OPEN LETTER

Understanding Ethical, Legal and Societal Issues (ELSIs) in Human Biobanking and Genomics for Research and Healthcare in Zimbabwe: The Genomics Inheritance Law Ethics and Society GILES initiative [version 1; peer review: 2 approved with reservations]

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Abstract

Biobanks and human genomics applications are key for understanding health, disease and heredity in Africa and globally. Growing interest in these technologies calls for strengthening relevant legal, ethical and policy systems to address knowledge disparities and ensure protection of society, while supporting advancement of science. In Zimbabwe there is limited understanding of ethical, legal, and societal issues (ELSI) for biobanking and genomics. The Genomics Inheritance Law Ethics and Society (GILES) initiative was established in 2015 to explore the current status and gaps in the ethical and legal frameworks, knowledge among various stakeholders, and to establish capacity for addressing ELSI of biobanking and genomics as applied in biomedical and population research, and healthcare. A multi-methods approach was applied including document reviews, focus group discussions and in-depth interviews among health and research professionals, and community members in six provinces comprising urban, peri-urban and rural areas. Emerging findings indicates a need for updating guidelines and policies for addressing ELSI in biobanking and genomics research in Zimbabwe. Emerging terminologies such as biobanking and...
genomics lack clarity suggesting a need for increased awareness and educational tools for health professionals, research scientists and community members. Common concerns relating to consent processes, sample and data use and sharing, particularly where there is trans-national flow of biospecimens and data, call for nationally tailored ELSI frameworks aligned to regional and international initiatives. This paper describes the strategy undertaken for the development and implementation of the GILES project and discusses the importance of such an initiative for characterisation of ELSI of human biobanking and genomics in Zimbabwe and Africa. Conducting this explorative study among a wide range of stakeholders over a countrywide geographical regions, established one of the most comprehensive studies for ELSI of human biobanking and genomics in Africa.

**Keywords**
biobanking, human genomics, genomic research, ethics, ELSI, Zimbabwe, Africa

This article is included in the [African Society of Human Genetics](https://www.africanhuman.genetics) gateway.
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Competing interests: No competing interests were disclosed.

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The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

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Introduction

Biobanks of human biospecimen collections are key resources for understanding individual and population diversity, and are integral to healthcare research, medical care, and drug discovery. Linked to biobanking, advances in technology are enabling large-scale biochemical and genomic analysis, generating substantial amounts of data of personal and health relevance with ethical implications for communities and populations. Although the benefits of human biobanking and genomics applications are well recognised, ethical, legal and social challenges arise alongside unclear regulations and policies, and limited understanding among research scientists, healthcare professionals and the wider public. In particular, African countries are faced with a growing need for the application of genomics in medicine and research. African genomics and population data are drawing regional and global interests as they add rich genomic background diversity to existing efforts to fully understand human genomic variation. This plays an important role in biomarker identification, improving disease diagnostics, and development of targeted therapies, which take into account interplay of environmental and demographic factors.

The need for ELSI research for biobanking and human genomics in Africa

Recently, several consortia have embarked on projects to characterize African population genomics. The largest consortium is the Human Heredity and Health in Africa (H3Africa) program, which is focused on supporting biobanking and collaborative genomics research for understanding population genomic diversity in relation to disease susceptibility, diagnosis and association with environmental factors. This and other ongoing initiatives create the need for anticipating and addressing emerging issues in human genomics notably: increased biobanking activities, whole genome sequencing, genome wide association studies, large scale databases and bioinformatics. Zimbabwean researchers are actively contributing to this initiative, and other related continent-wide consortia whereby associated ethical, legal, and societal issues (ELSI) remain under-explored. For example, despite the expectations of the international collaborative projects in the cross-border storage of human biospecimens and depositing of research results in consortia databases for access by scientists locally and abroad, differing terms and norms which are likely to present barriers to access and use are not well addressed. In addition, the unidirectional flow of samples and data out of Africa has created a sense of exploitation and distrust and the African genomics research community are playing a leading role in addressing such concerns and limitations as they become more likely to occur.

