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

PARTICIPANT SIGNATURE SECTION

To be completed by the participant if they have capacity to give consent and can sign for themselves

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 (V27.0 30-Jun-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 storage and sharing: I understand that information about my progress in the study will be stored on computers supervised by the University of Oxford, and this information will be kept securely and confidentially. I understand that data from which I cannot be identified may be shared with other research groups or the manufacturers of the treatments tested in RECOVERY. This information would only be used for medical research.

6. GP: I understand that my GP may be informed of any issues relevant to my participation in the RECOVERY trial.

7. Samples: I am aware that nose swabs may be taken and sent to a central 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.

……	…….	……../……../……
PRINTED full name of participant	Signature	Today's date
……	…….	……../……../……
PRINTED full name of person taking consent (must have completed RECOVERY consent training)	Signature	Today's date

Make 1 copy for participant; 1 copy for researcher site file; 1 (original) to be kept in participant's medical notes

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

WITNESSED CONSENT SECTION

To be completed by an impartial witness if the participant has capacity to give consent but is not able to read the text and/or sign for themselves

- 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 full name of witness Signature Today's date

……
Witness type (family member/independent member of staff/other witness independent of RECOVERY)

…… ……. ……../……../……
PRINTED full name of person taking consent Signature Today's date
(must have completed RECOVERY consent training)

Make 1 copy for participant; 1 copy for researcher site file; 1 (original) to be kept in participant's medical notes

LEGAL REPRESENTATIVE CONSENT SECTION

To be completed by a legal representative if the patient lacks capacity to give consent due to the severity of their medical condition (e.g. acute respiratory failure or need for immediate ventilation) or a 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 possible if they regain capacity, 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 full name of Legal Representative Signature Today's date

……
Relationship to participant *(or state 'professional' if clinician acting as legal representative)*

…… ……. ……../……../……
PRINTED full name of person taking consent Signature Today's date
(must have completed RECOVERY consent training)

Make 1 copy for legal representative; 1 copy for researcher site file; 1 (original) to be kept in participant's medical notes

Invitation to participate

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

WHAT YOU SHOULD KNOW ABOUT THIS RESEARCH STUDY:

1) Why is this research being done?

Your doctors have found that you have a lung infection called pneumonia, which may be caused by several different organisms. This study is trying to improve the treatment of two types of pneumonia:

- Influenza pneumonia, which is caused by the influenza ('flu') virus.
- Pneumonia caused by bacteria that live in the throat (usually called 'community-acquired pneumonia').

Your doctor will tell you which type of pneumonia you have. 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 a type of steroid, dexamethasone, and other treatments reduce the risk of dying for some patients hospitalised with COVID-19 pneumonia. There are several other treatments which may turn out to be helpful (or possibly harmful) when used in the treatment of influenza pneumonia or community-acquired pneumonia. This study aims to find out whether any of these additional treatments are helpful.

2) 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 we are investigating for influenza pneumonia include two anti-viral treatments, oseltamivir and baloxavir, and dexamethasone.
- The treatment we are investigating for community-acquired pneumonia is 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 conducted by researchers at the University of Oxford, which acts as the sponsor for the research, working with doctors at many hospitals across the UK.

4) Who is being included in the study?

Patients may be included in this study if they are in hospital and have influenza pneumonia confirmed by a laboratory test, 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 over 6 months ago (although not into the same comparison more than once).

5) 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 flu a nasal swab may be collected now and once more in 5 days. The results from these swabs will not be available to your medical team because they are for research and are not validated for clinical use, and the samples will be destroyed once testing is complete. If you are discharged before day 5 you may be asked if you would be willing to take a swab sample at home and post it back (free of charge). This is optional.

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 (including NHS England, the UK Health Security Agency, other

equivalent bodies, and genetic or other research databases if you have provided samples to them) 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. For pregnant women, we will collect your and your baby's outcome from the UK Obstetric Surveillance System. We may write to you to tell you about the trial periodically, but you will be able to opt-out of these letters if you wish. Your GP may be informed of any issues relevant to your 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. Your study treatment may or may not help you personally, but this study should help future patients.

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

- 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 in adults.

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

8) Women who are pregnant

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 has not been used in pregnant women before but is considered to have an acceptably low level of risk to use in pregnant women in this trial by a national expert panel. Your medical team will discuss with you whether you would be willing to receive any of these medications.

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, then we will stop doing this (although de-identified information collected up to that point will continue to be analysed by the research team). Details of how to contact us are provided below.

10) If I have any questions or problems, who can I call?

If you have any questions while in hospital please speak to your hospital medical team. Further information about the study is available on the study website (www.recoverytrial.net). If you wish to contact the trial team after you have been discharged, email us at recoverytrial@ndph.ox.ac.uk or call (free) on 0808 164 4060.

11) 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 information that could identify you 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.

Data from which you cannot be identified ('de-identified' data) may be shared with other research groups doing similar research, or the manufacturers of treatments tested in RECOVERY. The de-identified data will not be combined with other information in a way that could identify you, and will only be used for medical research. Our privacy notice has more detail on how your data may be used (www.recoverytrial.net/study-faq/data-privacy).

12) Do I have to take part?

No. Joining the study is voluntary. Your decision whether to take part will not affect the care you receive.

13) Are there any financial costs or payments?

No. All trial treatments are free. Neither you nor your medical staff will be paid for your participation in this study.

14) 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). It has been funded by UK Research and Innovation, the National Institute for Health and Care Research, and a charity called Flu Lab, 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. NHS indemnity operates in respect of the clinical treatment that is provided.