

## Part 1. RESEARCH PARTICIPANT INFORMATION SHEET

### Factors affecting transmission of SARS-CoV-2 in Households of SARS-CoV-2 patients in Sub-Saharan Africa

#### “ANTICOV-EPI”

Investigators: Dr X (site principal investigator)

Study site: XXX

Sponsor: XXX

You/your child are invited to take part in a research study on the new coronavirus, called COVID-19. Before you decide whether to participate or not in this study, it is important that you understand the information in this form, because it explains your rights, our responsibilities to you, the purpose, procedures, possible benefits, risks and inconveniences related to this study, and the right to refuse or stop your participation at any time.

Please, feel free to ask any questions at any time. Your/your child participation is completely voluntary. You can talk to anyone you trust about the study and you can take your time to think about whether you want to participate or not. In case you decide to participate, make sure you keep this background information and the signed consent form with you throughout the entire study period.

#### PURPOSE AND DESCRIPTION OF THE STUDY

This research study is done to learn more about the impact of the new coronavirus (COVID-19) on your/your child's health and the potential transmission of COVID-19 to other members in your household. COVID-19 is a disease caused by the SARS-CoV-2 coronavirus, a new emerging virus of which many aspects remain to be investigated. Besides gaining more knowledge on clinical features including the efficacy and safety of drugs, it is therefore also crucial to better understand how the disease is spreading amongst the population and what are risks factor for infection. In this study, we also want to evaluate a new test for COVID-19 by comparing it to the current routine COVID-19 test used in your country. The new test is a rapid test giving a result within 15 minutes, whereas the results of the routine test can take several days.

Several studies are currently ongoing throughout the world in which the efficacy and safety of drugs as a treatment for COVID-19 are being evaluated. One of these studies is the ANTICOV study in which patients with mild COVID-19 will be treated either according standard of care (paracetamol) or with antiviral drugs such as hydroxychloroquine or a combination of ritonavir/lopinavir or other drugs of which potential beneficial effects towards treatment of COVID-19 are evaluated.

Treatment of COVID-19 positive patients with mild disease aims to prevent progression of these patients to severe disease and ultimately cure the patients. In addition, such therapy could however also reduce

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the risk for transmission of the infection to other people which are in close contact with the COVID-19 positive patient (and this independent of the efficacy of the therapy for the COVID-19 positive patient).

You/your child are invited to participate in this study as your household is accessible for the study team and since you have been tested positive for COVID-19 and agreed to participate in the ANTICOV study OR since you/your child are living in the same household as one of your family members who was recently tested positive for COVID-19 and is himself/herself participating to the ANTICOV study. Your participation in this study is dependent on the participation of the majority of your household and on how many in your household have already tested positive for COVID-19. We are also contacting the other people living in your household to ask them if they would also like to join the study.

This epidemiology study will be conducted in approximately 700 households spread over multiple African countries. In each household in which at least 1 member was found COVID positive in the ANTICOV study, all household members will be invited to participate in this study.

### **HOW THE STUDY IS DONE**

If you accept to be part of this study or accept on behalf of child, and if you meet the conditions to participate, you will be asked to sign a consent form (see part 2 of this document).

During a first visit to your household, we will use a questionnaire to collect some basic information about your household and some demographic data such as for example your/ your child's age and gender and your relation and contacts to the member of your household that was found COVID-19 positive. We will also collect info on your/your child's health status, the occurrence of clinical symptoms related to COVID and your behaviours that could transmit the virus as well the implementation of protective measures against transmission of COVID. On this first visit, the interview should last about 1 hour.

Besides the collection of this information, we will also request to take two respiratory samples (one for the new test and one for the routine test) and a blood sample at the end of this visit of only a few drops of blood through a fingerprick. The respiratory samples will be a superficial nose swab taken by the study team or yourself from both nostrils. It could also be a saliva sample that you provide by spitting in a sterile container given to you by someone from the study team if no one from the study team can help you with the swab. If you don't wish to have both respiratory samples taken at any time in the study, you can remain in the study while only being taken one respiratory sample per visit. Only giving one respiratory sample will not affect your participation in this study.

We will also ask you to keep a simple daily symptom diary for one month where you can record any symptoms you or your child experience. Every day, filling in this diary should take you 5-10 minutes.

In addition to this first visit to your household, we will visit your household again four more times (at 7, 14, 21 and 28 days) after the present visit. During these follow-up visits to your household, we will ask again about you/your child's contact with the index case, and behaviours, look at your symptom diary and ask some more questions about your health. At these visits, the interview should last about 30 minutes. If you/your child have certain symptoms indicating possible COVID-19 disease, and you/your child has low oxygen levels, we will refer you/your child to standard medical care. At the first two following visits,, we will request two respiratory samples, but only 1 respiratory sample at the two other visits after that. Every two weeks we will request a few drops of blood through a fingerprick.

