.
- Questions were asked about sanctions that might be applied if researchers tried to identify participants. It was suggested that the Material Transfer Agreement be robust and that breaches be publicised. A question was raised about how conflicts between UK law and that of an applicant’s country might be addressed.

*UK Biobank response:* There is no preferential or exclusive access to the Resource, with all applicants subject to the same application process and approval criteria. The Access Sub-Committee is responsible for approving all applications to use the Resource. It is to be chaired by a person with ethics and/or legal expertise and the members will be senior scientists with relevant expertise. UK Biobank has an arrangement to obtain independent ethics advice on applications as required. All researchers will be required to comply with the conditions in the Material Transfer Agreement, which is governed by UK law. The issue of benefit sharing will be kept under review as experience with use of the Resource is gained.

**(3) Charges:** 39 respondents had concerns about the proposed access charges.

- The majority of these respondents were concerned that the proposed charge for administration of the application process was too high for academic researchers. A significant proportion felt that asking commercial interests to pay more would be acceptable. One comment drew attention to the statement in the EGF that charges may be higher for organisations likely to derive greater financial benefit.
- A small number of respondents thought that the cost-recovery model was a good one and that the proposed fees were reasonable. But, concerns were raised by others that the application fee was excessive and might be a barrier to access. One respondent asked if there had been any scoping with regard to charges.

- Some respondents did not find the reasons given for imposing charges or for the proposed level of those charges to be clear, particularly since the preliminary stage was aimed at researchers finding out whether or not UK Biobank was likely to be able to supply the data and/or samples required for their research.

*UK Biobank response:* The proposed charge for making an application has been reduced to £250, with any additional costs (such as those related to providing data or samples) to be charged on a cost-recovery basis and payable only on execution of the Material Transfer Agreement for successful applications. UK Biobank will keep this policy under review, including the possibility of having different levels of charge for different types of user.

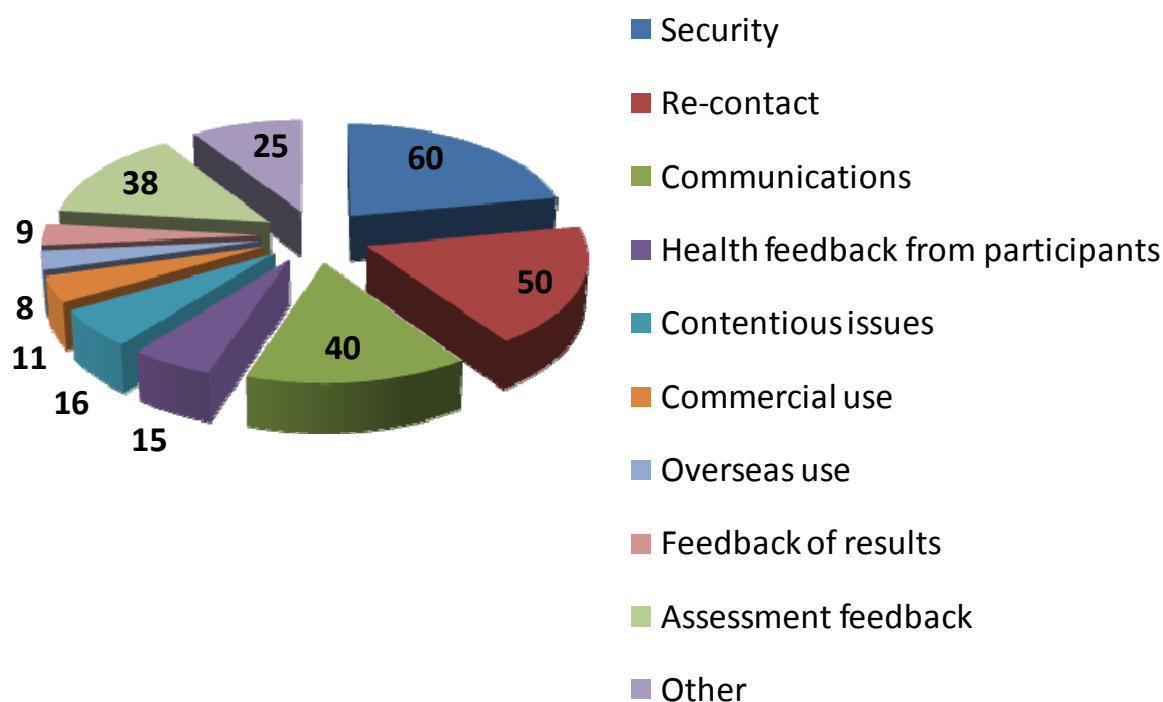
**(4) Access:** 27 respondents commented on access to the Resource, with institutions more likely to ask how fairness would be ensured in terms of access.

