RESEARCH PARTICIPANT INFORMED CONSENT AND PRIVACY AUTHORIZATION FORM

Protocol #: 17-EI-N167

Protocol Title: Persistence of Ebola Virus in Ocular Tissues and Outcomes of Cataract Surgery in Survivors of Ebola Virus Disease

Sponsors: National Eye Institute (NEI), National Institutes of Health and Ministry of Health of Liberia

Liberian Lead Associate Investigator: Fred Amegashie, MD

NEI Principal Investigator: Rachel Bishop, MD

Site: Liberia, West Africa

1.0 WHAT YOU SHOULD KNOW ABOUT THIS STUDY:

- You are being asked to join a research study. We are asking you to be in this study because you either had Ebola or you live with or had close contact with someone who had Ebola, and you need surgery to remove cataracts from at least one eye. This consent form explains the research study and your part in the study. A cataract is a clouding of the lens of your eye that can make your vision blurry and/or dim.

- Please read the form carefully, or have someone you trust read and explain it to you. Take as much time as you need.

- Ask the study team to explain any words or information that you do not understand.

- You are a volunteer. If you join the study, you can change your mind later. You can decide not to take part or you can quit at any time. There will be no penalty or loss of benefits if you decide to quit the study. Your care within your community will not be affected.

- If you are the Legal Authorized Representative (LAR) signing for a child or an adult ward, the word “you” in this consent form refers to that child or adult ward.
2.0 WHAT IS THIS STUDY ABOUT?

This study is about eye problems and cataract surgery in Ebola survivors. We have found that many Ebola survivors develop eye problems, like cataracts, after they recover from Ebola. This study is being done to help us understand why some Ebola survivors get these problems. As part of this study, we will do research tests to look for pieces of the Ebola virus in the eyes of Ebola survivors.

We also want to study how well cataract surgery works to improve vision in Ebola survivors who get cataracts. To do this, we will follow two groups of people: Ebola survivors and people who had close contact with someone who had Ebola. We will compare these groups after cataract surgery, on one eye, to see if the surgery works as well for Ebola survivors as it does for people who never had Ebola.

This research may help us one day develop better care and treatments for eye disease in Ebola survivors.

3.0 HOW MANY PEOPLE WILL BE IN THIS STUDY?

We expect about 120 people to join the study. This number will include up to 60 survivors of Ebola infection and up to 60 close contacts.

4.0 WHAT WILL HAPPEN IF YOU JOIN THIS STUDY?

The consent process helps you decide if you want to join the study. It has two parts. The first part is a group information session which uses a picture flip book to help show parts of the study. Next you meet one-on-one with a study team member. The entire consent form will be read out loud so if you cannot read for any reason, either because you did not learn to read or because you cannot see, you will hear all the details about the study. There will be as much time as you need to ask questions.

Screening Visit: At this visit you will have a physical exam and a complete eye exam including testing how well you see, measuring your eye pressure, and checking your eye movements. To examine the inside of your eye, your pupil will be dilated with eye drops. While your pupils are dilated we may take pictures of the inside of your eye.
If you were not in PREVAIL 3, 4, or 5, we will test your blood for syphilis, an infection, and HIV, which is the virus that causes AIDS, and antibodies against the Ebola virus. In some cases, inflammation in the eyes can occur because of HIV or syphilis. A member of the study team will let you know if these tests will be done, and they will counsel you before the tests and when you receive your results. Blood will be drawn through a needle in your arm. We will draw no more than five teaspoons of blood.

There is a possibility of eye inflammation after cataract surgery. Severe eye inflammation may require high dose steroids or other medications that can be harmful to a developing fetus. In addition, advanced pregnancy can cause complications during eye surgery. Therefore, if you are able to become pregnant you will have a pregnancy test at the screening visit and one week before the cataract surgery. You will not be able to participate if the pregnancy test is positive.

If you are the LAR consenting for a child or adult ward, and they are able to become pregnant, we will also do a pregnancy test. Children and adult wards who are pregnant may not take part in this study. If the pregnancy test is positive, we will inform both you and your child or ward. If your child or ward objects to having this required test, they should not participate in this study.

