

## Appendix 4: Information sheet and consent form

### STUDY INFORMATION FOR PARTICIPANTS AND THEIR REPRESENTATIVES

<b>Study Title</b>	Aspirin, losartan and simvastatin in hospitalised COVID-19 patients: a multinational randomised open-label factorial trial (CRASH-19)
<b>Leaflet Version Number / Date</b>	

#### Invitation to take part:

This hospital is taking part in an international study to find treatments for COVID-19 infection. We are inviting adults aged 40 years and older who have been admitted to hospital with suspected or confirmed COVID-19 infection to join this research study. This form gives information about the study including the aims, risks and benefits of taking part. If you agree to take part, we will ask you to sign a consent form.

#### WHAT YOU SHOULD KNOW ABOUT THIS RESEARCH STUDY:

##### 1) Why is this research being done?

Your doctors suspect, or have confirmed, that you have an infection called COVID-19. This is caused by a type of virus called SARS-CoV-2, or coronavirus for short. About 8 out of 10 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 more intensive medical care including oxygen or ventilation before they do so. However, a few percent do not get better.

There are currently no drugs to treat COVID-19 although there are several being developed. This study is being done to find out if by giving additional treatments to support the heart and lungs while patients are ill, we can improve how well they do.

##### 2) What is the purpose of this study?

This study aims to compare three different treatments that are known to help people with heart and breathing problems and which may be useful for patients with COVID-19. Although these treatments are promising, nobody knows if either will be more effective in helping patients recover than the usual standard of care at your hospital (which everyone will receive).

The treatments which may be given to you, in addition to the usual standard of care at your hospital, are:

- Aspirin (commonly used to prevent heart attacks and strokes)
- Losartan (commonly used to treat high blood pressure, protect the kidneys and reduce strain on the heart)
- Simvastatin (commonly used to lower cholesterol)
- Combination of aspirin and/or losartan and/or simvastatin

- Standard care with no additional treatment

### 3) Who is doing the study?

The study is run by a team of researchers at the London School of Hygiene and Tropical Medicine (University of London) in the United Kingdom. Doctors and nurses in hospitals around the world are also taking part.

### 4) Who is being included in the study?

Patients may be included in this study if they are at least 40 years of age and the doctor suspects or has confirmed COVID-19 infection. Patients will not be included if the doctor thinks there is a particular reason why the study treatments are not suitable, for example you are known to have an allergy to one of them. Patients already on a mechanical breathing machine cannot take part either. About 10,000 patients worldwide will be taking part in this study. It is up to you to decide if you wish to take part or not.

### 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. Brief details about your health and medical conditions will then be entered into a computer. The computer will then randomly decide which of the treatment groups to put you into. In all cases this will include the usual standard of care for your hospital. It may also include an additional treatment, which will be given by mouth or if you are too unwell, by a tube in your gut which is feeding you. Neither you nor your doctors can choose which of the treatments you will be given. If you have been allocated one, two or three of the treatments, you will receive them once per day for a maximum of 28 days or until you are discharged from hospital whichever is sooner. Additional information about your health will be recorded and entered into a computer but no additional visits will be required after you leave the hospital.

### 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 indigestion, unusual bleeding and dizziness), there is the unlikely possibility of a severe reaction to a 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 are familiar with the use of the study drugs and will be aware of whether there are any particular side effects that they should look out for.

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

Yes. If you or your doctor want to stop the study treatment at any time, 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 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 contact?**

If you have any questions or problems please speak to your hospital medical team. Further information about the study is also available on the study website (<http://crash19.lshtm.ac.uk/>).

**10) What information do you keep 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 from the London School of Hygiene and Tropical Medicine (University of London), and the regulatory authorities who check that the study is being carried out correctly. Some hospitals may not be able to store a copy of the paper consent form due the risk of spreading coronavirus. In this case a copy of the consent form which will have your name and signature on it will be stored electronically at the the study coordinating centre in London. This information will be handled confidentially and will not be passed on to anyone else.. Your name will not be used when the results are published. A privacy notice is on the study website.

**11) Do I have to take part?**

It is up to you to decide to join the study, joining 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?**

The study treatment is 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 the London School of Hygiene and Tropical Medicine, not the makers of any of the study drugs. If we find out any new information that might affect your decision to stay in the study, we will give it to you. If something goes wrong and you are harmed during the study, the London School of Hygiene & Tropical Medicine would be responsible for claims for any non-negligent harm. To look after your interests, this study has been carefully checked by an independent group of people called a Research Ethics Committee [Insert Name]. They agreed that it is okay [for us to do this study]. The final results of the study will be available on the study website once published.

## PARTICIPANT CONSENT FORM

**Study Title:** Aspirin, losartan and simvastatin in hospitalised COVID-19 patients: a multinational randomised open-label factorial trial (CRASH-19)

<b>Hospital Name:</b> (use CAPITALS)	
<b>Participant Name:</b> (use CAPITALS)	
<b>Randomisation Number:</b> (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 (**VERSION NO. & DATE**) 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 London School of Hygiene and Tropical Medicine, and regulatory authorities to check that the study is being carried out correctly.

**4. Access to my medical information:** I agree that medical information (without my personal information) collected by the doctors and nurses at hospitals which provide me with care can be sent to the London School of Hygiene & Tropical Medicine. I also agree that this information which cannot identify me in anyway can also be shared with other researchers on a public database.

**5. Data stored on computer:** I understand that information about my progress in the study will be recorded on a database, and that this data will be stored on computers supervised by the London School of Hygiene and Tropical Medicine. I understand that this information will be kept securely and confidentially.

**6. Access to this consent form:** I give permission for a digital copy of this consent form, which contains my name, to be made available to the London School of Hygiene & Tropical Medicine if necessary.

**7. Agreement to take part:** I agree to take part in the above study.

..... Name of participant (Use CAPITALS)	..... Signature/ Thumbprint or other mark (if unable to sign)	...../...../..... Today's date
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..... Name of consent taker (Use CAPITALS)	..... Signature	...../...../..... Today's date
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**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.

..... Name of Witness (Use CAPITALS)	..... Signature	...../...../..... Today's date
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*\*1 copy for participant; 1 copy to be kept in medical notes; Original for Investigator's site file. If high risk of cross-infection from storage of consent form, electronic copy to be sent to LSHTM; copy for participant*

## REPRESENTATIVE CONSENT FORM

**Study Title:** Aspirin, losartan and simvastatin in hospitalised COVID-19 patients: a multinational randomised open-label factorial trial (CRASH-19)

<b>Hospital Name:</b> (use CAPITALS)	
<b>Participant Name:</b> (use CAPITALS)	
<b>Randomisation Number:</b> (enter after randomisation)	

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

- I have read the information (or had it read to me) and had an opportunity to ask questions.
- I understand that the participant 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 participant would consent to take part in this study.

..... Name of Representative (Use CAPITALS)	..... Signature / Thumbprint or other mark (if unable to sign)	...../...../..... Today's date
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Relationship to participant

..... Name of consent taker (Use CAPITALS)	..... Signature	...../...../..... Today's date
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*\*1 copy for Representative; 1 copy to be kept in medical notes; Original for Investigator's site file. If high risk of cross-infection from storage of consent form, electronic copy to be sent to LSHTM; 1 copy for representative*