



# The governance of genomic biobank research in Africa: reframing the regulatory tilt

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## ABSTRACT

Genomic biobank research has experienced exponential growth in recent years. It represents a real opportunity to remedy global health inequity that has seen limited investment in diseases affecting populations from low- and middle-income countries. Previous research in Africa was limited to so-called parachute research, whereby samples were taken from local populations for use in high-income countries with no local oversight or use of the sample. These exploitative practices must be guarded against, but

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the current regulation of genomic research in Africa adopts a precautionary approach that at times is restrictive in nature. We argue that the regulation and oversight of genomic biobank research should guard against exploitative research, but in a manner that promotes reciprocal benefit and not restrictive research practices. To achieve this, there must be a rebalancing of the regulatory tilt.

KEYWORDS: regulation, ethics, genomics, biobank, Africa, reciprocity

## I. INTRODUCTION

Genomic biobank research, that is biobanking with the aim of fostering genomic research, has brought about a change in our approach to medical research. In such research, biological samples and biological data (collectively here referred to as biological materials) are collected, stored, and potentially re-used to advance genomic research. These biological materials can easily be shared and moved across borders to be re-used by researchers who were not originally involved in their collection. The rise of genomic biobank research has been accompanied by a broader science policy shift toward 'open science' that advocates the wide sharing of samples and data.

The ease with which biological materials can now be stored, transported across borders, used and re-used has required a re-examination of long-held ethical principles. In particular, the 'one-study, one informed consent' paradigm is unsuitable in a realm, where the sharing or reuse of biological material is not only encouraged but also may be a condition of funding.<sup>1</sup> Requiring that every participant is re-contacted and re-consented each time the materials are to be re-used is burdensome and could potentially lead to the waste of a valuable resource. In response to this, there has been a growing acceptance internationally of broad consent, a consenting model through which a participant donates their biological materials for future research use, subject to further oversight by a research ethics committee (REC) or data access committee.<sup>2</sup> Furthermore, there is growing recognition that the anonymization of biological materials may not be possible and the confidentiality and privacy of the participant can no longer be guaranteed.<sup>3</sup>

Genomic biobank research is often transnational research that involves international collaborations and as a result, regulation of this research is increasingly complex. The regulation of genomic biobank research is polycentric in nature and often involves national and international actors and instruments, and rules and policies, which have been developed in an uncoordinated manner.<sup>4</sup> At the national level, this can include

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- 1 David Secko, Nina Preto, Simon Niemeyer, Michael Burgess, *Informed Consent in Biobank Research: A Deliberative Approach to the Debate*, 68 Soc Sci Med. 781, 782 (2009).
  - 2 See Christine Grady, Lisa Eckstein, Ben Berkman, Dan Brock, Robert Cook-Deegan, Stephanie M. Fullerton, Hank Greely, Mats G. Hansson, Sara Hull, Scott Kim, Bernie Lo, Rebecca Pentz, Laura Rodriguez, Carol Weil, Benjamin S. Wilfond, David Wendler, *Broad Consent for Research with Biological Samples: Workshop Conclusions*, 15 AJOB. 34–42 (2015). Paulina Tindana, Jantina De Vries, *Broad Consent for Genomic Research and Biobanking: Perspectives from Low- and Middle-Income Countries*, 17 Annu Rev Genomics Hum Genet. 1 (2016).
  - 3 Jeantine Lunshof, Ruth Chadwick, George M. Church, *Hippocrates Revisited? Old Ideals and New Realities*, 2 Genomic Med. 1,3 (2008).
  - 4 JANE KAYE, SUSAN GIBBONS, CATHERINE HEENEY, ANDREW SMART, GOVERNING BIOBANKS: UNDERSTANDING THE INTERPLAY BETWEEN LAW AND PRACTICE, 318 (2012).





divided into three categories: jurisdictions where no regulations exist; jurisdictions that have regulations that are so specific that they quickly become outdated as the technology develops; and jurisdictions that have some regulations, but they are lacking certain key components.

In the first category where no regulations exist, De Vries *et al.* identified national regulatory frameworks for only 22 countries, despite the study attempting to source the regulations in all African jurisdictions. It is quite possible that the other countries—which would be more than 30—have no official national or local ethics guidance for health research. A national governance system should provide certainty and accountability in the legal and ethical conduct of research, and a lack of national guidelines or regulations is problematic as it is unclear what rules and procedures govern the research. Arbitrary decisions will be made on an *ad hoc* basis by a local REC and it is unlikely there will be consistency of approach. It also makes it unclear what procedures, if any, are put in place to guard against exploitative research and research practices.

Juxtaposed with these jurisdictions are the second category of African countries that have specific and detailed provisions on genomic and biobank research. This includes Malawi, Zambia, Ethiopia, Nigerian, Rwanda, and South Africa.<sup>17</sup> While regulating genomic biobank research is important, in these cases, the regulations are often unsatisfactory, and at times are so specific that they are quickly outdated as technology develops. This has occurred in Malawi and Zambia, where the regulations are particularly restrictive for genomic research. While there have been calls for specific regulations pertaining to genomic biobank research,<sup>18</sup> there must be some flexibility and reflexivity of approach, so that the regulations can adapt to changes and developments in the science.<sup>19</sup>

The majority of African jurisdictions fall into the third category, whereby genomic biobank research is regulated within the general health research frameworks, although only implicitly in some cases and more explicitly in others. Gaps identified in the De Vries study were a lack of provisions on consent, ownership, reuse of samples, data sharing, exportation/importation, and transfer of samples.<sup>20</sup> Considering these are

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Missi Oukem-Boyer, Ciara Staunton, Aminu Yakubu, Paulina Tindana, The H3Africa Consortium, *Regulation of Genomic Biobank Research in Africa: A Content Analysis of Ethics Guidelines, Policies and Procedures from 22 African countries*, 18 *BMC Med Ethics*. 1 (2017). Francis Barchi, Madison T Little, *National Ethics Guidance in Sub-Saharan Africa on the Collection and Use of Human Biological Specimens: A Systematic Review*, 17 *BMC Med Ethics*. 64 (2016). M. Sathar, Ames Dhai, *Laws, Regulations and Guidelines of Developed Countries, Developing Countries in Africa, and BRICS Regions Pertaining to the Use of Human Biological Material (HBM) in Research*, 5 *S Afr J Bioethics and Law*. 54–5 (2012). Annelize Gertruida Nienaber. *Consent to and Authorisation of the Export and Use of Human Biological Specimens for Future Research—Perspectives from Three African Countries*, 44 *Comp Int Law J Southern Africa*. 225–54 (2011). Santa Slokenberga, Jane Reichel, Rachel Niringiye, Talishiea Croxton, Carmen Swanepoel, June Okal, *EU Data Transfer Rules and African Legal Realities: Is Data Exchange for Biobank Research Realistic?* 9 *Int Data Privacy Law*. 30 (2019).

