The Global Forum on Bioethics in Research (GFBR) will hold a two-day meeting in Cape Town, South Africa, on 13-14 November 2018 on the theme of: “the ethics of data sharing and biobanking in health research”.

Data sharing and biobanking are increasingly being used to support global health research. These approaches have the potential to increase scientific efficiency by maximising the utility of data and samples. However, they also give rise to ethical challenges which are made harder in low- and middle-income country (LMIC) settings due to existing disparities in infrastructure and knowledge. Debate is required on how to foster data sharing and biobanking practice that is equitable and respectful to the interests of those involved, including participants, communities, researchers and funders. These issues are particularly acute in global collaborative research which can give rise to concerns about ownership, control, and sustainability, particularly in LMIC settings. Ultimately if research is to be carried out efficiently, effectively and ethically, there is a need for robust governance practices and for more discussion as to what these processes should be.

As part of the upcoming meeting, the GFBR is seeking case studies that bring attention to key ethical issues that have emerged in data sharing and biobanking research in LMIC settings. We will also be having panel sessions, including a panel on guidance and policy issues. We are seeking proposals that provide an overview and critique of existing guidance on data sharing and biobanking and/or identify gaps in current guidance and propose solutions. We also welcome proposals that highlight the policy issues from a LMIC perspective. The GFBR is also seeking participants to attend the meeting, with places awarded on a competitive basis.

This notice contains details on the following:

1. CALL FOR CASE STUDIES
2. CALL FOR PROPOSALS ON GUIDANCE AND POLICY ISSUES
3. CALL FOR PARTICIPANTS
4. DEADLINE
5. AWARDS: DECISION MAKING AND ELIGIBILITY FOR FUNDING
6. NOTIFICATION
7. CHECKLIST FOR APPLICANTS

All applicants are encouraged to read the background paper for further details on the meeting theme.

If you have any questions about this call, please email gfbr@wellcome.ac.uk.
1. CALL FOR CASE STUDIES

We invite applicants to submit case studies highlighting ethical issues associated with “the ethics of data sharing and biobanking in health research”. These case studies could: demonstrate the development of good practice; highlight challenges; demonstrate situations in which ethical practice failed; or present unresolved questions for the global community. We welcome case studies from any stakeholder perspective, including policy-makers, researchers, clinicians and healthcare workers. Case studies should focus on issues around conducting research.

Support will be provided to successful applicants for developing the case studies into a format suitable for them to present at the meeting. It is anticipated that case studies will be presented by their authors, one or two experts will provide commentary on the issues presented, and then participants at the meeting will discuss the challenges and questions raised by the case studies.

Case studies should be 2 pages maximum (in Microsoft Word or pdf format), clearly articulated in English and contain the following sections:

1. Title
2. Brief description of the research project
3. Background - relevant facts about the host country/community and disease studied (if disease specific)
4. Ethical issues with commentary on each issue
5. Conclusions and two recommendations for how to improve the ethics of, and ethical approaches to, conducting data sharing and biobanking research. The recommendations can relate to the field broadly or be specific to the case study.

In general, case studies should focus on research in LMICs and highlight no more than three ethical issues for discussion. These might be framed around - but are not limited to - the following questions, which are grouped into three broad themes:

Respecting participants and communities

Overarching question: What constitutes ‘genuine’ community engagement for data sharing and biobanking research in LMICs?

- What methods can be used to engage communities in a way that increases trustworthiness in data sharing and biobanking?
- How can tissue removal, storage and disposal be managed in a way that is culturally sensitive?
- Which community engagement approaches could be used to ensure community involvement in access decisions?

1 For guidance on how to write a case study, please see the case studies from last year’s GFBR meeting, available at: [link]

2 However, we do not want to exclude case studies from high income countries if there could be valuable lessons to learn, and some parallel or relevant ethical considerations. If your case study relates to a high income country please use the commentary section to draw-out the relevance for research in LMICs.
Promoting equity

*Overarching question:* What are the key drivers and barriers to data sharing and biobanking in LMIC settings?

