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Benefit Sharing

From Compensation to Collaboration

Kadri Simm

15.1 INTRODUCTION

Benefit sharing pertains to the distribution of benefits and burdens arising from research. More specifically, it concerns what, if anything, is owed to individuals, communities or even populations that participate in research (benefits to investors, to other populations or the social value of research more generally understood are not the focus of benefit sharing).

Traditionally, health research has been concerned with compensating those participants who have been more or less directly involved. The practice of benefit sharing, especially in agriculture, introduced a perspective that recognised the contributions of communities and populations in safeguarding biological resources.[1] The issue is further complicated in human genetics as genetic information is by nature shared, and thus implicates individuals and communities who might not have participated in research in the traditional sense. At the same time, contemporary global research activities have increasingly been associated with for-profit companies. Some of their practices – 'helicopter research', ethics dumping – have given credence to broader political and social worries that have now been harnessed to the concept of benefit sharing, which was initially used within more limited research settings.

Framing benefit-sharing debates are several central concepts – the duty to avoid exploitation, the rights and interests of all research stakeholders, the requirements of fairness and compensation, and the various principles of distributive justice. In many ways, benefit sharing as an ethics and governance framework attempts to deal with most of those concerns and anxieties. Thus, responses to the question, 'why is benefit sharing a duty?' vary. In practical terms, benefit sharing is a thoroughly context-sensitive topic. It matters which risks and harms are involved in research (if any), who the investigators and funders are (for-profit, local, NGOs etc), where research takes place (developed or low- or middle-income countries), who is involved (e.g. vulnerable groups), what local needs are, and whether research is successful.

In what follows, I will give a brief overview of the ethical arguments and historical dynamics behind benefit-sharing practices, then outline major governance frameworks and discuss the potential problems around applying this concept in health research. The overall aim of this chapter is to highlight the complexity of benefit sharing and argue that success hinges on the careful balancing of universal research ethics duties with the particularities of concrete research

[1] Well-known examples of problematic research that motivated the international community to formulate benefit-sharing framework were the Neem tree and Canavan-disease controversies.

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projects taking place in distinct locations. Benefit sharing is no panacea for solving the inequalities of access and opportunities associated with global health research. Yet it can be a profoundly empowering tool, especially as the framework is shifting from compensation to collaboration.

15.2 HISTORY AND RATIONALE OF BENEFIT SHARING

Looking back, the rationale behind access and benefit-sharing justifications has been dynamic. It was originally employed in the context of agriculture and non-human biological resources (plants, animals, microorganisms). The 1992 UN Convention on Biological Diversity (CBD) acknowledged national sovereignty in all genetic resources and requested 'fair and equitable sharing of the benefits arising out of the utilization of genetic resources'.[2] As the majority of the world's biological diversity is found in developing countries, benefit sharing was seen as a necessary instrument in guaranteeing these countries' continuing interest in safeguarding this heritage and curbing biopiracy (when indigenous knowledge and resources are patented or otherwise exploited by third parties with no permission or compensation for the locals). The supplementary Nagoya Protocol on Access and Benefit-sharing (2010) is a legal framework that supports the implementation of the objectives of CBD.[3]

Since the 1990s, benefit sharing emerged as an important component of health research and made its appearance in various international documents (in the rest of the chapter, I will focus on benefit sharing in health research only, excluding research on non-human materials and populations). The Human Genome Organisation (HUGO) Ethics Committee Statement on benefit sharing formulates:

> A benefit is a good that contributes to the well-being of an individual and/or a given community (e.g. by region, tribe, disease-group …). Benefits transcend avoidance of harm (non-maleficence) in so far as they promote the welfare of an individual and/or of a community. Thus, a benefit is not identical with profit in the monetary or economic sense. Determining a benefit depends on needs, values, priorities and cultural expectations.[4]

Benefits put forward by scientists, as well as the pharmaceutical industry, patients, investors and public health officials, span a wide array of potential valued 'goods', from improved health and science to financial gains and wider social benefits.[5] A fixed definition of what would constitute a benefit would be quite useless, or worse, unfair (an informative list of possible benefits regarding non-human research is available from the annex of the Nagoya Protocol). Potential benefits and harms arising from clinical trials would be rather different from those associated with population biobanks, for example. Benefits can be related to healthcare, but they could also encompass other socially important goals, such as support for infrastructure, development of local research capacities and build-up of community resilience. The kind and scope of potential

[2] United Nations 'Convention on Biological Diversity', (United Nations, 1992).

