*Original Research Paper*

# Stakeholder views on future use of biological samples in Malawi and South Africa

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**ABSTRACT**

**Background:** Current advances in biomedical research have introduced new ethical challenges regarding the storage and future use of biological samples in low- and middle-income settings. Few studies have explored key stakeholder views on storage and future use of biological samples in sub-Saharan Africa. Therefore, an empirical study was conducted to understand key stakeholder views on storage and future use of biological samples in Malawi and South Africa. The main objective was to explore key stakeholder views on current policies on storage and future use of biological samples and use the information obtained to advise on policy implications for future use of biological samples in Malawi and South Africa.
**Methodology:** This was a qualitative study involving in-depth interviews and focus group discussions. Seventy-eight participants were recruited in both countries and took part in 34 IDIs and 6 FGDs. Audio-recordings were transcribed verbatim, and data analyzed thematically, iteratively and inductively using ATLAS. The study was conducted in Cape Town, South Africa, and Blantyre and Lilongwe in Malawi.
**Results:** Most participants recommended future use of biological samples and their indefinite storage. Majority of the participants felt donors of biological samples are the rightful owners of the samples. Few participants recommended that biological samples for a specific study must be destroyed at the end of the study.
**Conclusion:** These findings may inform ongoing ethical debates on storage and future use of biological samples. They may also inform policy changes in Malawi and South Africa on the length of storage of biological samples.

**Key words:** Biological samples, indefinite storage, destruction of samples, focus group discussion and in-depth interview.

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## Introduction

The national research policies in Malawi are currently very conservative in some respects. They do not allow future use of biological samples and data collected in biomedical research [1]. The policies also do not allow retrospective analyses of biological samples whose aims are not related to original research projects that collected them [1]. In addition, biological samples and data collected for a specific biomedical research project in the country cannot be stored for more than five years and health research projects that specifically aim at collecting and storing biological

samples for future research are not allowed [2]. There are also restrictions on shipment of biological samples outside Malawi [3]. However, some funders of biomedical research in Malawi such as the National Institutes of Health (NIH) and the Wellcome Trust encourage H3Africa researchers to deposit biological samples in H3Africa biorepositories for future research, including research on other diseases [4]. Although this is not a requirement for funding, both funders are supportive of this policy as it will facilitate future research, ensure biological sample sharing, and is consistent with current international research practices [2]. This position of the H3Africa funders has become a contentious issue among researchers, research ethics committee (REC) members and policymakers in Malawi [3].

In contrast, the recent South African Department of Health (DOH) research ethics regulations and guidelines allow future research purposes on condition that researchers apply for ethics review and approval of any future research [5]. The South African research ethics regulations and guidelines on future use of biological samples and data collected in biomedical research are consistent with the vision of the H3Africa Initiative, which allows future and secondary uses of biological samples and data in advancing knowledge to improve health. Recommendations from the H3Africa Consortium Ethics Consultation Meetings informed these recent South African research ethics regulations and guidelines on future use of biological samples and data. In fact, the H3Africa Consortium hosted two Ethics Consultation Meetings in South Africa in 2014 and Zambia in 2015, which aimed to contribute to the development of best practice for genomics and bio-banking research in Africa. The meetings, which targeted members of RECs across Africa that reviewed H3Africa research proposals, policymakers, researchers and funders, also explored the relation between broad consent and governance of secondary data, including sample access. During the ethics consultation meetings, some participants argued that the controversies on future use of biological samples in some sub-Saharan African countries were not based on factual knowledge or a good understanding of what was at stake – rather, there was opposition to it merely because it represented a shift in thinking about the indefinite use of the samples [6]. Some participants from Malawi indicated that the country's strict regulations on future use of biological samples are limiting opportunities for promotion of potentially beneficial biomedical research [6]. However, the current regulations on future use of biological samples in Malawi are based on the genuine concerns raised by regulatory authorities about the possible exploitation of the samples and data collected from research participants in primary research projects in the country by researchers and the lack of biobanks for storing the samples for future research purposes [3]. To address these issues, some participants recommended education of REC members and policy makers in these areas while others recommended that empirical studies be conducted to provide evidence that would be used to empower policymakers in making informed policy decisions on acceptable consent models, and the future use of biological samples and data collected in biomedical research.

