**Benefit sharing in the new Indian National Ethical Guidelines for Biomedical and Health Research Involving Human Participants: opportunities and threats**

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**Abstract**

Even if not an ethical principle *per se*, benefit sharing is an important tool to achieve justice in international research. It comes back a transversal issue through the new Indian Ethical Guidelines for Biomedical and Health Research Involving Human Participants: the guidelines invoke this principle, using the wording “maximization of benefit” instead of “benefit sharing”, with reference to responsible conduct of research, ownership of biobanks and data repositories, informed consent process, community engagement, international collaborative research, and research in emergency or disasters. This approach may be seen as quite innovative, in that it sees benefit sharing (i.e. maximization of benefit) as a key-ethics requirement. Unfortunately, the guidelines do not state explicitly that it is relevant to all research involving human participants and not only to specific situations such as biobanks, research in emergencies and international collaborations; and they seem to consider that the risk of lack of benefit sharing is mainly or only related to international collaborations. Another important drawback is the frequent use of a noncommittal language: wording such as “could be considered” and “may be offered” suggest that the next proposition is open, and not mandatory, thus different ECs are left with the choice to act, or not to act, upon benefit sharing measures in a discretionary manner. Therefore, further elaboration is needed, for the guidelines be more explicit and become a positive model for other countries and ethics bodies.

**Introduction**

Middle-income countries (MICs) are playing an increasingly important role in biomedical and health research. From an ethics perspective, eventual financial and other rewards of such research should always be fairly shared with research participants and their communities (1). For instance, if a clinical trial conducted in a MIC contributes to reaching positive conclusions regarding a new intervention, that intervention should become available to the community in which the trial was conducted (2). Or, if human biological samples are collected from a vulnerable community during an infectious disease outbreak, any results from research conducted on those samples should be made available to the community by using all possible ‘access mechanisms’ (3).

These requirements are generally framed under the concept of “benefit sharing”. Even if not an ethical principle *per se*, benefit sharing is an important tool to achieve justice in international research (4). But differently from other ethics requirements that are widely accepted and adopted, such as the independent ethics review of research protocols and the informed consent procedure, benefit sharing is still poorly known. In particular, it is poorly understood and implemented by many key-research stakeholders, including researchers, sponsors, regulators and, sometimes, ethics committees. To date, there is not a general, straightforward, transdisciplinary definition of benefit sharing in medical research. An unambiguous definition was only proposed for genetic resources: “the action of giving a portion of advantages/profits derived from the use of human genetic resources to the resource providers in order to achieve justice in exchange, with particular emphasis on the clear provision of benefits to those who may lack reasonable access to resulting products and services” (4).

Benefit sharing should be considered at different levels, including the research communities and society as a whole. Benefit sharing at community level appears to be especially relevant when research is conducted within socially vulnerable and/or economically disadvantaged groups. For instance, the CIOMS guidelines state in the commentary on guideline 2 that when research is conducted in resource-low settings, “from the inception of research planning, it is important to ensure full participation of communities in all steps of the project, including discussions of the relevance of the research for the community, its risks and potential individual benefits, and how any successful products and possible financial gain will be distributed, for example through a benefit-sharing agreement” (5). The article 15 of the UNESCO Universal Declaration on Bioethics and Human Rights states that the benefits resulting from any scientific research and its applications should be shared with society as a whole and within the international community, in particular with developing countries, provided that they do not constitute improper inducements to participate in research (such benefits may take various forms, e.g. special assistance to those who part in the research, access to quality health care, provision of products stemming from research, support for health services, access to scientific and technological knowledge, capacity-building facilities for research purposes, etc.) (6). Emanuel and colleagues contend, in their framework for clinical research conducted in developing countries, that recruited participants and communities should “receive benefits from the conduct and results of research”, through fairly sharing “financial and other rewards of the research” (7). Unfortunately, the current Helsinki Declaration (8) omits an explicit reference to a fair level of additional benefits for the community (9, 10). The Good Clinical Practices (GCP) code of the International Conference of Harmonization (ICH) is completely silent on the notion of benefit sharing (11). Even if it is not *per se* an ethics guideline, the ICH GCP code *de facto* guides national legislators and funding agencies in assessing, reviewing and prioritizing research; thus, principles and standards that are not addressed in the ICH GCP are very likely to go underfunded or poorly implemented (12). In practice, in absence of a national or international legislation enforcing it, it is entirely up to the research sponsors and funders to decide how far they wish to go in applying the principle of “benefit-sharing” (12-14).

