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A Framework for Tiered Informed Consent for Health Genomics Research in Africa

Victoria Nembaware[$,1], **Katherine Johnston**[$,2], **Alpha A Diallo**[3], **Maritha J Kotze**[4,5], **Alice Matimba**[6], **Keymanthri Moodley**[7], **Godfrey B Tangwa**[8], **Rispah Torrorey-Sawe**[4,9], **Nicki Tiffin**[*,2,10,11]

[1]Division of Human Genetics, University of Cape Town, South Africa

[2]Computational Biology Division, Department of Integrative Biomedical Sciences, University of Cape Town, South Africa

[3]Ministry of Health (Guinea) and University of Conakry

[4]Division of Chemical Pathology, Department of Pathology, Faculty of Medicine and Health Sciences, Stellenbosch University, South Africa

[5]Tygerberg and National Health Laboratory Service, Tygerberg Hospital, Parow, South Africa.

[6]Wellcome Genome Campus Advanced Courses and Scientific Conferences, Hinxton, UK

[7]Centre for Medical Ethics & Law, Department of Medicine, Faculty of Health Sciences, Stellenbosch University, South Africa

[8]University of Yaounde 1 and Cameroon Bioethics Initiative (CAMBIN), Yaounde, Cameroon

[9]Immunology Department, School of Medicine, College of Health Sciences, Moi University, Kenya.

[10]Wellcome Centre for Infectious Disease Research in Africa, Institute for Infectious Disease and Molecular Medicine, University of Cape Town, South Africa

[11]Centre for Infectious Disease Epidemiology and Research, Public Health and Family Medicine, University of Cape Town, Cape Town, South Africa

Abstract

The scope for health genomics research in Africa is rapidly expanding, and standardisation of sample and data collection and processing can facilitate much larger study sizes through collaborative networks, and meta-analyses with greater statistical power to identify aetiological factors. The global health benefits that can result from data sharing and meta-analysis for health conditions are indisputable, and exploring the diversity and depth of African genomes can improve the health care provided to Africans as well as informing the identification of aetiological variants in rest-of-world populations. In the enthusiastic pursuit of such sample and data sharing and re-use, however, the preferences, permissions and wishes of the participants who provide those

*Corresponding author.

$These two authors contributed equally

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resources for research should be unambiguously understood, faithfully recorded and rigorously upheld. To do so in a systematic way can ensure participant protection, and can also facilitate sample and data reuse and meta-analysis through standardised approaches to recording and storing individual participants' consents and dissents. Here, we present a framework for tiered consent for health genome research in Africa which we believe can capture the choices of participants accurately in a standardised way. We describe information that should be shared with participants, the different tiers of consent and how they might be explained to participants, and provide a generic template for participant information and tiered consent questions that can be re-purposed for specific studies. We also propose a schema for storing tiered consent data and describe a flexible approach for mapping individual consents to data use ontologies as they become available or evolve.

1. Introduction

The African landscape for human genome research is unfolding rapidly, fuelled by the falling price of next generation sequencing technologies as well as an international thirst for research access to human genome data from African populations. The genomic depth and diversity of African populations promise to provide novel insights into function and dysfunction of human biology, and to pave the way to diagnostic, prognostic and therapeutic advances both for African and rest-of-world populations[1,2]. Conducting human genome research in Africa can be logistically challenging[3,4], but equally challenging is the process of recruiting African participants - many of whom experience knowledge and/or poverty-related vulnerabilities[5,6] - for genome research whilst ensuring they are properly informed, truly consenting and that they retain autonomy and agency.

To date, much has been written about the ethical imperatives, moral obligations and logistical challenges in obtaining informed consent for genomic research from African participants (for example, see[5,7–11]). Where dynamic consent may provide autonomy and choice to participants through ongoing engagement about the use of their samples data through online media[12,13], in the majority of African environments this model cannot be implemented because of logistical constraints such suboptimal internet access, a paucity of smart phones and other digital devices. Broad consent is another mechanism by which participants consent to all future use of their samples as mandated through an established governance structure such as an access committee, but this comes at the cost of autonomy and choice by participants around how they would like their samples and data used[10,14]. Tiered informed consent can address many of these challenges by providing sufficient information about intended specimen/data use, storage, and opportunity to withdraw from the study; and ensuring that participants can individually select a level of specimen and/or data sharing with which they are comfortable by responding to a series of specific questions that address different levels of use and onward specimen/data sharing[10,15–17].

