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 (V14.0 30-Jun-2021) 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. GP: I understand that my GP may be informed of any issues relevant to my participation in the RECOVERY trial.

7. OPTIONAL [for participants at sites assessing dimethyl fumarate]: I agree to take part in the extra assessment of dimethyl fumarate. [Leave boxes blank if not relevant.]

Yes	No

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 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.

This trial showed that low doses of dexamethasone (a type of steroid) reduces the risk of dying for some patients hospitalised with COVID-19. There are several others 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. 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, include Baricitinib (in UK only), a treatment for rheumatoid arthritis), high dose dexamethasone (if you have low oxygen levels; outside UK only) or empagliflozin. 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. At some sites we may also assess other treatments; further details are on the last page and your study team can tell you if this is relevant for you or not.

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 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. Women of child-bearing potential will have a pregnancy test. 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 and it may also include an additional treatment. Neither you nor your doctors can choose which of these options you will be allocated.

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. 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. 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 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?

Baricitinib may cause tummy upset and blood test abnormalities, rarely including low blood counts, for which you will be monitored. They may increase your risk of other infections, as might high dose dexamethasone which may also disturb sleep and (in people with diabetes) raise blood sugar. Empagliflozin may cause urine or genital tract infections, like thrush. If you have diabetes, empagliflozin also lowers blood sugar in people taking insulin or some other diabetes treatments so your doctors may adjust the doses of those; it may also cause a condition called ketoacidosis (which rarely can be life-threatening), which is treated with a drip and insulin. There is also the unlikely possibility of a severe reaction to any study drug. At some sites, other treatments may also be assessed. 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. Pregnant women will not receive baricitinib or empagliflozin as they may be harmful in pregnancy or when breast-feeding. The other treatments have previously been used in pregnancy for other medical conditions without safety concerns being raised.

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 is 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 (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.

If your study team have requested you consider participating in the assessment of dimethyl fumarate (UK only) please read the next page. Otherwise you may stop reading here.

14) What is dimethyl fumarate and why is it being tested?

Dimethyl fumarate is a treatment currently used for multiple sclerosis and psoriasis (a skin condition) which might prevent your immune system from over-reacting to COVID-19, but we do not know for sure whether to assess it in a large group of participants yet. We wish to understand the detailed effects of dimethyl fumarate on people with COVID-19 among about 400 people by conducting some extra tests (see below). The results of these will help us decide whether to continue and enrol several thousand people into an assessment of the drug.

15) What are the potential risks of this part of the study?

Dimethyl fumarate sometimes causes 'flushing' (an unpleasant but not dangerous experience of redness and warmth especially in the face, sometimes associated with itching) and tummy upset. Blood test abnormalities are possible and you will be monitored for these. There is also the unlikely possibility of a severe reaction to any study drug. The effects on pregnant women and breast-fed babies are uncertain so such women should not participate in this part of the study.

16) What are the extra assessments being done?

We would like to measure how well your lungs are getting oxygen into your blood and whether dimethyl fumarate improves this. We would do this on four occasions over the next 10 days (or until you go home if sooner). This will involve measuring your blood oxygen levels (with a clothes peg-like device on your finger, toe or ear) while the amount of any supplemental oxygen you receive is slowly reduced. If you feel unwell at any time during this measurement, it would be stopped and your oxygen supply returned to normal. It will take up to about 30 minutes each time.

We will also assess the severity of your disease on a daily basis (just by reviewing your medical records) and ask you how well you are tolerating the dimethyl fumarate and if you have had any side-effects.

We will also collect the results of some blood tests that you may have done as part of your routine care. If they are not done as part of your routine care, it would require about 3 mL of blood to be taken on one or two occasions. Once analysed at your hospital laboratory they would be destroyed.

17) Can I stop the study treatment or my participation early?

If you or your doctor want to stop the study treatment or your involvement in this part of the study before the course has been completed, then you are free to do so.

18) Do I have to take part?

No. Joining this part of the study is voluntary. You can still join the rest of the study without participating in this part.