Biobanking, genomics and emerging ELSIs in Zimbabwe

In Zimbabwe, human biospecimen collections or biobanks have largely focused on infectious diseases, national surveillance programs, disease outbreaks and molecular diagnostic applications. In this work, we acknowledge the existence of biobanks both in their rudimentary and advanced form, and the potential for their samples to be used for a wider variety of human genomics applications than for which they were originally collected. To date, the Biobank and Pharmacogenetics Database of African Populations is the only openly reported resource, which marked a significant step in multi-national collaborative biobanking efforts, and was designed for the study of variations associated with drug response in Africa. Such activities were established with limited knowledge and expertise about ELSIs and create a basis for strengthening the current structures for human biobanking and genomics sciences oversight.

Although biobanking and genomics are still in their infancy in Zimbabwe, growing interest and participation of local researchers in international collaborative consortia promises new avenues for research and medical solutions important to public health. For example, a local pharmacogenetics-based study indicated that the prescribed use of the anti-HIV drug efavirenz may result in severe side effects among patients due to highly prevalent variants in the gene encoding the drug metabolising CYP2B6 which were associated with decreased drug clearance, and thereby increasing risk of side effects such as depression and other neuropsychiatric complications. Clinical trials to assess the possibility of reducing dose and cost-effectiveness of pharmacogenetics-based prescriptions are underway. The benefit of such examples of translational research cannot be underestimated and more clinical research involving biobanking and genomics is highly anticipated in the near future. As more awareness builds among researchers, healthcare professionals and policymakers, the applications of biobanking, genomics research and bioinformatics will increase bringing to light the deficiencies in the current ELSI framework in Zimbabwe.

In the wider community, individual and society beliefs, practices and perceptions influence participation in biospecimen collection for human genomics. As with most African countries, Zimbabwe is undergoing socio-economic and cultural as well as religious transitions, which impacts on beliefs and practices towards health research involving biobanking. In Africa, blood sample collection is a major area of concern among community and religious groups, and may be viewed by many as part of “witchcraft”.

Zimbabwe is a landlocked country in the Southern African region with a population of approximately 15 million inhabitants. Being centrally located, Zimbabwe provides a major link for trade and migration, and access to a diverse ethnic and highly literate population. While Zimbabwe is undergoing constitutional reforms, scientific and technological advances, protection of researchers and participants may become more compromised. Ethico-legal consequences and risks of psychosocial harm, stigma and genetic discrimination also need to be addressed. These challenges present an opportunity for Zimbabwean researchers to contribute to the growing debate on ELSI of and development of appropriately tailored frameworks in line with various ongoing initiatives to build capacity for addressing and regulating current end emerging issues for biobanking and human genomics applications in Africa.

The Zimbabwe ELSI initiative for biobanking and genomics: GILES

Driven by the need to understand the current status and to determine needs for building capacity and harmonised guidelines
for addressing ELSI of biobanking and human genomics in Zimbabwe, the Genomics Inheritance Law Ethics and Society (GILES) initiative was launched in 2015. The strategy involving steps to establish empirical evidence for ELSI regulations and knowledge-based participation in biobanking and human genomics for research and healthcare is shown in Figure 1.

The research team consisted of a multidisciplinary team with expertise in bioethics, genomics, medicine, medical laboratory sciences, sociology, psychology and psychiatry.

The GILES project employed a multi-methods approach, which included document reviews and an explorative qualitative study with targeted informant interviews and focus group discussions to understand the ELSIs and governance of biobanking and human genomics for health research and clinical applications in Zimbabwe. The qualitative method was used to establish subjective experiences of participants regarding biobanking and genomics as a basis for development of more focused studies and theoretical framework in future. The study was conducted in six provinces namely – Harare, Bulawayo, Mashonaland East, Manicaland, Matabeleland North and Matabeleland South (Figure 2). The site selection was primarily based on the researchers' affiliations in Harare and Mutare (Manicaland province). Historically, these regions have been favoured for clinical research work and represent the major ethnic group who speak the Shona language. Therefore, further considerations were made to include a wider ethnicity and geographical representation from the Matabeleland region. The Ndebele-speaking population are mostly located in Matabeleland North and Matabeleland South, with Bulawayo as the capital city. Populations in this region are often under-represented in health research despite representing the second most populous ethnic group in Zimbabwe.

