Brief Summary – Inaugural GFBR Meeting
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It would be impossible to tie up the discussions of the last two days in a neat and wholesome way, and at the same time do justice to the diverse views and deep insights that were expressed. What follows, therefore, is by no means a comprehensive summary of the conference proceedings, but rather, a brief review that also reflects the biases of the writer.

In the last two days, we have addressed questions ranging from the ethics of placebo-controlled trials, to the standard of care that sponsors of research are required to provide to study participants, and to how the benefits of research should accrue to study populations. While addressing such nitty-gritty issues, however, the discussion was continually and inevitably pulled in the direction of more overarching and fundamental questions pertaining to resource allocation, inter-country disparities, decision-making, and the balance of power.

It might be helpful to view the plethora of concerns that were raised at this forum as falling into three concentric circles radiating outwards.
At the core, are the ethical concerns that are specific to the conduct of research. There was consensus on some of these, while agreement was not reached on some others. With respect to the use of placebo-controlled trials where a proven therapy becomes available, for example, the sentiment that economic issues should not be the determining factor was pitted against concerns that scientific validity should be ensured.

With respect to the standard of care that should be provided to study participants, discussion was uneven. Although there appeared to be some agreement at first with the standard of 'best attainable and sustainable', others later spoke out vehemently against this view. Nevertheless even among those who had agreed to it, questions raised with regard to who has the obligation to provide care, for how long, and who decides what is sustainable, did not have any clear-cut answers.

There seemed to be wider consensus, however, surrounding the issue of benefit sharing; that sponsors, host governments and researchers should strive toward arrangements where there is technology transfer and capacity strengthening rather than just an agreement to supply a particular research product to a study population.

Through all these issues, there was a recurring comment that we should pay attention to the element of process. That before any study is carried out, there should be an explicit agreement on benefit-sharing among the partners. In relation to this, there were concerns that there should be transparency. Sponsors, for example, should be upfront with regards to their interests in the research project and their motivation for supporting it, while host countries should have an idea of what is going to happen after the research process is over. It was pointed out that communities that are stakeholders should also be involved in the decision-making process, and that this would in a way ensure transparency.

The good part of one afternoon was devoted to a discussion of community involvement. But even before that, and indeed, throughout the two days, there were a lot of concerns raised on who constitutes the community, who speaks for the community, and how best to achieve community involvement. Although the practicalities of the situation in many countries necessitate that external researchers and sponsors negotiate with governments, there was a recognition from this forum that governments in many cases do not represent communities and that there is a need to realise obligations to the community, in particular, when they are disenfranchised communities. How that can be done was, however, not so well explored, particularly in cases where communities do not have organized structures.

This last issue serves, in a way, to propel us from the core of the concentric circles, consisting of the more specific concerns, to the next concentric circle of concerns, which has to do with the wider context in which the research is conducted. This set of concerns addresses the structural disparities that is the reality within which research takes place. Some point out that this type of concern is

expressed by the CIOMS standard which specify that the goals of the research should be responsive to the health needs and priorities of the host country.

There were many concerns raised in this category, but I will highlight only three. First, was the concern that benefit sharing should not only be considered narrowly in terms of making the products of research available in the host country after the research is over, but also in terms of how health care accessibility can be improved for a study population, or in the country in which the study was carried out.

Second, concerns were expressed with respect to how inequitable balances of power could be redressed. While it is recognized that negotiation among stakeholders of a research study will reflect the relative balance of power, no clear consensus emerged as to how this should be dealt with. Although, in the last session of the forum, the public-private partnership was considered as one model that can be used to address this question, nevertheless, the responses to this model were varied, and ranged from general approval to caution, and even suspicion.

Third, questions were raised with regard to the responsibility of governments in providing health care, and the role of researchers in questioning the priorities underlying resource allocation. For example, one question might be whether or not it is ethical to ignore the political and social context in which the research is being carried out. Another question could be whether or not sponsors and researchers should negotiate with governments on benefit sharing, while being fully aware that these benefits do not reach communities.

Finally, as we move outward to the last concentric circle of concerns, the existing paradigm of research and research ethics was itself questioned. The concern was raised that there seems to be a trend in changing ethical guidelines to fit the current research that is taking place, rather than to change the guidelines so that ethical considerations shape the research paradigm itself.

In this regard, there was discomfort expressed that, more and more, pharmaceutical companies appear to be dictating the research agenda. There was a call for international bodies to set guidelines and for a greater impetus in involving communities. The active role of communities in the HIV/AIDS case was considered exemplary. Among other things, community advisory boards emerged as a model.

Ethical standards are also the outcome of struggle and negotiation among the various stakeholders. The community should be empowered to play an effective role as major stakeholder. In the current trend of globalisation, where the power of national governments is progressively weakened, the organization of communities will be imperative.

Where communities are empowered to play a major role, they will not only participate in negotiations over benefit sharing, but will be involved at the outset, in the setting of the research agenda. This would mean, however, that researchers, sponsors, and host governments, will have to give up their key role and their power in determining what should be researched, how it should be done, or even whether something is worthy of research at all. When this happens, it will be through this process of community involvement that the paradigm of research and research ethics will also change.