- There were concerns that the procedures may be too complex (detering potential applicants), especially for simple data requests. It was recognised that access needs to be regulated, but it should not be overly bureaucratic.
- Difficulties arising from a possible delay between the approval of a preliminary application and the submission of a main application were raised (for example when scientists need to secure funding).
- There were questions about how UK Biobank might ensure that larger and/or better funded organisations did not obtain disproportional access, and how decisions on the release of samples for competing applications would be made. Some respondents favoured preferential access for UK academic researchers over those from overseas or from the commercial sector.
- It was suggested that collaboration between researchers be encouraged and the release of data to more than one research group at the same time be considered.

*UK Biobank response:* The objective of the Access Procedures is to encourage the extensive and appropriate use of the Resource for health-related research that is in the public interest. Access to biological samples that are limited and depletable will be carefully controlled and coordinated by UK Biobank. From the inception of the project, it has been made clear that the Resource is to be made available to all bona fide researchers without preferential or exclusive access, including those working outside the UK or for commercial organisations. Such uses may well “add value” to the Resource by funding analyses of the biological samples which will then be available for UK scientists to use for their own health-related research. In response to comments about access to data, the procedures have been modified to indicate that different research groups may be provided simultaneously with the same data.

## Comments on UK Biobank more generally

With respect to the more general comments made about UK Biobank, Figure 4 shows that about three-quarters related to security, re-contact, communications and feedback of results, with some overlap between these categories.



**Figure 4: Comments relating more generally to UK Biobank**

**(5) Security:** 60 respondents had questions about UK Biobank's security systems and its commitment to keeping participant information confidential.

- It was expected that UK Biobank's commitment to anonymity would be stringently upheld. The use of the words "*as far as possible*" in the draft procedures with regard to maintaining confidentiality and anonymity troubled some respondents who felt this reflected a watering down of the project's original commitment.
- There was also interest in how anonymity would be protected during re-contact. Another asked what risk assessment mechanisms were in place to maintain anonymity if data were merged by researchers with other data sources.
- On the other hand, 7 respondents indicated that matters of anonymity should not necessarily get in the way of research. "*We obviously do not want to appear in the tabloids, but we are not as worried about full anonymity as some scandals have made the authorities believe we are*", one said.



- Some participants asked for more information about how their details are kept safe and about the systems that safeguard anonymity and prevent abuses. 8 individuals had concerns about hacking and a few suggested that UK Biobank staff could be a weak link. For example, one asked “*What safeguards are there against carelessness and sabotage?*”
- Some felt that UK Biobank’s commitment to preventing access by the police and other agencies needed strengthening. One respondent said it might be useful if examples could be provided of circumstances under which UK Biobank might be forced by the courts to allow access to the Resource. It was suggested that participants should be alerted if this ever became likely.
- Respondents expected UK Biobank to adhere to the Data Protection Act and to learn, where possible, from other organisations. Periodic review of the security systems and keeping up with advances in technology was suggested.
- The question of maintaining researcher confidentiality when initiating contact between scientists was also raised.

*UK Biobank response:* In order that the participants’ confidentiality and anonymity is properly protected, robust security systems are in place. All access to information that identifies participants is restricted and monitored. Regular external testing is conducted in order to identify any areas for improvement. All access attempts by the police or other agencies will resisted vigorously and reported to participants.

**(6) Re-contact:** 50 respondents expressed an interest in, or offered advice on, approached to re-contact of participants.

