



# **H3Africa Guideline for Informed Consent**

Developed by the H3Africa Working Group on Ethics and  
Regulatory Issues for the Human Heredity and Health in Africa  
(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 tools and data to address health inequities in both communicable and non-communicable diseases. Initial H3Africa projects – funded from 2012 onwards – have ended or are about to be finalised, and the Consortium is currently entering Phase 2. Globally, genomics research raises a host of ethical issues. Some of these issues are unique to African countries and related to the different contexts, belief systems and places where the research is conducted. The H3Africa Working Group on Ethics and Regulatory Issues, which is composed of representatives from each of the H3Africa funded research projects continues to consider and provide guidance needed to address the ethical issues in the H3Africa projects.

One of the ethical challenges in genomic research, which H3Africa investigators have encountered relates to informed consent. Obtaining informed consent for genomic research is challenging for many reasons, regardless of whether the research is conducted in Africa or elsewhere. Challenges are, for instance, how to explain complex biomedical concepts like ‘genomics’, but also how best to permit use of genomic data (and, increasingly, genomic material) for secondary analyses by investigators who were not involved in the original project, while promoting respect for participants’ say on such uses and benefits to them. In this regard, such uses may mean that it is in principle not possible to withdraw consent once the sample or data have been committed beyond a certain point. For instance, once data have been used in a publication, those data cannot be withdrawn from that publication. In the context of sample and data sharing, it may therefore no longer be appropriate to seek consent for specific projects only. As sample and data sharing are foundational principles of the H3Africa initiative, we have elected to adopt broad consent (defined herein) for genomic studies as a starting point for the guidelines presented in this document.

In the African context, the challenges with consent are further amplified by the fact that a considerable proportion of the potential research participants may have received only basic education, live in rural areas, have limited access to healthcare, or be poor. In addition, for some cultures and communities in Africa, the Western focus on autonomy (and, therefore, individual informed consent) may not resonate with a more communitarian worldview observed in these settings – thus, obtaining appropriate informed consent in these settings is best achieved when preceded by thorough community engagement. For those whose inadequate access to education left them with limited literacy skills, verbal and other types of recorded consent that may be acceptable remains a topic of academic debate. For this reason, it is important that the development of a consent process is informed by a wider community engagement effort aiming to meaningfully engage with prospective research participants and their communities to identify and discuss the ethical aspects of the research.

The current guideline draws on experiences gained in Phase 1 of H3Africa projects. Specifically, this Third Edition takes into account the kinds of consent models used in Phase 1 H3Africa research {Munung, 2016 #1743}, empirical evidence relating to their effectiveness {Masiye, 2017 #2416}{Marshall, 2014 #1616;Rotimi, 2010 #1107;Rotimi, 2007 #159;Marshall, 2006 #1105}{Tindana, 2016 #1736}, the views of research ethics committees on the use of broad consent {De Vries, 2016 #1730;de Vries, 2015 #1673;Ramsay, 2014 #1629} and any regulatory obstacles that may prevent the use of broad consent in Africa {de Vries, 2017 #2384}. The purpose of these guidelines is begin to set standards and to promote best practice, where this currently exists. Where appropriate, the guidelines have been designed to make allowance of regional differences. Africa, after all, is a continent, which is home to thousands of different population groups with widely varying customs, languages and beliefs.

## Acknowledgements

This Third Edition of the H3Africa Informed Consent guideline was developed to provide more current guidance to H3Africa researchers in developing their informed consent processes and documents. It builds on the previous editions adding what is now known since the last edition released in 2014. Specifically, it provides more details on broad consent and governance issues and provides mechanisms to promote and improve understanding of informed consent among populations with limited comprehension capabilities due to their stage of development or associated health conditions. The H3Africa Ethics & Regulatory Issues Working Group is appreciated for developing this revised document. Special thanks is extended to the following members of the Working Group Aminu Yakubu, (Chair) Give new affiliation, Nigeria, Paulina Tindana, Navrongo Health Research Centre, Ghana, Jantina De Vries, University of Cape Town, South Africa, Megan Campbell, University of Cape Town, South Africa, Nchangwi Syntia Munung, University of Cape Town, South Africa and PABIN, Cameroon, Katherine Littler, Wellcome Trust, UK, Patricia Marshall, Case Western Reserve University, USA, Himla Soodyall, NHLS and University of Witwatersrand, South Africa, Janet Seeley, MRC/UVRI Uganda Research Unit on AIDS, Uganda, Ebony Madden, National Human Genome Research Institute, USA, Sheryl McCurdy, University of Texas-Houston, USA, Vincent Pius Alibu, Makerere University, Uganda, Laura Rodriguez, NIH National Human Genome Research Institute, USA, Jennifer Troyer, NIH National Human Genome Research Institute, USA. The development of this document would not have been possible without the generous support of the National Institutes of Health USA and the Wellcome Trust foundation, UK who both provided logistics to ensure that the necessary meetings and consultations were held to inform the document.

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## Introduction

The Human Heredity and Health in Africa (H3Africa) Consortium is a collection of cutting-edge research studies and infrastructural and educational capacity building projects that continues to generate insight into the contribution of genomics to communicable and non-communicable diseases, train African investigators in genomic science and create or expand existing genomic infrastructure in Africa. It is currently entering its second phase of funding, which is likely to last until 2022. Of key importance in this project, is the need to obtain valid consent from participants. Drawing on existing national and international guidelines as well as experiences of the members of the H3Africa Working Group on Ethics, this document is intended to help H3Africa investigators in designing consent processes and associated documents for H3Africa genomic studies. In this document, we suggest what kinds of information should be covered in the consent process, give examples of how to explain key concepts of genomic research, discuss how consent documentation relates to the process of obtaining valid consent, and propose methods of evaluating the quality of the informed consent process. Specific guidelines for community engagement in genomics research in Africa are also available on the H3Africa website, [www.h3africa.org/consortium/documents](http://www.h3africa.org/consortium/documents).

H3Africa studies are being conducted in many different research settings, including but not limited to rural settlements, village clinics and secondary or tertiary hospitals in urbanized settings. Prospective participants may be educated and well-informed – for instance where research takes place in large urban hospitals – or they may have only received very basic or no education and have limited access to healthcare or modern media. Genomic studies require the collection of samples and data from both patients and healthy people. This can be a challenge especially when the collection of blood samples is associated with disease and treatment. H3Africa investigators will need to design consent processes that are appropriate for each of these settings and target populations.

The purpose of this revision is specifically to draw insights on best practices from the 1<sup>st</sup> round of H3Africa projects and to guide investigators currently designing consent materials for participant recruitment in genomic studies.

In this version, most importantly broad consent has been emphasized as the default form of consent for all H3Africa projects and in support, provided more context and conditions for its optimal application. This is because we believe it is the most practical form of consent that would facilitate sample and data sharing, which are at the heart of genomics research world-wide. We have however also emphasized the role of the H3Africa Data and Sample Access Policy in further supporting broad consent in way that it provides optimal protection for research participants. The section on designing informed consent has been further broken down into sections to provide

improved clarity with the addition of a sub-section talking about other aspects of informed consent, like consultations with gate-keepers, seeking permission from authorities etc. Practical examples on ways to design informed consent in order to improve understanding have also been cited from two H3Africa 1<sup>st</sup> phase projects. Considering the need to ensure valid consent for some populations that may have difficulty in comprehension for one reason or the other, we have included one section that talks about the need to pay attention to these populations, and another section that encourages researchers to evaluate their informed consent practices in some of these situations in order to identify ways to improve comprehension in the process. Lastly, sample informed consent templates from some of the 1<sup>st</sup> phase projects have been provided so they can be easily adapted for use by H3Africa grantees where necessary.

It is believed that these few additions and changes would be found very useful by the H3Africa grantees in designing their project-specific informed consent processes and documents. This would contribute immensely towards promoting the ethical implementation and achieving the goal of the H3Africa initiative.

