Global Forum on Bioethics in Research

Meeting report:

Ethics of data sharing and biobanking in health research

Stellenbosch, South Africa

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W: www.gfbr.global **E:** gfbr@wellcome.ac.uk

CONTENTS

Executive Summary

Grounding: The Global Forum on Bioethics in Research (GFBR) convened in Stellenbosch, South Africa in November 2018, to explore the 'Ethics of data sharing and biobanking in health research'. A total of 95 participants from 35 countries attended the two-day meeting, with the majority from low- and middle- income countries (LMICs). Case study presentations and first-hand experiences were used as the basis for discussion.

- **Data sharing and biobanking have the potential to increase scientific efficiency by maximising the availability and utility of data and samples**. Research funders and journals are increasingly promoting open sharing to improve the transparency and utility of research, with the ultimate aim of improving health. However, the research community are also concerned about the harms of data and sample sharing, such as the potential to **exacerbate existing inequalities,** particularly if data and sample sharing benefits only researchers from well-resourced institutions, leaving researchers in low-resourced settings worse off. Prompted by these concerns, the ethics of data sharing and biobanking was chosen as a focus for the annual GFBR meeting. GFBR aims to give voice to LMIC perspectives on pressing issues in global health research.

- The cases presented at the meeting highlighted that there is **no 'one-size-fits-all' and any data and sample sharing approach will need to be context specific**. Issues of consent, participant and community engagement and trust cut across the full range of data and sample sharing scenarios but different starting points bring different ethical questions. For example, when thinking about historic samples and data the question will be whether they can be used at all. But if a new biobank is being set up that raises a different set of questions (e.g. about appropriate consent processes).

- **There is a need for more community and public engagement around data sharing and biobanking**. Engagement to serve the needs and agenda of participants and communities was considered to be ethically important to be respectful of participants and communities. However, engagement merely as a way to educate participants and communities to get their consent seems to be the more usual practice. **Engagement should not merely be about education but should aim to identify the interests of all stakeholders involved so this understanding can be used to inform culturally appropriate approaches for data sharing or biobank procedures.**

- The meeting illustrated that whilst consent and community engagement are both essential, they are not sufficient for research to be ethical. Alongside good consent and community engagement practices, **a governance system is needed that offers a basis for trust**: one that takes account of questions of justice, equity and fairness and respect for participants and communities, including consideration of benefit, interests, and appropriate protections.

- Values such as equity and public/global good as well as principles such as stewardship should govern data sharing and biobanks. However, **what 'good governance' looks like (what form of consent is appropriate and administratively feasible; how privacy will be protected; what purposes are regarded as acceptable; whether regulation is in the form of laws and/or guidelines etc.) will depend on the context – there is no overarching 'right' answer**.

- Data sharing and biobanking approaches need to **look more broadly at benefits and interests.** As a way to demonstrate respect, research findings and knowledge produced should be communicated to participants and communities in a cycle of engagement. Ultimately, to be respectful, it should be a 'two-way street' with respect to benefit distribution i.e. **participants and communities should also benefit in some ways from the sharing of their samples and data**, including the possible return of aggregate or individual results. More broadly, there is a need to focus on the value of what is being done and **sharing data where this adds value, not simply sharing for its own sake**. Similarly, when weighing up benefits and burdens of sharing, the ethical importance of doing research with a reasonable prospect of benefiting people should not be overlooked.

- In this context 'inequity' is generally manifested as predatory action by high income country (HIC) researchers who offer no benefits locally. However, inequity comes in many different forms e.g. when sample and data collectors are not appropriately acknowledged; when those 'on the ground' are not the ones suggesting the research questions; or when researchers do not have the tools to access and analyse freely available data. **A broad shift in research culture is required to address existing inequities** and to address institutional policies, funder requirements and issues of authorship, that can de-incentivise collaboration and data and sample sharing. Equity can be promoted by:
    - Giving proper **recognition to primary data collectors** (including in the publishing process) and recognising **all intellectual contributions to the research process** (e.g. data analysts)
    - Providing **opportunities for local researchers to influence the research agenda so research responds to issues of local importance** as well as global concerns
    - **Prioritising access by local researchers** (e.g. delaying the release of data and samples to outside investigators to allow time for local researchers to publish or requiring meaningful collaboration with local researchers)
    - **Supporting researchers through the development of tools and resources** that make it easier and quicker for them to access and share quality data and samples
    - **Capacity strengthening** (e.g. via online courses and workshops) to help researchers produce, access and analyse data and samples
    - **Creating the structures and incentives to support and underpin capacity building initiatives** (e.g. jobs, funded time, route to academic recognition)
    - **Providing opportunities for communities of disease-focused researchers to work together** (for example in regional hubs), sharing experiences and bringing added value through meta-analyses of their data
    - **Developing the capacity of research ethics committees (RECs)** to review data and sample sharing protocols and to advise on issues of equity.

Introduction

The Global Forum on Bioethics in Research (GFBR) convened in Stellenbosch, South Africa in November 2018, to explore the "*Ethics of data sharing and biobanking in health research*". With experts in bioethics, biobanking, data sharing, research ethics, policy, regulation and research from 35 countries (see map of GFBR participants' countries), the meeting delved into ethical issues with respect to the equitable sharing of data and samples. The meeting content and selection of sessions and speakers was organised by an international Planning Committee made up of experts in data sharing and biobanking.[1] The meeting was structured around the following themes: respecting participants and communities; advancing good governance – national developments; advancing good governance – international aspects; promoting equity; national and international guidance and policy.

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 capacity. These issues are particularly acute in global collaborative research which can give rise to concerns about ownership, control, and sustainability, particularly in LMIC settings.

This meeting brought together participants from a range of countries and disciplines to debate 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. 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. The aim of this GFBR was to help promote open global dialogue on how to address the challenges – and embrace the opportunities – for sharing data and samples ethically.

GFBR participants were selected competitively, based on their potential to actively contribute to the discussions and to achieve impact after the meeting. Participants were encouraged to report the meeting recommendations in their home countries and to continue the discussion in their local context. Fellowships were available for LMIC participants to explore issues that arose during the GFBR meeting in greater detail, establish new collaborations, and develop new ideas for resolving issues that could not be resolved at the meeting itself. Past GFBR participants have given presentations on the meeting theme to their local RECs and at other conferences and published papers. It is anticipated that participants from this GFBR meeting will likewise take the discussion home and foster debate in their local context on what constitutes a data sharing and biobanking practice that is equitable and respectful to the interests of all those involved.

[1] Jantina de Vries, South Africa; Niresh Bhagwandin, South Africa; Calvin Ho, Singapore; Athula Sumathipala, UK; Susan Bull, UK; Claudia Emerson, Canada; Naomi Waithira, Thailand; Fabiana Arzuaga, Argentina; Gloria Mason, Liberia; Doug Wassenaar, South Africa; Ross Upshur, Canada and Katherine Littler, Switzerland

