

# The H3Africa policy framework: negotiating fairness in genomics

Jantina de Vries<sup>1</sup>, Paulina Tindana<sup>2</sup>, Katherine Littler<sup>3</sup>, Michèle Ramsay<sup>4</sup>, Charles Rotimi<sup>5</sup>, Akin Abayomi<sup>6</sup>, Nicola Mulder<sup>7</sup>, and Bongani M. Mayosi<sup>8</sup>

<sup>1</sup> Department of Medicine, University of Cape Town, UCT Centre for Clinical Research, Old Main Building, Groote Schuur Hospital, Observatory, Cape Town 7925, South Africa

<sup>2</sup> Navrongo Health Research Centre, Ghana Health Service, PO Box 114, Navrongo, Ghana

<sup>3</sup> Wellcome Trust, Gibbs Building, London, NW1 2BE, UK

<sup>4</sup> Division of Human Genetics, School of Pathology, Faculty of Health Sciences, University of the Witwatersrand and National Health Laboratory Service, PO Box 1038, Johannesburg 2000, South Africa

<sup>5</sup> Sydney Brenner Institute for Molecular Bioscience, University of the Witwatersrand, Johannesburg, Parktown 2193, South Africa

<sup>6</sup> Center for Research on Genomics and Global Health, MSC 5635, Bethesda, MD 20892-5635, USA

<sup>7</sup> NSB-H3A Biobank, National Health Laboratory Services of South Africa, Faculty of Medicine and Health Sciences, Stellenbosch University, Tygerberg Hospital, Cape Town 7505, South Africa

<sup>8</sup> Institute of Infectious Disease and Molecular Medicine, UCT Faculty of Health Sciences, Observatory 7925, South Africa

**Human Heredity and Health in Africa (H3Africa) research seeks to promote fair collaboration between scientists in Africa and those from elsewhere. Here, we outline how concerns over inequality and exploitation led to a policy framework that places a firm focus on African leadership and capacity building as guiding principles for African genomics research.**

## Introduction

The historical underrepresentation of people of African ancestry in genomics research [1,2], with only a few studies focusing on or including people of African ancestry, has the potential of widening the health gap between Africa and the rest of the world by generating knowledge and interventions that may help in understanding or treating disease in Africa [3]. The H3Africa Consortium seeks to harness genomics technologies to investigate diseases pertinent to African patients [2]. Central to this aim is fostering collaboration between scientists in Africa and elsewhere. Of ethical importance is that H3Africa builds equitable partnerships between researchers and other key stakeholders. Equitable, or fair, partnerships can help build strong research systems [4]. They are also a means to counter exploitation and promote mutual respect and trust [5], and offer an opportunity to ensure that research is responsive to local health needs and that data interpretation is contextualised.

H3Africa builds on a growing body of work seeking to define what constitutes fair partnerships [6–10]. Here, we outline four key components of that policy framework that together seek to establish more ‘fair’ ways of working together, most notably by advocating preferential access

to funding, samples, and data for African researchers. We hope that these examples can set a new standard for international collaborative health research that involves samples and data from African patients.

## African leadership

An important aspect of H3Africa research is that it is under the leadership of scientists on the African continent, with grants awarded to, and managed by, African institutions. The expectation is that such research will be more successful in capitalising on the insight and experience of African clinicians and researchers, help in data interpretation and translation of results to the clinical setting, and build research capacity [2,6,7]. In the case of H3Africa, funding was allocated exclusively to researchers with a primary institutional affiliation in Africa, and the majority of co-applicants also had to be based in Africa. In addition, the majority of funds have to be spent in Africa. The H3Africa Steering Committee comprises H3Africa lead investigators (currently 23) and two representatives of the two funding bodies that support it. Additional representatives of the funding bodies join the meetings but do not have voting rights. The effect is that African scientists are developing the policies governing the genomic research taking place, and that H3Africa is establishing a South-to-South network (i.e., a collaboration network between scientists based in the Global South) of genomic scientists, with the academic discourse now occurring in Africa and between African scientists [11,12]. This is one recognised element of fair partnerships [7,8].

