IRB NUMBER: 05-17-16.
IRB APPROVAL DATE: 4/7/2020
IRB EFFECTIVE DATE: 4/8/2020
IRB EXPIRATION DATE: 4/6/2021

UNIVERSITY HOSPITALS CLEVELAND MEDICAL CENTER
CONSENT FOR INVESTIGATIONAL STUDIES
(v.09.2016)

Project Title: Reducing the Burden of Chronic Psychotic Disorders in Tanzania – Survey

Principal Investigator: Dr. Jessie Mbwambo (Tanzania) and Dr. Martha Sajatovic (USA)

Introduction/Purpose
You are invited to participate in a research study. You were chosen as a possible participant for this study because you have been diagnosed with a chronic psychotic disorder (CPD) and you have missed some of your psychiatric medication doses in the past month.

Doctors at University Hospitals Cleveland Medical Center (UHCMC) and Case Western Reserve University (CWRU) Department of Psychiatry in the US and The Muhimbili University of Health and Allied Sciences (MUHAS) in Tanzania want to find out reasons that people are non-adherent (do not take all of their medications) for CPD (schizophrenia or schizoaffective disorder).

This study is funded by the National Institute of Health in the United States. You will be one of 100 participants enrolled in this research.

Study Procedures
If you agree to be in the study you will be asked to complete a questionnaire about reasons you do not always take your CPD medication.

Risks
The risks to you from participating in this research study include possible discomfort from thinking about your mental and physical health during the survey. You will be allowed to skip any questions that you do not want to answer.

The greatest risk is to your privacy. However, your results will be recorded and kept in a confidential manner and will only be available to study staff.

Benefits
There are no direct benefits to you by your participation in this study. Your participation in this study may aid in our understanding of the best treatments for those with CPD disorder that have difficulty sticking with treatment.

Alternatives to Study Participation
You may choose to not take part in this study.

Financial Information
You will receive TSh. 23,000 for completing the questionnaire.

There is no cost to you or your insurance for participation in this research study.

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Confidentiality
We will do everything we can to keep your personal information confidential. Your name or any other information that could directly identify you is replaced with a "code." A list linking your code to your name is kept by the original researchers. This coding makes it harder for other people to find out who you are.

Your personal information may be disclosed if required by law. No publication of this study will use your name or identify you personally.

People who may review your records include: The Muhimbili University of Health and Allied Sciences (MUHAS) and/or University Hospitals Cleveland Medical Center Institutional Review Board, Ethics Committee, other local regulatory agencies, National Institutes of Health, Office for Human Research Protections, study staff, study monitors, and their designees.

Summary of your rights as a participant in a research study
Your participation in this research study is voluntary. Refusing to participate will not alter your usual health care or involve any penalty or loss of benefits to which you are otherwise entitled. If you decide to join the study, you may withdraw at any time and for any reason without penalty or loss of benefits. If information generated from this study is published or presented, your identity will not be revealed. In the event new information becomes available that may affect the risks or benefits associated with this study or your willingness to participate in it, you will be notified so that you can decide whether or not to continue participating.

If injury occurs as a result of your involvement in this research, medical treatment is available from the Muhimbili National Hospital or another medical facility but you/your medical insurance will be responsible for the cost of this treatment. A research injury is an injury that happens as a result of taking part in this research study. If you are injured by a medical treatment or procedure that you would have received even if you were not in the study, that is not considered a "research injury". There are no plans for payment of medical expenses or other payments, including lost wages, for any research related injury. To help avoid injury, it is very important to follow all study directions.

Disclosure of your study records
Efforts will be made to keep the personal information in your research record private and confidential, but absolute confidentiality cannot be guaranteed. The University Hospitals Cleveland Medical Center Institutional Review Board may review your study records. If this study is regulated by the Food and Drug Administration (FDA), there is a possibility that the FDA might inspect your records. In addition, for treatment studies, the study sponsor and possibly

foreign regulatory agencies may also review your records. If your records are reviewed your identity could become known.

Contact information

_____ has described to you what is going to be done, the risks, hazards, and benefits involved. The Principal Investigator Dr. Jessie Mbwambo can also be contacted at +255 754 339 747. If you have any questions, concerns or complaints about the study in the future, you may also contact them later.

If the researchers cannot be reached, or if you would like to talk to someone other than the researcher(s) about; concerns regarding the study; research participant's rights; research-related injury; or other human subject issues, please call the Directorate of Research and Publications, at 2152489 or write to: Directorate of Research and Publications, P.O. Box 65001, Dar es Salaam.

Signature
Signing below indicates that you have been informed about the research study in which you voluntarily agree to participate; that you have asked any questions about the study that you may have; and that the information given to you has permitted you to make a fully informed and free decision about your participation in the study. By signing this consent form, you do not waive any legal rights, and the investigator(s) or sponsor(s) are not relieved of any liability they may have. A copy of this consent form will be provided to you.

x	
Signature of Participant	Date
x	
Printed Name of Participant	
If participant does not have the capacity to consent and protocol is approved for inclusion	
x	
Signature of Legally Authorized Representative (LAR) or Next of Kin	Date
x	
Printed name of Legally Authorized Representative (LAR) or Next of Kin	

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If Next of Kin, please mark ONE relationship from list below (in descending order of priority):									
	Spouse		Adult Child		Custodial Parent		Adult Sibling		Adult relative (related by blood or adoption)

Study personnel (only individuals designated on the checklist may obtain consent)

x	
Signature of person obtaining informed consent	Date
x	
Printed name of person obtaining informed consent	