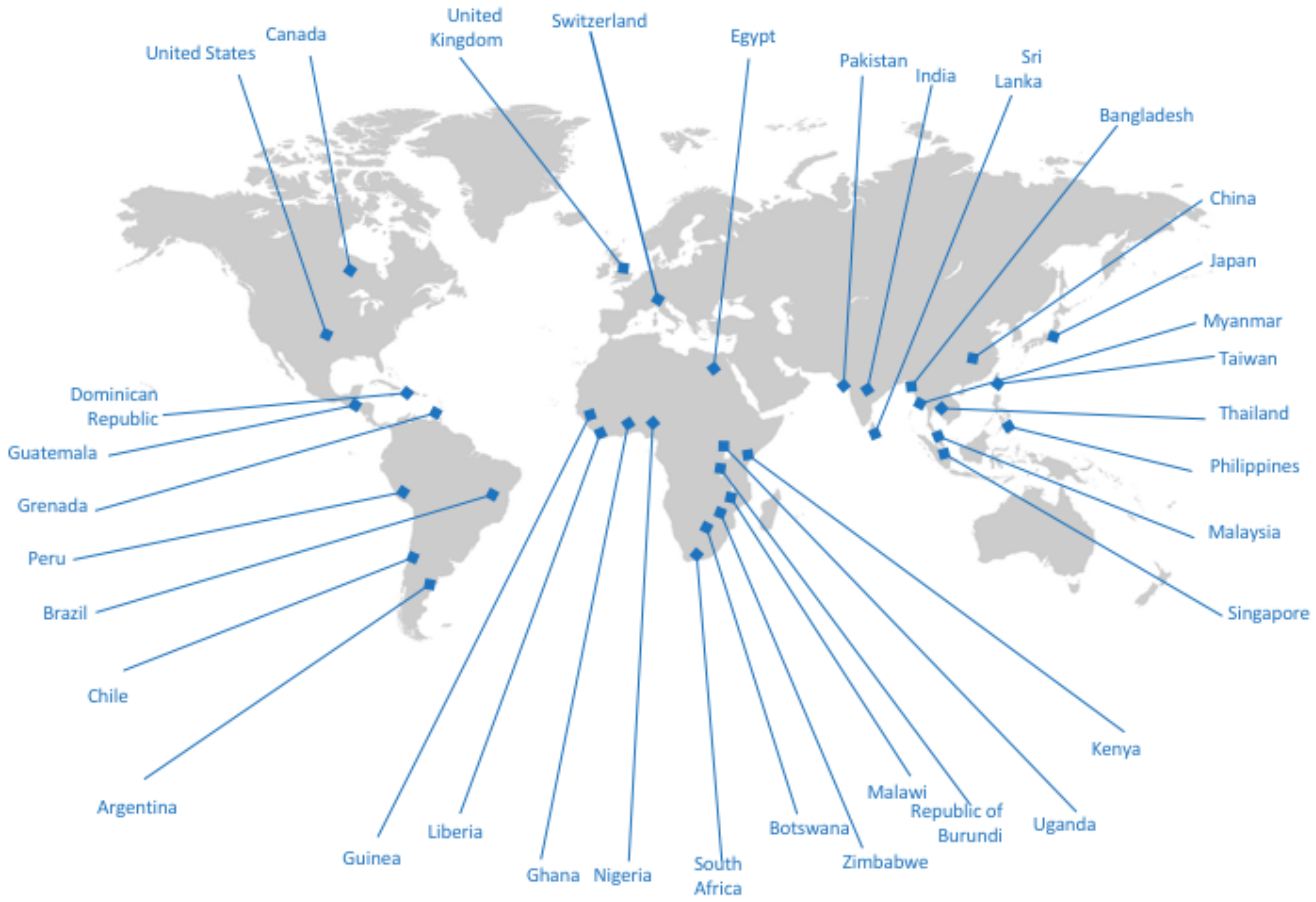

Figure 1 GFBR participants: 95 participants from 35 countries came together to discuss this important issue with a wide range of academic and clinical expertise: bioethicists, clinicians, biobankers, researchers, community practitioners, policymakers, social scientists, regulators, and funders, at all levels career stages. 71 participants were from LMICs.

1. Respecting participants and communities

A range of data sharing and biobanking scenarios were presented at the meeting including:

- Legacy clinical samples where consent was not initially sought for research
- Legacy research data and samples, collected for a specific research purpose where consent was not sought for broad future use
- Electronic medical records and public health datasets (collected without consent) being used for research
- Establishing a new biobank or data sharing programme.

Issues of consent, participant and community engagement and trust cut across the scenarios but the different starting points brought different ethical questions. For **legacy samples and data**, being seen to follow due process in determining whether and when it is possible to use consent waiver approaches will be essential for trust. Due process could involve demonstration of social value, stakeholder engagement, and ethical review. Similar issues may arise in connection with the use of **public health datasets** for research purposes (where no consent was given): in what circumstances can this be justified? Establishing a new **biobank or data sharing programme** raises different questions, for example, whether broad or dynamic consent can be used, in conjunction with an appropriate governance structure.

Consent

GFBR participants agreed that data and sample sharing policies must recognise the fundamental differences between using data and samples with, or without, informed consent from participants. Where informed consent has been given by participants for the sharing and re-use of data or samples, the decision to share is less complicated. However, where no informed consent for sharing and re-use was obtained from participants (e.g. legacy samples and data), requests for access must be more carefully considered. **Context plays a large part in determining the most appropriate consent model**.

GFBR participants discussed how **legacy clinical samples and data** should be managed if they are requested for research purposes. Some advocated for re-contact and consent for research use, as a way to prevent exploitation. However, others questioned whether seeking consent is the best or only way to show respect and prevent exploitation. Other mechanisms could be employed so the value of remnant samples is not lost, while showing respect for the individuals without relying on consent. For example, a **risk assessment test** by a REC was considered important to inform the decision on whether or not to allow the use. Ethics review should also consider the notion of public good in determining whether a waiver of consent is justified, and **community engagement or participation could be used to define the public good**. If needed, community leaders could be asked for their authorisation**.**

Similar issues arise in relation to **legacy research data and samples** that were collected for a specific purpose. In this context, **secondary use could be acceptable within a wider interpretation of consent**, i.e. if the consent is for research on HIV outcomes, then this could be interpreted as use in any HIV study but not for a malaria study. Again, **the risks and benefits should be assessed by a REC and a decision made as to whether there is an ethical justification for interpreting consent broadly**. In some countries (e.g. India) the decision on whether samples and data can be used without consent falls to government bodies.

Case study 1 focused on the Provincial Health Data Centre (PHDC) in the Western Cape Province, South Africa and the use of **electronic medical records** for research. The author asserted that it seems inappropriate to disseminate an individual's health data – a private and sensitive type of personal data – for research without explicit agreement from that individual. Although arguments could be made for waivers of consent if there is high social value, it was argued that deciding what truly benefits individuals and the health of the population is deeply subjective, and researchers are likely to have inherent bias in favour of data sharing that supports the research enterprise and their own research interests.

The author proposed a method of **tiered consent**[2] for (i) use of anonymised electronic medical records (EMR) for research; (ii) use of identified EMR for research and (iii) future contact from researchers to solicit study participation. At their first consultation within the public health service each individual would be given the option to provide, or explicitly withhold, consent for each tier. It was agreed that such an approach would need to be undertaken with extensive community engagement and discussion to ensure stakeholder input into the proposed tiered consent process. In the interim, the PHDC is considering an information campaign offering health care clients the option to opt out of their EMR data being used in anonymised, de-identified or aggregated health data sharing.

Case study 1: Participant protection and good data governance for research using routine electronic records from a Health Information Exchange in the Western Cape Province, South Africa

Nicki Tiffin, University of Cape Town, South Africa

In the Western Cape Province, South Africa, data captured from routine electronic medical records (EMR) and administrative data are updated daily, collated and linked by the Provincial Health Data Centre (PHDC) in a comprehensive, real-time Health Information Exchange. The primary aim of the PHDC is to improve patient continuity of care and health outcomes using these collated data; with a secondary application for epidemiological and clinical research using derived datasets. This case study investigated the ethics and data governance implications for sharing data from routine EMRs for research purposes; and explored the data governance structure currently implemented at the PHDC.

Many GFBR participants accepted **broad consent** as an appropriate consent mechanism for **biobanks**, provided that:

- There is a clear justification for taking this approach (and it is not simply for the convenience of researchers)
- An appropriate governance structure is in place
- There is fair benefit to the public

[2] Several models of consent were discussed at the meeting, including tiered, layered, broad and dynamic. Tiered and layered suggest that participants can consent at the outset to broad categories of future use (for example, disease specific research or relating to the use of identified or de-identified data and samples). Broad consent, as then name suggests, is generally for a broader use e.g. 'for health-related research'. Dynamic consent involves a more interactive relationship between the participant and research and mechanisms are in place for participants to express their preferences as they may change over time. For all models, withdrawal from future research is always an option, providing the stored data and samples remain linked to personal identifiers.

