SOP Number 02
SOP Title Inclusion/Exclusion Criteria and Baseline CRF SOP
Version 1.2

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1. PURPOSE

To describe the process for collecting data for the Inclusion/Exclusion Criteria and Baseline Case Report Forms for the FALCON C-19 study.

2. DEFINITIONS

ED – Emergency Department
CRF – Case Report Form
FALCON C-19 – Faciliating AcceLerated Clinical evalusation Of Novel diagnostics tests for COVID-19 (FALCON C-19)
SOP – Standard Operating Procedure

3. DOCUMENT VERSIONS

Group 1 Inclusion/Exclusion Criteria CRF v1.1 25/11/2020
Group 2 Inclusion/Exclusion Criteria CRF v1.1 25/11/2020
Baseline CRF v1.6 26/01/2021

4. SPECIFIC PROCEDURES

General Completion Instructions

Where the participant has been included because they have had a COVID-19 swab come back with a positive result, this will be referred to in the following document as Group 2. Not all the fields on the CRF will be specific to Group 2 participants.

Inclusion/Exclusion Criteria CRF

Inclusion criteria: Participants should fit into one of two groups:

- **Group 1:** Query COVID-19 patients that are being seen in the Emergency Department, or are asmptomatic and require testing for other reasons, e.g. they're being admitted for an elective/emergency surgery, staff that are taking part in a testing programme at work
- **Group2:** Known COVID-19 positive inpatients. These patients would have been admitted for another reason but during routine testing have tested positive for COVID-19, e.g. have been exposed whilst on the ward

Exclusion criteria: This set of criteria is for both groups of participants. If answer to any of them is 'Y', then participant is not eligible for the study.

Type of consent obtained: Tick the relevant box. If Personal Consultee is selected, record the relationship to the participant on the line below.

Date of consent: Date consent was taken

Consent obtained by: The name of the person taking the consent from the participant/consultee. This person should be delegated to do so on the delegation log.

Baseline CRF:

Demographics: Please record participant's date of birth, gender and ethnicity. Gender refers to participant's gender at birth.

Date/time of admission: This is the date and time that the patient was admitted to hospital. If participant came through the Emergency Department (Group 1), this is the date and time the participant was admitted to ED. For Group 2 participants, this is the date and time they were admitted to hospital.

Date/time clinical SARS-CoV-2 swab: This is the date and time of the SARS-CoV-2 swab that is being used as part of the eligibility criteria. The participant needs to be recruited and have research swabs done within 24hrs of this clinical swab in order to be included in FALCON C-19.

Presenting features: Tick the boxes of any features reported by the participant or recorded in the clinical notes. For Group 2 cohort of participants, please tick other and state reason for admission.

Symptom duration: Record in days the duration of the diagnostic symptom with the longest duration. If participant is part of the Group 2 cohort and they were asymptomatic, please record as not applicable.

Past medical history: Tick the box if the patient has any significant medical history or chronic diseases.
Heart disease: Any previous or current heart disease requiring ongoing treatment or follow-up, including coronary heart disease, congenital heart disease, cardiomyopathy, heart failure, arrhythmia, pacemaker or other implanted device
Renal impairment: Chronic kidney disease recorded in medical records
Steroid therapy: Prednisolone, hydrocortisone, fludrocortisone or cortisone, prescribed for more than one month and continued to date
Asthma: Diagnosis recorded in medical records
Other chronic lung disease: Chronic obstructive pulmonary disease (COPD), emphysema, pulmonary fibrosis, bronchiectasis, cystic fibrosis or other chronic lung disease recorded in medical records. Please specify which chronic lung disease in space provided
Diabetes: Type 1 or 2 diabetes recorded in medical records
Active malignancy (last 6 months): Any malignancy (including recurrent or metastatic) diagnosed or treated within the last 6 months
Immunosuppression: Any reduction of the immune system due to immunosuppressant drugs (excluding steroids) or disease affecting the immune system
Hypertension: Any diagnosis of hypertension recorded on the medical record, regardless of whether it is treated. Do not include high blood pressure recorded during assessment

Antibiotics this illness: This refers to any antibiotics that the participant may have had before their admission for this current illness, e.g. if their GP has prescribed antibiotics for their current symptoms

COVID status:
Contact with confirmed COVID-19 case: Record if the patient has had any contact with a confirmed COVID-19 case. If yes, please record their relationship to the patient, i.e. write 'Father' if the patient's father has confirmed case of COVID-19
Contact with suspected COVID-19 case: Record if the patient has had contact with someone displaying COVID-19 symptoms but hasn't had a confirmed positive test result. Must have been within 2 meters of someone displaying symptoms for more than 15 minutes.
Test for previous SARS-CoV-2 infection: Record if the patient has had a test for active SARS-CoV-2 infection (not an antibody test) at any point prior to admission. Record result of this test.

COVID vaccine: Record whether or not the participant has had the SARS-CoV-2 vaccine. If Yes, record which vaccine participant had, the month and year of their first dose, and the month and year of their second dose.

Observations:
Group 1: Record the first measurement of the respiratory rate, pulse rate, temperature, blood pressure and peripheral oxygen saturation, along with the inspired oxygen concentration being used then the peripheral oxygen saturation was measured. If patient on 21% FiO_2, this can be recorded as room air. Record the first measurement of the eye, verbal and motor components of the Glasgow Coma Scale. Record whether the patient was alert (A), verbally responsive (V), responsive to pain (P) or unresponsive (U) on presentation to hospital.

Group 2: If the participant's SARS-CoV-2 swab was taken 72hrs after their admission, record the observations taken on the same day as the SARS-CoV-2 swab.

Admission Tests and Investigations: Record if blood samples were taken for laboratory analysis. If yes, record the results of the first sample taken after arrival at hospital in the relevant boxes. If a blood test was not requested, tick 'Not done'.
SARS-CoV-2: If RNA was detected, the CT value needs to be recorded. This information should be available from your lab and just denotes how much SARS-CoV-2 RNA was detected in the sample. The PCR kit used to run the test also needs to be recorded for every participant (not just the participants where RNA was detected). Again, this information should be available from your lab.
Record the findings of the first chest X-ray, CT, ultrasound (US) or ECG requested after arrival at hospital. If a particular test wasn't requested, tick 'Not done'.
For those participants who have a historical abnormal ECG, this should be recorded as 'Abnormal' on the CRF.
Group 2: Please use the tests and investigations that are within 24hrs of their clinical SARS-CoV-2 swab.

Antibiotics whilst admitted: Record if participant was given any antibiotics during their admission to hospital. If yes, record what antibiotic they were given, and where it was given, e.g. Emergency Department, Ward, ICU.

Disposition: Record where the patient was disposed to after admission.

CRF completion: Record the name of the person completing the CRF and the date it was completed.

If you have any queries, please contact Eloïse Cook (FALCON C-19 Trial Co-ordinator) on FALCONstudy@mft.nhs.uk or 0161 701 7540