

Perspectives and ethical considerations for return of genetics and genomics research results: a qualitative study of genomics researchers in Uganda

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Abstract

Background: Return of genetics and genomics research results has been a subject of ongoing global debate on what constitutes socially acceptable and ethical approaches for sharing individual and aggregate genomic results with participants. Such feedback to research participants is an ethical requirement to update participants on results related to the study particularly those that are deemed significant. Although there is limited literature, debate continues in the African setting on what constitutes appropriate practice regarding return of results for genetics and genomics research.

The study explored the perspectives and ethical considerations of genomics researchers for return of genetics and genomics research results in a Ugandan setting.

Methods: This was a qualitative study of researchers in Uganda using semi-structured interview schedules for In-depth interviews. The researchers were purposively selected based on their active involvement in conducting genetics and genomics research in the country. A total of 30 researchers participated in the study and were interviewed on their perspectives and ethical considerations for the return of genetics and genomics research results. Data were analysed through content analysis along the main themes of the study. Content analysis was conducted using a comprehensive thematic matrix, to identify common patterns arising from the narratives. QSR International NVivo software was used to support data analysis.

Findings: Return of genetics and genomics research results was generally acceptable to genomics researchers and some researchers had either returned individual or aggregate results. The main reasons for sharing results included actionability, benefits and the clinical utility of the results to the participants. Ethical considerations for appropriate return of results included a need for effective community engagement, genetic counselling prior to disclosure of the results, adequate informed consent and proper assessment of the implications of, or consequences of returning of results. However, the approaches to return of results is not standardised due to lack of ethics and regulatory guidelines to govern the practice in the country.

Conclusion: Return of genetics and genomics research results to participants is generally acceptable to genomics researchers and several researchers have returned either individual or aggregate results. Ethical considerations for return of genetics and genomics research results are numerous though their application is not regulated due to lack of appropriate local ethical guidelines.

Introduction

Genetics and genomics research (GGR) raises a number of ethical challenges both at the national and international level[1-5]. Issues such as informed consent, privacy and confidentiality, risk and benefit analysis as well as community engagement are still unsettled, particularly with respect to return of genomics research results[6, 7].

Globally, there is on-going debate on what constitutes socially acceptable and ethical approaches for sharing either individual or aggregate GGR results and incidental findings with participants [8-22] While feedback to research participants is an ethical requirement aimed at updating participants on study findings particularly those deemed significant. It has been observed by the H3Africa network that and there is little guidance available on how genomic research results can be returned to participants on the African continent and virtually no empirical data on preferences, perspectives contextual factors relevant to African stakeholders on return of results [9]. Literature in the Ugandan setting has addressed aspects such as existing ethical guidelines for genomics and bio-banking, models of informed consent for genomics research as well as perspectives of genomics research participants on what constitutes good ethical practice [6, 8]. A number of guidelines towards ethical conduct of GGR have been put in place including development of frameworks to guide such processes[9- 11]. However, these frameworks are generic and need to be contextualized to the local settings where such research is conducted. For Uganda, contextualized ethical guidelines for conduct of GGR will significantly

complement the available general guidance for conduct of research involving humans as research participants [23]. This is expected to set standards and address some of the demands for improved ethical conduct of research like greater openness and improved comprehension by research participants [24,25]. The fact that these issues have neither been addressed nor studied in a Uganda setting where there are a number of on-going genomics studies highlights the significance and urgency of the subject matter. This study explored the perceptions, experiences and ethical considerations by genomics researchers concerning return of GGR results in order to inform development of ethical guidelines for a Ugandan setting.

