AUTHORISED REPRESENTATIVE OF PARTICIPANT INFORMATION AND INFORMED CONSENT FORM

Protocol no:	**RECOVERY**
Protocol title:	**RANDOMISED EVALUATION OF COVID-19 THERAPY (RECOVERY)** Note: the full title reflects the trial's initial focus on COVID-19 alone when it opened in 2020.
Sponsor	**University of Oxford, United Kingdom**
Principal Investigator	*[Enter PI name and address]*
Site Telephone Number	*Enter site number(s) including 24-hour emergency number*
Participant no:	

Invitation to participate in a clinical study

Good day, my name is..... (INSERT NAME OF PERSON OBTAINING CONSENT), I am a..... (INSERT DESIGNATION) at.....(INSERT NAME OF INSTITUTION/DEPARTMENT).
We are inviting people who have been admitted to hospital with (or suspected to have) COVID-19 to join this research study comparing possible treatments.

I would like to invite your child/partner/relative to consider participating in a research study, entitled RECOVERY. However, your child/partner/relative is severely ill and will not be able to give consent at this stage. As the legal guardian / authorised representative, we would like to obtain consent from you, on behalf of your child/partner/relative. He/she will be given an opportunity to give his/her own consent, as soon as he/she is able to do so.

Before agreeing for your child/partner/relative to participate, it is important that you read and understand the purpose of the study, the benefits, risks, discomforts, and precautions that are available to your child/partner/relative, and your right to withdraw your child/partner/relative from the study at any time. This information leaflet is to help you to decide if you would like your child/partner/relative to participate. You need to understand what is involved before you agree for your child/partner/relative to take part in this study.

This form gives information about the study including the aims, risks and benefits of taking part. There may be some words you don't understand. If so, please ask me to stop and explain or clarify. If you have questions later, ask me or any study doctors. We will be available to answer any questions.

WHAT YOU SHOULD KNOW ABOUT THIS RESEARCH STUDY:

1) Why is this research being done?

The doctors have found, or suspect, that your child/partner/relative has a lung disease called influenza ("flu") or bacterial pneumonia.

The RECOVERY trial has already shown that low doses of a medication called dexamethasone (a type of steroid) reduces the risk of dying for some patients hospitalised with COVID-19. There are several others which may turn out to be helpful (or possibly harmful) when added to the usual standard of care for influenza or bacterial pneumonia. This study aims to find out whether any of these additional treatments are of any help.

2) What is the purpose of this study?

This study aims to compare several different treatments that may be useful for patients with influenza or pneumonia. Although these treatments show promise, nobody knows if any of them will help patients recover more effectively than the usual standard of care all patients at this hospital will receive. However, the side-effects are well-known from other uses and the doctor will be able to monitor your child/partner/relative appropriately.

The treatments for influenza, which may be given on top of your usual care, include anti-viral treatments, oseltamivir or baloxavir, and low-dose dexamethasone. The treatments for bacterial pneumonia, which may be given on top of your usual care, are low-dose dexamethasone. At present, we don't know whether any of these will work. However, the side-effects are already well-known from other uses and so your doctor will be able to monitor you appropriately.

3) Who is doing the study?

The study is being led by researchers at the University of Oxford, which acts as the sponsor for the research. In South Africa, it is being led by the Wits Health Consortium, working with doctors at many hospitals in South Africa.

4) Who is being included in the study?

Participants may be included in this study if they have influenza or bacterial pneumonia either confirmed by a laboratory test for coronavirus or considered likely by their doctors, and are in hospital.
Participants will be aged 18 years and older. Participants will not be included if the attending doctor thinks there is a particular reason why the study medications would not be suitable.

5) What happens next if I agree for my child/partner/relative to be included in this study?

If you decide your child/partner/relative can join, you will be asked to sign this consent form. Next, brief details about your child/partner/relative, and answering a few questions about their health and medical conditions will be entered into a computer. The computer will then allocate him/her at random (like rolling a dice) to one of the possible treatment options. In all cases this will include the usual standard of care for this hospital. It may also include one or more of the study medications. Neither you nor the doctors can choose which of these options they will be allocated.

Additional information about your child/partner/relative's health will be recorded and entered into the study computer but no extra visits will be needed after he/she leaves the hospital. Information on the trial participants may be obtained confidentially from national databases after he/she leaves the hospital, so that the study team can get more detailed or longer-term information about the effects of the study treatments on your child/partner/relative's health for up to 10 years after the end of his/her participation. The study doctor may also be informed of any issues relevant to his/her participation in the trial.

