

**MEDICAL RESEARCH COUNCIL AND WELLCOME TRUST  
REVIEW OF THE UK BIOBANK ETHICS AND GOVERNANCE COUNCIL  
REPORT OF THE EXPERT REVIEW PANEL – JUNE 2015**

**Executive Summary**

The Ethics and Governance Council has worked successfully with UK Biobank and the Funders to steer the project through the set-up phase into the operational phase. During this time the EGC has become an internationally respected governance body that other biobanks have looked to as a model of good practice. That said, the landscape in the UK has changed for the UK Biobank and internationally, with more biobanks, and more specialized expertise available. The opportunity going forward is for the UK Biobank to further establish itself as an exemplar of the highest ethical standards of practice. The 7 Findings and 16 Recommendations contained in this report are offered in that spirit.

**Main Findings**

1. The Ethics and Governance Council (EGC) continues to be integral to the ongoing success of UK Biobank.
2. The Ethics Governance Framework (EGF) must be revised to reflect current activities of the UK Biobank and the revised responsibilities of the EGC.
3. As the UK Biobank has moved from a start-up to an operational phase, the EGC remit will need to be updated accordingly to address the ways it can and should provide advice on ethical issues as applied to UK Biobank policies.
4. The opportunity now exists for the UK Biobank to be more transparent in the way it fulfils its requirement to comply with the EGF.
5. The EGC is most effective and the UK Biobank is most productive when there are open and constructive lines of communication between the groups, and the respective Chairs in particular.
6. Given the overall changes in the biobank environment, and with UK Biobank in particular, certain changes will be necessary to support EGC operations.
7. Whilst the Panel concluded that the EGC should primarily be a body that focuses on UK Biobank, it recognized the need for a national approach to the ethics and governance issues relevant to all biobanks.

**Summary of Recommendations**

1. The Funders should continue to support the UK Biobank EGC consistent with the recommendations outlined below.

2. The Funders should initiate the process of revising the entire EGF soon, preferably within 90 days of the receipt of this report.
3. The Funders and UK Biobank should, with direct input from the EGC, jointly develop metrics against which the EGF can be assessed.
4. Revisions to the EGF should be considered periodically as a matter of good governance, at least every five years, and more frequently if a specific need arises. With advice from the EGC, UK Biobank and the Funders should identify the 'triggers' that should prompt and necessitate revisions to the EGF.
5. The EGC's Remit should be amended to reflect its updated function to advise the UK Biobank on what the EGC deems to be those issues and topics the UK Biobank should consider in developing its own policy.
6. That the EGC Remit be amended to reflect the practice that the recommendations it makes to UK Biobank should be seriously considered for adoption, with a mechanism available to the UK Biobank to indicate its intention to adopt or not adopt such recommendation.
7. That an Annual General Meeting (AGM) be established as a formal mechanism for public reporting, discussion and future planning of the UK Biobank.
8. That the occasion of the AGM should be used for a separate in-camera working meeting of the UK Biobank, the EGC, and the Funders to discuss and resolve any challenges that have emerged, and identify key issues to be worked on in the coming year. This should be a required meeting for the Funders, UK Biobank, and the EGC.
9. That planning for an AGM be jointly organised by the UK Biobank and the EGC, with the EGC taking the lead, in consultation with the Funders and that the first AGM should take place within the next calendar year.
10. A new Memorandum of Agreement should be prepared between UK Biobank and EGC that clarifies all aspects of their relationship including new responsibilities of the EGC as proposed in this report.
11. That a process be established by the Funders to recruit the new Chair with the advice of the UK Biobank, noting also that it would not be appropriate for UK Biobank to play an active role in the recruitment process itself. This process should continue to be in keeping with the Nolan Principles of Public Life.
12. That EGC membership should be reduced in size in accord with their new Remit.
13. With the AGM providing one required meeting of the UK Biobank and EGC each year, the number of additional meetings for the EGC may be limited, perhaps to two additional face-to-face meetings per year. Further, the EGC Chair should continue to attend UK Biobank

board meetings to keep abreast of the issues and raise those that he/she thinks the EGC needs to address.

