HOW TO OBTAIN CONSENT

Before any data can be collected, and a patient randomised, you must complete the informed consent process.

The consent procedure should be adapted (in line with the protocol) based on the patient's capacity and the clinical situation.

Consent can be obtained from
- Patient
- Relative
- Professional legal representative

Important points when obtaining consent
- Assess capacity of patient first and decide the best pathway for obtaining consent
- Provide participant information sheet and allow time for patient/relative to read and ask questions. The clinical situation must be considered. They may be scared, concerned and anxious.
- Participation is voluntary and patients are free to withdraw at any time. The care they receive at the hospital will not be affected
- Some of the participant's data will be shared with the trial team at the coordinating centre – this will be subject to strict confidentiality

Who can take consent?
Any site staff who the principal investigator is satisfied has the necessary training and experience. They must have read this guidance document (in addition to other mandatory trial training) and completed the training log to confirm this

How to document informed consent
- Electronic consent form
- Paper consent form

As there is a potential risk of cross-infection by removing paper documents from the clinical area for secure storage, should consider **obtaining consent electronically** on the tablet provided.

Always:
- follow the COVID-19 infection control policy for your hospital when obtaining consent
- ensure that patient/relative/representative and person taking consent have adhered to your local infection control policy including, washing their hands with soap or alcohol hand sanitiser
- ensure Tablet and pen are cleaned before and after use

A copy of the Participant Information Sheet and consent form should be provided to the participant/relative:
- If the participant/relative has a phone they can take a photo of the .pdf electronic or paper consent form
- If the participant/relative has an email address, email .pdf or photo of the consent form
- Alternatively if they prefer, you could send via WhatsApp
- Print .pdf copy of consent form outside of the infected area
- Photocopy paper consent form outside of the infected area

Delete photos and email attachment of the consent form after it has been sent

If paper consent form used:
- The original completed form must remain at site – stored securely under control of Principal Investigator
- A copy should be placed in the medical records

If consent is not obtained for a patient in the trial this must be reported to the Clinical Trials Unit (CTU) immediately by emailing crash19@Lshtm.ac.uk. This is a serious breach of the Protocol.

If patient is unable to read or write

- Explain trial in the presence of an impartial witness who must countersign the consent form
- Obtain mark (e.g. thumbprint) from patient/relative if they are unable to write
- An impartial witness is someone independent from the trial, i.e. not involved in the trial. E.g. hospital staff member, or an adult accompanying the patient at hospital. They must be able to read and write.

If Professional Legal Representative consent is obtained

Obtain consent from

- the patient's personal representative or
- directly from the patient if they recover, at the earliest opportunity for ongoing trial procedures

If a participant dies before consent is obtained

- It is the treating clinician's decision as to whether relatives can be approached to obtain consent

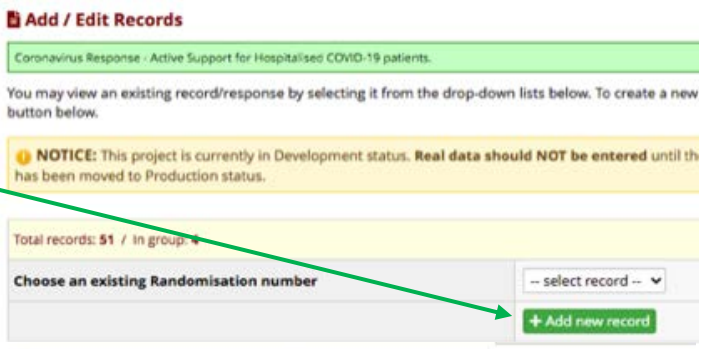
HOW TO COMPLETE THE ELECTRONIC CONSENT FORM:

Log into the trial database using your personal log in details

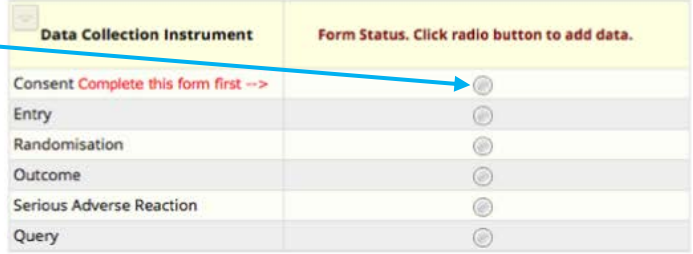
On the left-hand side navigation panel, under the header of 'Data Collection' click 'Add/Edit Records'