The controversies on broad consent and future use of stored biological samples and data also dominate deliberations at REC meetings in South Africa [personal communications with REC members at Stellenbosch University]. While the regulations in South Africa allow researchers to obtain broad consent from research participants and allow future use of stored biological samples collected in biomedical research, some key-stakeholders such as REC members, Community Advisory Board (CAB) members and Patient Advocacy Group (PAG) members are not clear about the conditions for future unspecified use of these samples and data by researchers. These key-stakeholders claim that current policies on future use of biological samples in South Africa were not informed by stakeholder views. Hence, the study described below attempted to provide empirical evidence on key stakeholder views on future use of biological samples in Malawi and South Africa.

## Methodology

### Study design

The study employed a cross-sectional descriptive design to collect data from research participants. This design was chosen in order to describe participants' views on collection, storage and future use of biological samples at the specific time point, under the regulations currently in force in both countries.

**Data Collection Methods and Study Setting**

Qualitative research methods, namely in-depth interviews (IDIs) and focus group discussions (FGDs), were used to collect data from study participants in both Malawi and South Africa. This approach allowed the investigators to obtain in-depth information from the study participants.

The study was carried out in Malawi and South Africa. The two study contexts in sub-Saharan Africa were selected because they have distinct and often contrasting policies on future use of biological samples and data collected in biomedical research. In Malawi, future use of biological samples and data collected in biomedical research is not allowed while in South Africa, these are allowed. These differences in policies provided rich data for comparison among stakeholders involved in biomedical research in the two countries.

The study targeted key stakeholders in biomedical research in both countries. The stakeholders included policymakers in the Ministries/Departments of Health, funders of biomedical research, REC members, Community Advisory Board (CAB) members, Patient Advisory Group (PAG) members and research participants taking part in biomedical research. More specifically, the study recruited policymakers from the Malawian Ministry of Health (MOH) and the National Commission for Science and Technology (NCST), sponsors/funders of biomedical research in Malawi, Malawian CAB members, PAG members; and research participants taking part in biomedical research in Malawi. The study also recruited policymakers from the Department of Health in South Africa, funders of biomedical research in South Africa, South African REC members, CAB members, PAG members and research participants taking part in biomedical research in South Africa.

**Participant recruitment and enrolment**

A purposive sampling method was used to recruit all participants in this study. This method was chosen to gather data from key stakeholders that developed, implemented, or were affected by policies on biological samples in both countries. An attempt was made to recruit a representative sample of both males and females, and of different ages in each category to adequately capture the heterogeneity among the key stakeholders. Demographic data consisting of sex, age, language, and highest attained educational qualification was collected from each participant. In total, seventy-eight (78) study participants were recruited, and forty (40) individual interviews and focus groups (34 IDIs and 6 FGDs) were conducted in the two countries. IDIs were conducted with policymakers, sponsors/funders, REC members, PAG members and CAB members in both countries while FGDs were conducted with research participants who are taking part in biomedical research in either Malawi and South Africa. The FGDs were conducted before the IDIs and data from the FGDs informed questions that were asked during the IDIs. Details about the total number of interviews and the categories of respondents recruited in each site are shown in Table 1 below.

**Results**

The claim of this present study mainly addresses the role of IRBs to perform thorough scrutiny in implementation research ethics during the pandemic period in remote rural settings without adequate healthcare infrastructure to achieve quality ethics oversight. One study from India provided strong evidence to foster ethical biomedical and health research during the COVID-19 pandemic. Each proposal fulfilled the specific components in designing the implementation research study. Table 1 summarized the specific ethical challenges encountered in each proposal.