Methods

Data collection entailed face to face in-depth interviews conducted in English. The interviews collected data on researchers' perceptions, experiences and ethical considerations on the return of GGR results. The main domains covered in the interviews included information about the respondents' GGR and return of results perceptions, experience and practices, procedures involved in their studies and ethical guidance for decision making. Responses were audio recorded and complemented by notes taken by a research assistant. Recorded information was transcribed verbatim and checked for accuracy before analysis. Data were analysed through content analysis along the main themes of the study. Content analysis was conducted using a comprehensive thematic matrix that included codes, categories and themes to identify common patterns arising from the narratives. The coding was done both deductively and inductively. Transcripts were further reviewed for emerging themes which were integrated into the thematic matrix. Multiple people JO, BK, DES were involved in applying and confirming application of codes across all transcripts and disagreements were resolved by cross checking with the recorded data. NVivo software (QSR international 2020) was used to support data analysis and illustrative quotes were extracted.

Ethical considerations:

Ethics review and approval was obtained from the Makerere University School of Biomedical Sciences Higher Degrees and Research Ethics Committee ref. SBS 628, followed by clearance by the Uganda National Council for Science and Technology (UNCST) ref. SS268ES.

All the methods were carried out in accordance with relevant guidelines and regulations. Only adult individuals of 18 years and above both male and female who had provided informed consent participated in the study. No participant identifying information was recorded.

Findings

Of the 30 study participants, 23 were male with a mean age of 41 years (range, 29–65 years). All were residents of Uganda and affiliates of five research institutions in the central, western, eastern and northern parts of the country. The participants' main job roles included academic and researcher roles with most 24/30 (80%) having at least five years of GGR experience. Table 1.

Their fields of specialization included molecular biology, immunology, microbiology, biochemistry, pharmacology, internal medicine, transfusion medicine, surgery and obstetrics and gynaecology. Type of studies conducted by respondent included molecular diagnostics, pharmaco-genetics, pharmaco-genomics, molecular genotyping, microbio-genotyping and haematological genomics. Content analysis identified five themes and these were perceptions, appropriate community engagement, genetic counselling, informed consent and implications, experience and practices.

Table 1: Participant Characteristics

Attribute	No of participants N=30	Male	Female
Age range			
Missing age	1		1
20-29	1	1	0
30-39	10	8	2
40-49	10	8	2
50-59	6	6	0
60-69	2	0	2
Education level			
Masters	9	8	1
PhD	21	15	6
Employment/ Position			
Researcher	6	5	1
Lab associate	3	3	0
Dean	2	1	1
Lecturer	11	10	1
Professor	4	2	2
Senior scientist	1	0	1
Director	2	1	1
Graduate fellow	1	1	0
Duration/experience in genomics research			
1-4 years	6	5	1
5-10 years	15	13	2
11-15 years	5	3	2
>15> years	4	2	2

Table of demographic characteristics of genetics and genomics researchers. Note: Many of the participants held multiple roles and positions

1. Perceptions

Most respondents supported the return of individual and aggregate genetic and genomic research results. Respondents gave various reasons in support of the return of results including it being an ethical imperative, sharing of knowledge with the research communities to satisfy their curiosity, and as a direct benefit to participants in case of actionable results.

"Of course it is necessary to report results and if someone has a condition that is going to affect their livelihood, you definitely need to report. And like I mentioned, our reports go directly to the clinicians who are helping out on these patients." R022

"I think it is because when there is a finding the owner of the results has that right to know to get that information." R004

"I would return those results to Patient if I knew those results were going to help a patient receive better treatment, or if i knew they were going to affect his Prognosis. If a Patient is not going to do well, its good to tell them that because of "A,B and C", you are likely not to do very well in this state." R001

Other respondent thought that it is good to share genetics and genomics results if such findings are likely to lead to public health interventions.

"Yeah like exactly what I have said especially if it is actionable or of public health importance it should be because who wants to have for example breast cancer when it can be cured when we know that if we find it early and we act early the chances are zero, the benefits outweigh the risks." R015

"If it really has a big implication on public health that needs to be reported but sometimes it may not have a direct benefit. So, you weigh the risks and benefits." R022

To some of the respondents, failure to communicate potential clinically beneficial results could count as a violation of the 'do no harm' principle:

"Do no harm is one of the cardinal principles of ethics, if you're doing a study and one of the outcomes of the study is showing something that could affect the patient you're obliged to give the results." R013

The issue of confidentiality in the return of results was emphasized.

