RECOVERY

RECOVERY TRIAL – INFORMED CONSENT FORM

For parents/guardians and young people aged 16-17 years

UNIVERSITY OF OXFORD

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

PARENT/GUARDIAN/PARTICIPANT SIGNATURE SECTION

To be completed by parent/guardian, or participant if they are aged 16-17 years

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 (V16.0 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 / my child's participation is voluntary and that I am free to withdraw [my child] at any time, without giving any reason, and without my/his/her medical care or legal rights being affected.

3. Access to study data about my child: I give permission for relevant sections of my / my child's 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/my child's medical information: I agree that medical information collected by the doctors and hospitals which provide me/my child 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 the scheduled follow-up period. I understand that information that identifies me/my child 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/my child's progress in the study will be stored on computers supervised by the University of Oxford, and that 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/my child's participation in the RECOVERY trial.

7. Samples: I am aware that nose swabs may be 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 [for my child] to take part in the above study.

……	…….	……../……../…….
PRINTED name of parent/guardian/participant (if aged 16-17)	Signature	Today's date
……	…….	……../……../…….
PRINTED name of person taking consent	Signature	Today's date

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

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

WITNESSED CONSENT SECTION

If parent/guardian is not able to be present physically or sign for themselves but has capacity to give consent

- I witnessed accurate reading of the consent form to the potential participant's parent/guardian, who could ask any questions and got satisfactory replies.
- I confirm that they gave their consent freely.

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

* a witness must not be a member of the RECOVERY study team

Make 1 copy for parent/guardian; 1 copy for researcher site file; 1 (original) to be kept in participant medical notes

Hospital Name: (use CAPITALS)	
Child/Young Person Name(use CAPITALS)**:**	
Study ID: (enter after randomisation)	

ASSENT SECTION

Information about the RECOVERY Trial for children who are 10-15 years old

Your doctors have found, or suspect, you have an infection called influenza pneumonia. Influenza (or 'flu') pneumonia is caused by the influenza virus. Most children and young people who get flu get better without coming to hospital. Of those who are admitted to hospital, some will need more treatment such as oxygen or machines to help breathing.

The RECOVERY trial has so far found that some medicines are helpful in people who are admitted to hospital with another kind of virus (coronavirus). The reason we are doing this study is to find out if the medicines being tested help people get better quicker from flu infection.

All of the medicines you might receive in the study have been used to treat children with other medical conditions. The medicines are listed in the more detailed information given to your parents or guardian. You can have your own copy if you wish. If you and your parents/guardian decide that you can take part then:
- the study doctors and nurses will examine you to check it is safe for you to take part in the study.
- young women will also have a urine pregnancy test if they might receive certain medicines. This needs to be done even if you are certain you are not pregnant.
- a computer will decide which extra treatment you will receive as part of the study.
- if you and your parents/guardian decide you can take part then they will sign a consent form and if you want to you can sign below to show you also have understood this information and agree to take part.

If you have any other questions please ask your parents, your doctors or nurses or the research doctors or nurses.

Signature …… Today's date……../……../……

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

Information about the RECOVERY Trial for younger children

(to be read with parents/guardian)

You have come into hospital because you are poorly with a virus called flu (also called influenza).

The doctors and nurses in the hospital will be doing all they can to help you get better.

Your parents (or guardians) have agreed for you to take part in a study to find out whether there are extra medicines that can help children and grown-ups get better faster.

What will happen?

- the nurses and doctors will listen to your chest to make sure it is safe for you to take part.

- you will have the new medicine as one of your treatments in hospital.

- when enough children and grown-ups have taken part, we will work out whether the new medicines work.

- if you have any other questions, please ask your parents, your doctors or nurses.

Invitation to participate

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

Please note: Some of the treatments described below may not be available at your hospital or suitable for you or your child (or you/your child may have received them already). Your doctor will be able to explain which treatments would be considered for you as part of this trial.

WHAT YOU SHOULD KNOW ABOUT THIS RESEARCH STUDY:

1) Why is this research being done?

Your doctors have found that you/your child has a disease called influenza pneumonia. Influenza (or 'flu') pneumonia is caused by the influenza virus. The large majority of people who get flu get better without coming to hospital. Of those who are admitted to hospital, the large majority also get better, but some may need oxygen or mechanical ventilation (a machine to help with breathing) before they do so.

The RECOVERY trial has shown that dexamethasone (a steroid medicine) and other treatments can be used to treat adults with COVID-19, which is caused by a different virus that can also affect the lungs. We now want to find out which treatments can help people get better more quickly from flu. There are several medicines we are testing that may turn out to be helpful (or possibly harmful) when added to the usual standard care for influenza pneumonia.

2) What is the purpose of this study?

This study aims to compare several different treatments that may be useful for patients with influenza pneumonia. These treatments are usually taken by mouth, although some may be given into the vein via a cannula if needed. Although these treatments show promise, nobody knows if any of them will turn out to be more effective in helping patients recover than the usual standard of care all patients at your hospital will receive.

The treatments may include (depending on your/your child's age):

- Oseltamivir (an antiviral treatment often used to treat flu) – for patients of any age.
- Baloxavir (a newer type of antiviral treatment) – for patients aged 12 years and over, weighing at least 40kg.
- Dexamethasone (a type of steroid) – for patients of any age.

At present, we don't know whether any of these are effective. The doctors treating you/your child are able to exclude treatments from the randomisation process, if these treatments are not suitable for you/your child, however they are not able to pick exactly which of the suitable treatments you/your child receives.

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 of any age (including babies) may be included in this study if they have influenza pneumonia confirmed by a laboratory test and are in hospital. Patients will not be included if the attending doctor thinks there is a particular reason why none of the study treatments are suitable. Patients may be included if they have previously been recruited into RECOVERY over 6 months ago (although not into the same comparison more than once).

5) What happens next if I agree that I/my child can be included in this study?

If you decide for you/your child to take part, you will be asked to sign the consent form. Next, you will be asked for brief details identifying you/your child and answering a few questions about your/your child's health and medical conditions; these will be entered into a computer. Young females of child-bearing potential will have a urine pregnancy test before being able to join the trial. Nose swabs will 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/your child are discharged before day 5, you may be asked to take this swab at home. This is optional.

The computer will then allocate you/your child at random (like rolling a dice) to one of the possible treatment options, depending on 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 options you/your child will be allocated.

Additional information about you/your child's health will be recorded and entered into the study computer but no additional physical visits will be required after you/your child leaves the hospital. In some instances, information about your/your child's health (both prior to, during, and after the study) may be obtained from medical records or databases (including NHS England, Public Health England, other equivalent bodies, and genetic or other research databases if your child has 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/your child's health for up to 10 years after the end of your/your child's participation. We may write to you to tell you about the trial periodically, but you will be able to opt-out of these communications if you prefer. Your/your child's 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. The study treatment may or may not help your child 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 or allergic reactions.
- Baloxavir rarely causes allergic reactions, but has no other known side effects in people aged 12 years and over.

With all treatments there is the unlikely possibility of a severe reaction. All treatments offered to children of different ages have been used before in children and young people of the same ages. Once you/your child has been included in the study, you and the doctors will know which treatment the computer has allocated for you/your child. The doctors will be aware of whether there are any particular side effects that they should look out for and will be able to monitor you/your child appropriately.

8) Young people who are pregnant

Young people 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, people who are pregnant or breastfeeding will receive an alternative steroid). Baloxavir has not been given to 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 child's 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/your child, 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).

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 will also be 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/your child's 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 the University of Oxford 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 you/your child have to take part?

No. Joining the study is voluntary. The decision whether to take part will not affect you/your child's care.

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.