14. Given the new Remit of the EGC, the Secretariat should be reduced from a full time to a part-time appointment.

15. The EGC annual budget should remain between £100,000 - £120,000 per annum, noting that a marginal increase may be required, to reflect the costs of holding the AGM. Consideration would need to be given for whether the AGM would need to be costed separately. However, this is a new model of operating for the EGC, so the budget will need reviewing by the Funders at the end of the second year.

16. The Funders should explore the idea of supporting development of a national EGC that would interface with all UK biobanks and cohort studies.

These recommendations are felt to be straightforward to implement, cost-neutral, and likely to ensure the UK Biobank remains at the forefront of translational science globally.

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A. Background

1. The Ethics and Governance Council (EGC) was established by the MRC and the Wellcome Trust in 2004 to act as an independent guardian of the Ethics and Governance Framework (EGF) of UK Biobank and to advise on the interests of the participants and the public more generally. At the time of establishment, both the concept of an ethics framework and an independent governance council were considered novel and necessary. The function of the EGC flows from the EGF.
2. The EGC was last reviewed in 2010 as part of a quinquennial funding review of the UK Biobank initiative as a whole. Although there was a recommendation by the 2010 panel that a further review should be undertaken in 2013, the Funders considered it prudent to wait until UK Biobank had been open for research for a reasonable period of time, around two years, before a further review should take place. (Due to issues of timing, this review took place independently of a review of UK Biobank). Once again, the Funders have convened an expert review panel, and the membership is as follows (full biosketches are available in Annex A).
  - Eric Meslin, Indiana University (Chair)
  - Martin Bobrow, Cambridge University
  - Jennifer Harris, Norwegian Institute of Public Health
  - Debbie Lawlor, University of Bristol
  - Jonathan Montgomery, Nuffield Council on Bioethics
3. The Panel understood their Terms of Reference (see Annex B) to focus primarily on the future direction of the EGC, using the information gathered about the EGC's activities and performance over the last five years, to shape their recommendations on how it should operate going forward. To that end, the Panel reviewed the 2010 Review report and decided that unless there had been a material change in the circumstances described in that report or the findings of that report, those areas will not be covered again in this report.
4. The review process included:
  - Review of the 2010 EGC Review Report
  - Written evidence submitted by the EGC
  - Written evidence submitted by UK Biobank
  - Report of cohort studies' interviews
  - Commissioned focus group work with a selection of UK Biobank participants to gather their views on the EGC
  - Informed input with known experts in the area (see Annex B)

5. The Panel carried out its work initially on email, then via teleconference, followed by a face-to-face meeting in February 2015<sup>1</sup> at the Wellcome Trust to interview the Chief Executive Officer (CEO) of UK Biobank, the Chair of the EGC, one past and one current member of the EGC. A debriefing of the EGC chair was provided by the Expert Panel Review Chair.

## **B. Panel Findings and Recommendations**

The Ethics and Governance Council has worked successfully with UK Biobank and the Funders to steer the project through the set-up phase into the operational phase. During this time the EGC has become an internationally respected governance body that other biobanks have looked to as a model of good practice. That said, the landscape in the UK has changed for the UK Biobank and internationally, with more biobanks, and more specialized expertise available. The opportunity going forward is for the UK Biobank to further establish itself as an exemplar of the highest ethical standards of practice. The Findings and 16 Recommendations contained in this report are offered in that spirit.

### **Continued Need for an EGC**

#### **Findings**

*The Ethics and Governance Council (EGC) continues to be integral to the ongoing success of UK Biobank.* The continued presence of an ethics and governance body is integral to the ongoing success of the UK Biobank project and provides necessary reassurance to both participants<sup>2</sup> and the general public. The Panel further concurs with the 2010 Expert Panel that the EGC's existence helped satisfy the informal 'social contract' between UK Biobank, participants and the public. There is both an important symbolic and practical requirement for large-scale studies of this kind to have a governance structure in place to provide an assurance to the funders, the research community and the public that the UK Biobank aspires to the highest ethical standards. That said, and as noted elsewhere in this report, the evolution of biobanking both domestically and internationally, coupled with increased research on ethical issues and dissemination of new guidance documents suggests that the original need for the EGC can be revisited.

#### **Recommendation**

1. The Funders should continue to support the UK Biobank EGC consistent with the recommendations outlined below.

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<sup>1</sup> Martin Bobrow was unable to attend the face-to-face meeting

<sup>2</sup> This was supported by the participant focus group work. Although none of the participants could recall hearing about the EGC, they all were positive when informed of its existence and that it was independent of UK Biobank.