With the launch of the H3Africa genotyping chip, an array of 2.7 million genomic variants designed specifically for African populations[18], opportunities increase for genomic studies and meta-analyses combining data and samples from multiple cohorts of African participants. For these to become a reality undertaken with an ethical mandate, the correct

information must be provided to research participants and their preferences must be accurately understood, faithfully recorded and implemented with integrity. Here we propose a framework for tiered informed consent processes undertaken in Africa, in order to promote ethically sound consent practices for human genome research undertaken on the Continent. It is intended for adult participants who are competent to give consent.

2. Methods

The framework is derived from the authors' experiences in undertaking and evaluating informed consent, and a generic template document showcasing participant information and capture of informed consent choices has been compiled accordingly (supplementary file). The template is provided in English, although validated translation into participants' primary language/s is recommended, and we will work towards French and Portugese translations in the near future. Framework tenets include ease of understanding for both fieldworkers and participants, practical for administration in a busy environment like a clinic, and inclusion of all key components of participant information and consent, although not all may be appropriate for every study. We describe here a set of core components for participant information for competent, adult participants, and delineate strata of participant consent that we recommend are each addressed in their own right. We also provide recommendations for efficient data capture and standardisation of individual consent preferences.

3. What information should be provided in the informed consent documents?

Inherent in ethical research is the balancing of benefits and risk, at the micro level for the individual, the meso level for a community, and the macro level for a population. Whilst an Ethics Review Board or Research Ethics Committee (REC) should consider all levels in approving a study for further research, the right of the individual to decline or accept participation remains paramount and the participant information leaflet must provide necessary and sufficient information for them to exercise this right in a considered way. Here, we propose a framework of core concepts for the provision of participant information, and highlight for each point how localised knowledge can inform the tiered consent process.

3.1. Information about genetics

Most people have an inherent understanding of heredity in humans, and African colloquialisms often speak to this, for example a Shona proverb "Mhembwe rudzi inozvara mwana ane kazhumu", which translates into English as "The child of a duiker (small antelope) is a duiker" with English equivalence to "Like father, like son", or "The apple doesn't fall far from the tree". This inherent understanding and local language can be harnessed in explaining heredity and genes as overall concepts, especially combined with examples such as height or facial similarity that are anecdotally accessible to everyone and emotionally neutral. Caucasian-centric phenotype examples are often inappropriate for African participants, with an obvious example being eye or hair colour.

Specific information about genetics in health and disease can also be related to locally prevalent health conditions as well as the study in question – whilst always providing clarity where genetic factors underlying a disease are complex or undetermined to prevent misunderstanding, anxiety or family conflict: for example, whilst genetic factors might have some influence on susceptibility or outcomes for an infectious disease such as malaria, it should be explained to participants that environmental and other factors are the chief drivers of being infected with malaria.

3.2. The focus of the study, and who is doing the research

Clear and simple language, and the use of local names for health conditions, can help to explain the research question/s in the study. A sentence such as “We want to understand whether genes might affect how likely someone is to get sick from bilharzia” is more accessible than “The primary study objective is to elucidate the genetic aetiology of schistosomiasis” for a rural African population exposed to schistosomes. In the same space, however, accuracy of information supports transparency and researchers should not confuse straightforward language with incomplete information. When recruiting controls alongside cases, it is also possible to explain that comparing samples from those who have a health condition to those who do not allows us to better understand what contributes to getting the illness.

In describing who is doing the study, local researchers and institutions should always be the primary contact point for the study in order to be familiar, un-intimidating, identifiable and contactable for participants.

