

# ATTACHMENT 10. CONSENT FOR SAMPLE COLLECTION

## What is the purpose of this investigation?

The purpose of this part of the investigation is to learn more about where Oropouche virus might be found in the body. This includes what body samples the virus can be found in and how long the virus is in these samples. This will tell us about how healthcare providers can diagnose Oropouche and how the virus might be spread. This will help us provide guidance to people on how to protect themselves and others from getting sick.

## What do you want me to do if I decide to take part in this part of the investigation?

We would like to collect samples of [blood, *if applicable based on timing of enrollment post symptom onset*], saliva, urine, and either semen or vaginal fluids. If you are breastfeeding, we would also like to obtain a sample of your breast milk. Blood samples would be collected by a trained healthcare provider at a health department clinic, your doctor's office, or at your home. You would collect other samples yourself at your home. We would provide instructions on how to collect samples. We will give you all the materials you will need to collect and mail the samples back to us.

All samples would be collected weekly until 4 weeks after you first felt sick. Then, we would like to collect all samples except for blood every 2 weeks until 12 weeks and once at 16 weeks after you first felt sick. The exact number of sample collections depends on how long between your illness and now. There could be as few as one collection, or as many as eight. You may decide to stop taking part at any time during the study. You can also decide to only take and submit certain samples.

### Sample Collection Details:

- **Blood:** a trained healthcare provider will collect about half a tablespoon (7 ml) from a vein in your arm.
- **Saliva:** we will give you a soft cotton swab to place between your cheek and gum and rub gently for about a minute.
- **Urine:** we will give you a sterile cup to collect a urine sample.
- **Females only:** we will give you another soft cotton swab to touch your vagina and collect a sample of vaginal fluids yourself. If you are breastfeeding we will ask you to express some of your breast milk into a cup that we provide.
- **Males only:** for the semen collection, we will ask you to masturbate and provide semen in a cup that we provide.

Samples will be sent to a laboratory at CDC in Colorado. All samples will be tested to see if parts of Oropouche virus are in the sample. If the sample tests positive for parts of Oropouche virus, a portion of that sample will undergo further testing to see if the virus is still alive. Blood samples will also be tested for antibodies (proteins in the blood that fight germs) to Oropouche virus. You will NOT be given your test results.

After this study is over, we would like to store your samples. Your samples might be used for other studies to better understand Oropouche or other similar diseases. Your samples will NOT be used for human genetic testing. You can still take part in this study even if you do not want us to store your samples. At the end of this form, we will ask you to tell us whether or not you agree to let us store your samples. If you agree, you can contact us at any time to request your samples be removed from storage.

## Are there any risks to me if I decide to be in the investigation?

The risks of being a part of this study are very small and most have to do with getting the blood sample. When we take blood from the arm with a sterile needle, you may feel some pain or get dizzy. You may also get a bruise or red mark where the needle goes into the skin. Very few people also get an infection. Putting a swab in your mouth to take saliva can feel uncomfortable. There are no known risks for urinating into a cup. Collection of semen/vaginal fluids may make you feel uncomfortable. We would provide instructions on how to safely collect your samples.

Only project staff will have access to your personal information. All efforts will be made to keep your personal information confidential, however, there is a small risk that information we collect could become available to staff who are not involved in the investigation.

**Are there any benefits to me if I decide to participate in the investigation?**

You might not benefit directly from the investigation. However, information from this investigation will help us learn about the Oropouche virus and how to prevent Oropouche from spreading in the future. You will not be paid for participating.

**Will the information I give to you be kept private?**

Anything you share with us will be kept private to the extent allowed by law. The surveys you complete will not have your name or address. We will keep track of your name and contact information only to contact you about the investigation. Your information will be stored digitally in a secure place. No one other than investigation staff should see this material. Your name will not be used in any reports that are written about the investigation's results.

**Will I be contacted in the future?**

Only if you agree, we may contact you about other projects about this virus.

**Do I have to participate in this investigation?**

Taking part in the investigation is voluntary. You may decide not to take part or to quit the investigation at any time. If you refuse to be in the investigation or drop out of the investigation, you may do so without any negative effects to you.

**Who should I contact if I have questions or think I may have been harmed by this investigation?**

Please feel free to ask any questions you may have about the investigation at any time. If you have questions later, you may contact [name and phone number of staff member from CDC or state health department, TBD]

**Do you have any additional questions?**

[Flesch-Kincaid Grade Level 7.7]

Once all questions have been answered:

We will now ask you to verbally agree or disagree to take part in this part of the investigation. We will send you a copy of this form for your records.

- |                           |                          |                                      |   |
|---------------------------|--------------------------|--------------------------------------|---|
| <input type="radio"/> Yes | <input type="radio"/> No |                                      | I have been told about the investigation. I have been allowed to ask questions and have had all of my questions answered. <i>If no, address additional questions.</i> |
| <input type="radio"/> Yes | <input type="radio"/> No | <input type="radio"/> Not applicable | I agree to participate by having samples of my blood collected  |
| <input type="radio"/> Yes | <input type="radio"/> No |                                      | I agree to participate by giving samples of my saliva (spit)  |
| <input type="radio"/> Yes | <input type="radio"/> No |                                      | I agree to participate by giving samples of my urine  |
| <input type="radio"/> Yes | <input type="radio"/> No |                                      | I agree to participate by giving samples of my semen or vaginal fluids  |
| <input type="radio"/> Yes | <input type="radio"/> No | <input type="radio"/> Not applicable | I agree to participate by giving a sample of my breast  |

milk

Yes     No

I agree to allow my samples to be stored for future possible work on Oropouche virus or related viruses

Yes     No

I agree to being contacted again in the future

Name of person giving verbal consent: \_\_\_\_\_

Name of person obtaining verbal consent: \_\_\_\_\_

Date/time: \_\_\_\_\_

Address or email address participant would like consent forms sent to: \_\_\_\_\_

\_\_\_\_\_