**Appendix 2 - Initial Contact Script and Screening Form**

Initial Contact Script

Hello my name is: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_, I am one of the staff members from name of the centre. Our team is conducting a study on medications for COVID-19 in non-hospitalized patients called, CanTreatCOVID. Thank you for getting in touch with us regarding your interest in participating. I am contacting you today to see if you have any questions about the study and if you are still interested, I am going to ask you a couple of questions to check if you are eligible. Do you have about 30 minutes to go through this process?

[Answer any questions]

Are you still interested in participating in the study?

[No] – Thank you for your time.

[Yes] – I will now ask you a series of questions to check if you are eligible for the study.

[No] – When can I call you to check your eligibility?

[Yes] – If you appear to be eligible to participate in the study and you are interested, I can then briefly explain how the study works.

[Start completing the screening questionnaire on REDCap]

Throughout the conversation, pause and see if patients have any questions, make sure you answer all of their questions before proceeding.

[Screen Failure] Due to [reason], it appears that you are not eligible for this study. Thank you for taking the time to speak with us today.

[Screen Successful] You are eligible for the study based on this screening process. I will now review the study information sheet and consent form with you. A pharmacist will be in touch with you as soon as possible to confirm that your current medications are safe to take with the medications being evaluated in the study at this time.

[Go through ICF]

[Email ICF to participant and request written signature, if possible]

[Complete master linking log]

Screening Form

Date of visit: DD-MMM-YYYY

**1. Where did you hear about this study?**

☐ CanTreatCOVID website

☐ Social media

☐ Public communications (e.g., posters, advertisements)

☐ A letter was mailed to my residence

☐ My primary care provider

☐ Other, please specify? \_\_\_\_\_\_\_\_\_\_\_\_\_\_

**2. Inclusion and exclusion criteria**

**Inclusion criteria (all should be Yes)**

|  |  |
| --- | --- |
| **a.** **Patients have a positive SARS-CoV-2 test (PCR or RAT) with proof of a positive test provided via a picture of the result and symptoms beginning within 2 days of screening date** | O Yes  O No |
| **b. Patients over 18 (at least one of the following criteria should be Yes)** | O Yes  O No |
| 1. Age ≥50 years (does not need any other risk criteria) | O Yes  O No |
| 2. Chronic respiratory disease (including COPD, cystic fibrosis and asthma requiring at least daily use of preventative and/or reliever medication) | O Yes  O No |
| 3. Chronic heart or vascular disease | O Yes  O No |
| 4. Chronic kidney disease | O Yes  O No |
| 5. Chronic liver disease | O Yes  O No |
| 6. Chronic neurological disease (including dementia, stroke, epilepsy) | O Yes  O No |
| 7. Severe and profound learning disability | O Yes  O No |
| 8. Down’s syndrome | O Yes  O No |
| 9. Diabetes (Type 1 or Type 2) | O Yes  O No |
| 10. Immunosuppression: primary (e.g., inherited immune disorders resulting from genetic mutations) or secondary due to disease or treatment (e.g., sickle cell, HIV, cancer, chemotherapy) | O Yes  O No |
| 11. Solid organ, bone marrow and stem cell transplant recipients | O Yes  O No |
| 12. Morbid obesity (BMI >35) | O Yes  O No |
| 13. Severe mental illness | O Yes  O No |
| 14. Care home resident | O Yes  O No |

**Exclusion Criteria**

|  |  |
| --- | --- |
| Were any exclusion criteria met? | O Yes  O No |
| What was the exclusion criteria? (check all that apply): | |
| 1. Admitted to hospital or in an emergency department for more than 24 hours | O |
| 2. Previously randomized to CanTreatCOVID | O |
| 3. Currently participating in a clinical trial of a therapeutic agent for acute SARS-CoV-2 infection that is not/suspected not compatible with the study therapeutics | O |
| 4. Already taking a study therapeutic or contraindication to a study therapeutic *[research assistant to read out list of contraindicated drugs]* | O |
| 5. Inability for participant or caregiver to provide informed consent | O |
| Paxlovid Exclusion Criteria | |
| 6. History of clinically significant hypersensitivity to the active substances in Paxlovid™ (nirmatrelvir /ritonavir) or to any of its excipients | O |
| 7. Known rare hereditary problems of galactose intolerance, total lactase deficiency or glucose-galactose malabsorption | O |
| 8. Current severe liver impairment (characterized by severe ascites, encephalopathy, jaundice, or prolonged INR. People with liver disease without any of these features are eligible | O |
| 9. Moderate or severe renal disease (defined as CKD stage 3, 4 or 5 or current acute kidney injury or most recent eGFR in the past 6 months <60 ml/min) | O |
| 10. Currently taking Paxlovid™ | O |
| 11. Has a known or suspected pregnancy | O |
| 12. Breastfeeding | O |
| 13. Is of childbearing potential and is not willing to use a highly effective contraceptive | O |

**Screen Failure**

|  |  |
| --- | --- |
| **In the opinion of the research assistant, is the participant considered a screen failure?** | O Yes  O No |
| **Date the participant was considered a screen failure?** | DD-MMM-YYYY |
| **Reason for screen failure?** | O Inclusion or Exclusion Criteria Unmet  O No Consent obtained |