

H3Africa Guidelines for Community Engagement

Developed by the H3Africa Working Group on Ethics and
Regulatory Issues for the Human Heredity and Health (H3Africa)
Consortium

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Preface

The H3Africa programme seeks to foster genomic research expertise on the African continent with the goal of using genomic methods to address health inequities in both communicable and non-communicable diseases. Under the H3Africa banner, genomic research on conditions such as cardiovascular disease, rheumatic heart disease and diabetes is supported. Genomics research in Africa raises a host of ethical issues, some of which are unique to the continent and its people, and others of which are similar to issues raised elsewhere in the world. In order to address these, the H3Africa consortium established a Working Group on Ethics, which is composed from representatives of each of the H3Africa funded research projects.

One of the primary challenges facing H3Africa investigators relates to informed consent, and the H3Africa Working Group on Ethics and Regulatory Issues developed Guidelines for Informed Consent in August 2013, available through the H3Africa website, www.h3africa.org. However, the Working Group recognises that some of the challenges relating to informed consent may be difficult to address in a one-off consent process. For this reason, the Working Group feels that community engagement is equally critical for the ethical conduct of research. The Working Group developed these guidelines for Community Engagement to help researchers design an appropriate community engagement process. The Working Group is currently engaging in a critical evaluation of community engagement experiences in genomics research in Africa to date, and will revise these guidelines as our understanding of this challenging area improves. In developing these guidelines, we relied on work done previously by other genomic research projects in Africa. Specifically, we would like to acknowledge the efforts of the International HapMap Consortium, MalariaGEN and 1000Genomes.

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1. Defining Community and Public Engagement

Community engagement, in broad terms, is a multi-faceted process of working collaboratively with a specific group or groups of people on a shared goal or common interest. In the context of health research, this may involve a range of activities and interactions between researchers (or dedicated staff within their institutions) and members of communities that are affected by or involved in research. The nature of these interactions and the level of the community's involvement in the research process depend on the goals of the engagement effort. This may range from just providing information about a proposed research project, consulting with gatekeepers of the community, soliciting the views and inputs of community members prior, during and after research, feeding back research findings, to building partnerships with the community. Methods of engagement could range from rather informal and ad hoc to more formal and of longer duration – for instance, setting up community advisory boards (CABs) to facilitate communication between the research team and the community to provide insights in the language, culture and context specific factors within the community that will impact on the research process and helping the research team to negotiate these challenges with the community. Some forms of engagement may be essential for conducting high-quality, ethically sound population-based research. These would include, for instance, providing information about the project or feeding back research findings to those involved. Other forms of engagement may simply add value to the research or have intrinsic value.

Community engagement differentiates itself from wider 'public engagement' in that it specifically targets communities of people who are directly affected by or involved in research. Public engagement on the other hand targets a broader audience and uses different (less targeted) means of engagement such as public meetings or meetings with policy makers, radio or television programmes or newspaper articles. Public engagement seeks to foster discussion and debate for the mutual benefit of science and the public, and aims to place scientific developments within the broader cultural landscape. The boundaries between the two are diffuse however and activities may overlap depending on the goals of the engagement. More recently, 'community involvement' was used to designate research done by or with community members (see for instance www.invo.org.uk/) and we do not refer to that kind of research in these guidelines.

Engagement activities can be built around a specific research project, around a research field (such as for instance 'malaria research') or around all research taking place within an institution. Community engagement normally targets any group who is either affected by research, or who is involved in it, whilst the audience of public engagement is broader and encapsulates people not directly involved in research.

Community and public engagement are deeply contextual and it is not possible to develop generic principles or rules about how it should be done. What is appropriate depends on where research takes place, the nature of the project that is being carried out, the presence or absence of other engagement activities, available funding to facilitate engagement and so forth. The purpose of these guidelines is not, therefore, to prescribe a certain form of engagement for H3Africa investigators. Rather, the purpose is to introduce the basic principles and means of engagement to enable H3Africa investigators to develop an engagement strategy that is appropriate to their project and research setting.