**Benefit sharing in the new Indian National Ethical Guidelines for Biomedical and Health Research Involving Human Participants**

The Indian Council of Medical Research issued in 2017 the new National Ethical Guidelines for Biomedical and Health Research Involving Human Participants, applicable to all biomedical, social and behavioural science research for health conducted in India and involving human participants, their biological material and data (15).

*Benefit sharing as a principle*

“Benefit sharing” is not mentioned as a principle as such in the guidelines. However, the “principle of maximization of benefit”, listed in the Statement of General Principles, strongly suggests incorporating the concept of benefit sharing, by requiring that “due care is taken to design and conduct the research in such a way as to directly or indirectly maximize the benefits to the research participants and/or to the society”. Noteworthy, the previous version of the guidelines (2006) mentioned jointly the “principles of the maximisation of the public interest and of distributivejustice**“,** whereby **“**the research or experiment and its subsequent applicative use are conducted and used to benefit all human kind and not just those who are socially better off but also the least advantaged; and in particular, the research participants themselves and or the community from which they are drawn”. Even if the more usual wording of “benefit sharing” is not adopted in either versions of the guidelines, the new formulation seems more focused and straightforward, and it is complemented by the principle of reciprocity (invoked under the heading “Public Health Research”), which requires that “individuals or communities, who have borne a disproportionate share of burden or risks for the benefit of others be given some form of benefit. The benefit should be context specific, such as protection from further exposure, access to food, healthcare, clothing and shelter, communication or compensation for lost income”. Importantly, and related to the principle of benefit sharing, the chapter on General Ethical Issues includes in either versions a specific provision on “ancillary care”, i.e. “participants may be offered free medical care for non-research-related conditions or incidental findings if these occur during the course of participation in the research, provided such compensation does not amount to undue inducement as determined by the EC” (2.7.1).

*Benefit sharing as a transversal issue*

“Benefit sharing” often comes through the document as a transversal ethical issue, even if differently worded in the different sections.

First, it is stated in relation to distributive justice that “plans for direct or indirect benefit sharing in all types of research with participants, donors of biological materials or data should be included in the study, especially if there is a potential for commercialization. This should be decided a priori, in consultation with the stakeholders, and reviewed by the Ethics Committee (EC)” (2.4.4). This reflects the approach of the guidelines of 2006 (“The research protocol should outline the benefits that persons / communities /countries participating in such research should experience as a result of their participation”). Interestingly, the “post-trial access of research benefits to participants and their communities” (that is a specific way to implement benefit sharing) is mentioned elsewhere as an example of contemporary ethical issues under debate in biomedical and health research (3.1.2), even if it was already extensively present in the previous version.

Second, it is stated in “post research access and benefit sharing” that benefit sharing should be modulated at different levels: “the benefits accruing from research should be made accessible to individuals, communities and populations whenever relevant” (2.11). Some concrete suggestions are provided on how the principle may be translated into practice, which were already present in the guidelines of 2006: “sometimes, more than the benefit to the individual participant, the community may be given benefit in an indirect way, by improving their living conditions, establishing counselling centres, clinics or schools, and providing education on good health practices” (2.11).