## Updating the Ethics and Governance Framework (EGF)

### Findings

*The Ethics Governance Framework (EGF) must be revised to reflect current activities of the UK Biobank and the revised responsibilities of the EGC.* The EGF may be seen as a living ‘constitution’ for the UK Biobank project and as such is central to the functioning and legitimacy of the EGC and the UK Biobank project. The current version (v.3 October 2007) was written at the outset of the UK Biobank. Moreover, it is the UK Biobank in which the funders have vested responsibility for the EGF. That said, it is the Panel’s view that the current EGF has not been amended to reflect changes that have occurred since the operational phase has begun and is consequently out of date. Failure to update and modify the EGF where appropriate runs a risk of inhibiting the progress of UK Biobank. The Panel understands that UK Biobank plans to update the EGF following the completion of the Imaging pilot project. The Panel strongly endorses this plan.

### Recommendations

2. The Funders should initiate the process of revising the entire EGF soon, preferably within 90 days of the receipt of this report;
3. The Funders and UK Biobank should, with direct input from the EGC, jointly develop metrics against which the EGF can be assessed;
4. Revisions to the EGF should be considered periodically as a matter of good governance, at least every five years, and more frequently if a specific need arises. With advice from the EGC, UK Biobank and the Funders should identify the ‘triggers’ that should prompt and necessitate revisions to the EGF.

## Updating the Role and Function of the EGC

### Findings

*As the UK Biobank has moved from a start-up to an operational phase, the EGC remit will need to be updated accordingly to address the ways it can and should provide advice on ethical issues as applied to UK Biobank policies.* The current EGC Remit gives it authority to “act as an independent guardian of the UK Biobank’s EGF and advise on its revision”. UK Biobank is now fully operational, with studies underway, investigators making applications to use materials and data, and published studies being disseminated in the literature. Many of the issues seen as critical to the UK Biobank during its development phase, such as informed consent, are much better understood today. In most instances these issues have been adequately addressed as policy or procedure by the UK Biobank, and the EGC’s role is less persuasive. There are however, emerging issues in biobanking that warrant the kind of attention that the EGC could be equipped to advise about. As such it is appropriate to revisit the EGC Remit.

The Panel is convinced that some functions are not appropriate for the EGC to undertake going forward. These include:

- Reviewing and offering advice on research protocols and submissions to the UK Biobank;
- Monitoring active protocols and other projects, a responsibility that is most appropriately left to committees with authority and expertise to monitor ongoing projects;
- Auditing the activities of the UK Biobank to ensure compliance with the EGF a responsibility that is most appropriately left with the UK Biobank, for example under the auspices of an audit committee;
- Undertaking external engagement with UK Biobank participants (a view shared with the 2010 External Review)

The Panel means for this to be understood in three ways: First, that the EGC should use its expertise to identify emerging ethical issues in biobank research so as to advise the UK Biobank about the need to update or develop UK Biobank policy in response to these issues.<sup>3</sup> Second, that the EGC should be expert on the EGF so that any advice given to the UK Biobank reflects current expectations of participants, scientists and stakeholders, regarding the role and function of the UK Biobank. Finally, that any recommendations made to UK Biobank about change in existing policy, would be taken onboard by the UK Biobank and adopted, unless there were good reasons not to. Without specifying a timetable, the Panel is of the view that the UK Biobank should respond in a timely manner as to its plans regarding such recommendations.

The Panel envisions this function being operationalized through regular interactions between the UK Biobank and the EGC, in particular through close and constructive conversation between the UK Biobank, the EGC, and the Funders (See Recommendation #10); and in presentations made at the Annual General Meeting (See Recommendation #7).

### Recommendations

5. The EGC's Remit should be amended to reflect its updated function to advise the UK Biobank on what the EGC deems to be those issues and topics the UK Biobank should consider in developing its own policy.

6. That the EGC Remit be amended to reflect the practice that the recommendations it makes to UK Biobank should be seriously considered for adoption, with a mechanism available to the UK Biobank to indicate its intention to adopt or not adopt such recommendation.