"You need to tell only those who are affected because issues like stigmatization come up. If you say the following ten have this disease, you are creating problems for those people because they will be segregated." R014

Respondents who did not favour return of results had different reasons for not doing so. These included the feeling that participants would not understand the findings, the lack of qualified genetic counsellors, the feeling that bad news should not be shared, the fact that some testing are not done within the country and the fact that the GGR was not meant for diagnostic purposes.

"We don't have a genetic counsellor on our team because our study doesn't need one. A genetic counsellor would be important for a diagnostic clinic where a patient comes in with a condition that needs to be diagnosed. So ours is more of a population study." R011

"Yes, like when you land on paternity information and there is a disconnect, such information is not easy to disclose. Should not be disclosed?" R017

"unless it is medically proven that a certain condition causes a certain condition but if it's just for research and you know that, ooh... they linked this gene to this kind of situation, once it is not really proven then you don't need to disclose." R022

Barrier to Return of Results:

Respondents highlighted a number of factors that impede the return of GGR results including interpretation of what is clinically significant, which is left at the discretion of the researchers, the meaning of the findings and understanding of the vocabulary by the participants as observed below.

"It could be difficult to return results which don't make sense to the participants I mean for example what would the patient understand with sequence?" R009

"I don't know we have not thought about returning[results] because...sometimes there is no mechanism of returning this data. How do you give a genetical data base to a person in Kabulasoke [remote village]. I don't see how that happens and then again it might be the framework and feasibility and what would be its benefits visa vis putting it in the public domain." R009

"We could have but we didn't. it is very scientific that some of those things don't make sense to even scientists." R027

Respondents highlighted the need for appreciation and evaluation of the implications of returning results such as stigma, discrimination, litigation or family breakups that may arise from such return of results both to the individual research participant, the family members of the participant and the entire community. Additionally, the fact that getting one genetic condition is not enough for someone developing a disease condition and the fact that genetics do not always lead to Phenotypic presentation.

"So ahaa, obviously you must think about what those results mean? What do they mean? Do they mean that this particular population you know, ends up being targeted as a disadvantaged population, stigmatized or segregated." R007

"And these issues I think they have legal implications,..... you really have to rethink and then probably get advice on how best to handle these things like you have said context matters." R009

Role of formal Guidance:

Many respondents observed that for results to be returned ethically and appropriately, there is need for proper oversight based on a contextualized regulatory framework and guidelines and these could be implemented in the protocols using Standard operating Procedures (SOPs) as evidenced by the following observations.

"We need to have some guidelines and polices in place especially for clinical research or studies that go deep to look at the genetics of individuals in a hope of coming up with better treatment options for these people." R002

"It requires for people like me and you to develop the guidelines, Standard Operating Procedures (SOPs) to really put this knowledge into context so then that makes a lot of sense that's where the future is going." R009

2. Appropriate Communication of Research Results:

Community engagement

It was observed that GGR results not only affect the individual research participant but also can potentially extend to involve one's family and sometimes the community where the research is conducted. Given this, it was thought important to reach out to the community and prepare them for any effects of returning results of such research before it is conducted. Such community engagement would guide researchers in terms of the sensitivity of the subject matter of the research, the potential impact and how to go about return of results. Respondents had positive experience with community engagement and made suggestion on possible approaches. The approaches to be employed could vary from talking to community leaders, holding community meetings, radio talk shows with call-ins or through Community Advisory Boards (CABs).

"When we needed to know the burden of disease in the community, we' first told them what the protocol is all about and then how the community would contribute. This is particularly when we wanted to take samples that are community based to compare with samples which are hospital-based surveys. We've done this and even collected samples." R024

"For the community, we decided to coordinate with opinion leaders." R025

Genetic Counselling

Respondents observed that, for return of GGR results to be meaningful, safe and effective, there is need for appropriate genetic counselling by qualified individuals who are able to accurately explain the meaning and implications of both participation in GGR as well as associated results.

