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ARTICLES

# COMMUNITY MEMBERS' ENGAGEMENT WITH AND INVOLVEMENT IN GENOMIC RESEARCH: LESSONS TO LEARN FROM THE FIELD

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***ABSTRACT***
*In this paper, we describe the potential role laypersons on ethics committees can play in ensuring community concerns are addressed in the design and implementation of genomic research. We draw inferences from the outcome of an empirical study of the impact of training of laypersons to address community engagement issues in ethics review of research protocol. While this paper does not advocate a particular solution, it describes the importance of community engagement in genomic research, the current limitations there are in engaging communities in the design of these research projects and how communities can be indirectly engaged in the design and implementation of genomic research through the engagement of laypersons on ethics committees. However, to ensure that these laypersons can play this role, their capacity needs to be built to play this role appropriately. There is evidence to show that where resources are invested in building the capacity of laypersons to play their role as community 'watchdogs' in research, they play this role aptly. Community engagement is important in genomic research as genomic researchers will increasingly require community perspectives in critical ethics decision making.*

## INTRODUCTION

Genomics is the study of an organism's whole hereditary information that is present in its genes (DNA) and the use of its genes. It deals with the use of genome information in association with other information to provide answers in biology and medicine. Genomic research has the potential to be used for a wide range of purposes, including the study of complex diseases like cardiovascular diseases,[1] diabetes[2] and cancers.[3] While the findings from genomic research have significant potential to improve human health, the strong role environmental factors play in the expression of disease cannot be ignored. Integration of new genetic information into the design and analysis of

[1] S.E. Humphries, P.J. Talmud, C. Cox, W. Sutherland & J. Mann. Genetic factors affecting the consistency and magnitude of changes in plasma cholesterol in response to dietary challenge. *Quart. J. Med.* 1996; 89: 671–680; J.A. Kuivenhoven, J.W. Jukema, A.H. Zwinderman, P. de Knijff, R. McPherson, A.V.G. Bruschke, K.I. Lie & J.J.P. Kastelein. The role of a common variant of the cholesteryl ester transfer protein gene in the progression of coronary atherosclerosis. *N. Engl. J. Med.* 1998; 338: 86–93.

[2] L.J. Scott, K.L. Mohlke, L.L. Bonnycastle, C.J. Willer, L.Y. Li, W.L. Duren et al. A genome-wide association study of Type 2 Diabetes in Finns detects multiple susceptibility variants. *Science.* 2007; 316: 1341–1345.

[3] D. Yang, S. Khan, Y. Sun, K. Hess, I. Shmulevich, A.K. Sood & W. Zhang. Association of BRCA1 and BRCA2 mutations with survival, chemotherapy sensitivity, and gene mutator phenotype in patients with ovarian cancer. *JAMA.* 2011; 306: 1557–1565; K.L. Bolton, G. Chenevix-Trench, C. Goh, S. Sadetzki, S.J. Ramus, B.Y. Karlan, et al. Association between BRCA1 and BRCA2 mutations and survival in women with invasive epithelial ovarian cancer. *JAMA.* 2012; 307: 382–390.

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epidemiological studies can help clarify causal relationships between both life-style and genetic factors, and risks of disease.[4]

Genomic research raises many ethical, social and legal issues associated with population health, the provision of health care, and research. These include consideration of diverse social, cultural and religious perspectives on genetics and health, possible discrimination by employers or health insurers based on details of outcomes of genetic studies, and the need to define ethical standards for work with human research participants or tissues.