The health authorities are instrumental to accessing communities for research in Zimbabwe. We sought permission from the Ministry of Health and Child Care to engage with healthcare workers and members of the communities through local clinics and hospitals. Social scientists from the GILES project team guided the interviews and discussions. For effective communication with the individuals and communities around Zimbabwe, questionnaires were developed in English language and translated into local languages Shona and Ndebele. Interviews were conducted in the appropriate languages and were audiotaped and transcribed then translated into English for analysis.

ELSI regulations
There exist gaps in the current guidelines and policies for addressing ELSI of biobanking and genomics in Zimbabwe. With

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**Figure 1.** GILES initiative strategy.
emerging issues, including large scale biobanking, next generation sequencing and genomics, informed consent processes, ownership, commercialisation, widespread data use and sharing, the current ethical review and regulatory structures are inadequate, thereby presenting a challenge for upholding ELSI requirements which ensure participant and researcher protection while optimizing the benefits of research in Zimbabwe. To understand how ELSI are addressed and regulated in Zimbabwe and how they are used to govern biobanking and genomics for human health research and clinical applications, desk reviews of legal and policy documents, and regulatory instruments were conducted. Content analysis will determine the presence and absence of information or guidelines regarding the collection, storage, exportation and analysis of biological specimens and data, biospecimen and data sharing, data security and consent.

Application of ELSI in research projects

We hypothesised that there is poor consistency in the manner in which ELSIs of biobanking and genomics are addressed in research projects reflecting the need for clearer and enforced guidelines. Specific issues of interest included privacy and confidentiality protections, community consultation and engagement, biorepositories (use, governance and security, specimen sharing and transfers), data sharing and security, informed consent features, descriptions of risks and benefits, long-term storage and implementation of sample disposal plans. All human subject research protocols are submitted for review, approval and registration through institutional and the national research ethics committee at the Medical Research Council of Zimbabwe (MRCZ). This provided a rich source of materials to analyse the current practices among researchers in addressing ELSIs of biobanking and genomics by reviewing protocols, which involve human subjects and biospecimen collection/biobanking and genetics/genomics

Knowledge, attitudes and practice of ELSI of biobanking and genomics

Due to emerging terms such as biobanking, such terminologies are not well understood among community members and also healthcare professionals. This includes the chain of biospecimen collection to storage activities, which lack clarity and are surrounded in controversy and other beliefs. Although there is familiarity with genetics in some traditional and cultural applications, concerns may be raised about consent, confidentiality and stigma. Research scientists and healthcare workers collect biospecimens, which are targeted for, or have potential to be used for human genomics research or clinical diagnosis. The wider community represent current and prospective donors of biospecimen collection and participants in genetic or genomic analysis. Their level of understanding, expectations and experiences are key to determination of needs for awareness and educational resources.

To establish empirical evidence of these needs, we aimed to characterize the broad range of knowledge, attitudes and perceptions about biobanking and genomics, and the rationales behind...
them. In-Depth Interviews were conducted among 31 individuals consisting of 3 spiritual and religious leaders, 11 researchers, 5 regulatory and ethics experts, 9 health service providers, 2 policymakers and 1 journalist. Focus Group Discussions were conducted among healthcare workers and community members from 6 provinces (Table 1). We used topic guides and prompt statements to explore general issues about biobanking of biospecimens and their use in genomic analysis in healthcare and research.

Community engagement and education are key to fulfilling ethical requirements by promoting understanding of complex subjects such as biobanking and genomics. The H3Africa consortium researchers are actively incorporating such strategies into their research programs. The participation of the various stakeholders in the GILES project has facilitated a first step towards community engagement in biobanking and genomics in Zimbabwe. This has created a foundation, which may be useful for future research and capacity building programmes tailored for the diverse local and regional communities.

**Challenges, lessons learnt and opportunities for the GILES initiative**
Challenges were largely faced in the project implementation and are highlighted below.

- For a wide geographical spread, the process of getting support letters and approvals from the relevant government departments, local authorities and other universities was mired in bureaucracy, slowing down project momentum and timelines.
- Since this was the first time such a study was being implemented the protocol development process was long and involved back and forth meetings particularly in refining the methodology, tools and translations into the two main local languages.
- Although the team consisted of experts from diverse backgrounds - medicine, psychology, ethics, biomedical sciences and sociology, the majority were novices in the subjects of biobanking and genomics. Therefore, informational sessions formed part of the project strategy to ensure good understanding of the subject topics under study.

