Practical guidance in understanding the nuance of benefit sharing and what this means for South African health research ethics committees: Part 1

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Benefit sharing in health research is a complex and contentious topic, raising practical challenges. This article examines preferred terminologies and the roles of various stakeholders at multiple levels, providing critical insights for South African Research Ethics Committees (RECs). It explores the terminological clarity needed in defining 'benefit' and 'benefit sharing', particularly through the framework suggested by the DS-I Africa Law group. The article highlights significant deficiencies within the National Department of Health Guidelines, which lack specificity in addressing benefit sharing, creating regulatory confusion. Additionally, it analyses the relevance of four South African Acts – the Intellectual Property Rights from Publicly Financed Research and Development Act (IPRA), the Indigenous Knowledge Act (IKA), the National Environmental Management: Biodiversity Act (NEMBA) and the National Health Act (NHA) – each addressing benefit sharing in varying contexts. These legislative frameworks are discussed to assist RECs in ensuring ethical benefit sharing practices and to clarify the legality and applicability of benefit sharing. In conclusion, this article recommends the implementation of the terminology and differentiation offered here. By offering a foundational understanding, this article aims to support RECs in their critical role of navigating benefit sharing complexities within the South African research landscape.

Keywords: benefit sharing, legal position, nuanced understanding, practical guidance, research ethics committees, South Africa

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Benefit sharing in health research has become a topic of much debate, with arguments for and against it. Proponents of benefit sharing argue that it promotes equity, enhances research participation, fosters trust and collaboration, supports community development and aligns with the ethical principles of beneficence, justice and respect for persons.[1-4] Opponents of benefit sharing, on the other hand, argue that it presents many ethical challenges, creates financial burdens on researchers and research institutions, distorts incentives, may hold the potential to create dependency and brings concerns regarding commercialisation.[2,5,6]

Scholars and policymakers have underscored the importance of defining 'benefit sharing' and 'benefit'. Schroeder proposed that benefit sharing involves providing a portion of advantages or profits from human genetic resources to providers, prioritising those without reasonable access to healthcare products. However, his focus on 'profit' introduces a financial connotation that may limit this definition's scope.[7] Similarly, Hayden described benefit sharing as ensuring returns to research participants due to their role in generating lucrative products in biotechnology, diagnostics and pharmaceuticals, also emphasising monetary aspects.[8] Dauda expanded this to the distribution of goods and advantages to participants, communities and nations involved in research.[9] Hoffmann took a broader perspective, emphasising equitable access to scientific progress and facilitating benefit transfers from developed to developing regions, leaving the term 'benefit' open-ended.[10]

As the concept moved from theory to practice, RECs began facing benefit sharing in research protocols, requiring more concrete definitions. For assistance, RECs may have turned to international instruments. However, key guidelines often lack specificity. For instance, the International Ethical Guidelines for Health-related Research Involving Humans (CIOMS Guidelines)[11] refer to benefit sharing but do not define it explicitly, while the Universal Declaration of Human Rights offers a broad yet vague right to scientific benefits.[12] The Universal Declaration on Bioethics and Human Rights (Bioethics Declaration),[13] however, specifies that benefits from scientific research should reach society, especially developing nations, identifying forms of benefits like healthcare access, diagnostic products, capacity-building and support for health services. This breadth, though valuable, may complicate REC decision-making owing to its general focus on 'society as a whole' without specifying beneficiaries.[13] The Declaration's recommendations also lack binding authority unless incorporated into domestic law.

Guidelines from statutory bodies and organisations also provide insights. The Human Genome Organisation (HUGO) frames benefits as goods that enhance the well-being of individuals or communities, distinguishing them from mere financial gain and suggesting that cultural and social contexts shape what constitutes a benefit.[14] Following HUGO, the Academy of Science of South Africa (ASSAf) acknowledges that benefits from genomic research may include tangible resources, healthcare and capacity-building.[15,16] These

ethical frameworks, however, lack consistency, are often non-binding and do not align closely with the South African context, limiting their utility for RECs.