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<sup>3</sup> To take one example, at the time of this writing (June 2015), the biobank community is engaged in an active conversation about CRISPR/cas9 (gene editing) technology and its ethical implications for science. We can envision the EGC providing relevant information to the UK Biobank about the applicability of the EGF to this type of research.

## Establishing a UK Biobank 'Annual General Meeting'

### Findings

*The opportunity now exists for the UK Biobank to be more transparent in the way it fulfills its requirement to comply with the EGF.* The Panel is of the view that given new developments in the science of biobanking, in light of the UK Biobank's capacity for domestic and international leadership in this area of science, and in view of the need for greater transparency in the relationship between the UK Biobank and the EGC that a greater emphasis on public disclosure of activities is warranted.

### Recommendations

7. That an Annual General Meeting (AGM) be established as a formal mechanism for public reporting, discussion and future planning of the UK Biobank. The specific purpose of the AGM would be to:

- Provide an opportunity for the UK Biobank CEO to give a public update – a “State of the UK Biobank” to reflect on accomplishments, strategies for future work and other relevant information including announcements of new policies, projects, or initiatives;
- Provide an opportunity for the EGC Chair to give a public update - a “State of the EGC” in which the Chair can report on the ways in which the UK Biobank is being responsive to the EGC, and the identification of emerging issues that may warrant further policy attention by the EGC;
- Provide the public and other stakeholders with a venue for inquiring directly about the overall function of the UK Biobank, the EGC and related matters;
- Provide the Funders with an opportunity to report on its impressions of the prior year and any emerging issues it foresees;
- Identify any areas of ethical concern that may need to be addressed to sustain the confidence of stakeholders, including participants.

8. That the occasion of the AGM should be used for a separate in-camera working meeting of the UK Biobank, the EGC, and the Funders to discuss and resolve any challenges that have emerged, and identify key issues to be worked on in the coming year. This should be a required meeting for the Funders, UK Biobank, and the EGC.

9. That planning for an AGM be jointly organised by the UK Biobank and the EGC, with the EGC taking the lead, in consultation with the Funders and that the first AGM should take place within the next calendar year.<sup>4</sup>

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<sup>4</sup> The Panel is not in a position to recommend specific planning details of the *in-camera* meeting or the AGM, but it is envisioned that the AGM would be jointly planned by both

## Building on the Current EGC/UK Biobank Relationship

### Findings

*The EGC is most effective and the UK Biobank is most productive when there are open and constructive lines of communication between the groups, and the respective Chair/CEO in particular.* During the Panel's deliberations the issue of the complexity of the relationship between UK Biobank and the EGC was repeatedly raised. The Panel also noted several examples in which regular interactions between the EGC Chair and the UK Biobank CEO enhanced the collaboration between the groups. Whilst the Panel viewed the relationship between the two bodies as a positive one it also noted that this may partly be a result of the cordial relationship between the Chair and the CEO, one of whom (EGC) will soon be stepping down. The Panel considered the AGM (see above) to be an important new initiative to continue to build on the positive relationship between the two bodies.

### Recommendation

10. A new Memorandum of Agreement (MOA) should be prepared between UK Biobank and EGC that clarifies all aspects of their relationship including new responsibilities of the EGC as proposed in this report including but not limited to:

- Remit of the EGC and its overall relationship with the UK Biobank
- Mechanisms for information sharing and briefing
- Responsibilities in regards to the AGM

The development of the MOA would be overseen by the Funders, and reviewed at the AGM.

## Operational and Budget Issues

### Findings

*Given the overall changes in the biobank environment, and with UK Biobank in particular, certain changes will be necessary to support EGC operations.* These changes include issues of membership, meeting schedules, work practices, secretariat, and budget. The Panel is not inclined to make specific management recommendations but it did come to conclusions on these topics.

- Regarding chair and members, the Panel found that the current Chair Prof. Brownsword has provided exemplary leadership of the EGC but is stepping down. This position is of critical importance for the success of the EGC going forward and recruitment of the right person is key. Similarly, whilst the Panel considered the caliber of the membership to be

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groups, and would require a number of pre-meetings, and that a regular agenda would be developed.

high, they considered the current membership to be larger than necessary to carry out the new remit.