## **Key characteristics of H3Africa studies relevant for consent**

All the H3Africa studies share some characteristics that are relevant to the consent process. These are:

- I. The projects are primarily genomic research studies. Although the various studies may also involve other research components – for instance, some studies may integrate genomic methods with an epidemiological study design – H3Africa focuses specifically on genomic research. This means that the main risks for genomic studies tend not to be related to study procedures per se, but more to issues like privacy and confidentiality of the personal information collected or generated. Genomic information is unique to individuals and there is always a theoretical risk that participants could be identified if additional genetic information for the person is also available in the public domain. The likelihood of this happening can be reduced if safeguards are in place, but even so, absolute guarantees of confidentiality cannot be made;
- II. In addition to samples from people who are suffering from the disease under investigation, the projects need to collect samples from healthy volunteers as controls. Because in many settings across Africa, the collection of a blood sample is associated with disease and treatment, this could raise concern – especially if the consent documents speak of a disease that the person does not currently have;
- III. As is true for all genomic and genetic studies, genetic material is shared by genetically related persons and so information from one individual may also identify or be relevant to



their biological relatives or even community members. Consent is usually obtained only from the individual, however;

- IV. H3Africa research studies will share phenotypic and genomic data for secondary analysis. This means that although samples may be collected for a study on a particular disease, the genomic data may be analyzed for many different diseases. Also, the data may be analyzed to look at population differences or to test new tools for analyzing genomic information. The consent information and processes need to make this clear to potential participants;
- V. Samples from many of the H3Africa research studies will be deposited in H3Africa biorepositories for secondary use. These repositories are located in Uganda, Nigeria and South Africa. When samples are deposited in the biorepository, they can be used for other research in the future, including research on other diseases. NIH-funded studies are required to deposit study samples in an H3Africa biorepository and consent therefore needs to be obtained for this. Although this is not a requirement of funding for the Wellcome Trust, the Wellcome Trust is supportive of this policy as it will facilitate research in Africa in the future. WT funded investigators should consider seeking consent for sample sharing and deposition in an H3Africa biorepository (subject to national legal requirements) as well.

## **Informed Consent Models – Broad Consent**

Over the course of H3Africa Phase 1, conceptual thinking about the appropriateness of different consent models that can be used for genomics research have evolved considerably – largely related to the ethical permissibility of collection and storage of specimen for future research uses, as well as the consent that ought to support the actual use of the specimen in the future. Current consent models range from specific consent requiring consent for each research use, to broad consent that gives permission for unspecified future research use of stored biospecimens or data with some restrictions {Grady et al, 2015, Tasse et al 2010, Salvaterra et al 2008}.

### **a. Broad Consent**

Broad consent means that consent is not project specific, but allows the storage and use of samples and data for secondary research projects with content and process restrictions (Grady et al 2015). ‘Content restrictions’ can describe the kinds of future studies that may (not) be conducted with the data – for instance, samples may only be used for health-related research, or for health-related and population research. ‘Process restrictions’ relate to restrictions to the process by which samples and data were collected or will be made available – for instance, H3Africa samples will only be made available to researchers who have received permission from the H3Africa Data and Biospecimens Access Committee (DBAC).. In this sense, broad consent is different from ‘open’ or ‘blanket’ consent, which is consent for absolutely any research project.

Tindana and De Vries explored empirical evidence relating to the use of broad consent for genomics research in Africa (Tindana and De Vries 2016), and concluded that whilst there are no a priori reasons to prevent the use of broad consent for genomics research in Africa, it is important that samples and data are shared in the context of a robust governance framework that should seek to promote global health and research equity and take into account five key elements: respect, authentic community engagement and trust building, the preservation of privacy and confidentiality, feedback of results, and capacity strengthening. More recently, Bull (2016) argued that data sharing should be 'equitable', meaning that it actively acknowledges and seeks to redress existing power imbalances between researchers in higher- and lower and middle income countries (Bull 2016).

In this guideline, broad consent is put forward as the preferred and recommended consent model for H3Africa studies for a number of reasons. First, it allows for the sharing of biospecimens and genomic data with other researchers. This is considered the most efficient way to ensure that they are used to further the science that is required to better understand and potentially develop means of addressing diseases that affect African populations better. Second, because it is not 'blanket' consent, it is a transparent means of seeking the permission of research participants to have a say in the use of their data/samples for future research of their interest. Third, broad consent now is considered acceptable only when it is accompanied by an arrangement (governance arrangement/framework) that ensures that data and specimen are shared only when the proposed future research agrees with the consent given by the participants. Some of these arrangements include having some form of committee/procedure for approving requests for use of data or samples; and also ensuring that an ethics committee, which also ensures among others, that proposal to use the data/samples are in line with initial consent given, approves all such studies. Considering these safeguards, the use of broad consent is no longer considered to erode participant autonomy and/or protection per se {Grady, 2015 #1691} but could be considered as 'consent for governance' {Tindana, 2016 #1736}{Sheehan, 2011 #2454}. When it is used in conjunction with genuine community engagement and a clearly articulated governance framework as highlighted previously, it is possible that broad consent may strengthen participant protection {Grady, 2015 #1691}. Furthermore, the use of broad consent appears to be either passively permitted or specifically recommended for research in all but three African countries {Barchi, 2016 #2455}{de Vries, 2017 #2384}.

For these reasons, the WG recommends that H3Africa researchers use a broad consent model when enrolling participants in genomics studies or biobanks, except where it is legally not permissible or there is a supporting ethical argument that it would put the participants at a greater risk of harm. H3Africa has got a Data and Sample Sharing Policy ([link](#)) that provides the governance mechanism that will ensure adequate protection of participant choice in re-use of sample and

secondary research using stored data. The policy describes the Data and Biospecimens Access Committee, which will consider the content of the consent form (and thus the permissions that participants gave when their samples were collected) when allowing other researchers access to stored data and samples for future studies. There is also the “Ethics and Governance Framework for Best Practice in Genomics Research and Biobanking in Africa”(link) developed by the H3Africa Consortium in collaboration with other stakeholders, which is a guide to help countries and institutions in Africa to develop their own governance mechanisms outside the H3Africa project.

## **b. Tiered Consent**

Some researchers have argued that broad consent adopts an all-or-none approach, sort of coercing participants to enroll in the primary study and agreeing to sample sharing for future use at the same time. A practical way of addressing this concern is through a layered or tiered approach (first seeking consent for the primary study, and then for sample sharing). One approach might be to develop two separate consent documents. Another might be to add a tick box to the consent documents to indicate whether people would/would not like their samples stored for future research. If investigators decide to follow this option, however, they need to develop a good management plan to ensure that the participant’s choices are respected. This may be technologically or practically difficult, and people need to carefully consider the implications before deciding to use a layered consent approach. Another option would be to seek broad consent with permission to re-contact a participant if there is ambiguity about an intended use, or to indicate that secondary access requests will be reviewed by the local ethics committee. At all times, it is important that participants know how to contact the investigators should participants reconsider their decision.

An example of a tiered or layered consent option is the following:

***“Tick the option you choose:***

*I do not want my sample to be shared with other scientists.*

***OR***

*My sample can be shared with other scientists for research in a field related to [describe the field of your study, e.g. cardiovascular research].*

***OR***

*My sample can be shared with other scientists for health research in any field.”*

## Developing the informed consent documents

### a. Designing the documents

Consent documentation<sup>1</sup> normally consists of a) one or more information leaflets or sheets, and b) a signature sheet. In these guidelines, we refer to these together as ‘informed consent documents’. Consent documents should be written in clear, simple language that can be understood by the research participants. When developing the consent documents, it is important to think about the likely literacy and health & research literacy levels and understandings of ‘disease transmission’ processes of the research participants, and try to tailor the consent document appropriately. Ideally, consent forms should be piloted for comprehension and adjustments made as necessary.

Consent documents should be translated into a language that the research participants understand and metaphors and phrases applicable to the context should be used to convey information about the research project more clearly. In certain parts of Africa, this may sometimes be a challenge, for instance when the vernacular language is spoken, but not written. In some cases, people may prefer to read the English language consent document but to have the study explained in their own language because their own language is not normally put in writing. Also, some African languages may not have words for concepts like ‘data’, ‘research’ or ‘genomics’ but they could be explained using analogies. Most, if not all cultures will have some understanding of the concept of “inheritance” and genomic scientists should explore how communities or population groups refer to the heritability of traits. In some cases, investigators might like to explore alternative means of communicating with participants about the study. Examples include developing a video or film about the project that potential research participants can watch prior to the consent process, or developing a cartoon about the study. Both of these have been used for medical and genomic research in a variety of African and other settings and specifically in phase 1 of the H3Africa projects.

