THE ETHICAL CHALLENGES IN THE CONSENTING PROCESS WHEN CONDUCTING GENOMIC RESEARCH IN LOW LITERACY SETTINGS

Daima Athumani Bukini, BSc, MBE

Master Public Health Dissertation
Muhimbili University of Health and Allied Sciences
October 2014

THE ETHICAL CHALLENGES IN THE CONSENTING PROCESS WHEN CONDUCTING GENOMIC RESEARCH IN LOW LITERACY SETTINGS

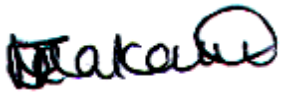
Daima Athumani Bukini, BSc, MBE

A Dissertation in Partial Fulfillment of the Requirement for the Degree of Master in Public Health of Muhimbili University of Health and Allied Sciences

Muhimbili University of Health and Allied Sciences
October 2014

CERTIFICATION

The undersigned certify that she has read and hereby recommend for acceptance by Muhimbili University of Health and Allied Sciences a dissertation entitled **"*The Ethical Challenges in the Consenting Process when Conducting Genomic Research in Low Literacy Settings*"** in fulfillment of the requirements for the degree of Master of Public Health of Muhimbili University of Health and Allied Sciences



……

Dr. Julie Makani

(Supervisor)

……

Date

DECLARATION AND COPY RIGHT

I **Daima Athumani Bukini**, declare that this dissertation is my original work and that it has not been presented and will not be presented to any other University for a similar or any other degree award.

Candidate's signature ……. Date……

This dissertation is a copyright material protected under the Berne convention, the copyright Act 1999 and other international and national enactments, in that behalf, on intellectual property. It may not be reproduced by any means, in full or in part, except for short extracts in fair dealing for research or private study, critical scholarly review or discourse with an acknowledgement, without the written permission of the Directorate of Postgraduate Studies on behalf of both the author and the Muhimbili University of Health and Allied Sciences.

ACKNOWLEDGEMENT

I would first like to express my sincere gratitude to the School of Public Health and Social Sciences at Muhimbili University of Health and Allied Sciences for their facilitation and material support throughout the course of the dissertation and the CDC Project for the financial support which enabled me to complete the research work but also attending the whole MPH Programme.

My special appreciation goes to my mentor and supervisor Dr. Julie Makani, who has been the cornerstone to the successful completion of the dissertation. I would like also to acknowledge the valuable inputs I have been receiving from Dr. Columba Mbekenga especially in the methodology and data analysis sections as well as in refining the contents of the dissertation.

To Sr. Rehema Nkingi and the whole team of Muhimbili –Wellcome Programme (the nurses, physicians and laboratory staff) I would like to say thank you for allowing me to be part of your team and providing me with all the assistance I needed during data collection despite the busy schedule at the Sickle Cell Disease clinic.

Finally, special thanks to my family for the unconditional love, encouragement and support they have showed me throughout the course of this program and when doing my dissertation.

DEDICATION

I dedicate this dissertation to my mother **Asha Abdallah Mikidadi** and my precious daughters **Ruby** and **Destiny;** I love you so very much!

.

ABSTRACT

Background: Genomic researches have proven to be valuable tools in identifying genetic variants that have a role in disease causation. The value of conducting these type of researches cannot be underestimated in developing countries where there is high disease burden. However, there is a need to identify, analyze and address specific ethical challenges arising when conducting genomic researches in populations with lower literacy level in order to protect the research participants and interest of scientists in these particular settings.

Objective: The study explored challenges associated with obtaining a valid informed consent when conducting genomic research in individuals with low literacy level.

Methodology: The methodology was based on qualitative data involving focus-group discussions, in-depth interviews as well as observation of the consent process. Research team and research participants involved in the Sickle cell Disease study at Muhimbili National Hospital were the target group. The data obtained from the FGDs and IDIs were transcribed into meaningful codes depending on the nature of the responses and were analyzed using thematic analysis.

Results and Discussion: Findings indicated that literacy level was not a key factor influencing participant understandings, adequacy of the information provided to the participants and the methods used to communicate the information were the contributing factors. Preferred mode of provision of the information was through video or group sessions in the presence of nurses or doctors to ensure comprehension of the information. Benefits of the research and return of results were considered by participants to be more important sections during the consenting process than others.

Recommendations: The findings from this study will be used to develop a tool to guide the researchers in eliciting informed consent in the context of genomic research. Regular sessions to remind and update the researchers and research participants are also recommended for good clinical practices and protection of the research participants.

TABLE OF CONTENTS

CERTIFICATION iii

DECLARATION AND COPY RIGHT iv

ACKNOWLEDGEMENT v

DEDICATION vi

ABSTRACT vii

LIST OF TABLES xi

LIST OF FIGURES xi

LIST OF ABBREVIATIONS xii

DEFINITION OF TERMS xiii

CHAPTER ONE 1

1.0 INTRODUCTION 1

1.1 BACKGROUND INFORMATION 1

1.2 STATEMENT OF PROBLEM 3

1.3 THE CONCEPTUAL FRAMEWORK 4

1.4 RESEARCH QUESTIONS 5

1.5 RESEARCH OBJECTIVES 6

1.5.1 General Objective 6

1.5.2 Specific Objectives 6

1.6 RATIONALE 7

CHAPTER TWO 8

2.0 LITERATURE REVIEW 8

CHAPTER THREE 11

3.0 METHODOLOGY 11

3.1 DESCRIPTION OF THE STUDY SETTING 11

3.2 DESCRIPTION OF THE STUDY POPULATION 11

3.3 SAMPLING PROCEDURES 12

3.4 STUDY DESIGN 12

3.4.1 Focus Group Discussions 13
3.4.2 In-Depth Interviews 13
3.4.3 Participant Observation 13
3.5 DATA ANALYSIS 14
3.6 ETHICAL CONSIDERATION 14
3.7 INCLUSION CRITERIA 14
3.8 EXCLUSION CRITERIA 14
CHAPTER FOUR 15
4.0 RESULTS 15
4.1 FOCUS GROUP DISCUSSIONS 15
4.2 IN DEPTH INTERVIEW 15
4.3 PARTICIPANT OBSERVATIONS 16
4.4 THEMATIC AREAS 17
4.4.1 Participants understanding not influenced by their literacy level 21
4.4.2 Failure to Distinguish Research from Clinical Care 22
4.4.3 In-adequate information about the study provided to the study participants 23
4.4.4 Participants enrolled before the legal age to consent (18 years)
4.4.5 Participants sections of interest in the consent: 25
4.4.5.1 Return of results 25
4.4.5.2 Benefits of the researches 26
4.4.6 Measure of participant comprehension- mixed thoughts 26
4.4.7 Presentation of the information 28
4.4.8 Not clear who has the role of consenting 29
4.4.9 Education needs 29
CHAPTER FIVE 31
5.0 DISCUSSION 31
5.1 STUDY LIMITATION 34

CHAPTER SIX 35

6.0 CONCLUSION AND RECOMMENDATIONS 35

6.1 CONCLUSION 35

6.2 RECOMMENDATIONS 35

7.0 REFERENCES: 37

8.0 APPENDIXES 39

8.1 APPENDIX 1: FGD GUIDE- RESEARCHERS 39

8.2 APPENDIX 2: FGD GUIDE- RESEARCH PARTICIPANTS 41

8.3 APPENDIX 3: IDI GUIDE- RESEARCHERS 43

8.4 APPENDIX 4: IDI GUIDE- RESEARCH PARTICIPANTS 45

8.5 APPENDIX 5: PARTICIPANT OBSERVATION CHECKLIST 47

8.6 APPENDIX 6: INFORMED CONSENT FORM- ENGLISH VERSION 48

8.7 APPENDIX 7: FOMU YA RIDHAA YA KUSHIRIKI- SWAHILI 51

LIST OF TABLES

Table 1: Characteristics of participants in the Focus Group Discussion 15

Table 2: Characteristics of participants for the In-Depth Interviews 16

Table 3: Themes and sub-themes evolved in the study- thematic contents..... 18

LIST OF FIGURES

Figure 1: Conceptual framework showing inter-relationship between Genomic Research, Literacy level and how it can affect validity of the consent 4

LIST OF ABBREVIATIONS

GWAS	-	Genome Wide Association Studies
SCD	-	Sickle Cell Disease
H3Africa	-	Human Heredity and Health in Africa
MalariaGen	-	Malaria genomic epidemiology network
FGDs	-	Focus Group Discussions
IDIs	-	In-Depth Interviews
MNH	-	Muhimbili National Hospital
MUHAS	-	Muhimbili University of Health and Allied Sciences
REC	-	Research Ethics Committee

DEFINITION OF TERMS

Genomic Research is the comprehensive examination of an organism's entire set of genes and their interactions.