## The H3Africa policy framework

H3Africa has developed policies for sample and data sharing, as well as the terms of reference for the committee deciding on sample and data access [2]. The various policies were developed by several H3Africa Working Groups, comprising representatives of each of the currently funded 21 research projects. These policies took about 12 months to develop in an iterative process involving the working

Corresponding author: de Vries, J. ([Jantina.devries@uct.ac.za](mailto:Jantina.devries@uct.ac.za)).

Keywords: Africa; genomics; ethics; fairness; H3Africa.

0168-9525/

© 2015 The Authors. Published by Elsevier Ltd. This is an open access article under the CC BY-NC-ND license (<http://creativecommons.org/licenses/by-nc-nd/4.0/>). <http://dx.doi.org/10.1016/j.tig.2014.11.004>



groups, the H3Africa members, and contact sessions at the H3Africa meetings. Policy proposals are pending ratification by the H3Africa Steering Committee. The policy framework offers three further examples of how notions of fairness were incorporated in the work of the Consortium.

### The data-sharing policy

In line with international standards, H3Africa researchers are required to make genomic data available for secondary research. H3Africa researchers are granted a minimum of 11 months before genomic and phenotype data are publicly released, after which the data are under publication embargo for a further 12 months or until the first publication. Therefore, the total timeframe for the public release of data is 23 months. This is significantly longer than for other projects funded by the same agencies\*. The reason for this extended period of exclusive access is to enable African scientists to analyse and publish their data before others can, and is similar to a previous large genomics research project that occurred in Africa [13]. Training is currently under way through H3A-BioNet, a continental bioinformatics network that offers courses, mentorship, and infrastructural support for the analysis of genomic data. In addition to these extended timelines, applicants wishing access to data need to describe how their proposed use will contribute to capacity building and health improvement in Africa. The hope is that, by prompting secondary users to consider this, there will be greater awareness of the need to establish a more fair way of working with researchers in Africa.

### The sample-sharing policy

A prominent ethical concern in research in Africa relates to ownership over samples and, to a lesser extent, data. Samples and their movement across borders seem to have become symbolic of concerns over exploitation and fairness and, therefore, have become stringently regulated in many African countries [14]. Examples of regulatory approaches are strict export criteria, and requirements for export permits and material transfer agreements.

The proposal that samples collected in H3Africa need to be shared for secondary use through one of the H3Africa biorepositories in development, has created considerable controversy. This proposal generated suspicions that H3Africa research is just a way of making available African samples to researchers elsewhere. To address such concerns, careful thought has gone into developing a policy framework that would not only allay such fears, but also promote African-led research on African samples. The current policy proposal is that external researchers can apply for samples but, for a period of 3 years, they will only be made available either to researchers based in Africa, or to researchers outside of Africa who both work with researchers in Africa and develop a clear plan for capacity building. In other words, for 3 years, samples can

only be used for research that strengthens African research capacity. Unlike data, biospecimens are a limited resource that can be depleted, so careful consideration is required when providing access to these. Integrated into the policy is a requirement for new data generated from these samples to be submitted to the same public repository as H3Africa data.

### The data and biospecimen access committee

A final component of the policy framework where considerations of fairness have been discussed is the composition of the committee that will decide on access requests: the Data and Biospecimen Access Committee (DBAC). Given that the DBAC will control access to African samples, H3Africa researchers felt that it was necessary for this committee to comprise primarily individuals based in Africa, but that it could also include researchers outside of Africa with experience working in Africa, to allow relevant expertise from across the world to be brought to bear. Ideally, the DBAC should have representation from across relevant scientific disciplines, such as genomics, bioinformatics, and ethics, as well as non-science stakeholders, such as a patient advocate.