[3] Secretariat of the Convention on Biological Diversity, 'Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization to the Convention on Biological Diversity', (United Nations Secretariat of the Convention on Biological Diversity, 2011).

[4] Human Genome Organization Ethics Committee, 'Genetic Benefit-Sharing', (2000) *Science*, 290(5489), 49.

[5] K. Simm, 'Benefit-Sharing: An Inquiry Regarding the Meaning and Limits of the Concept in Human Genetic Research', (2005) *Genomics, Society and Policy*, 1(2), 29–40.

benefits has few limits, although the minimum threshold for satisfying the 'reasonable availability' should surpass the simple licensing of drugs or interventions with market prices.[6]

When is an appropriate time for benefit sharing? These issues deserve consideration from the very earliest phases of research design. It is necessary to find out the characteristics and needs of the potential research sites to ensure that the planned investigations, as well as potential benefits, respond to those needs. Equally, benefit sharing could involve long-term follow up of participants or training and employment of community members that continues for years after research has ended.

The HUGO statement on benefit sharing mapped the following justifications for the concept in human genetic research:

1. Descriptive argument: There is an 'emerging international consensus'[7] that benefits should be shared with participants.
2. Common heritage argument – we all share (in one sense) the same genome, so there is a shared interest in genetic heritage of humankind; thus, the Human Genome Project should benefit all humanity.
3. Justice-based arguments – compensatory (compensation in return for contribution), procedural (procedural justice should be adhered to in benefit-sharing) and distributive (equitable allocation and access to resources and goods) justice as important aspects to consider.
4. Solidarity argument on two levels: first, as a potential basis for benefit sharing among a group of research participants (communities, host populations); second, to foster health for wider communities and eventually the whole of humanity, thus benefits should not be limited strictly to those participating in research.[8]

Of these various justifications, the overall concern fuelling benefit-sharing debates has been justice, and the concept itself has been likened to a device in the toolbox of justice.[9] Yet, justice is notoriously difficult to pin down given that the principles of justice vary – one can refer to equality as fundamental, or point at the importance of merit, and in healthcare contexts the principle of need has often served as central. Decisions about what justice requires (i.e. what principles are important in a particular context) can result in divergent benefit-sharing patterns and practices – how benefits are defined and by whom, as well as with whom the sharing is foreseen.[10] Certain justifications necessarily exclude or include specific groups or communities. For example, the compensatory logic associated with the principles of merit and desert would benefit those directly involved but could leave out those who did not directly participate but are nevertheless part of the community. Focus on a shared human heritage of genetic resources tends to disregard the needs and deserts of particular communities where research is undertaken. This is why, for example, in the agricultural and plant genetics context, the early employment of the global heritage model was quickly replaced by the nationalisation and property model of genetic resources.[11] The patenting practices through which the 'shared free resources' were

[6] E. J. Emanuel, 'Benefits to Host Countries' in E. J. Emanuel et al. (eds), *The Oxford Textbook of Clinical Research Ethics* (Oxford University Press, 2008), p. 722.
[7] HUGO Ethics Committee, 'Statement on Benefit-Sharing', (Human Genome Organisation, 2000).
[8] K. Simm, *Benefit-Sharing: An Inquiry into Justification*, PhD thesis, Tartu University, (2005).
[9] D. Schroeder, 'Benefit-Sharing: It's Time for a Definition', (2007) *Journal of Medical Ethics*, 33(4), 205–209.
[10] K. Simm, 'Benefit-Sharing: A Look at the History of an Ethics Concern', (2007) *Nature Reviews Genetics*, 8(7), 496.
[11] E. Tsioumani,' Beyond Access and Benefit-Sharing: Lessons from the Law and Governance of Agricultural Biodiversity', (2018) *The Journal of World Intellectual Property*, 21(3–4), 106–122.

turned into private profits and property were eventually rejected and the nationalisation of biological resources took over as the dominant framework.