If you agree to be in this study and you are an Ebola survivor or a close contact of an Ebola survivor with antibodies to Ebola in your blood, we will take some fluid from the front of the eye with the cataract using a small needle. We will then test the fluid from your eye for pieces of the Ebola virus. To do this, we will first numb your eye with special eye drops. Then, we will use a needle to carefully collect some of the fluid from the front part of your eye. We will then do a research test on this fluid to look for parts of the Ebola virus. If our research test shows that you have pieces of the Ebola virus in your eye, you will be done with this study. You will not have cataract surgery or any more visits as part of this study. If you do not have Ebola virus in your eye, you will be scheduled for cataract surgery on the eye that was tested for Ebola virus.

If you agree to be in this study and you are a close contact of someone who had Ebola, you may be scheduled for cataract surgery right away.

Surgery Visit: If you are an Ebola survivor you will only have surgery on one eye even if you have cataracts in both eyes. This is because we do not know if cataract surgery is safe to perform in Ebola survivors. The cataract surgery will be done on your eye with the worse vision due to cataract. If you are
a control participant, you will have surgery on at least one eye, the eye with worse vision. If possible, we may offer control participants who have cataracts in both eyes the option of having surgery in their second eye. We will only do this if we have enough time left to offer this to everyone control participant with cataracts in both eyes, in order to be fair.

For the cataract surgery, we will first use a needle to numb the tissues around your eye with medicine. The surgeon will then use a scalpel to make a small opening in the eye. The cataract will be removed through this opening. As part of the surgery, the part of your eye called the lens will be removed and replaced with a new plastic clear one. We will keep the lens that is removed for our research tests. After the surgery, we will watch you carefully. If you do not develop any problems during this time, you will be allowed to go home. We will give you medicine and instructions on how to care for your eye as it heals.

If you had HIV, syphilis, and Ebola antibody tests at the screening visit, before the surgery, we will tell you the results of these tests. If you need treatment, we will discuss this with you as well as how to find care. If you have HIV or syphilis, you can still be in this study.

Follow up Visits (Day 1, Week 1, Month 1, Month 3, Month 6, Month 9, and Month 12): You will return to the eye clinic for follow-up visits one day, one week, one month, and three, six, nine and twelve months after your cataract surgery. At these visits, we will do an eye exam to check your eye health and vision. These tests may include testing how well you see and measuring your eye pressure. For examination of the inside of the eye, your pupil will be dilated with eye drops. Photographs of the inside of the eye may be taken during the eye examination and while your eyes are dilated. While your eyes are dilated we may also measure the thickness of your retina.

You may need more than the study visits listed above in order to heal well after cataract surgery. For example, if you have a lot of inflammation in your eye after surgery, your eye surgeon may ask you to come to a clinical follow-up visit at two weeks after surgery, or at any other time. Where you live will guide where you will get your eye exams after surgery so you can receive care near where you live. For example, you might be asked to see an eye surgeon in Lofa if you live in Lofa. If you live in Monrovia, you might be asked to see an eye surgeon at the New Sight Eye Center. If you have a complication no matter where you live, you might be asked to see an eye surgeon at the L.V. Prasad Eye Clinic at JFK Hospital. If you are asked to see the specialist at the L.V. Prasad Eye Clinic and you live in Lofa you will receive transportation for that visit.
If you are breastfeeding and after your surgery have a lot of inflammation which must be treated with oral steroids, we will use a dosing schedule to lessen the risk to your breastfeeding child. This schedule will include waiting four hours after breastfeeding before taking your steroid pill(s).

If you have healed without any problems, you will be finished with the study and not have any more visits for this study after the 12-month follow-up visit. If you need more time to heal than 12 months, then you will have more visits. This will be decided by the eye surgeon during the follow-up visits. You can be followed and receive eye care related to your cataract surgery for up to two years after the surgery. If you are enrolled on another PREVAIL study that requires eye exams, you will continue to get those eye exams on the proper schedule.

We may contact you in the future as part of our ongoing research.