- What constitutes ethical and equitable sharing of data and samples in international collaborations?
- What are the challenges faced by researchers in LMICs in developing and managing international collaborations in data sharing/biobanking research?
- What are the opportunities to translate theoretical access to data and samples into practical access to data and samples for researchers in LMICs?
- What are effective ways to address researchers’ concerns that mechanisms for data sharing may adversely affect their career development?
- Is the use of data sharing and biobanking an important and useful way of doing research in LMICs and why? Is developing these capacities important and appropriate in resource limited setting?
- What benefits should data sharing and biobanking research aim to deliver and who should be the beneficiaries? Who decides on these matters and how can the realisation of benefits be promoted (e.g. through good governance)?
- What are the opportunities and challenges of commercialisation?

Advancing good governance

*Overarching questions:* How do you ensure that governance processes are appropriate and fit for purpose in LMICs? What are the roles and responsibilities of stakeholders (e.g. researchers, funder, policy-makers, etc.) in facilitating ethical and equitable data sharing and biobanking practices?

- Who has the capacity or authority (e.g. Data Access Committees, Ethics Review Boards) to evaluate data sharing applications?
- How can we develop and implement accountable, efficient, fair and proportionate governance frameworks to support ethical best practice in biobanking and data sharing, with harmonisation across borders?
- What would sustainability models for biobanks and data repositories look like?
- Is the best path forward to build capacity for repositories in LMICs or would it be better to focus on ensuring access, credit and benefit while storing samples where capacity already exists?

In addition, please provide the following information in Microsoft Word or pdf format:

- Short letter of intent not exceeding one page, outlining:
  - Why you would like to participate in the GFBR meeting;
  - Your interest in or experience of data sharing and biobanking;
  - The ways in which you would disseminate the meeting outcomes in your local and regional context.
- Name, institution and contact information.
- Short CV (2 pages maximum) clearly stating:
  - Your primary discipline (e.g. clinical research, medicine, ethics, sociology, law, biostatistics, policy-making, regulatory, public health etc.)
Your career stage (early, mid, senior)
• Contact information and email addresses of two references
• Whether you require funding to cover travel and accommodation costs, or you are self-funding. Please note that funding will be prioritised for applicants from LMICs. Applicants from other countries are welcome to apply if they can self-fund their attendance.

If you are unsure about the suitability of a possible case study or would like to discuss your proposed case study further, please email gfbr@wellcome.ac.uk.

2. CALL FOR PROPOSALS ON GUIDANCE AND POLICY ISSUES

We are seeking proposals that provide an overview and critique of existing guidance or policy issues on data sharing and biobanking and/or identify gaps in current guidance and propose solutions. The proposal could relate to guidance or policy issues at the national, regional or international level, including addressing regulatory challenges.

Proposals might be framed around - but are not limited to - the following questions:
• What are the governance and regulatory needs and how can these be addressed?
• Can guidance help to address some of the ethical challenges and if so, what form should these take and what should they include?

Support will be provided to successful applicants for developing their proposal into a format suitable for them to present at the meeting.

Proposals should be no more than 2 pages maximum (in Microsoft Word or pdf format), clearly articulated in English and contain the following sections:

1. Title
2. Brief description of the context e.g. what guidance or policy issue will you address, is it national/regional/international.
3. Commentary, conclusion and recommendation

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  o The ways in which you would disseminate the meeting outcomes in your local and regional context.
• Name, institution and contact information.
• Short CV (1-2 pages) clearly stating:
  o Your primary discipline (e.g. clinical research, medicine, ethics, sociology, law, biostatistics, policy-making, regulatory, public health etc.)
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If you are unsure about the suitability of your proposal and would like to discuss it, please email gfbr@wellcome.ac.uk.

3. CALL FOR PARTICIPANTS

Who can attend the GFBR meeting?

The majority of participants are selected through a competitive process. Up to 80 participants will be selected from those eligible who apply by the deadline. We are seeking broad geographical representation, a mix of disciplinary expertise including researchers, clinicians, healthcare workers, bioethicists, policy-makers, health system functionaries and lawyers, and a combination of people who are early in their careers and leaders in their fields.