Genetic Studies are studies of a single gene or a small number of genes to determine specific genes roles in diseases or physical characteristics of an individual.

Valid Consent is a consent given by a competent individual, voluntarily and when the participant has adequately been informed and understood the information provided.

MalariaGen, a genomic epidemiology network, data sharing community working to develop new tools to control Malaria by integrating epidemiology with genome science.

Low literacy level, as defined in this research study includes individuals who have lower than ordinary level secondary school education. Assuming that those with secondary education have the ability to comprehend, think through and communicate during the consenting process. And therefore literacy used in this research is not merely the ability to read and write but rather comprehension of the information.

CHAPTER ONE

1.0 INTRODUCTION

1.1 BACKGROUND INFORMATION

There is increase in recognition of the need for research in developing countries where there is high disease burden, and Genome- Wide Association studies (GWAS) have proven to be powerful means of identifying genetic variants that play a role in disease causation (Jantina et al, 2011), and therefore applying the methods of genomics research to the disease problems affecting countries in the developing world is one way of addressing the imbalance.

Genetic Studies have opened up unprecedented possibilities for healthcare, but also ethical and social dilemmas about how these can be achieved, particularly in developing countries (Langlois, 2013). Research in genomics most of the time presents important ethical challenges in the recruitment of participants regardless of where it is conducted.

Genetics has the potential to transform health and health care in both developed and developing countries. Infectious diseases such as Malaria, HIV/ AIDS, Tuberculosis may involve several hundred genes and genomic research enables the study of these complex diseases in the search for the causes, effective vaccines and treatments (Langlois, 2013).

In the survey conducted in 2002 on the top ten technologies for improving health in developing countries, genomic research was mentioned to be one of the promising technologies to transform health care in low and middle-income countries (Singer, 2002). Scientists in developing countries believed that there is an urgent need to incorporate genetic approaches into health services since it is relatively inexpensive helps to develop skills in molecular biology and provides a basis for developing national expertise in genomics (Alwan, 2003). Developing countries too can harness human genetic variation to benefit their population and economies (Daar et al, 2008).

Therefore, there are good ethical reasons for encouraging genomic research on diseases affecting populations in lower average income and literacy levels to be able to decrease the

substantial global inequalities that exist in mortality, quality of life and disease incidence in their settings (Jantina, 2011).

The complexity of genetic information, its metabolic processes and pathways, the implications of the risks involved, return of results, handling of incidental findings, and storage of sample for future unknown use challenges the well informed component in the consent process (Kegley, 2004). Prospective participants in lower income countries are more likely to be poor and have limited access to healthcare, education and other resources; therefore carrying out research in these settings presents challenges of different order to those in higher income countries.

A critical challenge of conducting genomic research is how to obtain a valid consent and if the research is done in lower literacy settings the other challenge is how to provide appropriate information to participants in a comprehensible manner.

Peculiarity of some of the aspects in the consenting process when dealing with genetic research are nature of the potential benefits, the implications of the risks involved, issues on return of results, handling of incidental findings, storage of sample for future unknown use and the complexity of science involved; poses issues that are quite different from other types of health research such as clinical trials and biomedical research involving human subjects (Nyika, 2009).

1.2 STATEMENT OF PROBLEM

In recent years there has been an increase in the number of genomic researches conducted in the developing countries due to the advances in the high genotyping technology in the developed countries (Jantina, 2011). Literature shows that genomic research presents a number of ethical challenges whenever they are conducted (Clayton, 2009: Jantina, 2011).

However, the challenges presented in the developing world are quite different from those presented in the developed world. One of the highly documented issues identified is the challenge in obtaining *valid* informed consent that can be correlated with the literacy level of most of the participants in the developing countries (Nyika, 2009: Jantina, 2011).

This research explored whether participants are making informed decision when enrolling in genomic researches by looking at the complexity of science involved and terminologies used in these researches vis-a-vis the literacy level of most of the participants in the settings.

This study un-packed the challenges in the informed consent process that exist when conducting genomic research in population characterized with low literacy levels.

1.3 THE CONCEPTUAL FRAMEWORK

Below illustration explain how the concepts explored in this research are interlinked with each other.

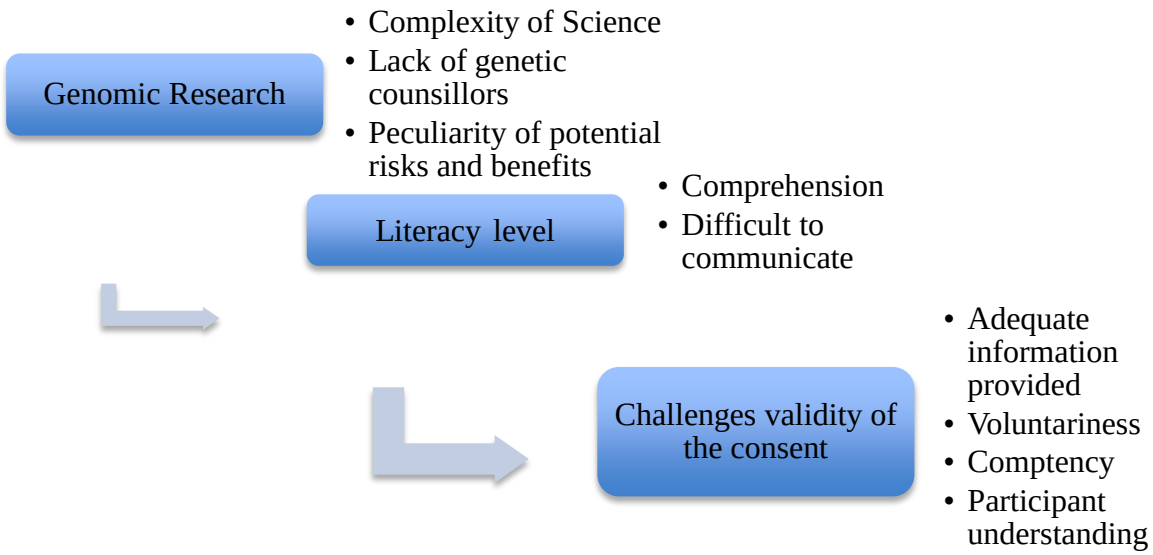


Figure 1: Conceptual framework showing inter-relationship between Genomic Research, Literacy level and how it can affect validity of the consent (Source: Author)

This framework shows the various issues that challenges the validity of consent in genomic researches. The scientific terminologies used to explain the procedures, purposes, risks in the researches are quite difficult for participants with low literacy level to comprehend and making an informed decision as indicated by Arrow number 1. This is not only difficult for the participants but also the researchers to try and make the participants understand; what words and terminologies should be used, what examples should be used and also what methods can be used. In the developed countries genetic counselors who are trained nurses handling genetic diseases are the ones used to conduct the consenting process, lack of them in the developing countries compound the problem. Arrow number 2 shows different ways the validity of the consenting process can be compromised. Several studies have been conducted in Africa to explore the general challenges of conducting genomic researches in the developing countries (Nyika, 2009; Alwan, 2003; Daar et al, 2008; Bull, 2007; Tekola et al, 2009).

1.4 RESEARCH QUESTIONS

The study addressed the following key research questions:

1. What are the procedures used by research nurses and physicians in obtaining a valid, fair and inclusive informed consent?
2. Are the information provided in the informed consent process appropriate and comprehensible to the research participants?
3. What is the level of understanding of the information provided in the consenting process amongst the participants?
4. What are the perceptions of the researchers and research participant involved in the SCD study on the overall consenting process of the study?

1.5 RESEARCH OBJECTIVES

1.5.1 General Objective

To explore the challenges in obtaining a valid informed consent when conducting genomic research in populations characterized with low literacy level.

1.5.2 Specific Objectives

1. To assess procedures of obtaining a valid informed consent amongst the research nurses and physicians of Sickle Cell Disease study at Muhimbili National Hospital.
2. To evaluate the appropriateness and comprehension of the information provided to the research participant enrolled in the Sickle Cell Disease study at Muhimbili National Hospital.
3. To assess understanding of the information provided in the consenting process to the research participants enrolled in the Sickle Cell Disease Study at Muhimbili National Hospital.
4. To investigate perceptions of the researchers and research participants involved in the SCD study on the overall consenting process in the study.

1.6 RATIONALE

The Study will inform on how the consent process is effective in providing appropriate information in a comprehensible manner in supporting informed decision making to individual with low literacy. The results can also be used in the designing and implementing consent processes in the context of genomics research on populations characterized by low literacy levels.

The results will not only improve the informed consent process in genomic research but will also increase participants understanding on research in SCD and their general perceptions on genomic research. And will also increase participation and engagement of our communities in scientific research through building a trustworthy relationship and ultimately contribute to provide evidence that will improve their health.

