

Part 1. RESEARCH PARTICIPANT INFORMATION SHEET

The impact of COVID-19 treatment on the type, strength and duration of antibody and cellular immune responses in SARS-CoV-2 patients in sub-Saharan Africa “ANTICOV_IMMUNO”

Investigator: Dr Y (principal investigator)
Study site: XXX
Sponsor: XXX

INTRODUCTION

Thank you for participating in the household epidemiology study. In addition, we would like to invite you to take part in an ancillary research study in which we want to evaluate the reaction of your body against the new coronavirus infection (COVID-19). Before you decide whether to participate or not in this study, it is important that you understand the information in this form. 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 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.

WHY THE STUDY IS BEING DONE

You are invited to participate in this study since you previously agreed to participate in the household epidemiology study, and since you tested positive for the coronavirus but without any symptoms of the disease.

This research study is done to learn more about the reaction (or so called ‘immune response’) of the human body against the coronavirus. In the present study, we want to evaluate how strong this reaction is, how long it lasts, if it protects you from a new encounter with the virus, and how it differs in patients with symptoms.

This study will be conducted in multiple African countries. For this, we will invite 200 people who have been tested positive for the coronavirus from the household epidemiology study but who have no symptoms to participate. In addition, for comparison reasons, we will also invite 800 patients with mild symptoms to participate.

HOW THE STUDY IS DONE

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

There will be no change in the visits and tests you will undergo for the household epidemiology study if you agree to participate in this additional study, only some additional visits will be added. Also, if you would not like to participate in this additional study, there will be no changes in relation to your participation in the household epidemiology study.

Besides the visits at your home planned for the household epidemiological study, we will request you to come to your hospital or health centre for 4 additional study visits:

- A first visit as soon as possible after your last visit in the household study at one month (Month 1b)
- A second visit 3 months after your enrolment in the epidemiological study (Month 3)
- A third visit 6 months after your enrolment in the epidemiological study (Month 6)
- A fourth and last visit 12 months after your enrolment in the epidemiological study (Month 12)

During all 4 visits (Months 1b, 3, 6 and 12), we will continue to collect information on your medical history and clinical signs. In addition to the collection of this info, we will also request to take the following samples at all 4 visits (Months 1b, 3, 6 and 12):

- Up to 2 tablespoons of blood sample collected in 3 tubes.
- 1 saliva sample (collected by spitting in a container given to you by someone from the study team)

You will not be given any extra drug as part of this additional study.

RISKS AND INCONVENIENCES

The collection of maximum 2 tablespoons of blood in 3 blood tubes (with a needle prick) is not harmful to your health. This blood volume represents less than 1% of your total blood volume and is too small to affect your health. You may experience some discomfort from the blood sampling: you may feel dizzy for a very short time or faint following the needle prick and/or you can develop a bruise or swelling (and very rarely, an infection) at the spot where the needle went in your arm.

If at any point in time you are worried about any new or evolving symptom during the study, you please do not hesitate to contact the study team.

BENEFITS

Outside a close monitoring of your health during a 1-year period, your participation in this study will mainly benefit the community. The information that will be obtained in this study will help understand the reaction of the human body to the virus, how strong and durable it is and if it protects you against a new encounter with the virus. All this information will help to decide how to stop the coronavirus spreading in the community, if confinements are required and will help those creating a vaccine.

In addition, you will receive regular and free testing for the presence of the coronavirus in your body during a 1-year period. As such, study personnel will contact you immediately if a test shows that you have the coronavirus again and you will get early health care and treatment if necessary. You will also receive proper advice on how to protect yourself against a re-encounter with the virus.

COMPENSATION

You will not be paid for your participation, but you will 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. You will not have to pay for any of the study specific examinations or tests planned for this study. You will be referred to national care program in case your health deteriorates during the follow-up period of this study.

TRANSPORTATION

While you are sick with the coronavirus on unable to visit the hospital, a member of the study personnel will discuss with you the possibility of private transport to ensure that you cannot infect others or can still perform your planned visit, respectively.

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 get harmed or have questions about injuries as a result of being in the study, please inform study doctor or a member of the study personnel for more information.

STORAGE OF BIOLOGICAL SAMPLES

We would like to store your collected respiratory and blood samples for a maximum of 25 years [to be adapted based on local regulatory requirements] after study completion, to be used by any of the study collaborators for future scientific research on infectious diseases. Such future studies will 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 Barcelona Global Health Institute (ISGlobal) and the Antwerp Institute of Tropical Medicine (ITM). Your samples can be sent for analysis and storage to ISGlobal and ITM if the tests cannot be performed in the ENTER THE 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 additional study.

YOUR RIGHTS IN THE STUDY

The study has been reviewed and approved by the ethics committee and the regulatory body in ENTER THE NAME OF THE COUNTRY

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 decided to participate in the study, you remain free to withdraw from the study at any time without having to explain the reason. If you withdraw from the study, you have the right to ask that no more data will 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 when laboratory tests are completed. Ask the study doctor or a member of the study personnel how to arrange to receive this information.

Personal data concerning you will be collected by the study personnel, stored in a computer and sent out of ENTER THE NAME OF THE COUNTRY to analyse the results of the study. In ENTER THE NAME OF THE COUNTRY, there may be laws on the protection of personal data and, if so, these laws will be respected. You will be given a study code so it will not be possible to identify you personally in our database and we will do everything to protect your privacy. 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 diagnosis of COVID-19 since, in some countries, it may be compulsory to report this information to government authorities.

The collected data 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 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.

CONTACT PERSON IN CASE OF QUESTIONS

If you have any questions concerning your participation in this study, your rights or if you think you 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 e-mail:

Study doctor/researcher telephone:

This study has been approved by the following review boards: Institutional Review Board of the Institute of Tropical Medicine, Belgium; Ethics Committee of the University of Antwerp, Belgium. These Ethics Committees also perform ongoing reviews of the study to make sure it is carried out in the safest way possible and that your rights and wellbeing are protected.

Part 2. INFORMED CONSENT FORM

CONFIDENTIAL

The impact of COVID-19 treatment on the type, strength and duration of antibody and cellular immune responses in SARS-CoV-2 patients in sub-Saharan Africa
“ANTICOV_IMMUNO”

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 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 my samples are stored after completion of this study and may be used for future scientific research related to 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)

Date: ___ / ___ / _____

Name of legal representative:

Relation of legal representative to the participant:

Signature (or thumbprint) of legal representative:

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 legal guardian) about all the relevant aspects of this study. I confirm that he/she has consented voluntarily to participate in the study.

Date: __ / __ / ____

Signature: