MEDICAL RESEARCH COUNCIL AND WELLCOME TRUST
REVIEW OF THE UK BIOBANK ETHICS AND GOVERNANCE COUNCIL
JULY 2010

EXECUTIVE SUMMARY

The Medical Research Council and the Wellcome Trust aim to review major investments every five years. This report records the recommendations of an expert panel chaired by Professor Genevra Richardson, which was set up by the two funders to review the UK Biobank Ethics and Governance Council (EGC). The Panel's findings will form a key input into a review of UK Biobank initiative as a whole to be conducted in late July 2010.

Quality of past performance

The Panel concluded that overall the quality of the work by the EGC was high and provided good value for money. During the resource development phase the EGC had provided well-considered and valuable advice, most of which had been acted upon by UK Biobank. The EGC had added value to the development and modification of the Ethics and Governance Framework (EGF) to ensure that ethical issues that had arisen during the initiative had been robustly addressed.

The Panel agreed that the EGC's terms of reference remained appropriate and that it was vital that its central role in monitoring the EGF should be maintained. However, the Panel concluded that there was a need to clarify the different roles of the EGC and UK Biobank with regard to engaging with participants and the public. It agreed that the EGC did not need to place as much emphasis on public engagement in future. It also concluded that the research commissioned by the EGC had been of variable quality.

The Panel found the operational processes of the EGC to be effective and well-managed. The Panel noted that a full-time dedicated secretarial presence ensured continuity of contact for participants and, through delegation, enabled the Chair and the EGC to operate successfully. The current balance of expertise on the EGC was deemed to be suitable. Although no clear consensus was expressed on the optimal size of the EGC, the Panel considered that it could operate effectively with a reduced membership, as long as this reduction was phased in over time.

The Panel concluded that, although the relationship between EGC and UK Biobank was complex, it was effective and appropriate and enabled the EGC to maintain its independence. The system of non-executive enforcement had worked well and should be seen against the background of existing regulatory requirements and the potential for funder imposed sanctions. Good communication was critical to maintaining an effective working relationship and regular interactions between the Chair and the Director can greatly enhance this relationship. It would also be beneficial to establish an official point-of-contact at UK Biobank with whom the EGC Secretary could liaise on a routine basis.

Finally, the Panel specifically commended the exemplary chairmanship of Professor Graeme Laurie, and Professor Alastair Campbell before him, and the effective and capable work throughout by the Secretary, Adrienne Hunt.

Future considerations

The Panel concluded that it would be premature to expand the remit of the EGC beyond UK Biobank since the initiative was sufficiently large and complicated to require a specific body to advise on ethics and governance. However the experience and advice of the EGC was valuable and should be shared with other population cohort studies (and vice versa).

For the immediate future, the Panel felt the EGC should focus strongly on their work to ensure that the Access and IP Procedures are timely, robust and fit for purpose. Once the UK Biobank resource becomes available for access, sometime in 2011, the EGC will have to focus on monitoring the ethical and governance issues arising from access.

The Panel would like to refer the question of UK Biobank's in-house ethics expertise to the Review of UK Biobank itself. At present UK Biobank seeks ethics advice in an ad-hoc manner and the Panel would like consideration to be given to whether UK Biobank should obtain dedicated ethics advice on a contractual basis to assist with issues as they arise.

Summary of Key recommendations

- The core focus of the EGC should remain unchanged. Monitoring the conformity of UK Biobank with the Ethics and Governance Framework (EGF) should remain a central responsibility;
- The EGC should continue to be both reactive and proactive in advising Biobank. In the immediate future, the focus should be on Access and IP Procedures;
- The role of the EGC in public and participant engagement activities should be clarified in relation to the expectations of the funders and the EGC should not carry out an advocacy role with the public on behalf of UK Biobank;
- The respective roles, procedures and communications mechanisms of the EGC and UK Biobank should be clarified in a memorandum of understanding between the two organisations.
- A crisis management plan identifying responsibilities for resolution of controversial issues should be developed jointly with UK Biobank. This should be a priority in the EGC work plan;
- The EGC should retain its ability to identify policy or ethics research needs but should not itself undertake the commissioning of such research;
- The EGC Secretariat post is still justified and should remain full-time;
- The funders should consider how best to enable the experience of EGC to be shared with other cohort initiatives;
- Whilst other large scale cohorts might benefit from dedicated ethical advice, the time was not right to expand the EGC remit to advise other projects;
- The EGC should be reviewed in three years time (2013) to determine whether its remit remains appropriate.
- UK Biobank should look to secure in-house ethics expertise to allow it to both respond to emerging challenges and anticipate them.