In recognition of the ethical implications of conducting genomic research, there have been multiple discussions with a view of developing frameworks and having consensus statements on how to proceed with such research. Such discussions include how to handle the outcomes of analysis of the enormous volume of valuable data produced during the conduct of these research projects which may result in the discovery of health related information directly and indirectly linked to the primary objective of the study, both of which that may be of clinical significance to a study participant. Also, the uncertain future research use of the study samples and data, the implications of the data for family members, and the expectations of publicly releasing the data to facilitate research thereby making the data publicly accessible, are realities that challenge existing research ethical norms and seem particularly acute in the context of genomic research.[5]

These ethical dilemmas have to be handled by the multiple stakeholders involved with the implementation of genomic research. They include individuals, families, communities and the public at large, who all need to be protected. Thus, any ethical frameworks developed for the genomic research field will need to give deep consideration to issues related to community engagement in genomic research far beyond the current context of discussions that extensively focus on addressing ethical issues related to individual engagement and protection in genomic research. Moreso, with the launch of the Human Heredity for Health in Africa (H3Africa) project, it will become increasingly important to address ethical issues that are critical and relevant to the context of engaging African communities in genomic research.

Unfortunately, little effort has been made to develop an ethical framework that concretely addresses community engagement in all genomic research, unlike what is observed in the HIV prevention research field. The biomedical HIV prevention research field has worked well in advance on this issue having held debates,[6] and developed ethical guideline documents.[7] This paper will describe how the field of biomedical HIV prevention research has effectively developed a community engagement guideline – a working guidance document that community members, community advocates, researchers, sponsors and policy makers find as a useful planning, monitoring and advocacy tool.

This paper also recognises that there are existing ethical resources (ethics committees and experts) who are important stakeholders engaged indirectly with the design and implementation of genomic research. These ethical resources need to understand and address the complex ethical challenges associated with the design and implementation of genomic research such as implications that affects the ethics norms associated with population health and the provision of health care.[8] There are also laypersons (community representatives) on these committees who are expected to provide comments on issues that address community concerns (both ethical and social) in the design and implementation of genomic research. Yet, their capacity may be limited; and where capacity exists, it is more focused on conventional and traditional research with little understanding of the unique ethical issues associated with genomic research.[9] Although, it may be likely that other professional on the ethics committee may lack the competency to evaluate genomic research protocols, this paper however limits its discussion to laypersons on the ethics committee in view of the critical importance of their role in addressing community engagement in community based research. This paper suggests the need to invest in building the capacity of laypersons on ethics committees to enable them provide needed input into research protocols that will be

[4] C.W. Willet. Balancing life-style and genomics research for disease prevention. *Science.* 2002; 296: 695–698.

[5] T. Caulfied, A.L. McGuire, M. Cho, J.A. Buchanan, M.M. Burgess, U. Danilczyk, et al. Research ethics recommendations for whole-genome research: consensus statement. *PLoS Biol* 2008; 6: e73. doi:10.1371/journal.pbio.0060073.

[6] L. Miller, M.O. Folayan, D. Allman, B. Nkala, L.M. Kasirye, L.R. Mingote, G. Calazans, R. Mburu, F. Ntombela, M. & Ditmore. How Ethical is Your Clinical Trial. *Int J Clin Pract* 2010; 64: 1179–1182.

[7] National Institute of Allergy and Infectious Diseases HIV/AIDS Clinical Trials Research. 2009. *Community Recommendations Working Group, Community Partners. Recommendations for Community Involvement.* Bethesda, MD; Joint United Nations Programme on HIV/AIDS (UNAIDS) and World Health Organization. 2007. *Ethical considerations in biomedical HIV prevention trials.* http://data.unaids.org/pub/Report/2007/JC1399_ethical_considerations_en.pdf. [Accessed 26 Jan 2013]; Joint United Nations Programme on HIV / AIDS (UNAIDS), AVAC. 2011. UNAIDS / 07.30E / JC1364E. *Good Participatory Practice Guidelines for Biomedical HIV Prevention Trials*. Geneva: UNAIDS. http://www.unaids.org/en/media/unaids/contentassets/documents/unaidspublication/2011/20110629_JC1853_GPP_Guidelines_2011.pdf. [Accessed 26 Jan 2013].

[8] M.M. Burgess. Beyond consent: Ethical and social issues in genetic testing. *Nat Rev Genet* 2001; 2: 9–14.