Lastly, South African RECs may turn to domestic regulatory tools for guidance. Our ethical instruments are, as will be shown, insufficient while the legal landscape is complex and built on differing Acts, each providing for benefit sharing in a different, nuanced context which impacts on what RECs need to take into consideration before approving a proposed study. RECs act as the guardians of research and fair scientific progress and will have to ask: What exactly is benefit sharing? What qualifies as a benefit? Who should benefit? When is benefit sharing appropriate and when might it be implemented or what requirements must be met for benefit sharing to be legally permitted? RECs will also have to answer these questions and must do so in accordance with existing ethical guidelines and extant law. As such, clarity on the relevant regulatory framework is of paramount importance.

The present article, Part 1, the first in a series, is aimed at providing guidance in understanding the nuance of benefit sharing and what it means for South African RECs by offering answers to the questions posed above. In Part 2, focus will shift to providing practical guidance to RECs, especially in the context of health research involving human participants or human biological material. However, for this practical guidance to be of value, RECs must first have a clear conception of benefit sharing and how it is regulated in South Africa. This article will therefore first offer terminological clarification by providing suggested preferred definitions for various relevant concepts. The question of who may benefit will also be addressed by dissecting the differing levels and stakeholders involved in benefit sharing. To assess the appropriateness of benefit sharing, a critique of the ethical instruments, with particular attention to the National Department of Health of South Africa's Ethics in Health Research: Principles, Processes and Structures (NDoH Guidelines),[17] and analysis of the relevant South African legislation in general will be provided, accompanied by some comments on the legal implications when encountered by health RECs. These include the Intellectual Property Rights from Publicly Financed Research and Development Act of 2008 (IPRA),[18] Protection, Promotion, Development and Management of Indigenous Knowledge Act of 2019 (IKA),[19] National Environmental Management: Biodiversity Act of 2004 (NEMBA)[20] and National Health Act of 2003 (NHA).[21]

WHAT DOES 'BENEFIT SHARING' AND 'BENEFIT' MEAN? SUGGESTED PREFERRED TERMINOLOGY

Kamau *et al*., members of the Legal Aspects of Using Data Science in Health Innovation in Africa (DS-I Africa Law) group, have attempted to remedy the uncertainty surrounding what 'benefit sharing' and 'benefit' might mean and have put forward suggested terminology.[22] This is a specialist group, focusing on the legal dimensions of using data science for health discovery and innovation in Africa and have paid particular attention to the concept of benefit sharing.[23] As the one of the aims of this article is the provision of clarity in the handling of benefit sharing for South African RECs, it is submitted that the definitions provided by this group are greatly enlightening and appropriate. It must be noted that although the terminological clarification below is comprehensively set out in Kamau *et al*., an exposition thereof is required in this article as well in order to provide comprehensive insight and guidance to RECs.[22]

The DS-I Africa Law group take a novel approach to defining benefit sharing by first determining what constitutes a 'benefit'. This makes sense as only once we determine what 'benefits' entail, can we determine how they should be shared and what 'benefit sharing' would therefore involve. They offer nuanced definitions for 'benefit'; 'benefits inherent in research'; 'benefits as rewards for participation in research'; and 'benefit sharing'.[22]

Benefit

The DS-I Africa Law group suggest that 'benefit' be understood as any tangible or intangible advantage which advances the interests and/or well-being of person(s). These persons may be research participants, donors of human biological material for research purposes or members of the public in general.[22]

Benefit inherent to research

'Benefits inherent to research' have been defined as benefits that are essential characteristics of the research interaction with human research participants, according to the DS-I Africa Law group. These then include benefits as envisioned under a favourable risk-benefit profile; free medical services forming part and parcel or necessarily incidental to the research such as medical care, insurance or indemnity for harms or risks; or the accrual of knowledge to participants and the wider public with regard to the utility, or lack thereof, of envisioned therapies.[22]

Benefits as reward for participation

A 'reward' may be understood as any form of benefit over and above the benefits inherent to research. This is a benefit that stems from a researcher or research sponsor and that accrues to research participants. Rewards may be monetary or non-monetary in the form of goods, services and access to resources.[22]

The DS-I Africa Law group then further differentiates between kinds of rewards in the form of 'reimbursement', 'compensation' and 'non-compensatory rewards.'