The first respiratory sample will be used to evaluate the new test which will give a result within about 15 minutes of sample collection and during the visit. However, since this is a new test still in evaluation, all

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results - both positive and negative - will need to be confirmed by the routine test to tell if you/your child are infected with the virus which causes COVID-19. For this routine test, the second respiratory sample will be used. The blood samples will be used for testing if your/your child's body developed an antibody response against this infection. The samples may also be tested for other respiratory pathogens. In case you miss a visit you may still be able to participate in the study.

### **RISKS AND INCONVENIENCES**

Two respiratory samples will be collected at each study visit. This entails no risk to your health or your child's health, although taking a nose swab could feel uncomfortable.

Besides these respiratory samples, also a few drops of blood will be collected every 2 weeks with a fingerprick. This blood volume is too small to affect your health. You can experience some discomfort from the blood sampling: you may transiently feel dizzy or faint and you can develop a bruise or swelling (and rarely, an infection) at the spot where you were pricked.

If you would be worried about any new or evolving symptom during the study, please do not hesitate to contact the study team at the contact number below.

Importantly, members of the study team that will visit your household could be wearing protective clothing including a face mask and gloves. This might make you feel uncomfortable towards the other households in your community. The study team will make every effort to best keep your privacy, and to avoid your household being identified by the community as affected by COVID-19 and therefore possibly stigmatized. We will also be keeping your privacy from the other members of the household. No data except for your COVID-19 results will be shared with members of the household. In case you get sick with COVID-19, we will have to inform the other members of your household, as per national guidelines.

### **BENEFITS**

No antiviral drugs or any other treatment will be provided as part of this study. However, by participating in this study your/your child's health status will be closely monitored and you will be referred to standard medical care in case you are diagnosed with COVID-19. If you/ your child test positive for the COVID-19 virus you will be told as soon as the result is known. You may be approached for to be included in other trials to investigate treatment or your body's response to infection.

The ultimate goal and future benefits are a better understanding of the transmission of COVID-19 in a population, as evaluated by the different clinical parameters and data collected from the households participating in this study. A better insight in this could help to understand on how spreading of COVID could be decreased or prevented.

### **COMPENSATION**

You will not have to pay for any of the study specific examinations or procedures planned for this study. However, costs related to worsening of your condition due to COVID-19 (e.g. hospitalization for COVID-19) will not be covered by the study. Instead you will be referred to standard medical care. You will not be paid for your participation, but you may be reimbursed for any transportation costs or for missed days of work related to your participation in the study. Ask the study doctor or a member of the study personnel for more information.

### **INSURANCE**

The sponsor of this study has obtained an insurance to cover any possible harm or injury that may be caused by participation in the study. If you/your child get harmed or have questions about injuries as a

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result of being in the study, please inform study doctor or a member of the study personnel at number below for more information.

### **STORAGE OF BIOLOGICAL SAMPLES**

We would like to store your/your child's collected respiratory samples and blood samples for a maximum of 25 years [to be adapted based on local regulatory requirements] after end of study to be used by any collaborators for future scientific research on infectious diseases. Any future studies will have to be separately approved by the Ethics Committee. For future studies not on infectious diseases, we may separately contact you asking permission to perform the new research, if required by the ethics committee.

This study is carried out in collaboration with the Institute of Tropical Medicine (ITM), Barcelona Global Health Institute (ISGlobal). Your samples can be sent for analysis and storage to ITM, ISGlobal or possibly another institution out of [ENTER NAME OF THE COUNTRY]. In no case, personal identification data will be shared as explained below.

You can indicate if you agree with this future research in Part 2 of this document.

If you decide that you do not want us to store your respiratory samples and blood samples, your biological samples will be discarded at the end of the study. This will not affect your participation in this ancillary study.

### **Your Rights in the Study**

The study has been reviewed and approved by the ethics committee and the regulatory agency in [ENTER NAME OF THE COUNTRY]. Any use of your data for future studies unrelated to the context described in this document is only possible with the approval of an ethics committee.

You have the right to refuse to participate in the study. If you decide not to participate in the study, this will not have any effect on the quality of the medical care you receive for COVID-19. If you decide to participate in the study, you are still free to withdraw from the study at any time without having to explain the reason even after you have signed this Informed Consent Form. If you withdraw from the study, you have the right to ask that no more data be collected concerning you. We will keep the information and the samples from you that we have already obtained, unless you disagree.