To conclude, benefit-sharing negotiations always entail choices between some publics over others and upholding of certain principles before others. The above considerations about what justice requires have historically played a role in benefit-sharing discussions and none of them may be discounted as irrational or irrelevant. So how have these justice-related concerns been framed, operationalised, and translated into regulation and governance?

15.3 REGULATION AND GOVERNANCE FRAMEWORKS

Ethically sound and respectful research practices do not only benefit researchers, participants and science but also support public trust towards research in general.[12] All approaches to benefit sharing assume the baseline of the usual ethics requirements for research (thus benefit sharing does not substitute some or all ethics principles but is to be considered an additional one). In 1993, the Council for International Organisations of Medical Sciences (CIOMS) argued that 'any product developed will be made reasonably available to inhabitants of the underdeveloped community in which the research was carried out'.[13] In the latest updated Guidelines from 2016, exploitative research was defined as the kind of research that did not respond to the health needs of the community where it took place or who would later not be able to access or afford the resulting product.[14]

The prominence of benefit sharing as an ethics requirement in global health research is exemplified by the existence of many national[15] and international documents, statements and opinions. Both national and international health research organisations, policy think tanks and research funders have thought it important to discuss and state their views on the matter. Most discuss benefit sharing in the context of research in developing countries: the European Group on Ethics in Science and New Technologies to the European Commission's *Opinion on Ethical Aspects of Clinical Research in Developing Countries* (2003), the Nuffield Council on Bioethics' *The Ethics of Research Related to Healthcare in Developing Countries* (first paper in 2002), the US National Bioethics Advisory Commission's *Ethical and Policy Issues in International Research* (2001), and the Wellcome Trust's Statement on *Research Involving People Living in Developing Countries: Position Statement and Guidance Notes for Applicants*.[16] Even general health research frameworks have included references to benefit

[12] C. D. DeAnglis, 'Conflict of Interest and the Public Trust', (2000) *JAMA*, 284(17), 2237–2238.

[13] Council for International Organizations of Medical Sciences (CIOMS), 'International Ethical Guidelines for Biomedical Research Involving Human Subjects', (CIOMS, 1993), 2nd version.

[14] CIOMS, 'International Ethical Guidelines for Health-Related Research Involving Humans', (CIOMS, 2016), 4th edition.

[15] An early example of national regulation on benefit-sharing comes from the Canadian provinces of Newfoundland and Labrador. E.g. D. Pullman and A. Latus, 'Benefit-Sharing in Smaller Markets: The Case of Newfoundland and Labrador', (2003) *Community Genetics*, 6(3), 178–181.

[16] European Group on Ethics in Science and New Technologies to the European Commission (2003), 'Opinion on Ethical Aspects of Clinical Research in Developing Countries', (European Group on Ethics in Science and New Technologies to the European Commission, 2003); Nuffield Council on Bioethics, 'The Ethics of Research Related to Healthcare in Developing Countries', (Nuffield Council on Bioethics, 2002); US National Bioethics Advisory Commission (NBCA), 'Ethical and Policy Issues in International Research: Clinical Trials in Developing Countries: Report and Recommendations of the National Bioethics Advisory Commission', (Rockville, MD: NBAC, 2001), Vol. 1; Wellcome Trust, 'Research Involving People Living in Developing Countries: Position Statement and Guidance Notes for Applicants', (Wellcome), www.wellcome.ac.uk/funding/guidance/guidance-notes-research-involving-people-low-and-middle-income-countries.

sharing in their more recent drafts – for example the WHO's *Good Clinical Practice*, the World Medical Association's Declaration of Helsinki (2013), and the UNESCO Universal Declaration on Bioethics and Human Rights (2005).[17]