- 17 Pascalina Chanda-Kapata, Nathan Kapata, Albertina Ngomah Moraes, Gershom Chongwe, James Munthali, *Genomic Research in Zambia: Confronting the Ethics, Policy and Regulatory Frontiers in the 21st Century*, 13 *Health Res Policy Syst*. 60 (2015).
- 18 Jantina de Vries, Akin Abayomi, Katherine Littler, Ebony Madden, Sheryl McCurdy, Odile Ouwe Missi Oukem-Boyer, Janet Seeley, Ciara Staunton, Godfrey Tangwa, Paulina Tindana, Jennifer Troyer, *The H3Africa Working Group on Ethics. Addressing Ethical Issues in H3Africa Research—The Views of Research Ethics Committee Members*, 9 *HUGO*. 1 (2015).
- 19 Graeme Laurie, *Reflexive Governance in Biobanking: On the Value of Policy Led Approaches and the Need to Recognize the Limits of Law*, 130 *Hum Genet*. (2011) 130:347–356.
- 20 Jantina de Vries, Syntia Nchangwi Munung, Alice Matimba, Sheryl McCurdy, Odile Ouwe Missi Oukem-Boyer, Ciara Staunton, Aminu Yakubu, Paulina Tindana, The H3Africa Consortium, *Regulation of Genomic*

issues that have an important bearing on genomics research, the absence in specificity in the regulations on these topics is concerning. This suggests that, at the least, the regulations fail to sufficiently prevent exploitative research.

A second important feature of these regulations is that they tend to adopt a precautionary approach, which prescribes that in a state of scientific uncertainty, we should avoid acting, or if we do act, we should act with extreme caution. Because in the case of genomic biobanking, this principle most clearly manifests in the context of ethical concerns, we will use the term the *ethical* precautionary approach.

In the African context, while it is imperative that regulations prevent exploitative research and collaborations, this ethical precautionary approach at times has the net effect of resulting in restrictive legislation. For example, in Zambia, the 2013 Health Research Act specifically prohibits broad consent for future unspecified research as section 47(2) states that biological materials cannot be withdrawn and used for ‘any unspecified future health research activity or unspecified storage.’ Similarly in South Africa, there have been concerns expressed that the use of broad consent for the sharing of genomic data is not permissible under the Protection of Personal Information Act 2013.<sup>21</sup>

Precautionary measures in and of themselves are not a problem and ‘the State is authorized to act in a precautionary way for the sake of the integrity of the Community.’<sup>22</sup> However, currently there is concern and some anecdotal evidence that overly precautionary measures adopted to protect against exploitative research collaborations is hampering research and efforts to develop capacity.<sup>23</sup> In seeking to guard against exploitative research and collaborations, the ethical precautionary approach could have a considerable negative impact on the research generally.

### III. SHIFTING THE REGULATORY TILT

The regulation of genomic biobank research should not overly restrict the research or prevent collaborations. Rather the focus should be on guarding against *exploitative* research and *exploitative* collaborations. By shifting our focus in this manner, we can view genomic biobank research as something that is to be welcomed and important in strengthening research capacity in Africa.<sup>24</sup> Regulations thus should serve the goal of supporting non-exploitative research and an important part of this is addressing many of the gaps in the regulations that have been identified above. As such, we argue that there should be a shift in the regulatory tilt.

The regulatory tilt refers to the extent to which regulations are permitting or prohibiting research, and cases of ambiguity will be decided in favor of however the

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*Biobank Research in Africa: A Content Analysis of Ethics Guidelines, Policies and Procedures from 22 African Countries*, 18 BMC Med Ethics. 1 (2017).

21 Ciara Staunton, Rachel Adams, Marietjie Botes, Edward S. Dove, Lyn Horn, Melodie Labuschaigne, Glaudina Loots, Safia Mahomed, Jennifer Makuba, Antonel Olckers, Michael S. Pepper, Anne Pope, Michele Ramsay, Nora Ni Loideain, Jantina de Vries, *Safeguarding the Future of Genomic Research in South Africa: Broad Consent and the Protection of Personal Information Act 2013*, 109 South African Med J. 468 (2019).

22 ROGER BROWNSWORD, RIGHTS, REGULATION AND THE TECHNOLOGICAL REVOLUTION 451 (2008).

23 See below the section on stakeholder engagement.

24 Ambrose Wonkam, Bongani Moyasi, *Genomic Medicine in Africa: Promise, Problems and Prospects*, 6 Genome Med. 11 (2014).



samples, data and benefits in a fair, transparent and equitable manner; ensuring quality and interoperability of samples and their associated data; improving public awareness, trust and participation in biobanks; and defining the role of the private sector in the use of knowledge derived from biobank operations.<sup>31</sup>

In the African context, two pertinent documents reflect these changes in values. The *San Code of Research Ethics*<sup>32</sup> was developed in response to exploitative and discriminatory research published in *Nature* involving members of the San Community.<sup>33</sup> The Code focuses on respect, honesty, justice, and fairness, care and due process as key values to be considered when engaging with the San community for research. More specifically for genomic biobank research, the H3Africa Consortium embarked on a 3-year stakeholder engagement and developed the *Ethics and Governance Framework for Best Practice in Genomic Research and Biobanking in Africa*.<sup>34</sup> The Framework is guided by the principles of solidarity or communal-based worldviews, fairness, equity, and reciprocity.

Although other guidelines and codes of practices do exist for genomic biobank research, these new guidelines and codes of conduct are informed by past injustices and inequitable collaborations. They do not seek to limit collaborations, but to foster equitable research for the benefit of the local populations. As such they align and help to inform our regulatory tilt and the principles of solidarity, reciprocity, justice, and trust that are so important in these documents can inform the development or revision of regulations that are reflective of this proposed new regulatory tilt. In particular, they can help to identify some procedural and substantive norms that should underpin the regulation of genomic biobank research in Africa. We will now briefly consider each in turn.

