RECOVERY TRIAL

PARTICIPANT INFORMATION SHEET

1. Introduction of the study

We are inviting people who have been admitted to hospital with pneumonia to consent to join this research study, which is comparing possible treatments. This form gives information about the study including the aims, risks and benefits of taking part.

Please read this information sheet carefully or have someone read it to you. You will be given a copy of this form to keep.

2. Why is this research being done?

Your doctors have found that you have a lung disease called pneumonia, caused by influenza, or other organisms. Influenza pneumonia is caused by a flu virus. Other types of pneumonia are typically caused by bacteria that live in the throat (this is usually just called 'community-acquired pneumonia'). Most patients who get these infections get better without coming to hospital. Of those who are admitted to hospital, most also get better, but some may need oxygen or mechanical ventilation before they do so. However, a few percent do not get better.

This trial has already shown that low doses of a type of steroid, dexamethasone, and other treatments reduce the risk of dying for some patients hospitalised with COVID-19. There are several other treatments which may turn out to be helpful (or possibly harmful) when used in the treatment of pneumonia caused by influenza or other organisms. This study aims to find out whether any of these additional treatments are helpful.

3. What is the purpose of this study?

This study aims to compare several different treatments that may be useful for patients with 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 your hospital will receive.

- The treatments for influenza pneumonia include two anti-viral treatments, oseltamivir and baloxavir, and low-dose dexamethasone.
- The treatment for community-acquired pneumonia includes 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.

4. Who is doing the study?

This study is being sponsored by University of Oxford. In Nepal, this study is being conducted in Sukraraj Tropical and Infectious Disease Hospital, Nepal APF Hospital and National Academy of Medical Sciences, Bir Hospital with the involvement of clinical researchers, doctors, nurses, and health workers after approval from all concerned ethics committee.

5. Who is being involved in the study?

Patients may be included in this study if they are in hospital and have influenza confirmed by an RDT, or if their doctor has diagnosed community-acquired pneumonia. Patients will not be included if the attending doctor thinks none of the study treatments are suitable for them. Patients may be included if they have been recruited into RECOVERY >6 months ago (although not into the same comparison more than once).

6. What happens next if I agree to be included in this study?

If you decide to join, you will be asked to sign the consent form. Next, brief details identifying you and answering a few questions about your health and medical conditions will be entered into a computer. If you are a woman of child-bearing potential, you will have a pregnancy test. If you have influenza, then a nose or throat swab will be taken to confirm the infection.

The computer will then allocate you at random (like rolling a dice) to one (or sometimes more) of the possible treatment options, depending on what illness you have and what your doctors think is suitable. Other than being allocated to receive, or not receive, the study treatment, you will be given the same standard care as if you did not join the study. Neither you nor your doctors can choose which of these treatments you will be allocated. Additional information about your health will be recorded and entered into the study computer. No additional visits will be required after you leave the hospital.

Information about your health (before, during, and after the study) may be obtained from medical records or databases so that the study team can get more detailed or longer term information about the effects of the study treatments on your health for up to 10 years after your discharge. Your treating doctor may be informed of any issues relevant to your participation in the trial.

7. 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. Your study treatment may or may not help you personally, but this study should help future patients. You will receive all trial treatment free of cost. We will reimburse up to a maximum of NPR 15,000 to you for the basic laboratory investigations and bed charges during your enrolment in the study. Additionally, the cost of influenza PCR will be reimbursed based on the actual amount paid. If you or your relative transfer the sample for PCR tests yourselves, then a fixed amount of Nrs 1000 will be provided to compensate for your cost and time.

8. What are the possible risks of being in the study?

There is unlikely possibility of a severe reaction to any study drug.

- Dexamethasone (and other steroids) may disturb sleep and increase the risk of infections. In people with diabetes it can raise blood sugar.
- Oseltamivir may cause headache, tummy upset and allergic reactions.
- Baloxavir rarely causes allergic reactions, but has no other known side effects.

Please ask your hospital doctor if you would like more information. Once you have been included in the study, you and your doctors will know which treatment the computer has allocated for you. Your doctors will be aware of whether there are any particular side effects that they should look out for.

Women who are pregnant may be included, however, the effect of some of the treatments on unborn babies is uncertain. Steroids and oseltamivir have previously been used in pregnancy for other medical conditions without safety concerns being raised (but because dexamethasone could have effects on the baby, pregnant and breastfeeding women will receive an alternative steroid). Baloxavir have not been used in pregnant women before but are considered to have an acceptably low level of risk to use in pregnant women in this trial by an expert panel from the UK. In Nepal, pregnant and breastfeeding women will be excluded from receiving baloxavir.