- Participants are informed that their samples and data will be used for health-related research broadly and that future uses cannot be anticipated at the time of consent
- Participants are informed about the range of researchers who may use the biobank (e.g. national, international, academic, commercial)
- Trust of participants is maintained through data protection mechanisms
- Participants are informed (or have access to) information about the results arising from the research (if not from the use of their specific data and samples).

Communicating the certainties and uncertainties associated with broad future use is a challenge. **Engagement activities should be used throughout a biobank's lifetime to underpin and give legitimacy to the broad consent model.** For example, when a biobank is established, participants' understanding of consent should be assessed with a view to enhancing the consent process and materials and to understanding participants' expectations of the project. Later in the biobank's life, engagement should be used to explain to participants how the biobank is being used. When dealing with potentially sensitive issues (e.g. access by industry or the use of new technologies) or vulnerable populations, broader public engagement could be considered. This may also enhance trustworthiness of the biobank and position the community as its stewards.

GFBR participants acknowledged that **dynamic consent** may be harder to implement in LMICs due to lack of communication technology and the challenges of locating people through phones or emails. Broad consent is more feasible though it was noted that with respect to left-over clinical diagnostic samples, participants' consent may be based on acquiescence to the authority of healthcare workers/professionals. **Policy paper 2** described that in the context of India, broad consent reinforces the public's notion that consent is taken to protect the interests of researchers, and not to respect the wishes of participants. It was also noted that broad consent may be alien to LMIC participants and communities who may be more accustomed to specific consent. In some countries, broad consent is not currently an option as regulation requires specific consent (e.g. Zambia).

Case study 6 proposed a model of **layered consent** in the context of a proposed **biobank** in Liberia. This approach was considered necessary given the widespread fear in Liberia that samples collected in clinical and research settings may be tested for stigmatizing diseases (e.g. HIV) against a person's will. Therefore, in the Liberian context, broad consent may not be appropriate as people may want to know the intended uses of their samples. Layered consent would show respect for potential biobank participants by allowing them to authorise specific research uses, as well as the type of communication they want to receive regarding the use, export, retrieval and disposal of their samples.

Case study 6: Rumours and fears endanger feasibility of biobanking in Liberia: Culturally-congruent standards are needed to ensure trustworthiness

Mandella King, St. Josepth's Catholic Hospital, Liberia

In early 2016, the Barcelona Institute for Global Health (ISGlobal) established a research collaboration in Liberia with the Saint Joseph's Catholic Hospital (SJCH) and the Liberia Medicines and Health Products Regulatory Authority (LMHRA). With funding from the European and Developing Countries Clinical Trials Partnership, two ISGlobal-led projects started. Both projects aimed to build hospital and regulatory authority staff capacities to conduct research on infectious diseases. In 2016-17, a mixed-methods study was undertaken to assess the burden of malaria among pregnant women attending antenatal care at the Saint Joseph's Catholic Hospital, Liberia. Within this study, qualitative research methodologies were used to explore pregnant women's, traditional leaders' and health personnel's perspectives on barriers and opportunities for pregnant women to consent to participate in malaria research. To inform the design of the study and to plan dissemination at community-level, a group of ten traditional leaders received training in medical research ethics and were invited to constitute a Community Advisory Board (C.A.B). An ancillary aim to the qualitative inquiry and to the C.A.B activities was to explore drivers of acceptability to engage in research that may involve collection, transport, storage, and use of blood specimens. This work will inform the feasibility of a SJCH-hosted biorepository of blood samples obtained from malaria-exposed individual attending hospital services. This case study described the ethical issues drawn from the qualitative inquiry findings.

Benefits and interests

GFBR participants agreed that respect for participants and communities should go beyond consent and protection of confidentiality and privacy, especially when data and samples are exported to HICs for analysis (due to the lack of technology in the LMIC setting). As a way to demonstrate respect, **research findings and knowledge produced should be communicated to participants and communities in a cycle of engagement**. Ultimately, to be respectful, it should be a 'two-way street' with respect to benefit distribution i.e. participants and communities should also benefit in some ways from the sharing of their samples and data. **Policy paper 2** called for benefits to include the return of 'actionable' findings to participants which have 'clinical significance'.

Some GFBR participants argued that a human rights framework promoting research to meet the needs of humanity whilst protecting individual autonomy and privacy interests is necessary to safeguard equitable data and sample sharing and fair benefit distribution in biomedical research. We need to **look more broadly at what kind of benefit-sharing might be possible** (and when and with whom).

In the context of population-based biobanks – which often receive some public funds – researchers should show that they can 'add value' through research in terms of bringing potential direct or future benefits to the community from which the biobanked samples and data were derived. In addition, such benefits and any intellectual property developed should be monitored by a gatekeeper to ensure fairness in distribution. In some countries (e.g. Taiwan), overseas researchers can only gain access through collaboration with local researchers. This is to promote benefits flowing back to the community.

It was suggested that **funders should provide funds for the distribution of post-research benefits to communities, including for dissemination activities**.

Case study 6 described the widespread rumours in Liberia about samples being exported for **commercial gain**

abroad, raising revenue that is never shared with the researched communities. The authors noted that this rumour could be further accentuated as the proposed Liberian biobank would largely depend on charging for cost recovery in order to be sustainable. However, qualitative work with community members found they may not be opposed to commercialisation; providing that a benefit sharing plan engages them and their communities. The authors concluded that **to improve trustworthiness, a clear accountability and benefit sharing plan needs to be agreed upon** by research, regulatory, hospital staff and the affected communities. Accurate information on accountability, human resources, financial and sustainability issues would also help communities better understand the issues facing the biobank and hopefully help gain trust in biobanking research in Liberia.

In public health emergencies, respect for participants and communities requires prompt and efficient use of relevant data and samples. An example was given from the Zika outbreak in the Americas, where affected countries shared their data and samples with Brazil for the pragmatic reason that it was the only country with the capacity for vaccine production. However, it was acknowledged that in public health emergencies, 'local' interests can conflict: there can be a distinction between patients' interests in moving research on quickly (even if this means moving data and samples abroad), and the interests of researchers who might want to focus on capacity building (see section 3).

Engaging participants and communities

GFBR participants agreed **there is a need for more community and public engagement around data sharing and biobanking**. Community engagement should not be equated to consent, although both are important. Engagement to serve the needs and agenda of participants and communities was considered to be ethically important to demonstrate respect. However, engagement merely a way to educate participants and communities to get their consent seems to be the more usual practice.

Engagement should not merely be about education but should aim to identify the interests of all stakeholders involved so this understanding can be used to inform culturally appropriate approaches for data sharing or biobank procedures. Engagement should include two-way communications with patients, research participants, communities and groups such as indigenous populations. Non-local researchers should not make assumptions that they know what cultural practices are, should not assume that they are fixed, and should not assume that they cannot be challenged or changed (e.g. burial practices during the Ebola outbreak).

Case study 2 advocated for the use of community consultation to inform culturally appropriate educative programmes that take account of the community beliefs, customs and rituals. This research sought the perspectives of Aymaras leaders from the Peruvian Highland and showed the benefit of the approach and its favourable impact on the acceptance of the use of biobanking in indigenous communities. It was also recommended that RECs can be strengthened by promoting active participation of community members.

Discussion focused on whether respect for cultural sensitivities should supersede the potential scientific gains arising from international research. However, GFBR participants agreed that the two need not be mutually exclusive. In fact, increase in cultural sensitivity may itself be a gain of international collaboration if done in appropriate ways. There are certain cultural beliefs e.g. the need for whole body integrity which conflict with export of bodily samples overseas. Such beliefs need to be taken seriously and not be dismissed as superstitious or unscientific – respectful mutual discussion and agreement on the public good of such research may help break down barriers towards sample/data export. In any case, such beliefs may evolve through time to be more accepting of export, particularly if research demonstrates evidence of scientific and social value for these communities.