Looking first at solidarity, solidarity-based approaches to genomic biobank research have gained prominence in some HICs. Prainsack and Buyx have argued that biobank governance should be guided by solidarity alongside autonomy<sup>35</sup> as such an approach would more appropriately reflect altruistic motivations to participate. Prainsack and Buyx argue that solidarity overlaps with other concepts such as charity, reciprocity, altruism, or empathy, but for them, their definition of solidarity (in its simplest form) is ‘manifestations of people’s willingness to carry costs (financial, social, emotional, or otherwise) to assist others.’<sup>36</sup>

As discussed in the H3Africa Framework, solidarity is reflective of the communitarian worldview prevalent in African societies. Such a worldview focuses on the inter-

31 Haidan Chen, Tikki Pang, *A Call for Global Governance of Biobanks*, 93 Bull WHO. 113, 117 (2015).

32 San Council, *San Code of Research Ethics* (2017), <http://trust-project.eu/wp-content/uploads/2017/03/San-Code-of-RESEARCH-Ethics-Booklet-final.pdf> (accessed June 11, 2001).

33 Roger Chennells, Andries Steenkamp, ‘*International Genomics Research Involving the San People*’ in ETHICS DUMPING 15 (Doris Schroeder, Julie Cook, Francois Hirsch, Solveig Fenet, Vasantha Muthuswamy eds., 2018).

34 H3Africa, *Ethics and Governance Framework for Best Practice in Genomic Research and Biobanking in Africa*, <https://h3africa.org/9-news/361-framework-for-african-genomics-and-biobanking> (accessed June 11, 2018). Aminu Yakubu, Paulina Tindana, Alice Matimba, Syntia Munung, Katherine Littler, Ciara Staunton, Jantina de Vries, *Model Framework for Governance of Genomic Research and Biobanking in Africa—A Content Description*, 1 AAS Open Res. 13 (2018).

35 Barbara Prainsack, Alena Buyx, *A Solidarity Based-Approach to the Governance of Research Biobanks*, 21 Med Law Rev. 71–91 (2013).

36 *Ibid*, 75.

connectedness of society, recognizing that individuals are shaped by their relations to people around them, and emphasizes respectful and harmonious relationships between individuals, and between individuals and their environment. However, this view of solidarity places importance on 'reciprocity, consultation, and accountability' and is in part informed by abuses of research in the past. There is some expectation that 'the community also contributes to the individual's sustainable wellbeing.'<sup>37</sup>

This formulation of solidarity differs from that as outlined by Prainsack and Buyx. It signifies that an individual is willing to be involved and donate a sample for some communal benefit. This manifestation of solidarity would be supportive of broad consent, but there must be accountability to ensure benefit. If we understand broad consent as 'consent for governance,'<sup>38</sup> researchers must be accountable within this governance framework. Indeed this is not unique to the African context and in other resource limited settings, the importance of accountability in the relationship between the research team and the community involved in genomic biobank research has been highlighted.<sup>39</sup> We thus consider accountability to be an essential component of the governance of broad consent in Africa and this brings us to our first procedural norm: procedural accountability.

As part of solidarity, the H3Africa Framework places emphasis on the importance of consultation. Community engagement is increasingly recognized as a critical component in the ethical conduct of health research, and this is particularly pertinent in communitarian societies. However, it is not just the research itself that must be informed by community engagement, but the regulations themselves. If we are to truly foster non-exploitative research, we must be adequately informed about the different ways in which participants have been exploited. As noted by James *et al.*, 'researchers who have not been grounded in, or are dismissive of, the historical context that shape values and beliefs . . . cannot adequately assess "risk" related to cultural harms as perceived by . . . groups.'<sup>40</sup> Equally, if research is to be for some communal benefit, there must be an understanding of this benefit. Thus, the development of genomic biobank regulations and the implementation of the research must be supported by community engagement. We consider community engagement to be both a procedural and substantive norm.

Now turning to reciprocity, as discussed, the conceptualization of solidarity in H3Africa puts emphasis on the importance of reciprocity and recognizes that 'as much as the individual contributes to the community, the community also contributes to

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37 H3Africa, *Ethics and Governance Framework for Best Practice in Genomic Research and Biobanking in Africa*, <https://h3africa.org/9-news/361-framework-for-african-genomics-and-biobanking> (accessed June 11, 2018).

38 Barbara A. Koenig, *Have We Asked Too Much of Consent?* 44 *Hastings Centre Rep.* 33 (2014). Paulina Tindana, Jantina De Vries, *Broad Consent for Genomic Research and Biobanking: Perspectives from Low- and Middle-Income Countries*, 17 *Annu Rev Genomics Hum Genet.*, 375, 388 (2016).

39 Angela Beaton, Maui Hudson, Moe Milne, Ramari Viola Port, Khyla Russell, Barry Smith, Valmaine Toki, Lynley Uerata, Phillip Wilcox, Karen Bartholomew, Helen Wihongi, *Engaging Māori in Biobanking and Genomic Research: A Model for Biobanks to Guide Culturally Informed Governance, Operational, and Community Engagement Activities*, 19 *Gen Med.* 345, 348 (2017).

40 Rosalina James, Rebecca Tsosie, Puneet Sahota, Myra Parker, Denise Dillard, Ileen Sylvester, John Lewis, Joseph Klejka, LeeAnna Muzquiz, Polly Olsen, Ron Whitener, Wylie Burke; for the Kiana Group, *Exploring Pathways to Trust: A Tribal Perspective on Data Sharing*, 16 *Gen Med* 820. 822 (2014).

the individual's sustainable wellbeing.' Once again this is not unique to the African context and there is evidence that some indigenous groups expect reciprocity as a guiding value in genomic and biobanking research, which should be built into the process of donation and sharing of biological materials.<sup>41</sup> Reciprocal benefits can take the form of capacity building, improvements to health, or employment opportunities for community members. Reciprocity is important at both a national and local level. Nationally, the regulations should be informed by reciprocity as a mechanism through which exploitative research is avoided. Locally, reciprocity and possible reciprocal benefits should be discussed as part of community engagement. As such, it informs both procedural and substantive law. With regards to justice, there has been a historical lack of fairness in the access and use of biological samples obtained in Africa. Past research practices often saw the uni-directional flow of samples for use in other HICs, thereby preventing their use by local researchers, but it also prevented local oversight of the sample. To remedy this, the fair use of biological materials must be supported by procedural and distributive justice throughout the research process. Procedural justice is concerned with the fairness and transparency of decision-making processes and an integral part of that is establishing local and national policies on the use of biological materials that are informed by community engagement. Local and national oversight can help to prevent or at least limit exploitative research practices and ensure that there are transparent processes in decisions on the use of the materials. Having policies in place can also promote certainty and transparency and legitimize decisions on the use of the biological materials. As such procedural justice should be a procedural norm. However, it must be recognized that these biological materials are a valuable resource and there may be justified reasons (such as capacity building) to warrant putting some limits on its access. In the context of data sharing, controlling data access is seen as important in protecting the rights and interests of the parties involved in genomic data sharing<sup>42</sup> and the same would apply to biological samples themselves. Thus in the development of substantive legislation and policies on genomic biobank research, distributive justice should be a guiding norm.