Click 'Add new record'

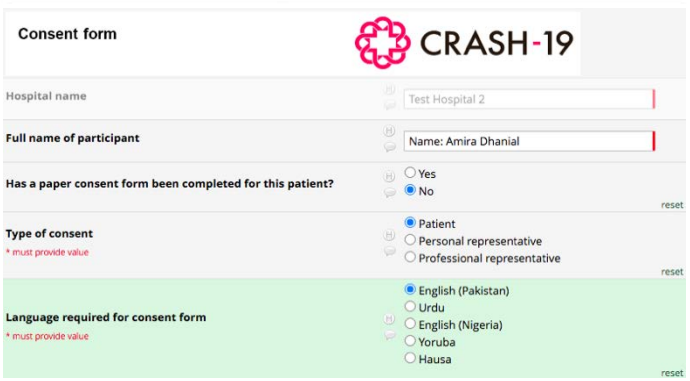
The consent form is the 1st form to be added for each patient.



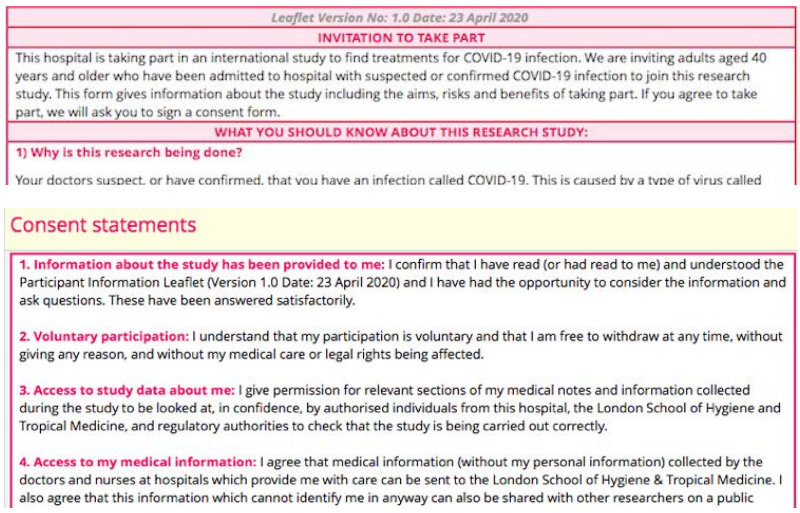
Click radio button next to the 'Consent'. This will take you to the consent form.



Complete these questions



Let the consent giver read the information sheet and consent form


Leaflet Version No: 1.0 Date: 23 April 2020

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

Consent statements

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 1.0 Date: 23 April 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.

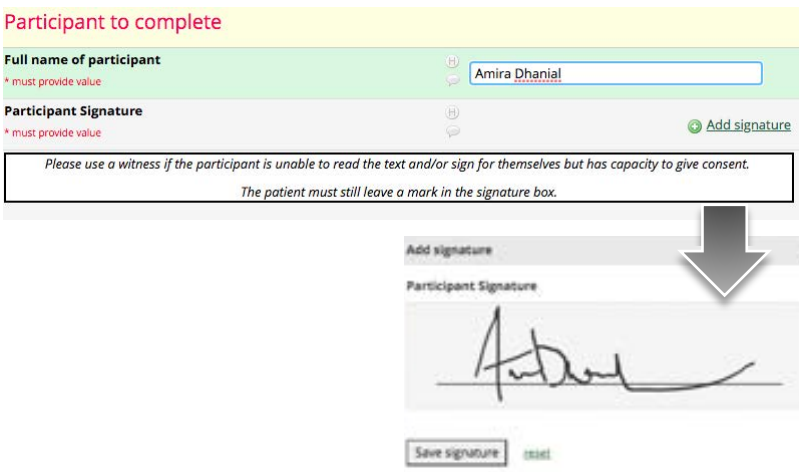
3. Access to study data about me: I give permission for relevant sections of my medical notes and information collected during the study to be looked at, in confidence, by authorised individuals from this hospital, the London School of Hygiene and Tropical Medicine, and regulatory authorities to check 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

Consent giver to complete:

- Their name
- Signature

If the participant is unable to read the text and/or sign for themslves, a mark should be provided. Their name should be completed by the impartial witness.


