# RECOVERY TRIAL – INFORMED CONSENT FORM

**Consent form for parents and young people age 16 and 17 years old**

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|---|---|
| **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 Leaflet (V15.0 22-Jun-2023) 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 stored on computer:** I understand that information about my/my child's 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. 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 a blood sample and nasal/mouth swabs may be sent to a central laboratory for measurement of coronavirus and immune responses against it and/or 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.

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

**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) | |

**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

**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) | |

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

Your doctors have found, or suspect, you have an infection called influenza pneumonia "flu" or COVID-19. COVID-19 is caused by a type of virus called a coronavirus. Influenza pneumonia is caused by a 'flu' virus which is different. Most children and young people who get coronavirus 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 coronavirus.

The reason we are doing this study is to find out if the medicines currently being tested help people get better quicker from coronavirus or 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 and take some blood tests 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 - the medicines are only given in hospital: when you go home the study treatment will be stopped.
- 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……../……../……

**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 read with parents/guardian)

You have come into hospital because you are poorly with flu or coronavirus .

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 and check your blood tests to make sure it is safe for you to take part

- you will have the new medicine as one of your treatments in hospital. You won't have to take the medicine after you go home.

- 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 for parents/guardians of children 15 years and under and for young people age 16 and 17 years old

We are inviting people of any age who have been admitted to hospital with influenza pneumonia and/or COVID-19, 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 and/or COVID-19. COVID-19 is a condition caused by a type of virus called SARS-CoV-2, or coronavirus for short. Influenza pneumonia is also caused by a virus, different to COVID-19. About 19 out of 20 patients who get these viruses 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 (a machine to help with breathing) before they do so. However, a few percent do not get better.

The RECOVERY trial has recently shown that dexamethasone (a steroid medicine) and other treatments can be used to treat adults with COVID-19 who need oxygen. There are several other medicines which may turn out to be helpful (or possibly harmful) when added to the usual standard of care for COVID-19 or influenza 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 pneumonia and/or COVID-19. Some are taken by mouth and some are given into the veins via a cannula. 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 at your hospital (which all patients will receive).

The treatments, which may be given to children and young people in addition to the usual care at your hospital, are different depending on whether the child/young person has respiratory infection due to current COVID-19 infection and/or influenza pneumonia

For children and young people with **COVID-19 pneumonia**, treatment may include sotrovimab (a monoclonal antibody treatment against coronavirus). Sotrovimab is licensed for treating children ≥12 years old (and ≥40 kg), although they have not been included in previous trials.

For children and young people with **influenza pneumonia** (with or without COVID-19), treatments may include (depending on your/your child's age) oseltamivir, baloxavir (both are antiviral treatments) and low-dose dexamethasone (a type of steroid). At present, we don't know whether any of these are effective. However, the side-effects are well-known from other uses and your doctor will be able to monitor you appropriately.

At present, we don't know whether any of these are effective. However, the side-effects are well-known from other uses and your doctor will be able to monitor you/your child appropriately. Only medicines used before to treat children of your/your child's age group will be given to them as part of the trial. 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 COVID-19 and/or influenza pneumonia confirmed by a laboratory test, or are suspected of having PIMS-TS, 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 >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 be offered anakinra. If you/your child might receive sotrovimab a blood sample will be sent to a central laboratory for measurement of coronavirus and immune responses against it, and nasal and mouth swabs may be collected now and twice more in the next 5 days. If you/your child have 'flu nasal and mouth swabs will be collected now and once more in 5 days. The results of all these tests will not be available to your medical team because they are for research and are not validated for clinical application, 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. In all cases this will include the usual standard of care for your hospital. It may also include an additional treatment, which might be given by mouth, by injection under the skin or into a vein via a cannula. Neither you nor the doctors can choose which of these options you/your child will be allocated to.

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 Digital, 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.

**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?**

- Oseltamivir may cause headache, tummy upset or allergic reactions.
- Baloxavir rarely causes allergic reactions, but has no other known side effects.
- Sotrovimab is given by intravenous infusion and may cause allergic reactions during the infusion, but severe reactions have been rare.

With all treatments there is the unlikely possibility of a severe reaction. All treatments offered to children of different ages have been used in children and young people of the same ages to treat other medical conditions. 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.

**8) Young people who may be pregnant**

Women who are pregnant may be included, however, the effect of some of the treatments on unborn babies is uncertain. Baloxavir and sotrovimab have not been given to pregnant women before but are considered to have an acceptably low level of risk to use in pregnant women in this trial by a national expert panel. If females do receive treatment and are not already pregnant, as a precaution, we advise they should not get pregnant within 3 months of the completion of the trial treatment(s). Please ask your hospital doctor if you would like more information.

**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, please speak to your hospital medical team. Further information about the study will also be available on the study website (www.recoverytrial.net).

**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 the information 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. A privacy notice is on the study website (www.recoverytrial.net).

**12) Do you/your child have to take part and are there any financial costs or payments?**

Joining the study is voluntary. The decision whether to take part will not affect you/your child's care. All trial treatments will be free. Neither you nor the medical staff will be paid for your/your child's participation in this study.

**13) 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 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. NHS indemnity operates in respect of the clinical treatment that is provided.