[9] T. Lemmens & D. Waring. Eds. 2006. *Law and ethics in biomedical research: Regulation, conflict of interest, and liability*. Toronto: University of Toronto Press.

useful in addressing some of the complex ethical challenges that may otherwise require extensive dialogue with community members to resolve.

## THE GOOD PARTICIPATORY PRACTICE GUIDELINES: A GUIDELINE FOR ENGAGING COMMUNITIES IN BIOMEDICAL HIV PREVENTION RESEARCH

The Good Participatory Practice Guidelines (GPP) in Biomedical HIV Prevention Trials[10] is the first set of global guidelines to describe how trial sponsors and implementers should effectively engage with community stakeholders when conducting biomedical HIV prevention trials. The GPP guidelines are designed to provide trial funders, sponsors and implementers with systematic guidance on how to effectively engage with all stakeholders in the design and conduct of biomedical HIV prevention trials so as to facilitate more equitable partnerships, shared understanding of the research process, and increase the likelihood of successful implementation of the biomedical HIV research process. The guidelines identify core principles that serve as the foundation of relationships between trial entities and community stakeholders. Examples of such principles are respect, research literacy, ethical and scientific integrity and transparency. The standard practices of good stakeholder engagement explain how specific activities and actions can facilitate appropriate community engagement at each stage of the trial life-cycle. A unique aspect of the GPP guidelines is that not only can they be used as a guide to outline successful stakeholder engagement practices, but they can also be utilised as a tool to assess effective collaborative processes by community stakeholders, trial implementers and trial sponsors.[11]

In creating a global guidance document for stakeholder engagement, there was a requirement to balance specificity of guidelines that will promote shared stakeholder engagement practices across research networks and research communities on the one hand, and the need for sensitivity to local variation on the other. In an effort to address this concern, the GPP guidelines were developed to be broad enough to allow for variation in cultural norms and practices of trial sites across the globe, but specific enough to provide a suitable framework to facilitate successful adoption of key activities.[12]

Its development was through extensive consultative processes that spanned over seven years. The process was initially led by UNAIDS and AVAC in 2005 in response to the controversies and debates of pre-exposure prophylaxis trials in Cambodia and Cameroon. The GPP guidelines were born out of a recommendation from this process. The first edition was published in 2007 after extensive global consultation with global stakeholders that included community advocates, researchers, ethicists and policy makers.[13] Between 2007 and 2010, AVAC raised awareness about the guidelines encouraging various biomedical HIV prevention sites and stakeholders to pilot the guidelines. AVAC issued small grants to 12 organisations globally to seek further feedback and critique from a diverse group of stakeholders to the guidelines. The results from the consultations were compiled and the draft version of the revised GPP guidelines was launched for public comment at the AIDS conference in Vienna in July 2010. Public comments were received until the end of 2010. The second edition of the guidelines, the 2011 edition, was published and launched for public use in July 2011 at the World AIDS Conference in Rome. Trial sites and community stakeholders have used the GPP guidelines as a tool to identify successes and areas for improvement around community engagement efforts.[14]

There have since been active efforts to promote awareness and use of the guideline since 2007 through the organisations of seminars, development of training tools, and implementing training workshops for the various identified stakeholders. The recommendation made by the US administration through the Presidential Commission for the Study of Bioethical Issues in September 2011 for community engagement based on the GPP is an acknowledgement of the usefulness of this guideline in promoting effective community engagement.[15]

## COMMUNITY ENGAGEMENT WITH GENOMIC RESEARCH

There are community concerns with genomic research.[16] These concerns are not only limited to the possibility that

[10] Joint United Nations Programme on HIV / AIDS (UNAIDS), AVAC. *op. cit.* note 7.

[11] Miller et al. *op. cit.* note 6.

[12] Ibid.

[13] Creating effective partnerships for HIV prevention trials: report of a UNAIDS Consultation, Geneva 20–21 June 2005. *AIDS.* 2006: 20: W1–W11.

