



OPEN LETTER

# **REVISED** Model framework for governance of genomic research and biobanking in Africa – a content description [version 2; peer review: 3 approved]

Aminu Yakubu <sup>1</sup>, Paulina Tindana<sup>2</sup>, Alice Matimba <sup>3</sup>, Katherine Littler<sup>4</sup>, Nchangwi Syntia Munung<sup>5</sup>, Ebony Madden<sup>6</sup>, Ciara Staunton <sup>7</sup>, Jantina De Vries <sup>5</sup>

<sup>1</sup>Department of Health Planning, Research & Statistics, Federal Ministry of Health, Abuja, Nigeria

<sup>2</sup>Navrongo Health Research Centre, Ghana Health Service, Navrongo, Ghana

<sup>3</sup>Wellcome Genome Campus Advanced Courses and Scientific Conferences, Cambridge, UK

<sup>4</sup>Global Policy, Wellcome Trust, London, UK

<sup>5</sup>Department of Medicine, University of Cape Town, Cape Town, South Africa

<sup>6</sup>Division of Genomic Medicine, National Human Genome Research Institute, National Institutes of Health, Rockville, MD, USA

<sup>7</sup>Law Department, Middlesex University, London, UK

**v2** First published: 18 Apr 2018, 1:13 (<https://doi.org/10.12688/aasopenres.12844.1>)

Latest published: 12 Dec 2018, 1:13 (<https://doi.org/10.12688/aasopenres.12844.2>)

## Abstract

Genomic research and biobanking are expanding globally, with a promise to fast-track the research needed to improve approaches to disease treatment and prevention through scientific collaborations such as the Human Heredity and Health in Africa (H3Africa) initiative. Integral to this type of research is the availability of samples and data for research. The need for broad access brings along a host of ethical concerns, including those related to privacy and confidentiality, as well as fairness and equity in access and capacity to utilise these samples between scientists from the high income and low income countries. Addressing these concerns while promoting genomic research, especially in Africa, requires the implementation of a sound governance framework. In this paper, we describe the contents of a Framework for Best Practice for Genomics Research and biobanking in Africa that was developed, under the auspices of the H3Africa initiative. This framework is broad enough to be used and adapted by African countries to facilitate the development of country-specific guidelines and to help improve the conduct and governance of genomics research.

## Keywords

genomics research, biobanking, governance



This article is included in the [African Society of Human Genetics gateway](#).

## Open Peer Review

Reviewer Status

	Invited Reviewers		
	1	2	3
<b>version 2</b> published 12 Dec 2018			
<b>version 1</b> published 18 Apr 2018	 report	 report	 report

- Kieran O'Doherty** , University of Guelph, Guelph, Canada  
**Kim Chuong**, University of Guelph, Guelph, Canada
- Ellen Wright Clayton** , Vanderbilt University Medical Center (VUMC), Nashville, USA
- Don Chalmers**, University of Tasmania, Hobart, Australia

Any reports and responses or comments on the article can be found at the end of the article.

**Corresponding author:** Aminu Yakubu ([yakubu.aminu@gmail.com](mailto:yakubu.aminu@gmail.com))

**Author roles:** **Yakubu A:** Conceptualization, Writing – Original Draft Preparation, Writing – Review & Editing; **Tindana P:** Conceptualization, Writing – Review & Editing; **Matimba A:** Writing – Review & Editing; **Littler K:** Writing – Review & Editing; **Munung NS:** Writing – Review & Editing; **Madden E:** Writing – Review & Editing; **Stanton C:** Writing – Review & Editing; **De Vries J:** Conceptualization, Writing – Review & Editing

**Competing interests:** No competing interests were disclosed.

**Grant information:** This work is supported by the Human Heredity and Health in Africa (H3Africa) in Partnership with the African Academy of Sciences. The Framework drafting meeting was supported by a grant from the Wellcome Trust (WT201245/Z/16/Z). During the development of this Framework, Jantina de Vries was supported by the RHDGen grant, a H3Africa grant funded by the Wellcome Trust (WT099313MA) and the Stigma in African Genomics grant funded by the National Human Genome Research Institute of the National Institutes of Health under Award Number U01HG008226.

*The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.*

**Copyright:** © 2018 Yakubu A *et al.* This is an open access article distributed under the terms of the [Creative Commons Attribution Licence](https://creativecommons.org/licenses/by/4.0/), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited. The author(s) is/are employees of the US Government and therefore domestic copyright protection in USA does not apply to this work. The work may be protected under the copyright laws of other jurisdictions when used in those jurisdictions.

**How to cite this article:** Yakubu A, Tindana P, Matimba A *et al.* **Model framework for governance of genomic research and biobanking in Africa – a content description [version 2; peer review: 3 approved]** AAS Open Research 2018, 1:13 (<https://doi.org/10.12688/aasopenres.12844.2>)

**First published:** 18 Apr 2018, 1:13 (<https://doi.org/10.12688/aasopenres.12844.1>)

**REVISED Amendments from Version 1**

In this second version of our paper, we have added a bit more text to reflect some more recent discourse on the “Ubuntu” philosophy, being a key underlying philosophy initially considered for the framework - instead a Communitarian World View was adopted. In the first version, we inadvertently mentioned that there were ‘five core principles’, whereas they are four, which has now been corrected. We have now included some more discussion on the “African Intellectual Leadership”. We have linked this issue with the 10/90 gap and the issues raised about poor diversity and inclusion in genomics research. Some more text to further put community engagement in better context including description of what we mean by ‘genuine’ (vs tokenistic) community engagement has been added. We have also added a bit more text on our future engagement plans on the framework.

**See referee reports**

**Introduction**

The complete mapping of the human genome<sup>1</sup> brought along with it possibilities to better understand human health and its determinants which would help improve the way diseases and health conditions are managed. Since then, the number of genomic research studies and the need for biobanking has been growing globally<sup>2-4</sup>, with a steady increase in the number of such studies being conducted on the African continent<sup>5</sup>. Further scaling up genomics research with samples and data from diverse African populations<sup>6</sup> has great value considering that only a small portion of human diversity is found outside Africa<sup>7</sup>. Towards addressing this gap, a \$76 million initiative referred to as the Human Heredity and Health in Africa Initiative (H3Africa) was funded jointly by the National Institutes of Health in the US and Wellcome Trust in the UK<sup>3</sup>. In order to fast-track realization of the benefits inherent in genomics research, the global community agreed to principles of ‘open science’, which promotes the value of sharing and reuse of data and samples as a critical component of the contemporary scientific landscape<sup>8-10</sup>. Although this has the strong potential to facilitate scientific discovery, it also raises a number of ethical concerns which includes appropriate model of consent that will allow for such sharing of data and samples while upholding participant autonomy<sup>11-14</sup>; issues of withdrawal of consent<sup>15,16</sup>; ownership of samples and data<sup>17-20</sup>; privacy and confidentiality<sup>15,21-23</sup>; and benefit sharing<sup>24-26</sup>. Such issues are not peculiar to African countries, but require a different lens in further elucidating the contextual concerns in African settings. Furthermore, there are concerns about trust<sup>27</sup> and fairness in research collaborations<sup>10,28</sup>, increased vulnerability of research participants due to lower socio-economic levels, a history of exploitation of local populations and researchers<sup>29</sup>, and cultural issues that all must be considered in the governance of genomics research and biobanking in Africa.