**Table 1: Interview types, numbers, and category of respondents per research site**

| Type of Interview | Number of Interviews | Category of Respondents | Site |
|---|---|---|---|
| FGD | 3 | Research participants (n=25) | Malawi |
| FGD | 3 | Research participants (n=19) | South Africa |
| IDI | 2 | Policymakers | Malawi |
| IDI | 2 | Policymakers | South Africa |

| | | | |
|---|---|---|---|
| IDI | 2 | Funders | Malawi |
| IDI | 2 | Funders | South Africa |
| IDI | 5 | REC members | Malawi |
| IDI | 5 | REC members | South Africa |
| IDI | 4 | CAB members | Malawi |
| IDI | 4 | CAB members | South Africa |
| IDI | 4 | PAG members | Malawi |
| IDI | 4 | PAG members | South Africa |
| **TOTAL** | **40** | | |

In Malawi, research participants and CAB members were identified through the Malawi-Liverpool-Wellcome Trust, members of PAG were identified through the Malawi Human Rights Watch and the Malawi Cancer Consortium, and REC members were identified through two research ethics committees that review both biomedical and social science research in the country namely the College of Medicine Research and Ethics Committee (CoMREC) and the Malawi University of Science and Technology Research Ethics Committee (MUSTREC). Researchers who conduct biomedical research whose health research studies were reviewed by the MUSTREC and CoMREC were identified by sponsors/funders of such research in Malawi. Two funders of biomedical research in Malawi were approached by the Principal Investigator physically in their offices. Malawi-Liverpool-Wellcome Trust (MLW) and Johns Hopkins University (JHU) have branches in Blantyre, and these were the research funders that were approached and agreed to participate in in-depth interviews.

In South Africa, research participants and CAB members were identified through the research centres and units based at the Stellenbosch University Faculty of Medicine and Health Sciences including the Desmond Tutu TB Centre (DTTC), Family Clinical Research Unit (FAMCRU), African Cancer Institute, Centre for Tuberculosis Research and TREAD Research. Members of PAGs were identified through the Centre for Medical Ethics and Law at Stellenbosch University and REC members were identified through the National Health Research Ethics Council (NHREC). The targeted RECs were the 2 Stellenbosch University Health Research Ethics Committees (HRECs). Two sponsors/funders of biomedical research from the Medical Research Council (MRC) were recruited into the study. The sponsors/funders of biomedical research were identified through researchers based at the Stellenbosch University who had been recruited into the study. The principal investigator approached potential participants via emails and those who expressed their willingness to participate in the interviews were scheduled to take part in the in-depth interviews. Researchers who were conducting biomedical research in the two countries identified research participants who were participating in their biomedical research studies. Potential research participants were informed about the new study being conducted to understand participants' preferences on future use of biological samples and requested their participation. The principal investigator explained details of the study to those who were interested, gave them copies of the study information sheet and scheduled them for FGDs on separate days. On the day of the FGD, the principal investigator or research assistant explained details of the study again using the information sheet for FGD participants and obtained written informed consent from each of them before conducting the FGD. The research assistant facilitated the FGDs in English in South Africa while the principal investigator facilitated the FGDs in Chichewa in Malawi. Participants who took part in the IDIs were approached via emails which explained the objective of the study, and requested the potential participants who were willing to take part in the study to express their willingness to do so in their response email. Those who expressed their willingness to participate in the interviews were asked to choose whether they wanted to be interviewed virtually or in-person. The potential participants were then scheduled for the IDIs. Individuals who had chosen to be interviewed virtually received both a consent form and an interview guide via email. They were asked to sign the consent form and return it to the principal investigator. Those who had chosen to be interviewed in-person were also sent a copy of the interview guide and consent form by e-mail, and written informed consent was sought from them on the day of the interview.