All of the above documents constitute what may be called soft law (i.e. non-binding instruments), yet a number of them have been influential in regulating health research practices (especially the WHO, CIOMS and funders' guidelines). When applied routinely, such ethics regulations could be considered customary international law,[18] but there have also been calls to formulate dedicated legal instruments to provide stronger support for benefit-sharing negotiations.[19] The latest attempt to ensure that benefit sharing constitutes an important normative aspect of research is the *Global Code of Conduct for Research in Resource-Poor Settings* (2018), which the European Commission endorsed as a reference document for its research funding programme Horizon 2020.[20]

While declarations and guidelines can highlight important principles and values for research, their interpretation and implementation are less straightforward. Over time, the developments in health research practices and the pressures from various stakeholders have resulted in a repeated re-framing of benefit sharing as various competing accounts have been promoted.

The earliest versions advanced a duty to benefit the particular people participating in research or a somewhat wider circle of beneficiaries (communities or populations in the case of Low and Middle Income Countries (LMICs)). This is the '*reasonable availability model*' espoused by CIOMS, which has traditionally tied the benefits to products or interventions resulting from a particular research project. An ethical prerequisite here is that research should respond to the health needs of the community and therefore any positive results of research are directly relevant to those needs.

A somewhat overlapping concept of post-trial obligations has also been argued for and applied in the context of health research, especially clinical trials. The language of post-trial obligations has its roots in the 2000 edition of the Declaration of Helsinki (§30: 'At the conclusion of the study, every patient entered into the study should be assured of access to the best proven prophylactic, diagnostic and therapeutic methods identified by the study.').[21] Later versions of the Declaration specify this duty further. Post-trial obligations are often formulated as prior agreements that are signed between stakeholders before research is begun and there exist a number of successful examples of post-trial access agreements globally.[22]

The reasonable availability model has been roundly criticised for a variety of reasons.[23] Most importantly, it is said that the focus on types of benefits arising from particular research projects

[17] World Health Organization, 'Handbook for Good Clinical Research Practice', (WHO, 2002).; WMA, 'Declaration of Helsinki', (WMA, 2000); UNESCO, 'Universal Declaration on Bioethics and Human Rights', (UNESCO, 2005).

[18] P. Andanda et al., 'Legal Frameworks for Benefit-Sharing: From Biodiversity to Human Genomics' in D. Schroeder and J. Cook Lucas (eds), *Benefit-sharing. From Biodiversity to Human Genetics* (Springer, 2013), pp. 33–64.

[19] B. Dauda and K. Dierickx, 'Benefit-Sharing: An Exploration on the Contextual Discourse of a Changing Concept', (2013) *BMC Medical Ethics*, 14(1), 36.

[20] D. Schroeder et al., 'Global Code of Conduct for Research in Resource-Poor Settings' (*GlobalCodeofConduct*), www.globalcodeofconduct.org/.

[21] WMA, 'Declaration of Helsinki'.

[22] E.g. J. M. Lavery, 'The Obligation to Ensure Access to Beneficial Treatments for Research Participants at the Conclusion of Clinical Trials' in E. J. Emanuel et al. (eds), *The Oxford Textbook of Clinical Research Ethics* (Oxford University Press, 2008), pp. 697–708; A. K. Page, 'Prior Agreements in International Clinical Trials: Ensuring the Benefits of Research to Developing Countries', (2002) *Yale Journal of Health Policy, Law and Ethics*, 3(1), 35–66.

[23] Participants in the 2001 Conference on Ethical Aspects of Research in Developing Countries, 'Moral Standards for Research in Developing Countries: From 'Reasonable availability' to 'Fair Benefits'', (2004) *Hastings Center Report*, 34(3), 17–27; Emanuel, 'Benefits to Host Countries', p. 723

does not adequately remove the dangers of exploitation and it unnecessarily limits the scope of potential benefits. Thus, the alternative *'fair benefits' model* was proposed, widening the scope of potential benefits as well as beneficiaries.[24] Benefits should not be limited to the results of particular research projects, and the distribution of benefits could take place both during as well as after research. Yet, while the increased flexibility in benefit-sharing discussions is a pragmatically useful development, it might also involve adverse side-effects. For example, a community might agree to participate in research that will not target their health needs at all, but will provide other benefits that they need.[25] This means that some of the fundamental ethical premises of research in LMICs have been effectively replaced. Perhaps this is acceptable – after all, such flexibility can be construed as less paternalistic and respectful of local needs. But it could also hint at the problematic infiltration of commercial bargaining rules into health research, which I discuss further below.