CHAPTER TWO

2.0 LITERATURE REVIEW

One of the ethical challenges of conducting genomic research in the developing world is on how to obtain valid consent bearing in mind that majority of the research participants in the settings have low literacy levels (Nyika, 2009) have. Designing and implementing consent processes in the context of genomics research on populations characterized by low literacy levels presents many challenges to the researchers and research participants.

The Declaration of Helsinki has already revealed that the cornerstone of ethical research is obtaining a valid informed consent. However, the interpretation on how to obtain the consent is not straightforward and therefore little guidance is provided from the report. The complication is deeper when it comes to genomic studies because there are novel issues that need to be addressed in the consenting process (Declaration of Helsinki, 2013; Chokshi et al, 2007).

The elements of a valid consent process must be: adequately informed and understood, voluntary and given by someone who is competent. This should also be the case in genomic research, where the major challenge is on the informational and comprehension parts specifically when the research is being conducted in populations with lower literacy levels. Conducting genetic researches in the settings have already revealed shortcomings in the consent process (Kegley, 2004).

The heart of the informed consent lies in providing adequate information in a comprehensible manner, however, in genomic research these perceptions are compromised with the complexity of genetic information, metabolic processes and pathways but also the human difficulty in comprehending challenges the concept of being well informed and increase the doubts on the informational component of the consent process (Kegley, 2004: Devries, 2011: Nyika, 2009). Hence, the critical challenge to achieving valid consent in lower literacy settings arises in relation to providing appropriate information in a comprehensible manner (Devries, 2011). Having a well-written consent form does not guarantee participants understanding

particularly in populations with underdeveloped local languages and high levels of illiteracy that rely on verbal explanations about research (Tindana, 2013).

Disclosure and comprehension of information in the consent form are addressed in the sections that explain the purpose of the research and what the research involves (risks, benefits, study duration, procedures). In ensuring that participants must not come to the research under pressure, there need to be a section in the informed consent form that emphasizes voluntariness. A clear description of how participants can withdraw from the research (Chokshi et al, 2007).

The competence of research participants is also important to have a valid consent. Children, very elderly people, people with mental health problems or impaired decision making abilities for other reasons are considered incompetent and researchers must take special protection mechanisms to ensure the validity of the consent.

A study on genomic research and validity of consent suggested that the achievement of a valid consent in genetic studies lies upon both perspective of protecting individuals and building trust between communities and research groups. And the study has also emphasized that scientists in the field do have that ultimate obligation to ensure valid consent is obtained (Chokshi et al, 2007).

Seeking consent for genetic research and genomic research can be challenging particularly in populations with lower literacy levels, therefore it is important to recognize that some aspects of complex genomic research may be less of interest and less well understood by research participants and such gaps in understanding may not be entirely addressed by the best practices in the design and conduct of consent processes (Tindana, 2013).

Results from another study conducted in Kenya looking at experiences with community engagement and informed consent in genetic cohort study indicated that some of the challenges from the field workers were around misunderstandings about research, perceived pressure for recruitment and challenges in explaining the study to the research participants (Marsh et al, 2010). Therefore, field workers conducting informed consent also are facing complex issues in terms of understanding and communication skills that are key influences on

ethical practices. Furthermore lack of trainings in genetics for physicians and the shortage of genetic counselors in the settings have increased the difficulty in communicating the science to the research participants (Kegley, 2004).

The scale and complexity of genomic research has sometime necessitated formation of consortium, MalariaGen Network is one example. MalariaGen network has sought to address some of the challenges of conducting genomic research through development of an informed consent template and guidelines through consultation with ethics committee members. Further research were conducted in two MalariaGen sites (Gambia and Cameroon) investing on how best to obtain consent in genomic studies in low-income countries (MalariaGen website)

Currently, there are initiatives in Africa through the Human Heredity and Health in Africa) with partnership among the African Society of Human Genetics (AfSHG), the Wellcome Trust and the National Institutes of Health which draws scientific experts of diverse backgrounds in the world to identify the major scientific, ethical and practical issues pertaining to development of a large scale genomics research programs in Africa (H3Africa Report, 2011). One of the key agenda of the H3Africa is to ensure genomics researches in Africa are performed with the highest ethical, legal and socially appropriate standards for research. Obtaining a valid informed consent has also been considered as of significant importance.

There is no study conducted in Tanzania that explores on the informed consent process when conducting genomic researches in Tanzania. A study conducted by Nyika (1999), looked on the general practical challenges of conducting genetic and genomic research in limited resource countries and informed consent was mentioned as part of the challenges. In addition, This research study unpack the specific challenges in the informed consent process when conducting genomic research in low literacy settings using a case of a sickle cell disease study at Muhimbili National Hospital in Dar es Salaam, Tanzania with an objective of developing contextualized procedures of obtaining consent in genomic researches when conducted amongst participants with low literacy level.

CHAPTER THREE

3.0 METHODOLOGY

3.1 DESCRIPTION OF THE STUDY SETTING

Muhimbili National Hospital is a national referral hospital and University teaching hospital located along Upanga west in Ilala District of Dar es Salaam, Tanzania. The hospital has 900 bed facilities, attending 1,000 to 1,200 outpatients per day, admitting 1,000 to 1,200 inpatients per day. Serving four million people living in the Dar es Salaam region, the Hospital has 2700 employees of whom 300 are doctors and specialists, 900 are registered and enrolled nurses and the remaining are supporting operations employees. The SCD clinic at MNH provides outpatient care, screening services for SCD, counseling and public education. The clinic received over 3000 patients from different regions of Tanzania.

3.2 DESCRIPTION OF THE STUDY POPULATION

The Sickle Cell Disease study cohort at Muhimbili National Hospital started in 2004, with over 3000 patients and is said to be the largest single centre sickle cohort in the world (Muhimbili Wellcome programme website, assessed on 09th October, 2014). A total of 212 tribes are presented in this cohort with most patients coming from the Zaramo, Ndengereko, Sukuma and Nyamwezi tribes. The age ranges from <1 to 50 years old with a median of 12 years. Individuals involved in the study have been recruited through the outpatient clinic and some are still being recruited. On average (based on the cohort dataset), most of the participants have low literacy level. Low literacy level, as defined in this research study includes individuals who have lower than ordinary level secondary school education. Assuming that those with secondary education have the ability to comprehend, think through and communicate during the consenting process. And therefore literacy used in this research is not merely the ability to read and write but rather comprehension of the information.

Genetic studies currently conducted within the cohort include:

1. Defining spectrum of Sickle cell disease in East Africa: A clinic epidemiological study-MalariaGen

2. Genetic determinants of Clinical Heterogeneity in Sickle Cell Disease

3. Role of genetic factors in determining HbF

4. Genetic epidemiology of Malaria and Haemoglobinopathy in Tanga

5. Epidemiology of F-Cells in SCD

6. Determining Haplotype of SCD patients

3.3 SAMPLING PROCEDURES

Participants were purposively selected to be able to obtain the required information to address the research objectives. The IDIs and FGDs targeted participants who are coming for follow ups in the clinic who have been enrolled in the study for a couple of months or years, age and ability to comprehend the required information were also taken into consideration Participant observations targeted the newly enrolled patients (entry) to be able to observe how the consenting process is being handled. Selection was also convenient because it depends on the patients who are available at that particular day. Total sample size was forty-seven (n=47).

3.4 STUDY DESIGN

The methodology was based on qualitative data involving focus-group discussions, in-depth interviews and participant observations. Research participants, research nurses and physicians involved in the Sickle cell Disease Study at Muhimbili National Hospital were being the target group. Qualitative methodology was appropriate for this study because the primary purpose was to explore the views and understanding of the study participants and experiences of the researchers in eliciting informed consent (Tekola et al, 2009). Information from the IDIs and FGDs were collected until no new relevant ideas emerged from further interviews or discussions (Mason, 2010).

Focus Group Discussions were tailored to address specific objective number four that was investigating perceptions of the researchers and research participants involved in the SCD study on the overall consenting process. In-depth interviews were addressing specific objective number two and three. Participant observations were answering specific objective number one, which was appraising procedures of obtaining a valid informed consent.

3.4.1 Focus Group Discussions

In total five (5) Focus Group Discussions were conducted with the research participants and selection was based on age, gender, level of education, employment status and duration in the study. FGD guides were prepared for the researchers in the study and research participants.

For the research participants: the composition of the FGDs took into consideration the duration of the research participants in the study (and the nature of the study involved), whether the patients are new (entry) or coming for follow ups. Actions were taken to ensure male and female were mixed in both FGDs to see whether different issues will be generated based on the gender. The FGDs were tailored to answer the research questions on exploring perceptions and understanding of researchers and research participants on the informed consent process to participate in genomic research.