3.3. What will you be asked to provide or do, for this study

A brief explanation of exactly what will be requested in terms of visits, data collection and sample collection can be provided in simple language, and common use estimates of volumes can inform participants about collection of blood or saliva, for example referring to “about two teaspoons” of blood provides more information that “10ml”.

3.4. What are the potential risks and benefits of this study to the participant?

There are often no direct benefits from participation in genome research, which should be honestly stated if true. Research studies may be confused by participants with an offer of additional health care or an opportunity for cure, and it is advisable to explicitly state where this is not the case. Researchers should recognise and respect, however, that participants of low socioeconomic status or poor education levels by Western standards may also value altruistic behaviour and wish to contribute to the wellbeing of others or the advancement of science without personal benefit[19,20].

Communication of risks for genomic studies is complicated by the unknowable nature of future risks associated with genome or genotype data: the rapidly evolving knowledge landscape makes it impossible to catalogue future possible use of such data. Real risks can include re-identification of individuals and exposure of personal health information from genomic and health data in the event of data breach or unsupervised data reuse[21–23] as well as stigmatisation of families, communities or ethnic groups. Another risk that should be

communicated is that the participant may receive unwanted information about their own health, or information that negatively impacts family members or the local community who did not necessarily consent to the study. Describing risks alongside clear and practical plans for risk mitigation processes in place can provide reassurance to participants that risks have been appropriately identified and planned for.

Where remuneration is offered for costs incurred by study participation, or refreshments provided, we recommend that these should be detailed in a separate, independent section, and should not be confused with 'study benefits'.

3.5. Privacy protection, data and specimen protection protocols

The processes and infrastructure that have been put in place to protect data and specimens can be briefly outlined, to assure participants that privacy protection is in place. Sample storage location and security measures should be detailed – including geographical location of sample and data storage and use, as well as what data will be generated from each sample, how those data will be used further and by whom. Where appropriate, information can be provided about committees who will oversee access, as well as details of any intended sharing of aggregated or group-level data with collaborators, scientific journals, international collaborators or online platforms.

3.6. Return of results

We recommend that plans to return findings from genome-related research must be accompanied by an established process approved by a research ethics committee and medical specialists for evaluating whether findings (incidental or otherwise) meet criteria for offering results to individual participants; and whether findings are actionable or not. The consent process should acknowledge and enable the participant's right not to know certain results, both actionable and not actionable within their current context. Furthermore, the process of identifying and disclosing research results should involve professionals with the appropriate expertise. An overview or summary of this process can be communicated to participants.

For a primary study, whether or not individual results will be available from the study should be explicitly described; or where results will be available for return, the format and process for returning results should be clearly communicated. For example, the information for participants might state that no results will be returned to individuals because the findings from the current study will not be enough on their own to provide accurate health-related information, and only after much more research in the future can this study contribute to accurate information at an individual level; or it may state that the clinical doctor who initiated a clinical test will provide the results during a clinical consultation with the participant. The results could also be provided in an informative and adaptable report released by appropriately-registered medical scientists working in close collaboration with clinicians or genetic counsellors as the intermediary between scientist and participant

This section also needs to inform participants about what action will be taken where a communicable disease is identified, both in terms of how the participant will be informed and plans for linkage to care; and also in the case of notifiable infectious diseases that must

legally be reported to a central/national registry. Information can be provided about how study findings will be shared with the participant community, for example through a project website (with provided URLs) and/or newsletters by email or hard copy. Intended publication of results within the research sector can also be described.

3.7. Who can be contacted with questions, concerns, and how to withdraw consent

Concise contact information must be provided for any questions or concerns the participant might have before, during or after the study. It is also recommended to provide contact details for an oversight body independent to the study researchers, such as an Ethics Review board or institutional committee who can follow up any concerns or queries without bias. Clear instructions on how to withdraw from the study must also be provided, ensuring that such an avenue to withdraw from the study is easily accessible to the participants. A statement reassuring participants that withdrawal will not affect their access to standard health care is also advisable where study recruitment has taken place through a health facility.