*Colleagues at Centre for Medical Ethics and Law, Stellenbosch University, developed a 13 minutes video called “[Biobanking and Beyond](#)” used to illustrate the entire process of participating in research highlighting the consent process and rights of donors regarding the sharing and continuing use of their biospecimen. ([youtube link](#))*

*The Collaborative African Genomics Network (CAfGEN) project also developed a comic book series as part of its “Genome Adventures” community outreach initiative. Also titled ‘[Genome Adventures](#)’, the comic book series, which is in four parts illustrates in a fun way, the informed consent process highlighting how information is provided around*

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<sup>1</sup>In this document, we refer to ‘consent documents’ to describe all and any documents developed for use during the process of seeking consent. This normally includes a participant information sheet (sometimes also called an information brochure or leaflet) and a signature sheet (also called the consent record form, consent form or something similar).

*the various elements of the informed consent in order to foster research enrollment in a HIV-TB genomics research. The books are now translated into four local languages that are widely spoken in various African Countries – Setswana, Swahili, Luganda, Arabic and Hausa, in order to have a wide reach.*

Usually, field workers and study nurses understand a lot about what participants prefer, what they already know, what they are likely to understand and so forth. It is very important to involve field staff in the development of consent documents. Others, like community gatekeepers and representatives, could also be asked for input at this stage – most feasibly through a process of community engagement (see H3Africa Guidelines for Community Engagement for more information about this process). You can determine for instance, whether people are likely to be able to read a form written in the vernacular, whether they are already familiar with concepts like inheritance, what challenges they usually encounter when seeking consent, what analogies can be used to explain scientific concepts and so forth. This information should be used in developing the consent forms for your study.

Lastly, it is important that the layout of consent document(s) is clear and the content is provided in a concise manner. A confusing layout (for instance, small font and/or margins or many titles that are underlined) can make it difficult to read and follow the information in it. Local and national research ethics committees may have their own guidelines as to how to structure the consent documents and these should be followed as much as possible.

Once the consent documents have been developed and approved, it is important that those who are going to seek consent (such as nurses and fieldworkers) are provided with adequate training. Training should focus both on how to obtain valid consent (why is it important, what are the challenges and so forth), and on key scientific aspects of the project to enable them to explain the project to participants or respond to questions.

A few things to avoid if possible in the consent documents:

- Professional jargon
- Underlining or italicizing large blocks of print
- Capital letters for titles or long pieces of text
- Use of acronyms
- Confusing layout.

## **b. Information for inclusion in H3Africa consent documents**

There are many international guidelines available that detail the content of consent documents. Examples of such guidelines are those provided by the Council for International Organizations of Medical Sciences (2002; 2017), the World Medical Association (2013) and the International

Conference on Harmonisation (1996). Some consent elements are required by local laws, regulations, or other guidance in the country where the research will be conducted. Where this is the case, then H3Africa projects need to include these elements in their forms.

**Broad consent that allows “broad” access to data and samples is the default consent model for H3Africa Studies. All H3Africa consent documents need to make mention of data sharing. All consent documents for studies that are funded by the NIH need to seek consent for sample sharing, and this is also recommended for studies funded by the Wellcome Trust.**

Consistent with other guidelines, we strongly recommend that the following elements should be included in consent documents:

- A statement that the study involves *research*, an explanation of the *purposes* of the research, the *expected duration* of the subject's participation, a description of the procedures to be followed and the identification of any study procedures which are experimental;
- A description of the type of human biological sample to be collected, quantity and rationale
- A description of any reasonably foreseeable *risks* or discomforts to the subject;
- A description of any *benefits* to the subject or to others which may reasonably be expected from the research;
- A statement describing the extent, if any, to which *confidentiality* of records identifying the subject will be maintained;
- A statement that participation is *voluntary*, refusal to participate will involve no penalty or loss of benefits to which the subject is otherwise entitled and the subject may *withdraw* from the study at any time without penalty or loss of benefits to which the subject is otherwise entitled. Procedures for withdrawing should be given. It should be clarified that whilst *the subject* has the right to withdraw, samples and data that have already been distributed or analysed cannot be rescinded;
- A statement about *the nature of the project* and the fact that there will be *data* (and/or) *sample sharing*;
- An explanation of whom to *contact* for answers to pertinent questions about the research and research subjects' rights, and whom to contact in the event of a research-related injury to the subject. This should typically include names and institutional affiliations of local study staff and regulatory officials (where applicable).

Where appropriate, the following elements should also be included:

- Anticipated circumstances under which the subject's participation may be terminated by the investigator (but this may only be relevant where the genomic study is integrated in another study such as a clinical trial);

- An explanation of appropriate alternative procedures or courses of treatment, if any, that might be advantageous to the subject (only relevant where the genomic study is integrated in another study that involves an intervention for health purposes);
- The approximate number of subjects involved in the study;
- For research involving more than minimal risk, an explanation as to whether any compensation or any medical treatments are available if injury occurs and, if so, what they consist of, or where further information may be obtained;
- If relevant, any particular risks to groups that may arise as a result of a person's individual participation;
- A statement on the possibility that commercial products may be developed by others who use H3Africa samples or data.

Not all of the above elements may be relevant to all studies, and some studies may need to add additional elements to their consent documents for example the need for sample export and the rationale. Any other information that pertains to the study and that will be useful for the individual as he or she decides whether or not to take part in the study should be added to the consent document or provided orally at the time of consent if requested by the potential participant. Furthermore, an institution's Research Ethics Committee (REC) or Institutional Review Board (IRB) may require additional elements that are not specifically listed in guidelines or regulations to ensure that adequate information is presented in accordance with institutional policy and law.

### **c. Documentation of processes not included in the consent form**

Obtaining informed consent requires consultation with stakeholders and appropriate authorities and in a number of instances obtaining 'permissions' to consent the individuals for your study. It is typical for example, in an African setting to firstly obtain the permission of community/district chiefs to enter their community to conduct research. This may be part of an elaborate community engagement/consultation process, which is described in section 9 of this document. Investigators should always consider the need for obtaining permissions for entry into communities, households, or institutions. Where any of these is required, the information that will be communicated to the community leaders/or other authorities including heads of households for example must be documented and standardized. They must be part of the set of consent documents developed for the research and included in the ethics committee review application package.



## **Discussion of suggested elements for H3Africa research studies and sample language**

The excerpts with sample language provided here are relevant to H3Africa and genomic studies. Researchers are encouraged whenever their IC documents contains any of these elements, to ensure that the language they adopt, reflects the same or similar meaning and covers the essential issues provided herein.

### **a. Study title**

Try to come up with a short simple study title – avoid any words, acronyms or phrases that might be misconstrued. Ideally, the study title needs to be broad in order to address not only the primary study but also future research using data and samples collected by other researchers. Alternatively, you could have a lay title under the official title of your project. For instance, “Genomics of Disease X”.

### **b. Who are the investigators?**

For example: *“This study will be carried out by investigators from institution XX. We are working with other investigators in XX different countries in Africa to study [Disease ABC]. Our study is part of the Human Heredity and Health in Africa (“H3Africa”) project.”*

Note: it is important to mention the H3Africa Consortium in the consent documents, because most of the policies concerning data release, sample sharing and so forth will be developed at the level of the Consortium, not for individual projects.

### **c. Purpose and scope of the research**

Describe the problem that this research project is trying to solve. Also, describe the types of diseases or conditions being studied for which the samples and data may be used (including not only the initial study, but any possible future studies that may use the samples). Consider whether to specify a certain group of disease (for instance, cardiovascular disease or cancers) or to just say ‘other diseases’.

#### **Sample language:**

*“This consent form will tell you why we want to do this study.*

*As you may know, many people have [Disease ABC]. We hope to discover how some people get sick with this disease. We hope that one day we could make a medicine that may help us treat this disease. There is some information about [Disease ABC] among people who live in Europe and America. This study is the first time we will study [Disease ABC] in Africa.*

*In the future, the information and samples that you provide for this study may be used to study other diseases by other investigators. You will not get any benefit directly from this*



*study. But we hope that the information we get may benefit others who have [Disease ABC] in the future.*

*Please ask us questions about anything you do not understand or if you would like more information. We are happy to explain this to you more than once.*

*Please take whatever time you need to talk about the study with your doctor or nurse, the study staff, or your family and friends.”*

#### **d. What will the study involve?**

For example, will the participants be requested to provide a blood sample or provide medical information? What is the rationale for sample collection, what quantity. You should also give an indication of how long it will take to participate in the study. In the informed consent document, it is important to not deviate too far from the topic of study with unrelated examples to explain difficult concepts such as genetics or genomics. But on the other hand, you should also seek to make sure that all the necessary information a person might want to consider to make an appropriately informed choice, is present in the informed consent document.

