RANDOMISED EVALUATION OF COVID-19 THERAPY (RECOVERY)

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 (V5.0 14-May-2020) 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 the scheduled follow-up period. 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. OPTIONAL: Convalescent plasma: I am aware that I may be offered convalescent plasma as one of the treatments I may receive. I have indicated my agreement (or not) to receive this by initialing the appropriate box.

I agree	I do not agree

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

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

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

I understand that the patient will be asked to confirm their consent 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

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

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

Invitation to participate

We are inviting people who have been admitted to hospital with (or suspected to have) 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. You may also be invited to participate in additional studies related to the RECOVERY trial (so-called "substudies").

WHAT YOU SHOULD KNOW ABOUT THIS RESEARCH STUDY:

1) Why is this research being done?

Your doctors have found, or suspect, that you have a lung disease called COVID-19. This condition is caused by a type of virus called SARS-CoV-2, or coronavirus for short.

About 19 out of 20 patients who get coronavirus 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.

There are no drugs of proven value against COVID-19 although there are several which may turn out to be helpful (or possibly harmful) when added to the usual standard of care. 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 COVID-19. These treatments have been recommended for testing by the expert panel that advises the Chief Medical Officer in England. Some are tablets and some are injections. 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 in addition to the usual care at your hospital, are: Lopinavir-Ritonavir (commonly used to treat HIV); corticosteroids (a type of steroid, which are used in a range of conditions typically to reduce inflammation [the precise type differing in pregnant women and other participants, but all in common use]); hydroxychloroquine (a treatment for malaria); or azithromycin (a commonly-used antibiotic).

You may also receive convalescent plasma (the liquid part of blood which carries blood cells around the body) which has been collected from individuals who have recovered from COVID-19 infection and contains antibodies to the virus that may help you fight the virus. For patients whose condition is more severe, tocilizumab (a treatment for rheumatoid arthritis) is also an option. At present, we don't know whether any of these are effective in treating COVID-19. However, the side-effects are well-known from other uses and 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 at least 18 years of age, have COVID-19 confirmed by a laboratory test for coronavirus (or considered likely by their doctors), 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.

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 willing to have convalescent plasma you may need 1 or 2 extra blood tests (to check your blood group), in line with standard NHS procedures. The computer will then allocate you 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, injection or inhalation. Neither you nor your doctors can choose which of these options you will be allocated. If your condition is severe or should deteriorate, then your doctors may

choose to enter you into a second phase in which the computer will allocate you at random again to one of the further possible treatment options (in addition to your previous study treatment and always including usual standard of care for your hospital).

Additional information about your health will be recorded and entered into the study computer but no additional visits will be required after you leave the hospital. In some instances, information about your health (both prior to, during, and after the study) may be obtained about you from medical records or databases (including NHS Digital, Public Health England, 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 the end of your participation.

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?

Apart from the known side effects of these treatments (which may include tummy upset, 'flu-like symptoms, and blood test abnormalities), there is the unlikely possibility of a severe reaction to a study drug. Although Tocilizumab has been very rarely associated with liver damage in prolonged use this is not expected to be a problem with the short-term administration in this study. The potential side effects of plasma transfusions include allergic reactions (rash, fever, chills) and increased difficulty breathing and are easily treated. The plasma will undergo all the usual testing for the presence of other infections, but a very small risk of infection transmission does remain. 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 - although all the treatments have previously been used in pregnancy for other medical conditions without safety concerns being raised. If you do receive treatment and are not already pregnant, as a precaution, we advise that you should not get pregnant within 3 months of the completion of the trial treatment(s).

8) 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 that has been collected up to that point will continue to be analysed by the research team).

9) 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).

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, the staff at the study coordinating centre, and the regulatory authorities who check that the study is being carried out correctly. A privacy notice is on the study website (https://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) Are there any financial costs or payments?

All trial treatments will be free. Neither you nor your medical staff will be paid for your participation in this study.

13) 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. 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.