4. What questions should be asked for each component of the tiered consent

We have compiled here a series of questions that each defines a tier of the consent process. The first question defines inclusion in the primary study, and is the only question that must be answered yes in order to proceed. The questions that then follow are designed to be free-standing, and each can be independently agreed to – or not – in their own right. This allows participants to determine a particular combination of uses of their data or biospecimens with which they feel comfortable.

Question 1: Agreement for the collection of data/biospecimen for the primary study.

> “Do you agree for us to collect this saliva/blood sample and your health information for this study we have described, about how genes might affect [specific health phenotype]?”

This is the defining question for consent to participate in the primary study for which participants are being recruited, and for which information has been specifically provided. Often in health research, this might be a specific disease, for example tuberculosis or hypertension.

Question 2: Agreement for secondary data/biospecimen use for other studies for the same phenotype/health condition.

> “Do you agree for us to use your genetic sample together with your health information for other studies in the future that want to study the effect of genes on [specific health phenotype]?”

This requests information for re-use of the sample and data only for other studies that are about the same phenotype. This provides an opportunity for individuals to further research in a disease that they might feel particularly strongly about due to personal

experience whilst not committing to general research use in other types of health research.

Question 3: Agreement for more general secondary data/biospecimen use in other unrelated studies.

> "Do you agree for us to use your genetic sample together with your health information for other studies in the future to study the effect of genes on other conditions or biological processes?"

For individuals who wish to participate in general health and/or genomics research, this option enables general re-use of data and samples in future studies that are not yet defined or known. This also provides the option for those who are not comfortable with wider re-use of their data/sample to clearly define a boundary for secondary use.

Question 4: Agreement for inclusion in aggregated data (e.g. genome summary data) for the study.

> "Sometimes researchers combine the genetic information from everyone in the study and provide a summary of genetic data for the whole group. Do you agree for us to use your information when providing combined information about the whole research group (x total individuals in this study)?"

Recent policy change by the National Institutes of Health[24] about open sharing of genome summary data from studies has prompted consideration of the sharing of these data. The risk of stigmatisation or discrimination of ethnic groups is significant in Africa, where genetic distance between ethnic subgroups can be large and each ethnic group can be small and easily identified. Historically, "ethnicity" can also be a sensitive or volatile identifier. We therefore believe that consent should be obtained before individuals' data are released in aggregate study-level data, particularly given historical and current ethnic sensitivities. Similarly, providing a total number for the study can give an indication to the participant as to the likelihood of being re-identified.

Question 5: Agreement for re-contact to solicit participation in follow-on studies or future sub-studies.

> "Sometimes, what we find from a study like this might lead to new studies being done in the future. Can other researchers contact you in the future to invite you to take part in other research studies?"

Re-contact of individuals can be difficult due to high geographic mobility of some African populations, shared or transitory ownership of mobile phones, informal residential addresses and limited modes of contact. Some individuals may, however, be willing to be contacted about participation in additional studies especially if it can facilitate access to specialist health care. Re-contact outside the current study for which consent has been obtained may violate privacy of participants and constitute

inappropriate or even illegal secondary use of personal information, unless consent has been given specifically for such re-contact.

Question 6: Agreement for return of defined genetic findings from the current study.

> "In this study, we hope to identify genetic factors that mean someone is more likely to [outcome, such as susceptibility to a disease]. If someone has this genetic factor, there is [no treatment/we recommend × treatment]. If we find during this study that you have this kind of genetic factor, would you like us to tell you this information?"

Health genomics studies are often designed to answer a defined question about genetic factors that impact health, and in this instance consent regarding the return of results may be easier to delineate, and has been explored for non-African settings. Recommendations suggest that participant should be asked if they wish to receive clearly identified, actionable or non-actionable genetic findings from the study[25]. It is possible to define up front what the results might mean, in practical terms, for the participant, and what treatment might be recommended for certain genotypes and this provides an opportunity for the participant to decide in advance, based on contextualised information combined with their personal preferences, whether they would like to know this information. Challenges can arise where access to health care is limited – can a participant access a recommended intervention or treatment? Can they afford it? Researchers and Ethics Review boards need to ensure that they adequately address these questions within the context of the study environment to maximise benefits to individuals through diagnostic and therapeutic information whilst minimising emotional and societal harms where such information cannot be used to improve health outcomes.