Finally, empirical evidence has highlighted the importance of trust in the governance and success of genomic biobank research. Participants must trust the biobank, they must trust the researchers, and the work must be conducted in such a way that participation is seen as a 'trustworthy activity.'<sup>43</sup> There has been the suggestion in many LMICs that participants' trust in research has been eroded and by implication, trust in researchers, but there has also been a loss of trust experienced between researchers in

41 Angela Beaton, Maui Hudson, Moe Milne, Ramari Viola Port, Khyla Russell, Barry Smith, Valmaine Toki, Lynley Uerata, Phillip Wilcox, Karen Bartholomew, Helen Wihongi, *Engaging Māori in Biobanking and Genomic Research: A Model for Biobanks to Guide Culturally Informed Governance, Operational, and Community Engagement Activities*, 19 *Gen Med.* 345, 347 (2017). Rosalina James, Rebecca Tsosie, Puneet Sahota, Myra Parker, Denise Dillard, Ileen Sylvester, John Lewis, Joseph Klejka, LeeAnna Muzquiz, Polly Olsen, Ron Whitener, Wylie Burke; for the Kiana Group, *Exploring Pathways to Trust: A Tribal Perspective on Data Sharing*, 16 *Gen Med.* 820, 822 (2014).

42 Mahsa Shabani, Pascal Borry, *You Want the Right Amount of Oversight': Interviews with Data Access Committee Members and Experts on Genomic Data Access*, 18 *Genet Med.* 892, 892 (2016).

43 Susan Wallace, Bartha Maria Knoppers, *The Role of P3G in Encouraging Public Trust in Biobanks in TRUST IN BIOBANKING* 189 (Peter Dabrock, Jochen Taupitz, Jens Ried eds., 2012).

LMICs *vis a vis* researchers in HICs.<sup>44</sup> Trust is important on different levels and each must be addressed in the governance framework for genomic biobanking in Africa: trust between the participant and the researcher to whom they are donating their sample and data; trust between the participant and the institution in which the materials are stored; participant trust in the governance framework; trust between the regulators and those implementing the research; and trust between researchers in Africa and other international collaborators. A governance system that is built upon regulations, which are legitimate, reflective of local values, and ensure accountability supports the development of trustworthy relationships. Trust reinforces the importance of procedural accountability, but to fully understand and address these differing layers of trust, there should be wide stakeholder engagement on these matters. As such we consider stakeholder engagement to be our final procedural norm.

#### IV. BENCHMARKS FOR GOOD GOVERNANCE FOR GENOMIC BIOBANK RESEARCH IN AFRICA

In an effort to reduce bureaucracy and improve the regulatory process, discussion often focuses on good governance and key features that should support governance to improve regulation. Within the European Union, the 2001 Mandelkern Report on Better Regulation, which forms the basis of better regulation within the EU, set out seven key principles for better regulation: necessity, proportionality, subsidiarity, transparency, accountability, accessibility, and simplicity.<sup>45</sup> In the UK, the Better Regulation Task Force identified proportionality, accountability, consistency, transparency, and targeting as its principles of ‘Better Regulation.’<sup>46</sup> Good governance and better regulation is also a feature of many international organizations, including the OECD which sees improved regulatory policy as one of the key tools that governments can use to improve societal welfare.<sup>47</sup> Good governance is also seen as one of the principles and objectives of the African Union (AU)<sup>48</sup> and transparency, accountability and participatory democracy are seen as important features of good governance within the AU.<sup>49</sup> In the context of genomic biobank research, O’Doherty *et al.* have identified representativeness, accountability, transparency, reflective, and sustainability as necessary

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44 Syntia Munung, Bongani M. Mayosi, Jantina de Vries, *Genomics Research in Africa and its Impact on Global Health: Insights from African Researchers*, E12 *Genomic Med Global Health*. doi: 10.1017/ghg.2018.3 (2018).

45 Mandelkern Report on Better Regulation (2001) i. For more on the EU’s Better Regulation Policy see Commission communication *Smart Regulation in the European Union* COM (2010) 543. Communication from the Commission to the Council, the European Parliament, the European Economic and Social Committee and the Committee of the Regions, ‘A Strategic Review of Better Regulation in the European Union’ COM (2006) 690 final, COM (2006) 691 final. Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions—Second strategic review of Better Regulation in the European Union COM (2008) 33 final, COM (2008) 35 final, Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions—Third strategic review of Better Regulation in the European Union COM/2009/0015 final, Communication from the Commission—Action plan ‘Simplifying and Improving the Regulatory Environment’ COM (2002) 0278 final.

46 Better Regulation Taskforce, *Principles of Good Regulation* (2007).

47 OECD, *Better Regulation Practices Across the European Union* (2019).

48 Constitutive Act of the African Union (2000).

49 African Union, *African Charter on Democracy Elections and Governance* (2007).

conditions for biobank governance.<sup>50</sup> Shabani *et al.* have identified objectivity, fairness, transparency, and accountability as important in improving the governance of accessing genomic data.<sup>51</sup>

In developing and revising its governance of genomic biobank research, African law makers should consider each of these principles. The Better Regulation principles have also been used as the basis on which to analyze biobank regulations in the UK.<sup>52</sup> However, so as to ensure that regulations support our proposed reframing of the regulatory tilt, we consider that law makers in Africa should be particularly guided by the procedural norms (procedural accountability, community engagement, reciprocity, and stakeholder engagement) and substantive norms (community engagement, reciprocity) that we have outlined. In the final section of this paper, we will outline how these norms should be reflected in a governance framework through an identification of certain benchmarks for good governance for genomic biobank research in Africa. These benchmarks are to be considered to be in addition to the above principles of good governance and Better Regulation and are what we propose are particularly pertinent in achieving this re-framed regulatory tilt.