Participant to complete

Full name of participant
* must provide value
Amira Dhanial

Participant Signature
* must provide value
Add signature

Please use a witness if the participant is unable to read the text and/or sign for themselves but has capacity to give consent.

The patient must still leave a mark in the signature box.

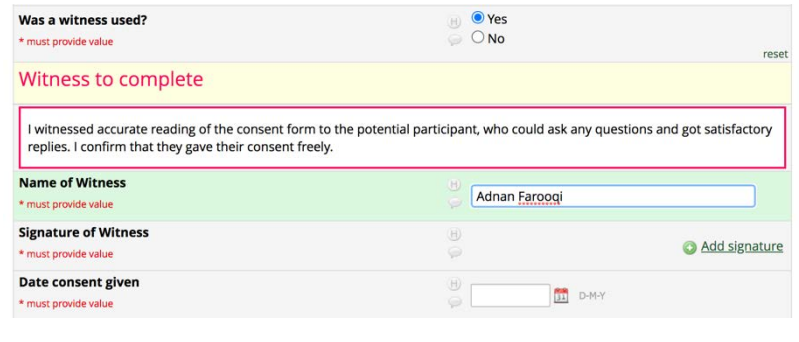
Add signature

Participant Signature

Save signature reset

If a witness is required, the witness should complete this section:

- Name
- Signature


Was a witness used?
* must provide value
Yes
No
reset

Witness to complete

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.

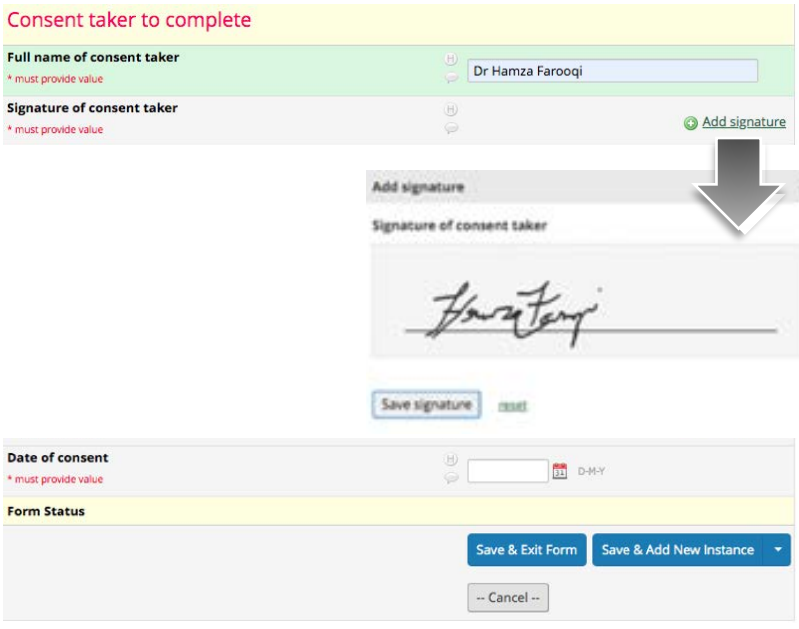
Name of Witness
* must provide value
Adnan Farooqi

Signature of Witness
* must provide value
Add signature

Date consent given
* must provide value
D-M-Y

Consent taker to complete this section

- Name
- Signature
- Date consent obtained
- Save the form


Consent taker to complete

Full name of consent taker
* must provide value
Dr Hamza Farooqi

Signature of consent taker
* must provide value
Add signature

Add signature

Signature of consent taker

Save signature reset

Date of consent
* must provide value
D-M-Y

Form Status

Save & Exit Form | Save & Add New Instance

-- Cancel --

HOW TO COMPLETE THE PAPER CONSENT FORM:

Please note, the paper consent form should only be completed if you are unable to use the electronic consent form.