5.0 WHAT RESEARCH TESTS WILL BE DONE?

If you are an Ebola survivor, we will test some of the fluid we collect from your eye to look for a certain part of the Ebola virus. This will tell us if you have Ebola virus in your eye. We will share the results of this test with you. We will store any leftover fluid for future research tests.

If you have cataract surgery on this study, we will test the lens that we remove from your eye for pieces of Ebola virus. We will also store your lens for future research tests.

When this research is concluded, we may provide the general results of this study to hospital and community leaders to share with the community.

6.0 WHAT WILL HAPPEN TO YOUR EYE FLUID AND LENS SAMPLES AND PERSONAL INFORMATION?

We will store your eye fluid and lens samples, and blood, as well as the data (information) that we collect from you, for a very long time to use for future research on Ebola. Your stored samples and data will be marked with a code and not with your name. Only researchers linked to this study can get the codes.
Your study information will be placed in a secure electronic system for use by other researchers. It will not include your name. Researchers must request permission to look at information in this system. They may then use the information for future research, including topics not related to Ebola. This allows the information to be shared broadly for research purposes. You will not get any information about future research.

We must get approval from the Liberian and US ethics boards that review this study before we share samples and data with other researchers. Other information, such as your sex, age, or health history might also be shared, but your name will not. Your samples will not be sold. You will not be paid for any products that result from this research. We will make every reasonable effort to protect the confidentiality of your information, however there is a risk of loss of confidentiality.

If you change your mind and decide you do not want us to store your samples or data, please let us know. We will do our best to follow your wishes but cannot promise that we will always be able to destroy your samples or data.

7.0 WHAT ARE THE RISKS OR DISCOMFORTS OF THE STUDY?

History and physical examination risks: There is minimal medical risk or discomfort from the physical exam.

Eye examination risks: There is minimal medical risk from the tests of vision, measuring eye pressure or retinal thickness or eye photography. The eye drops used to dilate your eyes may sting. You may have glare and blurry vision for several hours while your eyes are dilated. Some people are allergic to eye drops. Some people have a temporary increase in eye pressure which would make your eye become red or painful. These problems will be treated if they occur.

Taking fluid from the front of the eye: Risks include bleeding in the eye, infection in the eye, damage to your eye and possible loss of vision from these complications.

Cataract surgery and numbing of the eye to prevent pain: Risks include discomfort when the needle is placed near the eye to provide the numbing medicine, bleeding around the injection site or behind the eye, bleeding in the eye, infection in the eye, damage to the eye, inflammation in the eye that could cause
glaucoma (an increase in eye pressure that requires treatment) or could require anti-inflammation medicines such as steroid pills that could cause side effects to your general health (such as high blood pressure and diabetes), which may require treatment. Risks also include a need for more eye surgery to manage complications and possible loss of vision from complications.

If you are an Ebola survivor, you may find out that you still have pieces of the Ebola virus in your eye. It might be upsetting to learn this information and you may feel stigma.

If you are a close contact of a survivor you may learn that you have Ebola antibodies in your blood. This may be upsetting and you will be offered counseling.

Blood draw risks: You may have some discomfort and bruising from the needle insertion. Some people feel light-headed or faint.

Confidentiality risks: We will be careful to keep your study information confidential, but there is a small risk that someone not involved in the study could get this information.

Risks to infants of breastfeeding women: If you are nursing a child there may be a risk to your child from participating in this study.

During the surgery, we will inject numbing medicine around your eye. The medicine should not get into your breastmilk. There is minimal risk to your nursing baby from the cataract surgery itself.

However, one of the risks of surgery is severe eye inflammation afterwards. If you develop severe eye inflammation after surgery, you will need strong medicine to take by mouth. The medicine is a steroid. If you have severe eye inflammation and do not take the medicine, you could become permanently blind in that eye. If you take high doses of this medicine, some may get into your breast milk. Your baby can get the medication when he or she nurses. Theoretically the risks to the baby could include stomach upset, vomiting, restlessness, abnormal weight gain, and increase in blood sugar. The risks of these happening are small. However, we can’t completely erase the risk. To be safe, you should wait four hours after taking the medicine before nursing. You could even choose to temporarily bottle feed your baby while you are on high doses of the steroid. If you are a nursing mother, you should consider these risks before agreeing to participate in this study.
You will be provided with a phone number to contact the study team should you have problems after your surgery.

