

#1: SAMPLE CONSENT FORM

NOTE: This informed consent document is adapted from a template made available from the World Health Organization.

Your health, our priority.

Regional Health Center
1234 Main Street
Washington, DC

Informed Consent form for men and women who attend the Regional Health Clinic, and who we are inviting to participate in research on Z Disease. The title of our project is “Evaluating the Effectiveness of Drug XYZ on the Treatment of Disease Z as Compared to Standard Treatment with Drug ABC”

[Key Element #3: Who is conducting the study]

Principal Investigator: Marcus Sandler, MD
Study Coordinator: Holly Gray, LPN
Conducted by: Regional Health Center, Washington, DC
Sponsored By: The National Centers of Health
IRB Approval #A5-009-63D, January 1, 2013

This Informed Consent Form has two parts:

- Information Sheet (to share information about the research with you)
- Certificate of Consent (for signatures if you agree to take part)

You will be given a copy of the full Informed Consent Form

[Key Element #3: Who is conducting the study]

Introduction

I am Marcus Sandler, MD, working for the Regional Health Center Research Institute. We are doing research on Z disease, which is very common in this country. I am going to give you information and invite you to be part of this research. You do not have to decide today whether or not you will participate in the research. Before you decide, you can talk to anyone you feel comfortable with about the research.

There may be some words that you do not understand. Please ask me to stop as we go through the information and I will take time to explain. If you have questions later, you can ask them of me, the study doctor or the staff.

[Key Element #1: Purpose]

Purpose of the research

Z Disease is one of the most common and dangerous diseases in this region. The drugs that are currently used to help people with Z disease are not as good as we would like them to be. In fact, only 40 out of every 100 people given the Z disease drug ABC are completely cured. There is a new drug which may work better. The reason we are doing this research is to find out if the new drug XYZ is better than drug ABC which is currently being used.

Type of Research Study

This research will involve blood samples being taken from your arm four times, ingestion of a drug by mouth one time, and 6 visits to the clinic.

[Key Element #2: Why you were asked]

Participant selection

We are inviting all adults with Z disease who attend the Regional Health Clinic to participate in the research on the new Z disease drug.

Voluntary Participation

Your participation in this research is entirely voluntary. It is your choice whether to participate or not. Whether you choose to participate or not, all the services you receive at this clinic will continue and nothing will change. If you choose not to participate in this research project, you will be offered the treatment that is routinely offered in this clinic/hospital for disease Z, and we will tell you more about it later. You may change your mind later and stop participating even if you agreed earlier.

Information on the Trial Drug XYZ

The drug we are testing in this research is called XYZ. It has been tested before with people who do not have Z disease but who live in areas where Z disease is common. We now want to test the drug on people who have disease. This second research is called a "phase 2" trial.

The drug XYZ is made by Company C. You should know that it has a few side effects. One of the side effects, or problems, is that you may feel tired for the first day after being given the drug. Also, 20% of the people who tried the drug in previous research experienced temporary swelling where the injection entered the skin. We know of no other problem or risks.

Some participants in the research will not be given the drug which we are testing. Instead, they will be given the drug ABC, the drug which is most commonly used in this region to treat Z disease. There is no risk associated with that drug and no known problems. It does not, however, cure Z disease as often as we would like.

Procedures and Protocol

A. Unfamiliar Procedures

Because we do not know if the new Z disease drug is better than the currently available drug for treating malaria, we need to compare the two. To do this, we will put people taking part in this

research into two groups. The groups are selected by chance, as if by tossing a coin (randomization).

Participants in one group will be given the test drug while participants in the other group will be given the drug that is currently being used for Z disease. It is important that neither you nor we know which of the two drugs you are given. This information will be in our files, but we will not look at these files until after the research is finished. This is the best way we have for testing without being influenced by what we think or hope might happen. We will then compare which of the two has the best results.

The healthcare workers will be looking after you and the other participants very carefully during the study. If we are concerned about what the drug is doing, we will find out which drug you are getting and make changes. If there is anything you are concerned about or that is bothering you about the research please talk to me or one of the other researchers)

[Key Element #6: What you will be doing]

B. Description of the Process

During the research you make five visits to the clinic.

- In the first visit, a small amount of blood, equal to about a teaspoon, will be taken from your arm with a syringe. This blood will be tested for the presence of substances that help your body to fight infections. We will also ask you a few questions about your general health and measure how tall you are and how much you weigh.
- At the next visit, which will be two weeks later, you will again be asked some questions about your health and then you will be given either the test drug or the drug that is currently used for Z disease. As explained before, neither you nor we will know whether you have received the test or the currently used drug. The drug will be in the form of a pill, and you will be asked to swallow it.
- After one week, you will come back to the clinic for a blood test. This will involve taking another sample of blood, about the amount of 2 tablespoons, from your arm with a syringe.
- You will come back to the clinic two more times, at one week intervals, to have blood taken from your arm again.