You have the right to receive information on the results of the study once the study is finished or at the end of the samples analysis. Ask the study doctor or a member of the study personnel how to arrange to receive this information.

Personal data concerning you/your child will be collected by the study personnel, stored in a computer and sent out of [ENTER NAME OF THE COUNTRY] to analyse the results of the study. You have the right to review and correct your data as it is recorded in the study database. In [ENTER NAME OF THE COUNTRY], there may be laws on the protection of personal data and, if so, these laws will be respected. In the personal data used in the study, it will not be possible to identify you personally. All identifying details will be removed so that only the study personnel will know that you participated in the study. The only exception may concern your/your child's diagnosis of COVID-19 since, in some countries, it may be compulsory to report this information to government agencies.

Personal data concerning you will be shared with other international research teams, so that research efforts on COVID-19 around the world can be coordinated. The teams will not have any data that identifies you personally. If data concerning you are used in another study, you will not have to come back to the investigational centre or to fill out more questionnaires. Data concerning you, as well as information about

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the study will be kept for at least 25 years after the study ends. You have the right to retract your authorization from long-term storage at any time. This will not affect your participation in this study.

The sponsor of this study has obtained an insurance to cover any possible harm or injury that may be caused by participation in the study.

### **CONTACT PERSON IN CASE OF QUESTIONS**

If at any time during the study participation, you feel the need to get medical advice, if you have any questions concerning your participation in this study, your rights or if you think you/your child have been harmed as a result of the study, you can contact, now, during, or after the study:

Study doctor/researcher name:

Study doctor/researcher telephone number:

Study doctor/researcher e-mail:

**Part 2. INFORMED CONSENT FORM**

CONFIDENTIAL

**Factors affecting transmission of SARS-CoV-2 in Households of SARS-CoV-2 patients in Sub-Saharan Africa  
“ANTICOV-EPI”**

***Part which is destined only to the participant or his/her legal representative***

I have received a copy of the written participant information sheet. I also received verbally sufficient and understandable explanations, with enough time to ask questions, and my questions were satisfactorily answered.

I freely consent to participate in this study and that I will cooperate in the study examinations/activities. I am willing to give information concerning my medical history, use of medication and participation in other studies if any. My samples may be stored and analyzed in other countries if the tests are not available in my country.

If I ever want to stop participation, even after signing the informed consent, I know I can do so.  Yes /  No: I agree that respiratory and blood samples are stored for 25 years after end of study and may be used for future scientific research on infectious diseases

To be completed by the participant

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

Name of participant: .....

Signature (or thumbprint) of participant: .....

Note: the fingerprint replaces the signature, ONLY for illiterate participants (accompanied by a witness)

To be completed by the legal representative of the participant (in case of medical incapacitation or when the study participant is a minor (< 18 years of age))

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

Name of legal representative: .....

Relation of legal representative to the participant: .....

Signature (or thumbprint) of parent/legal guardian: .....

Note: the fingerprint replaces the signature, ONLY for illiterate participants (accompanied by a witness)

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**OPTIONAL IF COUNTRY NEEDS SECOND PARENTAL/GUARDIAN SIGNATURE**  
To be completed by a second legal representative of the participant (in case of medical incapacitation or when the study participant is a minor (< 18 years of age))

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

Name of legal representative: .....

Relation of legal representative to the participant: .....

Signature (or thumbprint) of second parent/legal guardian: .....

Note: the fingerprint replaces the signature, ONLY for illiterate participants (accompanied by a witness)

To be completed by the witness (in case the participant/legal guardian is illiterate)

Date: .....

Name of witness: .....

Signature of witness: .....

Note: If the participant (or legal guardian) is unable to read and/or write, an impartial witness should be present during the informed consent discussion. After the written informed consent form is read and explained to the participant (or tutor) and after (s)he has orally consented to participation in the study, and has provided fingerprint, the witness should complete the name of the participant and add the date of fingerprint, and sign and personally date the consent form. By signing the consent form, the witness attests that the information in the consent form and any other written information was accurately explained to, and apparently understood by the participant (or legal guardian), and that informed consent was freely given.

To be completed by the research staff obtaining the informed consent

I, undersigned, ..... confirm that I have informed the participant (and/or the parent/legal guardian) about all the relevant aspects of this study. I confirm that he/she has consented voluntarily for h/she or the minor under his/her legal guardianship to participate in the study.

In case the participant is a minor that is <18 years of age and ≥ 14 years of age, I confirm verbal assent was obtained from the minor participant:  Yes /  No

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

Signature: .....