Question 7: Agreement for return of unanticipated genetic findings from future studies

> "Sometimes, what we find from our research might include new information about your health. Would you like us to contact you again if we believe we have new information that may directly affect your health – if there is some kind of action or treatment that might be able to help you with the health issue (Yes/No), and if there is NO kind of action or treatment that might be able to help you with the health issue (Yes/No)?"

The return of results becomes more nuanced and harder to communicate when consent has been given for secondary use of data/biospecimens, because it is not possible to know what genetic or health findings might be made in the future for this individual. In this case, we propose that at the least a distinction should be made between actionable and non-actionable results to accommodate that some individuals might prefer to not know anything about their own aetiological genetic background, some may only wish to know about predisposition or susceptibility if there is an intervention available to them, and some prefer to know all possible genetic components to their health even if they cannot be addressed or managed. There is a critical role for the principal investigator and/or data access committee/ethics review

board to ensure that when access is granted to other researchers for secondary analysis, types of findings, the possibility of subsequent interventions and the mode of return of results are clearly stated, and provision made for the return of results in a consultative, informed and supported way where appropriate. Ongoing research into the return of results and how to define “actionable results” in Africa and LMICs in general is essential.

5. How to store informed consent choices

Common practice in Africa for cataloguing individual informed consent in genetic studies - where participants are commonly given only one consent option - include capturing whether participants consented on hardcopy and then rarely reviewing or sharing forward the consent to secondary users such as biorepositories, genomic database users or other regulatory bodies or access committees. Where informed consent is digitalized, it is usually simply an e-consent signature or a scanned copy of the signed consent form. Such databasing practices for consent do not support the tiered framework which requires accessible, query-able and actionable choices for individuals to opt out at various levels of the primary study and/or secondary analysis of their samples and data.

Some funders require the sharing of research data for secondary use via publicly accessible repositories and biorepositories. Consent interpretation and automated selection of data and samples for secondary use in public repositories can be challenging, however, due to the unstandardised and heterogeneous consent questions used to capture use restrictions and conditions. Different consent standards between fields such as clinical and genomic research also limit cross-disciplinary data-sharing[26]. To this end, ontologies such as the Informed Consent Ontology (ICO)[27] and Data Usage Ontology (DUO)[26] were developed to provide standardized terminology and systems to semantically label samples and data with their usage restrictions and conditions in a structured way. While ICO focuses on the process of obtaining informed consent, the DUO describes consent and other data governance categories, and has codes for nineteen primary and secondary data use cases. Tools, templates and software assist with practical implementation of DUO[28], capturing metadata of consents, restrictions and requirements for a study but without capturing individual consent choices[28]. The DUO[26] is missing some key consent codes for return of actionable and nonactionable, anticipated and unanticipated findings; release of aggregated data, and consent for participant re-contact after the study. It is likely, however, that the consent ontologies and coding will continue to evolve to meet such requirements.

There is a need for simple, low-cost, systematic strategies to capture, store, share and action tiered consent choices at an individual level through commonly used case reporting form platforms (for example REDCap[29]). Each informed consent question should have binary response options as checkbox items, the CRF should be versioned, and any consent changes exported to relevant laboratories, biobanks, data repositories or data analysts for actioning should sample destruction or deletion of data be required. An example of primary and secondary data use consents, and their corresponding DUO codes for a Sickle Cell Disease Genetic study are shown in Box 1.