### The future of genomic research in Africa

The focus on Africa seeks to ensure that African researchers have a fair chance to develop the capacity for genomic research and investigate diseases that they believe are pertinent to Africa. It also seeks to ensure that data will be interpreted in the context where they were collected. We hope that H3Africa will set a new gold standard for collaborative genomic research in Africa, and possibly for broader collaborative health research.

The exclusive focus on the 'Africanness' of researchers in their various roles (as primary applicants, secondary data and sample users, or members of the DBAC) of course raises important questions, both about what 'Africanness' really means, and about the ethical implications of restricting the utility of samples and data in this way. What should matter is that research that is conducted is of the highest ethical and scientific standard and leads to maximum patient benefit in the shortest period of time, regardless of where the research is conducted. This should be based on principles of fairness and inclusivity. The question is whether H3Africa policies will successfully and sustainably foster African-led genomic research, and build a generation of African scientists that are internationally competitive.

### Acknowledgements

This work reports on the policy framework for H3Africa that was developed with the input from a large number of people. We express thanks to all those that continue to contribute to the success of H3Africa projects. J.D.V. and B.M. are supported by a Wellcome Trust H3Africa grant (RHD Gen, WT099313MA); M.R. is supported by a NIH H3Africa grant (AWI-Gen, 1U54HG006938); C.R. is supported by a NIH H3Africa grant (ACCME, U54HG006947); A.A. is supported by a NIH H3Africa grant (1UH2HG007092); and N.M. is supported by an H3Africa grant (H3A BioNet, U41HG006941).

### References

- Rosenberg, N.A. *et al.* (2010) Genome-wide association studies in diverse populations. *Nat. Rev. Genet.* 11, 356–366

\*See the Draft NIH Data Sharing Policy available from <http://grants.nih.gov/grants/guide/notice-files/NOT-OD-13-119.html>. For information about the Wellcome Trust position, see <http://www.wellcome.ac.uk/About-us/Policy/Spotlight-issues/Data-sharing/Guidance-for-researchers/index.htm> (both accessed 3 December 2014)

- 2 H3Africa Consortium (2014) Research capacity. Enabling the genomic revolution in Africa. *Science* 344, 1346–1348
- 3 Need, A.C. and Goldstein, D.B. (2009) Next generation disparities in human genomics: concerns and remedies. *Trends Genet.* 25, 489–494
- 4 Edwards, D. *et al.* (2014) *Negotiating research contracts. Creating opportunities for stronger research and innovation systems*, Council on Health Research for Development, Geneva
- 5 Emanuel, E.J. *et al.* (2004) What makes clinical research in developing countries ethical? The benchmarks of ethical research. *J. Infect. Dis.* 189, 930–937
- 6 Chu, K.M. *et al.* (2014) Building research capacity in Africa: equity and global health collaborations. *PLoS Med.* 11, e1001612
- 7 Whitworth, J.A.G. *et al.* (2008) Strengthening capacity for health research in Africa. *Lancet* 372, 1590–1593
- 8 Binka, F. (2005) Editorial: North–South research co-laborations: a move towards a true partnership? *Trop. Med. Int. Health* 10, 207–209
- 9 Costello, A. and Zumla, A. (2000) Moving to research partnerships in developing countries. *BMJ* 321, 827–829
- 10 Tucker, T.J. and Makgoba, M.W. (2008) Public health. Public–private partnerships and scientific imperialism. *Science* 320, 1016–1017
- 11 Wonkam, A. and Mayosi, B.M. (2014) Genomic medicine in Africa: promise, problems and prospects. *Genome Med.* 6, 11
- 12 Ramsay, M. *et al.* (2011) Africa: the next frontier for human disease gene discovery? *Hum. Mol. Genet.* 20, R214–R220
- 13 Parker, M. *et al.* (2009) Ethical data release in genome-wide association studies in developing countries. *PLoS Med.* 6, e1000143
- 14 De Vries, J. *et al.* (2011) Ethical issues in human genomics research in developing countries. *BMC Med. Ethics* 12, 5