[14] N.S. Morar, R. White, M. Ukpong, L. Seyama, E. Chihota, J. Prince, M.Z. Chileshe, P. Kumwende & HPTN 035 community educators and the MTN CWG. *UNAIDS good participatory practice guidelines and principles imlemented in the HPTN 035 trial*. Microbicide 2010, Pittsburgh, USA. May 22nd to 25th, 2010. (Poster abstract 440).

[15] Presidential Commission for the Study of Bioethical Issues. 2011. *Moral Science: Protecting Participants in Human Subjects Research*. http://www.bioethics.gov/cms/node/558. [Accessed 26 Jan 2013].

[16] D. Levy, S. Brink. 2005. *A change of heart: How the Framingham Heart Study helped unravel the mysteries of cardiovascular disease*. New York: Knopf.

a socially identifiable population may be placed at risk by the identification of genetic disease features linked with their common identity (for example the associations of African-Americans with sickle-cell trait[17] and Ashkenazi Jews with specific BRCA1 alleles[18]), but also to the potential for contradictions of a population's sense of its own history,[19] broader forms of discrimination and stigmatization,[20] internalized psychosocial stress, or the disruption of a community's social equilibrium for socially identifiable communities.[21] Foster et al.[22] discuss the value of having communities review genomic research protocols in an effort to address these concerns. They note that such community review enables the identification of culturally specific risks which are of valid concern, as well as identification of potential conflicts between individual and group assessments of research-related risks. The potential value of having community involvement in the development and review of population-specific genetic studies were further echoed by Foster et al.[23] and Greenly.[24] They both concurred that community engagement not only enables the identification of research-related risks which researchers might not have been able to identify, but also gives the opportunity for communities to identify ways to minimise these risks.[25]

The field of genomic research has however not engaged with communities the same way as the HIV prevention field. While the concerns and need for community engagement in genomic research are recognised as valid, the Committee on Human Genome Diversity, National Research Council however suggested that such community consultation should be seen as a moral good and not an ethical obligation with statutory requirements.[26] This stance differs significantly from the view point of the HIV prevention field. De Vries et al.[27]also alluded to the need for statutory guidance for sustained and effective community engagement in the field of genomic research since collaborative partnership would be required for the implementation of genomic research in lower income countries. Caulfield et al.[28] also identified the need for research ethics guidance for the field even though the field was still in its infancy. The recent report by the US Commission for the Study of Bioethical[29] Issues further reinforces the need for the field to develop research ethics guidelines that promotes community engagement.

Advocates engaged with promoting community engagement in the biomedical HIV prevention trial field propose and advocate that community engagement in research should start at the stage of conceptualisation of the research.[30] However, current practices in the field of international research show that concepts for the research are often developed by the Northern partner with Southern collaborating investigators engaged as an effort *to 'build their capacity to learn something useful to science and/or practice in the North'*.[31] This is also observable within the genomic research field. Within the context of this reality, we question the feasibility of always getting the community involved with genomic research protocol development. We also question the feasibility of consistently getting the community involved with genomic research protocol development.

Yet community input is worthwhile in the contributions it came make to research design and outcomes. While this will indeed be quite beneficial for both parties, the realities on the field especially in low income communities like Africa, challenge the feasibility of development of the needed partnerships with research communities. The time between ethics committee approval of research protocol and commencement of research implementation is often so short that the feasibility of extensive community consultation needed to ensure equitable dialogue between researchers and communities is not feasible. Also, the Northern dominance in conceptualisation and design of genomic research protocols, and the low

[17] D. Phoenix, S. Lybrook, R. Trottier, F. Hodgin & L. Crandall. Sickle cell screening policies as portent: how will the Human Genome Project affect public sector genetic services? *J Natl Med Assoc* 1995; 87: 807–812.

[18] S.G. Stolberg. Concern among Jews is heightened as scientists deepen gene studies. *NY Times* 1998; April 22, section A.

[19] R.A. Grounds. The Yuchi community and the Human Genome Diversity Project. *Cult Survival* 1996; 19: 64–68.