3.4.2 In-Depth Interviews

In-Depth Interviews were conducted with the research participants and researchers (n= 17) addressing the question on comprehension and appropriateness of information provided to the research participants during the consenting process. Participants were selected purposely based on whether they were coming for follow-ups or they were newly recruited. Two (2) types of interview guides were prepared for the researchers and research participants. The interview instruments were prepared in English and translated into Swahili as appropriate.

3.4.3 Participant Observation

To appraise procedures of obtaining a valid, fair and inclusive informed consent amongst the research nurses and physicians of Sickle Cell Disease study at Muhimbili National Hospital, doctors were observed on how they were enrolling new patients and obtaining their consent to participate in the research. A standard participant observation checklist was used for all the observations.

3.5 DATA ANALYSIS

The information collected from the audio records and the field notebooks were first transcribed into word document and then formatted into text. The investigator and the research assistants independently code the statement from the transcription to develop initial classification of domains describing the specific thematic areas which was considered as a preliminary exploratory analysis. The identified themes were refined and sub-themes and categories of themes were extracted. In order to solve any discrepancies, redundant or repetitions the process was further re-checked for consistency. The themes were later linked with the research questions for interpretations to see whether they will be able to address the questions. The analysis used was based on the Pearson qualitative data analysis module (wps.prenhall.com/chet_mills_actionres last assessed on 15th October 2014)

3.6 ETHICAL CONSIDERATION

The study has been approved by the MUHAS-REC on 24th May 2014. Consent was sought from the participants prior to the conduct of the study and participants were asked to sign the consent forms upon agreeing to participate. In ensuring no breach of privacy and confidentiality, all the audio records from the IDIs and FGDs will be destroyed after five years from completion of the study. Participants were given numbers and no names were used. Except for the level of education no other personal information was collected from the participants.

3.7 INCLUSION CRITERIA

Participants considered having decision-making abilities for themselves or their families (in terms of caregivers) were included in the study without considering their literacy level.

3.8 EXCLUSION CRITERIA

Minors (including adolescents) were not included in this study because of their limited ability to comprehend the desired information for this study.

CHAPTER FOUR

4.0 RESULTS

4.1 FOCUS GROUP DISCUSSIONS

In total 30 patients participated in the Focus Group Discussions (5 FGDs were conducted, in each there were six participants per group). Nine male and 21 female, aged 18-40 participated in the discussions. 30% had at-least completed standard seven education (Table 1).

Table 1: Characteristics of participants in the Focus Group Discussion

Characteristic	Participants (N=30)
Male n *(%)*	7 (23)
Age *mean (min, max)*	26 (18, 40)
Education *n (%)*	
No formal education	5 (17)
At least Std 7	9 (30)
O-level	12 (40)
Some college education (certificates, Diploma)	4 (13)

4.2 IN DEPTH INTERVIEW

Saturation point was reached after interviewing a total of 17 IDIs, , thirteen (13) with the research participants and four with the field workers (doctors = 3, research nurse = 1). Three men and 14 women participated in the interviews, aged 24 to 43. Amongst the SCD research participants nine were parents or caretakers of children who have been enrolled in the SCD study and 46% had at least standard seven education (Table 2).

Table 2: Characteristics of participants for the In-Depth Interviews

Characteristic	Participants (N=17)
Male n *(%)*	3 (18)
Age *mean (min, max)*	33 (24, 43)
Education *n (%)*	
No formal education	3 (18)
At least Std 7	6 (35)
O-level	4 (23.5)
Some college education (certificates, Diploma, Degrees)	4 (23.5)

4.3 PARTICIPANT OBSERVATIONS

Six participant observations were also done to complement the FGDs and IDIs to address the specific objective number one that was assessing procedures used by the physicians to obtain valid informed consent which was measured by looking at the adequacy of the information provided, comprehension of the information to the participants, voluntariness and competency of the participants. A standard participant observation checklist (See Appendix 5) was used for all the six observations. The results have shown that for most of the observations (4 out of 6), the general information session was given more emphasis by the physicians than other sections of the informed consent (purpose, risks, benefits, duration, procedures, confidentiality and who to contact in case of any complaints about how the research was handled).

Comprehension of the participant was measured through questions and answers session, in all the observations physicians ensured that participant have understood the information provided through asking them questions. In all the observations, physicians ensured that participants have signed the consent forms as a proof that they have agreed to participate in the research and those who have agreed are those who have ability to make decision for themselves (competency).

4.4 THEMATIC AREAS

Nine Thematic areas were identified, the themes reflects and integrates results from the IDIs, FGDs and participant observations—literacy not to have an effect on participants understanding, Failure to distinguish or separate research from clinical care, Inadequate information provided to the research participants, participant enrolled before 18 years of age, Participants sections of interest in the consent (return of results and benefits of research), measure of participant comprehension, Participants choices on how information need to be the presented, Not clear who has the role of consenting and education needs (Table 3).

Table 3: Themes and sub-themes evolved in the study- thematic contents

Theme	Sub-theme
Literacy has no effect on participants understanding	Understanding of the research concepts High level of comprehension amongst those with low literacy level Higher literacy level accompanied by more mis-conception
Failure to distinguish or separate research from clinical care	Little knowledge on where does the research procedures starts Emphasis on the Clinical Care-researchers Have some relevancy with participants literacy level
Inadequate information about the study was provided to the study participants	Complexity of the information-difficult to communicate Information provided not at satisfactory level Strong need for education sessions to both researchers and research participants Decline of quality over time Time spent with the doctors Number of patient have increased

	considerably over the years
Participant enrollment before 18 years of age	No clue of being enrolled in research Assent for children above 7 years of age Re-consenting
Benefits of research and return of results are the sections that participants feel are important in the consent than other sections	Care and services offered at the clinic- benefits Understanding Progress of the disease- benefits Stopped going to traditional healers/ witch doctors- benefits Feedback of the research- return of results
Measure of participant comprehension	Opportunities to ask questions Time spent per patient Number of patients increased over time Doctor- patient power relation
Not clear who has the role of consenting	Physicians felt it is for the nurses and vice versa
Presentation of the information	Group Discussions One-to-one Practical and relevant examples

	Language Use- Simple terminologies
Education needs	Reproductive Health Knowledge Training peripheral health care workers Introduce seminars at the Adult clinic Screening for SS for couples SCD and other associated diseases like HIV/ AIDS & Mental Illnesses Disease Progression

4.4.1 Participants understanding not influenced by their literacy level

Most of the participants with lower than average education (at least standard seven) and some with no formal education did not seem to be concerned with the complexity of the information or the amount of information provided. According to most of them, having a formal education was not a contributing factor to understand the information provided. This observation was consistent during the IDIs, FGDs and during participant's observations.

"…Yes, it is easy to understand (I probe: is it because you are a college graduate? Another participant who is a standard seven leaver replied)…there is no such thing, it's all about the individual person and nothing to do with the level of education" FGD#3

"…I am not bothered by the information provided, it is not a problem for me to understand…we need to be educated more on the research and understanding will not be a problem"- FGD#5

During the IDIs, when participants with no formal education (those who cannot read or write) were asked to explain what comes into their mind when they hear the word 'research', below are some of their responses. The responses provided indicated that despite the lower education level, participants have shown greater understanding of the research concept.

"…Research is an investigation to understand about a certain disease problem in depth or looking for a cure of a certain disease"- IDI#9

"…. Research in SCD are done to understand the cure and looking for solutions on this problem"- IDI#11

The results from the IDIs conducted with the physicians and nurses shows that most of the time literacy level did not seem to be a factor that contribute to participants understanding although in some instances it does play a role.

"In the beginning it will be difficult for all of them to understand (despite their literacy) but as time goes by they get used to the terminologies and it became easier to explain to the patients, also literacy level may not have an effect because all of our participants are all SS and

therefore they have some knowledge however basis it is on SS that help them to understand despite the literacy level" IDI#3 with the researches

"Those with secondary school education and higher are the most stubborn participants to make them understand and comprehend the research, and most of the time they end up declining to participate, based on prior misconception that they have about research"IDI#1 with the researchers

Fewer participants with at least secondary education believed that education plays a major role to be able to understand the information.

"… It's true that for someone to understand this information it will depend on the individual person but also the level of education they possess"- IDI#7

In one of the IDIs conducted with the physicians (IDI#1) having low literacy level came out as a challenge that limit participants comprehension.

***"**Most of the participants have low literacy level and do not understand what the research is about, when you explain to them they feel shy to ask questions or to acknowledge that they have not understood, they just want to sign the forms and get over it, the next day they come they don't remember anything"IDI#1 with the researchers*

4.4.2 Failure to Distinguish Research from Clinical Care

Most of the participants were not able to distinguish or being able to separate the research practices from the clinical services offered at the clinic, when asked whether they know that they are participating in research.