"There should be some kind of counselling before you actually do these kinds of studies, so the people facilitating the consent process be trained in genetics study counselling because you don't know how people are going to behave when you give them these results." R001

"Yeah, there should be someone who is at least knowledgeable who understands the terms and who can explain in simple terms the implications of such studies and what happens if indeed an individual, a family or a community are carrying a certain gene that may not be very good in the eyes of the public so there should be this person who can talk to people". R003

Respondents observed that for medical genetics there is definitely a need for all sorts of counsellors; the counsellors that prepare participants, clinicians and the researchers themselves. They stressed the need for a counsellor who understands genomics and understands the implications of the kind of research to be conducted.

"Very very important, because of the possible outcomes, we should have genetic counsellors, whenever you talk about genetics first of all there is a lot of misunderstandings, so presence of genetic counsellors would help us sort out those possible misunderstandings." R005

"If the participant has been well counselled because its their right, it's their blood, they need to know." R030

It was also reported by some of the respondents that their studies had carried out some form of genetic counselling before return of results.

"The participants who come through our research program go through a very long process of counselling, for instance one of our studies, we first of all take two months and during that time we have been counselling we have been giving them opportunity to ask questions and after the two months is when we do the decisive tests and now by the time we give them the results, it's much easier." R024

However, despite the importance attached to the genetic counsellors, none of the respondents used qualified genetic counsellors or happened to be aware of any qualified genetic counsellor in the country.

"I don't think we have to call them specialized genetic counsellors, what we have been using are mainly social workers, psychologists, and then the doctors, the paediatricians and then ones for the terminal disease, we have just been using the palliative care team but we don't have a specific genetic counsellor." R025

"I would say they are specialized through practice not through training. So, they have gone through the protocol and the standard procedures for counseling but they have not general training on genetic counseling." R030

Informed consent and implications

To increase the ethical acceptability of returning individual and or aggregate results, it was deemed appropriate to obtain informed consent from participants prior to sharing individual and aggregate results, in order to enable the appreciation of the implications of the findings to the concerned participants. Additionally, informed consent highlights the potential risk of social harm to the family and at times, the community. They emphasized the importance of an informed consent

process that enhances participant comprehension; for instance, the use of simple language and visual aids such as videos. The respondents stressed the need for all information about the genetic testing to be disclosed but this can be done only after preparing whoever is going to receive that information.

"Informed consent to provide information on the possible results we are going to get, implications of what we are going to research on, and the fact that we are testing you but it may be affecting your community, your children etc. I think this preparation is done before the project starts, and a long before the actual results come out." R005

"Of course you have to go back looking through the consent. If you find something that is really important and the patient consented, you have to invite the patient back. Literally in a normal context this is supposed to be a genetic counsellor to give this information and genetic counselling...." R010

The respondents observed that while it was important for participants to consent for the return of results during the informed consent process, many of them did not provide such information to the participants.

"You explain to them the study what the study is going to do but we don't tell them that you're coming back to tell you what we have found in your gene." R008

It was also observed that there was need to be careful on assessing how returning results may affect the participants and their communities.

"In terms of feedback, you have to be very sensitive to the implications of your results to the participant and to the community, so those ones, you have the information, you have the discretion, to judge, that is your discretion as a researcher." R019

"If it really has a big implication on public health that needs to be reported but sometimes it may not have a direct benefit. So, you weigh the risks and benefits." R022

3. Experience and practices

A good proportion of respondents 8/30 had shared results of the genetics and genomics tests with the participants either directly or indirectly through the attending clinicians. Some of the findings shared were individual results, while others come as aggregate results and the procedures for sharing the results varied across studies. At least three approaches were used to communicate research results. They included: individual counselling followed by sharing of results by researchers themselves; submitting results to the attending clinicians for the necessary communication to respective individual study participants; or, in the case of aggregate results, through community meetings as highlighted below.