**Lessons learnt:**

- Use of well established community advisory boards was key for engaging critical stakeholders.
- Religious and traditional views have a huge influence on communities’ perceptions on participation in biobanking and genomics research
- Development of terminology for biobanking, genomics and ethics, may have benefited from wider consultation among various stakeholders prior to conducting the study.
- A generous amount of time was necessary for fieldwork especially in mobilization of participants, to ensure wide population coverage.

**Opportunities:**

- To develop educational material to improve awareness and participation in genomic research particularly and health research in general.
- To apply community engagement strategies to develop appropriate terminology and improved understanding of biobanking and genomics for use in research and health dialogue. This has potential to build relationships, increase trust, improve consent processes and empower local communities.
- To develop targeted community engagement interventions based on established beliefs, perceptions and practices.
- To develop updated guidelines and policies to guide research scientists and ethics committees.
- To strengthen capacity among research ethics committee members and regulatory authorities.

**Table 1. Number of focus group discussions participants by province.**

<table>
<thead>
<tr>
<th>Province</th>
<th>No. of participants by designation</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Healthcare workers</td>
<td>Community members</td>
</tr>
<tr>
<td>Harare</td>
<td>25</td>
<td>23</td>
</tr>
<tr>
<td>Mashonaland East</td>
<td></td>
<td>20</td>
</tr>
<tr>
<td>Bulawayo</td>
<td>35</td>
<td>24</td>
</tr>
<tr>
<td>Matebeleland South</td>
<td></td>
<td>14</td>
</tr>
<tr>
<td>Matebeleland North</td>
<td></td>
<td>9</td>
</tr>
<tr>
<td>Manicaland</td>
<td>20</td>
<td>19</td>
</tr>
<tr>
<td><strong>TOTAL</strong></td>
<td><strong>80</strong></td>
<td><strong>109</strong></td>
</tr>
</tbody>
</table>

**Conclusions and next steps**

The GILES initiative established a platform for the study of ELSI related to bio- and data resources for human genomics activities, which involve biospecimen collection, storage, analysis, data sharing and use (biobanking, databases and bioinformatics) in Zimbabwe. This was achieved through a multi-disciplinary approach involving research scientists, health and academic professionals and community members. The GILES initiative is innovative in being the first to address ELSI regarding the human genomics resources for health research and application in Zimbabwe. This was enriched by using a comprehensive methodology encompassing desk reviews and interviews and by involving a diverse research team of biomedical scientists, clinicians, public health and ethics experts and social scientists. Further comprehensive descriptions of findings will be reported separately.

Zimbabwe is a country that is experiencing growth in genomic research and biobanking and yet ELSI of human bioresources and genomics are inadequately applied and poorly understood.
Growing interest in the application of genomics in medicine and diagnostics implies that there is a need for a paradigm shift in the education and training of researchers, health professionals and the public on ELSI of biobanking and human genomics. The GILES initiative will culminate in strengthening capacity through education, training and community engagement. We envisage the use of local beliefs, perceptions and folklore in developing tools, which can provide more efficient means for research participant recruitment, awareness and consent processes for biobanking and genomics research. Capacity building will empower students, faculty and health professionals, researchers, regulatory authorities, public health scientists and the wider public. In the future, workshops will be conducted to develop recommendations, which will be availed to institutional review boards, research ethics committees, regulatory bodies and government in order to tailor the ELSI framework which protects and empowers research participants, researchers and health professionals while advancing biobanking and human genomics in Zimbabwe and the African region.

The limited understanding of ELSI applications for genomic research and healthcare in Zimbabwe is a situation, which also applies across the continent. The experiences in implementation of the GILES initiative and preliminary observations suggest a need for more thorough localised ELSI research projects in Africa to accommodate the diversity of cultural norms and levels of capacity in use of biobanking and human genomics technologies. This reiterates calls for the development of more tailored national and regional guidelines, which support the inevitable and growing nature of collaborative biobanking and genomics research.7,11. The GILES initiative presents an example, which may be used to conduct such explorative work in other African countries. It is also among a select few studies in Zimbabwe and Africa, which have employed an inclusive approach for exploring the needs for future development of an evidence-based ELSI framework. The will provide opportunities for education, community engagement and capacity building for tailored ethical frameworks appropriate for African communities.