Case study 2: Respect for participants and communities: Education with cultural adequacy to conduct research in indigenous Peruvian communities about shared data and biobanking

Agueda Munoz del Carpio Toia, Universidad Catolica de Santa Maria, Peru

The indigenous populations of Peru have a great ancestral cultural richness, but they also suffer from native environmental diseases and have genomic components that need to be researched. Collecting and biobanking samples from this population could provide a useful resource for such research. This case study described research with 40 Aymaras leaders of both genders from the Peruvian Highland. The first objective was to assess Aymaras leaders' attitudes and perceptions towards biobanking and to better understand the ethical safeguards that indigenous communities would require before accepting such uses of biological material. The second objective was to assess the impact of an educative program on their understanding and acceptance of biobanking. The program used booklets with drawings, videos and socio dramas to provide information about the use of biobanking to improve health.

Case study 5 demonstrated the benefits of engagement to balance sensational stories that appeared in local media concerning the Sri Lankan twin registry. Recognising the concerns as valid expressions of the mistrust the community had towards unethical researchers, the Institute for Research and Development, Sri Lanka (IRD) engaged in extensive awareness raising and community engagement activities, using multiple routes ranging from regular newspaper advertisements, feature articles, radio talks, exhibitions, leisure activities and television programmes to small group discussions and focus groups, as well as sensitising other professional and academic groups. Cultural activities engaging twins helped build an understanding of the benefits of research and build respect between the research team and the participants. GFBR participants agreed on the need for continuous engagement about the social value of research to all the stakeholders at all levels of hierarchy.

Case study 5: Twenty years of ethical challenges in setting up and maintaining a twin registry and biobank in Sri Lanka

Buddhika Fernando, Institute for Research and Development (IRD), Sri Lanka

The Sri Lankan twin registry, set up in 1997 with funding from the Wellcome Trust, is the first twin register in South Asia, and it is still one of the very few large-scale, functional, population based twin registries in a LMIC. Since the twin registry was set up at a time when research ethics was at a nascent stage of being codified in Sri Lanka, the team at the IRD, faced multiple challenges in ensuring that the ethical challenges specific to building a database in an LMIC were addressed. As the project progressed, the twin database expanded in to a biobank, bringing about further challenges related to the collection, storage, use and protection of bio-specimens. The lack of a broad ethical framework and overarching guidance was a key issue at the time. This was complicated by the lack of effective guidance on managing relationships with influential international research collaborations, in a manner that was both respectful of cultural sensitivities of the research participants/communities, and ensured that funds were utilized to their full potential, while research benefits were shared equitably. This case study discussed how the IRD identified, managed and overcame challenges in setting up the twin registry, the biobank and the ensuing research projects.

Challenges for community engagement include identifying the community to engage and to ensure you are engaging with the community in a meaningful way. There is a need to recognise that there are many different 'communities' involved – research participants, community leaders, the public, researchers, policy makers, civil

servants, regulators. There are also political considerations that researchers need to consider, recognising hierarchical relationships and navigating accordingly. The appointment of community advisory boards to aid researchers with determining the interests of communities was suggested, although some GFBR participants expressed doubts about their utility and authority to speak on behalf of the community. They asserted that in some cases, it is questionable as to whether community advisory boards are truly serving the interests of their communities or rather serving the interests of the researchers.

A further challenge is how to ensure that community engagement is carried out at all and carried out well. It can be particularly difficult to maintain a meaningful cycle of engagement given the short-term nature of many funding schemes. GFBR participants agreed that **funders should require their funded research to have an engagement plan**. This was the case for H3Africa where funding was contingent on the inclusion of engagement plans, and these were reviewed by engagement experts. Funders could further support their researchers by commissioning the development of evidence-based community engagement strategies. It should also fall to funders to establish monitoring mechanisms to ensure engagement is carried out on their funded projects.

Finally, it was acknowledged that respect for participants and communities in the context of data and sample sharing does not mean that researchers should fulfil whatever the needs and preferences of participants and communities are. Rather participants and communities should be empowered with information and understanding of data and sample sharing in a meaningful way i.e. how they might be contributing to the public or global good. Research on data and samples flowing from LMICs to HICs should be embedded within a governance structure to ensure that benefits of research are fairly distributed.

2. Advancing good governance

An important element to promote anticipated benefits and mitigate potential harms is governance. But what is good governance? Alongside good consent and community engagement practices, **a system is needed that offers a secure basis for trust**: one that takes account of questions of justice and respect for participants and communities, including consideration of benefit, interests, and appropriate protections. Governance can include: regulation/laws; international, national or funder specific policies; ethical/normative guidance published by WHO and similar organisations and institutional policies that implement ethical norms.

It was noted that many GFBR participants' countries have no governance framework for data sharing and biobanking and limited or unclear guidance. **Case study 4** described efforts by the National Biorepository of Uganda to set up a biorepository for future research purposes. For regulatory purposes, oversight of research involving humans as research participants in Uganda is done first at the organization level by RECs and second at national level by the Uganda Council for Science and Technology (UNCST) in collaboration with Uganda National Research Organization (UNHRO). Submission to the organisational REC was unsuccessful as the committee deemed the establishment of a biorepository to be outside their remit. The proposal also remains unapproved at UNCST as it has no current regulations governing the establishment and operation of biobanks. On the one hand, the lack of regulation has hampered the efforts of The National Biorepository to receive formal approval. On the other hand, the lack of regulation has resulted in an unregulated proliferation of independent biobanks and/or biorepositories established to serve specific research interests in Uganda.

In such situations, stakeholder engagement can be a powerful way to move discussions forward. Colleagues from the Ugandan National Biorepository brought together stakeholders from UNCST, lawyers from Ministry of Justice and Constitutional Affairs, REC members, district health officers, hospital directors and others. As a result, the UNCST was tasked with writing biorepository guidelines based on international standards and it was agreed that clinical and laboratory request forms should be modified to include a broad consent for storage and future use for research. For remnant samples already in storage without consent, the National Biorepository is seeking government advice through the attorney general.

Case study 4: Establishment of the National Biorepository in Uganda: Some regulatory and ethical uncertainties

Hellen Nasumba, Central Public Health Laboratories, Uganda

The National Biorepository was set up in September 2016 out of a need to store human biological specimens to promote low cost public health and academic research. The National Biorepository is owned by the Government of Uganda under the custodianship of Central Public Health Laboratories. For the last two years, the National Biorepository has sought informed consent for long term storage and use of remnant clinical samples mainly from the centralized reference HIV early infant diagnosis, viral load and isolates of antimicrobial drug resistance surveillance and disease outbreak investigations. A Biorepository Governance Committee has been appointed to oversee the activities of the bio-repository, provide direction on priority samples and to store and regulate access to the repository resources. Plans are underway to create collaborations with universities and research institutions to promote biospecimen access. In addition, the biorepository will provide training in bio-repository science to medical students and health workers.