- Regarding number of meetings, The Panel concluded that the current structure of all-day quarterly meetings is no longer needed. That said, the Panel strongly supported the importance of regular interaction and information sharing between UK Biobank and the EGC and emphasized the importance of information sharing between the UK Biobank and EGC as critical to the success of the enterprise, as noted in other recommendations.
- Regarding the secretariat the Panel noted the valuable role of the secretariat to the operations of the EGC during its start-up phase. However, given the new EGC remit, and a smaller group with fewer meetings, the Panel concluded that a full-time post would not be required.
- Regarding the budget, the Panel considered that the changes recommended in this report should not significantly alter the current level of funding but considered that the spend would be more appropriately directed to the future aims of the EGC.

### Recommendations

11. Chair. That a process be established by the Funders to recruit the new Chair with the advice of the UK Biobank, noting also that it would not be appropriate for UK Biobank to play an active role in the recruitment process itself. This process should continue to be in keeping with the Nolan Principles of Public Life.

12. Members. The EGC membership should be reduced in size in accord with their new Remit (e.g., 5-8). While the determination of member expertise should be left to the EGC and the Funders, in consultation with UK Biobank, the panel notes the following as a guide to implementing this recommendation:

- Practical experience in ethics, policy and governmental issues in relation to biobanking would be an asset;
- Continuing the practice of a single lay member (i.e. member of the general public, person without a specialised or professional interest) would not be an appropriate way to accommodate the issue of participant representation. Instead, the Panel considered that the AGM would be one way to engage participant perspective.

13. Meetings. With the AGM providing one required meeting of the UK Biobank and EGC each year, the number of additional meetings for the EGC may be limited, perhaps to two additional face-to-face meetings per year. Further, the EGC Chair should continue to attend UK Biobank board meetings to keep abreast of the issues and raise those that he/she thinks the EGC needs to address.

14. Secretariat. Given the new Remit of the EGC, the Secretariat should be reduced from a full time to a part-time appointment.

15. Budget. The EGC annual budget should remain between £100,000 - £120,000 per annum, noting that a marginal increase may be required, to reflect the costs of holding the AGM. Consideration would need to be given for whether the AGM would need to be costed separately. However, this is a new model of operating for the EGC, so the budget will need reviewing by the Funders at the end of the second year.

### Potential for Greater Impact

#### Findings

*Whilst the Panel concluded that the EGC should primarily be a body that focuses on UK Biobank, it recognized the need for a national approach to the ethics and governance issues relevant to all biobanks. As part of their terms of reference, the Panel was asked to consider the role that the EGC plays in the broader ethics and governance landscape in the UK, and to assess its overall role/profile within this landscape including cohort studies generally in order to enhance the capacity for cross-analysis within the UK and between the UK with biobank studies in other countries.*

#### Recommendation

16. The Funders should explore the idea of supporting development of a national EGC that would interface with all UK biobanks and cohort studies. Such a council would need sufficient expertise in bioethics plus other practical experience in issues such as data access so that the UK can maximize the scientific return from their collective biobank and longitudinal studies endeavours. The Panel did not consider it its place to discuss details, such as, whether this body could be formed from a pre-existing council or whether a fresh council would need to be established.

## **ANNEX A: Panel Biosketches**

### **Eric Meslin (Chair)**

Eric M. Meslin is founding Director of the Indiana University Center for Bioethics which celebrated its 10<sup>th</sup> anniversary in 2011. He is also Associate Dean for Bioethics in the Indiana University School of Medicine, and is Professor of Medicine; of Medical & Molecular Genetics; of Bioethics and Law; and of Philosophy. In 2012 he was appointed as Indiana University's first Professor of Bioethics.

Among his other leadership positions at IU he directs the Indiana University-Moi University Academic Research Ethics Partnership, an NIH-funded bioethics training program in Eldoret, Kenya; the Bioethics and Subject Advocacy Program of the Indiana Clinical and Translational Science Institute; and co-directs the Indiana University Center for Law, Ethics and Applied Research in Health Information (CLEAR).

Born in Canada, Dr. Meslin received his B.A. from York University (Toronto), and his M.A. and Ph.D. from Georgetown University. Prior to coming to Indiana, he was director of bioethics research for the ELSI program at the National Human Genome Research Institute (1996-98), and Executive Director of the U.S. National Bioethics Advisory Commission (1998-2001) appointed by President Bill Clinton.