The research takes place over 5 weeks in total. During that time, it will be necessary for you to come to the clinic/hospital/health facility 5 days for 0.5-1 hours each day. We would like to meet with you three months after your last clinic visit for a final check-up.

In total, you will be asked to come 6 times to the clinic in 4.5 months. At the end of 4.5 months, the research will be finished.

[Key Element #4: Possible risks]

Side Effects

As already mentioned, this drug can have some unwanted effects. It can make you tired and it can cause some temporary swelling around the place where the injection goes into your arm. It is possible that it may also cause some problems that we are not aware of. However, we will follow you closely and keep track of any unwanted effects or any problems. We may use some

other medicines to decrease the symptoms of the side effects or reactions. Or we may stop the use of one or more drugs. If this is necessary we will discuss it together with you and you will always be consulted before we move to the next step.

Risks

By participating in this research it is possible that you will be at greater risk than you would otherwise be. There is, for example, a risk that your disease will not get better and that the new medicine doesn't work even as well as the old one.

[Key Element #5: Possible benefits]

Benefits

If you participate in this research, you will have the following benefits: any interim illnesses will be treated at no charge to you. If your child falls sick during this period he/she will be treated free of charge. There may not be any benefit for you but your participation is likely to help us find the answer to the research question. There may not be any benefit to the society at this stage of the research, but future generations are likely to benefit.

[Key Element #7: Incentives]

Reimbursements

We will give you \$30 to pay for your travel to the clinic/parking and we will give you \$100 for lost work time. You will not be given any other money or gifts to take part in this research.

[Key Element #10: Privacy and Confidentiality]

Confidentiality

The information that we collect from this research project will be kept confidential. Information about you that will be collected during the research will be put away and no-one but the researchers will be able to see it. Any information about you will have a number on it instead of your name. Only the researchers will know what your number is and we will lock that information up with a lock and key. It will not be shared with or given to anyone except the principal investigator, the study coordinator, the sponsors, and your clinician.

Sharing the Results

The knowledge that we get from doing this research will be shared with you through community meetings before it is made widely available to the public. Confidential information will not be shared. There will be small meetings in the community and these will be announced. After these meetings, we will publish the results in order that other interested people may learn from our research.

[Key Element #9: Participation is voluntary]

Right to Refuse or Withdraw

You do not have to take part in this research if you do not wish to do so and refusing to participate will not affect your treatment at this clinic in any way. You will still have all the benefits that you would otherwise have at this clinic. You may stop participating in the research at any time that you wish without losing any of your rights as a patient here. Your treatment at this clinic will not be affected in any way.

Alternatives to Participating

If you do not wish to take part in the research, you will be provided with the established standard treatment available at the Regional Health Center. People who have Z disease are given drug ABC.

[Key Element #8: Who to contact]

Who to Contact

If you have any questions you may ask them now or later, even after the study has started. If you wish to ask questions later, you may contact any of the following:

Marcus Sandler, MD
Regional Health Clinic

Holly Gray, LPN
Regional Health Clinic

Approval

This proposal has been reviewed and approved by the Regional Health Clinic IRB, which is a committee whose task it is to make sure that research participants are protected from harm. If you wish to find out more about the IRB, contact Alexis Hullivan at 301-555-0021 or ahullivan@email.org. It has also been reviewed by the Ethics Review Committee of the National Health Center (NHC), which is funding/sponsoring/supporting the study.

You can ask me any more questions about any part of the research study, if you wish to. Do you have any questions?

PART II: Certificate of Consent

I have read the foregoing information, or it has been read to me. I have had the opportunity to ask questions about it and any questions that I have asked have been answered to my satisfaction. I consent voluntarily to participate as a participant in this research.

Print Name of Participant _____

Signature of Participant _____

Date _____

Day/month/year

Statement by the researcher/person taking consent

I confirm that the participant was given an opportunity to ask questions about the study, and all the questions asked by the participant have been answered correctly and to the best of my ability. I confirm that the individual has not been coerced into giving consent, and the consent has been given freely and voluntarily.

A copy of this ICF has been provided to the participant.

Print Name of Researcher/person taking the consent _____

Signature of Researcher /person taking the consent _____

Date _____

Day/month/year