#### A. Legislative framework

As discussed previously, it is thought that many jurisdictions in Africa do not have any national regulations for genomic biobank research. Regulations can clearly outline the rules and policies that govern the use and re-use of biological materials and importantly, specify the conditions under which non-exploitative research and collaborations can take place. The purpose of our re-framed regulatory tilt is to protect the participant from exploitative research and equally protect the research from exploitative research and collaborations. These regulations can thus limit the use and re-use of the materials, particularly if they are to achieve either of those stated aims. Regulations however cannot only prevent exploitative research, but also encourage non-exploitative research by putting some limits on the research, provided this is in the interests of capacity building. For example, national regulations can mandate that the use of samples and data require a local principal investigator, or that samples will only be used overseas if accompanied by an African student.

It is less important whether jurisdictions enact specific regulations for genomic biobank research or regulate it within existing regulations for health research. What is essential is that there is a national legislative scheme in place and that it aligns with the regulatory tilt. However, in developing general data protection regulations that seek to regulate the use of all types of personal data, law makers in Africa must be mindful that the use of data for health research and for genomic biobank research require sector-level responses to fill the regulatory gaps left by general data protection regulations.<sup>53</sup>

50 Kieran C. O'Doherty, Michael M. Burgess, Kelly Edwards, Richard P. Gallagher, Alice K. Hawkins, Jane Kaye, Veronica McCaffrey, David E. Winickoff, *From Consent to Institutions: Designing Adaptive Governance for Genomic Biobanks*, 73 Soc Sci Med. 367, 369 (2011).

51 Masha Shabani, Stephanie Dyke, Yann Joly, Pascal Borry, *Controlled Access under Review: Improving the Governance of Genomic Data Access*, 13 PLoS Biol. e1002339.

52 Jane Kaye, Susan Gibbons, Catherine Heeney, Michale Parker, Andrew Smart, *Governing Biobanks: Understanding the Interplay Between Law and Practice* (Hart Publishing, 2012).

53 For example, in South Africa, a Code of Conduct has been called for to provide guidance on the application of the Protection of Personal Information Act 2013 for genomic research. Ciara Staunton, Rachel Adams,

Stakeholder engagement will be key in informing the development of the content and substantive elements of these regulations. At a minimum they should regulate for consent for future use of samples and data; use, re-use, and exportation of samples and data; oversight of the use and regulatory approval; capacity building; benefit sharing; community engagement; sample ownership and custodianship; and data sharing. It is of particular concern that it appears that many jurisdictions in Africa lack regulations on data sharing and protection for genomic biobank research, and there are concerns that institutions in Africa do not have robust frameworks in place to oversee the use of genomic data.<sup>54</sup> This could also make adhering to the strict provisions of international regulations such as the EU General Data Protection Regulation (GDPR) that can at times apply to researchers in Africa challenging, and may compromise the ability of researchers in Africa to collaborate with European institutions as well as access EU funding. Where data protection regulations do exist, they are quite similar to the GDPR and may not be reflective of the context in which they operate.<sup>55</sup> For example, restrictions on access to data, or preferential treatment to local researchers for a certain period to enable them to maximize the use of the materials, can develop capacity in this area.<sup>56</sup> Although this is contrary to international best practice and some funding requirements, which puts emphasis on rapid release of data, the interests of science in Africa may require putting short-term restrictions on the sharing of data.<sup>57</sup>

### B. Stakeholder engagement

Internationally, there is growing recognition of the importance of stakeholder engagement not only in research but also in the development of regulations. The OECD's 2012 recommendations require engagement with stakeholders at all levels, both in developing and reviewing regulations. Guidance on how this can be done is currently being developed in its *Best Practice Principles on Stakeholder Engagement*.<sup>58</sup> Central also to the European Commission's Better Regulation Agenda is the involvement of stakeholders, and in particular EU citizens, in the design and evaluation of regulations. Good governance is also partly determined by the extent to which the functions of the

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Marietjie Botes, Edward S. Dove, Lyn Horn, Melodie Labuschaigne, Claudina Loots, Safia Mahomed, Jennifer Makuba, Antonel Olckers, Michael S. Pepper, Anne Pope, Michele Ramsay, Nora Ni Loideain, Jantina de Vries, *Safeguarding the Future of Genomic Research in South Africa: Broad Consent and the Protection of Personal Information Act 2013*, 109 South African Med J. 468 (2019).

54 Ciara Staunton, Rachel Adams, Akin Abayomi, Edward S. Dove, Natalie Harriman, Lyn Horn, Melodie Labuschaigne, Nicola Mulder, Antonel Olckers, Anne Pope, Carmen Swanepoel, Nora Ni Loideain, Jantina de Vries, "Ethical and Practical Issues to Consider in the Governance of Data Sharing for Genomic and Human Research Data in South Africa: A Meeting Report," AAS Open Res. 2:15 (2019).

55 Ciara Staunton, Rachel Adams, Dominique Anderson, Tay Croxton, Dorcus Kamuya, Marienne Munene, Carmen Swanepoel, "Protection of Personal Information Act 2013 and Data Protection for Health Research in South Africa," Int Data Privacy Law J. (2019, forthcoming).

56 Aminu Yakubu, Paulina Tindana, Alice Matimba, Syntia Munung, Katherine Littler, Ciara Staunton, Jantina de Vries, *Model Framework for Governance of Genomic Research and Biobanking in Africa—A Content Description*, 1 AAS Open Res. 13 (2018).

57 Michael Parker, Dominic Kwiatkowski, *The Ethics of Sustainable Genomic Research in Africa*, 17 Genome Biol. 44 (2016).

58 OECD *Public Consultation on the Draft OECD Best Practice Principles on Stakeholder Engagement in Regulatory Policy*, <http://www.oecd.org/gov/regulatory-policy/public-consultation-best-practice-principles-on-stakeholder-engagement.htm> (accessed Dec. 10, 2018).

State reflect the values of the stakeholders.<sup>59</sup> Seen in this way, effective governance is a partnership between the State and the relevant stakeholders, with stakeholders having an important role in both development and implementation of regulations.