8.0 ARE THERE BENEFITS TO BEING IN THE STUDY?

You may benefit by having cataract surgery on this study. Most people have a large improvement in their vision after this surgery.

What we learn from this study may improve eye care and treatment decisions for Ebola survivors in the future.

9.0 WILL IT COST YOU ANYTHING TO BE IN THIS STUDY?

It will not cost you anything to be in this study.

10.0 WILL YOU BE PAID IF YOU JOIN THIS STUDY?

No, you will not be paid. However, you will be provided an allowance at each visit for your time and to help with your costs of traveling to participate in this study.

On your initial screening visit to JFK and each time you travel to the ELWA clinic, you will be given an allowance of $20 and each time you travel to JFK Hospital for a follow up visit, you will receive a $10 allowance. Also, if you need more eye follow-up visits than the scheduled study visits, you will receive a $10 allowance for each follow-up visit.

If you are a participant traveling to the ELWA clinic from Lofa, your travel, lodging, food and other expenses have been provided by Samaritan’s Purse and you will not be given an additional allowance for study visits. You will stay in this lodging for multiple days, in order to participate in the study visits that are needed before surgery, to receive surgery, and then to get follow-up exams until it is safe for you to go home.

Everyone who gets surgery on this study will have to spend the night in lodging near ELWA hospital the night before and the night after surgery. If you are an Ebola survivor, you might also have to stay overnight.
before the anterior chamber tap procedure. You will receive food while you stay in lodging. The lodging will be paid for by the study.

11.0 HOW WILL YOUR PRIVACY BE PROTECTED?

We will keep your study information private. All files with your information will be kept in locked cabinets or secure computers. People responsible for making sure that the research is done properly may look at your study records. This might include people from the Liberian Agencies and the United States including the NIH and their designees. All of these people will also keep your identity private. Results from this study may be shared with local medical providers or government health organizations to help them better understand Ebola virus infection.

12.0 WHAT OTHER THINGS SHOULD YOU KNOW ABOUT THIS RESEARCH STUDY?

a. What is the Ethics and Scientific Review Committee and how does it protect you?
Your government’s National Research Ethics Board will review this study. It protects the rights and welfare of the people taking part in those studies. You can contact the coordinator of the National Research Ethics Board (Tel: +231-777-697-606/+231-886-697-606) to answer questions you may have about being part of this study and your rights as someone who is in a study. The Ethics committee at the United States NIH has also reviewed and approved this research.

b. What do you do if you have questions about the study?
If you have questions about the study, you may contact the principal investigator or Liberian lead associate investigator. Dr. Fred Amegashie (Liberia) can be reached by phone +231 (0)886552229, or by email drfredamegashie@gmail.com. Dr. Rachel Bishop (NIH) can be reached by email bishopra@nei.nih.gov.

c. What should you do if you are injured or ill as a result of being in this study?
We do not expect any harm from participating in this study. However, unforeseeable risks may be present. The study doctors will give you short-term medical care if you are hurt by being in this study.

d. What are your alternatives to participating in this study?
You may choose not to participate in this study but to continue to receive standard care for cataracts from your own physicians.
If you agree to be in this study, please sign or put your fingerprint below.

_____________________________________________  Date: _____/_____/_____
Signature or fingerprint of participant or guardian (LAR)  dd mm yy

_______________________________________________________
Printed name of participant or guardian (LAR)

_____________________________________________  Date: _____/_____/_____
Signature of Investigator  dd mm yy

_______________________________________________________
Printed name of Investigator
**Witness to Consent Interview**

On the date given next to my signature, I witnessed the consent interview for the Research Study named above in this document. I attest that the information in this consent form was explained to the subject, and the subject indicated that his/her questions and concerns were adequately addressed.

______________________________________________
Date: _____/_____/_____
Signature of witness

_______________________________________________________
Printed name of witness