Supplementary guidance for new participant pathway during COVID-19 pandemic (*effective from 13-03-20 – see appendix 4 – Protocol V7 13-03-20)*

Participant visits:

- Phone the participant on the day their visit is due.
- Complete the CRF as fully as is possible over the phone.
- Complete the questionnaires as fully as possible over the phone.
- Remember to ask about the occurrence of AEs, exacerbations and changes to con meds at every telephone call. Please be extra vigilant about this and document that the participant has been asked about these in the medical notes and record the patient's answers (*even if the answer to these questions is none*).
- Complete AE Log, Pulmonary Exacerbation Record and update Con Meds Log as required.
- Discuss with participant how they prefer to receive their trial medication e.g. family or friend collecting for them or delivery by taxi (*Local Working Practice Guideline (WPG) must be followed for this – see below*).
- Add the missed face-to-face visit number to the breach log. This is not a breach and does not need reporting to Sponsor (*it is just recorded so we can keep a record of the number of missed visits*). The only breaches would be if the phone call or elements of the phone call that could be covered, like questionnaires, are not done.
- Complete Medical Notes visit/continuation sheets for filing as source data in the medical notes. Document that this was a telephone visit and visit number.
- Add at the top of the CRF visit page that this visit was completed by phone.
- Score through CRF sections and state 'not done' for assessments you were unable to complete over the phone.
- PI or designated medic must sign AE and breach logs off as usual.
- Upload the CRF and visit questionnaires to LabKey in the usual way.
- Please remember to phone participants as per the TRUST schedule to ensure patients are starting and stopping their medication every 28-days as per protocol. This is a good time to remind them to complete and

return their monthly QOL-B questionnaires also (*note these questionnaires are not uploaded to LabKey and are saved with the patients CRF until the patient finishes all their visits. Further guidance on where to send these will follow at a later stage*).

Trial medication:

- All randomised participants are to keep taking their IMP.
- Each site must prepare their own local WPG/SOP for IMP delivery to the participant, have it reviewed and signed off by their Lead Clinical Trials Pharmacist and PI. Please send a copy to the trial management team at **respiratorytrials@dundee.ac.uk** Please refer to Working Practice Guidelines (WPGs) provided as examples.
- Completed prescription is sent to pharmacy, dispensed and collected by Research team as usual.
- With medics likely to be extremely busy on the wards, please plan ahead and remember prescriptions can be signed by them up to 7 days in advance of the visit (*for any visits from visit 3 onwards*).
- Ask patients to store all used IMP containers ready to be returned to pharmacy when appropriate for accountability.
- Used handsets should not be returned to the hospital. The monitoring team have asked that research staff advise participants to dispose of these at home.

Safety Reporting:

- If a patient reports any symptoms of COVID-19 including:
  - Fever
  - Cough
  - Difficulty breathing

They must not attend for a research visit. Advise the patient to follow the COVID-19 pathway England – online at https://111.nhs.uk/covid-19 or phone 111. Scotland – call GP surgery or 111(NHS 24) if it is closed.

- Discuss with PI and report to CI and trial management team.
- Please ask about the occurrence of AEs, exacerbations, changes to con meds and hospitalisations at every telephone call.
- If the patient is admitted to hospital, an SAE form will need submitting within 24 hours of the staff member becoming aware of the SAE.
- SAE forms need to be downloaded every time an SAE happens from here https://www.ahspartnership.org.uk/tasc/for-researchers/sops/safety-and-pharmacovigilance
- Always go to the link provided above to find the latest version of the SAE form to complete. The PI/designated doctor must assess for seriousness and causality before sign off and submit directly to pharmacovigilance.tayside@nhs.net
- If the PI is not immediately available to sign the SAE form, the research nurse should submit the SAE form within 24 hours, copying in the PI to the e-mail and asking the PI to confirm to PV that they have reviewed the SAE form and will sign electronically.
- Please do not forget to copy in both James j.chalmers@dundee.ac.uk and the trial management team RespiratoryTrials@dundee.ac.uk with any SAE submission, as we need to submit any SAE forms to the funder within 15 calendar days.
- The CI/PI will make a clinical judgment as to whether an AE is of sufficient severity to require the participant's discontinuation of treatment as per protocol.
- Please keep the trial management team informed of any staff changes and forward updated delegation logs and contact details as appropriate.