To apply to attend, please provide the following information in Microsoft Word or pdf format, in English:

- Short letter of intent not exceeding one page, outlining:
  - Why you would like to participate in the GFBR meeting;
  - Your interest in or experience of data sharing and biobanking;
  - What you can contribute as a meeting participant and the ways in which you would disseminate the meeting outcomes in your local and regional context.

- Name, institution and contact information

- Short CV (1-2 pages)
  - Your primary discipline (e.g. clinical research, medicine, ethics, sociology, law, biostatistics, policy-making, regulatory, public health etc.)
  - Your career stage (early, mid, senior)

- Contact information and email addresses of two references

- Whether you require funding to cover travel and accommodation costs, or you are self-funding. Please note that funding will be prioritised for applicants from LMICs. Applicants from other countries are welcome to apply if they can self-fund their attendance.

4. DEADLINE

All applications should be sent to gfbr@wellcome.ac.uk by 21.00 BST on Wednesday 16 May 2018, in English. Please specify in the subject line whether you are applying to attend, present a case study or present on guidance or a policy issue. Applications received after the deadline will not be considered.

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3 The GFBR also directly invites a number of participants e.g. expert speakers or representatives of key organisations.
5. AWARDS: DECISION MAKING AND ELIGIBILITY FOR FUNDING

Successful applicants from LMICs who require full funding will receive an award to cover:

- return travel to the meeting (economy airfare and standard ground transportation costs);
- accommodation (2 or 3 nights maximum, including meals);
- a single entry visa (if required).

Participants will be expected to meet all other costs.

The GFBR Planning Committee will select successful candidates (both self-funded and those applying for funded places). The selection committee will consider the following factors when considering the applications:

- **Country of origin.** We would like to ensure a representative distribution of participants from different regions;
- **Background/current area of expertise.** We would like to seek representation from many different disciplines relating to the theme of the meeting;
- **Experience of ethical issues** related to data sharing and biobanking;
- **Reasons for attending the meeting.** We hope to attract participants who will be able to actively contribute to the meeting and who expect to achieve impact from the meeting;
- **Case study applications and guidance/policy proposals only:** *Relevance of the case/proposal to the meeting theme and research in LMICs.*

If your case study or guidance/policy proposal is not selected your name will automatically go forward to be considered in the applications to attend. Applicants are encouraged to submit a case study or a proposal on guidance and policy issues.

6. NOTIFICATION

All applicants will be informed of the Planning Committee’s decision by the **30 June 2018.** The decision of the committee will be final.

7. CHECKLIST FOR APPLICANTS

Please use the following checklist to make sure you have provided all the requested information in your application, in English.

<table>
<thead>
<tr>
<th>All applicants:</th>
<th>Short letter of intent (1 page)</th>
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<tbody>
<tr>
<td></td>
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**Support for the GFBR:** The Wellcome Trust, the Bill & Melinda Gates Foundation, the UK Medical Research Council and the National Institutes of Health are providing funding for this meeting.

**Members of the Planning Committee for this meeting are:**
Jantina de Vries, University of Cape Town, South Africa;
Niresh Bhagwandin, Medical Research Council, South Africa;
Calvin Ho, National University of Singapore, Singapore;
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Claudia Emerson, McMaster University, Canada;
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Fabiana Arzuaga, Advisory Commission on Biobank, Ministry of Science, Argentina;
Doug Wassenaar, University of KwaZulu-Natal, South Africa;
Ross Upshur, University of Toronto, Canada;
Katherine Littler, Wellcome, UK.

**Members of the permanent GFBR Steering Committee are:** Anant Bhan, India; Katherine Littler, UK; Michael Parker, UK; Rachel Knowles, UK; Carla Saenz, USA; Barbara Sina, USA; Douglas Wassenaar, South Africa, Ross Upshur, Canada; Paul Ndebele, Zimbabwe; Teck Chuan Voo, Singapore and Phaik Yeong Cheah, Thailand.

16 April 2018