9. Can I stop the study treatment or my participation early?

If you or your 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 you, you are free to say so (although de-identified information collected up to that point will continue to be analysed by the research team).

10. What information do you hold about me and how do you keep it private?

All information about you and your health will be kept private. The only people allowed to look at the information will be the doctors who are running the study, authorised staff at Oxford University and your hospital, and the regulatory authorities who check that the study is being carried out correctly. A privacy notice is on the study website (www.recoverytrial.net/study-faq/data-privacy).

11. Do I have to take part?

Joining the study is voluntary. Your decision whether to take part will not affect the care you receive at this hospital.

12. What else can you tell me?

The study has been approved by the Medicines and Healthcare products Regulatory Agency (MHRA) and by the Cambridge East Research Ethics Committee (Health Research Authority, ref 20/EE/0101). The study in Nepal has been approved by the Nepal Health Research Council and Department of Drug Administration and relevant IRB/IRC. It 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.

13. If I have any questions or problems, who can I call?

If you have any questions, please speak to your hospital medical team. Further information about the study is available on the study website (www.recoverytrial.net).

If you have any questions later, you can contact <Details of Local PI>

You can also contact us at Oxford University Clinical Unit Nepal, Jhamsikhel, Phone number: 01-5911730

If you feel that you have not been treated as outlined in this document, or have any questions about your rights as a participant, you can contact <ERB, NHRC, contact number: 01-4254220.

Thank you for your time.

[Insert Logo Here]

RECOVERY TRIAL

INFORMED CONSENT FORM

Hospital Name: (use CAPITALS)	
Patient Name: (use CAPITALS)	
Study ID: (enter after randomisation)	

1. **Information about the study has been provided to me:** I confirm that I have read (or had read to me) and understood the Participant Information Sheet (V3.0 1 April 2025) and I have had the opportunity to consider the information and ask questions. These have been answered satisfactorily.
2. **Voluntary participation:** I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without my medical care or legal rights being affected.
3. **Access to study data about me:** I give permission for relevant sections of my medical notes and information collected during the study to be looked at, in confidence, by authorised individuals from this hospital, the University of Oxford, and regulatory authorities to check that the study is being carried out correctly.
4. **Access to my medical information:** I agree that medical information collected by the doctors and hospitals which provide me with care and which may be located in local or national health and research organizations (including hospital admission, civil registration, audit and research data) may be provided to the study coordinating centre both during and for up to 10 years after my discharge. I understand that information that identifies me will be passed securely to such bodies to make this possible and that I can opt out of this at any time by writing to the coordinating centre team.
5. **Data stored on computer:** I understand that information about my progress in the study will be recorded on a computer database, and that this data will be stored on computers supervised by the University of Oxford. I understand that this information will be kept securely and confidentially.
6. **Treating physician:** I understand that my treating physician may be informed of any issues relevant to my participation in the RECOVERY trial.
7. **Samples:** I am aware that a nose/throat swab may be sent to a laboratory for measurement of influenza virus.
8. **Agreement to take part:** I have read the information (or had it read to me), had an opportunity to ask questions and agree to take part in the above study.

Participant:

……	……	……../……../……	Fingerprint of participant if illiterate
PRINTED name	Signature	Today's date	

If participant is not able to read the text and/or sign for themselves but has capacity to give consent

I witnessed accurate reading of the consent form to the potential participant, who could ask any questions and got satisfactory replies.

I confirm that they gave their consent freely.

…….	…….	……../……../……
PRINTED name of witness	Signature	Today's date

If participant is unable to give consent due to the severity of their medical condition (e.g. acute respiratory failure or need for immediate ventilation) or prior condition:

I have read the information (or had it read to me) and had an opportunity to ask questions.

I have no other involvement in the RECOVERY trial.

I understand that the patient will be informed about the trial as soon as they have the capacity to do so and that if they wish, they will be able to withdraw from the study without it affecting their medical care.

I believe that if they were able to, the patient would wish to take part in this study.

……	……	……../……../……
PRINTED name of Legal Representative	Signature	Today's date

……

Relationship to participant

Investigator/Designee:

I, the undersigned, have fully explained the relevant information of this study to the person named above and will provide her/him with a copy of this signed and dated informed consent form.

……	……	……../……../……
PRINTED name of person taking consent	Signature	Today's date