BACKGROUND

1. UK Biobank is a prospective longitudinal cohort study of 500,000 individuals, aged 40-69. It was established in 2002 by the Medical Research Council (MRC) and the Wellcome Trust with the aim of providing a resource to investigate the genetic and environmental factors that contribute to the incidence of common diseases of adult life. It will be reviewed by the funders in late July 2010.

2. In 2003, an Interim Advisory Group (IAG), chaired by Dr William Lowrance, was tasked with considering the elements of ethics and governance under which the UK Biobank should operate. The IAG devised an Ethics and Governance Framework (EGF), a 'living document' that sets out the commitments and standards to which Biobank should operate during the creation, maintenance and use of the resource.

3. The concept of an ethics framework and an independent oversight committee for a prospective cohort study was novel but considered necessary for the following reasons:

   - increased public awareness and sensitivity to the kinds of scientific and ethics issues that were envisioned (e.g. extensive use of biological samples and other information, broad consent, security of data, and privacy implications for participants and their relatives);
   - the unprecedented advances occurring in bioinformatics and biotechnology;
   - the scale of UK Biobank and its status as an international resource;
   - the broad potential (and, to some extent, unforeseeable) uses to which the data and samples might be put in the future, which challenges the adequacy of traditional 'informed consent'; and
   - the potential for use of the data and samples for research leading to commercial profit.

4. In 2005, the funders handed ownership of the EGF to UK Biobank together with the responsibility for future updating and development. Decisions would be made by UK Biobank, with the UK Biobank Ethics and Governance Council (EGC) providing independent advice on revisions.

5. After public consultation and further development by the IAG, the MRC and the Wellcome Trust established the EGC as an independent committee in November 2004, under the chairmanship of Professor Alastair Campbell. At the time it was established it was seen as a world 'first'. The five core responsibilities of the EGC are to:

   - review in order to advise and report publicly on the conformity of UK Biobank's activities with the EGF;
   - consider and advise on revisions to the EGF that may be required to respond to changes in the legislative or regulatory context, developments in ethics or advances in science or technology;
   - advise on UK Biobank policies that relate to or flow from the EGF (such as those on recruitment, access, or complaints handling);
   - keep under review applications for access to the UK Biobank resource with regard to the interests of research participants and in accordance with the Intellectual Property and Access Policy; and

- approve any transfer of the UK Biobank resource (or substantial parts of it) to a third party, for example in the event of a liquidation, as set out in the Memorandum and Articles of Association of UK Biobank Limited.

6. The EGC was established to be completely independent of UK Biobank. As constituted, it is neither part of UK Biobank nor answerable to UK Biobank. Its remit is to:

   - act as an independent guardian of the UK Biobank EGF and advise on its revision;
   - monitor and report publicly on the conformity of the UK Biobank project with the EGF; and
   - advise more generally on the interests of research participants and the general public in relation to UK Biobank.

7. In September 2006, Professor Graeme Laurie took over the chairmanship of the EGC from Professor Campbell. Professor Laurie will stand down as Chair from January 2011.