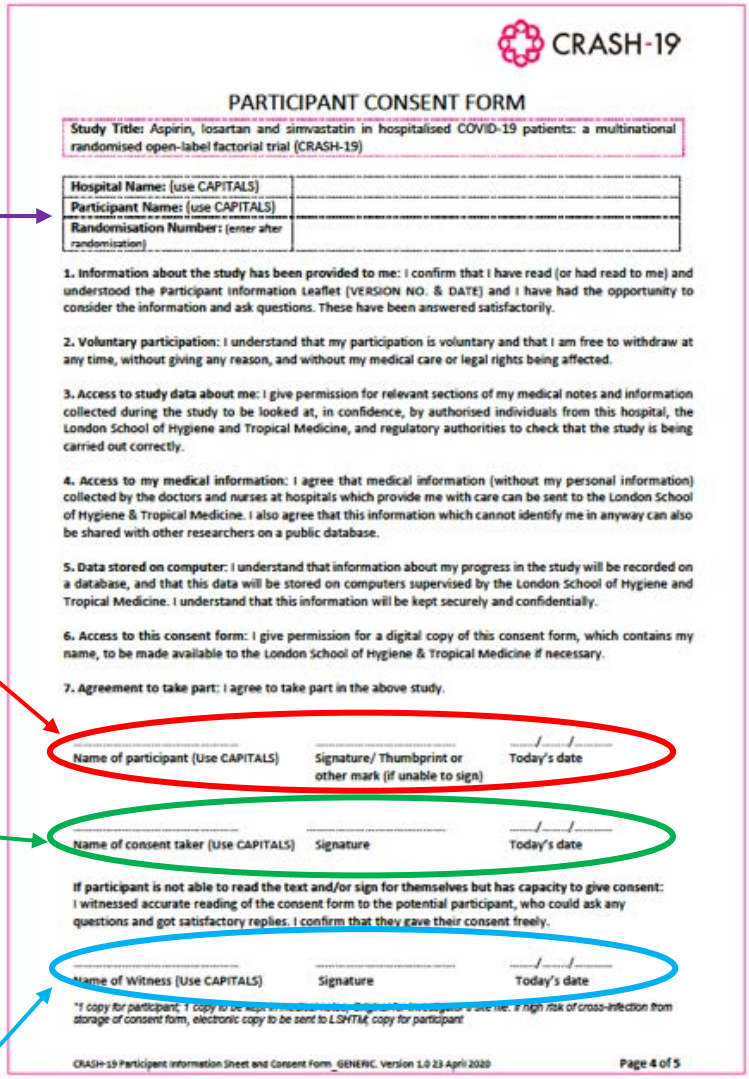
Investigator completes the header information

Participant writes their name, signature and the date on the form.

If the participant is unable to sign, a mark or thumbprint should be provided. Their name and the date should be completed by the impartial witness.

The person taking consent writes their own name, signature and the date on the form.

If a witness is required, the witness should complete this section.
They should also complete the participants name and the date



CRASH-19

PARTICIPANT CONSENT FORM

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

Hospital Name: (use CAPITALS)	
Participant Name: (use CAPITALS)	
Randomisation Number: (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
		...../...../.....

Name of consent taker (Use CAPITALS)	Signature	Today's date
		...../...../.....

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
		...../...../.....

storage of consent form, electronic copy to be sent to LSHTM, copy for participant

CRASH-19 Participant Information Sheet and Consent Form_GENERIC Version 1.0 23 April 2020 Page 4 of 5

We have illustrated above how to complete each section of the participant consent form. The principles also apply to the representative consent form; the representative should write their own name, signature and date the form. they should also write their relationship to the participant.

CONSENT PROCESS FLOWCHART

CRASH-19

PATIENT FULFILS ELIGIBILITY CRITERIA?

YES

Is patient ***competent*** to give valid written consent?

YES

- Patient given information sheet (electronic or hard copy)
- Patient completes the participant consent form (electronic or hard copy)

If patient is unable to read/ write

- Explain the trial in the presence of an independent witness
- Obtain mark (e.g. thumbprint) from patient
- Independent witness must sign the form

NO

Is a relative ***present and has capacity*** to act as the patient's Personal Representative?

YES

Relative agrees to give consent?

NO

DO NOT INCLUDE IN TRIAL

YES

- Give Relative information sheet
- Relative completes the representative consent form (electronic or hard copy)

NO

Treating / responsible clinician (independent of the clinician seeking to enrol the patient) willing to act as Professional Legal Representative (PLR)

YES

- Complete the representative consent form (electronic or hard copy)
- Obtain consent from patient's personal representative (or directly from the patient if they recover) at the earliest opportunity for ongoing trial procedures
- If the patient dies before consent is obtained, it will be the treating clinician's decision as to whether relatives can be approached to obtain consent

NO

DO NOT INCLUDE IN TRIAL