STOP-COVID19 | Superiority Trial Of Protease inhibition in COVID-19

Informed Consent

Informed consent

- PI responsibility
- Must follow GCP guidelines
- PI may delegate to individuals with experience of informed consent in CTIMPS - must be listed on the delegation log
- Patients admitted to hospital with a possible diagnosis of COVID-19 will be given a Participant Information Sheet (PIS)
- Due to the requirement to begin treatment quickly, patients may have less than 24 hours to provide consent after being given PIS

Informed consent: with capacity

	Participant Information Sheet (PIS)		Informed Consent Form (ICF)	ICF completed by	Where ICF completed	Filing ICF
Patient has capacity to read PIS, give informed consent and complete ICF themselves	• Participant Information Sheet • Brief Participant Information Sheet	Given to participant.	Informed Consent Form	Participant and delegated Research Staff Witness statement not required.	At bedside Staff will wear appropriate personal protective equipment (PPE) and follow local infection control measures	Original photographed and then given to participant. Copies printed and filed in ISF & medical record OR Original put in sealed envelope and opened after 7 days then original filed in ISF, copies given to participant and filed in medical record.
Patient has capacity to give informed consent but NOT able to read PIS or complete ICF themselves e.g. too unwell, PIS/ICF not available in their language or unable to read or write	• Participant Information Sheet • Brief Participant Information Sheet	Participant Information Sheet read to participant Copy given to participant.	Informed Consent Form	Delegated Research Staff Witness independent from trial: witness statement at bottom on ICF completed. Boxes for initials left blank.	Outside COVID-19 room.	Original filed in ISF, copies given to participant and filed in medical record.

Informed consent: with capacity, non-English speakers

- Translated PIS and ICF are available in: Bengali, French, Polish, Portuguese, Punjabi and Urdu https://stop-covid19.org.uk/trial-documents-2/
- Verbal translation to discuss the trial and receive consent will be required
  - Relative/staff/NHS translation service
- A plan should be in place for how telephone calls will be carried out on discharge of participants.
- Where no PIS and ICF are available in participant's language the PIS and ICF may be read to them in a language they understand. ICF should be completed as above guidance for: *Patient has capacity give informed consent but NOT able read PIS or complete ICF themselves e.g. too unwell, PIS/ICF not available in their language or unable to read or write*

Informed consent: lacking capacity

- Capacity for informed consent is decided by the patients' treating clinician or PI/delegate.
- Patient will be given information about the trial in keeping with their capacity to understand.

SCOTLAND

- Personal legal representative:
  - Adult's Welfare Guardian or Welfare Attorney, or if not appointed:
  - The adult's nearest relative,

  If not available,
- Professional legal representative:
  - a doctor responsible for the medical treatment of the adult if they are independent of the trial, or a person nominated by the healthcare provider.

ENGLAND & WALES

- Personal legal representative:
  - a person not connected with the conduct of the trial who is suitable to act as the legal representative by virtue of their relationship with the adult, and is available and willing to do so.

  If one is not available,
- Professional legal representative:
  - a doctor responsible for the medical treatment of the adult if they are independent of the study, or a person nominated by the healthcare provider.

Informed consent: lacking capacity

Patients who do not have capacity to give consent

- Relatives are unlikely to be present in hospital
- Informed consent will be given by a Professional Legal Representative.
- **Before consent is given by the Professional Legal Representative, the research team will endeavor to contact the participant's relative:**
  - Telephone discussion to request verbal consent from the personal representative
  - Legal Representative PIS via Website/Email/Mail
  - Record Personal Legal Representative decision in medical notes
- Verbal wish to enrol obtained > Professional Legal Representative consent
- Verbal wish to enrol declined > do not enrol patient.
- Where participants may get discharged without regaining capacity e.g. underlying condition such as dementia, ensure there are plans in place for this to enable participant to receive IMP and for follow-up phone calls.

STOP-COVID19

Informed consent: lacking capacity

	Participant Information Sheet (PIS)		Informed Consent Form (ICF)	ICF completed by	Where ICF completed	Filing ICF
Patient does not have capacity to give informed consent – relative present	• Participant Information Sheet – Legal Representative • Brief Participant Information Sheet – Legal Representative	Given to relative	Informed Consent Form – Legal Representative	Relative (Personal Legal Representative) and delegated Research Staff. Boxes should be initialled by relative.	Outside COVID-19 room.	Original filed in ISF, copies given to relative and filed in medical record
Patient does not have capacity to give informed consent – relative NOT present	• Participant Information Sheet – Legal Representative • Brief Participant Information Sheet – Legal Representative	Given to Professional Legal Representative. Copy given to relative (email/post/view on website)	Informed Consent Form – Legal Representative	Relative to be phoned, trial discussed and wishes of relative to be followed (this is not consent). Record in medical record. Doctor independent from trial - Professional Legal Representative (PLR) and delegated Research Staff. Boxes to be initialled by PLR	Outside COVID-19 room.	Original filed in ISF, copies given to Professional Legal Representative and filed in medical record

Informed consent: recovered capacity

- If participant recovers capacity to consent during the trial, informed consent will be obtained:
  - In hospital they will be given a Recovered Capacity PIS and consented face to face as soon as practical.
  - Should be completed before discharge
  - If discharged from hospital the trial staff will discuss the trial with them over the phone and mail a consent form for the participant to complete and return.
  - If participant does not want to participate further they will be asked to agree to their data collected to that point being used in the analysis. If they refuse, their data will be removed. The decision of the participant will be recorded in the medical records.

STOP-COVID19

Informed consent: recovered capacity

	Participant Information Sheet (PIS)		Informed Consent Form (ICF)	ICF completed by	Where ICF completed	Filing ICF
Patient recovers capacity	• Participant Information Sheet – Recovered Capacity • Brief Participant Information Sheet	Given to participant.	Informed Consent Form – Recovered Capacity	Participant and delegated Research Staff Witness statement not required.	At bedside Staff will wear appropriate personal protective equipment (PPE) and follow local infection control measures	Original photographed and then given to participant. Copy printed and filed in ISF OR Original put in sealed envelope and opened after 7 days then original filed in ISF and copy given/posted to participant

Informed consent: lost capacity

Patients who lose capacity to give consent during the trial

- Previous wishes & consent remain legally binding unless the protocol changes significantly.
- If the protocol changes significantly their legal representative will be asked for their consent.
- The CI or delegate will consult with carers and note any signs of objection from the participant. If signs are noted the participant will be withdrawn.
- The participant may be withdrawn from further trial intervention and agreement sought for continued data collection.