Reimbursement

'Reimbursement' is a monetary reward meant to offset the actual expenses incurred by a research participant in order to enable their participation. Reimbursement is limited, however, to expenses which may be represented in pecuniary terms. This includes travel or transportation, accommodation expenses and loss of income.[22]

Compensation

'Compensation' includes but is a broader concept than reimbursement. It is a monetary or non-monetary reward that is intended to offset any losses incurred by a research participant while participating in research. This may include financial remuneration to offset pecuniary loss suffered in the form of transport costs, loss of income or/and the cost of medical treatment, and non-pecuniary loss such as loss of time, discomfort experienced, risk taken and inconvenience.[22]

Non-compensatory reward

A 'non-compensatory reward' is a reward given to a research participant in return for their participation in research or donation of biological material. This type of reward is not intended to offset costs as is the case with reimbursement or compensation. It is therefore rather aimed at any other purpose, such as incentivising research participation.[22]

Benefit sharing

Since the meaning of 'benefit' has now been refined and nuanced, 'benefit sharing' may be understood as an agreement whereby a person or group who is set to benefit from a research project – the so-called benefit providers – commit to sharing these benefits by conferring a non-compensatory reward to another person or group – the beneficiaries. Stated differently, benefit sharing surpasses benefits inherent to research, reimbursement and compensation and includes, for example, payment as consideration for research participation.

As the questions of what exactly benefit sharing is and what qualifies as a benefit have been answered, attention must be given to the questions of who should benefit and when benefit sharing may be appropriate.

LEVELS AND STAKEHOLDERS: WHO SHOULD BENEFIT?

To provide clarity to RECs in the handling of benefit sharing, it is essential to also clarify to whom these benefits may be conferred. Simms first attempted to outline various actors involved in the sharing of benefits by identifying four stakeholder levels, namely individual; communal; national or state, and global level; and three types of benefits, namely health, commercial and scientific. Simms also outlined what these benefits at these levels might be.[24] A scientific benefit at individual, communal, national and global level would be non-instrumental knowledge in the development of science and knowledge. A commercial benefit at national level would be the development of biotechnology and related sectors or the creation of new jobs, for example. At an individual level, a commercial benefit would constitute a profit to investors in research.[24] No mention is made of commercial benefits to the research participant at individual level. Health benefits at a global level would be the eradication of disease, for example, while at a national level it might be efficient healthcare services and policy planning. Health as a benefit at a communal level could be relief to disease-related populations and designer medications or other aspects of personalised medicine at an individual level.[24] Simms further distinguished between a universal benefit-sharing framework with the benefit types identified, and a specific benefit-sharing framework directed towards those who directly participate in research.[24] This is reminiscent of the DS-I Africa Law group's description of a benefit as advancing the interests and/or well-being of research participants, donors of human biological material, or members of the public in general. This classification system devised by Simms marked a good starting point in providing nuance to benefit sharing and benefits, but it was focussed on genomics research and is therefore slightly narrow, considering the broad scope of health research.

Bedeker *et al*. elaborated on the idea of levels of benefit sharing and created a detailed framework for researchers, funders, RECs and stakeholders for identifying benefit-sharing opportunities in research programmes.[2] As such, Bedeker *et al*. identified nine types or categories of benefit sharing or types of benefits and three levels of stakeholders.