"We only report what is beneficial or useful to the patient and this information is reported to the respective doctor. So, we tell the doctors; this patient of yours has this type of virus so they will not be responding to this kind of treatment." R022

"What I know is that for us we were giving individual results...Fortunately, the results were good, people were excited and they had to go and tell everyone that you know what this has potential..." R005

"Yes for instance we typed over 2000 community samples for 3 conditions, sickle cell disease, beta-thalassemia and glucose-6-phosphate dehydrogenase and those that we return, we return all the results as individual results and those that we found positive, we've been able to refer them to specialized treatment centres." R024

It was also observed that the amount of information provided to research participants varied across studies with some giving definitive test results while others shared just bits of the genetic information. Other aspect included how the research participants have used their genetics and genomics research results particularly when seeking health care.

"Now some of my clients can tell whether you are doing HD electrophoresis or E10 because they have the printout of results and they have challenged some of the clinicians who don't have such equipment. So, to me it is very empowering for research participants to know these." R024

"Yes, we have to give them some information of what we found. Why I say some information? Explaining genetics to anybody is complex, but we have to go back to the participants and give them, not individual, but as a group. So, we don't give individual responses." R026

Respondents also shared their experiences on community engagement during the conduct of their genetics and genomics research studies highlighted below.

"We also developed a video to try to explain to lay people what we think the genes are, something which is sort of understandable for them, so we use examples for example we start with a cell, we tell them what a cell is, we tell them a cell is just like a building block of the body so it is like when you are putting blocks together then that is the cell." R025

"We realized the leadership within the community is very important so the consent was just not limited to the individual subjects in the study, we had to move on to the leadership. Yes, I agree, maybe community consent might be of use in the context of this kind of thing." R010

Challenges to return of results:

Other studies did not return findings to participants for various reasons including the fact that the samples had been de-identified hence difficult to trace the individuals who had been tested. While others used samples that had originally been used for a different primary study hence the researchers of the secondary research had no intention and did not returning results. Others observed the fact that not all genes express themselves phenotypically, many genetic mutations are not yet linked to particular diseases, while some respondent thought that participants may not understand the meaning of such genomics results.

"No, but us we don't report directly to individuals because in all genetic studies, we have to de-identify the data, we cannot trace back the individuals, it's one of the ethical aspect of this, we work with de-identified data. We can't report directly to individuals but we can report to community. Yes, maybe aggregated results but nothing personal." R011

Respondent highlighted challenges encountered when it comes to return of genetics and genomics results including the lack of guidelines and regulations on what constitutes appropriate practice.

"I don't think there is a particular procedure other than riding on the fact that we had informed the REC that we shall disseminate findings. So we just went back to the hospital which was the base and, maybe the other thing done was we spoke with the in-charge of the children's ward and also the one who was in charge of the Out Patients Department of the paediatrics unit... but we didn't follow any procedures or follow up participants." R003

Discussion

The study set out to explore researchers' perceptions, experiences and ethical considerations for return of GGR results. Our study results show that return of results is generally acceptable among researchers, and some researchers reported returning results to study participants. Content analysis identified five themes including perceptions, appropriate community engagement, genetic counselling, informed consent and implications, experience and practices. A number of challenges were identified including interpretation of what is beneficial or clinically significant, meaning of the findings, understanding of GGR vocabulary by the participants and the lack of a context specific ethical and regulatory framework. Ethical issues surrounding the return of GGR results including the extent to which such results should be shared with participants have been extensively discussed globally[12-19]. But such debate is quite limited in the African setting