Third, a further level for benefit sharing appears, like in the previous guidelines, when it comes to “collaborative research”, “international collaboration in biomedical and health research”, and “research undertaken with assistance and/or collaboration from international organizations”, where scientific benefits should be fairly shared with local researchers: “the participating centres should function as partners with the collaborator(s) and sponsor(s) in terms of ownership of samples and data, analysis, dissemination, publication and intellectual property rights (IPR) as appropriate. There must be free flow of knowledge and capacity at bilateral/multilateral levels” (3.8.1.); “Indian participating centres should function as partners with the collaborator(s) and sponsor(s) in terms of ownership of samples and data, analysis, dissemination, publication and IPR related to research in India, as may be considered appropriate” (3.8.3); and “researchers and EC members should be trained to understand and recognize ethical perspectives that reflect India’s best interests”(3.8.3). Noteworthy, the need of “an ethical framework based on equality and equity” to guide such collaborations is due to the “different levels of development in terms of infrastructure, expertise, social and cultural perceptions, laws relating to IPR, ethical review procedures, etc.” (3.8.3)

Fourth, the collection, storage and export of biological samples, always subject to ethics review, almost invariably raise issues related to benefit sharing: “if there is exchange of biological material involved between collaborating sites, the EC may require appropriate Memorandum of Understanding and/or Material Transfer Agreements (MTA) to safeguard the interests of participants and ensure compliance while addressing issues related to confidentiality, sharing of data, joint publications, benefit sharing, etc.”; “any research involving exchange of biological material/specimens with collaborating institution(s) outside India must sign an MTA justifying the purpose and quantity of the sample being collected and addressing issues related to confidentiality, sharing of data, joint publication policy, IPR and benefit sharing, post analysis handling of the leftover biological materials, safety norms, etc.” (3.8.1.). The guidelines explicitly address benefit sharing issues in relation to biological materials, biobanking and datasets (11.4.5): “biological materials and/or data have potential commercial value, but the participants’ contribution and their share in this benefit is very often not known to them”, thus the informed consent document should “emphasize this aspect, with necessary clauses for clarity about benefit sharing”, and “describe whether donors, their families, or communities would receive any financial or non-financial benefits by having access to the products, tests, or discoveries resulting from the research”. Also, “the benefits accrued, if any, should be returned to the communities from where the donors were drawn in community-based studies; and to the maximum extent possible, benefits should be indirect or in kind”.

Fifth, the guidelines clearly recognize that issues related to benefit sharing should be considered and reviewed by ECs (section 7), by looking at “how the benefits of the research will be disseminated to the community”. It is also clarified that “post research plan/benefit sharing” is one of the element that should be reviewed by an EC **“**if research on biological material and/or data leads to commercialization”; and that in human genetic testing research, the consent form may include explanations/details on “issues related to ownership rights, IPR concerns, commercialization aspects, benefit sharing”.

Finally, specific issues related to post-research benefit (that is a specific way to implement benefit sharing) arise when research is conducted during humanitarian emergencies and disasters (12.6):” sponsors and researchers should strive to continue to provide beneficial interventions, which were part of the research initiative, even after the completion of research and till the local administrative and social support system is restored to provide regular services”. Research conducted in emergency/disaster and involving a foreign researcher/institution, should also provide benefit by helping “in developing the capacity of local researchers and sites, and provide key learning points to the policy makers and the community (12.9.5).

**Discussion**

*Benefit sharing (maximization of benefit) in the new guidelines*

The new guidelines comprehensively cover the “traditional” ethics issues, such as the informed consent process and the independent ethics review, as well as various new “contemporary issues”, such as the use of underprivileged and vulnerable groups as participants, the research on emerging technologies, and the “post-trial access of research benefits to participants and their communities”. The latter, already present in the previous version, goes beyond the simple post-trial access “for the participants”: it is generally described as a way to implement benefit sharing at community level, that is the moral obligation to make any newly-developed therapeutic, preventive or diagnostic intervention promptly and routinely available to all those in need in the community that hosted the research. However, post-trial access is only applicable to studies that actually result in, or contribute to, the development of a new therapeutic, preventive or diagnostic intervention, and it represents only one of the possible forms that benefit sharing can take. Other authors thus include improved access to quality health care for the research community, upgrade/support for the local health services, capacity-building for research and routine care purposes, etc. (16).