He has held academic positions at the University of Toronto (1988-96); as Visiting Fellow at Green College, University of Oxford (1994-95); and as Professor-at-Large at the University of Western Australia (2008-2010). During 2012-2013 he was appointed the *Pierre de Fermat Chaire d'Excellence* at the Université de Toulouse.

Dr. Meslin has more than 150 published articles and book chapters on various topics in bioethics and science and is a co-editor of the *Cambridge University Press Bioethics and Law Series*. He has been a member of several boards and including the Institute of Medicine's Committee on Ethical and Scientific Issues in Studying the Safety of Approved Drugs; the Ethics Subcommittee to the Director of the U.S. Centers for Disease Control and Prevention; and the Board of Directors of Genome Canada.

On May 9, 2007 he was appointed a Chevalier de L'Order Nationale du Mérite (Knight of the National Order of Merit) by the French Ambassador to the United States for contributions to French bioethics policy.

### **Martin Bobrow**

Martin Bobrow is an Emeritus Fellow at Wolfson College Cambridge, formerly Professor of Medical Genetics and he is Non-Executive Director of Cambridge University Hospitals NHS Foundation Trust. He was born in Johannesburg, South Africa, graduated from the University of Witwatersrand and then worked in the MRC Population Genetics Unit, and the University Genetics Laboratory, in Oxford. He was then Professor of Human Genetics in Amsterdam and Prince Philip Professor of Paediatric Research at Guy's Hospital (UMDS), London. From 1995 until February 2005 he was Professor of Medical Genetics at the University of Cambridge.

He has been Deputy Chairman of the Wellcome Trust, Chairman of ULTRA (Unrelated Living Transplant Regulating Authority), Chairman of COMARE (Department of Health Advisory Committee on radiation in the Environment), Deputy Chairman of the Nuffield Council on Bioethics, and a member of the Medical Research Council and the Human Genetics Advisory Commission. He has also been Chair of the Academy of Medical Sciences working group examining the use of animals containing human material in scientific research as well as president of the UK Clinical Genetics Society. He has also chaired the Expert advisory Group on Data Access (EAGDA) and has extensive experience serving on data access committees, including as Chair of the Wellcome Trust Case Control Consortium and the International Cancer Genomics Consortium.

### **Jennifer Harris**

Professor Harris is a senior researcher in the Division of Epidemiology at the Norwegian Institute of Public Health (NIPH) in Oslo and an adjunct Professor in Genetic Epidemiology, Faculty of Health Sciences at the University of Southern Denmark. Since 2000 she has advised the Division of Behavioral and Social Research at the National Institute on Aging, NIH, USA on the development of Research directions that integrate genetics/genomics with a broad behavioral and social science portfolio.

She is also a research associate at The Center for Health, Law and Emerging Technologies (Helex) at the University of Oxford, UK. She has interdisciplinary training in life-span development and genetics, she was awarded a post-doctoral research fellowship at the Karolinska Institutet in Stockholm through the Jon D. and Catherine T. MacArthur Foundation, Research Network on Successful Aging. She founded the twin cohort panel at the NIPH and has been conducting twin research since 1985. She is the current President of the International Society for Twin Studies and in 2013 she received the James Shields Award for outstanding research in behavioral genetics using the twin method. Her twin studies include epigenetic investigation of twins discordant for autoimmune disease, a new study to investigate how social factors influence health and a large Nordic twin collaboration on cancer. She has extensive experience in international projects on the harmonization of large-scale biobanks in epidemiology. She led the European Union project *Promoting Harmonization of Epidemiological Biobanks in Europe* (PHOEBE) and she currently leads the strategic integration work within the 7<sup>th</sup> framework project *Biobank Standardisation and Harmonisation for Research Excellence in the European Union* (BioSHaRE-EU). She has broad commitment to the wider scientific community and serve on several steering boards, expert panels and scientific advisory committees including those of large-scale twin studies in the USA and Europe.

### **Debbie Lawlor**

Debbie Lawlor is Professor of Epidemiology and Head of Aetiological Epidemiology, MRC Integrative Epidemiology Unit and School of Social and Community Medicine, University of Bristol.