The latest re-framing, driven largely by funders, construes benefit sharing as a comprehensive *cooperative tool for capacity-building* that is justified via the larger framework of global health research and justice concerns.[26] In 2002, the Nuffield Council on Bioethics suggested that healthcare-related research in developing countries should proceed through genuine partnerships that provide transfer of knowledge and technology to strengthen the expertise of local partners. More recently, a group of influential research funders (NIH, Wellcome and the African Society of Human Genetics) have launched an H3Africa benefit-sharing vision where the more established avenues of 'reasonable availability' and 'fair benefits' have been replaced by straightforward requests for capacity building as the objective of collaborative research.[27] Such activities thus no longer constitute simply one of the options in the extensive list of potential benefits that parties to the benefit-sharing arrangement should consult and pick from. Benefit sharing is here no longer a positive side-effect or even an intended externality to a successful research project. Rather, it has been moved to the very core – it is one of the most important reasons the research collaboration should take place at all. In many ways, this is a welcome development, as benefit sharing has often been misunderstood as disbursement of tangible research 'results'.

15.4. WHAT, WHEN AND HOW: THE PRACTICALITIES OF BENEFIT SHARING

Much of the rationale for benefit sharing is articulated in the language of principles and values. Somewhat less guidance is given on the procedural aspects – how these principles and values are to be negotiated, prioritised and enforced. In most cases, a variety of potential benefits and beneficiaries can realistically be considered based on diverse justificatory reasons and local needs. Obviously, the host population needs to be the judge of the value of benefits to itself.[28] An answer to a practical question of whom does one talk to when negotiating with communities should look for engagement with those who might bear burdens for research, but are not given a voice (this concerns especially the voice of women in LMICs – their meaningful participation in

[24] Participants, 'Moral Standards', 2004.
[25] A. J. London and K. J. S. Zollmann, 'Research at the Auction Block: Problems for the Fair Benefits Approach to International Research', (2010) *Hastings Center Report*, 40(4), 36.
[26] E.g. F. Mutapi, 'Africa Should Set Its Own Health-Research Agenda', (2019) *Nature*, 575(7784), 567.
[27] B. Dauda and S. Joffe, 'The Benefit-Sharing Vision of H3Africa', (2018) *Developing World Bioethics*, 18(2), 165–170.
[28] Participants, 'Moral Standards', 2004.

all phases of benefit-sharing negotiations should be required[29]). At the same time, one needs to be conscious – and transparent – of the fact that defining and refining participant categories or negotiation partners is already a highly selective, political act.[30]

While community involvement is a crucial part of the benefit-sharing process, the mere fact of participation and consent does not necessarily guarantee the fairness of the agreement.[31] To ensure transparency and that involved communities and populations do have a fair chance to make up their minds about research participation, an influential statement recommended that publicly accessible repositories of previous benefit-sharing agreements be created.[32] This would provide a chance for stakeholders to assess the fairness of what they are offered and would support the procedural side of benefit sharing. Critics, however, have claimed that the principles and structures of transparency and fairness that the fair benefits approach supports might turn out to be an 'ethical Trojan horse'.[33] The proposed auction-like model could make host communities compete against each other in offering services to global research contract organisations, turning benefit-sharing negotiations into 'a race to the bottom'.[34] While the funders of non-profit research or even public–private partnerships could be held accountable for checking the fairness of the reached deals, much of for-profit research lacks such oversight structures.

