



## **MPOX ONE HEALTH STUDY**

**Understanding the animal and human and environmental factors of monkeypox spread in Nigeria**

### **Participant Information Sheet**

#### **ADULT CASE**

#### **Introduction**

The Mpox One Health Study is being conducted by Nigeria Centre for Disease Control (NCDC), in collaboration with UK Public Health Rapid Support Team (UK-PHRST) and the University of Oxford, under the ethical supervision of the London School of Hygiene and Tropical Medicine (LSHTM), under the ethical supervision of the London School of Hygiene and Tropical Medicine (LSHTM), and funded by UK Overseas Development Aid. The States participating in this study are Rivers, Ogun and Lagos. Other states may be included as needed.

We would like to invite you to take part in a research study about mpox (previously known as monkeypox). Joining this study is entirely up to you. Before you decide, you need to understand why the research is being done and what it would involve. One of our team members will go through this information sheet with you, and answer any questions you may have. Please ask questions if anything you read is not clear or if you would like more information. Please feel free to talk to others about the study if you wish. Take time to decide whether or not to take part.

This form gives information about the study including the aims, risks and benefits of taking part.

#### **What is the purpose of the study?**

Information about how the mpox virus spreads is limited. There is a need for research that looks closely at the different ways mpox may spread, including from human to human, from wild and domestic animals, and through contaminated environments, and to investigate what the risk factors are for this spread in households and among close contacts of people who have had mpox. We also want to know if people can be infected without having symptoms. We hope this knowledge will assist public health decision makers in Nigeria and elsewhere to improve prevention and response activities.

#### **Why have I been asked to take part?**

You are invited to take part in this study because your test result confirms mpox (previously known as monkeypox), or mpox is probable or suspected, and because we would like to understand more about how mpox is spread. To do this we will ask you questions about your exposure to the mpox case in your household and collect a blood sample to find out if you have been exposed to the mpox virus. We do this by looking for certain cells called antibodies in your blood which show that you have been exposed even if you have not been ill. We would also like to ask you and your contacts questions about your experience with mpox disease, to learn more about the disease and how it affects people in Nigeria.

People of all ages (children and adults, including pregnant women) can be included in our study. You can be enrolled when you are admitted to the hospital or if you are being treated at home or in the community. You can be included if you have been in a vaccine trial or other trials.

### **Do I have to take part?**

No. It is up to you to decide whether to take part or not. If you don't want to take part, that's ok. You can also decide to continue to participate in the clinical study but not in the One Health Study, or to participate in the One Health Study and not the clinical study. We will discuss the study together and give you a copy of this information sheet. If you agree to take part, we will then ask you to sign a consent form.

### **What will happen to me if I take part?**

If you volunteer to participate in this study, we will ask you to do the following things:

- To give us information about you: your age, sex, medical history (eg. chronic illness, vaccinations, past infections). We will also ask you about your exposure history including human, animal, or travel related exposures in the 3 weeks before your symptoms started.
- To help us understand the potential for mpox to spread through close body contact and sexual practices. This is important to inform prevention and education campaigns. If you are above 18 years old and had sexual exposure to the mpox case, we will ask you a series of questions privately about your sexual activity. To give you more privacy and confidentiality, if you want you will be able to complete this part of the questionnaire by yourself on a tablet. You are not obliged to answer these questions and there will be an option "prefer not to say", which you can choose. You can stop at any time if you are uncomfortable.
- To tell us about your clinical symptoms including information on when the rash, and where it has affected you. For each symptom, we will ask you to report severity using a scale from 1-5.
- To give us one blood sample, at the first visit and one at a follow up visit 28 days later.
- To give us contact details for your household members and up to 5 close contacts outside of the household, and your permission to contact them to ask for their participation in the research study. This is so that we can understand more about the risk of spread of mpox in households and other contacts.
- To learn about the presence of mpox virus in animals around and inside your house, we will ask your consent, and/or the consent of your household head, to set traps and capture any wild animals in the surroundings of your household, and collect samples from domestic animals in your household to check to the presence of mpox virus to see if they have been exposed to mpox virus
- If you're and/or your head of household allows, we will also collect samples by swabbing your household surfaces to test for the presence of mpox virus there.

The **First Visit** will last 45 minutes to one hour. We will ask you to consent to take part and then go through the baseline questionnaire with you. We will do this with each person in the household who consents to take part. We will collect ten (10)mls of blood from adult household members and five (5) mls of blood from household children.

The **Follow-up Visit** will take place around 28 days later and last from 20 minutes to 1 hour. We will go through a follow-up questionnaire about any symptoms you may have experienced since the first visit and ask you about your experience and perception of the mpox disease. We will collect the same blood samples as we did at the baseline visit.

Your participation in the study will end after the second visit.

### **What are the possible risks and disadvantages?**

**Blood tests:** Taking blood can be associated with pain at the needle site and rarely with infection. You may feel discomfort or minor bleeding and possibly some bruising from the needle prick

**Inconvenience:** You may feel some inconvenience by the visit to your household, or the time spent participating in interviews. You may also feel discomfort answering personal questions about your sexual activity, even though we will ask you about this in private. You can choose not to answer any questions that the study team ask you at any point during the interview. If you feel more comfortable, a meeting with the study team can be arranged somewhere else to give you privacy.