2. Why engage the community in genomic research?

Genomic research is similar to medical research in many respects: it involves human participants, focuses on research questions that are relevant to health, and often involves people that suffer from a particular medical condition. As is true for a lot of other research, the results of genomic research may not be directly clinically applicable. Genomics research does not generally include an intervention that provides tangible rewards for participation – although components of the research process may be considered beneficial. The main output of genomic research to date has been information about the involvement of particular genetic factors in disease causation or prevention and could involve any of the following:

- samples are collected from patients *but also* from healthy volunteers. It can be difficult to explain to people why this is the case;
- samples and data can be stored and used in the future for other research projects by investigators who were not involved in the original project;
- genetic and genomic information reveal something about the likely health of an individual in the future, and in very few cases can identify conditions that the individual will suffer from at an older age (such as Huntington's). These are sometimes called 'incidental findings';
- genomic information is relevant not only to the individual, but also to the people that they are genetically related to, such as their family, community members (if they have lived together for generations) and their population group. Results are often presented as if they have relevance to the wider population group (e.g. ethnic group) and not just to the individuals who were included in the studies.

Community engagement can have both intrinsic and instrumental value to the research process. In terms of intrinsic value, engaging the community is important as a sign of respect for the values, culture and traditions of the community involved in research. This may be particularly important when research involves participants and communities that are relatively untouched by science and modern medicine – as may be the case for communities that are unfamiliar with genomic studies. Community engagement can be seen as a means of protecting

the rights and interests of relevant communities and avoiding any form of exploitation. Community engagement is also an important step in determining the (health) needs and expectations of the community, ensuring that there is an opportunity to consider whether and how these could reasonably be met within the scope of the project. Community engagement when done properly provides an opportunity for communities to gain more information about genomic research, its benefits and its implications for their society. It allows for the development of strategies for mitigating harmful consequences, such as stigma that might arise from incidental findings of genomic research. It also provides opportunities for community members to determine how they want to be described or represented in research findings, allowing community members to be stakeholders/ decision makers and rather than passive recipients or participants in genomic research.

Community engagement may also have instrumental value, in helping researchers design more culturally appropriate studies and study tools. For instance, community engagement can support consent processes by providing information over time; help in the design of consent documents; help researchers develop comprehensible ways of explaining their research; maximise opportunities for involving communities in decisions about data and sample sharing; address anxieties of and rumours about blood sampling and most importantly help build trust between the research team and research participants. More formal community engagement structures like community advisory boards can also provide a helpful negotiating space between the research team and the community when problems or concerns arise during the research project. Having a mechanism to articulate or present concerns fosters increased trust in the research process and improved research literacy within the community.

Community engagement can also facilitate the feedback of findings. As an important step in building relations with communities in which research takes place, engagement may be a means to ensure the longevity of research projects, which may be important for instance in epidemiological research. Increasingly, genomics research is embedded in such longer term research and engagement activities may form part of that broader research programme. For members of the community, engagement provides regular access to information and staff involved in the research institution which gives both formal and informal opportunities (beyond interactions with research staff) to voice concerns and make requests for clarifications and actions. Through engagement activities communities have an opportunity not only to influence the conduct of on-going research but also to shape future research activities in their community. Furthermore, community engagement may be required by ethics committees or national research guidelines.

More generally, community engagement efforts for genomic research can be used as a means to describe the study to the pool of people from whom participants will be drawn, to discuss

research design and tools and to understand how best to explain concepts like ‘genomics’ (drawing on existing understandings of inheritance).

Community engagement efforts for genomics should include some consideration of the above. For instance, these efforts could be directed at discussing:

- how key components of the research could best be described;
- how and whether a community should be identified/described in research outputs;
- whether data and sample sharing are appropriate, and under what conditions;
- Issues around return of incidental findings and mitigating possible harmful effects that might arise out of research participation.