including the Ugandan context [6, 8]. For this study, some of the respondents had returned results to participants either directly or indirectly through their clinicians. Individual results were communicated to participants, caregivers, or their attending clinicians, while in some studies aggregate results were communicated to participants, families or communities. However, respondents who did not return results or not in favour of return of results had different reasons including the fact that it was not possible to foresee the social impact of communicating such results, while from a technical point of view it was not possible to identify individual study participants since studies used de-identified data. In our study, return of GGR results for some studies was facilitated by effective preparation of the participants and their communities an approach that has been practiced in other related settings conducting similar research.[20, 21]. The researchers attributed this to preparation of the participants and communities through measures such as genetic counselling and community engagement. On the other hand, the main reasons for return of results was attributed to their actionability, benefits and the clinical utility of the results to the participants [21, 22]. However, although there are internationally accepted approaches for return of results including guidelines developed for the African setting by the H3Africa working group [9], decisions to return results by many of our respondents depended purely on the discretion of the researchers. This is a challenge because it contributes to the lack of standardisation across the different researchers. Reliance on researcher discretion was mainly attributed to the lack of official ethical guidelines regulating conduct of GGR in Uganda as well as lack of awareness of other guidelines. Our view is that without such standards to provide a basis for regulation, it will remain difficult to ensure ethical accountability in GGR in Uganda. Therefore, in order to minimize the arbitrariness of important decisions regarding ethical correctness and the resulting obligations in the conduct of GGR and improve ethical accountability, there is need to specify local ethical norms for this undertaking.

Community engagement was considered an important requirement for return of results particularly when returning aggregate results associated with the community. The need for meaningful community engagement is increasingly being promoted in international research guidelines with the aim of protecting communities from exploitation and harm while promoting research that is beneficial [24]. Community advisory boards have been employed mainly by clinical trials but different methods could be used based on the nature and setting of the study [25, 27]. Community engagement is essential because it facilitates the study community to appreciate the research and understand implications of its participation, while also helping researchers to contextualize their research to the study community by, among other things, taking into account local values and preferences [28].

Although genetic counselling is an ethical requirement and mandated in some settings as a pre-requisite for return of results [9], it is a relatively new concept and not appropriately practiced in the Ugandan setting. This situation is worsened by the general lack of qualified genetic counsellors across the various research institutions in the country as has been observed by our study. Yet this counselling was considered by the respondents as an important aspect in return of individual GGR results. This is necessitated by its potential to reduce or mitigate negative out comes and misconceptions associated with GGR. This is because genetic counsellors aid in facilitating individuals to understand what the research involves before accepting to participate and availing results in a simplified way in a bid to facilitate participants and, or communities who may not have the capacity to understand the meaning of the findings and the associated implications [1, 29-32]. There is need for capacity development for ethical conduct of GGR including aspects like genetic counselling.

The respondents observed that while it was important for participants to consent for the return of results during the informed consent process, many of them did not do it. This suggests the need for considerable attention and appropriate oversight by the research ethics committee (REC) based on contextualized guidelines [33, 34]. The return of genomics research results, if not done carefully, present the potential for breach of confidentiality and associated harms including psychological harm, stigmatization and family conflict for individual research participants, their families or the entire community [35, 36]. Other harms like denial of insurance or increased premiums and loss of income may occur as well. Participants should be given an opportunity to decide whether they would like to receive the results, mode of return of results and what type of results they want to receive [1, 37-39].

Limitations:

We acknowledge the fact that there is a potential for social desirability bias that could make respondents to report favouring what they think to be societally preferred under the circumstances.

Conclusions

Return of genetics and genomics research results to participants is generally acceptable to genomics researchers and several researchers have returned either individual or aggregate results. Ethical considerations for return of genetics and genomics research results are numerous though their application is not regulated due to lack of appropriate local ethical guidelines.

Practice implications:

There is need for standardization of the return of GGR results practices through appropriate oversight by RECs based on a contextualized ethical framework or guidelines.

Abbreviations

CABs-Community Advisory Boards

GGR-Genetics and Genomics Research

REC-Research Ethics committee

SOPs-Standard Operating Procedures

UNCST- Uganda National Council for Science and Technology

Declarations

Ethics approval and consent to participate: All the methods were carried out in accordance with relevant guidelines and regulations.

Consent for publication: Not applicable

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Authors Contributions:

JO, BK, NKS & JA conceptualized this study; JO, BK, JB, EM & JA developed data collection tools; JO, BK collected data; JO, BK & DES analysed data; all authors provided substantive intellectual contributions to the study and manuscript and approve of its content.