[20] S. Wolf. Beyond 'genetic discrimination': toward the broader harm of geneticism. *J Law Med Ethics* 1995; 23: 345–353.

[21] M.W. Foster, R.R. Sharp, W.L. Freeman, M. Chino, D. Bernsten & T.H. Carter. The Role of Community Review in Evaluating the Risks of Human Genetic Variation Research. *Am. J. Hum. Genet.* 1999; 64: 1719–1727.

[22] Foster et al. *op. cit.* note 21.

[23] M.W. Foster, D. Bernsten & T.H. Carter. A model agreement for genetic research with socially identifiable populations. *Am J Hum Genet* 1998; 63: 696–702.

[24] H.T. Greely. The control of genetic research: involving the "groups between." *Houston Law Review* 1997; 33: 1397–1430.

[25] J.H. Moore. Native Americans, scientists and the HGDP. *Cult Survival* 1996; 20: 60–62.

[26] Committee on Human Genome Diversity, National Research Council. 1997. *Evaluating human genetic diversity*. National Academy of Science, Washington, DC.

[27] J. de Vries, S.J. Bull, O. Doumbo, M. Ibrahim, O. Mercereau-Puijalon, D. Kwiatkowski & M. Parker. Ethical issues in human genomics research in developing countries. *BMC Medical Ethics* 2011, 12: 5. doi:10.1186/1472-6939-12-15.

[28] Caulfied et al. *op. cit* note 5.

[29] Presidential Commission for the Study of Bioethical Issues. *op. cit*. note 15.

[30] M. Ukpong, S. Clapp, R. White & the MTN CWG 2008. *Community engagement in research concept development: lessons from the Microbicide Trial Network (MTN)*. Microbicide 2008, New Delhi, India. (Oral abstract 88); ditto cite 6.

[31] P.G.H. Engel & N. Keizer. Research partnership: who decides? Review of a design process. *The Hague* 2006; 16. http://www.nuffic.nl/home/docs/events/kotm/research-partnerships.pdf. [Accessed 26 Jan 2013].

research literacy of southern communities where these research projects will be conducted pose challenges the development of such equitable partnerships.[32] In addition, the short timeframe makes it difficult to ensure that researchers' investments in building community research literacy would yield enough to ensure communities are empowered to relate with researchers as equitable partners.

There are equally a few other challenges that may not be peculiar to genomic research alone but of considerable importance when addressing and developing community engagement models. This include the need to identify who should actually be vested with the responsibility of building the capacity of the community, when such capacity building effort should commence and when a projects team's investment in capacity building efforts for the research community stop. De Vries et al. note that there might be challenges with identifying relevant communities and their representatives, as well as the challenges with identifying and establishing fair, inclusive and accountable procedures, principles and mechanism of engaging the community appropriate for the research setting.[33]

Despite these unresolved ambiguities, community engagement in research is considered an ethical imperative[8] as an ethically valid research process must be consistent with the ethical principles of all its partners including the community stakeholders.[34] It enhance protections and facilitate opportunities for research to improve human health. Also, it creates the needed opportunity for open and inclusive dialogue to enable community members learn about the context of conducting genomic research (and any other research), and facilitates culturally appropriate responses to these concerns without bridging the scientific validity and ethical integrity of the research.

The HIV treatment and prevention field has so well demonstrated the value of community engagement in research. The engagement of AIDS treatment activists in the 1980s around AIDS treatment trials was a demonstration of how community stakeholders not associated with the scientific field could play a role in setting the research agenda and making important contributions to the clinical trials process including its implementation and monitoring.[35] The need to standardise the implementation of community participation within the clinical trials process was further highlighted through the controversies that erupted between researchers and local voices around testing tenofovir disoproxil fumarate (TDF) for the prevention of HIV infection in pre-exposure prophylaxis (PrEP) studies in 2004 and 2005. Lessons learnt from the biomedical HIV prevention research field may well inform the need for the genomic research field to truly consider it an ethical obligation for researchers to engage communities in low income countries[36] very early in the research design process.[37]

