SFX-01 **t**reatment for **Acute Respiratory Infections** (STAR-Covid19)

Informed Consent

Informed consent

- PI responsibility; must follow GCP guidelines
- PI may delegate to individuals with experienced 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) and a brief PIS
- Due to the requirement to begin treatment quickly, patients may have less than 24 hours to provide consent after being given PIS. The consent process will not be complete until the patient has had all their questions answered and has spoken to the trial team physician
- The time and location for the informed consent discussion should be considered carefully, ensuring an appropriate location to enable discussion of sensitive issues and timing that takes account of the patient's condition and of clinical work. The discussion should be face to face and staff will wear appropriate personal protective equipment and follow local infection guidelines

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 completed.	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 flied in ISF & medical record OR Original put in sealed envelope and opened after 7 days then original filed in ISF, copies given/posted to participant and filed in medical record.
Patient has capacity give informed consent but NOT able read PIS or complete ICF themselves	• Participant Information Sheet • Brief Participant Information Sheet Participant Information Sheet read to participant	Given to participant	Informed Consent Form	Delegated Research Staff Witness statement at bottom on ICF completed by witness independent from trial. Boxes for initials left blank.	Outside COVID-19 room.	Original filed in ISF, copies given to participant and filed in medical record. On discharge taken home by participant or destroyed and clean copy given/posted to participant

* The Tayside site has a different, separate PIS taking account of extra assessments.

Informed consent – lacking capacity

- The patient's treating physician or PI/delegate will determine whether a patient has sufficient capacity to provide informed consent and will document this in the medical record
- The patient will be given information about the trial in keeping with their capacity to understand
- The legislation governing the requirements for legal representation is the Adults with Incapacity Act (Scotland) 2000, Mental Capacity Act and Medicines for Human Use (Clinical Trials) Regulations
- Patients can be represented by either a Personal or Professional Legal Representative
- STAR COVID has different documentation (PIS and ICF) for Personal and Professional representatives so it is important to use the correct forms

Informed consent – Legal Representation

- There is a hierarchy of individuals who are eligible to provide informed consent and this differs in Scotland and the rest of the UK due to different legislation

- In Scotland those who can act as legal representative are:

  Personal legal representative i.e.

  Adult's Welfare Guardian or Welfare Attorney, or if not appointed:
  The adult's nearest relative, if neither are reasonably contactable:

  Professional legal representative i.e. 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.

- In England and Wales those who can act as legal representative are:

  Personal legal representative i.e. 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 i.e. 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 – Legal Representation

- If a personal legal representative is present they will be given the Legal Representative Personal PIS together with the brief PIS and asked to consider giving consent for the patient to take part. If they do provide consent they will asked to complete the Legal Representative Personal ICF.

- If a personal legal representative is not present the research team will first endeavour to contact the participant's relative:
    - Telephone discussion to request verbal consent from the personal representative
    - Legal representative provided with the PIS via website/email/mail
    - Record personal legal representative decision in medical notes
- If verbal consent obtained, then the Professional Legal Representative will be asked to provide written informed consent on the Legal Representative Professional ICF
- If verbal consent from the personal legal representative denied the patient will NOT be enrolled into the study

Informed consent – lacking capacity

	Participant Information Sheet (PIS)		Informed Consent Form (ICF)	ICF completed by	Where ICF completed	Filing ICF
PERSONAL LEGAL REPRESENTATION; Patient does not have capacity to give informed consent – relative present	• Participant Information Sheet – Legal Representative Personal* • Brief Participant Information Sheet*	Given to relative	Informed Consent Form – Legal Representative Personal	Relative and delegated Research Staff	Outside COVID-19 room.	Original filed in ISF, copies given to relative and filed in medical record
PROFESSIONAL LEGAL REPRESENTATION; Patient does not have capacity to give informed consent – relative NOT present	• Participant Information Sheet – Legal Representative Professional* • Brief Participant Information Sheet*	Given to Professional Legal Representative. Participant Information Sheet – Legal Representative Personal given to relative (email/post/view on website)	Informed Consent Form – Legal Representative Professional	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

* The Tayside site has a different, separate PIS taking account of extra assessments.

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.

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	Participant and delegated Research Staff Witness statement not completed.	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 flied in ISF OR Original put in sealed envelope and opened after 7 days then original filed in ISF and copy given/posted to participant

* The Tayside site has a different, separate PIS taking account of extra assessments.

Informed consent – Lost capacity

- If participant loses capacity to provide ongoing 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.

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