REVIEW METHODOLOGY

8. The MRC and the Wellcome Trust convened an expert Review Panel to review the UK EGC, with membership as follows

Membership of the Review Panel	
Professor Genevra Richardson *(Chair)*	King's College London
Professor Mary Dixon-Woods	University of Leicester
Dr William Lowrance	Consultant in health research ethics and policy, France
Professor Veronica van Heyningen	MRC Human Genetics Unit, Edinburgh
Mr Hugh Whittall	Nuffield Council on Bioethics

9. The Panel endorsed the following terms of reference:

   - To consider the performance of the UK Biobank Ethics and Governance Council (EGC) in the light of evidence presented, which will include activities to date and responses to questionnaires completed by key stakeholders.
   - To consider how the EGC has fulfilled its role of assessing the compliance of UK Biobank with the Ethics and Governance Framework.
   - To consider in what ways the EGC has made a difference to and contributed to the success of the resource development phase of the project.
   - To consider any possible changes required in the operations of the EGC to enhance its effectiveness and value for money, including:
     - remit, membership and terms of reference
     - representation of, and relationship with, participants in UK Biobank
     - relationship with UK Biobank
     - role of the Secretariat
     - accountability
     - frequency of meetings
   - To make recommendations to the Funders over the future contribution of the EGC to UK Biobank, particularly in relation to arrangements for monitoring access and governance, as UK Biobank moves from the recruitment phase to the resource management phase.

10. The Review Panel met three times, in January 2010 at the beginning of the process; in May 2010 to interview the Director of UK Biobank and the Chair and Secretary of the EGC; and on 16 June 2010 to formulate recommendations to the funders.

11. The review included a commissioned internet survey conducted by the independent consultants People Science and Policy Ltd (PSP) (an Executive Summary of which is appended as Annex A). PSP approached 123 individuals, of whom 63 responded. More detailed follow up interviews were then conducted with ten of those consulted. Survey participants were from a range of sectors – including members of the UK Biobank Board and staff; current and past members of the EGC; potential users of Biobank; Biobank participants; ethicists and representatives from funding and regulatory bodies

12. The Review Panel's recommendations are based on the PSP report, the interviews with the Director, Chair and the Secretary; and the Panel's general discussions.

KEY FINDINGS

13. The Panel's findings are presented in four sections, which address the performance of the EGC over the past five to six years and plans for 2010-2015. These are:

- Operational framework – terms of reference, remit, meetings, membership, secretariat
- Activities
- Advice
- Relationships and communication.

1. OPERATIONAL FRAMEWORK

1.1 Purpose and remit

14. The role of the EGC was described by the Panel as one of helping to secure the 'social licence' for UK Biobank by acting as advisor on the interests of the general public.

15. In providing evidence for this review commentators did not propose any changes to the EGC's terms of reference. The Panel agreed that the terms of reference remained appropriate and were fulfilled well by the EGC, but felt there was a need to clarify the different roles of the EGC and UK Biobank in engaging with participants and the public. In particular, the Panel doubted whether it was appropriate for the EGC to engage directly with UK Biobank participants or 'the public' (this is discussed further in paragraph 42 below).

16. The Panel noted that survey respondents were generally positive about the purpose and remit of the EGC, although some seemed not to be fully aware of the EGC's role. In particular some respondents were unclear whether the EGC acted primarily as a watchdog or as an advisory body.

17. Whilst no data were available on the level of participant and public knowledge of the EGC, evidence was provided by UK Biobank that in the recruitment process

potential participants were reassured when they learnt of the existence and role of the EGC. The Panel thought that detailed knowledge may be less important than the ability to reassure those concerned that such a body existed, would represent their interests, and would monitor the integrity of the project.

18. The Panel felt that there was value in the EGC's ability to consider issues in detail. This full deliberation of complex issues was quite different from the approval process of a Research Ethics Committee (REC). The EGC's functions extend more widely than a REC and it can consider matters of emerging ethical and public interest.

19. The Panel concluded that while in principle other large scale studies might also benefit from dedicated ethical advice, in practice, with the access phase about to start, the time was not right to suggest expansion of the EGC remit to advise other projects. For the medium term, the EGC should continue to focus exclusively on UK Biobank. This does not preclude other studies from benefiting from the EGC's work.

20. The Panel did however accept that modification of the EGC remit could be considered once the transition to research use was completed. To assess whether this transition would be appropriate, the Panel recommends that the funders review the EGC in three years' time to judge whether the current purpose and remit remains appropriate.