Broader public engagement activities may also help build or maintain trust in the research enterprise as a whole – and this could be one of the most important reasons for engaging the broader public in research. Public engagement is a means of seeking broad support for scientific research in general, or for a specific type of research. This is important as public funding remains the primary means of supporting research.

3. Existing H3Africa community engagement activities

Between March and August 2013, the H3Africa Working Group on Ethics conducted a survey to identify the various community engagement activities taking place in the H3Africa Consortium. All the principal investigators on H3Africa projects responded to a request for information about their past experience in engaging communities, as well as their proposed activities for H3Africa projects. Around a third of the groups involved in H3Africa have got some experience using Community Engagement methods for genomic studies, and most groups are planning some form of engagement for their prospective H3Africa studies. Community engagement is mostly being used to facilitate recruitment, empower and respect communities, provide transparency and to identify issues and concerns relating to the research project. There was a wide variety of audiences targeted with and methods used for the community engagement activities. Most grants engaged in some form of consultation with community or tribal leaders. The methods investigators were planning to use for their H3Africa studies include consultation with existing Community Advisory Boards, sensitization through faith-based organizations and professional organizations, meetings, interviews and workshops with community members and the development of newsletters and radio and TV programmes. It is clear that these strategies include aspects of both community and public engagement.

Challenges reported were: difficulties about communicating about genomics research, and specifically finding appropriate language to interpret difficult technical concepts; managing community expectations about the research project, and specifically expectations about the

speed and availability of research results. Issues of migration of study populations and the difficulty that ensued with maintaining messages over long periods of time were noted, as were resistance to the study due to previous experiences with other research teams. Investigators expressed uncertainty about what would be the best Community Engagement tools to use for H3Africa research. A complication in this regard was that studies often stretch across countries and include a wide variety of communities in rural and urban areas.

4. Key points to consider when designing an engagement strategy

4.1 Defining the goal of engagement

A first and essential step in developing an engagement strategy is to define your goals of engagement – in other words, why you want to engage. It is important to recognise that community engagement is an ethical requirement and some ethics committees may require a description of your community engagement goals and strategies in your research protocol. The goals of engagement may include: to secure the support of the community for your research project, to improve understanding of the research process; and to solicit views and inputs of community members on aspects of the research. Based on these goals, the first step is to define the key messages or components of the research that you want to engage people on. In other words, before defining the community that you will engage, you need to know what you are hoping to get their input on – whether that is to do with the project you are envisaging doing, or the fact that it is genomic research, or perhaps some aspects of genomic research such as sample and data sharing.

Once you have clear goals for engagement and know what your message is going to be, then you will be in a much better position to gauge which community or public will best be engaged with and the extent of engagement needed to achieve this task. This could also help to determine if the process of engagement should be limited to specific communities or extended to the general public.

4.2 Defining ‘the community’ or ‘the public’ in research

There is no standard definition of community. What counts as ‘community’ in your research is dependent on the nature of the research, the participants who will be enrolled in it, the social and political context and the goals of the engagement activity. Different kinds of communities can be identified, for instance those defined by:

- residence or physical location (neighbourhoods in cities or villages);
- ethnicity;
- illness or disease;
- religious or political beliefs;

- sexual orientation;
- behaviour that is engaged in by individuals (for instance, drug use)
- profession (for instance, nurses, mine-workers and so forth)
- situation in life (for instance, being in prison, single mothers).

