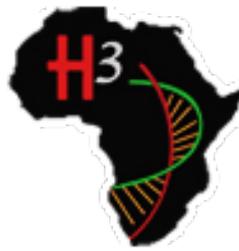# H3Africa Guidelines for Community Engagement (Version Two)



Developed by the H3Africa Community Engagement Working Group for the Human Heredity and Health (H3Africa) Consortium

September 2017

# 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, trypanosomiasis 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, while others are similar to those raised elsewhere in the world.

One of the key ethical challenges in African genomics work relates to how communities are involved in it. Over the years, community engagement has emerged as a key area in developing best ethical practice for researchers involved in H3Africa. In response to this, the H3A Community Engagement Working Group (CEWG) was established in 2015 to support the implementation of CE activities across the consortium. To get a deeper understanding of how the concept and practice of CE is practically implemented within the H3Africa consortium, the CEWG also conducted a study to map CE activities within H3Africa. This exercise enabled us to identify the expertise, needs, challenges and opportunities for engaging communities in genomic research on the continent. The project followed an initial literature review that aimed at identifying examples of effective CE models, approaches and models that can support genomic studies *(Tindana et al 2015)*. In March 2016, the CEWG organised a workshop to examine best practices for CE within the H3A consortium and to identify methods for evaluating CE *(Tindana et al 2017)*.

The current revised guidelines draw on insights from the literature review, the mapping exercise and the CE evaluation workshop to guide researchers in developing their CE activities. We draw on experiences from the first phase of H3Africa projects which were carried out between 2013 and 2017 and insights on what constitutes best ethical practice. We have included new sections to highlight the need for trained and dedicated staff to support projects' CE activities. To respond to growing expectations for feedback from target communities, we have included some key points to consider for community and group feedback.

# Acknowledgements

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# Contents

# 1. Defining Community and Public Engagement

Community engagement (CE), 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 consulting with gatekeepers of the community, soliciting the views and inputs of community members prior to, during and after research, feeding back research findings, to building partnerships with the community. Methods of engagement range from informal to more formal activities including those of longer duration. Community advisory boards (CABs), for example, may be established to facilitate communication between the research team and the community to provide insights on language, culture and context specific factors that will impact on the research process.

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 encapsulates people not directly involved in research. 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. Engagement activities can be built around a specific research project, around a research field (such as 'malaria research') or around all research taking place within an institution. The boundaries between community engagement and public engagement are diffuse, however, and activities may overlap depending on the goals of the engagement.

Community and public engagement are deeply contextual. What is appropriate depends on where research takes place, the nature of the project that is being carried out, the goals of the engagement, 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.

These guidelines do not refer to Community-Based Participatory Research or more generally 'community involvement' to designate research done by or with community members (see for instance www.invo.org.uk/).

## 2. Key Features of Genomic research

Human genomic research is similar to medical research in many respects:

- it involves human participants
- focuses on research questions that are relevant to health
- often involves people who 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. Genomic 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. It could involve any of the following

after education about the topic is provided and informed consent is obtained:

- Samples are collected from patients but also from healthy volunteers. It can be difficult to explain to people why this is the case;
- There is seldom a direct benefit for participant involvement or the broader community that participant may represent, raising important questions about reciprocity for sample donation.
- 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;
- We are unable to foresee how the science of genomics research will develop in the future, creating considerable uncertainty about how samples will be used for future research, raising important questions about consent
- Genetic and genomic information reveal something about the likely health of an individual, and in very few cases can identify conditions that the individual will suffer from at an older age (such as Huntington's). However, there is uncertainty about how best to manage feedback of 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. Although this raises important questions about the potential for discrimination and stigmatization of that population based on genomics findings.

## 3.   Why engage the community in genomic research?

CE 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 the integrity of the researcher and can demonstrate respect for the values, culture and traditions of the community involved in research. The Instrumental value of CE is supporting the informed consent process, managing potential research-related risks that may arise and facilitating access to the target community.

- CE provides a valuable platform for identifying and managing potential research-related risks posed by genomics research. On a macro level, this may include the risk of exploitation of local research teams and the target communities, within local settings it may focus on ensuring adequate informed consent and negotiations around benefit, reciprocity between the local research teams and the target community. Within the community, CE may focus on protecting against the risk of stigmatization and discrimination.