21. The Panel endorsed the continuation of the central role of the EGC in ensuring that the EGF was followed and remained fit for purpose. It is important that the EGC should continue to think ahead and advise on necessary amendments. The Panel confirmed that it was appropriate for the EGC to choose the topics on which it provided advice to the UK Biobank, and that it was not helpful to draw too firm a line between monitoring and advising.

1.2 Membership

22. The Panel noted that appointment of EGC members followed the Nolan Principles for Standards in Public Life, in keeping with other bodies in the public domain. This transparency of process was appropriate for a body of this kind and operationally it worked well.

23. At the time of the review, there were 12 members, with expertise encompassing law, bioethics, philosophy, biomedical science, social science, consumer issues, management, the NHS and epidemiology. The span of expertise was open to adjustment, depending on EGC activities. The current balance of expertise on the EGC was judged to be appropriate by the Panel. It was noted that the independence and effectiveness of the EGC depends on the calibre of people serving on the Committee at any given time.

24. No consensus emerged on the appropriate size of the Committee during the review. The EGC submitted evidence in favour of keeping the council at 12 members on the basis that a breadth of expertise was needed, whilst other respondents believed that a reduced size would allow the Council to operate more effectively. The view of the Panel was that the EGC could operate successfully with reduced numbers (such as nine members) if the reduction occurred in a phased manner. If necessary, ad hoc expertise could be tapped for particular issues.

25. The Panel recognised that the EGC required additional expertise in bioinformatics and IT. Unfortunately the 2008 recruitment process and advertisement, which specifically identified information security as one of the priority areas for recruitment, had failed to find any suitable candidates. The EGC compensated by establishing an Information Security sub-group to examine the issues. The EGC has acknowledged that, if necessary, it may need to consider engaging external IT experts to inform its work.

26. While the Panel did not endorse the view that the expertise of the EGC was too theoretical in nature, it noted the importance of having members able to formulate pragmatic advice.

27. The Panel asked the funders to revisit the issue of honorarium payments. EGC members are currently paid an honorarium for attendance at the Council's main meetings but not for attendance at sub-group meetings. This may act to limit the participation of those who are self-employed or who need to take time from their annual employment.

1.3 Meetings

28. Currently the EGC holds four meetings a year, with an entire day set aside for the meeting. Opinions of survey respondents varied on the frequency of meetings and the Panel concluded that it must be for the EGC to decide what frequency of meetings would best meet its needs.

29. Most survey respondents thought that, in the interests of transparency, EGC minutes should be published. The Panel agreed and, while recognising that it is for the EGC to determine the precise format of the minutes, the Panel felt a shorter version would be welcome. The Panel recognised that it might be necessary to retain an 'in-camera' section of the meeting for particularly sensitive issues and that a suitable format would have to be found.

1.4 Secretariat

30. The EGC is supported by one permanent, full-time member of staff – the Secretary – who is employed by the Wellcome Trust and whose office is located in the Wellcome Trust headquarters.

31. The Panel found that the Secretary played an essential and central role in supporting both the committee and the Chair. The responsibilities of the post had included: administering the EGC (organising meetings, managing budgets, taking minutes), representing the EGC at selected external meetings, commissioning on the Council's behalf, supporting the Council in preparing papers, maintaining a website, supporting the recruitment and replacement of Council members, developing and managing procedures, and managing ad hoc Council activities.

32. The post holder, Adrienne Hunt, was congratulated on the high quality of her work.

33. The Panel agreed that the Secretary plays a crucial role in supporting the chair and it was anticipated that the new chair, who will commence duties in 2011, will also require substantial support. In addition, the constant EGC presence provided by the secretariat will remain important. In particular, the role of the secretariat will be critical in coordinating and implementing the crisis management plan (see

paragraph 43), once developed by the EGC and UK Biobank, and in monitoring the initial phase of access applications.

34. The Panel felt unanimously that during the coming phase a full-time post was justified, but that the post-holder might eventually take on some other duties in addition to serving the EGC.

2. ACTIVITIES

35. Since its inception, the EGC has engaged in a range of activities, including the development of advice (refer to Advice section below), creation of reports, holding open public meetings, provision of information through the website, convening of workshops and participating in external meetings.