For data coding, we propose that each tier of consent is captured as a binary variable (yes/no, 0/1), along with the date of consent. Because individuals may wish to modify their consents, the database structure should also allow addition of new consent data for an individual, with a combined unique date-study ID key. To facilitate easy identification of the most recent consent data, a “current” flag can be added (see table 1). If these binary values are accurately captured during the consent process, they can subsequently be mapped to existing consent codes from the DUO or other suitable ontologies. This proposed binary matrix design allows for simple and intuitive data capture as well as flexible mapping to data use ontologies as they become available or are updated (table 1). To improve fidelity of data capture, future work may involve image processing that can automatically capture and code responses from signed, scanned consent documents. We also recommend creation of a consent ‘metadata’ record for the study, which describes at a study level what type of informed consent questions were asked and captured during that study.

6. Discussion

The framework presented here is intended as a practical guide to preparing an informed consent document for a one-on-one consultation with an individual who is considering participation in a genetic or genome research study. It makes the assumption that other informational tools such as pamphlets, videos and flip charts are also used in the consent process and that a community engagement process precedes the research project and continues throughout the conduct of the project. Although it is beyond the scope of this publication, community engagement and discussion with key stakeholders prior to approaching individuals for consent or undertaking human genome research in Africa is paramount[14,30]. Activities such as constructing a genogram with the research participant can be both useful and ethnically neutral as an important interactive component of community engagement (CE) efforts for genetics and genomics research. Whilst informed consent from an individual is buy-in at the micro level, at the meso and macro level there are families, communities, religious groups, ethnic groups and populations who are all implicated by genomic data from consenting individuals[30,31]; and this is particularly impactful in Africa where populations are extremely diverse, are often genetically unique and re-identifiable, and where perceptions around ethnicity have previously fuelled life-threatening discord. Consent processes must, of necessity, be situated in this broader context[32]; and where possible there should be sufficient time between the participant receiving the informed consent documentation and the enrolment visit, to take into account respect for family and communal decision making where applicable. Re-cap of consent options at multiple visits is also recommended where possible.

During the compilation of this framework, we identified some issues that call for more thorough exploration to inform further our recommendations and understanding of implementation of tiered informed consent in Africa. Further review and analysis should be undertaken in these areas:

Return of results:

It is apparent that participant information for return of results for a specific study can describe exactly what types of results might be returned, but it becomes much harder to do so when there is agreement for secondary data analysis but it is not yet known what results might become available in the future. We recommend here that the return of results needs to be considered within the constraints and context of each study, but this is an area where there is high risk of unforeseeable harms to participants, families and communities; and the constraints and considerations would benefit from further research.

Informed consent during times of crisis:

The recent Ebola crisis in West Africa has highlighted issues around use of health-related samples towards the common good, and what happens to informed consent processes in times of crisis. Further exploration is required around situations where it may be permissible to waive informed consent in times of crisis, where minimum use of samples/data for public good may possibly override the right of an individual to informed consent, and where individuals may be too ill to consent. Within the tiered consent model, it may be possible to explore which levels of consent could be acceptably waived in such a scenario, and which remain non-negotiable.

Consent for vulnerable populations:

We wish to re-iterate that the guidelines here are intended for consent by competent and autonomous adult participants. Particularly in LMICs and in Africa, we have very many vulnerable participants, including those with limited access to health care, limited socio-economic resources, children and adolescents, disenfranchised women, persecuted ethnic groups, and those marginalised or criminalised because of their sexual orientation and/or gender identity. For all studies involving potentially vulnerable participants we recommend that specialist advice is sought to ensure that the informed consent process and recruitment are appropriate.

Intended commercialisation of study findings:

The intended commercialisation of study findings provides a special case for the consent process, and issues of direct and indirect beneficiation of participants requires further exploration. Such research needs to address the potential for coercion or inducement into study participation with promise of financial rewards, the community consultation around appropriate avenues to return benefits, and also social constructs and community pressure to participate that might arise from promise of community-level benefits with sufficient participation rates.

Legislative constraints for consent processes:

Protection of participant data and confidentiality is coming under increasing protection following from new legislation such as the General Data Protection Regulation framework in the European Union; and within each country it is essential that consent processes are compliant with national laws and regulations. In South Africa, for example, the Protection of Personal Information Act (POPIA) is under implementation, and may impact whether broad

consent for future studies may be legally obtained from participants. In such cases, local legal advice is necessary to ensure that local legislation is respected.