In addition to these ethical concerns, regulatory frameworks for health research in Africa are either non-existent, or where they exist, do not respond to the specific concerns raised by genomics research and biobanking<sup>10,23,30</sup>. Towards addressing this gap, the H3Africa Initiative considered it expedient to develop an ethics framework describing best practice for genomics research and

biobanking. Described in terms of core principles and elements, the Framework considered African political history of exploitations from the West and accounts of ethical concerns in conducting genomics research and biobanking<sup>30-33</sup> to inform the choice of these core principles and elements. The phenomenon of “parachute research” – where fully equipped research teams from other countries arrive at the site where research is needed, conduct their research independently of others, and then leave, has been long cited as a challenge for genuine collaborative research in Africa as well as other developing countries in the world. That such practices are not part of the past was highlighted during the recent Ebola epidemic in some West African countries where international researchers are said to have carted specimens away from the affected countries without any form of oversight or recourse to local regulations or regulators<sup>29</sup>. A permutation of these practices is where African researchers are reduced to the role of data and sample collectors, without genuine attempts to ensure their involvement beyond such functions. One way to remedy such practices is by fostering sustainable capacity building for African intellectual leadership in the conceptualization, design, implementation and reporting of locally appropriate studies<sup>30,34,35</sup> – this is one of the core elements of the framework described here. It is also one of the main goals of the H3Africa initiative including support for equipment and infrastructure to enable researchers to develop biobanks and conduct large-scale genomics studies.

The aim of this framework is to guide governance, address sample and data sharing concerns, as well as to serve as a resource for countries to develop their local regulations. The process of engagement that led to the development of this framework is reported in another manuscript<sup>36</sup>. This paper highlights the key contents of this framework and plans for its implementation across the African continent.

**An overarching philosophical basis**

In developing this ethics framework, it was important for key stakeholders to identify the overarching philosophical basis that should guide the development of ethical best practice for genomic research and biobanking. The issues of unfair research collaboration, lack of trust in research collaborations with scientists from the “West” and the related skepticisms among experts and community representatives<sup>30,37-39</sup> were key considerations. These remain genuine concerns that need to be addressed to promote inclusion of Africans in genomics research as the field progresses and the world benefits from its outcomes<sup>6</sup>. To ensure that African patients and researchers partake in genomic research to optimal benefit, we thought it important to adopt a normative basis from African cultural philosophy. “Ubuntu” is a largely South African worldview that focuses on the interrelatedness of humans in their quest for mutual co-existence and is one such African philosophy that was initially selected as a foundation for the framework<sup>40,41</sup>. There is strong ground to suggest the importance of principles of solidarity as articulated in the Ubuntu philosophy as a universal moral theory for sub Saharan Africa<sup>42,43</sup>. However, given its strong historical links to an era of struggle in apartheid South Africa and several accounts limiting it as a southern African philosophy<sup>44,45</sup>, its acceptance during

our consultations as a philosophical basis for the framework met with some resistance from stakeholders in other parts of Africa. Instead, upon consultation we agreed that the framework should adopt a more generic communal or solidarity-based worldview. Such a worldview recognises that individuals are shaped by their relations to people around them and emphasizes respectful and harmonious relationships between them. In the African research context, we agreed that a communitarian perspective would place central importance on reciprocity, consultation and accountability as key ethical values.

### Core Principles and Elements

The framework proposes a set of four core principles that ought to underpin guidance for genomic research and biobanking initiatives in Africa. Whilst these principles are not new, they need to keep being emphasized to address particular concerns of African communities and scientists regarding trust and unfairness in research collaborations. A number of these principles have been echoed in a parallel initiative, the San Code of Ethics, which seeks to define how researchers ought to conduct their work when dealing with the San population in South Africa<sup>46,47</sup>. The four core principles of our framework emphasize the need for research to: a) be sensitive and respectful of African values and cultures; b) be designed primarily to benefit the African people, while acknowledged it may equally benefit the global population; c) ensure genuine and active intellectual participation of African investigators and other stakeholders in research and in dissemination of findings; and d) promote relationships characterised by respect, fairness, equity and reciprocity. As core principles, these aspects are non-negotiable and should be incorporated in the design and conduct of genomics research and biobanking initiatives in Africa.

### Key elements of the Framework for Best Practice

In addition to these core principles, the Framework also describes ten key areas that need to be addressed in order to ensure that the core principles elucidated in the framework are realised. They include: African intellectual leadership; Consent; Community engagement; Ethics review; Avoidance of group harm and stigma; Benefit sharing; Capacity building; International collaboration and export of samples; Feedback of individual genetic findings; and Good governance. These core elements are not mutually exclusive. For instance, high-level capacity building is key to ensuring African intellectual leadership. These elements were informed by a review of guidelines documents and other similar texts from institutions in the global North such as the Global Alliance for Genomics and Health<sup>48</sup> and the Organization for Economic Cooperation and Development<sup>49</sup> among others, and adapted to African experiences and context, thus ensuring alignment with global best practices.

### Highlights of the key elements of the framework

The gap in research investments between the north and south has been reported previously and considered unacceptable<sup>50</sup>. The persistence of this gap, more than two decades after it was initially described could strongly mitigate the potential of genomics research to provide novel insights into health disparities, foster better understanding of human biology, support improvement

in individual clinical care and informing genetic diagnosis among others<sup>6</sup>. The underrepresentation of scientists from low and middle income countries (LMICs)<sup>51</sup> and African countries in particular<sup>52</sup> at all levels of research is one key area of intervention, which when addressed could significantly reduce this gap. Thus, central to this framework is the requirement for all genomics research collaborations in Africa to ensure **African intellectual leadership** – that scientists who are Africans and/or based in African institutions should be engaged and supported to assume leadership roles in the design and implementation of both primary and secondary studies emergent therefrom with the H3Africa project being a good example<sup>10</sup>. This would further promote an earlier call that “developing countries must have the capacity to investigate their own health priorities”<sup>53</sup>, as well as the needed diversity to fully harness the potentials of genomics research in improving global health<sup>10</sup>. We do however recognise that for sustainability, this should be supported by more deliberate efforts by country governments to strengthen their health research systems.

Because sample and data sharing are essential to genomics research and biobanking, it is important that the **consent process** allows sharing and re-use whilst still respecting participant choice. While there are several models of informed consent that may support genomics research<sup>54</sup>, our framework promotes the use of broad consent. It is important to differentiate this from blanket consent, which is consent for sharing and use of data and specimen without any restrictions. Broad consent as understood in the framework allows for “*use of samples and/or data for unspecified future studies, but with conditions. These conditions can involve, for instance a restriction on the types of studies or diseases that samples/data can be used for; a specified oversight and approval process for future use; ongoing consultation with sample donors about future use, if possible; and a process allowing participants to withdraw samples or data from the storage facility that holds them*”. Although debates about appropriate consent models for genomics and biobanking continue, there is growing consensus that broad consent may be the ‘best compromise’ consent model<sup>55</sup>. In their critical presentation of the outcomes of a workshop which aimed to identify the appropriate consent model for collection of biospecimen for use in future research, Grady *et al.* (2015) submitted that broad consent was considered “ethically appropriate, and preferable to lack of consent for the majority of biospecimen collection for future research uses”<sup>54</sup>. Furthermore, Tindana and De Vries (2016) in their paper on the perspectives of broad consent for genomics research in LMICs concluded that there are no *a priori* reasons against the use of broad consent for genomics research in Africa<sup>56</sup>. Empirical research conducted since then suggests that participants may also be supportive of broad consent if done sensitively and respectfully<sup>57–59</sup>. The proposed framework for acceptable broad consent includes initial consent, oversight of future research projects, and, when feasible, mechanisms for maintaining contact and communication with specimen donors. There is, however, an agreement among most proponents of broad consent that for optimal participant protection, whenever broad consent is used in genomics research to allow for future research use, it needs to be accompanied with a mechanism that promotes

accountability and equity<sup>60</sup> in sharing specimen and/or data with other researchers while also ensuring that participants' choice are respected<sup>54,56</sup>.