- CE can be a means of ensuring communities are actively engaged in protecting their rights and interests.  It is a prerequisite for avoiding exploitation.

- CE is also an important step in determining the (health) needs and expectations of the community relative to the research project, ensuring that there is an opportunity to consider whether and how these could reasonably be met within the scope of the project.

- CE, when done properly, provides an opportunity for communities to gain more information about genomic research, its benefits, costs, and its implications for their society. It allows for the development of strategies for mitigating harmful consequences, such as stigma that might arise from findings of genomic research. It also provides opportunities for community members to determine if and how they want to be described or represented in research findings, allowing community members to be stakeholders/ decision makers rather than passive recipients or participants in genomic research.

- CE may also have instrumental value, in helping researchers design more culturally appropriate studies and study tools. For instance, CE 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.

- CE also helps address anxieties of and myths about blood sampling and related study procedures. Most importantly, it helps build trust between the research team and research participants. Trust is particularly important when ethical issues arise, and it is necessary to engage communities in order to solve these issues. Communities who understand and trust the research process will be more able and willing to assist when myths and misconceptions about research or a specific study occur.

- More formal community engagement structures such as 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.

- CE 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 in epidemiological research. Increasingly, genomic research is embedded in such long-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, CE may be required by research ethics committees, national research guidelines or research funding agencies.

CE efforts for genomics should include some consideration of the above and 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;
- How community expectations and benefit sharing should be negotiated
- Whether data and sample sharing are appropriate, and under what conditions;
- Issues around return of research 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.

# 4. Designing an engagement strategy - Key points to consider
- Define the goals of engagement
- Define the target community and/or public
- Identify strategies and methods of engagement
- Train dedicated CE personnel
- Discuss and address community expectations
- Anticipate and address CE challenges

## 4.1 Define the goal (s) of engagement
The first and essential step in developing an engagement strategy is to define the goals of engagement – in other words, why the need to engage. It is important to recognise that community engagement is an ethical requirement for some research projects and some research ethics committees. Research funders may require a description of your community engagement goals and strategies in the research protocol or grant application. The goals of engagement may include: to better understand the community, its members, and needs; to secure support of the community for the research project; to improve understanding of the research project and/or 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 being implemented. In other words, before engaging the community, there is a need to identify what the community input will be – whether it is to do with the project being envisaged, or the fact that it is genomic research, or perhaps some aspects of genomic research such as sample and data sharing.

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.

Once the goals for engagement and the intended message to the community are clearly set one is able 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 Define 'the community' or 'the public' in research
There is no standard definition of community. What counts as 'community' in a research project is dependent on the nature of the research, the participants who will be enrolled, the social and political

context and the goals of the engagement activity. Various 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 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 – in other words, "community" is dynamic. For instance; a community could be members of a patient group living in a particular area, such as the diabetes association of a particular region or country.

In addition to potential participants, 'the community' could also include patients' families and care givers, 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 first phase of H3Africa projects, many projects combined a disease-based definition of community with a geographical definition, i.e. targeting people in a specific geographical area. For instance, one project used the definition of 'Patients suffering from Kidney Disease, living within Accra and Kumasi in Ghana'. Other projects used only a geographical designation and defined community as 'individuals in the study catchment area who are involved in or affected by the study'. This definition included study participants (mothers, fathers and the study child) and their families as well as local stakeholders (provincial government healthcare workers and managers) involved with the clinics and hospital where the study operates.

## 4.3 Identify strategies, models and methods for community engagement

Once the target community and its geographical location are determined, then one can start mapping out specific activities to meet the engagement 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 engagement strategies 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.

**It is important to note that community engagement strategies may be combined to strengthen the impact of engagement.** Moreover, many longer-duration community engagement programmes use various kinds of short interventions to build relations with community members. H3Africa researchers have been quite innovative in their approaches, and have used, for example, comic books, pictographs, videos, theatrical engagement, and social media to engage their target communities. Below we list some existing engagement methods that could be adapted to specific projects or contexts.