Ideally, national data sharing platforms and biobanks will be supported by governance structures at both the national level (e.g. regulatory agencies, national REC, funders etc.) and at their institutional level (e.g. management committee, scientific committee, access committee, REC etc.). The governance framework will need to address:

- Requirements for consent and acceptability of consent models (broad, tiered etc.)
- Protection of privacy and confidentiality, including how participant data will be linked to identifiers (if at all)
- Mitigation of risks of harm to participants from data and sample sharing
- Engagement with participants and potential benefits (e.g. return of aggregate results)
- Whether individual results will be fed back to participants, and if so, the criteria and processes for doing so (e.g. if the finding is clinically actionable)
- Principles, criteria and processes to govern access. More stringent criteria may be required for samples that are precious and non-renewable (in comparison to data) and which should be used in a prioritised way in the public interest. This is especially important for biobanks that have benefitted from public money.
- How access fees will be determined – whether or not this will be on a cost recovery or other model and how best to promote use and equity in access (e.g. by a tiered pricing model)
- Whether commercialisation of research findings is permitted and, if so, how it will be managed
- Content of material transfer agreements

- Ethical review processes (of both the protocol that establishes the biobank/data sharing platform and of protocols submitted by researchers who want to use the resource)
- If and how monitoring and enforcement mechanisms will be put in place to ensure that samples and data are utilised responsibly and in compliance with the conditions of access when shared
- Whether and how publication or return of results to the biobank is required, including negative results, especially where these have an impact on policy
- How conflicts of interests will be managed between those establishing biobanks and those using the resource, especially where this is the same individual or group. (This was raised in the context of **case study 3** where some biobank directors in Taiwan applied to access large amounts of data for their own studies. Although recognised as a potential conflict, some GFBR participants acknowledged that not allowing such access may retard some types of research as the director may be the only person interested in carrying out the research or collecting and curating the data in the first place.)
- Whether the scale and/or nature of the biobank requires additional safeguards, such as oversight by an independent ethics body.

Specific policies and standard operating procedures should flow from the governance framework. For example, a sample and data management policy should provide guidance on, amongst other things, data quality, access and storage, in addition to defining the roles and responsibilities of those involved.

Case study 3: Taiwanese experience in data sharing in biobanking

Michael Tai, Chungshan Medical University, Taiwan

The first biobank in Taiwan was officially established at 2005 in Academia Sinica (AS), the largest and most prestigious research institute in Taiwan. The purpose of this biobank is to discover genetic diseases of Taiwanese people and promote their health. The project aims to recruit two hundred thousand residents to participate. So far more than that number of people has taken part in a cohort study project by providing their personal information, living habits and about half of them have also donated samples that are deposited in the AS biobank for study. Starting with one biobank, the number of biobank in Taiwan has increased to 31 in the last 13 years. Among them three are population based and others are disease oriented. This case study described a recent structural innovation project instigated by the Ministry of Health and Welfare of Taiwan to integrate all biobanks through data sharing. The aim is to shorten the time of scientific and ethical review so that researchers can start their studies with a minimum of delay.

Who is responsible for ensuring 'good' governance?

'Good governance' requires the action of many stakeholders – researchers, RECs, funders, governments and regulators. Governance demands connections between these stakeholders to promote an awareness and understanding of the importance of research and the need for meaningful data and samples.

Researchers: Too often 'ethics' is located only in the REC review, when actually all stakeholders should recognise their responsibility to support ethical conduct. While researchers rely on RECs to identify ethical issues and protect the community, GFBR participants called for a reflective approach in which researchers define ethical concerns and determine how they should be minimised.

Research Ethics Committees: Some GFBR participants recommended that RECs could play a key role in advising, reviewing and/or monitoring the establishment and use data sharing platforms and biobanks. For

example, RECs could monitor data and sample sharing and require researchers to indicate that they have a data sharing plan (while not necessarily taking a view on what should be in it). Others, however, were concerned that RECs do not have the time or resources to undertake monitoring, especially when there's a lack of regulation or clear guidance to inform their work. **Case study 8** drew attention to RECs' authority in this regard. The authors surveyed RECs in the Dominican Republic and found that none requested a data plan as part of their review process. But, even if they did, it is unclear if the researcher has a duty to respond to the request given that this area is unregulated in many LMICs.

Case study 8: Research Ethics Committees' request for data sharing plan as part of the ethics review process: Data from the National Research Ethics Committees Survey in the Dominican Republic

Julio Canario, National Research Center on Child and Maternal Health, Dominican Republic

The National Research Ethics Committees Survey aimed to identify the number of existing Research Ethics Committees (REC) in the Dominican Republic, their composition, organization, activities, ethics review and decision-making processes. The survey was implemented throughout 2017 and concluded in 2018. The last survey on RECs was conducted in 2009, and no updated data were available since that period. Around 400 health care organizations, academic and research-oriented organizations, both public and private, were contacted to verify the existence of a REC. A total of 25 RECs were identified and 19 of them completed the survey through an interview. RECs were asked whether they request a data sharing plan as part of the ethics review process. We found that the participating RECs were not asking for a data sharing plan as part of their review process. Its policies do not include data sharing terms nor do they have in place standard operational procedures nor templates to evaluate data sharing plans.

GFBR participants recommended that **review of data sharing and biobanking proposals should be centralised to specialist, accredited RECs**. Dedicated training could be provided and the committee's expertise would grow with experience. This responsibility could fall to the national REC, where such a committee exists. This would also mitigate the issue reported by some GFBR participants where some researchers 'shop around' for lenient RECs. Examples of national RECs taking a lead in the area of sample sharing were given: in Pakistan the national REC created guidelines for the collection, storage and shipping of samples which include the need for the committee's approval before samples are exported.

Governments and regulators: Many of the concerns around equity involve political considerations. Ideally, government should understand scientific knowledge and implement regulation and legislation to support it. **Policy paper 4** provided a good example of political engagement on the Ebola data platform where representatives of the Minister of Health from Guinea, Sierra Leone and Liberia serve on the platform's Steering Committee. The author described their presence on the committee as essential to ensure that these countries have the opportunity to define the goals, development and governance of the platform together with the international partners who lead the initiative.

Policy paper 4: Governance of health data sharing in post-Ebola West Africa: Lessons, realities and prospects

Alpha Ahmadou Diallo, University of Conakry and Ministry of Health, Guinea

The Ebola data platform has the objective of consolidating and harmonizing all the clinical, epidemiological and laboratory data obtained from patients with Ebola haemorrhagic fever and affected communities in West Africa. This data will be made available to the public and to scientific and humanitarian health communities to disseminate knowledge about the disease, support the expansion of research in West Africa, and improve patient care and future response to an outbreak. This paper focused on the experience of developing the Ebola data sharing platform, as a good example of an international collaboration that is a means of collective learning on the production and use of data as evidence on the one hand, and on public-private partnerships that engage with local partners and communities on the other.

GFBR participants discussed whether data sharing platforms and biobanks should be treated as a **public good** and only maintained by government agencies, in the public interest. However, there were concerns that government may lack expertise and that Universities can be better organised and have experts with relevant technical abilities. Also, data sharing platforms and biobanks are expensive and some countries would not be able to afford them without private funds.

Funders: The governance of the data sharing platforms and biobanks can be heavily influenced by funders' policies and grant conditions. For example:

- The UK Medical Research Council requires dual ethics review (both in the UK and in the country where the research will take place).
- The Wellcome Trust's policy on community engagement has raised awareness of community engagement in LMICs. Some GFBR participants recognised this as a benefit of an international funder's influence as their local RECs would not have suggested community engagement as a necessary element of research.
- Funders may set up – or require the establishment of – **data access committees**, either embedded within the research or independent of it (e.g. the H3Africa data access committee). Data access committees can provide a useful compliment to REC review in terms of assessing ethics and equity issues.

GFBR participants identified themselves as having a responsibility to take the findings from this meeting back to their home countries and to push for change where required. For instance, if RECs do not have the capacity to review data sharing and biobanking proposals, GFBR participants could gather evidence to support this and present it to the relevant authorities. More broadly, **bioethicists** should play a part in establishing appropriate and equitable governance of data sharing and biobanking.

In conclusion, GFBR participants broadly agreed that values such as equity and public/global good as well as principles such as stewardship should govern data sharing and biobanks. However, **what 'good governance' looks like will depend on the context – there is no overarching 'right' answer**. GFBR participants also recognised how difficult 'good governance' is to achieve, particularly in unstable and emergency settings.