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References

1. Berrios, C., et al., *Enrolling genomics research participants through a clinical setting: the impact of existing clinical relationships on informed consent and expectations for return of research results*. Journal of genetic counseling, 2018. **27**(1): p. 263-273.
2. Bycroft, C., et al., *The UK Biobank resource with deep phenotyping and genomic data*. Nature, 2018. **562**(7726): p. 203-209.
3. Zeng, J., et al., *RETRACTED: CGVD: a genomic variation database for Chinese populations*. Nucleic acids research, 2020. **48**(D1): p. D1174-D1180.
4. Middleton, A., et al., *'Your DNA, Your Say': global survey gathering attitudes toward genomics: design, delivery and methods*. Personalized medicine, 2018. **15**(04): p. 311-318.
5. Bledsoe, M.J., *Ethical legal and social issues of biobanking: past, present, and future*. Biopreservation and biobanking, 2017. **15**(2): p. 142-147.
6. Rutakumwa, R., et al., *What constitutes good ethical practice in genomic research in Africa? Perspectives of participants in a genomic research study in Uganda*. Global Bioethics, 2019: 8.p. 1-15.
7. Ma'n, H.Z. and B.M. Knoppers, *International normative perspectives on the return of individual research results and incidental findings in genomic biobanks*. Genetics in medicine, 2012. **14**(4): p. 484-489.
8. Munung NS, Marshall P, Campbell M, et al. Obtaining informed consent for genomics research in Africa: analysis of H3Africa consent documents. J Med Ethics 2016;42:132–137.
9. H3Africa Guideline for the Return of Individual Genetic Research Findings. <https://h3africa.org/wp-content/uploads/2018/05/H3Africa%20Feedback%20of%20Individual%20Genetic%20Results%20Policy.pdf> Accessed January 03, 2021
10. Bope, C.D., et al., *Dissecting in silico Mutation Prediction of Variants in African Genomes: Challenges and Perspectives*. Frontiers in Genetics, 2019. **10**.
11. Yakubu, A., et al., *Model framework for governance of genomic research and biobanking in Africa – a content description*. AAS open research, 2018. **1**.
12. Lolkema, M.P., et al., *Ethical, legal, and counseling challenges surrounding the return of genetic results in oncology*. Journal of clinical oncology, 2013. **31**(15): p. 1842-1848.
13. Siminoff, L.A., et al., *Confidentiality in biobanking research: A comparison of donor and nondonor families' understanding of risks*. Genetic testing and molecular biomarkers, 2017. **21**(3): p. 171-177.
14. Beskow, L.M. and W. Burke, *Offering individual genetic research results: context matters*. Science translational medicine, 2010. **2**(38): p. 38cm20-38cm20.
15. Bollinger, J.M., et al., *Public preferences regarding the return of individual genetic research results: findings from a qualitative focus group study*. Genetics in Medicine, 2012. **14**(4): p. 451-457.
16. Bredenoord, A.L., et al., *Disclosure of individual genetic data to research participants: the debate reconsidered*. Trends in Genetics, 2011. **27**(2): p. 41-47.
17. Hens, K., et al., *The return of individual research findings in paediatric genetic research*. Journal of Medical Ethics, 2011. **37**(3): p. 179-183.
18. Klitzman, R., et al., *Researchers' views on return of incidental genomic research results: qualitative and quantitative findings*. Genetics in Medicine, 2013. **15**(11): p. 888-895.
19. Knoppers, B.M., et al., *The emergence of an ethical duty to disclose genetic research results: international perspectives*. European Journal of Human Genetics, 2006. **14**(11): p. 1170-1178.

