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

Project Title: Reducing the Burden of Chronic Psychotic Disorders in Tanzania – Phase 3

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

Introduction/Purpose
You are invited to participate in a research study that may help treat your mental illness. 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. If you decide to be a part of this research study, you are giving up having your antipsychotic medication selected and having doses adjusted by your own treating psychiatrist during the 25-weeks (6 months) of the study. Your regular clinical provider will continue to make decisions about your other medications such as mood stabilizers, antidepressants, or other medications intended to treat mental illness.

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 how the injectable medication, haloperidol decanoate (Haldol Decanoate), combined with Customized Adherence Enhancement (CAE) psychosocial sessions, affect mental illness relapse and adherence to treatment for people with CPD (schizophrenia or schizoaffective disorder). Haloperidol decanoate is a long-acting injectable (LAI) medication and has been approved by the FDA for the treatment of CPD.

You will be one of 20 participants enrolled in this research.

There is a possibility that the research study team may become aware of new findings that may affect your willingness to continue participation. You will be informed of these new findings so that you may choose to continue or discontinue your voluntary participation.

Study Procedures
This study is funded by the National Institute of Health in the United States. The study will include answering interview questions, going to CAE sessions, and receiving injections of the psychiatric drug haloperidol decanoate for 25 weeks (about 6 months).

CAE sessions are designed to help you take your medications as prescribed and follow your treatment. CAE topics that may be assigned to you include: understanding your mental disorder, medication-taking routines, communication with your doctors and other care providers, and how using drugs or alcohol interferes with your treatment and recovery. During a CAE session, a mental health professional will use a treatment manual/guide and ask you questions addressing the CAE topic assigned to that particular session. All CAE sessions will be completed in a series of 8 face-to-face sessions with the study counselor over a 25 week (about 6 month) period.

During the study, the Research study counselor will be contacting your current mental health providers or will assist in connecting you with a mental health provider if you do not already have one, to make sure you can continue your treatment once you have completed the study.

The study also includes an injection (shot) of the LAI haloperidol decanoate at the beginning of the study, again one week later (if needed), and then about every 3-5 weeks for 24 weeks for a possible total of 8 injections. The injections and CAE sessions will typically take place during the same visits depending on how often you receive your medication shots.

Screening
If you decide to participate, you will begin the screening period, during which members of the research team will interview you using a standard set of interview questions to help decide if you qualify for the study. You will also have your blood drawn (approximately 2-4 teaspoons) for routine laboratory tests and will have an electrocardiogram (EKG), which is a painless test that measures your heart's electrical activity. These tests will be done to make sure you do not have any medical problems that could be affected by the study medicine. If you are not already taking oral (swallowing a pill by mouth) haloperidol (Haldol), you will first be started on oral haloperidol during the screening period. The screening visit is expected to last about 120 minutes (2 hours). The screening period can last from 1 day up to 3 weeks depending on your situation. You may be on oral medication from 3 days up to about 3 weeks depending on your situation.

Assessment Visits and Study Intervention
After the screening period, you will have Visit 1. Members of the research team will interview you again about your symptoms, behavior, treatment, and other parts of your life. You will be assigned to receive one or more CAE categories. The doctor will perform a physical and neurological examination and will review your medical history. During Visit 1, you will receive your first session of CAE and injection of the LAI. Visit 1 is expected to last about 210 minutes (3-1/2 hours).

You will return for CAE sessions, LAI injections, and interviews at Visit 2, Visit 3, Visit 4, Visit 5, Visit 6, Visit 7, and Visit 8. Visits 2, 3, 4, 6, and 7 will last about 90 minutes (1-1/2 hours). Visit 5 will last about 130 minutes (about 2 hours) and Visit 8 will last about 210 minutes (3-1/2 hours) due to additional tests that are given at both visits and a physical exam, EKG, and blood draw at Week 25.

If at any time you decide to drop out or quit from the CAE sessions or the LAI medication treatment, we ask that you still complete the rest of the interviews if possible.

Risks

The risks to you from participating in this research study include possible discomfort from talking about your mental and physical health during the interviews and CAE sessions. You will be allowed to skip any questions that you do not want to answer. Getting stuck by a needle to draw blood is painful; however, this discomfort lasts for only a very short time. For most people, a needle stick to get blood samples do not cause any serious problems; however, rarely they may cause bleeding, bruising, discomfort, infections, dizziness, or fainting.

