

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

K Littler, J Millum, D R Wassenaar, for the GFBR Interim Steering Committee

Katherine Littler is a senior policy adviser at the Wellcome Trust, UK; Joseph Millum is a bioethicist at the Clinical Center Department of Bioethics and Fogarty International Center, National Institutes of Health, USA; and Douglas Wassenaar is director of the South African Research Ethics Training Initiative at the University of KwaZulu-Natal, South Africa.

Corresponding author: D Wassenaar (wassenaar@ukzn.ac.za)

The Global Forum on 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.

S Afr JBL 2014;7(1):5-8. DOI:10.7196/SAJBL.312



The Global Forum for Bioethics in Research (GFBR) was established following the controversy in the 1990s over perinatal trials of 'short-course' zidovudine (AZT) for the prevention of HIV transmission. The use of placebo-controlled trials in countries in sub-Saharan Africa and

Southeast Asia was criticised as unethical in the *New England Journal of Medicine*^[1] for providing participants with less than the global best standard of care. But the debate over these trials largely lacked voices from the countries most affected by the HIV/AIDS epidemic – countries whose citizens were participants in the trials and whose patients eventually benefited significantly from them.^[2] A forum was needed in which representatives of all the stakeholders from developed and developing countries could freely discuss pressing issues in research ethics and work together towards solutions. The GFBR's originally stated purpose was therefore to provide an open and transparent dialogue between delegates from the global north and south about the ethical challenges they faced.^[3-5]

Each meeting focused on one or two current ethical challenges in the field of health research, ranging from post-trial obligations to the ethics of mental health research. Meetings prioritised case-based discussion, diversity of attendees, and the intersection of academic and practical perspectives. A special effort was made to include voices from resource-poor or vulnerable settings. Over 70% of participants at the nine meetings held between 1999 and 2008 were from low- and middle-income countries (LMICs). By the seventh meeting, in Lithuania, over 1 000 delegates from over 40 countries had attended.^[4]

Funding support and in-kind contributions were made by Aga Khan University (AKU), the Council on Health Research for Development (COHRED), Facultad Latinoamericana de Ciencias Sociales (FLACSO), the Fogarty International Center and other institutes of the US National Institutes of Health, Institut National de la Santé et de la Recherche Médicale (INSERM), the Medical Research Council

(MRC) (UK), the MRC (South Africa), the Rockefeller Foundation, the Wellcome Trust, and the World Health Organization (listed alphabetically). Country hosts of particular events also contributed to funding and supporting specific events – such support was often, but not always, from host country government sources.

The format of the GFBR positioned it uniquely on the international research ethics calendar, and it became a forum for open international dialogue on pressing or topical ethical issues affecting international health research. An informal steering committee managed the competitive selection of future hosts, based on the relevance of the topics proposed and applicants' general track record in health research ethics. Hosts were requested to maintain the generic format of GFBR meetings and bring opportunities for dialogue and debate to the foreground rather than formal presentations of papers.

The GFBR was designed and formatted to facilitate open and active engagement between delegates on specified topics of relevance to ethical issues in international health research. It created an environment 'where conflicting and unresolved ethical issues can be debated and explored without expectation of immediate resolution'.

^[5] In some ways it is easier to describe what the GFBR was not than to describe what it was: it was not a bioethics conference with formal papers and presenter-initiated workshops; it was not an ethics guideline drafting exercise; it was not a research ethics training event. Instead, each GFBR meeting focused on one or two linked themes, which were explored through short, focused case presentations from selected experts or stakeholders, followed by extensive small-group discussion of case studies, commentaries, and report-backs to facilitated plenary sessions. Topics covered included partnerships between sponsors and investigators in clinical trials in developing countries; ethical issues in public health research; the ethics of cluster-randomised trials; capacity building needs and governance of research ethics committees; the ethics of genomics research; benefit sharing; research involving indigenous and vulnerable populations;

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://gfbronline.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.'^[6]

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.^[7]

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 clear 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,^[6] 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.

Acknowledgements. Interim financial support of the ISC from the Wellcome Trust is acknowledged.

Disclaimer (JM). The views expressed are the author's own. They do not represent the position or policy of the National Institutes of Health, the US Public Health Service, or the US Department of Health and Human Services.

Members of the GFBR ISC. Elizabeth Bukusi, Kenya; Anant Bhan, India; Yali Cong, China; Catherine Elliott, UK; Patricia Garcia, Peru;

Katherine Littler, UK; Florencia Luna, Argentina; Joseph Millum, USA; Michael Parker, UK; Barbara Sina, USA; Douglas Wassenaar, South Africa.

References

1. Editorial. The ethics of clinical research in the third world. *N Engl J Med* 1997;337(12):847-849.
2. Chi BH, Stringer JSA, Moodley D. Antiretroviral drug regimens to prevent mother-to-child transmission of HIV: A review of scientific, program, and policy advances for sub-Saharan Africa. *Curr HIV/AIDS Rep* 2013;10(2):124-133. [<http://dx.doi.org/10.1007/s11904-013-0154-z>]
3. Loff B. Africans discuss ethics of biomedical research. *Lancet* 2002;359(9310):956. [[http://dx.doi.org/10.1016/S0140-6736\(02\)08059-5](http://dx.doi.org/10.1016/S0140-6736(02)08059-5)]
4. Realpe S, IJsselmuiden C. Global Forum on Bioethics in Research. Presentation at 8th Global Forum for Bioethics in Research, 2007. <http://gfbronline.com/presentations.htm> (accessed 7 February 2014).
5. Realpe S, Wang X, Jiminez-Santos E, IJsselmuiden, C. Global Forum on Bioethics in Research: Nearing 10 years of dialogue. Presentation at 9th Global Forum for Bioethics in Research, 2008. <http://gfbronline.com/presentations.htm> (accessed 7 February 2014).
6. <http://www.gfbronline.com/mission.htm> (accessed 7 February 2014).
7. <http://www.gfbronline.com/amis.htm> (accessed 7 February 2014).
8. http://www.gfbronline.com/PDFs/Evaluation_Report_Feb09.pdf.p.5 (accessed 7 February 2014).