"…I didn't get any information about the study, the information I was provided is only on how to care for my child"- IDI#2

"…We need to be told these researches are for what to be able to differentiate the routine clinical services and the research practices…"- FGD#3

However, participants have shown greater understanding about the clinical services offered at the SCD clinic than the researches they have been enrolled.

"…The only information I have been receiving, is on how to take care for my children, I know that when they have fever I need to send them to the hospital"- IDI # 6 from a mother who have two children with SS

"…I am coming to the clinic to check for my progress, if I have any problem I will be able to get the care I need"- IDI#1

The results from the IDIs held with the physicians and the participant observations conducted during the consenting process shows that physicians were emphasizing more on the clinical care offered at the clinic than the research part.

"..After screening, we explain in detail about SS…we inform participants what SS is, symptoms of the disease, why they need to come to the clinic and how to take care of a sick child" IDI#2 with the researchers

The results from observing the consenting process have shown that for most of the observations (4 out of 6), the general information session was given more emphasis by the physicians than other sections of the informed consent like the purpose of the study, risks involved from participating in the study, benefits of the research, duration, procedures involved, confidentiality and who to contact.

4.4.3 In-adequate information about the study provided to the study participants

Most of the participants felt that they have not received enough information to be able to understand details of the research and others did not think the information provided were adequately provided.

"…The truth is we are not getting enough information from the doctors and education is not being provided to that extent, only progress of your disease, but nothing more…that is at least my personal view"- FGD#2, this was given by a female member of the group who has at least college education

"…The information provided were not enough to be able to understand but I am sure anyone can understand those information if provided"- FGD#3, the response was provided by a female participant who has standard 7 education

There were those who think information provided were clear and can be understood and others had views that information provided were difficult to understand.

"…It needs time to understand the information and if you are not curious enough you will not be able to understand, however, time given was so short and answers were given in a rush way…."-IDI#12

Participants also mentioned that the quality of the information provided has been decreased over time.

"…I don't think we are now getting information as it used to be, as time goes by the number of clinic visits decreased and the time to stay with a doctor also have decreased"- FGD#1

"…. When I was young we used to attend the Makuti clinic, and we were all seated in the halls and the nurses and doctors provided us with information but since we have moved here nothing like that has been happening"- FGD#4

The research team also agreed that the content of the information provided decreased due to the increase in the number of patients over time that also affects the quality of the information.

" ..the problem is number of patients have considerably increased overtime and therefore we spend less time with them, where are we going to get the time to provide all those details" IDI#1 with the researchers

"..there are now many patients which affects the time that we spent with individual patients, the consent is done superficially…time has always been a challenge in obtaining the proper consent" IDI#3 with the researchers

"..There are few staff in the clinic which cause the participants not to get much information…" IDI#4 with the researchers

4.4.4 Participants enrolled before the legal age to consent (18 years) and some when seriously ill

Age at enrollment was considered to be a factor either for not recalling the information provided or not being aware of their participation in research.

"…. Time had passed since the last time we were enrolled, I can't recall if it was difficult or easy to understand…may be there is a need to be given the information again"- FGD#1

"…At that time I was only 7 years old and I wasn't involved in decision making, it was my father and the doctor who did all the talk…"- IDI#12

"..I do remember my father signing this form but I was there to witness, I was about 19 years old and my father looks satisfied with the information provided by the doctor. Although I don't recall given the forms to go back home and read them"- FGD#5

Some of the participants consent was taken when they were seriously ill and therefore affected their understanding of the research.

"…I was seriously ill on that day and therefore what I needed was for me to get the care I want….that's why I can't recall anything about this research "- IDI#4

4.4.5 Participants sections of interest in the consent:

4.4.5.1 Return of results

Participants were keen to understand the progress and feedback from the researches that they are participating and most of them would like to know how are they going to get the results of the research findings.

"We need to be given feedback on the researches we have done so far, number of researches and the results" – FGD#4

"…I think they need to be telling us more, e.g. When we are testing, what tests are we conducting and why and the methods…also feedback and what do those results mean"- FGD#4

"…I don't know how the disease is progressing and in what stage my child is, we are just coming here to get tested and for the drugs"- IDI#8

4.4.5.2 Benefits of the researches

Participants were mostly aware and concerned with the benefits of the research during the consenting process.

"…. Our children are sick and here you have opportunities to get various tests for free, for example TSCAN, there are no ques, you are also being refunded if you have used your own fund"- IDI#5

"…The only risk is wasting time but if you compare with the benefits I think it is OK"- IDI#9

". Before coming to the clinic, I did not know what drugs to give my child but now I know even what to do when my child is sick"- IDI#2

"…My child was getting all those swellings which she doesn't get anymore and the crisis have decreased"- IDI#6

"…When people ask about my child, I can now tell them she has SCD and not because someone has bewitched her and I no longer have to go to witchdoctors"- IDI#1

4.4.6 Measure of participant comprehension- mixed thoughts

Participants were divided; there were those who recall that they have been provided with opportunities to ask and be asked questions and those who don't. For those who asked some were satisfied with the answers provided to them.

"…For those who are upfront they can ask questions to the doctors but the doctors they just don't start to provide explanation, e.g. the tests we are doing at the clinic, its until you ask what are they for and what do these results mean"- FGD#1

"…. There are times when they use to give us chances to ask questions…May be its contributed to the number of people attending clinic, there is no time to listen to the patients one by one, sometime the environment is not that comfortable to start asking questions"- FGD#4

Participants also talked about how other environmental issues at the clinic interfere and affect the consenting process.

"…It is like this, before you even come out, another patient is already at the door waiting for you to come out or sometime standing inside the room waiting, you cannot ask anything"- FGD#2

"…. I was not given a chance to ask questions, if I had that chance it would have helped me to get a good understanding."- IDI#1

Others felt that they were provided with the opportunities to ask questions, which helped them to understand the details of the information about the research.

"…We were given opportunities to ask questions, doctors I recall responded very well and we were satisfied, I am now confident that I have fairly good understanding of the disease"- FGD#2

"…We were given opportunities to ask questions and the responses were good and there was enough time for us to also be asked questions"- FGD#3

"…I did ask questions, and they have also told me that in case the kids will be needed we will come to take them abroad to do more research on them"- IDI#5

"…I was given chance to ask questions and was satisfied with the responses provided, I wanted to know more on reproductive health when you have SCD"- IDI#7

Results from the physicians when asked whether and how they measure comprehension of the research information provided to the research participants were as follows;

" You can do that indirectly through engaging the participants in the discussions and also by giving them opportunities to ask questions also we do explain whenever there is a need to do that" IDI#2 with the researchers

"It is not easy to measure their understanding, sometimes you just ask them if they have understood and let them sign, most of them will tell you YES we have understood and just sign and finish with it"IDI#3 with the researchers

"I mostly use the Q&A, you ask them questions and you let them ask you questions. Personally I always ask them if they have understood and through the explaining you can learn if they have understood, just the way they talk you will know. If you don't do that the participant will come the next day knowing nothing" IDI#4 with the researchers

4.4.7 Presentation of the information

Participants suggested several methods that will improve the consenting process.

"…. Like this (indicating the group discussions), in the presence of doctors…because it can be very difficult to ask questions through the one to one method with a doctor…some people feel ashamed to ask questions but in the group discussions you don't feel that "- FGD#1

"…I am skeptical with the video method of providing information, I am not sure of it, it depends on the research type, and you just can't show everything…" – FGD#2

"…. We were provided the information in groups of 5 people and I think it helped to remember, although we both signed individually"- FGD#3

In one of the FGDs, when participants were asked who would they prefer to consent them it came out clearly that men preferred the one to one method with the physicians

"…We need enough time to sit with the doctors, and discuss in details the research issues and be given opportunity to ask questions, I do not fear the doctor…"FGD#5

Physicians also when asked on what do they think will be the best way to present information to the participants, they did responded as follows;

"…You have to ensure use of simple language, for example, you can explain something like SS genes in Swahili as "…chembe ulizochukua kwa mzazi huyu na huyu ndio inaweza kukusababishia SS…." and you can see something with only a single word can be explained using too many words, also another example in the Swahili consent form, genes has been translated as vinasaba, which is again something that need more explanation for someone to understand what it is" IDI#4 with the researchers

"..We don't go in deep to explain what genomics is, we mostly use real examples and terminologies that they can understand easily like for example to make them understand how did they inherit SS we use examples of children who has the same eye color, skin color as their parents.." IDI#1 with the researches

4.4.8 Not clear who has the role of consenting

The research information sheet was shown to the physicians at the clinic and they were asked if they have informed the participants about what was required in the forms and below were some of the responses

"I assume all this information were provided at the entry level from the registration desk done by the nurses, I don't have the information sheet only the signing page, up to when I start to see the patients they have already passed through all the sections and I assume they have got information about the research" IDI#1with the researchers

"The one who is seeing the patient should be the one who is supposed to consent the participants…this is the procedure anywhere. I will just provide them with general information and may be to witness how the process is being done" IDI#4 with the field staff

4.4.9 Education needs

Participants were interested to learn more on the different stages of the disease, reproductive health knowledge and screening for SS.