According to these authors, benefit-sharing stakeholders may be divided into three levels, namely macrolevel, mesolevel and microlevel stakeholders.[2] Macrolevel entails stakeholders who generally make decisions and provide services at a national or higher level which includes international, regional or national organisations; governments; policymakers; regulatory organisations and bodies; legislators and public health officials. Mesolevel stakeholders are those at a provincial, municipal or institutional level and may include larger community groups. Microlevel stakeholders are individuals, families or small community groups who operate at a personal or interpersonal level. The types of benefits identified by Bedeker *et al*. are financial, health and well-being, infrastructure, equipment, skills capacity, knowledge, service capacity, career development, and attribution and recognition.[2]

It is suggested that the detailed Bedeker *et al*. levels and the identification of concrete types of benefits offer the most assistance in providing clarity to RECs on the nuanced nature of benefit sharing and are therefore of great assistance in identifying and approaching such.

BENEFIT SHARING IN ETHICAL GUIDELINES

NDoH Guidelines

Health RECs are often the first to have to ask when benefit sharing is appropriate in order to be able to approve or reject a proposed research study. In answering this question, RECs may refer to ethical guidelines. In the context of benefit sharing in health research involving human participants and human biological material, however, relying on these may be unhelpful or limiting as the NDoH Guidelines[17] are insufficient in their provisions for benefit sharing in human participant health research, as will be shown.

Firstly, the Guidelines[17] mention benefit sharing, but do not contain a definition of 'benefit sharing' or 'benefits'.[17] In addition to the lack of conceptual clarity offered by the NDoH Guidelines[17] in regard to the meaning of benefit sharing related terminology, the Guidelines, for example, also fail to differentiate between the various stakeholders and forms of benefit sharing such as individual v. communal, or between financial v. non-financial benefit sharing.

Further, the Guidelines contain other problematic provisions in the context of benefit sharing such as their inclusion of various international instruments as supposed guiding documents for health researchers.[17] These include the Convention on Biological Diversity,[25] the Cartagena Protocol on Biosafety[26] and the Nagoya Protocol on Access and Benefit-Sharing (Nagoya Protocol).[27] It must be strongly noted that the Convention on Biological Diversity[25] and the subsequent Nagoya Protocol[27] are not applicable to human biological material. The Protocol specifically governs access to genetic resources and the fair and equitable sharing of benefits arising from their use; however, this is limited to non-human biological resources. Rather, the Protocol applies to genetic material from plants, animals and micro-organisms as well as traditional knowledge associated with these genetic resources.[27] The same applies to South Africa's Bioprospecting, Access and Benefit-Sharing Regulations (BABS) [28]

created under the NEMBA [20] in terms of which genetic material of human origin is expressly excluded. NEMBA is discussed in further detail below, but it must be noted here that these instruments focus on bioprospecting, indigenous biological resources from plants and animals and any associated traditional use or knowledge of these resources. This means that in terms of human biological material research, these instruments and the NDoH Guidelines offer little assistance to RECs.

In addition to the references to the above instruments, regulatory confusion is further created by the Guidelines' lack of legal integration of various South African Acts. The references to not only NEMBA,[20] but also to the NHA,[26] IKA[19] and IPRA[18] without clearly distinguishing when each of these pieces of legislation are relevant and applicable, and a failure to reflect distinctions in these Acts, may lead to confusion and potential non-compliance. These important distinctions are, however, discussed below to offer guidance to RECs.

Further issues found in the NDoH Guidelines relate to the unnuanced risk-benefit ratios.[17] These should underline the distinction between a 'benefit' as a 'benefit inherent to research' and a 'benefit' as understood in relation to benefit sharing as is discussed below. This also speaks to a conflation of concepts as found in the Guidelines' mention of the ethical principle of distributive justice.[17] Again, the Guidelines fail to distinguish that 'benefit' has two meanings: first, as inherent to the research itself which is weighed against risks (the expected benefits as reflected in the risk-benefit ratio), and second, benefits from the outcome of research which involve sharing in the results or profits. These ideas must be separated as the first relates to the likelihood of benefits arising as a natural part of research participation and the second refers to the fair distribution of benefits (distributive justice and benefit sharing). The Bioethics Declaration perhaps explains this sentiment best – benefits transcend the avoidance of harm.[13] It should also be noted that the Guidelines offer no practical framework for the implementation of benefit sharing, nor is guidance provided to assist in evaluating whether benefit-sharing (agreements) are compliant with the extant South African law(s).[17]

