The Global Forum for Bioethics in Research: Past, present and future

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The Global Forum for Bioethics in Research (GFBR) served as a global platform for debate on ethical issues in international health research between 1999 and 2008, bringing together research ethics experts, researchers, policy makers and community members from developing and developed countries. In total, nine GFBR meetings were held on six continents. Work is currently underway to revive the GFBR. This paper describes the purpose and history of the GFBR and presents key elements for its reinstatement, future functioning and sustainability. Potential participants and sponsors are encouraged to contribute actively to the future of this unique international research ethics event.

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post-trial access to drugs; and mental health research. Proceedings of each meeting were recorded by each host country, and were posted on an open access website hosted by AKU (http://gfbронline.com/).

In 2009, the funders of the GFBR put future meetings on hold in order to review its role, format, funding and governance. This has allowed a period of consultation through discussions with other funders and stakeholders, round-table consultations at the 2012 Global Forum for Health Research and the 2012 World Congress of Bioethics, a survey of past participants, and a questionnaire to experts in the field.

As a result of this consultative process, an Interim Steering Committee (ISC) facilitated by an informal coalition of funders (the Fogarty International Center, the MRC (UK) and the Wellcome Trust) has concluded that there is strong stakeholder support for the continuation of the GFBR as an event to promote and facilitate high-quality and inclusive international discussion of major emerging research ethics issues of global significance. Such a forum, in line with original GFBR objectives, will provide a platform for international dialogue to shape policies and practices that affect researchers, funders, government and societies. The GFBR would help ensure that the voices of all the relevant communities are heard – including those from developing and developed countries.

Future of the GFBR
The ISC has conducted several teleconferences to date. Work in progress is described below. The sustainability of the GFBR requires a wider funding base than existed during 1999 - 2008 for several principled and pragmatic reasons. It is advisable to have funding from a broad range of funders to reduce vulnerability to withdrawal (or undue influence) of a single major sponsor. Breadth of sponsorship would also strengthen the perceived independence of the GFBR from specific political or ideological positions as they arise from time to time. Breadth of sponsorship from a range of developed and developing country sources would also reinforce joint ownership and participation in a sustainable global event. The ISC has, for the present, decided to maintain the GFBR’s independence from industry sponsorship but this issue could itself be the subject of future GFBR debate.

Key recommendations
- The GFBR should be funded for an initial period of 5 years with a review at the end of the third year.
- The funding base of the GFBR should be expanded to achieve optimal core funding of up to US$450 000 per annum.
- The GFBR should build on its core aims and objectives and be more proactive and strategic than previously.
- The basic aims and mission of the GFBR are sound and should be preserved.
- A steering committee should be selected, based on a transparent selection process.
- A small part-time secretariat, stable for 5-year cycles, should be established to ensure that the GFBR is run efficiently and that institutional knowledge is maintained between meetings.
- The website for the GFBR should be expanded to provide a discussion forum and a clearing house for disseminating research ethics information and contacts internationally.
- Meetings should continue to be annual, but reports and outcomes of each GFBR must be published. Prior agreements with a journal publisher might be a criterion that the steering committee uses when selecting future GFBR event hosts competitively.
- Clear, stable, transparent governance policies and structures should be established.

Mission
The previous mission of the GFBR was: ‘To bring together key stakeholders from developing and developed countries to debate the ethics, social, legal and public policy issues related to health research in international settings.’

The GFBR’s aims were:
- to maintain and strengthen the protection of human participants in health research
- to provide a forum for developing country perspectives on ethical issues in research
- to explore opportunities to enhance capacity for ethical review of research
- to create a context for research involving human participants in which scientists, ethicists, community representatives, policy-makers, industry, and other relevant stakeholders in developing and developed countries can address ethical issues in ways that allow expeditious long-term joint management of research protocols.

An implicit aim of the GFBR, ‘to promote high ethical standards in research’, should be included as an explicit future aim.

Participants
GFBR meetings should remain relatively small in size. Between 70 and 100 participants allows for discussion between participants and preservation of the case study format and is sufficient to ensure a diversity of standpoints and regional and global representation. The GFBR must continue to attract a mix of participants from an appropriate range of fields and experience levels from within their respective professions and fields of activity. Participants will be selected on a competitive basis, based on structured submissions requiring a motivated account of each applicant’s engagement with the topics being focused on at a particular meeting. One of the main reasons the GFBR had influence and was so widely supported was the fact that many delegates were senior and actively engaged in their field; they could effectively spread and apply the ideas generated. It is also important to continue to support the more junior participants and ensure that their viewpoints are heard in these debates.

Frequency
Annual meetings would allow the GFBR to be responsive to the needs of the global community, enable participation from a range of people for greater sharing of knowledge and ideas, and ensure a process that develops momentum and memory.

Topics
The future GFBR should be strategic in its choice of topics. Having the GFBR pre-empt or respond promptly to emerging issues and policy developments was identified as important and as adding value during the consultation period. The steering committee and secretariat could be tasked to identify these current issues and support ancillary activities between meetings (funds permitting), such as an open call for topics by email. The steering committee and the secretariat could
then provide opportunities for stakeholders to give feedback on the ethical issues they find pressing, either by pro-active consultation or through an interactive electronic facility on a revised GFBR website.

