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POLICY AND SOCIETY BRIEF REPORT

Evolving perspectives on broad consent for genomics research and biobanking in Africa. Report of the Second H3Africa Ethics Consultation Meeting, 11 May 2015

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A report on the Second H3Africa Ethics Consultation Meeting, which was held in Livingstone, Zambia on 11 May 2015. The meeting demonstrated considerable evolution by African Research Ethics Committees on thinking about broad consent as a consent option for genomics research and biobanking. The meeting concluded with a call for broader engagement with policy makers across the continent in order to help these recognise the need for guidance and regulation where these do not exist and to explore harmonisation where appropriate and possible.

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In May 2015, the H3Africa Consortium hosted the Second H3Africa Ethics Consultation Meeting, which aimed to contribute to the development of best practice for consent to genomics and biobanking research in Africa. The meeting, which targeted members of Research Ethics Committees (RECs) across Africa participating in H3Africa research, also explored the relationship between broad consent and governance of secondary data and sample access. It built on the first H3Africa Ethics Consultation Meeting [1]. The

meeting was attended by close to 80 participants, including 41 members of 31 ethics committees from 15 African countries. Additional participants were members of the H3Africa Working Group on Ethics, who facilitated the meeting, and members of the H3Africa Steering Committee, including study PIs.

One of the primary topics for discussion related to the acceptability of broad consent for genomics research and biobanking. In order to be successfully implemented, it is important that samples and data collected for genomics research and biobanking are widely available for secondary use. The requirement for secondary use – meaning that samples and data can be used for research that was not part of the original study and that was not anticipated in the ethics approval process – means that it is difficult to

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seek the specific consent. The ideal would be to seek the so-called 'broad consent' – consent that allows the broad re-use of samples and data for future research. Broad consent is not the same as blanket consent, but constitutes consent for samples to be re-used for specific areas of research, under a governance framework that regulates access. Some have called this 'consent for governance' [2]. Such consent for governance is increasingly coming to be seen as an ethically acceptable consent model for genomics research and biobanking [3] and there are no compelling reasons for why broad consent should not be ethically acceptable in lower- and middle-income countries [4, 5]. However, there is considerable apprehension about the use of broad consent for such research, most notably by ethics review committees [1, 6]. The Second H3Africa Ethics Consultation Meeting focused on exploring what mechanisms need to be put in place in order for broad consent to be acceptable for use in Africa. In particular, we attempted to discuss which elements the H3Africa governance framework should comprise in order to provide appropriate safeguards assuring ethics committee members that participant interests would be sufficiently protected.

Broad consent

There appeared to have been a remarkable evolution in approaches to broad consent since the First H3Africa Ethics Consultation Meeting in 2014, with broad consent gradually appearing to become the norm for genomic studies and biobanking in many countries represented at this meeting. This was most apparent in meeting participants' greater willingness to explore whether and how broad consent could be adopted as a viable, ethical consent model for genomics research and biobanking in Africa. This is not to say that the use of broad consent no longer raises concerns or questions, or that REC members are no longer considering the implications of genomics research (and broad consent) on privacy, sovereignty and national heritage, which remained lively topics of discussion.

What became clear in the course of the discussions was the need to develop greater conceptual clarity about the difference between 'broad' and 'blanket' consent. Emerging international consensus would be that blanket consent is consent without any restrictions on downstream use whilst broad consent is consent for secondary use with conditions [3]. These conditions can for instance be specific areas of application or provisions for downstream governance, including access policies. Where that is desirable, a condition for secondary use could be that the original REC that approved sample collection would be involved in secondary access decisions, or that original committees would be regularly notified of access decisions. The extent to which original ethics committee are or should be involved in reviewing secondary access and use requests was an important topic of discussion at the meeting.

During the small group discussions the importance of education for REC members and policy makers on the ethical applicability and appropriateness of different consent models was emphasised. The sentiment was that committee members (and not just the ones present at the meeting) should be empowered to make informed decisions about the acceptability of proposed consent models. This should include clear guidance about the conditions that should accompany broad consent, including appropriate good governance mechanisms. The important role of community engagement in supporting the use of broad consent, building trust between stakeholders as well as confidence in the governance framework were also discussed.

Defining good governance for genomics and biobanking

The audience agreed with the Uganda National Council for Science and Technology that sample and data sharing policies should take into account the need to respect persons and communities, be cognisant of and pertinent to the health of sample donors and their populations, and promote the fair and equitable sharing of materials in a way that supports capacity development. Particularly the latter – that sharing should be fair and of benefit to researchers and patients in the African context – was considered very important and received considered attention during the meeting. For African RECs, policy makers and legislators, the key challenge lies in striking a balance between developing legislation, regulation or guidance that appropriately protects the interests of African researchers and research participants, whilst not limiting or restricting opportunities that could ultimately be beneficial for both. Some important contributions during the meeting came from participants who shared perspectives on how restrictive legislation and ethics guidance – developed to prevent exploitation and promote fairness – could in fact harm these interests by curtailing opportunities for African scientists to engage in international collaborations and use novel research methods.

Another important topic of discussion concerned the extent to which secondary use of samples and data should involve collaboration with scientists from the countries where the original study took place. This is a regulatory requirement in Uganda and other countries and could go some way in promoting fairness. However, it is not clear how this is effectively enforced and whether this leads to tokenistic rather than meaningful collaboration, and sustainable capacity building.

The meeting unearthed a tension between decision-making by RECs, and policy makers and legislators at national levels. RECs need to operate within the room for manoeuvre set by national policy and/or legal frameworks. Some REC members present at the meeting described that this sometimes raises tensions, particularly where the policy or legal framework is very specific. Others described



being uneasy about making decisions about genomic research and biobanking where there was a lack of legislation and regulation.

Participants focused on identifying a number of common elements of a good governance framework that were needed to legitimise broad consent, including transparency, accountability, fairness and consistency in decision-making. A key question in relation to good governance related to inclusiveness in the process of policy development and in decision-making around secondary use, and particularly about liaising with ethics committees or national ethics councils in the development of these. There was also considerable focus on the role of Material and, potentially, Data Transfer Agreements in regulating distant use of samples and data.

In summary, perspectives on and experiences of broad consent for genomics research and biobanking in Africa are evolving, with greater willingness on behalf of African REC members to consider the conditions under which the use of broad consent in genomic research and biobanking in Africa could be ethical. The consensus was that broad consent should be used in conjunction with a governance framework regulating secondary sample and data access and use. Key characteristics of this governance framework is that it needs to be fair and equitable, promote capacity building and ultimately empower African researchers to design, lead and conduct genomics research and biobanking for the benefit of African patients. The meeting concluded with a call to develop guidance for what would constitute best practice in genomics and biobanking research, which could

be used by ethics committees and national ethics councils to develop their own country-specific guidance. The H3Africa Working Group on Ethics is in the process of developing such guidance in the form of a Framework for Best Practice for Genomics Research and Biobanking in Africa, which will be discussed with members of national ethics councils and governments from over 20 African countries during the Third H3Africa Ethics Consultation Meeting that is to be held in Senegal in May 2016.

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