**Data Collection Methods**
Semi-structured interview guides were used to collect information from all participants. Each IDI took approximately 40 minutes while each FGD took approximately 55 minutes. All FGDs were conducted in-person at private venues in both countries. COVID-19 preventive measures including wearing of face masks, hand washing, use of hand sanitizer and physical distancing were observed during both face-to-face FGDs and IDIs. Open-ended questions were used to guide the interviews. All participants agreed to be audio-recorded during the IDIs and FGDs.

**Data Processing and Management**
All audio-recordings in the IDIs and FGDs were transcribed verbatim. The transcripts were coded according to the type(s) of interviews and the type of respondents who participated in the different interviews in both Malawi and South Africa. For example, an IDI conducted with a policymaker in Malawi was coded as MW_IDI_PM_01 while an IDI conducted with a policymaker in South Africa was coded as SA_IDI_PM_02. Similarly, a FGD conducted with research participants in Malawi was coded as MW_FGD_RP_01 while in South Africa, it was coded as SA_FGD_RP_02. All transcripts were saved on the laptop of the student investigator before each transcript was exported into ATLAS.ti for data analysis.

**Data Analysis**
Data was analysed thematically, iteratively and inductively. The preliminary thematic analysis of data at each stage of interviews informed interview questions for the subsequent interviews and by the time the final interviews were done, data saturation had been reached. A coding framework was developed after thorough reading of the transcripts, and it was further discussed and applied to the transcripts in ATLAS.ti as per standard thematic analysis guidelines [7-8].

**Ethical considerations**
The study received ethics approvals from both the Health Research Committee (HREC) of the Stellenbosch University Faculty of Medicine and Health Sciences in South Africa (Ethics Reference Number S19/01/005) and the College of Medicine Research Ethics Committee (COMREC) in Malawi (COMREC reference number P.08/19/2770). Individual written informed consent was obtained from each of the participants who agreed to take part in the study prior to their enrolment. All information obtained from the study participants was kept confidential. Data was stored in a password protected computer to prevent access by unauthorized persons.

**Demographic Characteristics of Study Participants**
Below are demographic characteristics of our participants.

**Table 2: Demographic Characteristics of Study Participants**

| Demographic Characteristics | | IDI Respondents (N = 34) | FGD Participants (N = 44) |
|---|---|---|---|
| **Gender** | Male | 13 | 18 |
| | Female | 21 | 26 |
| **Age** | 20 – 39 | 25 | 37 |
| | 40 – 65 | 9 | 7 |
| **First Language** | Afrikaans | 16 | 17 |
| | Chichewa | 14 | 25 |
| | English | 4 | 2 |
| **Highest Level of Education** | | | |
| | Primary | 3 | 12 |
| | Secondary | 14 | 26 |
| | Tertiary | 17 | 6 |
| **Ethnicity** | Black African | 25 | 29 |

| | | |
|---|---|---|
| Mixed race | 5 | 13 |
| White | 4 | 2 |

**Future Use of Biological Samples / Secondary Use of Biological Samples**

Study participants in both FGDs and IDIs were asked to express their views on future use or secondary use of biological samples. Most participants recommended future use of biological samples, for three key reasons. One of the main reasons given was that using samples in future research maximizes their utility. Secondly, future use of biological samples ensures that research participants are not put at an additional burden or risk of sample collection methods such as blood draws which may further inconvenience or traumatize some participants.

Below are direct quotations from research participants on the two reasons for recommending future use of biological samples:

*"Seriously if you just use the data for that specific study only, certainly you are putting your research participants at trauma with the research procedures you are doing. For example, it might seem okay for me but for some people it is traumatic to give a blood sample especially men. So, now let's say I am doing a genetic research study and in my work, I take blood samples from babies. So, if I can take blood just once and take enough blood samples and not too much, then it means you have enough samples to do all this work and any future work. Then I don't have to put them through those procedures again since I have enough samples and you can maximize your research" (SA-IDI-REC-005).*

*"It would make research more efficient and valuable if people were allowed to store samples and use available data and samples in future studies' (MW-IDI-Funder-002).*