RANDOMISED EVALUATION OF COVID-19 THERAPY (RECOVERY)

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 (V2.0 14-May-2020) 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 child's participation is voluntary and that I am free to withdraw my child at any time, without giving any reason, and without 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 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 child's medical information: I agree that medical information collected by the doctors and hospitals which provide 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 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 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. OPTIONAL: Convalescent plasma: I am aware that my child may be offered convalescent plasma as one of the treatments. I have indicated my agreement (or not) for them to receive this by initialing the appropriate box. If my child is <1 year old I understand that my child's identifiable data will need to be shared with NHS Blood & Transplant to ensure they get appropriate plasma.	**I agree**	**I do not agree**

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

**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 COVID-19. This condition is caused by a type of virus called a coronavirus. 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. At the moment, we do not know if any medicines can treat coronavirus.

The reason we are doing this study is to find out if the medicines being tested help people get better quicker from coronavirus.

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. 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 (including some to check your blood group if you agree to take part in the plasma part of the trial).
- 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……../……../……

Information about the RECOVERY Trial for younger children

(to read with parents/guardian)

You have come into hospital because you are poorly with 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 people 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 grownups 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

We are inviting people of any age who have been admitted to hospital with (or suspected to have) 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.

WHAT YOU SHOULD KNOW ABOUT THIS RESEARCH STUDY:

1) Why is this research being done?

Your doctors have found, or suspect, that your child has a disease called COVID-19. This condition is caused by a type of virus called SARS-CoV-2, or coronavirus for short. About 19 out of 20 patients who get coronavirus 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.

There are no drugs of proven value against COVID-19 although there are several which may turn out to be helpful (or possibly harmful) when added to the usual standard of care. 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 COVID-19. These treatments have been recommended for testing by the expert panel that advises the Chief Medical Officer in England. 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 in addition to the usual care at your hospital, are: Lopinavir-Ritonavir (commonly used to treat HIV); corticosteroids (a type of steroid, which are used in a range of conditions typically to reduce inflammation [the precise type differing in pregnant women, children and other participants, but all in common use]); hydroxychloroquine (a treatment for malaria); or azithromycin (a commonly-used antibiotic). These may also include convalescent plasma (the liquid part of blood which carries blood cells around the body) which has been collected from individuals who have recovered from COVID-19 infection and contains antibodies to the virus that may help you fight the virus. For patients whose condition is more severe, tocilizumab (a treatment for rheumatoid arthritis in adults and for arthritis in children) is also an option. At present, we don't know whether any of these are effective in treating COVID-19. However, the side-effects are well-known from other uses and your doctor will be able to monitor your child appropriately. Only medicines used before to treat children of your child's age group will be given to them as part of the trial.

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 confirmed by a laboratory test for coronavirus (or considered likely by their doctors), 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.

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

If you decide for your child to take part, you will be asked to sign the consent form. Next, brief details identifying your child and answering a few questions about your child's health and medical conditions will be entered into a computer. If you are willing for your child to have convalescent plasma you may need 1 or 2 extra blood tests (to check your blood group), in line with standard NHS procedures. The computer will then allocate 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 or into a vein via a cannula. Neither you nor the doctors can choose which of these options your child will be allocated to. If your child's condition is severe or should deteriorate, then your doctors may choose to enter your child into a second phase in

which the computer will allocate your child at random again to one of the further possible treatment options (in addition to your previous study treatment and always including usual standard of care for your hospital). Additional information about your child's health will be recorded and entered into the study computer but no additional visits will be required after your child leaves the hospital. In some instances, information about 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 child's health for up to 10 years after the end of your child's participation.

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?

Apart from the known side effects of these treatments (which may include tummy upset, 'flu-like symptoms, and blood test abnormalities), there is the unlikely possibility of a severe reaction to a study drug. The potential side effects of plasma transfusions include allergic reactions (rash, fever, chills) and increased difficulty breathing and are easily treated. The plasma will undergo all the usual testing for the presence of other infections, but a very small risk of infection transmission does remain. All treatments offered to children of different ages have been used in children of the same ages to treat other medical conditions. Although Tocilizumab has been very rarely associated with liver damage in prolonged use this is not expected to be a problem with the short-term administration in this study. Once your child has been included in the study, you and the doctors will know which treatment the computer has allocated for 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 - although all the treatments have previously been used in pregnancy for other medical conditions without safety concerns being raised. 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 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 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, the staff at the study coordinating centre, 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) Does my 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 your child's care. All trial treatments will be free. Neither you nor the medical staff will be paid for your child's participation in this study.

13) 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. 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.