3. Promoting equity

Disparities in resources and infrastructure mean the playing field between HIC and LMIC researchers is not level. Inequities are also found between LMICs and within countries (e.g. between different universities). A broad shift in research culture is required to address existing inequities and to address institutional policies, funder requirements and issues of authorship, that can de-incentivise collaboration and data and sample sharing. GFBR participants agreed that **there is a duty to reduce inequalities** i.e. to do more than just avoid exacerbating inequalities.

The following were identified as challenges for equitable sharing and use of data and samples:

- Lack of incentives to share and/or no benefits accruing to researchers and populations from which data and samples are collected
- Insufficient recognition of the intellectual contribution of primary data collectors
- Disincentives created by research 'collaborations' where local researchers are relegated to being data collectors rather than a full collaborators and co-authors
- Lack of time and resources (e.g. to curate data to maximise its utility to the broader scientific community)
- Concerns regarding international scrutiny of data quality and research methods
- Lack of clarity in open access policies on what data should be shared (e.g. analysis/results or raw data/ individual participant data) and when (**case study 7**)
- Perceived 'ownership' of data and samples, especially if researchers have used their own resources and effort for their collection (which is not uncommon in LMICs given the lack of research funding)
- Lack of regulation or legal uncertainty and unsupportive governments
- Lack of institutional or national capacity to conduct meaningful ethics review, which may give rise to a precautionary approach
- Lack of awareness of the existence of datasets and samples
- Lack of skills and resources to access and use data e.g. computing power or tools to download data, the right software to access data, the tools to analyse data.

Case study 7: The ethics of data sharing in the antenatal corticosteroids trial

Sunil Vernekar, Jawaharlal Nehru Medical College, India

The Antenatal Corticosteroids Trial (ACT) was an 18-month, two-arm, parallel, cluster-randomised trial done in geographical clusters at seven sites of the Global Network for Women's and Children's Health Research. Clusters were distinct geographical rural and semi-urban settings in Argentina, Zambia, Guatemala, Belgaum (India), Nagpur (India), Pakistan, and Kenya. Intervention clusters received a multifaceted intervention that consisted of health-provider training, posters, pregnancy disc, and uterine height tape to facilitate identification of women at risk of preterm birth, and kits for provision of antenatal corticosteroids. The study presented negative results showing not only that the intervention strategy was ineffective at reducing neonatal mortality in less-than- 5th-percentile infants, but also increased mortality in the population overall. Furthermore, the strategy seemed to increase the risk of maternal infectious morbidity. The subsequent interest from funding agencies and researchers around the global presented the study team with the challenge of what data to share (analysed/results data or raw data and individual participant data) and when to share.

The following aspects were considered key to promoting equity:

Recognition of primary data collectors and all intellectual contributions

Co-authorship is one method of acknowledging researchers' scientific contribution. To promote equity, journal publication rules could be changed so that the people who collected the data are given authorship or other significant academic recognition. Innovations are also needed in approaches for including data contributors in secondary data analyses while adhering to international guidelines on authorship criteria. Overall, **more transparency is required about the level and types of contributions that people make to research studies**.

GFBR participants agreed that **memorandums of understanding and collaborative agreements should be drawn up at the outset of research in order to facilitate equitable data sharing** and to avoid misunderstandings that can happen further down the line. This should include up-front agreement on authorship. **Case study 5** described a successful collaboration between Sri Lankan researchers and HIC partners who gave first authorship to Sri Lankan researchers and encouraged and supported capacity building.

RECs could play a role in ensuring there is appropriate recognition of those who provide and share data. For example, Zimbabwe's national REC has reviewed many data sharing proposals from local researchers. Taking account of issues of justice and benefit for the country, it has granted approvals that are conditional on local researchers receiving appropriate recognition. This has included a requirement that local researchers are involved up to and including the publication of the research findings.

Issues of local importance and local influence on the research agenda

Case study 8 described the situation in the Dominican Republic where most health research activities are conducted by the international pharmaceutical industry, other international institutions and universities. The implication of this trend is that funds are not allocated towards the diseases and conditions affecting the most vulnerable nor are they directed towards informing local health policy. At the same time, local researchers are contracted as principal investigators when in practice they are only dealing with collection of samples and/or data.

The inequity of this approach was highlighted when in 2016, the Dominican Republic reported one of the largest Zika virus outbreaks in the Americas. Despite the scale of the outbreak, national researchers did not participate as meaningful collaborators and were not involved in defining the research questions. Not only did this relegate them to mere data and sample collectors but it could also have implications for secondary analysis, for example, if a lack of control over the research questions led to data not being collected which could address local priorities if shared. GFBR participants agreed that there needs to be a 'two-way street' for international collaborative research with respect to benefit production and distribution. Ideally, **local researchers should be involved in setting the primary research question to ensure it addresses the health needs of the local population**.

GFBR participants agreed that researchers and sponsors should be aware of historical inequitable data and sample sharing practices and 'helicopter science' by predatory researchers who offer no benefit locally. Policies can take account of this issue through their access criteria. For example, **case study 1** described how the Western Cape Government Health department ensures that, where data from electronic health records can be ethically shared, they are shared with the primary purpose of improving health care and patient outcomes, for the benefit of health clients and/or health services which generated these data. **Case study 9** gave an example from The WorldWide Antimalarial Resistance Network (WWARN), which has developed a number of strategies

to enable equitable use of secondary data. Recent updates to the WWARN's technical, ethical and governance frameworks **give data contributors more choice about how their data can be accessed by others**, including the provision of contributor-controlled access where the contributor will review and decide on each individual request.

Case study 9: The Worldwide Antimalarial Resistance Network's efforts to "level the playing fields" for data sharing by researchers in malaria endemic countries

Karen Barnes, University of Cape Town, South Africa

The WorldWide Antimalarial Resistance Network (WWARN) was established in 2009 to understand and curtail the threat of antimalarial resistance. Key to the delivery of WWARN's research aims was engaging with global malaria researchers and convincing them to share their data with the central WWARN repository, at a time before data sharing was required by policy makers, funders and publishers. As the real and perceived barriers to data sharing were many and diverse, WWARN developed a number of strategies to enable and encourage ethical and equitable sharing of reliable data to inform malaria treatment policies and practices. This case study focused on efforts to promote equity in sharing of data by, and with, researchers from malaria-endemic countries. These efforts include capacity strengthening and technical support in data standardisation and quality, as well as inclusion of primary data generators in secondary analyses.

Capacity strengthening

Policy frameworks should recognise the difficulties faced by LMIC researchers and the need for new approaches to increase their capacity for research. This includes strengthening infrastructure as well as individual capacities to:

- conduct sample and data analyses (of both primary and secondary data)
- perform data standardisation
- perform complex data integration
- curate data and samples
- store data and samples
- develop policies that promote ethical and equitable data and sample sharing.

This highlights the importance of the kind of tools and support provided by platforms such as WWARN, which works with the malaria research community (**case study 9**). WWARN promotes equitable sharing by helping data contributors have more confidence in the data that they share. This is critical as concerns about sharing data often relate to concerns about critiques of their quality, rather than researchers wanting to control 'their' data. WWARN also promotes equitable use by providing technical support in data standardisation and quality, as well as inclusion of primary data generators in secondary analyses. Their activities include:

- **Development of tools and resources** to make it easier and quicker for people to collect and share quality data. Data contributors are given a report on their data, with outliers flagged (e.g. if any data points are unexpected). WWARN holds a long-term repository of data, which can be supplied back to researchers in either original or standardised form.
- The **creation of 'study groups'** of data contributors conducting individual patient / participant data meta-analyses to answer research questions that cannot be answered as reliably or efficiently by

individual studies or aggregate data meta-analyses. For many researchers, requirements to share data are theoretical or bureaucratic - while being in a study group helps demonstrate the practical benefits of sharing. Anyone can pose a question and the groups encourage the sharing of expertise in a way that means everyone contributes and everyone learns.