At a first reading, it seems that the guidelines do not consider benefit sharing as a central ethics principle, since it is not mentioned as such as a principle. However, it seems to us that the principle of “maximization of benefit” may and should be read as translation of the concept of “benefit sharing”. The alternative wording could, rather than minimizing the importance of the principle, emphasize the moral obligation to make the best effort to design the best (maximal) possible benefit sharing measures per each research, based on the characteristics of the research, of the community and of any other contextual determinants. The emphasis on this principle is echoed by the emphasis put by the guidelines on distributive justice as a privileged approach to build an ethical framework for research. However, the failure to use the most commonly used/accepted wording of “benefit sharing” entails a risk that readers fail to recognize the central role given to benefit sharing (or maximization of benefit) in the ethics review of a research protocol.

In addition to being spelled as a principle, benefit sharing (maximization of benefit) is a transversal issue that comes back through the document, with reference to responsible conduct of research, ownership of biobanks and data repositories, informed consent process, community engagement, international collaborative research, and research in emergency or disasters. When it comes to international collaboration in research, the concept of benefit sharing is extended from the relation *research group-community*, where the research group is morally compelled to share direct and indirect benefits with the community, to the relation *international research group-Indian researchers*, where the international research group is morally compelled to support the Indian peers to build on their skills, expertise and research infrastructure. This is in line the view of different authors, such as the NIDIAG group, which argued that transnational health research consortia should promote global health equity, among other things by advocating for an equal participation of researchers from low- and middle-income countries in the platforms that govern regulation, agenda, and financing of global clinical research (17).

Quite surprisingly, however, benefit sharing (maximization of benefit) does not explicitly appear in a few specific chapters, including those on behavioral research and on clinical trials (even if there are a few sparse mentions of post-trial access or obligations). We may assume that these cases are covered by the general principle of “maximization of benefit”, and by the general statement that ECs should always look at “how the benefits of the research will be disseminated to the community”. However, it would have been much clearer if benefit sharing had been explicitly mentioned under these headings, and especially under clinical trials, where issues like post-trial access to communities, upgrade of local infrastructures and capacity building are undoubtedly very relevant (16, 18-19). This may have been better (but still insufficiently) addressed in the previous version of the guidelines, which stated under the heading “Drug trial” that “after the clinical trial is over, if need the drug is found effective, it should be made mandatory that the sponsoring agency should provide the drug to the patient till it is marketed in the country and thereafter at a reduced rate for the participants whenever possible. A suitable *a priori* agreement should be reached on post trial benefits”, and which addressed other specific cases.

On a more positive note, the guidelines include a specific provision that “participants may be offered free medical care for non-research-related conditions or incidental findings if these occur during the course of participation in the research”. This is a very important point, that challenges a common view that medical research should not be mixed with health care and clinical issues, and that researchers’ responsibilities are limited to reaching the specific research objectives. By reiterating the call for the provision of “free medical care for non-research-related conditions or incidental findings”, the guidelines make a quite unique and brave statement that the researchers (and research sponsor) have broader responsibilities toward the participants, which cannot be limited to the act of providing, and the act of receiving, medical data and/or biological samples.

*Ethics Committee as key actors to ensure benefit sharing*

The guidelines give a central role to the Indian Ethics Committees. They are entrusted with full legitimacy and power to require that the ethics principles articulated in the guidelines are translated into procedures and practices. The ECs are the gatekeepers for the concrete measures that will be taken by researchers and sponsors to protect the research participants, their communities, and (in case of international projects) the local researchers. Importantly, the ECs can and should give due consideration to cultural and local sensitivities, and set extra requirements when needed. When it comes to benefit sharing (maximization of benefit), the ECs can and should check if a research protocol is giving due consideration to the best possible measures for sharing benefits with the research participants, the research community (e.g. in terms of improved access to food, healthcare, clothing and shelter, compensation for lost income, access to the findings of the research…), and the local researchers (e.g. in terms of opportunities for training, building research skills and networks, gaining decision-making power in international research…). This is very important, since guidelines, checklists and templates from most ECs and Institutional Review Boards (IRBs) do not include “benefit sharing” among the issues to be checked/reviewed (20, 21). This may result in insufficient protection of communities that host medical research programs, and can in a worst-case (but not unlikely) scenario favor conditions for exploitation of socially disadvantage groups, as it has been largely reported in biomedical and bioethics literature (22-26), including cases from India (27-29).