36. The Panel noted that the transition of UK Biobank to providing access to the resource would require a change in focus for the EGC. This is discussed further in paragraphs 53-55.

37. With regard to commissioned research, the Panel:

- supported the view held by some survey respondents that the purpose of the reports commissioned by the EGC was not entirely clear, including how these reports related to the core work of the EGC.
- considered that the quality was variable and that the reports were rather too theoretical and aimed at too academic an audience. It was also unclear how widely the reports had been accessed or used. On the basis of the evidence available, the Panel was unable to ascertain whether this was because of the way the authors were selected or briefed, or how the process was run.
- noted that the EGC believed that the reports had helped to inform its activities. The EGC argued that their ability to commission independent work had contributed to the sense of the Council acting as a truly independent body. However, the Panel concluded that the reports had turned out to have been of less practical value to the EGC than had been anticipated. The ad hoc commissioning was not seen as a strength.
- recognised the value of the EGC's ability to identify issues for research. Accordingly, the Panel recommends that the EGC refers such proposals to the funders (or other appropriate bodies), for the funders to consider and commission themselves and that the funders acknowledge the EGC's entitlement to ask for such proposals to be commissioned.

38. The EGC has held open public meetings in cities where UK Biobank had recruited. But attendance has been low, ranging from 70 attendees in London in November 2005 and at the Edinburgh meeting in 2008, to 30 at the Cardiff meeting in February 2009. The Panel acknowledged that these meetings were regarded by the EGC as an opportunity both for the public and participants to explore their understanding and voice concerns, and for the EGC to gauge the interests of these parties and to consider whether they are adequately reflected in the Council's work programme. Topics that have been raised at public meetings include: international transfer of data, security of information, the assessment centre visit and whether samples would be used in the commercial sector. Frequently Asked Questions have been developed for the EGC website as a result of these and other interactions with the public.

39. The EGC also responded to public enquiries, with a recent example being an enquiry regarding the creation of human-animal admixed embryos. However, the

Panel noted that there was no clear policy on how to handle evidence or opinions from the public. This is important, as the strongly held and effectively voiced opinions (whether based on fact or otherwise) of a small number of individuals can pose a risk to the legitimacy and reputation of the project.

40. A well-attended workshop on public involvement was held in December 2009, of which a draft report was made available to the Panel.

41. The EGC has been represented at external meetings and conferences, with attendance at 35 external events. It also participated in the Population Project in Genomics (P3G), an international consortium committed to fostering collaboration among researchers and projects in population genomics.

42. In considering the EGC's involvement in public engagement, the Panel made the following observations:

- The EGC should continue to maintain a website with a FAQ section to provide easy access to information about the EGC and its work.
- While the 2008 mid-term review by the funders called for additional public engagement activities to raise the profile of the EGC, the Panel was not persuaded that it was either necessary or appropriate for the EGC to undertake these activities. Evidence before the Panel suggested that the EGC was most effective when engaging with its core activities.
- Public engagement and communication with participants should primarily be a role for the UK Biobank, with advice provided by the EGC. The role that the EGC should have with regard to engaging with the public was not clear from the remit of the EGC and this should be clarified by the funders.
- Where public engagement activities are deemed appropriate, opportunity should be sought for the EGC to work with the Wellcome Trust Public Engagement Team, and to draw on MRC and Wellcome Trust communications expertise.
- The EGC might like to consider setting up a standing panel of participants to help it to gauge views on, for example, the proposed enhancements. Such a panel could not, of course, be representative of all views.

43. The Panel recommend that the EGC and UK Biobank work together to establish a joint crisis management plan which identifies responsibilities for the resolution of controversial issues. This should be a priority in the EGC's work plan.

3. ADVICE

3.1 Record

44. The Panel viewed the independence of the EGC as an obvious strength. Whilst the quality of the advice it has provided was not analysed as part of this review, the Panel concluded that the EGC has clearly made valuable and necessary contributions to the development of UK Biobank.