"People are getting us scared, there are many stories in the streets about SCD, SS patients are not allowed to have children, or she should only have one children, if you add another one you are going to die"- FGD#4

"...People are saying someone with SS cannot have children and if they gave birth, they will die, we need to educated on the risks of having children if you are SS"- FGD#1

"...I would like to know how the different diseases are associated with SS, e.g. If a SS patient is HIV positive how will they be? Will they be affected more?"- IDI#11

"...There are times when conflicts arise at family level between the parents, In my family, my father is saying I got that disease from my mother and my mother is saying the same thing and this is due to lack of proper education on SCD"- FGD

".... Time should be set-aside for education sessions, when we arrive we can all meet at one room and be given seminars about SCD...e.g. There is that myth out there that a SS kid will not reach 18 years of age, also that the SCD patients are not getting malaria"- FGD

"I have met another men and am expecting to have another baby with him, how would I know his SS status"- IDI#9

CHAPTER FIVE

5.0 DISCUSSION

This study un-covered number of issues surrounding the informed consent process in genomic research when conducted with-in population characterized to have low literacy level.

Although it was assumed that literacy level can influence participant understanding, results have shown that understanding of the concepts in genomic research were contributed much more on number of issues and literacy level was not considered by participants as hindering factor. The adequacy of the information provided to the participants, how comprehension was measured and the methods used to communicate the information were more likely to influence the understanding rather than the participant level of literacy. These results are supported by a study conducted in Gambia (Tekola et al, 2009), which indicated that ways in which information is being provided is the central component of the consenting process.

Informational component was considered to be key but there were specific sections that seem to be regarded by the participants to be more important and need to be given much emphasis during the consenting process than others. Benefits of the researches and return of results repeatedly appeared in the discussions as areas that require detail information and regular feedback. Most of the participants did not seem interested to understand the risks or procedures involved, insisting that the benefits of participating in the researches outweighs the risks.

Preferred presentation methods were use of practical examples and simple terminologies that can be easily understood by the participants. Providing information in groups either through seminars or video in the presence of nurses or doctors as moderators was the most preferred and practical way of communication. Male participants preferred one to one method with the doctors, however, due to increase in the number of patients at the clinic, time spent with the doctors have decreased considerably. And therefore, little time allocation for consenting participants, which compromise the quality of the information provided.

However, even though the participants preferred to be given information in groups but the consent agreement to participate in research should still be done individually after the group seminars to respect the principle of autonomy (Belmont Report, 2000) as well as privacy and confidentiality issues. This is also supported by the study done on tailoring consent to context (Tekola et al, 2009), that in some settings individual consent may be preceded with providing information in groups.

Thematic results for this study also indicated that some participants were enrolled in the study before the legal age of consent (18 years) and could not recall the information provided and some remember their parents consenting on their behalf. This explains the importance of re-consenting the research participants after a certain period to ensure that they maintain the same understanding of the research. Consent is not supposed to be a one –time event. Participants preferred to be reminded the research information at least once per year.

Researchers regarded the concept of informed consent to be more of routine activity. Ensuring Participants have signed the consent forms was taken seriously as a key criterion to validate the informed consent process. The other features like ensuring information was adequately provided, given voluntarily by competent individual was not carefully looked at. The increase in number of patients at the clinic has affected time patient spent with the doctors and therefore it is very difficult for the researchers to spend a lot of time doing the consent. The proposal to provide the information in-groups will assist in solving this problem.

Fewer participants stated not being comfortable asking questions to the doctors due to fear of being seen as ignorant, trusting that doctors knows it all and others waited to be given opportunities to ask before asking questions. Women were more sensitive to start asking questions than men.

> *..This came out from one of the FGDs were one of the female participant confessed that she has never asked questions because she is shy and usually wait for the doctors to start asking questions. And the responses from the men were (I don't feel shy, I prefer the one to one interaction with the doctors so that I will be able to ask them all my questions)*

This is considered typical in our environment and it requires pro-active measures from researchers to involve participants in the consenting process, and this cannot be overemphasized when female participants are involved.

Researchers measured participant understanding through questions and answers sections, which was done in two ways. Given the complexity of the information, the amount of information provided and participant's literacy level it was very important to check for their comprehension. Participants acknowledges that this was very helpful to assist them recall the information but also providing them opportunities to ask any questions they have to the doctors. The questions asked were mostly about progression of SCD, the tests done and interpretation of the results, causes of the disease, how to care for SCD patient and relationship between SCD and infectious diseases like HIV and Malaria.

Through the consent observations done we noted that the emphasis was given more on the clinical care than the research practices. Participant were more interested with the clinical care and did not take efforts to understand the research information provided, which might have skewed the information provided by the researchers and influence their ability to distinguish the clinical care and research practices.

One of the thematic area was not being clear on who has the role of consenting amongst the field staff (physicians and nurses), this observation necessitates a need to set clear procedures on who will be involved in the consenting process, so that all the field staff have understanding on whose responsibilities to provide research information to the participants when enrolled in researches. In certain contexts and studies, it takes more than the person who sees the patient to do the consenting. It has to be a team effort and may be start from the entry point (at the registration desk), when going through the nurse (through education sessions-explaining the information sheets in group sessions) and getting individual consent when contacting the physicians. In other cases, the procedure of consenting can even involve people outside the clinic, especially when it requires community engagement.

Although education needs was not the focus of this study but participants clearly indicated need for more knowledge and education on certain aspects of SCD. Reproductive health knowledge appeared to be more significant to the participants. This was observed in the adult clinic especially amongst the participants who have enrolled in the study before 18 years of age (who are now adult attending adult clinic on Thursdays) are keener to understand reproductive health choices and options that a SCD patient has. In addressing that the research team can plan to revive the education sessions provided during the MAKUTI clinic.

5.1 STUDY LIMITATION

During data collection participants were selected conveniently. All the participant's observations were conducted on Wednesdays (Children clinic) and therefore, the team ended up observing how parents or caregivers were consenting on behalf of their children. It was not possible to do FGDs on Wednesdays because the clinic was very busy and we could not find a private place to sit and have the discussions. Therefore, all FGDs were conducted at Adult clinic on Fridays. The IDIs were conducted on Wednesdays and Thursdays. The Results obtained from the participant observation may also be bias since when someone is being observed their attitude changes which may not reflect what they would have done in normal situation. However, the results were not affected because to be able to affect the results the participants were supposed to have enough knowledge on what a valid consent should be which did not seem to be a case for this study.

CHAPTER SIX

6.0 CONCLUSION AND RECOMMENDATIONS

6.1 CONCLUSION

Genomic researches are considered to be using very complex concepts which were assumed could challenge the information and comprehension component of the consenting process especially when conducted in population characterized to have low literacy level. Findings from this study have shown that the process of obtaining a valid consent wouldn't differ much in contexts. The main issues to look at during the consent is to ensure the information were provided adequately using simple languages and practical examples, but also comprehension of the participants measured during the process. The easiest way of measuring participant comprehension is through asking questions and also let them ask questions to the researchers. The methods which seems to be more practical in the settings, was providing the information first in groups whether through seminars, demonstrating the research through videos and seeking individual consent separately. However, all of these will require guidelines or a checklist to guide the field staff in ensuring that the consent is being obtained ethically. Involvement of research participants to have their perspectives is key when developing the guidelines.

6.2 RECOMMENDATIONS

The findings from this study will be used to;

1. Develop a tool to guide the researchers in eliciting informed consent in the context of genomic research.
    1.1. Presentation Method
    1.2. Language (terminologies) to be used
    1.3. Measure of Comprehension
    1.4. Focus areas
    1.5. Shared responsibilities amongst the research team

2. Conduct regular training sessions to the research team that will include the physicians, nurses, laboratory staff and clerical staff for them to be aware and also to remind and update on the procedures for consenting
3. Plan to have regular updates on the progress of the researches but also re-consenting the enrolled participants after 2 years of enrollment. This will address those who have enrolled before 18 years of age.
4. Revive the education sessions before start of the clinic on the services offered that will include the clinical care and the researches.