Consent to studies of population origins:

In this framework, we have not included secondary use consent for studies of ancestry or population origins. This omission is intentional, because of the complex nature of the risks and future use cases that are possible within this area of research. Recruiting participants for health research entails approaching people who may be ill or have ill family members, and have personal motivation to participate in health research. We propose that where there is intended population diversity genome research, that this should be addressed in a separate consent process to avoid a “bait and switch” approach where vulnerable participants are recruited on a health ticket and then provide consent to population diversity research as a secondary mechanism without necessarily understanding the full risks and implications of such research.

We recognise that the current framework is a starting point for implementing tiered informed consent within an African context. We include an example of participant information and tiered consent questions that we hope can be adapted and reused for individual contexts in Africa, other LMICs, and beyond – this example is not a final document but rather an illustration of options for how to describe and capture different scenarios for participant information and consent questions. We welcome dialogue and recommendations for improvements to our framework to the benefit of African participants, going forward.

Supplementary Material

Refer to Web version on PubMed Central for supplementary material.

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Box 1:

Illustration of the coding of consent forms of tiered consent forms for two participants being recruited into a Sickle Cell Disease genetic study.

Participant 1

1.1. Do you agree for us to use your genetic sample together with your health information for this study on the effect of genes on sickle cell disease? **Answer: Yes**

1.2. Do you agree for us to use your genetic sample together with your health information for other studies in the future that want to study genes on sickle cell disease? **Answer: Yes**

1.3. Do you agree for us to use your genetic sample together with your health information for other studies in the future to study effect of genes on other conditions or biological processes? **Answer: No**

Duo requirements/Restriction description: **Disease-specific research and clinical care**

Duo requirement code: **DS-(XX)(CC)**

Participant 2

1.1. Do you agree for us to use your genetic sample together with your health information for this study on the effect of genes on sickle cell disease? **Answer: Yes**

1.2: Do you agree for us to use your genetic sample together with your health information for other studies in the future that want to study genes on sickle cell disease? **Answer: Yes**

1.3: Do you agree for us to use your genetic sample together with your health information for other studies in the future to study effect of genes on other conditions or biological processes? **Answer: Yes**

Duo requirements/Restriction description: **Use of the data limited to health/medical/biomedical, NOT population origin/ancestry**

Duo requirement code: **HMB(CC)**

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Table 1.

Example of data coding and capture for tiered consent questions, with retrospective mapping to DUO.

Captured and stored binary variables from informed consent process, showing capture of response to each tier.												**Retrospective mapping to current ontologies, can be re-mapped as ontologies are updated or replaced[c].**	
Study_id	**date_of_consent**	**version_consent_document**	**is_current**	**Use for primary study of health condition**	**Use for other studies on this condition**	**Use for other studies on health or general biology**	**Use of aggregate data for entire study**	**Re-contact for future studies**	**Return of specific, described genetic results from primary study**	**Return of undefined, actionable results from other studies**	**Return of undefined, non-actionable results from other studies**	**DUO consent description**	**DUO code**
ID_1	2010-10-20	1	1	0	NA	NA	NA	NA	NA	NA	NA	no consent given	-
ID_2	2010-10-20	1	0	1	1	0	0[a]	1	1	1	1	Use of data must be related to [disease]	DS-[XX] (CC)
ID_2[b]	2010-10-25	1	1	1	0	0	0	0	1	0	0	Use of data is limited to use within an approved project	PS
ID_3	2010-10-20	1	1	1	1	0	1	1	1	1	1	Use of data must be related to [disease]	DS-[XX] (CC)
ID_4	2010-10-20	1	1	1	1	1	1	0	1	1	0	Use of the data limited to health/ medical/ biomedical, NOT population origin/ ancestry	HMB(CC)

[a] Currently, aggregate data use, re-contact and return of results are not coded in DUO.

[b] Shows change in consent for individual ID_2 and use of "current" 0/1 flag.

[c] Shaded fields shows fields that are retrospectively mapped using stored variables and can be updated.