A community can also be defined by a combination of the above, for instance the community could be members of a patient group living in a particular area such as the diabetes association of a particular region or country. How you define your community is also dependent on whether your research takes place in a rural or urban area, in small or large health facilities. When you define ‘the community’ in your research, you need to also consider whether and how it will be possible to contact and engage community members. ‘The community’ could also include patients’ families and caregivers, NGOs or not-for-profit organisations (NPOs) who provide interventions, support and services for patients and their families; as well as advocacy groups, clinicians treating these patients in context-relevant settings, and hospital facility boards who represent and advocate for these patients’ needs. For example in the H3Africa study “Genomics of Schizophrenia in South African Xhosa”, the community was defined broadly to include patients, caregivers, medical professionals and others (see Section 8.5 below). Representatives from these different contexts were selected to participate in a community advisory board that represented the patients targeted for the study. By contrast, in the Kilifi Birth Cohort study – which provided samples for the MalariaGEN study – the community was defined as all the people living in the catchment area of the district hospital (see Section 8.2 below). In the case of sample collections for the Nigerian component of the 1000 Genomes study, two ‘types’ of communities were identified: those living in relatively traditional villages and those working at one of the two largest local employers, a hospital and a university. People of the latter two communities were relatively well educated, and the hospital staff was organised in powerful unions. In this study, community engagement strategies were developed for each of these three different ‘communities’ (see Section 8.3 below).

As discussed previously, public engagement is broader than community engagement but there is a considerable overlap between the two. For some, the community engagement efforts in Kilifi – which encapsulated the entire catchment area of a district hospital (incorporating over 250,000 people) would count as public engagement for instance. By rule of thumb, those people who will be directly affected by or recruited into research are considered ‘the community’. People who are not in this category are ‘the public’. There is no limit to what ‘the public’ can be – but specific people may be targeted with engagement activities.

4.3 Identifying strategies, models and methods for community engagement

Once you have determined who and/or where your target community is, then you can start to map out specific activities that will make up your engagement effort to meet your goals. It is important to recognise that there is no one-size fits all for community engagement. Researchers can draw on a variety of communication tools and methods to tailor the engagement strategy to fit research needs, goals of engagement, funding and research constraints. Similarly, the community engagement strategy should be responsive to changes throughout the course of a study, and should be flexible enough to be shaped by experiences and interactions over time between participant and non-participant community members and staff.

There are many ways to engage with the people who are going to be affected by or involved in genomic research. Below we list some existing engagement methods that could be adapted to specific projects or contexts.

Informal or ad hoc community engagement mechanisms:

Consulting gatekeepers of the community: This can be done, first, by organising a series of meetings with gatekeepers of the community such as chiefs, elders, community representatives, opinion leaders, religious representatives and the like. In some settings, these initial meetings are a necessary requirement for gaining access into the community and approaching individual community members. These consultation processes could also help you to identify other relevant groups within the community, to learn about issues and concerns that community might have about the study, including seeking specific advice on the cultural context that may be relevant to the implementation of the study including recruitment of participants and to seek the community's support for the research. This process can be particularly helpful before the implementation of your research.

This stage of engagement may consist of various meetings with different groups. For instance, the traditional leaders and elders may need to be consulted separately from local policy makers. Opinion leaders are key individuals in the communities where research will take place, and can be for instance the teachers at the local school, a leading business person or other individuals that are important. In that case, the purpose of engagement is not so much 'getting access' as seeking to understand challenges and opportunities for conducting research in that particular community. It is important to note that perspectives and issues of marginalised groups might not be well represented during these meetings and further engagement with these groups might be required before commencement of the research.

Community meetings: Another engagement strategy could involve organising public meetings with members of the community. Strategies could include small group meetings, focus group discussions and surveys with specific groups within the community such as patient associations, women groups, male networks. It could also involve large community meetings such as "Town

Hall” meetings, durbars or barazas (community or public meetings) that are compatible with local political and community structures. The objective of these meetings would primarily be to discuss the research plan, topic or methods and to seek people’s views on these. Lessons learnt from these meetings should feed back in the way the study is conducted, for instance through changes to the consent documentation or the process of enrolment.