Unfortunately, there is a serious drawback to the enhanced role given to ECs, i.e. the language used in the guidelines is often quite noncommittal: frequently used wording such as “could be considered” and “may be offered” suggest that the next proposition is open, and not mandatory. Consequently, the ECs may be left with the choice to act upon benefit sharing measures, or not to act, in a very discretionary manner. In addition, a thorough assessment of the adequacy of benefit sharing measures is *per se* a complex issue, which depends on the nature of the research, on the needs and vulnerabilities of the concerned community, and on the characteristics of the research sponsor. Not all the ECs and EC members will be necessarily aware of the ethical relevance of such issue, nor will they be ready for this additional task. Specific training and sensitization activities may be needed to successfully translate this important ethics requirement into routine review practices.

This is especially (but not only) important in collaborative research: research protocols will most likely undergo ethics review also in the country of the sponsor, where the concerned EC will not necessarily focus on benefit sharing measures. The guidelines explicitly state that “a mechanism for communication between the ECs of different participating centres should be established” and that “in case of any conflict, the decision of the local EC based on relevant facts/guidelines/law of the land shall prevail” (3.8.2). Therefore, when it comes to benefit sharing (“maximization of benefit”), it is especially relevant that the Indian ECs are able to take on their role of gatekeeper, and when needed also inform and educate their peers abroad.

*A model approach to benefit sharing for other contexts*

The approach of the new Indian guidelines to sharing benefits with research communities, that is, *a transversal ethics requirement that should be implemented (and maximized) in all research, and the adequacy of which must be verified by the ethics reviewers*, could be seen as a positive model to be implemented in other countries and by other bodies. Noteworthy, this approach does not imply that benefit sharing measures are “mandatory” in any research, but rather that the researchers should either describe them or explicitly justify why they are absent.

However, before this may happen in practice, some important improvements are needed. First, the wording “benefit sharing” should be used instead of “maximization of benefit”, for consistency with other ethics guidelines, and for readers’ friendliness and clarity. Second, it should be explicit that this transversal requirement is relevant to *all research involving human participants, data and samples*, and not only to specific situations like biobanks, research in emergencies and international collaborations. Third, the document gives the impression that the risk of lack of benefit sharing, thus of exploitation in research, is mainly or only related to international collaborations, i.e. research conducted in India by foreign researchers and sponsors. While we agree that such circumstances (already emphasized in the previous version of the guidelines) may magnify the potential for exploitative practices, we note that the possibility of exploitative practices also in absence of interests from abroad should not be neglected.

Lastly, the guidelines are quite complex and not easy to read, thus they are not adequate to be used as a practical manual. For instance, somebody reading only the chapter on clinical trials will not learn about benefit sharing, and would ignore or neglect this requirement: he/she should read the whole document, to understand that ECs should always look at “how the benefits of the research will be disseminated to the community” irrespectively of the kind of research and, thus, including in clinical trials. Therefore, to make the guidelines a practical tool, there should be a pathway to implementation and practical guidance, to help ethics reviewers translating the principles into a handy guidance for the review processes. This may be achieved, for instance, by developing standardized training modules for new members of the ECs, and by proposing some “model review templates” that may be adopted by ECs for the different kind of research (for instance, with reference to the topic covered in this paper, such templates would always include a field on “benefit sharing”, to guide the ethics reviewer to systematically check for each protocol if benefit sharing are needed, if they are included in the protocol, and if they are adequate).

**Conclusions**

The approach of the Indian Ethical Guidelines for Biomedical and Health Research Involving Human Participants to research benefits sharing (maximization of benefit) is quite innovative, in that it sees it as a transversal ethics requirement that should be always implemented to the benefit of local communities and local researchers. However, some important improvements are needed before the guidelines may be used a handy guidance by Indian ECs, and before they may be proposed as a model for other countries and ethics bodies.

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