7.0 REFERENCES:

1. Alwan, Ala: Recommendations for introducing genetic services in developing countries. Nature Genetics Review 4, 61- 68 (January 2003)
2. A. Nyika: Ethical and Practical Challenges surrounding genetic and genomic research in developing countries. Acta Tropica, (2009).
3. Beatrice Seigul, Billie Jo Hardy, Peter Singer and Abdallah Daar: Genomic Medicine and Developing Countries: Creating a room of their own. Nature Reviews Genetics 9, 487-493 (June 2008).
4. Blatt, R. & Weiss, J. Informed consent: participation in genetic research studies. *Genet Resource.*7, 32−36 (1993).
5. Bull SJ: Consent to research in a Gambian context: legal, social and ethical issues. (PhD thesis). Kings College, London; 2007.
6. Cardinal G, Deschênes M, Knoppers BM, Hudson T, Labuda D, Bouchard G, Racine É, Fecteau C, Truong S, Laberge C: Statement of Principles on the Ethical Conduct of Human Genetic Research Involving Populations. (2003)
7. Dave Chokshi, Mahmadou Thera, Michael Parker, Mahamadou Diakite, Julie Makani, Dominic Kwiatkowski and Ogobara Doumbo: Valid Consent for Genomic Epidemiology in Developing Countries: Plos Med. April 2007
8. Fasil Tekola, Susan J. Bull, Bobbie Farside, Melanie J. Newport, Adebowale Adeyemo, Charles N. Rotimi, Gail Davey: Tailoring Consent to Context: Designing an Appropriate Consent Process for a Biomedical Study in a Low Income Setting. July 2009 | Volume 3 | Issue 7 | e482.
9. H3Africa Report: Harnessing Genomic Technologies Toward Improving Health in Africa: Opportunities and Challenges. Recommendations for the Human Health and Hereditary in Africa (H3Africa) initiative to the wellcome Trust and the National Institutes of Health (January 2011)

10. IH Office of Protection from Research Risks, in Human Genetic Research. In Protecting Human Research Subjects: Institutional Review Board Guidebook. Chapter 5H. (U.S. Government Printing Office, Washington, D.C., 1993
11. Jantina de Vries, Susan J Bull, Ogobara Doumbo, Muntaser Ibrahim, Odile Mercereau-Puijalon, Dominic Kwiatkowski and Michael Parker: Ethical issues in human genomics research in developing countries. *BMC Medical Ethics* 2011.
12. Jacquelyn Ann K Kegley: Challenges to Informed Consent; New developments in biomedical research and healthcare may mark the end of the traditional concept of informed consent. EMBO reports (2004) 5, 832 – 836
13. Mark Mason: Sample size and saturation in PhD studies using qualitative interviews. Forum Qualitative Social Research, Volume 11, No. 3, Art. 8- September 2010
14. NIH-DOE Working Group on the Ethical, Legal, and Social Implications of Human Genome Research. Genetic information and health insurance: report of the task force on genetic information and insurance. (National Center for Human Genome Research NIH Publication No. 93-3686,1993).
15. Philip R. Reilly[1], Mark R Boshar[2]& Steven H. Holtzman[2]. Ethical issues in genetic research: disclosure and informed consent. *Nature Genetics* 15, 16 - 20 (1997)
16. UK Human Genetics Commission Public Attitudes to Human Genetic Information. London: (2000) MORI Social Research
17. http://www.malariagen.net/home/ethics

8.0 APPENDIXES

8.1 APPENDIX 1: FGD GUIDE- RESEARCHERS

Moderator name:……

FGD #:……

Participant ID:……..

Thank you so much for agreeing to meet with us, As you know the objective of this study is to explore the ethical challenges in the consenting process when conducting genomic research in low literacy settings. The Discussion should take less than an hour. Again your participation is voluntary. You can decide not to answer any of the questions and we can stop the discussion anytime. If it is OK with you we will be tape recording the discussion so that we can make sure that we accurately capture your responses. We will not ever identify you by name and during the discussion please refer yourself with your ID no. We will do our very best to maintain your confidentiality.

Guide:

1. You have been working in the SCD Study at MNH, for more than 2 years now. Part of your activities includes eliciting informed consent. Do you have any guidelines to assist you in ensuring you obtain a valid consent? And do you think it is necessary to have the guidelines?
2. Can you explain in short from your own experiences the issues that are quite important in obtaining informed consent?
3. Genomic research seems to be very complex studies, in comparison to other health related researches but also the literacy level of most of the participants, how is it difficult or how is it easy to obtain the consent? What are the most difficult parts in the consenting process?
4. Do you have your own locally designed mechanisms to ensure you have been understood?
    a. Use of symbols

   b. Examples drawn from our societies
   c. Simple terminologies you are using

5. Some bioethicists argued that consent should not be the key requirement for ethical research in some settings. What are your takes in this argument? What should be considered as key for ethical research in settings where consent will be difficult to obtain?
6. Is there anything else that we have not asked about related to the study that you think we should ask about?
7. Is there anything else you would like to tell us about your experiences related to genomic research on SCD?

Thank you very much for your time, this was incredibly helpful. In the meantime if you think of anything else that might be helpful to our research. Please call me (business cards will be provided).

8.2 APPENDIX 2: FGD GUIDE- RESEARCH PARTICIPANTS

Moderator name:……

FGD #:……

Participant ID:……..

Thank you so much for agreeing to meet with us, As you know the objective of this study is to explore the ethical challenges in the consenting process when conducting genomic research in low literacy settings. The Discussion should take less than an hour. Again your participation is voluntary. You can decide not to answer any of the questions and we can stop the discussion anytime. If it is OK with you we will be tape recording the discussion so that we can make sure that we accurately capture your responses. We will not ever identify you by name and during the discussion please refer yourself with your ID no. We will do our very best to maintain your confidentiality.

Guide:

1. You are research participants in the SCD Study at MNH; you have agreed to participate in one of the on-going genetic/ genomic study conducted within the SCD Programme. Can you explain to me one or two issues about this genetic study?
2. How difficult and how easy was it in-terms of understanding the concepts, risks, and benefits of participating in genomic research?
3. Do you think of some ways that the consent could have been given? Or in what ways can the consent process be improved?
    a. Pictures
    b. Verbal
    c. Video/ Documentaries
    d. Any other method (participant may think), relevant to our social and cultural settings

4. Providing more information can sometime confuse participant and may be not everything is important for them to know. What specific issues do you think were important for you to know?
5. Is there anything else that we have not asked about related to the study that you think we should ask about?
6. Is there anything else you would like to tell us about your experiences in providing consent for genomic research on SCD?

Thank you very much for your time, this was incredibly helpful. In the meantime if you think of anything else that might be helpful to our research. Please call me (business cards will be provided).

8.3 APPENDIX 3: IDI GUIDE- RESEARCHERS

Interviewer name:……

Interview #:……

Participant ID:……..

Thank you so much for agreeing to meet with us, As you know the objective of this study is to explore the ethical challenges in the consenting process when conducting genomic research in low literacy settings. The interview should take less than an hour. Again your participation is voluntary. You can decide not to answer any of the questions and we can stop the interview anytime. If it is OK with you we will be tape recording the interview so that we can make sure that we accurately capture your responses. We will not ever identify you by name and during the discussion please refer yourself with your ID no. We will do our very best to maintain your confidentiality.

Guide:

1. One of the requirements to conduct ethical research is to obtain a valid consent (voluntary, given by a competent individual, understood by the participants). How do you ensure a valid consent is obtained in your research?
2. How do you measure comprehension of the research participants? (It shouldn't be necessarily a formal measurement, more from your own understanding and experiences)
3. From your personal experiences, how do you think it is different or challenging to seek consent in genomic/ genetic studies?
4. What kind of challenges do you usually encounter in the process?
5. Do you think the lack of genetic counselors in our settings has a role to play in how difficult it is to communicate with the participants?
6. What sorts of in-house trainings/ seminars will be relevant to you to help the process?
7. Is there anything else that we have not asked about related to the study that you think we should ask about?

8. Is there anything else you would like to tell us about your experiences related to genomic research on SCD?

Thank you very much for your time, this was incredibly helpful. In the meantime if you think of anything else that might be helpful to our research. Please call me (business cards will be provided).

8.4 APPENDIX 4: IDI GUIDE- RESEARCH PARTICIPANTS

Interviewer name:……

Interview #:……

Participant ID:……..

Thank you so much for agreeing to meet with us, As you know the objective of this study is to explore the ethical challenges in the consenting process when conducting genomic research in low literacy settings. The interview should take less than an hour. Again your participation is voluntary. You can decide not to answer any of the questions and we can stop the interview anytime. If it is OK with you we will be tape recording the discussion so that we can make sure that we accurately capture your responses. We will not ever identify you by name and during the interview please refer yourself with your ID no. We will do our very best to maintain your confidentiality.