In the context of biobanks, it has also been recommended that stakeholder engagement be one of the benchmarks for good governance.<sup>60</sup> Such engagement is necessary as internationally very few jurisdictions have introduced regulations in response to biobanks, leaving it to other stakeholders such as RECs, advisory boards, funders, and consortia to develop norms and procedures for biobanks.<sup>61</sup>

In Africa, there are similarly a multitude of stakeholders involved in the governance of genomic biobank research including RECs, national regulator bodies, international consortia, and individual biobanks.<sup>62</sup> In particular, the H3Africa Consortium directly engaged with REC members and national regulators in the development of its Governance Framework, and indirectly with other groups through dissemination of the draft Framework through meetings, networks and informal discussions.<sup>63</sup> Although it is intended that this document be used to guide the development of governance frameworks across the continent, national engagement is of particular importance for two reasons.

First, there are regional and cultural differences across the continent. Notably in early drafts of this framework, Ubuntu, which is a philosophy that focuses on the interrelatedness of humans, was selected as its normative basis. It soon became apparent that there was resistance as the term is seen as South African that has strong links to the apartheid struggle in South Africa, and is thus not reflective of developments elsewhere on the continent.<sup>64</sup> Regulations must thus be contextualized to the particular jurisdiction and this can be achieved in part through stakeholder engagement.

Second, those implementing the regulations should broadly support them, otherwise there will be a considerable disconnect between the law in the books and the law in action. It is irrelevant if the regulatory tilt is reframed if the implementation of the law shifts back to a more precautionary approach. This is perhaps best exemplified by the perception of broad consent in Africa. Globally, there has been a move toward recognition of broad consent as an ethically acceptable model of consent for genomic biobank research. The ease with which samples and data can be shared with relatively minimal risk to participants required a rethink of specific informed consent for this research. Broad consent has faced some resistance at a national level (such as Zambia

59 Sameen Siddiqia, Tayyeb I. Masuda, Sania Nishtarb, David H. Petersc, Belgacem Sabria, Khalif M. Bile, Mohamed A. Jama, *Framework for Assessing Governance of the Health System in Developing Countries: Gateway to Good Governance*, 90 *Health Policy*. 13, 13 (2009).

60 JANE KAYE, SUSAN GIBBONS, CATHERINE HEENEY, ANDREW SMART, *GOVERNING BIOBANKS: UNDERSTANDING THE INTERPLAY BETWEEN LAW AND PRACTICE*, 316 (2012).

61 See Jane Kaye, *From Single Biobanks to International Networks: Developing E-governance*, 130 *Hum Genet.* 377 (2011). Graeme Laurie, *Reflexive Governance in Biobanking: On the Value of Policy Led Approaches and the Need to Recognise the Limits of Law*, 130 *Hum Genet.* (2011) 130: 347–356.

62 Ciara Staunton, Paulina Tindana, Melany Hendricks, Keymanthri Moodley, *Rules of Engagement: Perspectives on stakeholder Engagement for Genomic Biobanking Research in South Africa*, 19 *BMC Med Ethics*. 19 (2018).

63 Aminu Yakubu, Paulina Tindana, Alice Matimba, Syntia Munung, Katherine Littler, Ciara Staunton, Jantina de Vries, *Model Framework for Governance of Genomic Research and Biobanking in Africa—A Content Description*, 1 *AAS Open Res.* 13 (2018).

64 *Ibid.*

where the use of broad consent is prohibited). However, where regulations do exist, the majority of jurisdictions explicitly or implicitly permit broad consent.<sup>65</sup>

Despite this, our engagement with RECs on the continent as part of the H3Africa Ethics and Regulatory Issues Working Group informed us that irrespective of the existence of regulations permitting broad consent, they were often hesitant to approve studies that sought to adopt broad consent as the consent model for genomic biobank research.<sup>66</sup> Similarly, engagement with research participants in Zambia has demonstrated support for broad consent but specific consent is mandated by the Health Research Act 2013.<sup>67</sup> This points to a disconnect between the law in statute and law in action and demonstrates the crucial importance of stakeholder engagement in developing regulations for genomic biobank research in Africa.

Stakeholder engagement can reveal any concerns with draft regulations as well as regulations that are in force, and help to ensure that the implementation of regulations is in line with the intent of law makers. In this way, it can also legitimize the regulations. Part of stakeholder engagement will involve engaging with communities, and this will be considered in further detail below.

### C. Institutional responsibility

Aligned with the development and reformulation of regulations, we must identify a process for ensuring accountability. Similar to stakeholder engagement, accountability and lines of accountability are key features of good governance.<sup>68</sup> The challenge is who should be the appropriate body that has responsibility for oversight of the research and hold the relevant parties to account.

In identifying the appropriate body, it may be useful to unpack their responsibilities. First, they will have responsibility for ensuring that the regulations are followed. Second, they will have oversight of the use, re-use, sharing, and possible export of samples. This will include overseeing access arrangements, intellectual property rights and by implication, bearing responsibility for the use of samples and data in research and perhaps the researchers using the sample. It is thus not just the use of the sample and data that the body will have responsibility for, but also holding the users of the resources to account and ensuring that the use and future use of the research is non-exploitative and has reciprocal benefits.

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65 Ciara Staunton, Keymanthri Moodley, *Challenges in Biobank Governance in Sub-Saharan Africa*, 14 BMC Med Ethics. 35 (2013). Jantina de Vries, Syntia Nchangwi Munung, Alice Matimba, Sheryl McCurdy, Odile Ouwe Missi Oukem-Boyer, Ciara Staunton, Aminu Yakubu, Paulina Tindana; the H3Africa Consortium, *Regulation of Genomic Biobank Research in Africa: A Content Analysis of Ethics Guidelines, Policies and Procedures from 22 African Countries*, 18 BMC Med Ethics. 1 (2017).

66 Jantina de Vries, Akin Abayomi, Katherine Littler, Ebony Madden, Sheryl McCurdy, Odile Ouwe Missi Oukem-Boyer, Janet Seeley, Ciara Staunton, Godfrey Tangwa, Paulina Tindana, Jennifer Troyer, The H3Africa Working Group on Ethics. *Addressing Ethical Issues in H3Africa Research—The Views of Research Ethics Committee Members*, 9 HUGO. 1 (2015).