15.5 WORRIES AND FUTURE CHALLENGES

While benefit sharing is by now a relatively standard and well-established requirement regarding ethical research practices (especially in LMICs), I would like to draw attention to several critical points that problematise the appropriateness and scope of benefit sharing in research settings.

Some of the most discussed worries associated with sharing benefits with research participants concern the dangers of therapeutic misconception and undue inducement. Research has traditionally been about serving future generations and producing generalisable knowledge. Focus on benefiting research participants introduces the risk that they might volunteer because they expect research to benefit them directly. While research participants are often well cared for, this should not be mistaken for therapy.

Undue inducement concerns instances where benefit-sharing negotiations result in overly generous and disproportionate advantages to participants such that their ability to rationally weigh the benefits and harms of participation might be jeopardised. In the LMIC context, the local public health infrastructure might be minimal or lacking; clinical trials and other types of research often offer services that are not otherwise available. Access to medical services might motivate research participation and raise the potential of undue inducement. In these situations, a proper balance between potential risks and benefits is crucial to ensure fairness and to distinguish undue inducement from fair compensation.

A different kind of unease about the extensive employment of benefit-sharing language and practices in health research was voiced already decades ago. Debates then revolved

[29] J. Cook Lucas and F. A Castillo, 'Fair for Women? A Gender Analysis of Benefit-Sharing' in D. Schroeder and J. Cook Lucas (eds), *Benefit-Sharing. From Biodiversity to Human Genetics* (Springer, 2013), pp. 129–152.

[30] C. Hayden, 'Taking as Giving: Bioscience, Exchange, and the Politics of Benefit-Sharing', (2007) *Social Studies of Science*, 37(5), 729–758.

[31] S. Gbadegesin and D. Wendler, 'Protecting Communities in Health Research from Exploitation', (2006) *Bioethics* 20 (5), 252.

[32] Participants, 'Moral Standards', 2004.

[33] London and Zollmann, 'Research at the Auction Block', 44.

[34] Ibid., 41.

around benefit sharing as a side-effect of unwelcome commercialisation of health research. Often focused on the patenting of the human genome,[35] the arguments ranged from the consequentialist (threats to scientific progress as it changes the altruistic motivation for scientific research) to the deontological (metaphysical dangers to the 'ethical self-understanding of the species'[36]). The worry was that benefit sharing as a conceptual framework had opened health research up to the vagaries of global commercial markets and had turned it into a shameless profit-driven activity, where the services of the participants were nothing but tradable commodities.

Over the past decade, we have grown used to the increasing prominence of for-profit health research. The noble idea of volunteering for research to support the project of science that may benefit humankind is no longer easily applicable nor ethically acceptable in the context of global biomedical research where powerful for-profit companies choose to do their research among possibly vulnerable populations in LMICs. While altruistic volunteering and even a gift-relationship dynamic might still be possible for health research within affluent and more sheltered communities, it would be distinctly unfair to insist on this rationale for other contexts. Even in developed countries, fierce battles regarding patenting and access to screening tests have taken place between those who contributed to research and those who were granted a patent (e.g. the Canavan disease controversy in the USA).

A different kind of worry is that if benefit sharing is motivated by the wider concerns of global justice ('an effective way of helping people in LMIC'[37]), then benefit-sharing practices and procedures are not well-equipped to deal with these much larger and complex challenges arising from global (and local) political, social and economic inequalities. Indeed, numerous funders have explicitly stated that too wide a scope for post-trial or benefit-sharing obligations (bordering on aid) is not to be required of investigators; some of the funders are, in fact, prohibited from funding healthcare provision. Furthermore, while it is clear that in many cases research is undertaken by for-profit companies who may go on to earn substantial benefits, there are also numerous trials and projects that do not translate into profits and may prove unsuccessful. Yet even such research constitutes valuable knowledge that is crucial to guide further research. The framework of benefit sharing as capacity-building gets around that challenge because it no longer focuses nor depends on the tangible results but on the cooperative aspects of research where 'negative' results are also valuable for involved local researchers.