The Framework considers that genuine **community engagement** (CE) is a key component of ensuring best practice in genomics research and biobanking in Africa, not in the least because it promotes respect for community values and perspectives and maximizes the social value of research<sup>61</sup>. Community engagement is one way to ensure that research conduct is aligned with a communitarian worldview. Furthermore, genuine community engagement is proposed as a condition for the use of broad consent<sup>54,56</sup>. To be clear, community engagement as put forward in the framework goes beyond tokenistic engagement which would involve a once-off meeting with some community members and rather denotes substantive engagement with various members of communities over time. The research team should seek to engage relevant communities at whom a particular project is targeted along the entire spectrum of research activities, from initial planning phases and data collection, to include the return of general study findings when projects end and policy translations where applicable. While there are several accounts of what it means to have a genuine community engagement<sup>62,63</sup>, to be considered meaningful, researchers should demonstrate that proposed CE initiatives are built on some of the known guiding principles or values of CE; adapting some of the related strategies as applicable<sup>64,65</sup>.

The framework recommends that all primary genomic research and biobanking studies must be reviewed by a competent research **ethics review** committee based in the country where samples are collected or stored. Research ethics review fulfils an important role in promoting ethical best practice and is key to the protection of research participants. Such a role is very important in the African research that takes place in the context of a high burden of disease, poor access to basic necessities and healthcare, low average income and literacy levels as well as unfamiliarity of most of the people with biomedical research generally and genomic research specifically. A particular challenge is the limited capacity of research ethics committees in Africa to review genomics research and biobanking projects<sup>66,67</sup>. Using a matrix that maps the various elements of this framework against important issues that ethics committees are recommended to consider, **Table 1** is proposed as a practical tool for ethics committees to provide oversight for good governance in genomics research and biobanking.

The **avoidance of group harm or stigma** is considered important particularly in the African research context where researchers may work with members of many different population groups, each characterised by their own language, culture and belief systems, some of which may be marginalised or discriminated against. Research may also involve groups of people suffering from stigmatised conditions or outlawed or stigmatising behaviours, phenotypes or lifestyles. In such a context, the reporting of genomic research results could aggravate existing stigma or marginalisation. An example is the way in which genomic research on the San included findings that were considered potentially stigmatising<sup>46,47</sup>.

In this example, Namibian San leaders were approached for participation in genomics research<sup>68</sup> without involvement of San political leadership or individuals with experience in science who could have properly explained the research project and who could have helped the research team in designing more appropriate consent processes. Whilst presented internationally as an example of 'best practice' for the involvement of 'indigenous' African populations<sup>69</sup>, this project, as well as its inconsiderate presentation of research results, was perceived as deeply offensive by the Namibian and South African San Councils and led to the development of the San Code for Ethics referenced earlier.

Because of this and other experiences, the framework requires researchers to be mindful of whether and how groups are identified in genomics research, and how research results are reported. Importantly, the framework suggests that community engagement may be one way to alleviate the potential for stigma. Genuine intellectual leadership by senior African researchers and their meaningful involvement in the preparation of manuscripts is equally important to ensure the respectful engagement with African populations and the responsible reporting of study findings.

In terms of **benefit sharing**, the framework proposes that genomics research and biobanking may bring intangible benefits in the form of general study results, social recognition, knowledge production and translation of relevant knowledge to healthcare practice. Whilst there may be some tangible benefits emanating from genomics research and biobanking in the form of (patentable) innovations or technologies, these are rare and should not be the focus of benefit sharing discussions. The framework describes, first, that it is imperative that researchers ensure that intangible benefits accrue to researchers and communities and they should be aware of this. It also describes that researchers should be mindful not to raise unrealistic expectations, and to clearly describe to communities and individuals the nature of potential benefits they can expect and those that they cannot.

**Capacity building** for African scientists is one of the central elements of the framework, and has been identified as one of the primary benefits emanating out of ongoing research endeavours such as H3Africa<sup>25,70</sup>. Building a critical mass of scholars in genomics and biobanking is essential to ensure the sustainability of these research approaches in Africa. Similarly, such a critical mass is needed to ensure that this research can be conducted by African research teams and under African intellectual leadership in the future, provided that capacity is built along the entire academic hierarchy and includes junior scientists as well as more senior ones. Importantly, capacity building would need to focus not just on training in genomics science and bioinformatics, but also in grants administration, contract negotiation, ethics and in transferable skills such as grant writing which enables sustainability of the genomics research. The expectation is that broad capacity building would ensure that research is responsive to the health needs of Africans, is sensitive to African ethical, legal and social issues, and that there is a strong avenue for the implementation of relevant research findings into national health policy and clinical practice.



**Table 1. Checklist for Ethics Committee Review of Governance Arrangements in Proposed Genomics Research Studies.**

Element	Explanation	Criteria
African intellectual leadership	The substantive contribution of scientists based at African institutions	Intellectual leadership or co-leadership of scientists at African institutions
Broad consent	Consent for the use of samples and/or data for unspecified future studies subject to conditions	Must be fully informed and voluntary Participants must be informed about the manner and extent to which they may withdraw from the study Must be supported by community engagement Must be supported by a good governance framework Must be subject to ethical review
Community engagement (OE)	The process of informing, consulting and actively involving relevant communities that have a legitimate interest in the research process	Must be an integral part of each research project Goals and process of CE must be clearly defined, planned and designed collaboratively This must be done at the start of the research CE must be evaluated
Ethics review	Ethics review promotes ethical conduct of research while providing assurances to the public that their welfare is being well taken care of as they contribute to knowledge and development	Every genomic research and biobanking study must be subject to ethics review Re-use of samples must be subject to review by a designated committee The use of samples must be subject to a sample access committee The use of data must be subject to data access committee review
Avoiding group harm or stigma	The reporting of genomic research results has the potential to aggravate existing stigma or marginalization, or punishment	Donors and research ethics committees must be told about any risk of group harm or stigma with the use or re-use of samples Stigma related concerns about the sharing of genomic samples and data should be subject to stakeholder engagement Where there are stigma related concerns, individuals from the countries and/or institutions where obtained should be considered Descriptors that may be perceived to be stigmatizing or prejudicial must be avoided
Benefit sharing	Benefit sharing regulates that benefits and burdens are distributed fairly and it is therefore key to ensuring that research collaboration is fair	Genomics research may likely yield intangible benefits like knowledge generation and capacity building, some of which may only translate into tangible benefits in future generations. General study results can count as one study benefit and should be fed back to communities in which research is conducted. This is essential to maintaining trust and can be incorporated in community engagement activities. If there is a realistic expectation of tangible benefit to a group, a benefit sharing plan must be agreed to after stakeholder engagement Consideration must be given to how genomic and biobanking research may confer benefits on participants
Capacity building	Genomic research and biobanking conducted in Africa should lead to substantive building of research capacity, including both human resources and research infrastructure	A capacity building plan must be included as part of each research project This must include infrastructure, personnel and administrative capacity building
International collaboration and export of samples	International collaboration and export of samples should promote the goals of reducing global health inequality and exploitation and strengthening the research system in the country where the samples were collected	Export of samples must be subject to ethics review Exportation of samples and collaboration must help build local capacity Exportation of samples must be indicated in the consent documents Exportation of samples must be subject to materials transfer agreements
Feedback of individual genetic research results	The feedback of findings in the African context considering difficulties of validating research findings in a diagnostic facility, the absence of healthcare workers trained in genetics that could provide feedback, and limited validation of genomic research findings in African populations	There is a need for wide stakeholder engagement to determine when feedback of findings should be provided and a plan on how this would be applied.
Good governance	Good governance helps build and maintain public trust and ensure transparency of genomic and biobanking research	Governance framework must include oversight on the use and reuse of samples There must be compliance with local, national and international guidelines and regulations Entities controlling access to samples must be comprised of members primarily residing on the African continent