Other South African guidelines

The NDoH Guidelines'[17] lack of clear and legally aligned descriptions of and provisions for benefit sharing become all the more concerning considering the lack of actionable, practical guidance to RECs offered by other instruments within the ethical health research regulatory environment. For example, neither the South African Medical Research Council's Guidelines on Responsible Research[29] nor Research Ethics Policy[30] specifically provide for benefit sharing. Although the Good Clinical Practice Guidelines[31] contain provisions on reimbursements and incentives, benefit sharing is not directly addressed. These guidelines do, however, hint at benefits beyond the understanding of a benefit in relation to risk as is seen in other South African instruments (as relating to benefits inherent to research). This is illustrated in the requirement that benefits such as sponsorships, materials or facilities and support for travel or accommodation to attend conferences be disclosed in conflict-of-interest statements. These benefits, however, clearly accrue to the researcher and not the participant. Our Material Transfer Agreement (MTA)[32] also offers little practical guidance on the handling of benefit-sharing agreements. The MTA itself states that it applies to agreements between institutions and not to research participants. Furthermore, the MTA has been criticised for merely establishing a non-binding framework[33] requiring that negotiations and discussions around benefit sharing take place during the transfer of materials, while not mandating any actual benefit sharing. This means that as long as transfer documents contain a heading related to benefit sharing, the document will be seen as legally compliant according to Kamau *et al*.[22]

The Health Professions Council of South Africa (HPCSA) guidelines, at least, refer to benefit sharing in Booklet 14.[34] These guidelines remind researchers to adhere to the NEMBA [20] in regard to benefit sharing with indigenous communities. Booklet 14 further reiterates to some extent the legal position as found in the NHA, discussed below, that donors of tissue and other human biological materials may not receive any financial or other benefits for their donation or from the research or any resulting commercial products. As is evidenced by the above discussion, scholarly opinion, policy documents and ethical instruments offer little direction to RECs on how to approach benefit sharing. As such, RECs must turn to the law for guidance.

APPROPRIATENESS OF BENEFIT SHARING IN TERMS OF SOUTH AFRICAN LAW

Four pieces of South African legislation provide for benefit sharing, albeit in differing contexts. It is important that RECs be familiar with the applicability and practical implications of each of these Acts, namely the IPRA,[18] IKA,[19] NEMBA [20] and NHA.[21]

IPRA

The IPRA may be applicable to health research using public funds. Publicly funded research is 'research and development undertaken using any funds allocated by a funding agency but excludes funds allocated for scholarships and bursaries'.[18] The IPRA regulates how intellectual property (IP) arising from such research should be handled, ensuring that it benefits the South African people.[18] In addition to providing that IP creators, such as individual researchers, have the right to share benefits with their institutions and that IP creators have the right to a portion of the revenue accruing to the institution from their IP,[18] the Act mandates that any IP generated from publicly funded research should be identified, protected and commercialised to benefit the broader South African public.[18] For health research, this could mean ensuring that health innovations (such as new treatments or medical technologies) are accessible and beneficial to the public. Although health research is not expressly mentioned in the Act, it could fall under its scope which would mean that when researchers develop new health interventions, treatments or technologies, they must navigate IP rights to ensure that these innovations are used in ways that improve public health in South Africa. RECs are responsible for overseeing the ethical conduct of health research which includes ensuring that research benefits the community. Under the IPRA, RECs may need to ensure that research aligns with the Act's requirements, particularly regarding the commercialisation and use of research outputs.

This means that RECs must consider the provisions of the IPRA when evaluating research proposals, especially in ensuring that IP is managed in a way that serves public interest. IPRA's benefit-sharing principles also imply that any health IP should consider benefits to the broader public, aligning with ethical principles of fairness and equity. In practice, RECs may need to collaborate with technology transfer offices or IP management teams to ensure that health research complies with IPRA and serves public health goals.