Guide:

1. How much information did you feel that you needed to be able to make a decision about whether or not to participate in the study?
2. Where you comfortable the way the process was being held? In what ways do you think it can be improved?
3. Have you participated in another study? If YES, how is it different from participating in genomic/ genetic studies?
4. How much did you understand in terms of the purpose for this study, the risks, benefits, and the general understanding of what this research is about
5. Is there anything else that we have not asked about related to the study that you think we should ask about?
6. Is there anything else you would like to tell us about your experiences related to genomic research on SCD?

Thank you very much for your time, this was incredibly helpful. In the meantime if you think of anything else that might be helpful to our research. Please call me (business cards will be provided).

8.5 APPENDIX 5: PARTICIPANT OBSERVATION CHECKLIST

Validity of the informed consent is measured by:

- Adequacy of the information provided to the research participants & Participant
- Understanding
- Voluntariness
- Competency

Observation type	**Adequately done**	**Half done**	**Not done properly**	**Not done at all**
1. Adequacy of information provided to the research participants **1.1** Purpose **1.2** Risks **1.3** Benefits **1.4** Duration **1.5** Procedures **1.6** Confidentiality **1.7** Who to contact				
2. Comprehension: Participant Understanding **2.1** Q & A Session				
3. Voluntariness **3.1** Option given to agree or not agreeing to participate **3.2** Option to withdraw from the study				
4. Competency **4.1** Age **4.2** Ability to read and write **4.3** Mental Capacity				

8.6 APPENDIX 6: INFORMED CONSENT FORM- ENGLISH VERSION

MUHIMBILI UNIVERSITY OF HEALTH AND ALLIED SCIENCES
DIRECTORATE OF RESEARCH AND PUBLICATIONS, MUHAS



ID-NO ……..

Greetings and Purpose of the Study

My name is Ms. Daima Athumani Bukini and I am a student at MUHAS doing a Master Program in Public Health. I am working on this research project with the objective of exploring the ethical challenges in the consenting process when conducting genomic research in low literacy settings.

What Participation Involves

If you agree to join the study, you will participate in the Focus Group Discussions along with other participants and again upon your approval we may conduct one to one interview with you. In other case we might ask your permission to witness (as observer) the way consent process is handled with you. We are not going to interact during observation. We hope you would not mind use of tape recorder to capture in detail the information collected from the focus group discussions and during the interview.

Confidentiality

All information we collect on forms will be entered into computers with only the study identification number. No personal information will be collected and the audio records will be destroyed at the end of the study.

Risks

We do not expect that any harm will happen to you because of joining this study. The only risk anticipated is breach of privacy and confidentiality which we researcher will take maximum precaution not to happen.

Rights to Withdraw and Alternatives

Taking part in this study is completely voluntarily. If you choose not to participate in the study or if you decide to stop participating in the study you will continue to receive all services that you would normally get from this hospital. You can stop participating in this study at any time, even if you have already given your consent. Refusal to participate or withdrawal from the study will not involve penalty or loss of any benefits to which you are otherwise entitled.

Benefits

If you agree to take part in this study, there will be no direct benefits to you, the information we are collecting will help improve the consent process for participants enrolled in genomic research. We also believe it is very important to get views of the communities in way researches are being done in our settings.

Compensation

Refreshments will be served during the group discussions and the interview and transport costs will be compensated depending on where you are staying.

In Case of Injury

We do not anticipate that any harm will occur to you as results of participation in the study

Who to Contact

If you ever have questions about this study, you should contact the study Coordinator or the Principal Investigator Ms. Daima Athumani Bukini, Muhimbili University of Health and Allied Sciences, P.O. Box 65001, Dar es Salaam). Tel. 0713 386387

If you ever have questions about your rights as a participant, you may call Prof. M. Moshi, Chairman of the Senate Research and Publications Committee, P.O. Box 65001, Dar es Salaam. Tel: 2152489.

Signature:

Do you agree?

Participant agrees …… Participant does NOT agree ……..

I, _____ have read the contents in this form. My questions have been answered. I agree to participate in this study.

Signature of participant _____

Signature of witness (if cannot read) _____

Signature of research assistant _____

Date of signed consent _____

8.7 APPENDIX 7: FOMU YA RIDHAA YA KUSHIRIKI- SWAHILI

CHUO KIKUU CHA AFYA NA SAYANSI SHIRIKISHI- MUHIMBILI
IDARA YA UTAFITI NA MACHAPISHO, MUHIMBILI

ID-NO ……..

Salaam na Lengo la Utafiti

Jina langu naitwa Daima Athumani Bukini ni mwanfunzi katika chuo kikuu cha afya na sayansi shirikishi, Muhimbili. Ninafanya utafiti unaolenga kufahamu vikwazo katika kutafuta ridhaa ya kushiriki katika tafiti za vinasaba kwenye mazingira ambayo elimu ya washiriki wengi wa tafiti hizo ni ndogo.

Ushiriki wako utahusu nini

Ukikubali kushiriki katika utafiti huu, utahitajika kushiriki katika mijadala pamoja na washiriki wengine na pia kwa ridhaa yako, tunaweza kuhitajika kufanya usahili na wewe peke yako. Kama utakua ni mshiriki mpya katika mradi wa siko seli tungependa kushuhudia namna ambavyo wafanyakazi wa afya wakiomba ridhaa yako ya kushiriki katika moja wapo ya miradi yao ya vinasaba. Wakati tunaangalia icho kitendo hatutachangia chochote, ushiriki wetu utakua ni kusikiliza tu. Tunatumai hautajali matumizi ya taperecorder katika kurecodi mahujiano katika mijadala na usahili kwa ridhaa yako.

Usiri

Maelezo yote yatakayokusanywa kwenye fomu na tape recorder yataingizwa katika compyuta yakiwa na namba yako ya ushiriki tu. Hatutaitaji maelezo yoyote yanayokuhusu wewe mwenyewe na mwisho wa utafiti tutafuta maelezo yote katika compyuta na tape recorder.

Hatari za ushiriki

Hatutegemei hatari yoyote katika kushiriki kwako kwenye utafiti huu. Hatari ambayo inaweza kutokea ni kutoa siri za majadiliano ambayo watafiti wanakuhakikishia watajitahidi kwa kadri ya uwezo wao isitokee.

Haki ya kukataa kushiriki au kujitoa katika kushiriki

Ushiriki wako katika utafiti huu ni hiari yako wewe mwenyewe. Ikiwa utaamua kutokushiriki katika utafiti huu au kujitoa katika ushiriki utaendelea kupata huduma zote ambazo ulikua unapata katika hospitali hii (hakuna uhusiano wa ushiriki wako na hospitali). Unaweza kuacha kushiriki mda wowote ata kama ulishatoa ridhaa ya kushiriki. Na kukataa kushiriki hakuna adhabu yoyote utakayopata au kupoteza faida zozote ulizotaraji kuzipata katika huduma yako.

Faida za ushiriki

Ikiwa utakubali kushiriki katika utafiti huu, hakuna faida za moja kwa moja utakazozipata. Maelezo tutakayokusanya katika utafiti huu yatasaidia muongozo wa jinsi ya kuomba ridhaa kwa washiriki wa tafiti zinazohusiana na vinasaba na kuhakikisha washiriki wanapewa maelezo yote juu ya tafiti izo na pia wanaelewa maelezo hayo. Na pia tunafkiri ni muhimu kupata mawazo yenu juu ya jinsi gani tafiti zifanyike katika mazingira yetu.

Fidia

Vinywaji vitatolewa kwa washiriki kipindi cha mijadala na usahili au mahojiano na pia tutawarudishia gharama za usafiri kutegemea na wapi mshiriki anatokea.

Ikitokea kuumizwa

Hatutaraji kwa namna yoyote ile mtu yeyote ataumia kwa kushiriki katika mradi huu.

Nani wa kuwasiliana nae

Ikitokea una maswali juu ya ushiriki wako katika utafiti huu, tafadhali wasiliana na mtafiti kwa kutumia anuani zifuatazo, Ms. Daima Athumani Bukini, Chuo kikuu cha Afya na Sayansi Shirikishi, Muhimbili, S.L.P. 65001, Dar es Salaam). Simu. 0713 386387

Au kama una swali juu ya haki yako katika ushiriki katika utafiti huu, unaweza kumpigia Prof. M. Moshi, Mwenyekiti wa kamati ya utafiti na machapisho, S. L. P. 65001, Dar es Salaam. Simu: 2152489.

Sahihi:

Je umekubali?

Mshiriki amekubali …… Mshiriki hajakubali ……..

Mimi, _____ nimesoma maelezo yote kuhusu utafiti huu. Maswali na madukuduku niliyonayo yamejibiwa. Nimekubali kushiriki katika utafiti huu.

Sahihi ya mshiriki _____

Sahihi ya shuhuda wa mshiriki (kwa wasiojua kusoma na kuandika) _____

Sahihi ya msaidizi wa utafiti _____

Tarehe ridhaa imesainiwa _____