6) What are the possible benefits of being in the study?

We do not know if any of the treatments being tested will have additional benefits. The study treatment may or may not help your child/partner/relative personally, but this study should help future patients.

7) What are the possible risks of being in the study?

Although dexamethasone will only be given for a short period in this study, it may increase your risk of other infections while it is given and for a few days afterwards. Dexamethasone may also disturb sleep and raise blood sugar.

Oseltamivir and baloxavir may sometimes cause nausea, vomiting, diarrhoea, and oseltamivir rarely causes allergic reactions.

Once your child/partner/relative has been included in the study, you and the study doctors will know which treatment the computer has allocated for him/her. The doctors will be aware of whether there are any particular side effects that they should look out for.

8) Can we stop the study treatment or my child/partner/relative's participation early?

If you or the study doctor want to stop the study treatment before the course has been completed, then you are free to do so. If you decide that you do not wish any more information to be collected about your child/partner/relative, you are free to say so (although de-identified information that has been collected up to that point will continue to be analysed by the research team).

9) What information do you hold about my child/partner/relative and how do you keep it private?

All information about your child/partner/relative's health will be kept private. The only people allowed to look at the information will be the researchers who are running the study, the staff at the study coordinating centre, and the regulatory authorities (the university's Human Research Ethics Committee and SAHPRA, the South African Health Products Regulatory Authority) who check that the study is being carried out correctly.

If you would like to read the full privacy notice of the RECOVERY study, it is available at www.recoverytrial.net/study-faq/data-privacy.

CONFIDENTIALITY:

- All information obtained during the course of this study, including hospital records, personal data and research data will be kept strictly confidential. Data that may be reported in scientific journals will not include any information that identifies you as a participant in this study.
- This information will be reviewed by authorised representatives of the Sponsor.
- The information might also be inspected by the National Health Research Ethics Council (NHREC), University of the Witwatersrand, Human Research Ethics Committee (HREC), the South African Health Products Regulatory Authority (SAHPRA) and/or the United States Food and Drug Administration (FDA), as well as your personal doctor. Therefore, you hereby authorise me to release your medical records to the Sponsor, its employees or agents, domestic and foreign regulatory health authorities, the South African Health Products Regulatory Authority (SAHPRA), the National Health Research Ethics Council (NHREC), and the University of the Witwatersrand, Human Research Ethics Committee (HREC).
- These records will be utilised by them only in connection with carrying out their obligations relating

to this clinical study.

- Any information uncovered regarding your child/partner/relative's test results or state of health as a result of participation in this study will be held in strict confidence. You will be informed of any finding of importance to your child/partner/relative's health or continued participation in this study, but this information will not be disclosed to any third party in addition to the ones mentioned above without your written permission. The only exception to this rule will be cases of communicable diseases where a legal duty of notification of the Department of Health exists. In this case, you will be informed of the intent to disclose such information to the authorised state agency.

10) Do I have to take part?

No, joining the study is voluntary. Your decision for your child/partner/relative to take part will not affect the care you receive at this hospital.

11) Are there any costs or payments?

All trial treatments will be free. Your child/partner/relative will not be paid to participate in this study, but his/her time and inconvenience will be reimbursed R400 for the in person clinic visit according to SAHPRA requirements and R150 on completion of telephonic follow up.

12) What else can you tell me?

The study is funded by UK Research and Innovation and the National Institute for Health Research, not the makers of any of the study treatments (who may provide the treatment free of charge to the trial). If we find out any new information that might affect your decision to stay in the study, we will give it to you. The University of Oxford, as Sponsor, has appropriate insurance in place in the unlikely event that you suffer any harm as a direct consequence of your participation in this study.

ABPI STATEMENT ON COMPENSATION*:*

Oxford University (Sponsor) has secured insurance to cover reasonable medical expenses incurred, as a result of study-related injury or illness, or death determined according to the guidelines laid down by the **Association of the British Pharmaceutical Industry (ABPI Compensation Guidelines Version 2014),** and **Guidelines for Good Practice in the Conduct of Clinical Trials in Human Participants in South Africa.** The insurer is Lloyd's South Africa, and the Insurance Policy number is **SYD21031999A.**

- You must notify us immediately of any complications, side effects and/or injuries during the study and the nature of the expenses to be covered.
- If a research related injury occurs, you have not waived any of the legal rights which you otherwise would have as a participant in this study by signing this form.