20. Forrest, L.E., et al., *Health first, genetics second: exploring families' experiences of communicating genetic information*. European Journal of Human Genetics, 2008. **16**(11): p. 1329-1335.
21. Schmidlen, T., et al., *Operationalizing the reciprocal engagement model of genetic counseling practice: A framework for the scalable delivery of genomic counseling and testing*. Journal of genetic counseling, 2018. **27**(5): p. 1111-1129.
22. Roberts, M.C., et al., *Possible barriers for genetic counselors returning actionable genetic research results across state lines*. Genetics in Medicine, 2017. **19**(11): p. 1202-1204.
23. Uganda National Council for Science and Technology [Internet]. National Guidelines for Research Involving Humans as Research Participant. 2014 [cited 2016 Oct 28]. Available from: www.uncst.go.ug
24. Nyirenda, D., et al., *'We are the eyes and ears of researchers and community': Understanding the role of community advisory groups in representing researchers and communities in Malawi*. Developing world bioethics, 2018. **18**(4): p. 420-428.
25. Strauss, R.P., et al., *The role of community advisory boards: involving communities in the informed consent process*. American journal of public health, 2001. **91**(12): p. 1938-1943.
26. OPHS WORKSHEET – 45 CFR 46.116(a) & (b) and 21 CFR 50.25. Informed Consent Checklist For Genetic/Genomic Testing, https://cphs.berkeley.edu/CPHS_informed_consent_dna.pdf, (accessed 2/12/202017)
27. Soofi, H. and E. van Leeuwen, *Within and beyond the communal turn to informed consent in industry-sponsored pharmacogenetics research: merits and challenges of community advisory boards*. Journal of community genetics, 2016. **7**(4): p. 261-270.
28. Weitzman, E.R., K.M. Magane, and L.E. Wisk, *How Returning Aggregate Research Results Impacts Interest in Research Engagement and Planned Actions Relevant to Health Care Decision Making: Cohort Study*. Journal of medical Internet research, 2018. **20**(12): p. e10647.
29. Druker, H., et al., *Genetic counselor recommendations for cancer predisposition evaluation and surveillance in the pediatric oncology patient*. Clinical Cancer Research, 2017. **23**(13): p. e91-e97.
30. Biesecker, B.B. *Genetic counselors as social and behavioral scientists in the era of precision medicine*. in *American Journal of Medical Genetics Part C: Seminars in Medical Genetics*. 2018. Wiley Online Library.
31. Hudson, P., et al., *Defining the role of a genetic counselor within pediatric hematology and oncology comprehensive care teams: Perspectives of the provider team and patients*. Journal of genetic counseling, 2019. **28**(6): p. 1139-1147.
32. Trepanier, A., et al., *Genetic cancer risk assessment and counseling: recommendations of the national society of genetic counselors*. Journal of genetic counseling, 2004. **13**(2): p. 83-114.
33. Zawati, M.n.H., et al., *Barriers and opportunities in consent and access procedures in low-and middle-income country biobanks: Meeting Notes from the BCNet Training and General Assembly*. Biopreservation and biobanking, 2018. **16**(3): p. 171-178.
34. Jarvik, G.P., et al., *Return of genomic results to research participants: the floor, the ceiling, and the choices in between*. The American Journal of Human Genetics, 2014. **94**(6): p. 818-826.
35. Fox, D., E. Spencer, and A. Torkamani, *Returning Results to Family Members: Professional Duties in Genomics Research in the United States*. Journal of Legal Medicine, 2018. **38**(2): p. 201-219.
36. Edwards, K.L., et al., *Controversies among Cancer Registry Participants, Genomic Researchers, and Institutional Review Boards about Returning Participants' Genomic Results*. Public health genomics, 2018. **21**(1-2): p. 18-26.
37. Middleton, A., et al., *Attitudes of nearly 7000 health professionals, genomic researchers and publics toward the return of incidental results from sequencing research*. European Journal of Human Genetics, 2016. **24**(1): p. 21-29.
38. Gaieski, J.B., et al., *Research participants' experiences with return of genetic research results and preferences for web-based alternatives*. Molecular genetics & genomic medicine, 2019. **7**(9): p. e898.

39. Fiallos, K., et al., *Choices for return of primary and secondary genomic research results of 790 members of families with Mendelian disease*. *European Journal of Human Genetics*, 2017. **25**(5): p. 530-537.
40. Downey, A.S., et al., *Advancing Practices for Returning Individual Research Results*, in *Returning Individual Research Results to Participants: Guidance for a New Research Paradigm*. 2018, National Academies Press (US).