**Outputs and dissemination**
The secretariat (discussed below) could play a crucial role in disseminating published GFBR discussion papers and interfacing with other national and international bioethics groups and committees. The GFBR website should become a key element of dissemination. A moderated discussion forum would help to stimulate and sustain discussion on GFBR topics and maintain links between forum participants and the wider community. It could also serve as a clearing house to connect forum participants and allow them to find local experts, share their ideas and solutions, and disseminate educational resources and opportunities.

**Governance**
Robust governance is essential for any future GFBR. There is a need for written terms of reference and governance processes, including criteria for deciding on host countries and choosing forum participants. The ISC would work with the first GFBR secretariat to develop standard operating procedures, to be agreed by the steering committee, so that each set of meeting organisers can build on the experiences of past hosts to deliver an effective and energetic meeting with appropriate attendees selected through a transparent competitive process. As part of the goal of ensuring inclusivity, the steering committee should have significant representation from LMICs, periodically rotated so that different regional voices are heard. In all respects, the GFBR should seek to be a model of global partnership. Identifying suitable models of partnership is a current ISC priority.

**Secretariat**
Most previous GFBRs were organised by different partner institutions with an annual change of secretariat. This resulted in continuity problems between meetings. As a result, in 2006/7, the funders established a ‘permanent’ co-ordinating secretariat, hosted by COHRED in Geneva, with funding from the European Commission. A 2009 evaluation of the secretariat showed strong support for it, as did a stakeholder engagement survey, despite some divergent views on its exact scope and role.

The ISC favours the establishment of a small, efficient, part-time GFBR secretariat that should be funded as a core component of the GFBR. This secretariat would maintain the infrastructure necessary to run the GFBR, retain institutional memory, and ensure continuity of debates that are started but not completed during meetings. The secretariat would be competitively selected, using predetermined criteria, for a 5-year period, subject to competitive renewal, funding permitting. The core activities of the secretariat should include:

- Support the steering committee.
- Administer the selection of successive GFBR hosts.
- Work with the successful local hosts to organise meetings and produce reports and publications.
- Conduct evaluations of the meetings and disseminate materials.
- Maintain the GFBR website.
- Facilitate the transition from one meeting to the next.
- Preserve the ethos of the GFBR; preserve institutional memory.

Ideally the secretariat should be continuously hosted in a single location to ensure staffing, financial and operational stability. Options under consideration are:

- Host in one of the funding organisations. This is a cost-effective model but could create perceived conflicts of interest. However, such conflicts have not been an issue in the Wellcome Trust’s experience with hosting the secretariat for the UK Biobank Ethics and Governance Council.
- Host at an institution in an LMIC. This would have the benefit of helping to build local capacity.
- Host in a neutral health research or policy organisation. A benefit is that such organisations have established contacts and infrastructure. However, this could be a more expensive option.

**Monitoring and evaluation**
The GFBR should be regularly monitored and evaluated. One of the first tasks of the steering committee, together with the ISC, will be to formulate a list of progress aims and operationalise them as concretely as possible. Annual monitoring with full review and evaluation after the third meeting is strongly recommended. The ISC has already developed a provisional monitoring and evaluation plan.

**Budget**
To reinforce a sustainable GFBR for at least a further 5 years, core funding committed for a period of 5 years would be required. There are several main components of the budget that require funding:

- annual travel and accommodation for 70 - 100 delegates
- part-time secretariat
- occasional face-to-face meetings of the steering committee (most could be tele- or videoconferences; the balance could coincide with the annual forum).

The total estimated cost per annum would be in the region of US$250 000 - 420 000, depending on the location of the secretariat and the annual forum itself. Ideally, the support would cover the maximum number of delegates and enable some meetings to be held in less accessible but important locations.

Not all funders are likely to be able to contribute equally, so a tiered funding model is recommended by the ISC. This will ensure that all partners contributing up to or over a specified threshold have an equal voice. Ensuring a balanced composition and rotation of funders on any future steering committee will help to secure this.

The ISC is currently generating a list of international funders who will be formally approached to pledge a contribution.

**Launch event**
Planning is underway to re-launch the GFBR at a satellite meeting of the International Association of Bioethics (IAB) World Congress of Bioethics in Mexico in June 2014. At this meeting the GFBR will host a one-day forum on a current controversial topic, host a launch event at which the permanent secretariat will be announced, and invite expressions of interest to host the next full GFBR in 2015.

**Conclusions**
The GFBR played a unique and important role in advancing international debate on current issues in research ethics. Lessons learned
during 1999 - 2009 suggest that a stable secretariat implementing a specified, popular vision, mission and operating principles will best serve this purpose for the next 5 - 10 years. A wider and more globally diverse pool of funders should broaden the funding base, which in turn will ensure better representation, stability and sustainability. The GFBR launch event that will take place at the IAB in Mexico in June 2014 is intended to draw on a broader, more globally inclusive pool of funders and set a renewed GFBR on course for at least a further 5 years of critical debate and discussion to promote high ethical standards in health research globally.

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References