Formal or longer duration community engagement mechanisms:

Community advisory boards (CABs): Projects could also set up community advisory boards in which a number of community representatives get together on a regular basis to act as intermediaries between the researchers and the community. Where ‘the community’ is a group of patients, one could involve a patient organisation for this purpose to ensure that the voices of people who are directly affected by the research are considered in the research process. CABs can provide input on the development and initiation of research, provide community insight to researchers to direct a needs-driven and locally relevant research, serve as a liaison between the research team and the community, educate communities on research projects and support the research team to evaluate the impact of research.

However investigators are advised to carefully consider community advisory board membership to ensure that constituents are able to fulfill these roles, as well as the power dynamics that might exist within the groups and influence the community engagement process. An example might be gender balance among others. Other considerations include whether there are particular language proficiencies, a minimum level of formal education, specific work or lived experiences that would be valuable for constituents to have such as the experience of being a patient suffering from the disease or illness being investigated by the project; or a family member, care-giver, volunteer, community support worker, hospital facility board member, NPO or advocacy group representative who has insight into the experiences of patients living with the illness of disease. A particular interest in community or health related issues may also be important in sustaining a constituent’s commitment to the process.

Research staff – including for instance fieldworkers and research nurses – need to be involved in the development of information materials to be used in the engagement activities, as they usually have a better understanding of how to communicate about the research project and its components. Materials need to be piloted by the staff who will use them, and then adapted accordingly.

4.4 Who will do the engaging?

Another important component of the engagement strategy is to decide who is going to do the actual engaging with the communities. Whereas in many instances, scientists are the persons who engage with the communities, it is also important to involve non-scientists in these

activities. From the experience of community engagement for the MalariaGEN genomic study, the Kilifi group suggests that it is really important to involve personnel with specific skills in community facilitation and different aspects of communication (Marsh et al 2010 and Vikci Marsh, personal communication). The skills needed to communicate effectively with community members are likely to be different from the skills held by project managers and scientific staff. Fieldworkers, research nurses and others may actually be better equipped for this component of the research project.

Depending on the extent of engagement, projects could explore the following:

- Setting up a community engagement team within the institution or project to be responsible for carrying out the engagement activities. This team could include a liaison officer, communication officer, social scientists, health communication officer and research scientists;
- The scientists themselves engaging with the community;
- The community advisory board;
- A combination of the above.

4.5 The role and expectations for community engagement

It is also advisable to clearly discuss the roles and expectations of both the research team and the community members, what is the extent of the engagement process and any compensation available for participation in the community engagement activities, if applicable. Where a community advisory board is instituted, it is important to clearly discuss how frequently the group will meet and for how long, how and by whom the meeting costs will be covered and how this will impact on the independence or autonomy of the group. It is also important to agree on the fundamental roles and responsibilities of the research team and for each of the community representatives and the community advisory board as a whole in the research process.

5. Extending engagement to the general public?

In genomic research, it may be important to extend the engagement process to the wider public, particularly in the case of projects that involve the creation of biobanks for future research purposes. This is in recognition that other relevant groups, apart from communities that may be directly involved in the research project, may have interests in genomic research. Examples of stakeholders that could be involved in this wider engagement are science journalists, national patient organisations, policy makers and so forth. Public engagement could serve as a means of addressing any public concerns and rumours about genomic research and building public confidence in the research process, as well as sharing findings of the research.

Public engagement strategies may involve collaborating with the media to develop e.g. radio or television programmes about the disease under study, the role of genetics in health, and the project. Engagement could also involve setting up 'science cafes', supporting the development of e.g. songs, drama, comics and so forth that discuss salient features of the research project. Target audiences for community and public engagement are likely to overlap.