Further detailed information on the payment of medical treatment and compensation due to injury can be obtained from the study doctor, who has a copy of the ABPI Guidelines (version 2014) and the Insurance Certificate, should you wish to review them.

The insurance does not cover, and **the Sponsor** will not pay for:

- Medical treatment of ***other*** injuries or illnesses
- Injury caused by non-observance of the protocol

I am indemnified by Oxford University conditional upon:

- My compliance with the applicable requirements of the study protocol
- My compliance with the regulations of the South African Health Products Regulatory Authority and the University of the Witwatersrand, Human Research Ethics Committee(HREC).
- The handling and administration of the study medication in accordance with instructions and guidelines provided in the protocol, subsequent amendments and related documents
- The indemnification is not intended to be and is not a substitute for my personal malpractice insurance.

  Please note that if your child/partner/relative has a life insurance policy, you should enquire whether the insurance company requires notification of participation in a clinical study. Information to date is that it should not affect any life insurance policy taken out. Nevertheless, you are strongly advised to clarify it with the company concerned.

13) If I have any questions or problems, who can I call?
For the duration of the study, your child/partner/relative will be under the care of ……. *(INSERT NAME OF STUDY DOCTOR)*. The 24-hour telephone number through which you can reach your study doctor: ……

If you want any information regarding your child/partner/relative's **rights as a research participant, or complaints regarding this research study**, you may contact Prof. Paul Ruff, Chairperson of the University of the Witwatersrand, Human Research Ethics Committee (HREC), which is an independent committee established to help protect the rights of research participants at (011) 717 2301.

14. ETHICAL APPROVAL:
This clinical study protocol has been submitted to the University of the Witwatersrand, **Human Research Ethics Committee (HREC)** and written approval has been granted by that committee.

The study has been structured in accordance with the **Declaration of Helsinki** (last updated: October 2024), which deals with the recommendations guiding doctors in biomedical research involving human participants. A copy may be obtained from me should you wish to review it.

PERSONAL DOCTOR / SPECIALIST NOTIFICATION OPTION:
Please indicate below, whether you want me to notify your child/partner/relative's personal doctor or specialist, regarding your child/partner/relative's participation in this study:

- **YES**, I want you to inform my child/partner/relative's personal doctor / specialist of my child/partner/relative's participation in this study.
- **NO**, I do not want you to inform my child/partner/relative's personal doctor / specialist regarding participation in this study.
- My child/partner/relative does not have a personal doctor / specialist

If you have questions about this research study, you should first discuss them with the study doctor or the ethics committee (contact details as provided on this form). After you have consulted your doctor or the ethics committee and if they have not provided you with answers to your satisfaction, you should write to the South African Health Products Regulatory Authority at:

The Chief Executive OfficerDr Boitumelo Semete-Makokotlela
South African Health Products Regulatory Authority
Loftus Park
Building A
402 Kirkness Street
Arcadia, Pretoria
0083
E-mail: Boitumelo.Semete@sahpra.org.za
Tel: 012 501 0413

Thank you for reading this Study Information Sheet.

INFORMED CONSENT:

- I hereby confirm that I have been informed by , ...*(INSERT NAME OF PERSON OBTAINING CONSENT)*, about the nature, conduct, benefits and risks of clinical study RECOVERY
- I have also received, read and understood the above written information (Participant Information Leaflet and Informed Consent) regarding the clinical study.
- I am aware that the results of the study, including personal details regarding my child/partner/relative's sex, age, date of birth, initials and diagnosis will be anonymously processed into a study report.
- In view of the requirements of research, I agree that the data collected during this study can be processed in a computerised system by the Sponsor or on their behalf.
- I may, at any stage, without prejudice, withdraw my consent and my child/partner/relative's participation in the study.
- I have had sufficient opportunity to ask questions and (of my own free will) declare my child/partner/relative prepared to participate in the study.

PARTICIPANT'S NAME

_____

AUTHORISED REPRESENTATIVE

Printed Name	Relationship to Participant	Signature	Date and Time

I,.....*(INSERT NAME OF STUDY DOCTOR)*, herewith confirm that the above participant's authorised representative has been fully informed about the nature, conduct and risks of the above study.

STUDY DOCTOR:

Printed Name	Signature	Date and Time

WITNESS (if informed consent was obtained from an illiterate participant by means of a thumbprint or cross)

I hereby verify that informed consent was obtained from the above participant. The participant has been informed about the risks and the benefits of the research, and has voluntarily provided consent to participate, without coercion, undue influence or inappropriate incentives.

Printed Name	Signature	Date and Time