IKA

RECs should also be aware of the provisions of the IKA[19] which provide for benefit sharing in the context of indigenous traditional knowledge. Amongst other matters, the IKA ensures equitable benefit sharing in instances where indigenous knowledge is used commercially. The IKA defines benefit sharing as 'the fair and equitable sharing of monetary and non-monetary benefits in terms of a benefit sharing agreement between the trustee of the indigenous community and the licence holder'.[19] South African indigenous communities are given exclusive rights over their knowledge which may include traditional medicines, practices or any cultural knowledge that could be used in health research or product development. As such, these communities also have the right to be acknowledged as the source of the knowledge and may limit unauthorised use thereof.[19] Much of the IKA deals with benefit sharing and it provides that where indigenous knowledge is used for commercial purposes, a benefit sharing agreement must be established between the indigenous community and the party using the knowledge.[19] These agreements are facilitated by the National Indigenous Knowledge Systems Office (NIKSO).[19]

As far as health research is concerned, RECs should be aware that the IKA is applicable to research that involves traditional medicines or indigenous knowledge related to health practices. Many traditional treatments are derived from indigenous knowledge and health researchers who wish to explore, test or develop such medicines must comply with the IKA's provisions. This involves acknowledging the source of the knowledge; establishing benefit sharing agreements with the indigenous community; and complying with ethical and legal standards set out in the IKA to ensure that the community benefits from any commercialisation of their knowledge.[19] In practice, this means that RECs will have to ensure that researchers have obtained the needed permissions from indigenous communities, respect the rights of the community, acknowledged the indigenous community's contributions and have secured the proper benefit sharing agreements. In considering the benefit sharing agreement, RECs will have to assess the fairness of the agreement and ensure that the indigenous community receives appropriate compensation or benefits, taking into regard the specific community they serve. RECs should also be aware that other traditional medicines and practices legislation, of which a full discussion falls outside the scope of this article, may be applicable.[35]

NEMBA

The NEMBA[20] also provides for benefit sharing. It should, however, again be noted that this Act applies only to non-human indigenous resources as was mentioned previously. The Act regulates bioprospecting activities which include collecting biological materials from the environment and, although not the primary focus of the Act,[20] these materials may in turn be used to develop products such as medicines. In relation to bioprospecting, NEMBA defines a benefit as 'any benefit, whether commercial or not, arising from bioprospecting involving such resources, and includes both monetary and non-monetary returns'.[20] The access and use of biological materials also require mandatory MTAs that ensure that those who provide access to biological resources receive a fair share of any benefits arising from their use.[20] Where health research is aimed at developing new medicines based on indigenous biological resources, NEMBA plays a crucial role in ensuring ethical access and equitable sharing of benefits. Researchers who engage in bioprospecting must adhere to the provisions of the Act, particularly when their research involves traditional knowledge or biodiversity resources that may have medicinal value. Researchers must ensure that any use of indigenous biological materials for the development of medicine is covered by MTAs and benefit-sharing agreements as these agreements aim to protect the rights of communities or individuals who own or manage the biological resources, ensuring they benefit from any potential commercial outcomes.

For health RECs, this means ensuring that research involving bioprospecting complies with NEMBA's legal framework – ensuring that researchers have proper agreements in place before accessing and using biological materials; and evaluating whether benefit-sharing agreements are fair and ethical which includes ensuring that the agreements provide clear benefits to those supplying the biological materials and that these benefits are aligned with the community's needs. Very importantly, as NEMBA does not specifically define 'benefit sharing', RECs will have to encourage clarity in research proposals in that researchers must clearly specify how they will share benefits with indigenous communities or access providers. In practice, RECs need to collaborate closely with researchers and ensure that their bioprospecting activities respect both the biodiversity laws under NEMBA and the ethical principles of equitable benefit sharing. This includes safeguarding the rights and interests of indigenous communities who provide biological resources for health research.