- **Skills sharing and capacity development** to help researchers access and use secondary data to answer questions of importance to malaria e.g. through online open access resources; training workshops conducted in Africa; hosting European & Developing Countries Clinical Trials Partnership (EDCTP)/Special Programme for Research and Training in Tropical Diseases (TDR) career development fellows from LMICs to gain the skills required to lead future efforts to make the best use of available data to inform policy and practice; contributing to work with other research communities to replicate the WWARN model for other neglected poverty-related diseases and emerging infections.

The impact of these efforts is demonstrated by the size of the WWARN platform which, thanks to the contributions of the global malaria research community, now holds over 80% of the world's individual patient clinical trial data on artemisinin-based combination antimalarials. However, WWARN has faced many challenges over the years and its capacity strengthening activities remain largely unfunded.

Promoting local researcher capacity through data and sample release policies

H3Africa was given as an example of how local capacity building is promoted through provisions in the project's data and sample release policy. Researchers on the African continent – or who collaborate with African scientists – have priority access to samples and the H3Africa access committee could reject proposals that do not have enough African capacity building built into the project. A moratorium is also in place for release of samples to outside investigators to allow time for publication of the H3Africa study for which the samples were collected.

Export of samples

Many GFBR participants had concerns regarding the export of samples from LMICs to HICs, in particular where this had happened during a public health emergency. It was argued that exporting samples diminishes the country's ability to build its own research capacity. However, it was also noted that building local capacity may involve the trade-off of delaying research while local researchers acquire the necessary skills.

Case study 5 provided an example when there was pressure on the Sri Lankan Twin Registry team to consider transferring samples to outside the country for genetic analysis. The local team decided that the detrimental impact of LMICs being relegated to data gatherers and losing the long-term benefits of developing local capacity, outweighed the benefits of faster research output achieved by transferring the samples abroad. The team delayed genetic research until they were confident of their ability to effectively manage the ethical and technical challenges. The authors argued that if capacity building in LMICs is made a condition of international collaborations, it could have an exponential positive impact on improving data analysis capacity in LMICs.

Recommendations for promoting equity

Innovative approaches and investments are required to promote equitable data sharing and biobanking. GFBR participants identified the following ways in which equity can be promoted, many of which require financial and policy commitments from funders, government and other institutions (e.g. journals):

- Increase investment in readily accessible **tools and resources to enhance the quality and efficiency of primary data collections** and support LMIC researchers to efficiently achieve required data standards.
- Invest in **platforms to support complex data integration and analyses**, with specific funding for data platforms that support poverty related disease research communities. It should be appreciated (by government and funders) that such platforms require long-term investment and sustainable infrastructure.
- **Incentivise data sharing and align academic promotion with data sharing mandates**. For example, often researchers are rewarded for original research, but not meta-analyses which may be more influential with policy-makers. Systems providing credit for sharing data where originators get credit for sharing datasets (e.g. through labelling of the dataset) could be implemented more widely.
- Find innovative ways to **recognise all intellectual contributions to the research process** (including, for example, primary data collectors, data analysts etc.). WWARN adopted a very inclusive approach to authorship early on but this resulted in it being difficult to tell who had really contributed. PubMed allows for recognition of 'collaborators' but again this may reflect very different contributions.
- **Facilitate the use of shared data and samples**. Curating data that will never be used by others is wasteful; but if data aren't curated and actively made available, people won't know about them. Funding streams should target this necessary aspect of promoting and supporting the use of data and samples once they have been made available.
- **Consider equity issues when developing a biobank or data sharing access fee policy** (e.g. where charges are applied, is tiered pricing economically or logistically feasible?).
- **New approaches to capacity building are required,** where people can meet and share experiences and skills. Online courses are not sufficient – there is a need for people to sit down and work through problems together, possibly using regional, disease-focused hubs based on a similar model to WWARN's study groups.
- Promote **capacity strengthening as a requirement for access by HIC researchers to data and/or samples generated in LMICs**. This recognises the value of sharing benefits - including developing the skills needed to enable local researchers to benefit from sharing and accessing data and samples.
- **Create structures and incentives to support and recognise capacity building initiatives** (e.g. funded time, academic recognition). This will require engagement with government, policy-makers, employers and funders.
- **Develop the capacity of RECs to review applications to establish or use data sharing platforms and biobanks**. Different regions experience similar structural problems with respect to scrutiny of sample and data sharing. RECs could share approaches and lessons learned.
- **Funders should perform an 'equity assessment' on their data sharing and biobanking policies.** Well-meaning policies, for example on open data, can exasperate issues of equity if not accompanied by capacity strengthening initiatives.

4. Regulation, policy and guidance

GFBR participants agreed that international guidelines and declarations such as the Council of International Organizations of Medical Sciences (CIOMS) Ethical Guidelines[3], the World Medical Association's Declaration of Helsinki[4] and the United Nations Educational, Scientific and Cultural Organization (UNESCO) Draft Declaration on Human Genetic Data[5] are useful but do not provide a consistent set of principles. **Policy paper 4**, on the governance of health data sharing in post-Ebola West Africa, argued that international guidelines are not sufficiently disseminated or internalised, hence gaps still exist in relation to critical aspects of data sharing practices.

This was discussed in **policy paper 1,** which described the impact of the 2016 CIOMS guidelines on the development of a biobanking governance framework in Argentina. The paper identified aspects to improve on in order to promote local and international collaboration, as well as to protect the rights of participants and local researchers. This included the need for:

- infrastructure and specialised personnel to support responsible data and sample management
- training for researchers that promotes the benefits of data and sample sharing and in ensuring that ethical requirements are observed
- training of REC members who are involved in the review of studies that use stored samples or data
- community engagement and education to better understand public views and attitudes and to promote public trust in biobanking.

Policy paper 1: A critical reflection on the development of a biobanking governance framework in Argentina

Ana Palmero, National Ministry of Health, Argentina

This paper provided an overview of a regulatory framework that is being developed by the National Ministry of Health of Argentina for biomedical research (other than clinical trials), and with focus on biobanking and sample/data sharing. It discussed the impact of the 2016 CIOMS Ethical Guidelines on setting out the key ethical issues and identified aspects that need further clarification in order to promote local and international collaboration, as well as to protect the rights of participants and local researchers.

Lack of regulation and guidance

Many LMIC countries have no regulatory or governance structures for biobanking and data sharing. For example, in Peru only clinical trials are regulated. Where there is no legal framework, researchers and RECs are left with the responsibility of taking decisions on their own. This situation carries the risk of different standards being applied and inadequate safeguards for the rights and welfare of research participants (**policy paper 1**).

[3] https://cioms.ch/wp-content/uploads/2017/01/WEB-CIOMS-EthicalGuidelines.pdf
[4] https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/
[5] http://www.unesco.org/new/en/social-and-human-sciences/themes/bioethics/human-genetic-data/

Law & regulation vs guidance

There was general agreement that data sharing and biobanks should be regulated but recognition that there is no universal model that fits every country. Contextual features are important in determining how data sharing and biobanks should be regulated and there is no 'one size fits all'.

Examples were given of legal approaches such as Singapore's Human Biomedical Research Act which lays out an accountability structure for researchers, research institutions and RECs. Discussion focused on whether guidance is sufficient or whether legislation and regulation is necessary to ethically regulate data sharing and biobanking. Some GFBR participants favoured the latter approach, arguing that legal certainty provides the best safeguard and is helpful for those who monitor research (e.g. regulatory bodies, RECs). However, primary legislation tends to be difficult and costly to amend. Other GFBR participants favoured setting up regulatory bodies and guidelines, and to complement these with secondary legislation/regulations which can be drawn up and amended more easily to respond to changing circumstances.