In reality however, as long as researchers conceive the idea for research, they will more often engage the community at the implementation stage. The realities of everyday life are such that active continued engagement of individuals at research sites in the design and implementation of multiple research projects, including genomic research, is not always feasible. However, these challenges do not undermine the need to engage the community. As illustrated by Miller et al.,[38] the controversial PrEP trials in Cameroon, Thailand and Cambodia are case studies of clinical trials reviewed and approved by multiple ethics committees, yet subsequently found unacceptable by some community stakeholders because of differing opinions of ethical requirements for the conduct of research in their communities. Differing perspectives on ethical discussion and perception of concerns by researchers and communities are grounds for potential conflicts that could lead to the disruption of studies, loss of valuable time and resources, and possible lawsuits by communities.[39]

## POTENTIAL SHORT TERM MEASURES: ENGAGING LAYPERSONS ON ETHICS COMMITTEES TO ADDRESS COMMUNITY CONCERNS

Some of the challenges highlighted above with respect to engaging large communities in genomic research may be addressed by building the capacity of a 'specialised' subset of the community as active participants in

[32] De Vries et al. *op. cit.* note 27.

[33] Ibid.

[34] K. Edwards, C. Lund & N. Gibson. Ethical validity: Expecting the unexpected in community-based research. *A Journal of Aboriginal and Indigenous Community Health* 2008; 6(3): 17–30; Council for International Organizations of Medical Sciences (CIOMS). 2002. *International Ethical Guidelines for Biomedical Research Involving Human Subjects*. Geneva: CIOMS, in collaboration with WHO. Available at: http://www.cioms.ch/frame_guidelines_nov_2002.htm. [Accessed 26 Jan 2013].

[35] Creating effective partnerships for HIV prevention trials: report of a UNAIDS Consultation *op cit* note 13; M. Harrington. Community involvement in HIV and tuberculosis research. *J Acquir Immune Defic Syndr* 2009; 52: S63–S66.

[36] Joint United Nations Programme on HIV/AIDS (UNAIDS) and World Health Organization *op cit* note 7.; Council for International Organizations of Medical Sciences (CIOMS). *Op cit* note 34.

[37] S.B. Trinidad, S.M. Fullerton, E.J. Ludman, G.P. Jarvik, E.B. Larson & W. Burke. Research practice and participant preferences: the growing gulf. *Science.* 2011; 331: 287–288.

[38] Miller et al. *op cit*. note 6.

[39] Trinidad et al. *op cit.* note 37.

research. Laypersons on ethics committees are expected to address community concerns in research protocols reviewed by the ethics committees, address community concerns during research monitoring exercises, and be objective during HREC deliberations, amongst the other roles of ethics committee members. The community of lay representatives on ethics committees is small, reachable, and has justifiable reasons for researchers and other interested parties to invest in building their capacity so they can play their role efficiently. Investing in the capacity building efforts of this sub-community has significant impact on their capacity to address community concerns during research protocol review.[40]

Evidence from a project designed by the New HIV Vaccine and Microbicide Advocacy Society in Nigeria shows that investing in building the capacity of laypersons on ethics committee can result in significant improvement in ethics committees' research protocols review especially with respect to providing feedback on community engagement efforts. The project invested in building the capacity of over 40 laypersons over a 3 year period (2008 to 2010) through the conduct of multiple trainings, and provision of technical support and updates to the trainees. Trainings were provided on how to review research protocols and provide constructive feedback and on how to monitor researches through organised workshops. Emphasis was placed on how to assess for community engagement efforts when reviewing research protocols and during research monitoring visits during the workshops. Paired t-test comparison of pre and post tests scores following each of the training workshops show significant differences in the test score with knowledge increasing after participation in trainings. The impact evaluation assessment showed that there was knowledge retention: the mean immediate workshop post test score for the respondents was 73.3% ± 9.8. The test score on re-evaluation was 61.7% ± 12.9. There was no significant difference between the two scores ($p = 0.11$). The paired t-test analysis also showed no significant difference between the two scores ($p = 0.052$). Feedbacks received from the telephone interviews and focus group discussions with other members of the ethics committee showed that the capacity of trained laypersons to review research protocols had improved. They were able to provide constructive feedback to protocols, address community concerns including the need to ensure research result dissemination to the communities, request for provision of evidence of community consultation during protocol development for community based research, and monitor continued community engagement during research monitoring exercises. Details on the design, content and structure of training, type of instruction and instructors have been extensively discussed in the paper by Folayan et al.[41]