Her research is in life course and genetic epidemiology of women's reproductive health and cardiometabolic health in women and men. She is interested in mechanisms linking women's reproductive health to her, and that of her offspring's, cardiometabolic health. She is involved in developing methods for improving causal inference in epidemiology. Much of her recent research has used genetic variants as instrumental variables for determining the causal effect of non-genetic risk factors on disease traits and clinical outcomes. She has also developed methods for and used family based studies to examine causal mechanisms in lifecourse epidemiology.

She has been involved in the establishment and/or maintenance of several population cohort and randomized controlled trial studies, including the Avon Longitudinal Study of Parents and Children (ALSPAC) birth cohort, the Born in Bradford (BiB) birth cohort, the British Women's Heart and Health Study (BWHHS) and the Active for Life Year 5 RCT (AFLY5). She is chair of the MRC Population Health Strategy Group and a member of the MRC Strategy Board.

### **Jonathan Montgomery**

Jonathan Montgomery is Professor of Health Care Law at University College London, Chair of the Health Research Authority and also of the Nuffield Council on Bioethics. His research work concerns health care law and also bioethics governance systems. Recent articles have considered the justification of legal protection of professional conscientious objection, the need for a new social contract for health research, and ethical issues related to participant-led research.

His previous national chair roles include the Advisory Committee on Clinical Excellence Awards (2005-14) and the Human Genetics Commission (2009-12). He served on local NHS boards in Hampshire and the Isle of Wight for over twenty years up to March 2013. He was a member of the panel of advisers to the Morecambe Bay Investigation into maternal and neonatal deaths, which reported in March 2015.

He chaired the UK Clinical Research Collaboration Working Party on a Strategy for Brain Tissue Banking, and sits on the Scientific Steering Committee of Brain Banks UK. He is a member of the Committee on the Ethical Aspects of Pandemic Influenza. He sat on the Organ Donation Taskforce for its work on presumed consent and has been a member of the Medical Ethics Committee of the British Medical Association. He has been involved in the preparation of ethical guidance in a number of areas of health practice and is currently chairing a task and finish group for the General Medical Council overseeing the revision of its guidance on confidentiality.

## Annex B: Panel Terms of Reference

1. To consider the overall performance of the UK Biobank Ethics and Governance Council (EGC)<sup>5</sup> regarding its three stated purposes:
  - a. To act as an independent guardian of the UK Biobank Ethics and Governance Framework (EGF) and advise on its revision;
  - b. To monitor and report publicly on the conformity of the UK Biobank project with the EGF;
  - c. To advise more generally on the interests of research participants and the general public in relation to UK Biobank
2. To consider the extent to which the EGC performance has improved, declined or remained unchanged since the prior review undertaken in 2010. Overall performance will be informed by :
  - a. evidence presented by the EGC and UK Biobank
  - b. results from a consultation completed by a sample of UK Biobank users as agreed to by UK Biobank;
  - c. discussions with members of the UK Cohort Community;
  - d. interviews with the Chair and members of the EGC (as available) and the CEO of Biobank
  - e. other knowledgeable persons and data as needed.
3. To consider how well the EGC has fulfilled its role and responsibility to assess the compliance of UK Biobank with the Ethics and Governance Framework<sup>6</sup>
4. To consider how well the EGC has fulfilled its role and responsibilities in terms of current accepted standards of ethical governance.
5. To consider ways the EGC has contributed to the success of UK Biobank's transition from the recruitment phase to the resource management phase, with particular attention to the EGC's role in the enhancements activities.
6. To consider and recommend any changes in the operations of the EGC to enhance its effectiveness and value for money, including:
  - a. Remit and Terms of Reference
  - b. Ethics and Governance Framework
  - c. Membership
  - d. Relationship with UK Biobank participants
  - e. Relationship with UK Biobank
  - f. Role of the Secretariat
  - g. Accountability
  - h. Operations (including frequency of meetings)
  - i. Budget

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<sup>5</sup> <http://www.egcukbiobank.org.uk/>

<sup>6</sup> <http://www.ukbiobank.ac.uk/ethics/egf.php>

7. To consider the role that the EGC plays in the broader ethics and governance landscape in the UK, and to assess its overall role/profile within this landscape.
8. To make recommendations to the Funders on what should be the nature of the future contributions of the EGC in providing advice and oversight to UK Biobank and what is needed to ensure the EGC is able to effectively carry its responsibilities out.