6. Anticipating and addressing challenges with community engagement

Engaging communities in genomic research involving humans is not without challenges. These may include the following:

- How to identify the relevant communities to engage with and ensuring that all relevant groups are included;
- How to earn the trust of the required communities such that they can agree to engage and maintain their involvement with the researchers;
- Community engagement is time-consuming and needs to anticipate research. If not started early, community engagement may delay the start of a project;
- The aims of community engagement may sometimes be in conflict with each other, or with the study aims– for instance, how would an aim to 'mobilise' communities to participate in a study sit alongside one to 'respect' the same individuals and their community? Similarly, there may be a challenge between the purpose of community engagement and the fact that policies are already set and committed to by investigators. An example is data and sample sharing in genomics research – these are a condition of funding and cannot be easily changed by individual investigators, even if the community engagement activity identifies community concerns about such policies;
- Community engagement has cost implications. Costs may involve employing a dedicated staff member, transport costs to community meetings, organizing focus group discussions and engaging with science journalists, costs of radio broadcasts etc. Finding (sustainable) funding to cover these activities may be hard, particularly if these were not initially budgeted for;
- Negotiating power dynamics within the group, expectations about the role of the group; balancing realistic project outcomes with the needs of the community.

It is important to anticipate these challenges and identify appropriate ways of addressing them. Budgeting for your community engagement activities when planning your research is important, as is starting the engagement process early.

7. Determining the effectiveness of your Community Engagement Strategy

Once the community engagement strategy is developed – involving the identification of the community, clearly defining the objectives for engaging the community and the adoption of specific methods for engaging the community – it is imperative to review and evaluate the

success of the community engagement process as a whole. Specifically, it is important to know whether the community engagement activities in actual fact led to greater comprehension of the study, and increased the means for community members to articulate concerns.

Community engagement involves a complex set of interventions with important social elements which generally means that it is very difficult, if not impossible, to evaluate it in a linear way – by setting outcome measures from the start and assessing progress in terms of these only. Also, some of the key concepts used in discussions about community engagement – for instance, a concept like ‘community understanding’ – are difficult to measure. For these reasons, researchers may learn more about their community engagement work by careful monitoring of processes over time rather than focused measurements towards indicators identified at the start. Since community engagement is itself a process, important new ‘indicators’ of progress are likely to emerge over the course of the study and these will only be recognized where community engagement is actively monitored during the course of a study. One important step in the evaluation of community engagement activities, however, is by critically revisiting the objectives of the community engagement strategy at the outset – were these relevant, did the engagement activity successfully engage community members on these issues, were community perspectives considered in the way the study was conducted and so forth.

There are various means that could be used to help evaluate a community engagement strategy. Some examples are:

- Using a theory of change methodology to identify unintended impacts, causal links, risks, assumptions and external factors that might have influenced the success of the community engagement strategy;
- Monitoring participation at events and meetings can help collect specific information on those who get involved. For example, how many people not affected by a particular disease turn up at a public sensitization meeting called by scientists;
- Documentary evidence which is usually collected may be useful (e.g. minutes of meetings) to trace discussions and concerns articulated;
- Interviews or focus groups, e.g. representatives of the community to seek their views on the extent to which community engagement strategies and activities have been useful and how this can be improved. This can be in a form of a questionnaire set out such that they can be used in a rating scale type of question, or more open-ended.

8. Examples of community engagement from previous genomic studies

8.1 MalariaGEN study in Navrongo, Ghana

The MalariaGEN project involved sample collection from many different countries and communities in Africa and Asia, and there was no single community engagement strategy to cover all of these. Rather, individual projects and investigators decided on the community

engagement strategy that was most appropriate for their studies and research setting. One example of a community engagement strategy for MalariaGEN is the one that was conducted in Navrongo, Northern Ghana (<http://www.malariagen.net/node/254>). The community was defined in geographical terms since participants were recruited from across the Kassena-Nankana District. The engagement strategy followed a model which has been established in the district for two decades (see Tindana et al 2006; Tindana et al 2011) and was carried out by the MalariaGEN research team and the communications team of the research Centre. The CE strategy started with a community entry process, which involved meetings with traditional leaders and elders to discuss the proposed research and to seek their permission to approach community members. This was in line with traditional practices of consulting ‘gatekeepers’ of the community before initiating any research activity and as a sign of respect for the communities’ values. This was followed by a ‘durbar’ (community gathering) with members of the community to discuss the research, to solicit views on key aspects of the research and to address potential issues that may arise such as the rationale for taking blood samples from children. Given that the project involved children, the research team also held small group meetings with women groups in the communities to discuss various aspects of the study including the rationale for recruiting both sick and healthy children.