Disclaimer
The views expressed in this article are those of the author(s). Publication in AAS Open Research does not imply endorsement by the AAS.

Ethical considerations
The GILES study was approved by the Joint Research Ethics Committee (JREC) at Parirenyatwa Central Hospital, and College of Health Sciences at University of Zimbabwe Reference: number 06/15. Additionally, the study was reviewed and approved by the national research ethics Committee at the Medical Research Council of Zimbabwe Reference number: MR/CZA/2051). Prior to the focus group discussions and in-depth interviews, written informed consent was obtained from all participants. All participants were given pseudonyms to use instead of their names for confidentiality purposes. Permissions to conduct interviews and document reviews were obtained from the heads of the relevant institutes and organisations. Permission to engage with community members was obtained from the Ministry of Health and Child Care as we used health centres to recruit community participants. Further permission was obtained from the community leaders from the respective communities.

Data availability
No data is associated with this article.

Grant information
Research reported in this publication was supported by The Common Fund and the National Human Genome Research Institute of the National Institutes of Health (NIH) under award number U01HG008224. The content is solely the responsibility of the authors and does not necessarily represent the official views of the National Institutes of Health.

The Genomics Inheritance Law Ethics and Society (GILES) project is funded as part of the H3Africa Initiative, which is supported by the AAS’s Alliance for Accelerating Excellence in Science in Africa (AESA) and the New Partnership for Africa’s Development Planning and Coordinating Agency (NEPAD Agency). Funding for this initiative is provided by the Wellcome Trust (UK) and the US NIH (USA).

The funders had no role in study design, data collection and analysis, decision to publish, or preparation of the manuscript.

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5. Wilson BJ, Nicholls SG: The Human Genome Project, and recent advances in


Open Peer Review

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Francis Masiye
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This manuscript presents interesting and novel primary data about views and opinions of research participants interviewed in a qualitative study nested within the Genomics Inheritance Law, Ethics and Society (GILES) initiative in Zimbabwe. The study appears to have been well designed and executed, but additional details about the structure of the manuscript, which should include the following order: background/introduction, objectives, methods, results/findings, discussion of the findings, recommendations and conclusions are needed. Additionally, this manuscript should have been classified as a research article and not as an open letter since it reports on findings of the qualitative study.

This manuscript has much to teach the bio-baking and genomics research community, but would benefit from revisions as follows:

1. The objectives of the empirical study should be articulated in the manuscript.
2. The methods section should explain how the qualitative data from the in-depth interviews (IDIs) and Focus Group Discussions (FGDs) was processed and analyzed.
3. The results section could benefit from a substantial organizational overhaul with an eye towards enhancing the clarity of the central message of the manuscript including direct quotations from research participants. Finally, enhancing the emphasis on key study findings that are novel, exciting, and have direct implications for addressing ethical, legal and societal issues (ELSI) for bio-banking and genomics in Africa is important.

Is the rationale for the Open Letter provided in sufficient detail?
Partly

Does the article adequately reference differing views and opinions?
Yes

Are all factual statements correct, and are statements and arguments made adequately supported by citations?
Partly
Is the Open Letter written in accessible language?
Yes

Where applicable, are recommendations and next steps explained clearly for others to follow?
Partly

**Competing Interests:** No competing interests were disclosed.

**Reviewer Expertise:** My scholarly interests are in Health Research Ethics, Bioethics, Public Health Ethics and Medical Anthropology.

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

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**Author Response 19 May 2019**

**Alice Matimba,** University of Zimbabwe, Harare, Zimbabwe

Thank you for reviewing our article. We have addressed the comments as indicated in bold below. This includes clarification of the objectives of the article as an Open letter providing an overview of the GILES initiative. More detailed manuscripts for the various results of the project are currently underway.