The outcome of the project showed that investment in building the capacity of laypersons on ethics committees can improve their ability to evaluate and make suggestions to address community concerns in research protocols. With the growing need for and interest in genomic research, training of laypersons on the ethics of genomic research will very well help ensure that community concerns are addressed in genomic research protocols where consultations with communities prior to the design of such research protocols had not taken place before submission of research protocols to ethics committees for review.

Training of laypersons on ethics committees may also have a trickling down effect into the community as these are community members who may share their acquired knowledge and skills with their communities. The chance for this to happen remains limited, however, as the laypersons on many ethics committee are not truly representative of any community: they are often chosen by the research institution rather than being nominated to the ethics committees by communities they serve. This limits the chances of these laypersons reporting back to or relating with any constituency within the community. Also, the feasibility of direct community engagement of laypersons on ethics committee on contents of research protocols is further limited by the oath of confidentiality placed on them as members of ethics committees: they do not have the freedom to publicly discuss research protocols they review with the community prior to its implementation. The work of laypersons will thereby compliment the role of Community Advisory Boards (CABs)[42] constituted for research projects who has the constituted authority to extensively discuss research protocols with the community and provide community feedback to researchers. Ethical frameworks that guide community engagement in genomic research may however want to deliberate more on how the roles of laypersons on ethics committees and that of CABs are well delineated.

[40] M.O. Folayan, A. Adaranijo, F. Durueke, A. Ajuwon, A. Adejumo, O. Ezechi, K. Oyedeji & O. Akanni. Impact of three years training on operations capacities of research ethics committees in Nigeria. Dev World Bioeth. 2012 Sep 24. doi: 10.1111/j.1471-8847.2012.00340.x. [Epub ahead of print].

[41] Folayan et al. *op cit.* note 40.

[42] The roles of CABs in clinical AIDS research have been well described and discuss in prior literatures. A good overview of the history, role and function of CABs can be read in the paper by K. West Slevin, M. Ukpong & L. Heise. 2008. *Community Engagement in HIV Prevention Trials: Evolution of the Field and Opportunities for Growth*. Aids2031 Science and Technology Working Group, No 11; L.E. Cox, J.R. Rouff, K.H. Svendsen, M. Markowitz & D.J. Abrams. Community advisory boards: their role in AIDS clinical trials. *Health Social Work* 1998; 23: 290–297.

## CONCLUSION

Community engagement throughout the lifecycle of genomic research should be considered an ethical imperative, and the need to development an ethical framework that helps promote such engagement is important. Lessons can be borrowed from the HIV prevention field. While there has been increasing interest in the process and practice of participatory action research in the last few years, there are still a number of types of research, including genomic research conducted in developing countries, which engage communities only at the implementation stage of the research. There is also the peculiar challenge of engaging communities in Africa with low research literacy.

Research and research projects like genomic research do grapple with how to successfully mobilise and build the capacity of local communities to engage with researchers throughout the research life cycle. Guidance documents could help facilitate this process. However, in the short term, where guidelines on how to ensure effective community engagement in the genomic research field does not exist, investing in building the capacity of laypersons – a critical subset of a research community that have the legitimate authority to review research protocols, monitor research, and ensure that community issues and concerns are addressed throughout the research lifecycle – to address some of the community concerns can serve as a short term measure. This group is identifiable, can be reached easily and is already vested in the process of community engagement in research. As community representatives on ethics committees, there is the prospect that they will also be invested in building capacities within their communities to directly engage with researchers in the long run.

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