45. A potential weakness raised by survey respondents is that UK Biobank is under no obligation to accept the EGC's advice because the EGC has no executive powers. The Panel observed that, in practice, UK Biobank had acted on EGC advice. In the event of disagreement the EGC has the option of communicating directly with the Board of UK Biobank, the funders and/or the press and the

public. It is therefore in UK Biobank's interest to resolve issues directly with the EGC, and this has been the case to date.

46. A primary role of the EGC is to comment on whether UK Biobank is adhering to the EGF and to advise on revision of the framework. Two revisions have been undertaken by UK Biobank since the management of the EGF was handed over to the Board of UK Biobank, the last revision occurring in October 2007. The Panel noted that the EGC had made a substantial contribution to these revisions, including the 'no further use' withdrawal option, and more recently, revisions to address possible consequences of enhancements to the protocol. Recently the EGC has advised UK Biobank on the need for revision of the EGF in relation to the development of the Access and IP Procedures, issues associated with re-contacting participants, and the (potential) imaging enhancements that UK Biobank proposes to undertake.

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47. It was not clear on the evidence available to the Panel that UK Biobank currently demonstrates full ownership of the EGF. To facilitate more active scrutiny of the EGF, the Panel, therefore, recommends that the EGC conduct a more regular dialogue with UK Biobank.

48. Advice provision by the EGC covers a broad spectrum and many different levels, from strategic to operational, and in each case may be reactive or proactive. This breadth is reflected in the details of reported activity:

    - Advice on policy covered areas such as equality and diversity of recruitment, the nature and frequency of re-contact for future studies, and risks of harm associated with participation.
    - Operational advice has been provided on the content of information leaflets, invitation letters and consent forms, and on standard operating procedures, and post-visit surveys.
    - The EGC monitored complaints, security provisions with respect to participants' privacy, and pilot studies.

49. UK Biobank confirmed to the Panel that the EGC's advice was highly useful even in the cases where there was an initial divergence of view. The Panel agreed with the view that a certain tension between UK Biobank's project management role and the EGC's remit to monitor the ethics and governance of the project was a healthy arrangement.

50. The Panel found that both UK Biobank and the EGC acknowledge that disagreement and tension surround the timetable for development of the Access and IP Procedures. UK Biobank considered that the EGC had exceeded its role in repeatedly calling for UK Biobank to produce this information. The EGC perspective was that the timetable mattered because from experience it took some time to reach a final, agreed policy, and that the policy had to be in place before access applications are considered (expected early 2011). The Panel thought that the EGC's stance was reasonable and it is within the Council's remit and expertise to advise UK Biobank on strategic timing.

51. The Panel agreed that the EGC would need to remain both reactive and proactive and to continue to focus on strategic, policy, and operational issues. It is crucial that the EGC retain the flexibility to adapt to a changing environment and the expertise to scan for scientific, technological and social issues that may affect the project.

52. The Panel questioned whether UK Biobank had sufficient access to in-house ethics expertise to allow it not only to respond to newly arising challenges, but to anticipate them. This question should be considered by the Review of UK Biobank. One way for UK Biobank to secure such in-house advice would be through a consultancy arrangement.

3.2 Future

53. The Panel advised the EGC to focus strongly on the principles of access and associated procedures in the immediate future. Reaching a final version of the Access and IP Procedures should take priority, now that recruitment was virtually complete. Other likely areas for EGC to comment on included: proposals for regulating the depletion of samples, criteria for re-contacting participants, requirements for publication, and the processes for returning research findings to the UK Biobank resource.

54. The Panel considered that once the UK Biobank resource becomes available for access, the role of the EGC should change from primarily advising on policy during recruitment to monitoring ethical issues arising from access. Possible aspects of the necessary monitoring include:

- overseeing the outcomes of the decision-making process: in order to retain a focus on overarching policy, the EGC should not make decisions on individual applications, but instead should see a summary of the applications.
- monitoring the access process: to advise on the dispute mechanisms established by UK Biobank.
- monitoring the public accountability of UK Biobank's access policy.

55. The EGC highlighted the importance of this monitoring role in its submission to the Panel and it envisages forming at least two new sub-groups to cover issues related to access and IP. In addition to matters directly related to access, areas of future EGC activity are likely to include information security and responding to UK Biobank initiatives.