Many GFBR participants questioned the ability of governments to put into place effective regulations that are enforceable and operate within a broader coherent governance system. They also identified the need for systems that are consistent within geographical regions. Governments should be engaged in these discussions so that they understand the issues and can develop regulatory frameworks that support data sharing and biobanking nationally and regionally. **Regional meetings of regulators, researchers, policy makers and RECs could be established to share experiences of governance, with a view to developing more consistent approaches.**

GFBR participants agreed on the need for clear institutional requirements. The case studies provided examples of institutional guidance:

- **Case study 1**: The Western Cape Government Health (WCGH) department in South Africa has data-sharing guidelines that delineate data-sharing options according to dataset characteristics. These include whether data requests are from within WCGH to directly inform health service operations, or from external researchers such as those at academic institutions; whether participant informed consent and/or institutional REC approval has been obtained; whether requested data will be anonymised and/or aggregated, and whether there is a risk of re-identification of individuals or stigmatisation of population groups. Currently, identified data will only be released beyond the health service if there is specific informed consent by participants in place.
- **Case study 5**: The IRD in Sri Lanka created research ethics guidelines titled 'Research Ethics from a Developing World Perspective'. The standards are based on a blend of existing international guidelines and the customs, social and moral norms of the Sri Lankan culture. They were developed with the help of Sri Lankan academics and researchers as well as input from international ethics experts.

Lack of definitions

Many GFBR participants reported that good governance can be hindered by unclear definitions e.g. as to what constitutes a biobank. **Policy paper 2** described the deficiencies of the 2006 Indian Council of Medical Research (ICMR) guidelines which had limited coverage of biobanking. While biobanks (mostly of stem cells, cord blood and 'waste tissue') proliferated as "research centres" in the private sector in India, no formal registration with a regulatory authority appears to be required and there were no licensing requirements. Given this, no official data is available on the numbers or locations of biobanks in India. It was also unclear under the 2006 guidelines, if stored biological samples used for research constituted human subject research and if residual samples from

clinical trials or diagnostic studies constituted a biobank. This results in considerable legal and ethical uncertainty as to how these 'biobanks' are being managed and regulated.

Policy paper 2: India's national guidelines on biobanking and data sharing and its ethical bearing on Indians

Manjulika Vaz, St John's Research Institute, India

The 2006 Indian Council of Medical Research (ICMR) ethical guidelines for biomedical research had limited coverage of biobanking. This gap was addressed in the 2017 ICMR Guidelines, which had a new section devoted to biological materials, biobanking and data sets. A group of experts used review articles, international guidelines and multiple consultations to formulate and finetune these guidelines. The main components are addressed at two levels: issues for researchers and issues for participants. The guidelines include such issues as ownership, benefit sharing and transfer of samples. This paper provided an overview of ICMR and discussed the gaps between the guideline, regulations and actualisation.

Restricted scope

Some countries have governance frameworks but these are restrictive, either intentionally, by omission or due to a lack of clarity. For example:

- In Egypt and India **export of samples from the country is prohibited**. It was noted that regulations that restrict export may have a negative impact on international collaboration. Also, where analysis and research must be done in-country, local RECs need to develop expertise in reviewing and regulating these studies. This can take time as the REC (and those analysing samples) need training; this helps builds capacity but delays the research. GFBR participants agreed that government policies should not be merely restrictive. Where governments restrict export of samples and require local analysis, plans should be in place for capacity building.
- **Policy paper 3** described how **broad consent is prohibited** under the Government of Malawi's governance framework on accessing, collecting, storing and using human biological specimens for research. Under the framework, approved research protocols are required to have consent and researchers are not allowed to collect samples for purposes beyond their immediate study objectives. The author argues that this denies potential participants of their right to make choices about the use of their samples in potentially beneficial future research.
- In addition, the Malawian guidance **does not allow secondary use of legacy samples without specific consent**. It also only allows samples to be kept for 5 years, unless REC approval is given for a further 5 years in the event that tests/analyses are incomplete. Samples are otherwise discarded or destroyed. The author argued that discarding or destroying samples leads to loss of present and future scientific and economic benefit, due to a failure to maximize benefit derivable from these already collected samples.

Policy paper 3: Critical review of the current governance framework on research involving human biological specimens in Malawi

Wongani Nyangulu, Dignitas International, Malawi

The government of Malawi allows access, collection, storage and use of human biological specimens for health-related research, but only for presently approved research protocols that meet ethical requirements including specific informed consent having been obtained from research participants. It does not permit use of stored specimens for future unspecified research nor does it allow broad consent to be obtained from participants for this purpose. This paper reviewed the governance framework on use of human biological specimens and data and made recommendations to maximise the social value of this type of research while ensuring adequate regulation and oversight.

Annex 1: Background information on GFBR and meeting content

The Global Forum on Bioethics in Research (GFBR) is the principal global platform for debate on ethical issues pertaining to international health research. Its core aims are to give voice to low- and middle- income country (LMIC) perspectives in debates about global health research ethics and to promote collaboration.

The Forum meets annually to address a specific topic in research ethics and is case study based. This approach enables participants to understand the practical issues "on the ground" in addition to broader ethical and policy questions. Up to 100 participants are selected for each meeting through a competitive process. Participants come from a diverse range of disciplines, countries and career stages and awards are available to LMIC colleagues to cover travel and accommodation.

25 case studies were submitted for this meeting, along with 16 guidance and policy papers. A further 80 applications were received from potential participants. 9 cases studies and 4 policy paper were selected for oral presentation (see insets throughout the report). Several other case studies and policy papers were presented at the meeting in the form of posters or short Pecha Kucha presentations:

Pecha Kuchas

1	**Regina Garcia** Zika in infants and pregnancy: Conducting research in the setting of a public health emergency
2	**Ravi Vaswani** Case of a prospective protocol on stored blood samples without consent for future use
3	**Farirai Mutenherwa** Ethical issues in HIV molecular epidemiology
4	**Vina Vaswani** Ethics of data sharing and biobanking: A policy paper: Who is the owner of my data?
5	**Kenneth Onyedibe** Biobanking in Africa: Could religion and witchcraft create an ethical bottleneck?

Posters

1	**Limbanazo Matandika** Understanding perspectives on the collection, storage and use of biological samples for future unspecified research purposes: The case of Malawi
2	**Nor Othman** The perspective of a research ethics committee in reviewing research proposals on sensitive clinical data from hospitals in Malaysia
3	**Jayakrishnan Thavody** Data sharing in large-scale international collaborative research - National Family Health Survey (NFHS) as an example from India
4	**Jonathan Ives** Developing research to improve informed consent practice in biobanking: A Sri Lankan experience
5	**Mary Kasule** Challenges of Institutional Review Board (IRB) in approval of data sharing and biobanking proposals amidst lack of country specific genomic research governance frameworks: Lessons learnt by the Botswana IRBs
6	**MS Ganachari** Challenges in reviewing and approving the research protocol of pharmacogenomic studies of multi center international researches
7	**Simisola Akintola** Advancing stewardship as a model of governance for data sharing in biobanking research in Nigeria
8	**Syntia Nchangwi** A principle and value based governance framework for genomics research and biobanking consortia in Africa
9	**David Nderitu** CIOMS (2016) guidance on data sharing and bio-banking: An analysis in view of the place of the human body in the African ontology of nature
10	**Elezebeth Mathews** Government data sharing policy: A key to research data access

Annex 2: List of abbreviations

GFBR: Global Forum on Bioethics in Research

LMIC: Low- and middle-income country

HIC: High income country

REC: Research ethics committee

SoC: Standard of care

PAHO: Pan American Health Organization

CIOMS: Council of International Organizations of Medical Sciences

UNESCO: United Nations Educational, Scientific and Cultural Organization

IRD: Institute for Research and Development, Sri Lanka

WWARN: The WorldWide Antimalarial Resistance Network

H3Africa: Human Heredity and Health in Africa

ICMR: Indian Council of Medical Research

EDCTP: European & Developing Countries Clinical Trials Partnership

TDR: Special Programme for Research and Training in Tropical Diseases

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Author: Adrienne Hunt

Full case study write-ups are available on the GFBR website.

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