67 Oliver Mweemba, John Musuku, Bongani M. Mayosi, Michael Parker, Rwamahe Rutakumwa, Janet Seeley, Paulina Tindana, Jantina De Vries, *Use of Broad Consent and Related Procedures in Genomics Research: Perspectives from Research Participants in the Genetics of Rheumatic Heart Disease (RHDGen) Study in a University Teaching Hospital in Zambia*, Global Bioethics. doi: 10.1080/11287462.2019.1592868 (2019).

68 See John Graham, Bruce Amos and Tim Plumpton, *Principles for Good Governance in the 21st Century*, [https://iog.ca/docs/2003\\_August\\_policybrief15.pdf](https://iog.ca/docs/2003_August_policybrief15.pdf) (accessed Dec. 10, 2018).

We have discussed the importance of trust in genomic biobank research and the different layers of trust that a governance framework must support. In the African context, Tindana *et al.* have described an entrustment model that supports broad consent. In this model, participants consent to the use of their sample in research and entrust researchers to use their sample wisely. It is then the institution to which the researcher belongs that has the obligation to ensure that the sample is used responsibly and to ‘reciprocate by providing tangible health benefits.’<sup>69</sup> For the authors, this model creates a moral responsibility that the sample is used wisely with reciprocal benefits. Thus, the researcher and the institution cannot do whatever they want with the sample. O’Neill notes that we cannot simply take matters on trust, but establish ‘robust systems of accountability’<sup>70</sup> and Tindana equally notes that such a model is only acceptable where the institution has well-founded relationships of trust with the community and it is supported by governance and accountability.<sup>71</sup> We have already begun to unpack certain benchmarks for this system of governance and note the importance of accountability, but it brings us back to our problem of identifying the body with powers of accountability and the system through which that accountability comes about.

A number of different legal approaches that would be supportive of such accountability have been discussed elsewhere.<sup>72</sup> Winickoff and Winickoff have proposed the idea of a charitable trust model, whereby an independent body manages the trust and ensures its use in accordance with the wishes of the donors.<sup>73</sup> Such an approach does embody elements of the solidarity-based approaches as it embodies this notion of ‘gifting’ (one presumes) for the benefit of others. Through the charitable trust, there will be independent oversight and accountability on the use and re-use of the sample. However, in such a model, the focus tends to be on the wishes of the donor, which is a much more autonomy-based understanding of solidarity that is not necessarily reflective of African values.

A model that may be more closely aligned to that proposed by Tindana *et al.* is the establishment of a fiduciary relationship between the institution and the participant. A fiduciary relationship arises when one party is entrusted to act on behalf of the best interests of another party, such as the doctor–patient relationship. The doctor has a moral responsibility to act in the interests of the patient, with legal consequences if the doctor does not fulfill their fiduciary duties. In this context, the researcher clearly could not be the trustee, as a trustee or agent cannot act in conflict of interest of the trustor or principal. Their primary obligation is to the research, and the best interests

69 Paulina Tindana, Sassy Molyneux, Susan Bull, Michael Parker, ‘It is an Entrustment’: *Broad Consent for Genomic Research and Biobanks in Sub-Saharan Africa*, *Dev World Bioethics*. doi: 10.1111/dewb.12178 (2017).

70 Oonora O’Neill, *Accountability, Trust and Informed Consent in Medical Practice and Research*, 4 *Clin Med*. 269, 269 (2004).

71 Paulina Tindana, Sassy Molyneux, Susan Bull, Michael Parker, ‘It is an Entrustment’: *Broad Consent for Genomic Research and Biobanks in Sub-Saharan Africa*, *Dev World Bioethics*. doi: 10.1111/dewb.12178 (2017).

72 Empirical research in the Māori context has stated that the different models should be discussed with stakeholders. See Angela Beaton, Maui Hudson, Moe Milne, Ramari Viola Port, Khyla Russell, Barry Smith, Valmaine Toki, Lynley Uerata, Phillip Wilcox, Karen Bartholomew, Helen Wihongi, *Engaging Māori in Biobanking and Genomic Research: A Model for Biobanks to Guide Culturally Informed Governance, Operational, and Community Engagement Activities*, 19 *Gen Med*. 345, 347 (2017).

73 David Winickoff, Richard Winickoff, *The Charitable Trust as a Model for Genomic Biobanks*, 349 *N Engl J*. 1180, 1181 (2003).

of the participant may at times be in conflict with the best interests of the research itself. Following from the entrustment model, the institution is to have certain moral responsibilities and as a corollary, has fiduciary duties to the participant.

One possible challenge to this fiduciary model is that it protects the duties owed by the trustee (ie the institution) to the trustor (ie the participant). Thus, one could argue that the institution must only protect or guard against any risks to the individual. Viewed through this lens, the institution is responsible for protecting the interests of the participant, which includes the responsible future use of the sample and data. However, the duties must be understood in the broader context of the research and the solidarity basis on which the samples were donated. The institution is thus also responsible for protecting the interests of the community, in which the biological materials are donated. Such a type of fiduciary relationship may work in the African context if the materials are held on trust for the benefit of the community.

A third approach that is perhaps more suitable to the genomic biobank context, is the corporate governance model that involves shareholders, directors, and a company. Under this approach, shareholders invest in the company. They are not involved in the day-to-day running of the company, but have the opportunity during the annual general meeting (AGM) or extraordinary general meetings (EGM) to vote and contribute to the strategic vision of the company. It is the directors who run the business, but they do so on behalf of the shareholders. The directors do not have fiduciary duties to the shareholders (except in specific circumstances), but rather to the company. Their duties include acting in the best interests of the company, ensuring that there is no conflict of interest, acting within the company's constitution and exercising independent judgment.<sup>74</sup>

Such a model could apply to the genomic biobank context with some adjustments. The shareholders will not be the collective participants, but rather the community from which the participants come. Thus, it is irrelevant if some individuals contributed more samples than others; they do not get extra 'votes.' The donation is for the communal benefit and it is thus the community to which the institution must feedback through AGMs or EGMs. The 'company' is the genomic biobank. It must act in the interests of that biobank to the extent that it must ensure that it has no conflicts of interest, exercise judgment in the exercise of its functions and also act within the governance framework of the genomic biobank. The best interests of the biobank must not be thought of as meaning 'the best interests of research.' Rather, as the institution must act with the shareholders in mind, the best interests of the biobank are to be seen as the use of the biological materials that is for the benefit of the community.