With regard to the **export of samples** to other countries, the framework acknowledges that this is often viewed as problematic by research ethics committees and other regulators, not in the least because it is viewed as perpetuating inequality. For this reason, the framework proposes that export should only be permitted where researchers can outline how their work will contribute to reducing global health inequality and what measures they have put in place to strengthen the research system in the country where the samples were collected. One example would be where junior and senior African students and researchers are meaningfully involved in all aspects of the research process, including aspects that happen in non-African laboratories and universities. Material Transfer Agreements (MTAs) are fundamental to underpin the fair export of samples. While the challenges around implementing MTAs remain, guidance offered for instance by the US Veterans Health Administration<sup>71</sup> and some model MTA templates such as the Uniform Biological Materials Transfer Agreement and its related templates<sup>72</sup>, could be useful in supporting institutions to navigate these challenges, arriving at MTAs that are more agreeable to collaborators in genomics research.

Whilst the framework offers some guidance on the **feedback of individual genetic research results**, it mainly proposes a range of questions that need to be considered in determining whether and under which conditions the return of research results may be appropriate in the African research context. Given the complexity of the issues, the H3Africa Consortium is developing a policy guiding researchers in how to decide which results to feedback, which expands on the summary guidance given in the framework.

Lastly, implementing a **good governance** regime is recommended in order to tie all these elements together towards optimal protection of participant in genomics research and biobanking. This should be a mechanism that provides oversight for re-use of samples and data sharing in line with the principles and elements set out in the framework. Such oversight is expected to among other things, ensure that decisions to provide access to sample and data for secondary use are sensitive to the need to promote genomics scholarship from African scientists and facilitate preferential use of data and access to samples for such scientists for a reasonable period of time. Such a preferential use provision is expected to further support African scientists, who may have challenges in engaging with the data and specimen available as fast as their counterparts due to systemic challenges such as poor power supply, poor access to academic databases for research, poor access to fast and reliable internet and so forth; or infrastructural challenges such as the availability of databases with comparable security protections that will allow for sharing data across countries and continents. In making these decisions however, it is important to find an appropriate balance between over-protection, which may hinder good science with potential benefit to humanity derivable from it. Typically, such a governance regime is achieved through the establishment of Sample Access Committees and Data Access Committee<sup>73</sup>. However, each country that seeks to use the

framework, as a guide may have to develop a structure that works best considering local peculiarities.

### Implementation mechanisms and amendments

The next step in our quest to consolidate and harmonize standards for African genomics research and biobanking is to engage broadly around the framework, and to develop template guidelines for adaptation.

Firstly, the framework provides the basis for further discussions and engagement with professional organisations, regulators and ethics committees across Africa. Through our consultation processes, we have built up a rich network of contacts with regulators and ethics committees at local, regional and national levels across the continent, and we are liaising with all of these to create awareness of the minimal standards described in the Framework. We are also liaising with professional science organisations including for instance the African Academy of Sciences (AAS), to explore how that organisation can take a leadership role in advancing ethical standards of genomics research and biobanking on the continent.

In terms of ensuring the incorporation of the standards outlined in the Framework into research practice, we are preparing more detailed guidelines that expand on the items in the Framework. This resource will be publicly available for use by ethics committees across the continent, and the hope is that ethics committees and national ethics councils will adapt and adopt the guidelines so that they become the gold standard for national regulation of genomics and biobanking. In order to ensure that they do, we will continue our engagement activities with committees and national councils, which are usually in the form of side meetings at the annual meetings of the H3Africa Consortium. In addition, we are increasingly involved in offering training to national and local ethics committees, which are invaluable in ensuring awareness of the Framework and guidelines emanating from them. Although there are no plans to commission formal evaluations on the uptake of the Framework, the H3Africa Working Group on Ethics and Community Engagement shall continue to collect information on references to the framework in publications as well as its use in country guidelines.

### Disclaimer

The views expressed in this article are those of the authors. Publication in *AAS Open Research* does not imply endorsement by the AAS.

### Data availability

No data are associated with this article.

---

### Grant information

This work is supported by the Human Heredity and Health in Africa (H3Africa) in Partnership with the African Academy of Sciences. The Framework drafting meeting was supported by a grant from the Wellcome Trust (WT201245/Z/16/Z). During the development of this Framework, Jantina de Vries was

supported by the RHDGen grant, a H3Africa grant funded by the Wellcome Trust (WT099313MA) and the Stigma in African Genomics grant funded by the National Human Genome Research Institute of the National Institutes of Health under Award Number U01HG008226.

*The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.*

### Acknowledgements

The development of the Framework was initiated and driven by the H3Africa Working Group on Ethics. All authors are part of the task force assigned by this Working Group to develop the Framework. They are reporting on the Framework on behalf of the Working Group. The process involved consultations with funding institutions - NIH and Wellcome Trust, stakeholders involved in genomics research and biobanking – the Bridging Biobanking and Biomedical Research across Europe and Africa (B3Africa) initiative and the Academy of Science of South Africa, as well as selected ethics committee members from Botswana, Uganda and Ethiopia. Akin Abayomi, Adamu Addissie, Julius Ecuru, Mark Guyer, Mary Kasule, Michael Pepper and Godfrey Tangwa, Ebony Madden, Patricia Marshall, Odile Ouwe Missi Oukem-Boyer provided comments through the H3A Working Group on Ethics. Clement Adebamowo and Michele Ramsay provided extensive comments through the H3Africa Steering Committee. The following provided comments

at some stage in the development of the Framework: Anne-Marie Tassé and Emily Kirby of the Public Population Project in Genomics and Society (P3G); Maimuna Mendy, Jane Reichel, Erisa Mwaka of B3Africa and BCNet; M'an Zawati and Bartha Maria Knoppers of the Centre of Genomics and Policy of McGill University; Doris Schroeder, Roger Chennels, Klaus Leisinger and Michelle Singh of the Trust Project; Colleagues from the Global Emerging Pathogens Treatment (GET) Consortium; Thaddeus Metz of the Philosophy Department of the University of Witwatersrand; Victoria de Menhil of the Broad Institute; Ilina Singh of the Department of Psychiatry of the University of Oxford.