##### **Sample language:**

*“We are asking to take XX ml of your blood – this is the same as XX tea/tablespoons. We will use your blood to study something called “genes”. These “genes” are present in all of us and are responsible for why people in families look like each other, but different from others. For example, some families are taller or shorter than others. This kind of information is passed from both the father and the mother to their children and on to their grandchildren, in other words, from one generation to the next. Some of these genes may prevent us from getting sick from condition XX in the first place. Some other genes may be one of the reasons we get sick when others do not.”*

Note that the use of cutlery to indicate blood quantities could reinforce ideas that blood collection serves purposes other than just research. You can also demonstrate the amount of blood drawn by e.g. filling a syringe or tube with colored liquid.

#### **e. What will happen to the samples?**

This section should describe the procedures that will happen to the samples – in as far as it is relevant for the participants to know. Where sample sharing is required, this section should also explain the plans to send the samples to a biorepository in Africa established for the H3Africa Consortium. It should also stipulate the biobank that samples will be sent to as well as make reference to the H3Africa biopspecimen and data sharing policy in the governance of access to stored samples. Note that it is currently not possible to include in the consent materials, a

complete description of the plans regarding the handling and access to samples as these are still under development.

One of the goals of the H3Africa biorepository is to make samples as widely available as possible to facilitate future research. Investigators should therefore consider seeking consent that is sufficiently broad to allow this, in as far as that is acceptable to research participants and research ethics committees or institutional review boards. A Data and Biospecimen Access Committee will govern access to H3Africa data and samples for secondary use. This committee will review merits of the secondary use request as well as risks involved as well as consent permissions for the data and sample being requested to ensure that access is provided in line with these. In addition, anyone seeking to use H3Africa samples for a secondary project needs to have obtained approval from the ethics committee at their institution.

The type of information that should be included is:

- That the samples will be coded so that all efforts will be made to protect the participants' privacy;
- Who will be the primary custodian(s) of the samples?;
- Who will have access to the samples (e.g., qualified investigators in universities, hospitals, government agencies, companies);
- How the biorepository will control and monitor access to the samples;
- The type of research that will be conducted. Broad or limited to the condition that they have given consent for;
- That the samples will not be sold, but that investigators may develop commercially valuable products based on studying the samples, and that if they do, participants will not be able to share in any profits ([http://h3africa.org/ethics\\_governance\\_resource-sharing.cfm](http://h3africa.org/ethics_governance_resource-sharing.cfm));
- What will happen with samples and data after patients die, and the effect of death on the right to withdraw. Options are for instance that this right is transferred to family members, or that it dissolves (meaning that samples can no longer be withdrawn when the participant dies).

The biorepository and data sharing policy is available on the website ([www.h3africa.org](http://www.h3africa.org)). Investigators must also carefully consider how (much) they will or need to explain about any possible commercialization, as this may deter participants from participating.

**Sample language:**

*“In order to do the research we have discussed, we must collect and store blood and health information from people like you with [Disease ABC]. We will do some of the tests right away. Other tests may be done in the future. Once we have done the research that we are planning for*

*this project, we would like to store your blood and information. We will store it together with the other samples that people have given from all over Africa as part of a big collection that is called a “biobank”. This “biobank” will be at Makerere University, Uganda, Witswaterand University, South Africa, or Institute of Human Virology, Nigeria. Scientists from all over the world can ask to use these samples for their research. Although the study you are being asked to participate in involves [Disease ABC], other scientists may like to use your sample to study other diseases. The samples will not be sold, but investigators may develop products based on studying your samples. If this happens, you will not be able to share in any profits.”*

## **f. Cell line creation**

The long-term goal of the H3Africa Consortium is to build capacity for the creation of cell lines from white blood cells. Cell lines can live in the laboratory indefinitely and will provide a resource for research in the future. Because cell lines replicate indefinitely, they provide a renewable resource of DNA, RNA and other cell products. It is not currently clear how the creation of cell lines will be perceived by African research participants, investigators and ethics committees, how best to explain this concept to research participants, and if people are likely to consent to this procedure. It is also not clear what kinds of concerns participants may have with the creation of cell lines. Further research will be required to investigate this. The creation of cell lines is not planned for the current H3A projects and seeking consent for this procedure is entirely optional at this stage.

If investigators ask participants for consent for the creation of cell lines from their white blood cells, the following language is suggested:

*“Your blood is built up of different things, including little things that are called cells. We would like to take some of these cells out of your blood. We will do something to your cells that makes them grow in the laboratory. We call this a “cell line”. With the cell line, we can always have access to some of your cells in the future, without asking for more samples from you. The kind of experiments we do may be related to [Disease ABC] but it is also possible that your sample will be used to study other diseases that affect people all over the world.”*

*With your permission, we would like to store your blood cells in a way that they last forever (scientists call this “immortalization of cell lines”). This would make it possible for researchers to use your blood cells for research on Disease X or other related diseases for indefinitely into the future.*

## **g. What will happen to the data?**

Genomic data generated in the context of H3Africa will be shared widely for secondary analysis and research, and investigators need to specifically seek consent for this. When data are shared with other investigators, they may for instance be analyzed for other diseases, for population ancestry

or to test new statistical tools for analysis. The current proposal is for data to be shared through the European Genome-Phenome Archive, together with accompanying phenotypic and demographic information. When data are shared, they will be coded so that the participants' privacy is protected as much as possible. However, because genomic information is unique to individuals, there is always a theoretical risk that participants could be identified if additional genetic information for the person is also available in the public domain. Investigators should also consider whether the risk that participants could be identified should be highlighted in the consent document.

***Sample language for how the data will be maintained (e.g., in accordance with H3Africa policy, in a database available to qualified investigators over the Internet):***

*"To protect your privacy, we will replace your name with a code. We will only use this code on your sample and information about you. We will do our best to keep the code private. It is however possible that someone could find out your name but this is very unlikely to happen."*

***Sample language for who will have access to the data (e.g., qualified investigators in universities, hospitals, government agencies, companies) and how access to the data will be controlled.***

*"A goal of H3Africa is to create a way for scientists to share and learn from each other, especially within Africa. One of the best ways to do this is for scientists to share research data. . Although the study you are being asked to participate in is related to Disease X, other scientists may like to use your samples and/or data to study other diseases. We would like your permission to share your health history, laboratory test results and your data with other scientists across the world. A special committee will look at each request to share data to find out what the researchers want to do and how they will protect your rights and choices based on the consent you provided. When we share this information, people will not know your name... There is a small chance that your data, together with the data of many other people, could be used to develop a commercial product such as a new drugs or vaccines. If this happens, there are no plans to share any profit with you."*

## **h. Voluntary nature of participation and right to withdrawal**

Valid consent for H3Africa should be voluntary. The consent documents should include a special heading on the voluntary nature of participation. The people trained to obtain consent should learn how to ensure that prospective participants are not pressured or coerced to participate. They should also be made aware of other sources of pressure such as community leaders and family members.

Participants should be made aware that they can withdraw from the study at any time in the future, meaning that any samples obtained from that person (or from his or her child) will be destroyed. However, it should also be made clear that once samples have been genotyped, it may

no longer be possible to withdraw the data derived from that sample and it may not be possible to destroy samples sent to other investigators. This is to say that although the original sample can be destroyed if requested, it may not be possible to recover data or samples that have already been used for analysis and publication by investigators. However, the data can be taken out of the data repository so that no additional investigators are able to download and work on the data. The name of a person to contact if a participant wants to withdraw from the study should appear in the consent document.

**Sample Language:**

*“It is your decision whether you take part in the study. In other words, it is up to you whether you want to participate in the study.”*

*“You can say “yes” and join the study; or you can also say “No,” you don’t want to join. If you participate in the study, you can change your mind later and decide that you don’t want to participate anymore and you do not want your blood to be used in this study. Please let us know and we will destroy the sample. If your sample has already been tested at the time you change your mind, your results and other data may have already been shared with other investigators. In that case, we will not be able to destroy this data. Your data can be removed from the central repository, however. That means that no additional researchers can get your data.”*

*“Whether you decide to join or not to join the study, the way we look after you in this clinic will be the same. It is your decision whether to be in the study or not.”*

### **i. Potential risks associated with the research**

Even though there are only minor risks associated with collecting a blood sample, it is important that you insert a special section in the informed consent document that discusses these risks. Inserting such a section might prevent the development of misunderstandings about the project (e.g. about its role in aggravating a disease). In genomic studies, there is a theoretical possibility that people could be identified even when data is anonymised, and this might also be discussed as a risk to the study. The types of risk you may want to mention in the informed consent are:

- Risks to the individual (e.g. breach of confidentiality) or to the family or clan;
- Physical risks (e.g., risks associated with blood draw) and;
- Non-physical risks (loss of privacy, discomfort associated with answering certain questions).