Benefit sharing is an attempt to offer the vulnerable and the burdened communities a fair and well-earned chance to improve their situation. This means that benefit sharing can sometimes rightfully be associated with the tendencies to commodify relations and objects that, in a different world, would perhaps be guided by other, more altruistic and less monetised motives. Yet, from the perspective of LMICs, the dynamic of benefit-sharing logic over the past decades has enabled those countries themselves to increasingly have a say in steering benefit sharing. It should no longer be constrained by a particular research project or be seen as contributing towards the local scarcities in a haphazard way of plugging the holes in responding to the most desperate needs. Rather, benefit sharing is increasingly construed as a

[35] R. Chadwick and A. Hedgecoe, 'Commercialisation of the Human Genome' in J. Burley and J. Harris (eds), *A Companion to Genethics* (Oxford: Blackwell, 2004), pp. 334–345.
[36] J. Habermas, *The Future of Human Nature* (Cambridge: Polity, 2003), p. 71.
[37] London and Zollmann, 'Research at the Auction Block', 37.

systematic tool within the wider project of collaboration, of taking control of one's resources and setting one's own research and health policies and priorities. In short, it is coming to be seen as crafting a space for a 'lab of their own'.[38]

Such an interpretation of benefit sharing frames it as part of a more general tendency of rethinking the function and practice of research and science in society. This has been visible, for example, in the European Commission's funding guidelines. The requirement of transparency in setting research priorities, the democratising of science through involvement of various stakeholder groups (e.g. patients) in the early stages of research, and the rhetoric of responsible research and innovation are all instances of opening up research as a social practice, shifting away from a view of research as a boxed-up end-product. Perhaps some benefit-sharing partnerships might already be viewed as examples of such 'power sharing',[39] although one should remain cautious in terms of the concept's ability to revolutionise health research around the globe.

Benefit sharing is not immune to the many changes happening in health research: learning healthcare systems are doing away with the once central distinctions between clinical and research ethics; multi-site research makes it difficult to assess the contributions of distinct locations and partners; and it is unclear what the relationship will be between benefit sharing and data sharing in the context of open data and the increased role of health-related data in health research. Certain flexibility that has always been necessary for a successful implementation of benefit-sharing frameworks – the integration of universal ethical principles with the particular research partnerships – needs to continue to ensure that, at least as long as we live in an imperfect world of great inequalities, benefit sharing can successfully be integrated into the evolving practices of health research. Yet we need to be cautious about pinning too many hopes on that one framework.

15.6 CONCLUSION

Benefit sharing in health research is by now a well-established ethical requirement. There are a plethora of documents and established best practices to guide the researchers, funders and regulators, as well as communities and other stakeholders. The rationale for benefit sharing has evolved and continues to do so. Starting from the idea that individuals and communities taking certain risks and accepting potential harms deserve compensation and should not be exploited, we have now reached frameworks that view capacity-building and development support as one of the primary goals of research cooperation.

Benefit sharing is an activity that is grounded in potentially conflicting sets of justifications. While that might seem philosophically problematic (leading to e.g. various inconsistencies, potentially contradictory duties), in pragmatic terms, detailed global agreements are not necessary. It is best to regard benefit sharing as a mandatory ethics frame(work) that is to be applied to all international research collaborations as it highlights certain moral concerns and provides conceptual and governance resources for dealing with those. But the actual agreements need to be contracted by particular stakeholders and the details of the planned

[38] R. Benjamin, 'A Lab of Their Own: Genomic Sovereignty as Postcolonial Science Policy', (2009) *Policy and Society*, 28(4), 341–355.

[39] D. E. Winickoff, 'From Benefit-Sharing to Power Sharing: Partnership Governance in Population Genomics Research' in J. Kaye and M. Stranger (eds), *Principles and Practice in Biobank Governance* (Routledge, 2016), pp. 53–65.

research and the distinct context will determine which sets of concerns are paramount, which justifications make sense, what benefits are realistic, and who should be involved. There is a danger of potential relativism involved in such a governance framework, but only combining universal research norms with unique contextual components provides the sensitivity and flexibility that is needed for ethical health research as a collaborative enterprise.

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