The research team observed that having these meetings prior to the individual consent process enhanced research understanding. It also enabled the research team to address the communities’ fears and anxieties around the use of blood samples in research. A key challenge in this engagement process was how to translate key concepts of genomic research into the languages used locally (Kasem and Nankana). The team found that there are no equivalent concepts in the local languages for genes, DNA, Database. This was rather described in lay terms and using analogies. Genes for instance was described as ‘the things in the blood that makes us different from one another’ (see <http://www.malariagen.net/node/254>). A qualitative study involving indepth interviews, focus group discussions and observations, was conducted at the end of the MalariaGEN project to assess participants’ understanding of genomic research and how the community engagement may have facilitated the informed consent process (see Tindana et al 2012).

8.2 MalariaGEN study in Kilifi, Kenya

The community engagement strategy for the Kenyan component of the MalariaGEN study was embedded within a much wider community engagement programme run by the research institution at which the study was conducted (Marsh et al 2010). Initial engagement activities aimed to consult local health partners, administrative leaders (chiefs and assistant chiefs, civil

servants responsible for security and communication) and KEMRI community representatives¹ on the acceptability of the genomic study, including seeking views on challenges and areas of likely sensitivity. These consultations were also used to seek community input on how to communicate the aims and procedures of the study and on the acceptability of the sampling method (heel prick), the proposed benefits and costs of the study, and of the testing of samples for homozygous Sickle Cell Disease (SCD). Consultation was undertaken through a series of workshops to explain and discuss these elements of the study.

The second stage of community engagement was to hold a series of large scale public meetings to include the population resident in the study area ('the community' for this study). The outputs of the earlier consultation had been used to develop key messages and leaflets for distribution at these meetings. Public meetings included study scientists and staff. The meetings were advertised through posters and local announcements a few days ahead, using vehicles with external audio systems. Local groups of drummers and singers participated at the start of meetings to draw the public in.

At the same time, study staff began training of field workers. Training was on technical aspects of the study (genomics research and SCD testing) and also on the wider context for this study, including the nature of research, the background of the research institution and fundamentals of research ethics, including research review processes and the importance of informed consent.

Throughout the study, members of the study team met weekly to discuss progress and any emerging community issues. Also throughout the study, participant families and other community members were encouraged to communicate with study staff with questions or issues related to the study, through sending messages with field workers, using the free 'helpline' at the office, writing letters or calling in to the office. Based on fieldworker and community reports, a follow up workshop was held with field workers to address issues in the consent process, particularly related to the length of the information sheet and challenges in communicating about the purpose of the study. A new information sheet was developed by field workers; this was introduced for use after application to national research ethics committee for amendment of this form.

¹ KEMRI Community Representatives are a volunteer network of around 200 local residents in the HDSS area, working in locational committees and selected by their communities, who support consultation activities between the programme and the community during a 3 year 'period of office'.