**Reviewer 2**

This manuscript presents interesting and novel primary data about views and opinions of research participants interviewed in a qualitative study nested within the Genomics Inheritance Law, Ethics and Society (GILES) initiative in Zimbabwe. The study appears to have been well designed and executed, but additional details about the structure of the manuscript, which should include the following order: background/introduction, objectives, methods, results/findings, discussion of the findings, recommendations and conclusions are needed. Additionally, this manuscript should have been classified as a research article and not as an open letter since it reports on findings of the qualitative study. – **The objectives of the article have been clarified to fit with expectations for the classification.**

This manuscript has much to teach the bio-baking and genomics research community, but would benefit from revisions as follows:

1. The objectives of the empirical study should be articulated in the manuscript. – **This has been revised to emphasise the main aim of the paper as well as the main aims of the GILES Initiative.**
2. The methods section should explain how the qualitative data from the in-depth interviews (IDIs) and Focus Group Discussions (FGDs) was processed and analyzed. – **As indicated in the main aim of the paper which was to describe the strategy and experiences of the GILES initiative. Detailed reports and results will be published in separate research manuscripts which will also provide more details on methods including management of qualitative data.**
3. The results section could benefit from a substantial organizational overhaul with an eye towards enhancing the clarity of the central message of the manuscript including direct quotations from research participants. Finally, enhancing the emphasis on key study findings that are novel, exciting, and have direct implications for addressing ethical, legal and societal issues (ELSI) for
bio-banking and genomics in Africa is important. – In line with the above the paper has been revised to emphasise its main aim in providing an overview of the strategy of the project, and experiences of the researchers. Detailed reports and results will be published in separate research manuscripts which will also provide more details on the study methods adopted for the different components of the GILES study.

Competing Interests: No competing interests were disclosed.

Reviewer Report 14 January 2019

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Overall, the presentation of this paper is a bit confusing.

1. In the abstract it is stated that the paper “describes the strategy undertaken for the development and implementation of the GILES project and discusses the importance of such an initiative for characterisation of ELSI of human biobanking and genomics in Zimbabwe and Africa”. However the way it is written is more inclined towards reporting the experiences of the GILES project.

2. “The GILES project employed a multi-methods approach, which included document reviews and an explorative qualitative study with targeted informant interviews and focus group discussions to understand the ELSIs and governance of biobanking and human genomics for health research and clinical applications in Zimbabwe”. But it seems the paper is presenting more of the experiences of the GILES project than an explorative qualitative study. The voice of the respondents is conspicuously missing. I think the main problem is with the rationale of this paper. I suggest that the introduction be revised and the precise objective of this paper be clearly articulated. Otherwise it is confusing in its current form.

3. “ELSI regulations”; “There exist gaps in the current guidelines and policies for addressing ELSI of biobanking and genomics in Zimbabwe”. Later on in the same paragraph the authors state “Content analysis will determine the presence and absence of information or guidelines regarding the collection, storage, exportation and analysis of biological specimens and data, biospecimen and data sharing, data security and consent.” It sounds like the content analysis is not yet done. Then, what is this paper reporting? Desk review?

4. Desk review of “legal and policy documents, and regulatory instruments” is vague. It is indicated that protocols were also reviewed. Which protocols? Protocols of which research? For which time period; since MRCZ was established? Etc. It is thus not clear which exact documents from MRCZ were reviewed. The documents should be explicitly stated and references cited where applicable.

5. The first paragraph of the “Knowledge, attitudes and practice of ELSI of biobanking and genomics” section is presented in present tense; is it a preamble? If so, was it from literature? Provide reference citation. Are these study findings?

6. “Application of ELSI in research projects” section indicates that FGDs and in-depth interviews were conducted however, how this was done is not clearly articulated. The last paragraph of this section
talks about community engagement and there seems to be a disconnect with the preceding sections. Please include a bridging statement.
7. At this point it difficult to tell whether this paper is presenting the experiences of the GILES project or perceptions and views of individual participants? It is a bit confusing to the reader.
8. Let this paper be revised to present the results of the desk review and experiences of the GILES project.
9. “The limited understanding of ELSI applications for genomic research and healthcare in Zimbabwe is a situation, which also applies across the continent”. It is not clear whether this statement is derived from the results or it's from literature?

Is the rationale for the Open Letter provided in sufficient detail?
Partly

Does the article adequately reference differing views and opinions?
Partly

Are all factual statements correct, and are statements and arguments made adequately supported by citations?
Partly

Is the Open Letter written in accessible language?
Yes

Where applicable, are recommendations and next steps explained clearly for others to follow?
Yes

Competing Interests: No competing interests were disclosed.