4. RELATIONSHIPS AND COMMUNICATION

4.1 Relationship with UK Biobank

56. Good communication between the two bodies was agreed to be critical. From the evidence provided for the review it was clear that the EGC Chair played a pivotal role. Whilst the differing priorities of the EGC and the UK Biobank could cause friction, overall the relationship was judged to be effective.

57. There was seen to be merit in a system of 'soft', non-executive enforcement, not least because this 'soft' enforcement is set against a background of general regulatory requirements and the potential for funders to withdraw funding. The Panel agreed with the EGC that introduction of executive powers for enforcing EGC advice would compromise the independence of the EGC.

58. The Panel advised the EGC to nurture its complex relationship with UK Biobank. The relationship was to some extent determined by the personal chemistry between the Chair and the UK Biobank Director. The forthcoming appointment of a new EGC Chair would test anew the relationship between the two bodies.

59. On an operational note, it was of some surprise to the Panel that no equivalent contact person existed in UK Biobank with whom the EGC Secretary could discuss day-to-day matters, and that consequently most matters were escalated to the Director. The Panel advised the EGC that the relationship between the two bodies would benefit from more routine interchange at two levels: regular meetings or telephone discussions, even in the absence of specific 'problems' between the Chair of the EGC and the Chief Executive Officer of UK Biobank; and meetings or telephone discussions between the EGC Secretary and an appropriate member(s) of the UK Biobank staff.

60. The Panel found a lack of clarity in the relationship between the EGC and the UK Biobank Board, although the current Chair is invited to attend meetings and to make presentations. It would be helpful if the Memorandum of Understanding between the two bodies were revisited to see if any alterations are necessary.

61. The Panel learnt that no representative of the EGC was invited to attend the International Scientific Advisory Board (ISAB) meetings of UK Biobank which meant that the EGC gained no advance knowledge of likely scientific developments. The Panel saw this as a missed opportunity for both bodies.

4.2 Relationship with funders

62. The Panel noted that the relationship with the funders was arms-length, with both the funders and the EGC recognising the importance of maintaining the independence of the EGC. This was found to be appropriate, and the Panel saw no reason to change the current mode of interaction.

4.3 Relationship with participants and the wider public

63. The Panel gave careful consideration to the EGC's relationship with both UK Biobank participants and the wider public. This issue is discussed in paragraph 42.

4.4 Relationship with biobanking community

64. The evidence from survey respondents who were primarily connected to the biobank community suggested that many were not well informed about the purpose and activities of the EGC, despite the high profile of UK Biobank within this community. Nevertheless there was evidence that the activities and policies of the EGC have been picked up by initiatives such as P3G.

65. The Panel agreed that it was important to ensure that others who are faced with similar issues can learn from the EGC's experiences. Not all biobanking projects have the benefit of a dedicated ethics and governance oversight mechanism of this kind and the knowledge gained by the EGC could add value to other studies. The Panel recognised that there are various ways to achieve this. For example, the funders might arrange general or topic-specific workshops for information-sharing within the biobank community. Although important, this role is secondary to the EGC's core aims and should be prioritised accordingly.

66. The EGC submission had indicated the intention to explore links with the Human Genetics Commission so as to avoid any replication of activities and ensure complementarity of working. The Panel endorsed this proposal and agreed that it was beneficial for the EGC also to establish links with other advisory groups on an international level.

CONCLUSIONS

67. The Review Panel agreed that the EGC was of great value to the UK Biobank project and played an essential role. Past investment was well justified and had provided very good value for money overall. The EGC was to be congratulated on providing a model of excellence in governance world-wide.

68. It was clear to the Panel that the need to provide UK Biobank with independent, tailored advice and monitoring on ethics and governance remained. The Panel took the view that the EGC was the best mechanism to provide this advice for the medium term.

69. The next few years would be a pivotal period for UK Biobank, when research use of the resource would begin. The Panel recommends a further review in three years' time (2013) in order to consider whether the current EGC mechanism should be retained or should evolve into a different means of providing ethics and governance advice.