8.3 1000 Genomes: Nigeria²

The 1000 Genomes project collected samples from population groups around the world, and also included samples from a variety of populations in Africa. Two of these were in Nigeria (the Esan people) and in Sierra Leone (the Mende people). In Nigeria, community engagement activities focused on the three different ‘communities’ from which participants were to be drawn: Esan villages, people working or studying at the local university, and people working in a local hospital. The university and hospital were the largest employers in the region where samples were collected and special consideration was taken around these potentially vulnerable study populations. The research team has worked with these communities for many years on research on Lassa fever, and had thus previously developed long-standing and strong relationships. In the rural villages, engagement took place along the same lines as described for the MalariaGEN Navrongo study: engaging traditional leaders first and then community members second. The university community was targeted through a seminar with a powerpoint presentation, and the hospital community was targeted through regular staff meetings and a meeting of the Nurses’ Union. In all three cases, community engagement served as a means to identify potential research participants as well as a means to engage and receive feedback on the project. Key messages were developed for the different components of the research project, such as for instance the fact that the project involved genomic research, the reasons for targeting that particular ethnic group and the relation of the project to the wider 1000Genomes project. The researchers put a lot of emphasis on the creation of cell lines and that these would live ‘in perpetuity’. All community engagement materials were developed in consultation with the local communities in order to be culturally appropriate. The team brought experts from the Harvard School of Public Health Quality Improvement Program on site during the first week of the collection to observe community engagement activities to ensure they met both the local and US ethical standards.

8.4 1000 Genomes: Sierra Leone

By contrast, the 1000Genomes Sierra Leone project did not present as a stand-alone project but was embedded in the broader engagement activities for studies on Lassa fever ongoing there. In this case, engagement activities did not only describe the research project, but were also used to share information about disease prevention and control with the communities. Because the community engagement activities in these projects were of long duration, the CE team had a good understanding of which communities were open to research collaboration, and this helped the researchers plan their project. Community engagement in this case followed what now seems to be the accepted format to working in traditional African villages: the first stage

² Our sincere thanks to Professors Pardis Sabeti, Christian Happi and Robert Garry for making available their community engagement resources for 1000 Genomes collections in Nigeria and Sierra Leone. This text is based on their fieldguides “Nigeria Trio Enrollment Guide” and “Sierra Leone Outreach Activities” which they made available to the H3Africa Working Group on Ethics and Regulatory Issues. The text was approved by all three scholars.

was a consultation with the community leaders to gain access to the community. This was followed by a community meeting during which the researchers present their projects, and community members ask questions, give feedback and so forth. There was no particular emphasis on the creation of cell lines. As in Nigeria, all community engagement materials were developed in consultation with the local communities in order to be culturally appropriate.

8.5 H3Africa Genomics of Schizophrenia in South Africa

The Genomics of Schizophrenia is a H3Africa project involving the Xhosa people South Africa. A project-specific community engagement mechanism was developed for use throughout the project. The main aims of the community engagement activities for this project were threefold: firstly to ensure that the project was presented to participants in a culture-sensitive manner that respected how these participants might conceptualize mental health, illness and schizophrenia specifically. Secondly community engagement aimed to gain the community advisory board members' input on the development of relevant information and informed consent materials for the study that clearly and accurately explained its scientific and methodological elements, and the development of linguistically and conceptually appropriate Xhosa language versions of this material. Finally, community engagement aimed to manage the potential for the stigmatization of communities, community members, their families and study participants. Regular feedback and engagement meetings with the community advisory boards will serve as a means to monitor the impact of the study in the community.

Considering these aims, selection of community advisory board members focused on identifying individuals within the community catchment areas targeted for data collection. Specifically, the project targeted individuals who had lived experiences either as patients diagnosed with schizophrenia or as family members, care-givers or community volunteers working with patients diagnosed with schizophrenia. The project also approached clinicians working with patients diagnosed with schizophrenia in state hospital contexts, and hospital facility board and advocacy group representatives. Careful initial contracting outlined the specific aims and expectations of the community advisory group as well as the time demands of the group and financial compensation for travel expenses to and from meetings. Continued engagement will focus on the informed consent process and managing the risk of stigmatization.

9. Feedback to the Working Group

These guidelines are work in progress and will be adapted as new insights are generated. We would like to receive feedback from H3Africa investigators about their usefulness, and also to share relevant community engagement experiences and lessons learnt. Comments can be sent to Dr. Jantina de Vries at jantina.devries@uct.ac.za.

10.Key References and resources

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