The Framework for the Responsible Sharing of Genomic and Health-Related Data developed by the Global Alliance for Genomics and Health (GA4GH) was a key resource as well as the OECD Guidelines on Human Biobanks and Genetic Research Databases, the Wellcome Trust Framework on the Feedback of Health-Related Findings in Research, the EC report 'Global Governance of Science', the EC report 'Ethical and Regulatory Challenges to Science and Research Policy at the Global Level' and country-specific ethics guidelines from 22 African countries, some of which were specific to genomic research and biobanking<sup>74</sup>.

A number of professionals and experts from organisations across Africa, Europe and the United States contributed to the development of the Framework – all are duly acknowledged in the Framework and this paper.

### References

- Collins FS, Morgan M, Patrinos A: **The Human Genome Project: lessons from large-scale biology.** *Science.* 2003; **300**(5617): 286–90.  
[PubMed Abstract](#) | [Publisher Full Text](#)
- McCarthy JJ, McLeod HL, Ginsburg GS: **Genomic medicine: a decade of successes, challenges, and opportunities.** *Sci Transl Med.* 2013; **5**(189): 189sr4.  
[PubMed Abstract](#) | [Publisher Full Text](#)
- H3Africa Consortium, Rotimi C, Abayomi A, et al.: **Research capacity. Enabling the genomic revolution in Africa.** *Science.* 2014; **344**(6190): 1346–1348.  
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- International HapMap Consortium: **The International HapMap Project.** *Nature.* 2003; **426**(6968): 789–96.  
[PubMed Abstract](#) | [Publisher Full Text](#)
- Gurdasani D, Carstensen T, Tekola-Ayele F, et al.: **The African Genome Variation Project shapes medical genetics in Africa.** *Nature.* 2015; **517**(7534): 327–32.  
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- Bentley AR, Callier S, Rotimi CN: **Diversity and inclusion in genomic research: why the uneven progress?** *J Community Genet.* 2017; **8**(4): 255–266.  
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- Tishkoff SA, Reed FA, Friedlaender FR, et al.: **The genetic structure and history of Africans and African Americans.** *Science.* 2009; **324**(5930): 1035–44.  
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- Marshall E: **Bermuda rules: community spirit, with teeth.** *Science.* 2001; **291**(5507): 1192.  
[PubMed Abstract](#) | [Publisher Full Text](#)
- Toronto International Data Release Workshop Authors, Birney E, Hudson TJ, et al.: **Prepublication data sharing.** *Nature.* 2009; **461**(7261): 168–70.  
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- de Vries J, Tindana P, Littler K, et al.: **The H3Africa policy framework: negotiating fairness in genomics.** *Trends Genet.* 2015; **31**(3): 117–9.  
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- Boddington P, Curren L, Kaye J, et al.: **Consent forms in genomics: the difference between law and practice.** *Eur J Health Law.* 2011; **18**(5): 491–519.  
[PubMed Abstract](#) | [Publisher Full Text](#)
- McGuire AL, Beskow LM: **Informed consent in genomics and genetic research.** *Annu Rev Genomics Hum Genet.* 2010; **11**: 361–81.  
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- Wendler D: **Broad versus blanket consent for research with human biological samples.** *Hastings Cent Rep.* 2013; **43**(5): 3–4.  
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- Nnamuchi O: **H3Africa: An Africa exemplar? Exploring its framework on protecting human research participants.** *Dev World Bioeth.* 2017; n/a–n/a.  
[PubMed Abstract](#) | [Publisher Full Text](#)
- Kaye J: **The tension between data sharing and the protection of privacy in genomics research.** *Annu Rev Genomics Hum Genet.* 2012; **13**(1): 415–431.  
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- Lowenthal J, Hull SC: **Framing the “Right to Withdraw” in the Use of Biospecimens for IPSC Research.** *Ethics in Biology, Engineering and Medicine: An International Journal.* 2013; **4**(1): 1–14.  
[Publisher Full Text](#)
- Hawkins AK, O'Doherty KC: **“Who owns your poop?”: insights regarding the intersection of human microbiome research and the ELSI aspects of biobanking and related studies.** *BMC Med Genomics.* 2011; **4**: 72.  
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- Haga SB, Beskow LM: **Ethical, legal, and social implications of biobanks for genetics research.** *Adv Genet.* 2008; **60**: 505–44.  
[PubMed Abstract](#) | [Publisher Full Text](#)
- Caulfield T, Rachul C, Nelson E: **Biobanking, consent, and control: a survey of Albertans on key research ethics issues.** *Biopreserv Biobank.* 2012; **10**(5): 433–8.  
[PubMed Abstract](#) | [Publisher Full Text](#)
- de Vries J, Abayomi A, Brandful J, et al.: **A perpetual source of DNA or something really different: ethical issues in the creation of cell lines for African genomics research.** *BMC Med Ethics.* 2014; **15**(1): 60.  
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- Heeney C, Hawkins N, de Vries J, et al.: **Assessing the privacy risks of data sharing in genomics.** *Public Health Genomics.* 2011; **14**(1): 17–25.  
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
- McGuire AL, Gibbs RA: **Genetics. No longer de-identified.** *Science.* 2006;