The possible side effects of the medication used in the study are listed below. We will ask you questions about side effects at each visit and you should call the study staff or your regular mental health provider if you experience troublesome side effects between visits. If you appear to be having trouble with side effects, the study doctor may adjust the dose of your study medication, may give you another prescription to treat the side effects, or in some cases, may stop your participation in the injection (shot) part of the study. You are also free to quit the study at any time without penalty.

Risks to taking study medication
To take the study drug haloperidol decanoate, some of the medicines you now take may have to be stopped. Stopping these medicines may cause a return of some symptoms that were under control. For example, stopping antipsychotics may cause insomnia (difficulty sleeping), or the appearance of abnormal muscle movements. Your study doctor may be able to give you medicine to help control these symptoms.

Risks of haloperidol and haloperidol decanoate
Risks to taking haloperidol and injectable haloperidol decanoate may include common side effects such as drowsiness, reduced drive or reduced interest in daily activities, reduced interest in things around you, and a decrease in your expressed emotions. Other side effects may include dizziness, blurred vision, upset stomach, loss of appetite, headache, drooling, dry mouth, sweating, and sleep problems. Most of these problems go away as your body adjusts to the medication. Serious side effects could include chest pain, aching muscles and joints, unusual bleeding or bruising, tremors, and involuntary (without your control) movements.

A particular type of involuntary movement, known as tardive dyskinesia, usually occurring to the face, tongue, or mouth could result from taking certain medicines such as haloperidol or haloperidol decanoate. This serious side effect can result from such medications at a rate of 3% to 5% per year for the first five years of treatment and 2% to 3% per year after that. Tardive dyskinesia may go away after stopping haloperidol or haloperidol decanoate, or may become permanent even after stopping the medication.

Rare, but very serious side effects from taking haloperidol and haloperidol decanoate could include fainting or fast/uneven heartbeat.

If you experience certain side effects (e.g. tremors, uncontrollable movement) from haloperidol or haloperidol decanoate, benztropine may be provided to you by the study doctor. Side effects from benztropine that are common include drowsiness, dry mouth, difficulty passing urine, and constipation. More serious side effects include skin rash, fast or irregular heartbeat, fever, confusion, depression, delusions or hallucinations, and eye pain. If you experience any of these serious side effects you should let the study doctor know immediately.

The study drug must be taken only by you. It must be kept in a safe place out of reach of children and other people who cannot read well or understand that they should not take it.

Participation in this study may involve risks that are currently unforeseeable due to the nature of this research. However, if any new risks become known in the future, you will be informed of them.

Reproductive Health/Sexual Activity
The effects of haloperidol and injectable haloperidol during pregnancy are unknown and there is no recommendation by the FDA for use during pregnancy. If you are a woman and are of child bearing age and have not gone through menopause or had a hysterectomy, you will be given a pregnancy test at screening and again at week 25 of the study. If the screening test indicates that you are pregnant, you will not be able to be part of the study. If the screening test indicates that you are not pregnant, you must agree to use a reliable form of birth control while you are in this study. The research assistant or doctor can give you more information about this if you need it. If you become pregnant during the study, you should report this to the research staff as soon as possible. If you become pregnant or the test at week 25 indicates that you are pregnant, you will stop receiving the study injections and your regular mental health provider will determine the best medication treatment for you. You may continue to participate in the interviews and CAE sessions if you so choose.

Benefits
There may be no direct benefit to you by your participation in this study as it is not possible to predict that you will have improvement in your symptoms with study medication or CAE sessions. 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 do not have to take part in this study to be treated for your illness or condition. The medication treatments used in this study are available in the community. If you decide to be a part of this research study, you are giving up the opportunity of having your antipsychotic medication selected and having doses adjusted by your own treating psychiatrist during the 25-week active phase of the study. Your regular clinical provider will continue to make decisions about your other medications such as mood stabilizers, antidepressants, or other medications intended to treat mental illness. If you do not wish to participate in this study your mental health provider may decide to treat you with injectable haloperidol decanoate (Haldol Decanoate) or an alternative medication such as oral haloperidol (Haldol), aripiprazole (Abilify), paliperidone (Invega, Invega Sustenna), molindone (Moban), olanzapine (Zyprexa, Zyprexa Zydis) or others.

Financial Information
You will receive TSh. 23,000 for participating in the Screening and assessment visits. Therefore, you could receive a possible total of TSh. 207,000. If the doctor decides you need to come in between visits, you may receive additional compensation for your time.

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

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.

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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	

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	