- Many of the individuals who commented on re-contact, welcomed such initiatives from UK Biobank and looked forward to taking part. But 2 respondents warned against “volunteer fatigue”, and it was recommended that such contacts not be too “*frequent, burdensome or worrying*”.
- The ability to re-contact participants in a controlled way was welcomed by one organisation. The need for scientific review of all research proposals that involved re-contact of participants was supported. It was suggested that UK Biobank ensure that participants understood why their further help was being sought.
- A question was raised about the maintenance of anonymity and confidentiality during re-contact. There was also concern that re-contact of participants might reveal health information to them that they did not know. For example, one person asked: “*what would happen if the purpose of re-contact was to do further research into the very condition that the participant did not know they had?*”

*UK Biobank response:* Proposals for re-contact will be the subject of careful review to ensure that the reasons for it are justified, that participants are not over-burdened and that inadvertent feedback of health information is avoided.

**(7) Communications:** 40 respondents made comments about various issues that were related to communications.

- Many of the participants who commented on communications expressed a desire to be kept informed about how the Resource is used and the results that emerge from it. For example, one said “*so we may feel good use is being made from our investment*”.
- One organisation suggested that UK Biobank be clearer on how it will engage with the public over the course of the project. There were six comments about whether participants would be involved directly in decision-making processes.
- One researcher suggested the provision of a list of universities granted access to the Resource. One individual said that UK Biobank should publish negative findings and those that might not be published (or receive publicity) elsewhere.

*UK Biobank response:* A new website for the project is being launched which will provide information about applications that are approved and the results that emerge from using the Resource. It is also intended that it provide a means for feedback and discussion by participants and the wider community on UK Biobank’s development. Regular newsletters will be sent to participants and, as necessary, possible areas of controversy drawn to their attention via the website, email and ordinary mail. All researchers will be required by the Material Transfer Agreement to publish their findings or make them available to UK Biobank so that they could be made public.

**(8) Overseas/commercial users:** 19 respondents made comments about uses of the Resource by overseas or commercial researchers.

- 8 respondents commented on access by researchers from overseas, with most expressing some concern. For example, two researchers suggested that UK researchers should have preferential access, and one was concerned that UK scientists would be at a disadvantage if it took them longer to obtain funding. On the other hand, one researcher said “*It must be right that the Resource is open to researchers from outside the UK.*”
- There was less comment about whether or not scientists from industry should be able to access the Resource. Some respondents expressed a lack of trust with the pharmaceutical industry, while another thought that use of the Resource by industry should be encouraged in order to help improve health.

*UK Biobank response:* As indicated in response to point 4 on Access, UK Biobank is committed to facilitating the widest possible use of the Resource for all health-related research that is in the public interest, without preferential or exclusive access. Use of the Resource by researchers working outside the UK or for commercial organisation was described explicitly in the information and consent materials provided to participants. Such uses may well “add value” to the Resource by funding analyses which will then be available for UK scientists to use for their own research.

**(9) Contentious uses:** 15 respondents had concerns about potentially contentious uses of the Resource (including by the tobacco industry).

- There was general support for UK Biobank's position that uses of the Resource by the tobacco industry would be resisted, and some respondents wished to see the policy extended to the drinks industry (and further).
- A few respondents were opposed to particular uses of the Resource: two did not want it to be used for animal-based research; one did not consider studies related to creating designer babies or "clinical suicides" to be acceptable. Others hoped that it would be used to support basic research or to test traditional medicines.
- Several of the respondents wished to be informed about possible controversial uses of the Resource that were being considered or were ongoing.

*UK Biobank response:* Potentially contentious uses of the Resource will be carefully considered by UK Biobank's Access Sub-Committee. Summaries of all approved applications will be placed on the project website, and those considered potentially contentious will be drawn to the attention of participants and the wider community.

**(10) Other responses:** There were a range of comments made about UK Biobank funding, the way in which samples are stored, and the project's scientific protocol. In addition, 38 participants commented on their baseline assessment visit, 15 provided information about recent changes in their health, and 9 asked about the possibility of feedback on their own health resulting from research undertaken on the Resource. Finally, some people did not comment on the Access Procedures, but instead just responded positively. For example: "*Thank you for your update*"; "*My pleasure, keep up the good work*".