**Sample language:**

*“We want to tell you that there are some risks with this study. For example, there is a small chance that things might not go well with taking your blood or the information we are collecting. Most of the time when we take blood it is safe, but sometimes, when we take the blood, people feel a bit faint or may get an infection. You may also get a bruise where we took*

*the blood. If this happens please let us know and you will be treated. Another potential risk of participating in this study is that information about you may become known to people who should not have this information. We will treat all your data confidentially. But because your genetic information is unique to you, there is always the likelihood that you may be identified in the future. We don't know if this is likely to happen, but we will do our very best to minimize this chance.."*

#### **j. Risks to groups and other unknown risks (e.g., group discrimination, stigmatization)**

There may be unknown risks to participation that an investigator might want to share with participants. For instance, research results could have the potential under certain circumstances to be misconstrued and used to discriminate and/or stigmatize a population. Whether this is a risk may depend on the disease you are investigating and the population groups you are including in the study. You may need to take this challenge more seriously if either the population group or the diseases under investigation are already stigmatized.

Some research ethics committees may insist that such unknown risks are mentioned in the consent form, and so we have included it here for completeness. However, considering a) that most participants will already find it challenging to understand genomic research and the consent documents and b) that the nature of these risks remains elusive and the risk small, we suggest one considers leaving this section out of the consent documents. Researchers should of course remain aware of the possibility of unknown risks arising for the community or population group. Where an ethics committee insists that these unknown risks are included, the following can be used as sample language.

##### **Sample Language:**

*"It is possible that when we report our study results, they will change the way others see your community. We will do our best not to let this happen, but cannot always prevent it."*

*"Since your sample will be stored in an H3Africa biobank, in the future, your blood could be used to do research that we are not able to predict with our current knowledge. If this happens there is a chance that something could go wrong and we can't be sure how it might affect your privacy or affect your community."*

#### **k. How participants' privacy will be protected**

As is standard practice for clinical research, it is important to stress that the identity of study participants will be protected at all times, and that data will be kept secure in locked cabinets in a locked room or in password protected databases. However, before making promises that cannot be

kept, it is important to think about the practicalities of ensuring confidentiality in your own laboratory. Expectations regarding confidentiality should be clearly stated and if possible include information about who will have access to the data and whether personal identifiers will be anonymised. Also, investigators should think through the practicalities of assigning code numbers to samples as they are collected/ arrive in the laboratory. It is also important to recognize that genomic data is unique and that it is therefore always theoretically possible that participants will be identified.

**Sample Language:**

*“Your blood samples will be stored in a locked freezer in our laboratory and your personal information on a secure computer. Also, after they are sent to the biobank they will be stored under lock and key. But your genomic information is unique to you, and also tells us something about your family. It is possible that someone may find out that you participated in this project. However, it is very unlikely that this will happen and we will do our very best to ensure that it will not.”*

## **I. Potential benefits associated with the research**

With regard to benefits resulting from the research, it is important not to exaggerate. The most important outcome of H3Africa studies will be ‘knowledge’ and capacity building. Even though a cure for a disease might in the long term be of benefit to the community, it is unrealistic to make any promises about how the community will practically benefit from participation in an H3Africa study. If you offer something in return for participation, such as nutritional supplements or food, then be brief about this (and possibly mention them under ‘compensation’ rather than benefits). Focusing too much on such benefits might lead to false inducement. The points you may want to mention in the informed consent are:

- Benefits to society;
- Likely lack of immediate benefit to participants (that the study involves research, not medical care).

**Sample language:**

*“This study will not help you [or your children] to get better but we hope it will benefit others in the future. What we are trying to do is very difficult and could take a long time. Whether you decide to join this study or not will not affect your treatment in our clinic. Your decision to join is of your own free will.”*



### **m. Participant compensation**

This information should be optional and will depend on the budget of the grant and on national (legal or ethical) regulations about compensation. Compensation should be limited to legitimate out of pocket expenses and should not be so large as to be an undue-inducement for participation.

**Sample language:**

*“We would like to pay you back for the time and money spent to participate in the study. We will cover the costs of your time away from work and travel to get here today.”*

### **n. Return of results**

It is generally considered good practice for investigators to feed back general study results, but there is no consensus about whether individual genomic study results should also be fed back. The decision on what individual results to feedback, if any, is very challenging and the specific context is important to make an appropriate determination. There are a number of considerations such as whether the test done is reliable (if it has been done to accredited diagnostic standards), as well as whether the finding is clearly linked to a disease. There are also those that argue that investigators or biobanks should only consider feeding back results indicating serious conditions that are medically actionable – but exactly what qualifies as ‘medically actionable’ in one African setting may be different from another. It will be important for the wider H3Africa Consortium to explore what kinds of results could meaningfully be returned to participants. Our recommendations here reflect this and are deliberately generic to allow for a tailored approach to be developed.

At the least, investigators should provide participants with information about whether or not individual research results will be returned in the consent documents. If investigators plan to return any individual results to participants, it is important to describe when and through what mechanisms this will happen. The investigator may wish to consider the potential for disclosed information to confuse the participant or to cause distress. If individual research results are returned to participants then investigators need to ensure that there are clear pathways to ensure participants are referred to properly qualified and resourced professionals including genetic counselors (refer to the H3Africa Feedback of Findings policy). Careful consideration of the likely resources needed to do this effectively must be made before embarking on any projects and be presented to ethics committees for review where appropriate.

**Sample language:**

*“We will study samples and information from many people; it may take many years before they know if the results have any meaning. However, when the study is finished we intend to provide combined results of our research (results representing all participants, not identified*



*individually) to participants through newsletters and other forms of communication. We think this will take about (x time in months/years). There is also a small chance that researchers could find something soon that might be important to you (your child). If this happens, we may contact you to find out if you would like to learn more (Investigator will need to add some language as to how this will happen, e.g., text message, in the course of care at the time they return to the clinic, etc.)."*

*"In general, individual results from this research project will not be given back to you or put into your medical records."*

If choosing to return results to participants, you can add:

*If you wish, you can choose to receive some of your test results (blood sugar level, for example). We will however not provide the results of those tests related to your genes. This is because scientists do not yet fully understand the role of these genes in disease, and so the information may not be directly useful to you. If these circumstances change and there are genetic results that are meaningful and related to your health, these results will be provided to you after appropriate discussion about their meaning"*

## **o. Assent from children**

In some studies, samples and clinical data from children may also be collected. In that case, parents or guardians will be asked for consent but children will be asked for their assent. Whether or not you need to obtain consent or assent depends on the age and maturity of the child, and is often articulated in national laws or national ethical guidelines. If children are old enough to understand the study, but have not yet reached legal maturity, then you may need to obtain consent from both the child and the parent or guardian. If you are unsure about the age of assent or how to proceed, then your ethics committee will be able to provide guidance. For older children (those nearing adolescence) you may wish to use the same consent form as for adults. For younger children, you would typically simplify information in a way that children in your age group are likely to understand. You may need different assent forms for different age groups.

### **Sample language:**

*"I am X, working for the Y Research Institute. We are doing research on [Disease ABC]. We would like to know what causes this disease. Hopefully this will help us make people with this disease better in the future. We would like to ask you if you will help us with this study. If you agree, we will need to collect some blood from your arm. The prick of the needle causes some pain, in the same way as an injection. You are allowed to say that you don't want to be in the study. Nobody will be angry with you if you say no. Before you decide, you can ask us questions, or you can talk to your mother and your father about this."*

## **Recording consent**

Standard practice is now to document consent with a signature on a separate sheet. In some instances, for those who may have more limited literacy skills or in the case where signatures on documents carry negative associations (e.g., based on past experiences with signed legal documents or fear that documents could link someone with some contested or illegal activity and fear of prosecution), you should consider asking someone to witness the consent process and sign the consent document to confirm that the information provided was accurately explained to and apparently understood by the participant and that consent was freely given. If the participant is unable to sign the consent document, an alternative is to ask people to thumbprint the signature sheet. Sometimes, participants may not like to sign or give a thumbprint or other mark. In that case also, it may help to ask a witness (for instance, a nurse who is not involved in the study or a family member) to affirm that the participant gave consent voluntarily.