Thirdly, some participants expressed an aspect of altruism associated with the recommendation of future use of biological samples in the sense that the biological samples may be used to develop interventions that may benefit future patients:

*"I would allow them to use the samples in future because I see the research, they gonna do helping other patients in future. So, they gonna do something good with it so I feel it's good for them to use it in future for the benefit of others" (SA-FGD-02).*

*"Many people are very scared to give blood; am also very scared but I don't worry about it because as long as am helping other people to get treatment or improve their health, then am proud of that and am very proud of my country that am able to give something that helps my country and others" (MW-FGD-003).*

As our previous paper has shown [9], most participants in our study who spoke positively about future use of biological samples were also in favour of broad consent that liberally allows for such use.

**Indefinite Storage of Biological Samples**

Most of the participants expressed a preference for indefinite storage of biological samples that are collected for a specific research project. They highlighted that storing samples for future use will ensure value for money since it is expensive to collect samples every time one has a research question. However, they also expressed the view that any future use of stored biological samples should receive ethical approval by a research ethics committee and must comply with national regulatory requirements:

*"Storage of samples allows you to do future research using the available samples and data as long as you obtain HREC approval for any future research on the samples and data. It makes life much easier, and it allows for so much more to be done within the field you are working in or with the limitations of the budget" (SA-IDI-REC-001).*

*"As far as I am concerned, it is much better and valuable to collect samples and deposit them in a biobank so that postgraduate students and other researchers can access the samples and analyze them for their studies instead of collecting fresh samples since it is expensive. What the other researchers need is ethics approval for their studies before they can use stored samples. It's unfortunate that everyone wants to collect fresh samples for their studies due to the regulatory restrictions for storage of samples in this country" (MW-IDI-Funder-02)*

*"We believe that storing the samples ensures value for money and gives access to other researchers to do multiple studies using the same sample. However, there is need for governance frameworks for access and use of the samples in storage and who benefits from use of the samples in terms of patents or publications etc and who*

*pays the costs for storage of the samples. Obviously, institutions who store the samples get them from the researchers but those who may wish to do any new studies using the samples may have to incur costs for using the samples…So, the governance structure for use and access to the samples must be in place and must be developed in accordance with the national regulatory requirements for access and use of samples" (SA-IDI-Funder-02).*

Some of the participants in Malawi who recommended indefinite storage of biological samples noted that there are capacity and resource challenges in regard to establishing biobanks where the samples can be stored.
For example, one of the participants said,
*"Keeping samples would be a better way to go but we do not have the capacity to keep the samples in biobanks and such policy framework is non-existent in this country. At least our friends overseas including our neighbors in SA can do that because they have the resources and capacity" (MW-IDI-Policymaker-02).*

**Destruction Of Biological Samples**
Some participants mostly from Malawi recommended that biological samples that are collected in a specific study must be destroyed on the study completion. Their reason for recommending this was that it was a policy in their country to have the samples destroyed at the end of each specific study, and all researchers must comply with the regulations. Thus, *"... Our policy is to destroy all leftover samples at the end of the study. Of course, the samples can be stored for a period of five years after the study in case there is need for further analysis, but one cannot use the left-over samples for any future research. ...that's why we say the left-over samples should be destroyed at the end of the study" (MW-IDI-Policymaker-001).*
Most REC members in Malawi stated that they are sceptical about biological samples that are sent abroad for further analysis as no one oversees the destruction of such samples after the analyses are over. They largely agreed with the motivation behind the policy that all samples must be destroyed at the end of the study and should not be sent outside the country for further analyses. For examples, one of the participants said; *"...We are always concerned when specimens are shipped outside the country for further analysis under a material transfer agreement because we don't know whether the samples get destroyed when the analysis is over. Although our researchers promise to ensure that the samples are destroyed after the analysis abroad, there is no one policing the destruction of the samples. I think it is for this reason our guidelines require researchers to discard the specimens at the end of the study (MW-IDI-REC-002)."*
Other participants also felt that a participant provides consent for a specific study and provides his or her biological sample for use in that study. This means that the permission provided for the use of the biological sample in the study is just for that one study and as such, any sample that remains after the specific study must be destroyed:
*"I wouldn't go for that …I would rather stick to my earlier permission for the samples to be used in this study only because we are consenting for the samples to be used for that purpose. So, any leftover sample must be discarded" (SA-IDI-PA-003).*
Here it is worth noting that the participants who recommended destruction of biological samples at the end of each study are the same participants who recommended specific consent in research studies in a previous paper published by us [9]. These participants also recommended re-consenting of participants whenever researchers decide to use their biological samples in future research.