- 312(5772): 370–371.  
[PubMed Abstract](#) | [Publisher Full Text](#)
23. Nnamuchi O: **Biobank/Genomic Research in Nigeria: Examining Relevant Privacy and Confidentiality Frameworks.** *J Law Med Ethics.* 2015; 43(4): 776–786.  
[PubMed Abstract](#)
  24. Dauda B, Dierickx K: **Benefit sharing: an exploration on the contextual discourse of a changing concept.** *BMC Med Ethics.* 2013; 14: 36.  
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
  25. Dauda B, Joffe S: **The benefit sharing vision of H3Africa.** *Dev World Bioeth.* 2018; 18(2): 165–170.  
[PubMed Abstract](#) | [Publisher Full Text](#)
  26. Simm K: **Benefit-sharing: an inquiry regarding the meaning and limits of the concept in human genetic research.** *Genomics Soc Policy.* 2005; 1(2): 29.  
[Publisher Full Text](#) | [Free Full Text](#)
  27. Moodley K, Singh S: **“It’s all about trust”: reflections of researchers on the complexity and controversy surrounding biobanking in South Africa.** *BMC Med Ethics.* 2016; 17(1): 57.  
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
  28. O’Daniel J, Haga SB: **Public perspectives on returning genetics and genomics research results.** *Public Health Genomics.* 2011; 14(6): 346–55.  
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
  29. Heymann DL, Liu J, Lillywhite L: **Partnerships, Not Parachutists, for Zika Research.** *N Engl J Med.* 2016; 374(16): 1504–1505.  
[PubMed Abstract](#) | [Publisher Full Text](#)
  30. Staunton C, Moodley K: **Challenges in biobank governance in Sub-Saharan Africa.** *BMC Med Ethics.* 2013; 14: 35.  
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
  31. de Vries J, Bull SJ, Doumbo O, et al.: **Ethical issues in human genomics research in developing countries.** *BMC Med Ethics.* 2011; 12(1): 5.  
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
  32. Wonkam A, Tekendo CN, Sama DJ, et al.: **Initiation of a medical genetics service in sub-Saharan Africa: experience of prenatal diagnosis in Cameroon.** *Eur J Med Genet.* 2011; 54(4): e399–404.  
[PubMed Abstract](#) | [Publisher Full Text](#)
  33. Wright KM, Bomblies K: **Evolutionary genetics: inheritance of a complex pollination syndrome.** *Curr Biol.* 2013; 23(12): R525–7.  
[PubMed Abstract](#) | [Publisher Full Text](#)
  34. MacDonald NE, Bortolussi R, Pemba S, et al.: **Supporting research leadership in Africa.** *Lancet Glob Health.* 2016; 4(6): e362.  
[PubMed Abstract](#) | [Publisher Full Text](#)
  35. Davies J, Mullan Z: **Research capacity in Africa—will the sun rise again?** *Lancet Glob Health.* 2016; 4(5): e287.  
[PubMed Abstract](#) | [Publisher Full Text](#)
  36. Tindana P, Yakubu A, Staunton C, et al.: **Engaging Research Ethics Committees to develop an Ethics and Governance Framework for Genomic research in Africa: The H3Africa Model.** *BMC Med Ethics.* 2018; [in press].
  37. Blystra Y, Lysaght T, Thiruvikraman J, et al.: **Ethical frameworks for obtaining informed consent in tumour profiling: an evidence-based case for Singapore.** *Hum Genomics.* 2017; 11(1): 31.  
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
  38. Sieber J: **Data Sharing in Historical Perspective.** *J Empir Res Hum Res Ethics.* 2015; 10(3): 215–216.  
[PubMed Abstract](#) | [Publisher Full Text](#)
  39. Tangwa GB: **Giving voice to African thought in medical research ethics.** *Theor Med Bioeth.* 2017; 38(2): 101–110.  
[PubMed Abstract](#) | [Publisher Full Text](#)
  40. Swanson D: **Ubuntu: An African contribution to (re)search for/with a ‘humble togetherness’.** *Journal of Contemporary Issues in Education.* 2007; 2(2): 15.  
[Publisher Full Text](#)
  41. Gade CBN: **What is Ubuntu,? Different Interpretations among South Africans of African Descent.** *S Afr J Philos.* 2012; 31(3): 484–503.  
[Publisher Full Text](#)
  42. Metz T, Gaie JBR: **The African ethic of Ubuntu/Botho: implications for research on morality.** *J Moral Educ.* 2010; 39(3): 273–290.  
[Publisher Full Text](#)
  43. van Niekerk J: **Ubuntu and moral value (Doctoral dissertation).** 2013.  
[Reference Source](#)
  44. Nkondo GM: **Ubuntu as public policy in South Africa: A conceptual framework.** *International Journal of African Renaissance Studies - Multi-, Inter- and Transdisciplinarity.* 2007; 2(1): 88–100.  
[Publisher Full Text](#)
  45. Metz T: **Ubuntu as a moral theory and human rights in South Africa.** *Afr Hum Rights Law J.* 2011; 11: 532–559.  
[Reference Source](#)
  46. Callaway E: **South Africa’s San people issue ethics code to scientists.** *Nature.* 2017; 543(7646): 475–476.  
[PubMed Abstract](#) | [Publisher Full Text](#)
  47. Chennells R, Steenkamp A: **International Genomics Research Involving the San People.** In *Ethics Dumping: Case Studies from North-South Research Collaborations.* D. Schroeder, et al., Editors. Springer International Publishing: Cham. 2018; 15–22.  
[Publisher Full Text](#)
  48. Knoppers BM: **Framework for responsible sharing of genomic and health-related data.** *Hugo J.* 2014; 8(1): 3.  
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
  49. OECD Organization for Economic Cooperation and Development: **OECD guidelines on human biobanks and genetic research databases.** *Eur J Health Law.* 2010; 17(2): 191–204.  
[PubMed Abstract](#)
  50. Vidyasagar D: **Global notes: the 10/90 gap disparities in global health research.** *J Perinatol.* 2006; 26(1): 55–56.  
[PubMed Abstract](#) | [Publisher Full Text](#)
  51. Medie PA, Kang AJ: **Global South scholars are missing from European and US journals. What can be done about it.** *The Conversation (Africa Edition).* 2018.  
[Reference Source](#)
  52. Okeke IN, Babalola CP, Byarugaba DK, et al.: **Broadening Participation in the Sciences within and from Africa: Purpose, Challenges, and Prospects.** *CBE Life Sci Educ.* 2017; 16(2): pii: es2.  
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
  53. Ramsay S: **No closure in sight for the 10/90 health-research gap.** *Lancet.* 2001; 358(9290): 1348.  
[PubMed Abstract](#) | [Publisher Full Text](#)
  54. Grady C, Eckstein L, Berkman B, et al.: **Broad Consent for Research With Biological Samples: Workshop Conclusions.** *Am J Bioeth.* 2015; 15(9): 34–42.  
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
  55. Jao I, Kombe F, Mwalukore S, et al.: **Involving Research Stakeholders in Developing Policy on Sharing Public Health Research Data in Kenya: Views on Fair Process for Informed Consent, Access Oversight, and Community Engagement.** *J Empir Res Hum Res Ethics.* 2015; 10(3): 264–277.  
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
  56. Tindana P, de Vries J: **Broad Consent for Genomic Research and Biobanking: Perspectives from Low- and Middle-Income Countries.** *Annu Rev Genomics Hum Genet.* 2016; 17(1): 375–393.  
[PubMed Abstract](#) | [Publisher Full Text](#)
  57. Sanderson SC, Brothers KB, Mercaldo ND, et al.: **Public Attitudes toward Consent and Data Sharing in Biobank Research: A Large Multi-site Experimental Survey in the US.** *Am J Hum Genet.* 2017; 100(3): 414–427.  
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
  58. Tindana P, Molyneux S, Bull S, et al.: **‘It is an entrustment’: Broad consent for genomic research and biobanks in Sub-Saharan Africa.** *Dev World Bioeth.* 2017.  
[PubMed Abstract](#) | [Publisher Full Text](#)
  59. Warner TD, Weil CJ, Andry C, et al.: **Broad Consent for Research on Biospecimens: The Views of Actual Donors at Four U.S. Medical Centers.** *J Empir Res Hum Res Ethics.* 2018; 13(2): 115–124.  
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
  60. Bull S: **Review: Ensuring global equity in open research.** Wellcome Trust. 2016.  
[Reference Source](#)
  61. Participants in the Community Engagement and Consent Workshop, Kilifi, Kenya, March 2011: **Consent and community engagement in diverse research contexts.** *J Empir Res Hum Res Ethics.* 2013; 8(4): 1–18.  
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
  62. Centers for Disease Control and Prevention: **Principles of community engagement (2nd ed).** Atlanta (GA): CDC/ATSDR Committee on Community Engagement; 2011.  
[Reference Source](#)
  63. Pratt B, de Vries J: **Community engagement in global health research that advances health equity.** *Bioethics.* 2018; 32(7): 454–463.  
[PubMed Abstract](#) | [Publisher Full Text](#)
  64. Ahmed SM, Palermo AG: **Community engagement in research: frameworks for education and peer review.** *Am J Public Health.* 2010; 100(8): 1380–7.  
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
  65. Kolopack PA, Parsons JA, Lavery JV: **What makes community engagement effective?: Lessons from the Eliminate Dengue Program in Queensland Australia.** *PLoS Negl Trop Dis.* 2015; 9(4): e0003713.  
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
  66. Ramsay M, de Vries J, Soodyall H, et al.: **Ethical issues in genomic research on the African continent: experiences and challenges to ethics review committees.** *Hum Genomics.* 2014; 8: 15.  
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
  67. Barchi F, Matlhagela K, Jones N, et al.: **“The keeping is the problem”: A qualitative study of IRB-member perspectives in Botswana on the collection, use, and storage of human biological samples for research.** *BMC Med Ethics.* 2015; 16: 54.  
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
  68. Schuster SC, Miller W, Ratan A, et al.: **Complete Khoisan and Bantu genomes from southern Africa.** *Nature.* 2010; 463(7283): 943–947.  
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
  69. Hayes V: **Indigenous genomics.** *Science.* 2011; 332(6030): 639.  
[PubMed Abstract](#) | [Publisher Full Text](#)
  70. Munung NS, Mayosi BM, de Vries J: **Equity in international health research collaborations in Africa: Perceptions and expectations of African researchers.** *PLoS One.* 2017; 12(10): e0186237.  
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)
  71. H3Africa Consortium: **H3Africa Consortium Data Sharing, Access and Release**