NHA

In South Africa, health research with human participants or which makes use of human biological material is primarily regulated by the NHA. Section 11 of the Act provides, inter alia, for health services for research purposes[21] and section 71 provides for research on human participants.[21] Although 'benefit sharing' is not expressly provided for in the Act, section 60 provides for matters of recompense and specifically payment in regard to the importation, acquisition or supply of tissue, blood, blood products and gametes. Section 60(4) states: 'It is an offence for a person — (a) who has donated tissue, a gamete, blood or a blood product to receive any form of financial or other reward for such donation, except for the reimbursement of reasonable costs incurred by him or her to provide such donation; and — (b) to sell or trade in tissue, gametes, blood or blood products, except as provided for in this Chapter.'

In a recent article by Thaldar and Shozi on the lawfulness of benefit sharing in South Africa, the authors reached the conclusion that benefit sharing is unlawful and criminal and that any benefit-sharing agreement would be null and void. They suggest that the only solution is for the national legislature to amend the NHA and then, specifically, section 60(4).[36] In other words, on the face of this provision, no one may receive any 'bonus', financial or otherwise, for their donation of the mentioned biological materials. Further, section 60(4)(b) of the NHA also outlaws the sale or trade in human tissue, blood, blood products and gametes. This would mean that RECs should outright reject any protocol which includes benefit sharing endeavors.[22]

Although the legal position seems *prima facie* clear and is quite simplistic, when delving slightly deeper, some questions arise as to whether a blanket prohibition on benefit sharing in human

participant health research is truly purported by this section. What if a person participates in research which does not entail the donation of the mentioned biological materials? Does 'person' mean that individual benefit sharing is prohibited but collective forms thereof are permitted? What does a 'reward' entail? Are research institutions wholly prohibited from engaging in benefit sharing in the exchange of the mentioned biological materials? RECs may be confronted with these intricate questions and, as such, a nuanced understanding of benefit sharing, benefits and the relevant stakeholders is required, as has been provided in this article. Part 2 of this series will also provide answers to these questions in due course.

CONCLUSION

This article attempted to provide South African health RECs with a nuanced understanding of benefit sharing by offering key terminologies, stakeholders and regulatory frameworks crucial to benefit sharing in South African health research. The suggested preferred terminology emphasises distinct definitions for 'benefit' and 'benefit sharing', as suggested by the DS-I Africa Law group, to aid RECs in interpreting ethical obligations clearly. It is suggested that these definitions be applied where relevant legislation does not expressly provide otherwise. Stakeholders were categorised at macro, meso and micro levels, allowing RECs to discern who should benefit and to what extent. It was further pointed out that while the NDoH Guidelines aim to guide RECs, they lack terminological clarity and alignment with legal standards, often creating more ambiguity than assistance.

This article also reviewed relevant legislation impacting benefit sharing: The IPRA mandates benefit sharing for publicly funded research, ensuring that innovations primarily benefit the South African public; the IKA requires benefit sharing when indigenous knowledge is commercially used, particularly in health research; the NEMBA governs non-human biological resources but impacts benefit sharing when such resources intersect with health research; and the NHA seemingly restricts benefit sharing related to human biological materials, presenting ethical challenges for RECs and leading to the following questions: What if a person participates in research which does not entail the donation of the mentioned biological materials? Does 'person' mean that individual benefit sharing is prohibited but collective forms thereof are permitted? What does a 'reward' entail? Are research institutions wholly prohibited from engaging in benefit sharing in the exchange of the mentioned biological materials?

This article equips RECs with a clearer understanding of benefit sharing within the South African legal context. In Part 2, the specific questions raised under the application of the NHA to benefit sharing in human participant and human biological material health research will be answered and clarified by demonstrating the application of the law. Guidance will also be provided to RECs in relation to the requirements for benefit sharing established by the IPRA, IKA and NEMBA. Finally, Part 2 will offer practical guidance to RECs to guide their decision-making by way of a diagram and the discussion of hypothetical scenarios illustrating the application of such.

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