## **Conducting research on vulnerable groups**

Several H3Africa projects conduct research on vulnerable groups including for instance children, pregnant women, and patients with mental illness. Because of their characteristics (for instance age) situation or symptoms associated with their illness, individuals in these groups may be less able to refuse research participation {Bracken-Roche et al 2017}. Their ability to give voluntary or informed consent may be impaired. In that case, special caution is required when seeking consent from such groups, often translating in a need to develop 'special protections'. These special protections may be for instance increased training of field staff seeking informed consent, to ensure that they are sensitive to prospective participants' vulnerability and aware of non-verbal signs that could signal so-called 'silent refusal' {Kamuya et al 2013}. Special protection may also involve e.g. staging the consent process to ensure consent is genuine and sustained over a period of time {Tindana et al 2012} or using screening tools and iterative learning to promote comprehension. When enrolling children, researchers may need to think creatively about how best to explain the study to children, and how to ensure assent.

## **Proposed methods of evaluating the quality of informed consent**

There is evidence that the quality of understanding during informed consent varies considerably in high and low-middle income countries, and that this quality of understanding can be considerably improved. Factors that improve quality of understanding during consent include one-on-one engagement between the participant and the recruiter, repetition and repeated explanation of information pertaining to important study elements like the overall

aim of the study, the associated risks and benefits; and the opportunity for question and answer sessions about specific research study elements.

There are now a number of tools that can be used in the informed consent process to screen and establish level of participants' understanding; and use that information to take additional steps to improve their understanding. For example, in a South African Study on genomics of schizophrenia, researchers used the University of California, San Diego Brief Assessment of Capacity to Consent Questionnaire (UBACC) tool in an iterative learning approach that showed large improvements in the quality of understanding during consent among both participants with the disease and healthy controls (Campbell et al).

Depending on the target population, H3Africa researchers may be required in some studies to demonstrate a participant's understanding of research study elements during the consent process. This is particularly relevant to studies targeting populations who may be perceived as vulnerable to exploitation, like those with cognitive impairments. In these instances researchers should consider the use of screening tools like the UBACC and other similar tools that best suit the nature of their studies and needs it to achieve this aim.

## **Community Engagement to support the individual informed consent process**

It is increasingly recognised that, in addition to obtaining informed consent from individual participants, it is important to conduct a process of community engagement (CE) or community consultation with relevant key stakeholders and communities. This is an important part of ethical research practice. CE is key to the conduct of genetics and genomic research for several reasons:

- Genetic and genomic studies may have implications for the research participants and the broader communities and populations of which they are a part. This is because the research involves the potential for comparing allele frequencies among groups whose ancestors come from different geographic regions, sometimes in a context where societal, racial, or ethnic discrimination exists.
- Given the complexities involved in conducting these studies, CE can support the consent process by providing a platform for potential participants to obtain information about the study and be better informed when deciding whether or not to participate in the study;
- Share their views about the ethical, social, and cultural issues the study raises for them, their immediate communities, and the broader communities and populations of which they are a part;

- Provide input into such matters as to how the samples from their locality will be collected and described;
- Remain informed about how the samples and the data are being used and about findings from future studies that use the samples or the data from individuals in their community.
- 

To be effective in achieving its goals, CE should take place before, during and after the research. It is very important to develop or utilize educational tools to explain the scientific concepts involved in genomic research and biobanking, which can support the consent process.

Methods of engagement may include organising meetings with community gatekeepers, patient groups and other relevant key stakeholders. In some cases, if this is not already in place, it may be appropriate to establish a Community Advisory Group or similar body to facilitate the providing of ongoing feedback about the study and about how the samples and data are being used. (see further CE guidance on the H3Africa community engagement guidelines)

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## Recommended further reading

### ***Books***

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### ***Articles***

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### **Guidelines**

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3. Guidelines on Ethics for Medical Research. Basic Principles. 2002. Medical Research Council, South Africa. Available at: <http://www.mrc.ac.za/ethics/ethicsbook1.pdf>
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5. H3Africa Feedback of Findings Policy document
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### **Websites**

1. National Human Genome Research Institute website on 'Ethical Issues': <http://www.genome.gov/10000006>
2. Stanford Medical School's Centre for Integration of Research on Genetics and Ethics (CIRGE): <http://cirge.stanford.edu/>

***Online courses***

GlobalHealthTrials have got an online course entitled '**Introduction to Reviewing Genomic Research**'. The course is free but requires registration. Those completing the course will receive a personalized certificate. The course is available here: <http://globalhealthtrials.tghn.org/elearning/other-resources/> (number 10 in the list).

## Annex: Sample Informed Consent Templates

The sample informed consent templates here are provided for reference. They can be used and adapted by H3Africa PIs for their specific studies. The templates are from previous H3Africa projects that have concluded. They were part of other templates assessed for their content and how well they captured the key elements and reflect the sort of language recommended in the last version of the H3Africa Informed Consent Guideline for inclusion in genomics research studies.

### a. Sample Template #1

#### **Host Genetic Factors Influencing HIV and TB Disease Progression in African Pediatric HIV**

##### **Introduction**

The Botswana-Baylor Children's Clinical Center of Excellence researchers are undertaking a study with other investigators from different countries to study HIV and HIV with TB. This is a multi, collaborative initiative and the study is part of the Human Heredity and Health in Africa ("H3Africa") project

Your child is invited to take part in this research study to help doctors and scientists learn more about how genes affect how quickly children with HIV or HIV and TB get sick from their infections. Your child is invited to be in the study because of his/her HIV or HIV and TB infection

The goal is to look at the genes of many children to try to discover new genes, or new patterns in the way genes are used, that may help understand reasons for how quickly HIV and TB progress. Genes are molecular units of heredity of a living organism in the body. Genes are in each cell of our bodies and hold information about how the cells and our bodies work

Please read this information and feel free to ask any questions before you agree to your child taking part in the study.

For this study, we will collect, store, and use blood samples, sputum samples and health information for research. If you agree, your child's blood sample and some of his or her health information will be put into our safe storage place at the Centre of Excellence.

The storage place (also known as a biorepository) is a collection of samples and health information from many people, stored for study. Researchers will use the samples and information now and in the future to learn more about health and many different diseases. Some researchers will study the genes in your child's samples.. This information is composed of a letter code called DNA. DNA is the code that you inherit from your parents and that you pass on to your children. New ways to study the code may be found in the future. Researchers can learn a lot by studying DNA and genes. Studying genes along with health information will help the researchers to better understand what causes certain diseases.

##### **Purpose**

The purpose of this study is to examine genes in children with HIV or HIV and TB to help understand why some children develop their diseases faster than others. Genes also have the information that determines how many of the soldiers of the body are made and how well they do their jobs; this information may also be passed on from parent to child. We will use blood cells to look for genes that may be connected with this process.



## **Expected Duration**

The study will take 3 years, but divided into two parts. The first year is when the blood and health information is taken once for genetic testing HIV study, and the last two years is the other part for the HIV and TB

The HIV genetic study will recruit 1000 participants in total, 500 from Botswana Baylor COE and 500 from Baylor Uganda. For the HIV and TB study, 2000 participants will be enrolled, 1000 from each site.

## **Procedures**

The research will be conducted at the following location(s): The BOTSWANA-BAYLOR CHILDREN'S CLINICAL CENTER OF EXCELLENCE; UNIVERSITY OF BOTSWANA; BCM CHILDREN'S FOUNDATION, UGANDA; MAKERERE UNIVERSITY; THE BAYLOR COLLEGE OF MEDICINE

1. This study will collect information from the questions you and your child answer and from the examination of your child, done to take care of the child's HIV and TB related problems. The information will be kept in a safe place.

2. Two (2) or three (3) teaspoons (10-15 ml) of blood will be drawn and sent for genetic testing. For the TB study, blood will be collected at 5 different times that are 6 months apart. The amount of blood each time is less than 2.5 ml per kilogram of body weight (1/2 teaspoon for every kilogram of body weight). The blood sample will be collected at the Botswana COE clinic, and then sent to University of Botswana for testing. Some of the processed samples will be stored at the University of Botswana and other sample sent to Makerere University and Baylor College of Medicine for further genetic processing.