**Policy.** 2014.

[Reference Source](#)

72. Office of Research and Development, Veterans Health Administration: **Draft guidance on material transfer agreements.**  
[Reference Source](#)
73. National Institutes of Health: **Uniform Biological Material Transfer Agreement:**

**Request for Comments.** NIH Guide, 1994; 23(24).

[Reference Source](#)

74. de Vries J, Munung SN, Matimba A, *et al.*: **Regulation of genomic and biobanking research in Africa: a content analysis of ethics guidelines, policies and procedures from 22 African countries.** *BMC Med Ethics.* 2017; 18(1): 8.  
[PubMed Abstract](#) | [Publisher Full Text](#) | [Free Full Text](#)

# Open Peer Review

Current Peer Review Status:   

---

## Version 1

Reviewer Report 26 June 2018

<https://doi.org/10.21956/aasopenres.13910.r26458>

© 2018 Chalmers D. This is an open access peer review report distributed under the terms of the [Creative Commons Attribution Licence](#), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.



### Don Chalmers

Centre for Law and Genetics, Faculty of Law, University of Tasmania, Hobart, Tas, Australia

This is a very well written and valuable account of the development of an ethical governance framework for genomic research and biobanking in Africa.

I strongly recommend indexing for the following reasons

1. The article sets a clear context for the H3Africa and the development of an autochthonous African model of consent for sharing genomic data and samples which respects autonomy; consent; ownership of samples and data; privacy and confidentiality; and, benefit sharing.
2. The article makes a valuable contribution to the continuing development of an overarching African philosophical basis for a “.. framework ...[with]a more generic communal or solidarity-based worldview”. This is different, as is the focus on the “..central importance on reciprocity, consultation and accountability’. This draws a clear distinction between the proposed African model and conventional western participant-focused ethical approaches, which can accompany “parachute research”, mentioned in the Introduction.
3. The article details the elements of this African best-practice genomics and biobanking framework based on “African intellectual leadership; Consent; Community engagement; Ethics review; Avoidance of group harm and stigma; Benefit sharing; Capacity building; International collaboration and export of samples; Feedback of individual genetic findings; and Good governance.
4. The implementation agenda for the H3Africa framework is briefly set out. Specifically noted is future engagement with professional organisations, regulators and ethics committees before drafting more detailed guidelines and engagement activities with ethics committees and national councils.

I have some suggestions for the authors

1. The brief mention of the principle of “ubuntu” is interesting and is there any more recent discussion since the footnote 35 2007 reference?

2. In the section on “Core Principles and elements’, the authors mention ‘five core principles” but only list four (a to d). They need to add the fifth
3. The authors highlight the elements of their proposed framework (see 3 above) but do not include any discussion on the principle of “African intellectual leadership”.
4. There has been a working connection between the H3Africa and the GA4GH and a reference could be included to this at: [https://www.ga4gh.org/news/ffY\\_2As3q-iv39gB2Un4Bw.article](https://www.ga4gh.org/news/ffY_2As3q-iv39gB2Un4Bw.article).
5. In the acknowledgements, the authors list the key resources of the Global Alliance for Genomics and Health (GA4GH) *Framework for the Responsible Sharing of Genomic and Health-Related Data*; the OECD *Guidelines on Human Biobanks and Genetic Research Databases*, 2009 the Wellcome Trust *Framework on the feedback of health-related findings in research*, 2014 the European Commission’s reports on *Global Governance of Science*, 2009 and *Ethical and Regulatory Challenges to Science and Research Policy at the Global Level* 2012 and the 22 African country-specific ethics guidelines.

These global collaborations and interactions are worthy of reference and comment in the text at the section “Key elements of the Framework for Best Practice’. This records that the authors are striking out on a path for Africa but one informed by international developments and collaborations.

Declaration of interest I have met Littler K and De Vries J but have never published with either.

**Is the rationale for the Open Letter provided in sufficient detail?**

Yes

**Does the article adequately reference differing views and opinions?**

Yes

**Are all factual statements correct, and are statements and arguments made adequately supported by citations?**

Yes

**Is the Open Letter written in accessible language?**

Yes

**Where applicable, are recommendations and next steps explained clearly for others to follow?**

Yes

**Competing Interests:** No competing interests were disclosed.

**I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.**

Author Response 12 Nov 2018

**aminu yakubu**, Federal Ministry of Health, Abuja, Nigeria

Dear Prof Chalmers,

Thank you for reviewing our paper. The team greatly valued comments and recommendations you provided. We have made necessary changes to the paper (which we shall be submitting shortly) in response to your comments. We have considered the suggestion for indexing and are in



discussion with the leadership of the Consortium on this regard. Here is a summary of our responses to your specific comments on the paper:

I have some suggestions for the authors

The brief mention of the principle of “ubuntu” is interesting and is there any more recent discussion since the footnote 35 2007 reference?

- Thank you. Though our aim was not to dwell much on describing Ubuntu, we have however added a little more text and references in response to this comment. We feel that provides the additional information suggested without going too deep.

In the section on “Core Principles and elements”, the authors mention “five core principles” but only list four (a to d). They need to add the fifth

- This was one oversight; we actually have only four principles. Error corrected, thank you. The authors highlight the elements of their proposed framework (see 3 above) but do not include any discussion on the principle of “African intellectual leadership”.

- We have now included some more discussion on this as suggested. We have linked this issue with the 10/90 gap and the issues raised about poor diversity and inclusion in genomics research. Thank you.

There has been a working connection between the H3Africa and the GA4GH and a reference could be included.

- Thank you for this observation. We believe the acknowledgement and the new citation (in response to comment 5 below) is sufficient to demonstrate the connection between the two for the purposes of this paper.

In the acknowledgements, the authors list the key resources of the Global Alliance for Genomics and Health (GA4GH) *Framework for the Responsible Sharing of Genomic and Health-Related Data*; the OECD *Guidelines on Human Biobanks and Genetic Research Databases*, 2009 the Wellcome Trust *Framework on the feedback of health-related findings in research*, 2014 the European Commission’s reports on *Global Governance of Science*, 2009 and *Ethical and Regulatory Challenges to Science and Research Policy at the Global Level* 2012 and the 22 African country-specific ethics guidelines.

These global collaborations and interactions are worthy of reference and comment in the text at the section “Key elements of the Framework for Best Practice”. This records that the authors are striking out on a path for Africa but one informed by international developments and collaborations.

- Thank you. We have included some reference while introducing the “Key Elements” section.

**Competing Interests:** We declare no competing interests

Reviewer Report 25 June 2018

<https://doi.org/10.21956/aasopenres.13910.r26476>

© 2018 Clayton E. This is an open access peer review report distributed under the terms of the [Creative Commons Attribution Licence](#), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.