**Consulting gatekeepers of the community:** This can be done, first, by organising a series of meetings with gatekeepers of the community such as chiefs, local administrators, elders, community

representatives, opinion leaders, religious leaders, youth groups, women groups and the like. In some settings, these initial meetings are a necessary requirement for gaining access into the community and approaching individual community members (Tindana et al 2011). These consultation processes could also help to identify other relevant groups within the community, to learn about issues and concerns that the community might have about the study, including seeking specific advice on the cultural context that may be relevant to the implementation of the study such as recruiting participants or seeking 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 meetings with various 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, teachers at the local school, a leading business person or other individuals with influence in the community. 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. Methods may include key informant interviews or field notes.

**Community meetings:** Another engagement strategy could involve organising public meetings with members of the community. Strategies could include small group meetings or focus group discussions with specific groups within the community such as patient associations, women groups, or 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 (example Navrongo AWI-Gen project which focused on cardiometabolic diseases). 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 guide the way the study is conducted, for instance through changes to the consent documentation or the process of enrolment. Approaches to community meetings may include informal notes or focus group methodologies.

In some cases, investigators may choose to conduct a community survey to assess personal or cultural values, knowledge of information relevant to the research being conducted, and concerns that may affect the implementation of a study.  Implementing a community survey requires the design of a survey questionnaire that adequately assesses the issues addressed.  It also requires the capacity to statistically analyse data collected. For example, the H3Africa Stroke Investigative Research Network (SIREN) conducted focus group discussions with stroke survivors and their carers; community stakeholders and community advisory board members which informed their community engagement strategies.

**Community advisory boards (CABs):** Projects could also set up community advisory boards in which several 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 consider a range of key stakeholders that may include patient advocacy groups, treating clinicians and patients themselves and their families 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. Several H3Africa projects have established CABs to support their CE activities. In some instances, it may be helpful to include members of the research team such as recruiters, during CAB meetings. One

H3A project, the SAX study, found this a particularly helpful way of problem-solving difficult ethical challenges on the group during recruitment (see Campbell et al, 2015).

However, investigators are advised to carefully consider community advisory board membership to ensure that constituents are able to fulfil these roles, as well as the power dynamics that might exist within the groups and influence the community engagement process (e.g gender balance). 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, NGO or advocacy group representative who has insight into the experiences of patients living with the illness or disease.

## 4.4 Trained and dedicated CE personnel

Experiences from the first phase of H3Africa projects have highlighted the importance of having trained and dedicated CE personnel to carry out the project's engagement activities. In multi-centre studies, this may require establishing a core CE team with representatives from the collaborating research sites.

Depending on the extent of engagement and the size of the project, projects could explore setting up a community engagement team comprised of a liaison officer, communication and/or health communication officer, social scientists, and the researchers themselves. Other study staff, including field workers, research nurses and study coordinators can also play a role in facilitating community engagement.

Effective community engagement requires a unique skill set that needs to be developed and nurtured. Skills need to include knowledge of qualitative and quantitative methodologies and knowledge of specific strategies for working with communities and building Community Advisory Boards. Community engagement skills training should be developed and made available in the context of H3Africa research projects.

## 4.5 Discuss the role and expectations for community engagement

It is advisable to clearly discuss the roles and expectations of both the research team and the community members, the extent of the engagement process and any remuneration 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 in the research process.

## 4.6. Anticipate and address 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 target communities such that they can agree to engage and maintain their involvement with the researchers.
- Community engagement is time-consuming and needs to be planned carefully and be appropriate to the research and also affordable within the grant.
- If not started early, community engagement may delay the start of a project.
- The aims of community engagement may sometimes be in conflict 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 genomic 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.
- CE is often not prioritized in planning and budgeting processes within many research projects. Costs for CE 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 included in the initial budget.
- Negotiating power dynamics within the group, expectations about the role of the group and balancing realistic project outcomes with the needs of the community.
- One H3Africa project which used the CAB model reported that even though the CAB provided an important space to discuss ethical challenges arising from the project, not all the recommendations made by the CAB were deemed appropriate. In some cases, CAB members were unable to provide appropriate recommendations for resolving ethical challenges arising from the project.
- Other projects also reported that many communities expect that the results of these projects will be shared with them, particularly individual health-related results. The challenge is how to address these expectations and whether there is an ethical obligation to provide these results to participants. Decisions to feedback would be project specific and should be thought about early on so that expectations can be managed.