The blood is built up of different small things called cells. We would like to take out some of these cells out of your child's blood. We may treat (do something to) the cells from your child's sample to allow us to grow them in a laboratory, we call this cell line. This creates a cell line, an unlimited supply of the cells for study for a long time, maybe forever, without asking for some more samples from your child. The cells from the cell line would be stored and used only for research that may be related to HIV, or HIV and TB, but it is possible that the sample maybe used to study other diseases that affect people around the world.

--Scientists at the University of Botswana, Makerere University and the Baylor College of Medicine will use the gene sample only for research on the genes and their connection to HIV and diseases related to HIV.

--Part of the blood sample (not the genes) will be used for non-gene testing. This testing could include counting the number of blood cells or other blood components.

--A sputum sample may also be collected from your child through a process known as sputum induction.

This sample will be used to look for evidence that your child has developed an active TB infection and to learn more about the type of TB and its characteristics.

--Your child's sample will not be available to you for any other kind of non-research or medical testing. We will store your child's samples and information in locked freezers in locked buildings. We will remove your child's name and any other information that could directly identify your child from his or her samples.

3. You will bring your child to the BOTSWANA-BAYLOR CHILDREN'S CLINICAL CENTER OF EXCELLENCE for approximately 3 hours. You will be given the opportunity to ask additional questions about the research. If your child is enrolled in the progression of HIV study, 10 milliliters (2 teaspoons) of blood will be drawn from your child, one time only. If your child is enrolled in the HIV with TB study, your child will be asked to participate when he or she is HIV positive and has a positive TB skin or blood test. At first visit, 15 milliliters (3 teaspoons) of blood will be drawn from your child. Your child will return to the clinic every six months over a 2-year period and 5 milliliters (1 teaspoon) of blood will be collected at each visit (5 totals). Experienced blood collectors will be used to obtain your child's sample to keep him/her as comfortable as possible. If your child has a positive test for TB, then during the next 2 years we may try to obtain a sputum sample from him/her. If your child is not old enough to produce the sample on their own, a process called, "sputum induction" will be used to obtain the sample. If your child has a positive test for TB, he/she will receive chest X-rays as part of routine clinical management. A chest X-ray is a simple, painless test that involves taking a picture of the inside of the chest to see if there is evidence of active TB disease.

Your child will continue to receive doctor's advice, prescription refills, and follow-up at the clinic for pediatric HIV and TB care and treatment according to the clinic's standard procedures. No new treatments will be introduced as a result of your child's participation in the study, and standard clinical procedures will not be affected by your decision to allow your child, to participate or not. During clinic visits, you will be asked questions about your child's health and your child will be examined by a qualified health care professional. Clinical laboratory testing will be done as usual, and medications will be prescribed and supplied using accepted treatment guidelines. Your child will not be denied treatment as a result of their involvement in the study.

4. Biobanking: If you give permission, we will put your child's blood samples (without identification) in a biobank that other approved researchers can use. Biobank is a sophisticated blood storage facility that it is not available locally in Botswana; therefore, Makerere University biobank will be used to store the sample after been processed

Here is some information that many people in studies about biobanks should know:

Researchers can ask to study the samples stored in the biobank. This includes researchers from University of Botswana, Makerere University and the Baylor College of Medicine. In addition, researchers from other universities, the government, and drug or health companies in the U.S. and other countries may ask to study the samples. A special committee will look at each request to study the samples to find out what the researchers want to do and how they will protect your child's rights. If the committee approves the research request, we might give the researchers samples and information from many people, including your child. All of the samples and information will be labeled with barcodes only. We will not share information that could directly identify your child (like your child's name, government identification number and address) without your permission.

#### **Who else will have access to my child's genetic information?**

Your child's name and other information that could directly identify him or her (such as address or government identification number) will not be shared. However, your child's genetic information without identification may be placed in a database.

Researchers can do more powerful studies about genetics when they share information from human samples. They share this information by putting it into scientific databases. These databases store information from many studies conducted in many different places. Researchers can then study the combined information to learn even more about health and many different diseases.

There are different kinds of databases. Some databases are restricted and can be used only by researchers who apply and are approved. Some of your child's genetic and health information might be placed into one or more of the restricted databases at the University of Botswana, Makerere University and the Baylor College of Medicine or other research institutions or the federal government. Your child's genetic and health information would **not** be placed in a database maintained by private companies. Some databases are public and anyone on the internet can use them.

**Your child's sample and health information would NOT be placed in a public database.**

Although your child's name and other information that could directly identify him or her (such as address or government issued identification number) will NOT be placed into any scientific database, your child's genetic information is unique to him or her and therefore there is a small chance that someone could trace it back to him or her. The risk of this happening is very small, but may grow in the future. Researchers will always have a duty to protect your privacy and to keep your child's information confidential.

This means that there will be data and/or sample sharing amongst the researchers

#### **How long will you store the samples and information?**

There is no limit on how long we will store your child's samples and information. We may keep using them for research for many years unless you decide to withdraw your child from the project.

#### **Will I find out the results of the research?**

You should not expect to get results about your child from research done through the biobank. Researchers will study samples and information from many people; it will take many years before they know if the results have any meaning. However, in the future it may be possible for researchers to give you your child's genetic research results and we will make efforts to explain to you of the results of the research. There is also a small chance that researchers could find something soon that might be important to your child's health. If this happens, we may contact you to find out if you would like to learn more. However, even if we find something important to your child's health, we cannot guarantee that you will be contacted.

#### **Will I be contacted in the future about this or other research?**

We may want to contact you in the future. You can decide now whether or not you want to be contacted. You can also change your mind later.

If you agree, we may contact you for several reasons. For example, we may ask for more samples or more information about your child's health. We may want to ask if you want your child to participate in other research. We will not notify you every time your child's samples and information are used. However, some researchers might do a study and need to contact you. For example, they might ask you and/or your child to do a phone interview or come in to be seen by a researcher or doctor. If a study like this is approved, someone from this project will tell you about the study so you can decide if you want to allow your child to participate. There will be a new consent process just for that study

#### **Research related health information**

Your research doctor may never be able to provide you with your research related health information.

#### **Potential Risks and Discomforts**

The blood draw will cause minor pain briefly and possibly a bruise. There is a small risk of infection. The gene testing may uncover other information about the risk of certain diseases. There is a risk of hearing unexpected and unwanted information if the results of the genetic testing are shared with you.

For the x-ray machine the amount of radiation received in the x-ray machine is about 10millirem. This low level of radiation is used routinely in clinics and hospitals worldwide and generally considered to be safe. A urine pregnancy test will be done in all females 9 years and older prior to the x-ray measurement.

There is a risk of loss of confidentiality. The staff will protect confidentiality by assigning a study identification number and storing information and blood samples with this number and without information like name and address that could identify your child. The information will be kept in a locked office or in a password-protected computer file available only to study staff. The confidentiality of the data will be maintained within legal limits. The blood samples will be kept in a laboratory in a freezer designed for these samples, with a study number but no name or other identifier. The samples will be kept in locked storage and available only to authorized researchers. The data from the study may be published; however, no names or other ways of identifying the subjects will be published.

Research records are separate from medical records. We will not place any information from this project in your child's medical records.

Researchers who study your child's sample and information will not know who your child is. We will give them only barcode numbers; we will not give them any information that directly identifies your child. The researchers must sign an agreement that they will not try to find out who your child is.

Study staff will update you in a timely way on any new information that may affect your decision to allow your child to stay in the study.

### **Potential Benefits**

The benefits of participating in this study may be: finding one or a few genes that another child in the family might inherit and have similar medical conditions. However, you may receive no direct benefit from participating.

### **Alternatives**

You may choose not to allow your child to participate in this study or agree to only parts of it.

### **Subject Costs and Payments**

You will not be asked to pay any costs related to this research.

You will not be paid for taking part in this study, however, you will be reimbursed for travel expenses to and from the clinic in the amount of P60 for you and your child for each study visit.

The participating institutions do not plan to pay royalties to you if a commercial product is developed from blood obtained from your child during this study.

### **Subject's Rights**

Your signature on this consent form means that you have received the information about this study and that you agree on behalf of your child to volunteer for this research study. Participation is entirely voluntary, refusal to participate will involve no penalty or loss benefits to which your child is otherwise entitled

If you withdraw, that is choose not to allow your child to take part in the research or if you decide to stop the child from taking part later, your child's benefits and services will stay the same as before this study was discussed with you. Your child will not lose these benefits, services, or rights.