**Ellen Wright Clayton** 

Center for Biomedical Ethics and Society, Vanderbilt University Medical Center (VUMC), Nashville, TN, USA

This is an important paper setting forth guiding principles for genomics research in Africa. The document is clear and well written and will be quite helpful for the work of putting concrete mechanisms in place that protect the interests of individuals and communities while building local capacity and advancing research to improve health.

I have only one substantive comment, which is that it would be helpful to say more about what the authors mean by community engagement, specifying to what extent and on what topics the community should have input. This is often a contested issue.

My other comments are minor:

Under core principles, there is an extra "of" on the second line.

I saw only four principles, not five.

On line 9 under consent process, I assume that "it" refers to broad consent. If so, that should be stated explicitly.

Under avoidance of group harm, there should not be a comma after note 52.

**Is the rationale for the Open Letter provided in sufficient detail?**

Yes

**Does the article adequately reference differing views and opinions?**

Yes

**Are all factual statements correct, and are statements and arguments made adequately supported by citations?**

Yes

**Is the Open Letter written in accessible language?**

Yes

**Where applicable, are recommendations and next steps explained clearly for others to follow?**

Yes

**Competing Interests:** No competing interests were disclosed.

**I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.**

Author Response 12 Nov 2018

**aminu yakubu**, Federal Ministry of Health, Abuja, Nigeria

Dear Prof Clayton

Thank you for reviewing our paper. We are pleased to learn that you consider it an important contribution to genomics research governance. We carefully reviewed your comments and taken the necessary actions and/or made the necessary modifications. Please find a summary below:

This is an important paper setting forth guiding principles for genomics research in Africa. The document is clear and well written and will be quite helpful for the work of putting concrete mechanisms in place that protect the interests of individuals and communities while building local capacity and advancing research to improve health.

I have only one substantive comment, which is that it would be helpful to say more about what the authors mean by community engagement, specifying to what extent and on what topics the community should have input. This is often a contested issue.

- Thank you for this comment. Indeed we share in your perspective but wanted to strike a balance between presenting CE within the scope of this descriptive paper and going in-depth to educate our readers more on the topic. However, because of this observation, we have added a bit more context.

My other comments are minor:

- Under core principles, there is an extra "of" on the second line.
  - Line removed, thank you.
- I saw only four principles, not five.
  - This was an oversight; there are actually four. This has been corrected.
- On line 9 under consent process, I assume that "it" refers to broad consent. If so, that should be stated explicitly.
  - Yes, it does. We have added that specificity. Thank you.
- Under avoidance of group harm, there should not be a comma after note 52.
  - Addressed, thank you.

**Competing Interests:** We declare no competing interests.

Reviewer Report 21 June 2018

<https://doi.org/10.21956/aasopenres.13910.r26442>

© 2018 O'Doherty K et al. This is an open access peer review report distributed under the terms of the [Creative Commons Attribution Licence](#), which permits unrestricted use, distribution, and reproduction in any medium, provided the original work is properly cited.



**Kieran O'Doherty** 

Department of Psychology, University of Guelph, Guelph, ON, Canada

**Kim Chuong**

Department of Psychology, University of Guelph, Guelph, ON, Canada

This article describes an ethics framework for genomics research and biobanking in Africa, which is valuable in the African public health context and to address global health inequality. The article is well-written and concise in its summary of the core principles and key elements of the framework. We see the contribution of the framework in the context of ELS implications of genomics and biobanks in its emphasis on the need for research to be sensitive and respectful of diverse cultures, values and belief systems of African populations. Also of significance is the goal to enhance capacity building and genuine intellectual participation of African researchers and stakeholders in genomics research. The authors of this article are to be commended for this important work.

Overall, the manuscript will make an important contribution. We have only minor suggestions for improvement. Although the key elements of the framework are well-presented, the authors do not address potential challenges that may be encountered while applying those key elements. We realise that the purpose of the article is to lay out the framework, and so does not address implementation issues. However, some additional detail may be good to add, in particular in the context of community engagement, which the authors emphasize as a key component for ensuring best practice in genomics research and biobanking in Africa. However, it is not clear from the framework what the authors mean by “genuine community engagement”. There is a rich literature on engaging community members in research and the values and challenges of doing so. Community engagement goes beyond the meaningful involvement of African researchers to include individuals from the broader population and specific groups, and will need to address issues such as power dynamics between researchers who are considered experts and community members.

#### Other issues:

On p. 3. The authors mention that “The process of engagement that led to the development of this framework is reported in another manuscript.” A reference to this manuscript should be provided.

The paragraph on export of samples to other countries is incomplete (p. 6).

The “implementation mechanisms and amendments” section (p. 7) describes the next steps for raising awareness and engaging health organisations and national councils with the framework. It would be great to have more detail regarding future evaluation of the framework and the Working Group’s engagement activities.

#### **Is the rationale for the Open Letter provided in sufficient detail?**

Yes

#### **Does the article adequately reference differing views and opinions?**

Partly

#### **Are all factual statements correct, and are statements and arguments made adequately supported by citations?**

Yes

#### **Is the Open Letter written in accessible language?**

Yes

#### **Where applicable, are recommendations and next steps explained clearly for others to follow?**

Yes



**Competing Interests:** No competing interests were disclosed.

**We confirm that we have read this submission and believe that we have an appropriate level of expertise to confirm that it is of an acceptable scientific standard.**

Author Response 20 Nov 2018

**aminu yakubu**, Federal Ministry of Health, Abuja, Nigeria

Dear Drs O'Doherty and Chuong,

On behalf of my co-authors, I wish to thank you for taking the time to review our paper. We thought your comments were insightful and have made some changes to the paper in response. Please find below a summary of our responses to your comments. We shall submit the revised version of the paper shortly.

Overall, the manuscript will make an important contribution. We have only minor suggestions for improvement. Although the key elements of the framework are well-presented, the authors do not address potential challenges that may be encountered while applying those key elements. We realise that the purpose of the article is to lay out the framework, and so does not address implementation issues. However, some additional detail may be good to add, in particular in the context of community engagement, which the authors emphasize as a key component for ensuring best practice in genomics research and biobanking in Africa. However, it is not clear from the framework what the authors mean by “genuine community engagement”. There is a rich literature on engaging community members in research and the values and challenges of doing so. Community engagement goes beyond the meaningful involvement of African researchers to include individuals from the broader population and specific groups, and will need to address issues such as power dynamics between researchers who are considered experts and community members.

- Thank you for this comment. Indeed we share in your perspective but wanted to strike a balance between presenting CE within the scope of this descriptive paper and going in-depth to educate our readers more on the topic. However, because of this observation, we have added a bit more context and specify what we mean by genuine (vs tokenistic) engagement.

Other issues:

On p. 3. The authors mention that “The process of engagement that led to the development of this framework is reported in another manuscript.” A reference to this manuscript should be provided.

- Thank you. We have cited the paper, which is now “in press” with the BMC Medical Ethics journal

The paragraph on export of samples to other countries is incomplete (p. 6).

- This omission is regretted. We wanted to make reference to the UBMTA and the VA guideline on MTAs. We have now done so. Thank you.

The “implementation mechanisms and amendments” section (p. 7) describes the next steps for

raising awareness and engaging health organisations and national councils with the framework. It would be great to have more detail regarding future evaluation of the framework and the Working Group's engagement activities.

- Thank you for this comment. We have added to our description of future steps.

***Competing Interests:*** We declare no competing interests.