**Ownership of Biological Samples**
Participants in this study were asked to state their opinions on who owns biological samples that are obtained in biomedical research. In response, there were different opinions on ownership of these samples. Most participants who took part in the FGDs in both countries felt that participants who provide the biological samples are their rightful owners.
For instance, one participant said:
*"I would actually say more on cellular level you understand because in your blood there is actually your genes which identify you and our genes are not the same maybe I have a good health condition where I don't get sick easily of a virus or bacteria. That is me. So, my blood is different from yours and you have your own blood.*

*It's like your biometric data. So, the blood I give the researcher is still me because it's my blood and not someone else's blood" (SA-FGD-003).*

Some FDG participants in both Malawi and South Africa felt that funders of the research are the ones who own the biological samples since they provide the funds that enable research to be conducted:

*"Whoever funds research is the one who owns everything that is for that research including the blood participants give. …It is like a customer who goes to the market with his money to buy stuff. The stuff he buys with his money belongs to him because the money is his" (MW-FGD-03).*

*"The funders and all those who provide the money own the research samples. We are there just to provide the samples for them" (SA-FGD-003).*

On the contrary, most participants, especially REC members and funders in the IDIs in both countries, felt that biological samples are owned by researchers who collect them because participants give away their rights over samples to researchers when they give permission for the researcher to collect the samples:

*"I would say that the researcher is custodian of samples on behalf of the participant, but I am referring to consent form. If the consent forms say that you are giving permission for any researcher to use your samples for future studies, you are giving them ownership to use your samples so whatever they decide to use your samples for, that will be their decision. The participant has been informed that it is the researcher's decision so when the participant signs, the participant is saying that they are giving permission to store their samples for 5 years and maybe someone comes for a study or scientific research priority study that they want to do. Then yes, it would be the researcher who decides" (MW-IDI-CAB-001).*

There were also a few participants from both FGDs and IDIs who felt that biological samples are owned by the government since some government documents in Malawi such as material transfer agreements state that samples collected from citizens are a property of the government.

*"I think samples are owned by the government" (SA-FGD-001).*

*"There is a statement in our MTA which says that samples collected in Malawi are the property of the Malawi Government. So, in my opinion, the government owns the samples" (MW-IDI-REC-002).*

**Discussion**

The findings of this study have highlighted some of the issues that involve collection, storage, and use of biological samples in biomedical research in two sub-Saharan African countries. Most participants in Malawi and South Africa preferred indefinite storage of biological samples and their secondary use in future research while few participants preferred destruction of biological samples and re-consenting of participants in future research. Additionally, most research participants who participated in the FGDs believed that donors of biological samples are rightful owners of the samples. These findings are consistent with findings of previous studies on stakeholder views on collection, storage, and future use of biological samples conducted in South Africa, Malawi and Uganda [10-12]. For example, in the study conducted in South Africa, it was reported that participants believed that they have ownership rights of their biological samples which is consistent with our study finding that participants are rightful owners of samples [10]. Similarly, the Malawian study reported that researchers supported sample storage for future use to maximize the value of samples and reduce costs associated with research [11]. The findings of the Malawian study are also consistent with one of our key findings from most research participants in the IDIs that future use of biological samples enhances the value and efficiency of biological samples. In the Ugandan study, it was also reported that participants generally supported the storing of samples for future research (95%) which is consistent with our finding from most of the IDI participants about indefinite storage of biological samples [12]. Similarly, a recent Jordanian study also found that most participants preferred reuse of biological samples and sharing bio-samples as long as it was explained in the signed consent form [13]. These findings are also consistent with a study conducted in Ghana and Kenya [14].