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.

## 5. Using Community Engagement for Group/Community feedback

Community engagement is recognised as an important process for the ethical conduct of genomic research. It should not just be an event but a process that is conducted prior to, during and after the research project. Whilst many projects in the first round of H3Africa conducted engagement activities at the start of projects and during sample collection, only few projects continued this engagement after sample collection has ended. Yet there is a real opportunity for community engagement activities to feed into research practice. For instance, on the one hand CE can be used to inform important or controversial issues around sample access and re-use (Tindana et al 2012; Emerson 2011). But CE can also be important in determining the appropriateness of returning research results, either to the group or to individuals. For instance, empirical ethics research in Ghana has identified that the feedback of generalised study results to communities is essential to maintain or promote communities' confidence

in the research process. Such confidence is necessary to ensure communities' ongoing participation in research, including in future research projects. Similarly, communities can assist researchers in deciding whether and which type of individual genetics research results should or could be fed back to participants. In this way, CE can help researchers articulate or fine-tune a 'return of results' policy that is informed by community concerns. This guide document highlights the importance of feedback to community and suggests some key points to consider in feeding back research results to communities participating in genomic research.

## 5.1.   Importance of feedback to communities

It is important to recognise that feedback to community is not just about reporting research results or findings but about sharing scientific knowledge. Feedback to community is important for the following reasons:

- Respect: Feedback to community is a demonstration of respect and acknowledging their important contribution to science.
- Beneficence: Feedback to Community is about sharing knowledge and that knowledge could help communities live healthy lifestyles which could contribute to positive health outcomes.
- Reciprocity: Giving back to the community.
- Building trust: Lack of feedback is likely to lead to mistrust in research and researchers.
- Sustaining relationships and supporting future research projects.
- Supporting broad consent; Developing a process for feeding back to the community as part of the research could also support the legitimacy of using broad consent as a model for genomics and biobanking.

## 5.2.   What to feedback

- At the community level, only aggregate data should be fed back.
- Feedback could also include sharing general information or new knowledge about the disease/illness being studied etc.

## 5.3.   Who should receive feedback

- Research participants
- Families of research participants
- Community leaders and gatekeepers
- Community advisory boards/patient advocacy groups
- Research Ethics Committees
- Policy makers
- *Other relevant health authorities*

## 5.4.   How to feedback

Community feedback requires teamwork and may involve some initial mapping exercise to determine what needs to be considered in the feedback process and how to tailor the process to the context.

- Establishing a team of well-trained communicators or CE practitioners with knowledge and understanding of genetics/genomics will be desirable. This team could include researchers, health professionals as well as well-trained language translators

Some of the useful strategies that could support the feedback process could include the following:

- Developing information leaflets on the key findings of the research and their implications
- Organising meetings with key stakeholders including community gatekeepers

- Engaging with science journalists
- Utilising radio and television programmes

# 6. Measuring the impact of Community Engagement Strategies

The H3Africa Community Engagement Working Group (CEWG) has made a compelling case for a science of community engagement for H3Africa projects (Tindana et al 2017). Once the community engagement strategy is developed – involving the identification of the community, clearly defining the objectives and goals 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 led to greater comprehension of the study, addressed key research-related risks such as potential stigmatization, respect for culturally and traditionally specific beliefs about the illness under investigation, and increased the opportunity for community members to articulate concerns.

CE involves a complex set of interventions with important social elements which generally makes it difficult 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 (e.g. community understanding) are difficult to measure. For these reasons, researchers may learn more about their CE work by careful monitoring of processes over time rather than focused measurements towards indicators identified at the start. Since CE 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 CE is actively monitored during the course of a study. One important step in the evaluation of CE activities, however, is by critically revisiting the objectives of the community engagement strategy from time to time – were these relevant? Did the engagement activity successfully engage community members on these issues? Were community perspectives considered as 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 theoretical frameworks and models from disciplines such as health systems research (e.g.: 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; how many people used the educational tools that were developed by the research team;
- 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. bringing together 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 the form of a questionnaire sent out that utilizes a rating scale type of question, or a more open-ended response format.

# 7. Feedback to the Working Group

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. Paulina Tindana (ptindana@gmail.com)

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