While your child has the right to withdraw, samples and data that have already been distributed or analysed cannot be taken back

You will be given a copy of this signed form to keep. You are not giving up any of your child's rights by signing this form. Even after you have signed this form, you may change your mind at any time. Please contact the study staff if you decide to stop the child from taking part in this study.

### **Your Health Information**

We may be collecting health information that could be linked to your child (protected health information). This protected health information might have your child's name, address, telephone number or something else that identifies you attached to it. The law wants us to get your permission to use your protected health information for this study. Your signature on this form means that you give us permission to use your protected health information for this research study.

If you decide to allow your child to take part in the study, your child's protected health information will not be given out except as described in this form. Everyone working with your child's protected health information will work to keep this information private. The results of the data from the study may be published. However, your child's will not be identified by name.

People who give medical care and ensure quality from the institutions where the research is being done, the sponsor(s) listed in the sections above, representatives of the sponsor, and regulatory agencies such as the Ministry of Health will be allowed to look at sections of your medical and research records related to this study. Because of the need for the investigator and study staff to release information to these parties, complete privacy cannot be guaranteed.

The people listed above will be able to access your child's information for as long as they need to, even after the study is completed.

If you decide to stop your child from taking part in the study or if your child is removed from the study, you may decide that you no longer allow your child's protected health information that identifies him/her to be used in this research study. Contact the study staff to tell them of this decision, and they will give you an address so that you can inform the investigator in writing. The investigator will honor your decision unless not being able to use your child's identifiable health information would affect the safety or quality of the research study.

## b. Sample Template #2

IRB Research approval number: #####

This approval will elapse on: dd/mm/yyyy

**Title of the research:** Contribution of genetic variation to pharmacokinetic variability and toxicity in patients undergoing multi-drug tuberculosis treatment in Sub-Saharan Africa. - RAFAgene project

**Principal Investigator (PI) and site-specific co-PIs:**

PI: Dr Dissou Affolabi	The National Hospital for Tuberculosis and Pulmonary Diseases (NHTPD) Cotonou, Benin
Co-Investigator: Prof. Oumou Bah Sow	Service de Pneumo Phtisiologie Centre Hospitalier Univesitaire Ignace Deen Conakry Guinee
Co-Investigator: Dr Marie Sarr	National TB Control Program Dakar Senegal
Co-Investigator: Ms. Thuli Mthiyane	Univeristy of Kwal-Zulu Natal Kwal-Zulu Natal Inkosi Albert Luthuli Central Hospital Durban South Africa
Co-Investigator Dr Helen McIlleron	University of Cape Town- Division of Clinical Pharmacology Cape Town South Africa
Co-Investigator Dr Andrew Owen	Department of Molecular and Clinical Pharmacology University of Liverpool, United Kingdom
Co-Investigator: Dr Corinne Merle	Department of Infectious Disease and Epidemiology London School of Hygiene & Tropical Medicine London United Kingdom

**Sponsor(s) of research:** This study is sponsored through the H3Africa Initiative by the National Institutes of Health, USA

**Purpose(s) of research:** Genes are present in all of us and carry hereditary information. This kind of information is passed from both the father and the mother to their children (which is why family members often look like each other). Some of these genes may make us more likely to get sick from tuberculosis, whilst other genes will prevent us from getting sick from tuberculosis or recover better with treatment.

The purpose of the study is to see which genes make a difference in a patient's TB treatment results. We will use information collected as part of the OFLOTUB and RAFA trials as well as new samples collected. This study is conducted in four countries in Sub-Saharan Africa (Benin, Guinea Conakry, Senegal and South Africa). We aim to recruit up to 630 participants.

**Procedure of the research:** You as participant of the OFLOTUB or RAFA trials (ref NCT00216385 and PACTR 201105000291300) are being asked to participate in this add-on study, the RAFAgene project. By better understanding which genes (what you inherit from your parents) affect the response to TB drug treatment. We hope that in the long-term we will find better treatments for TB patients.

A health professional of the trial team is contacting you to be part of this sub-study. If you agree, you will receive a health check as part of this study. You will also be asked to give a 10 ml (approximately 2 teaspoons) blood sample for long-term storage and analysis of your gene.

Once we have done the research that we are planning for this project, we would like to store your blood and information. We will store your biological samples together with the other samples that people have given from all over Africa as part of a big collection that is called a “biobank”. This “biobank” will be on the African continent. Investigators from all over the world can ask to use these samples for their research. In addition, we would like your permission to share your health history, laboratory test results or genomic information. If this information is shared, people will not know your name. Other investigators who want to use your data (without your name) will need to first ask permission from the biobank. They will need to agree only to use the data for scientific research. The data could for example be used by investigators from universities, hospitals or from companies that make and sell medicines. The information from this study will be given free of charge. Although the study you are being asked to participate in is a study that involves tuberculosis, other scientists may like to use your sample to study other diseases. The samples will not be sold, but investigators hope to develop new treatments based on studying the samples. If this happens, you will not be able to share in any profits.

**Expected duration of research and of participant(s)’ involvement:** We expect you to give one additional blood sample during or after the TB trial you are still or were enrolled in. You should not spend more than 1 hour during this visit.

**Risk(s):** The risks in participating in this study are very low. You may feel some discomfort when you have blood taken. This may include pain from the needle stick, bruising, or bleeding and rarely infections where the needle enters the vein.

**Costs to the participants, if any, of joining the research:** Your participation in this research will not cost you anything.

**Benefit(s):** The goal of this research is to understand whether genes (what you inherit from your parents) affect a patient’s response to TB drug treatment. We hope this will help us find the best treatment for patients, but we are not certain about this. If you agree, you will receive a health-check as part of your visit.

**Confidentiality:** All information collected in this study will be given code numbers and no name will be recorded. Your records (once anonymised) may be reviewed by the Ministry Of Health, NIH, National Regulatory/Health Agencies, study staff and study monitors.

**Voluntariness and withdrawal:** Your participation in this research is entirely voluntary. If you choose not to participate, this will not affect your treatment as part of ongoing trials in any way.

You can also choose to withdraw from the research at any time. Please note that the information and biological samples that have been obtained before you chose to withdraw may have or may be used in an anonymised form in laboratory analyses, reports and publications for many years. These cannot be removed anymore. However the researchers promise to make good faith effort to comply with your wishes as far as is practicable.

**Due inducement(s):** If you are asked to come to the clinic, you will be compensated for cost of transport to and from the research site (if applicable) but you will not be paid any fees for participating in this research.

**What happens to research participants and communities when the research is over:** If successful, long-term better TB drug treatment will be introduced into your community, however, you may not personally benefit from this research as the modification of drug treatment regimes may take some years to implement.

**Questions:** We have used some technical terms in this form. Please feel free to ask anything you don't understand and to consider this research and the consent form carefully -as long as you feel is necessary.

## INFORMED CONSENT FORM

**Title of the research:** Contribution of genetic variation to pharmacokinetic variability and toxicity in patients undergoing multi-drug tuberculosis treatment in Sub-Saharan Africa. - **RAFAgene project**

Please read/listen to the following statements and tick the YES box if you agree. If you do not agree and tick NO for any of the below 6 statements you will not be able to be in the study.

	Yes	No
The information sheet has been read to me and I understand it / I have read and understand the information sheet.		
I give permission for access to my OFLOTUB or RAFA trial records and for long-term storage and use of this and other information about me, for health-related research purposes (even after my incapacity or death).		
I understand that the information regarding me that is collected will remain confidential.		
I understand that none of my results will be given to me and that I will not benefit financially from taking part.		
I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason. Deciding not to take part or to withdraw from the study will not affect the care that I or any of my family is normally entitled to.		
I have had a chance to ask questions and have them answered.		
Please read/listen to the following statements and tick the YES box if you agree. If you say no, you can still participate in the study.		
I give permission for long-term storage and use of my blood for health-related laboratory tests and research purposes (even after my incapacity or death), and do not claim any rights to these samples.		
I understand if I am asked to come to the clinic that I will receive a health check as part of the study visit and if needed, will be referred to a health care provider		

_____	_____	_____
Name of participant/relative	Date (dd/mm/yyyy)	Signature or Thumbprint
_____	_____	_____
Name of the Witness	Date (dd/mm/yyyy)	Signature
_____	_____	_____
Name of person taking consent	Date (dd/mm/yyyy)	Signature or Thumbprint