### **What are the possible benefits?**

There are no direct medical benefits to you from taking part in this study. Your participation will help scientists better understand how the mpox virus spreads in a household and the community. This information may guide planning for how to share information about mpox with communities and to prevent the spread of mpox in future outbreaks. Although these benefits are possible, they are not guaranteed.

### **What if something goes wrong?**

If you become injured as a direct result of participating in this study, necessary medical treatment will be available at no additional cost to you. Consenting to this study does not waive your legal rights. The London School of Hygiene and Tropical Medicine holds insurance policies which apply to this study. If you experience harm or injury as a result of taking part in this study, you may be eligible to claim compensation.

### **Can I change my mind about taking part?**

Yes. You can stop being part of the study at any time. If you decide that you do not want more information to be collected about you, you are free to say so, although information that has been collected up to that point will continue to be used by the research team in a non-identifiable way.

### **What will happen to information collected about me?**

All information collected about you will be kept private. Only the study staff and authorities who check that the study is being carried out properly will be allowed to look at information about you. We will keep all information about you safe and secure. Results from this study will be shared with the clinicians, public health agencies and policymakers to improve the knowledge, prevention and care of mpox in Nigeria and elsewhere. But you will not be identifiable. Data may be sent to other study staff in the UK but this will be anonymised. This means that any information about you will have your name and address removed so that you cannot be recognised and your data will have a code number instead.

Your personal details, meaning your name and other identifiable information, will be kept in a different safe place to the other study information and will be destroyed 10 years after the end of the study. At the end of the project, the study data will be archived at NCDC on their local servers. No data will be deposited at LSHTM in the UK. If you consent to it, the data will be made available to other researchers worldwide for research and to improve medical knowledge and patient care. Your personal information will not be

included and there is no way that you can be identified. If the results of the study are published, your name will not be used and no information that discloses your identity will be released or published without your specific consent.

**What will happen to my samples?**

Specimens collected for this study are for research and will not be tested in real-time. Your samples will be sent from your local site to the NCDC National Reference Laboratory in Abuja. Samples will be securely stored and labelled only with a unique sample number (code number), for up to 3 - 5 years. The samples you give for this study will be tested alongside samples from other participants in the study to see if you have 'antibodies' that show that you have been infected with mpox at some time. Antibodies are cells produced by your body's immune system which can show that you may have been exposed to mpox infection even if you don't have symptoms. In this study, the tests we do are not to see if you have mpox now. But if when we meet you, you have symptoms that suggest you might have mpox, we will refer you to the health professionals who can help you find out if you have mpox.

The tests done on samples in this study will be done in laboratories in Nigeria, Some blood may be stored for potential future studies. You will be asked on your consent form if you agree to this or not. If you do not agree, your samples will not be stored for use by future studies. If you do agree, it's possible that your anonymised samples could be sent to other countries where research is taking place. All future research using stored samples will be reviewed by an independent ethics committee before it can take place and before any stored samples from this study are shared.

**What are your choices about how your information is used?**

You can stop being part of the study at any time, without giving a reason, but we will keep information about you that we already have.

**Will I be paid to participate in the study?**

You will not receive any payment for participating in the Mpox One Health study.

**Will there be any costs?**

Taking part in the Mpox One Health study will not result in any costs to you.

**What will happen to the results of this study?**

The study results will be published in a medical or scientific journal so that other doctors, scientists and public health professionals can learn from them. Your personal information will not be included in the study report and there is no way that you can be identified from it. The results of the study will also be shared and discussed with national health authorities in Nigeria to inform communication, prevention and care around mpox disease in Nigeria.

**Who is organising and funding this study?**

London School of Hygiene & Tropical Medicine is the sponsor for the research meaning that it is responsible for the project including the collection, storage and analysis of your data, and will act as the Data Controller to ensure that the study team look after your information and use it properly.

**Who has reviewed this study?**

All research involving human participants is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given approved by The London School of Hygiene and Tropical Medicine Research Ethics Committee (Approval No. 28801). The NHREC Ethics Committee has also reviewed the study and approved the study. (NHREC Approval Number NHREC/01/01/2007-06/09/2023) .

#### **Further information and contact details**

Thank you for taking time to read this information sheet. If you think you will take part in the study please read and sign the consent form.

If you would like any further information, or if you have a concern about any aspect of this study, please speak to the study team who will do their best to answer your questions. If you have any questions or concerns about your participation in the study that are not answered, you can contact Dr Olubunmi Omowunmi Olopha at the Nigeria Centre for Disease Control (NCDC), Plot 801 Ebitu Ukiwe, Jabi Abuja, Nigeria, [olubunmi.olopha@ncdc.gov.ng](mailto:olubunmi.olopha@ncdc.gov.ng), 0803 564 3363, or Dr Odianosen Ehiakhamen ([odianosen.ehiakhamen@ncdc.gov.ng](mailto:odianosen.ehiakhamen@ncdc.gov.ng), 0703 630 8005. You can also email at [info@ncdc.gov.ng](mailto:info@ncdc.gov.ng).

If you have concerns about your rights as a participant, you may contact NHREC via e-mail: [chairman@nhrec.net](mailto:chairman@nhrec.net); [deskofficer@nhrec.net](mailto:deskofficer@nhrec.net) or via phone +234-803-586-8293. If you remain unhappy and wish to complain formally, you can do this by contacting the sponsor: Patricia Henley at [rgio@lshtm.ac.uk](mailto:rgio@lshtm.ac.uk).