Reviewer Expertise: ELSI of biobanking, clinical ethics, bone health, human anatomy and spine disorders

I confirm that I have read this submission and believe that I have an appropriate level of expertise to confirm that it is of an acceptable scientific standard, however I have significant reservations, as outlined above.

Author Response 19 May 2019

Alice Matimba, University of Zimbabwe, Harare, Zimbabwe

Thank you for reviewing our article. We have addressed the comments as indicated in bold below. This includes clarification of the objectives of the article as an Open letter providing an overview of the GILES initiative. More detailed manuscripts for the various results of the project are currently underway.

Reviewer 1

Overall, the presentation of this paper is a bit confusing.
1. In the abstract it is stated that the paper “describes the strategy undertaken for the development and implementation of the GILES project and discusses the importance of such an initiative for characterisation of ELSI of human biobanking and genomics in Zimbabwe and Africa”.


However the way it is written is more inclined towards reporting the experiences of the GILES project. – This has been well noted and the abstract has been refined and inclined towards reporting of the strategy undertaken and experiences of the project.

2. “The GILES project employed a multi-methods approach, which included document reviews and an explorative qualitative study with targeted informant interviews and focus group discussions to understand the ELSIs and governance of biobanking and human genomics for health research and clinical applications in Zimbabwe”. But it seems the paper is presenting more of the experiences of the GILES project than an explorative qualitative study. The voice of the respondents is conspicuously missing. I think the main problem is with the rationale of this paper. I suggest that the introduction be revised and the precise objective of this paper be clearly articulated. Otherwise it is confusing in its current form. – The objective of the paper has been revised both in abstract and in the Introduction. We have also indicated that the key aim was to describe the strategy and that detailed methodology of the various activities and their results will be reported in separate research manuscripts.

3. “ELSI regulations”; “There exist gaps in the current guidelines and policies for addressing ELSI of biobanking and genomics in Zimbabwe”. Later on in the same paragraph the authors state “Content analysis will determine the presence and absence of information or guidelines regarding the collection, storage, exportation and analysis of biological specimens and data, biospecimen and data sharing, data security and consent.” It sounds like the content analysis is not yet done. Then, what is this paper reporting? Desk review? – This paragraph has been updated. As indicated above this manuscript summarises the methods and more details will be obtained in the full manuscripts which are underway.

4. Desk review of “legal and policy documents, and regulatory instruments” is vague. It is indicated that protocols were also reviewed. Which protocols? Protocols of which research? For which time period; since MRCZ was established? Etc. It is thus not clear which exact documents from MRCZ were reviewed. The documents should be explicitly stated and references cited where applicable. – As indicated above this manuscript summarises the methods and more details will be obtained in the full manuscripts which are underway. We have however provided clarification regarding the protocols reviewed.

5. The first paragraph of the “Knowledge, attitudes and practice of ELSI of biobanking and genomics” section is presented in present tense; is it a preamble? If so, was it from literature? Provide reference citation. Are these study findings? – This has been revised and references provided.

6. “Application of ELSI in research projects” section indicates that FGDs and in-depth interviews were conducted however, how this was done is not clearly articulated. The last paragraph of this section talks about community engagement and there seems to be a disconnect with the preceding sections. Please include a bridging statement. – This section has been revised to reflect the objective of the paper which aimed at providing an overview of the project, summarise activities undertaken and their rationale.

7. At this point it difficult to tell whether this paper is presenting the experiences of the GILES project or perceptions and views of individual participants? It is a bit confusing to the reader. – The former is correct. The revisions have highlighted the main aim of the paper describing strategy taken for the project, focusing on rationale and experiences of the research team.

8. Let this paper be revised to present the results of the desk review and experiences of the GILES project. – Please refer to points above reading the main aim of the paper at this stage. As an open letter, the paper does not take the format of a research article. – Paper has been revised accordingly in line with above comments.

9. “The limited understanding of ELSI applications for genomic research and healthcare in Zimbabwe is a situation, which also applies across the continent”. It is not clear whether this
statement is derived from the results or it’s from literature? – This sentence has been revised. The point is that more ELSI research is required and also more understanding and awareness about ethical issues in these advanced technologies is needed. This applies across all regions of the African continent where these technologies are only starting to be applied, and each country would need to tailor interventions appropriate to their settings.

**Competing Interests:** No competing interests were disclosed.