The advantage of such a model is that there are clear lines of responsibility and accountability. It describes the continued role that the participant community should have and ensures that the use and re-use of the biological material is not self-regulated by researchers. We propose that it is the institution that is hosting the biobank that must have ultimate oversight. This is supportive of the entrustment model discussed by Tindana, but also mirrors developments in the oversight of data protection. The emerging data protection regulations in Africa do specify clear lines of accountability

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74 For more on the fiduciary duties owed, see Frank H. Easterbrook, Daniel R. Fischel, *Contract and Fiduciary Duty*, 36 J Law Economics. 425 (1993).

with the research institution the body with overall responsibility.<sup>75</sup> Entrusting institutions with responsibility for samples *and* data ensures a much more coherent approach to the governance of samples and data.

In our view, institutions will serve two key functions. First, they must implement national regulations pertaining to genomic biobank research, and second, they must develop institutional policies. These policies will further guide the implementation of the research and will focus on the substantive rather than procedural elements of the law. It is at the individual project level, where reciprocal benefit sharing arrangements with the local community can be developed.

It is useful to refer to Schroeder who defines benefit sharing as:

“Benefit sharing is the action of giving a portion of advantages/profits derived from the use of human genetic resources to the resource providers to achieve justice in exchange, with a particular emphasis on the clear provision of benefits to those who may lack reasonable access to resulting healthcare products and services without providing unethical inducements.”<sup>76</sup>

Benefit sharing is thus much wider than direct benefit to the participant, but can include other benefits such as capacity building. Indeed it is this conceptualization of benefit that underpins the principles on which H3Africa was developed<sup>77</sup> and it is reflective of solidarity-based approaches of this research.

The possible content of benefit sharing arrangements is thus considerable and institutions should not adopt a policy on the specifics of such an arrangement. Rather, they should require that any research consider formalized benefit sharing with communities that is supported by community engagement.

#### D. Community engagement

This brings us to the final benchmark for good governance: community engagement. Community engagement is seen as a requirement for the ethical conduct of research and is a key feature of international codes of conduct for health research.<sup>78</sup> It is particularly necessary in the context of genomic biobank research as the research has implications for the family and community, as well as the individual. It can help to address the complex ethical and social factors with genomic biobank research.<sup>79</sup> Controversies surrounding the Havasupai Tribe and research involving members of the San community in genomic research demonstrate the problems that can arise when research is conducted without engaging members of the community.<sup>80</sup> It is of

75 Ciara Staunton, Rachel Adams, Dominique Anderson, Tay Croxton, Dorcus Kamuya, Marianne Munene, Carmen Swanepoel, ‘Protection of Personal Information Act 2013 and Data Protection for Health Research in South Africa,’ *Int Data Privacy Law J.* (2020, forthcoming).

76 Doris Schroeder, *Benefit Sharing: It’s Time for a Definition*, 33 *J Med Ethics*. 205, 208 (2007).

77 Bege Dauda, Steven Joffe, *The Benefit Sharing Vision of H3Africa*, 18 *Dev World Bioethics*. 165, 166 (2018).

78 Ezekiel J. Emanuel, David Wendler, Jack Killen, Christine Grady, *What Makes Clinical Research in Developing Countries Ethical? The Benchmarks of Ethical Research*, 189 *J Infect Diseases*. 930 (2004). H3Africa, *Ethics and Governance Framework for Best Practice in Genomic Research and Biobanking in Africa*, <https://h3africa.org/9-news/361-framework-for-african-genomics-and-biobanking> (accessed June 11, 2018).

79 Amy A. Lemke, Joel T. Wu, Carol Waudby, Jill Pulley, Carol P. Somkin, Susan Brown Trinidad, *Community Engagement in Biobanking: Experiences from the eMERGE Network*, 6 *Genomics Soc Policy*. 35 (2010).

80 Roger Chennells, Andries Steenkamp, ‘International Genomics Research Involving the San People’ in *ETHICS DUMPING 15* (Doris Schroeder, Julie Cook, Francois Hirsch, Solveig Fenet, Vasantha

particular salience in the African context, where a communitarian ethos permeates many societies. Decisions are often taken in consultation with the family and other members of the community. In addition, the traditional political structures give clear authority to the elders, tribal leaders, and chiefs. The approval of these community leaders will often be required prior to the commencement of the research. Thus, as part of the institutional oversight of the research, a community engagement strategy must be required as part of the research protocol. This should be supported by national regulations and should mandate that community engagement is an essential component of research, unless it is deemed to be unnecessary by a REC.

Community engagement should not however simply be seen as important in the design of the research itself. If the governance of genomic biobank research is to be sensitive to the context in which it operates,<sup>81</sup> the development of institutional policies must be informed by community engagement and the institutional oversight of the research should include community representation. By being a part of the design and implementation of governance frameworks, the community can become part of the accountability measures. As part of these accountability measures, there should be feedback of findings to the community, and where possible, the individual.

Ensuring community engagement in national policy and strongly encouraging feedback of findings must also be met with resources to support training and implementation. To do otherwise would only give lip-service to such measures. National training for community engagement will be necessary, but in resource limited settings requirements that a certain percentage of a grant be spent on community engagement (unless waived by a REC), could help to alleviate some resource concerns.

## V. CONCLUSION

The growth of genomic biobank research in Africa represents a real opportunity to help remedy global health disparity and develop scientific research capacity on the continent. Allied with this must be recognition of the exploitative research practices of the past and a commitment to ensuring ethical research practices. Good governance and oversight of the research can help ensure that exploitative research does not occur, but this must not result in precautionary based approaches that result in restrictive regulations. Rather, the focus should be on how best to remedy the problem (ie exploitative research and exploitative collaborations) in a way that can promote genomic research as a means to increase scientific knowledge and improve the health of the population, but in a manner that results in reciprocal benefits.

As a first step in achieving this, there is a need to shift the regulatory tilt to guard against such exploitative research and collaborations. Thus, the regulatory tilt is neither generally permissive nor restrictive, but rather focuses on preventing such research. By following our additional benchmarks of legislative framework, stakeholder engagement, institutional responsibility and community engagement for good governance for genomic biobank research in Africa, this can support law makers in Africa following this re-framed regulatory tilt.

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81 Brian Salter, Mavis Jones, *Biobanks and Bioethics the Politics of Legitimation*, 12 J Eur Pub Pol. 710, 724 (2005).

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