Contrary to these findings, Moodley [10] found that most participants had serious concerns about future use, benefit sharing as well as export of samples and almost half of the participants expressed a desire to be reconsented for any future use of their samples. These contrary opinions refer to the different arguments for both broad consent and specific consent. While specific consent allows

researchers to collect biological samples from research participants and use them in the specific research for which they are collected, it does not allow any future or secondary use of biological samples outside the scope of the current study. It requires researchers to re-consent research participants for new use of their biological samples that is outside the scope of the original consent. Proponents of specific consent are typically also those who recommend destruction of biological samples after the original study is over [2]. On the contrary, broad consent allows potentially fruitful and important future research to be conducted using previously collected and stored samples [15-17]. However, broad consent is also faulted for not providing participants the right to withdraw consent when they do not know the future studies they will participate in; and that sometimes it may be impossible for participants to know future study risks of harm [18-20].

Despite the different arguments for and against future use of biological samples, policy requirements for collecting, storing, and using biological samples and data for research remains a controversial issue in some countries [10,15,21]. While most high-income countries support future use of biological samples, some countries in low- and middle-income countries have developed stringent policies on their use [6]. Therefore, it is our hope that findings of this study contribute to the ongoing discussions about future or secondary use of biological samples in low- and middle-income countries. The study findings could also inform policy changes in Malawi especially on the current requirements for specific consent, storage and future use of biological samples.

## Conclusions

This empirical study has attempted to help fill the gap in literature on key stakeholder views on collection, storage, and future use of biological samples in biomedical research in Malawi and South Africa. The study has found that there are strong differences between key stakeholder views regarding destruction of biological samples and indefinite storage of biological samples. While most participants in South Africa and some participants in Malawi preferred use of stored biological samples in future research, some of them from Malawi recommended destruction of biological samples after the initial study is over. Study participants also had different opinions on ownership of samples with most participants in FGDs in both countries suggesting that biological samples are owned by donors while some participants in the IDIs in both Malawi and South Africa felt that samples are owned by researchers and funders of research. We hope that these findings will inform current debates on acceptable consent models and future use of biological samples in Malawi and South Africa. The findings may also inform current policies on storage and future use of biological samples especially in Malawi. Finally, we recommend further research on stakeholder perspectives on collection, storage, and future use of biological samples in other sub-Saharan countries since the findings from this study cannot be generalized to other countries in the region.

## Abbreviations

CAB: Community Advisory Board
COMREC: College of Medicine Research Ethics Committee
DNA: Deoxyribo-nucleic acid
DOH: Department of Health
DTTC: Desmond Tutu TB Centre
FAMCRU: Family Clinical Research Unit
FGD: Focus Group Discussion
HREC: Health Research Ethics Committee
IDI: In-Depth Interviews
MOH: Ministry of Health
MRC: Medical Research Council
MUSTREC: Malawi University of Science and Technology Research Ethics Committee
NCST: National Commission for Science and Technology
NHREC: National Health Research Ethics Council
NIH: National Institutes of Health
PAG: Patient Advocacy Group
REC: Research Ethics Committee
UNC: University of North Carolina

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***Authors' contributions***
*FM was involved in the conception, design, and development of study tools. FM was involved in data collection, and in transcription of interviews, and led data analysis and manuscript development. SR and WJ were involved in the conception, design and development of study tools and data analysis. Both SR and WJ supervised the research and provided input on research design and progress. They also reviewed the manuscript and provided substantive input into the manuscript. All authors read and approved the final manuscript.*

***Competing interests***
*The authors declare that they have no competing interests.*