Platform Randomised Trial of Treatments in the Community for Epidemic and Pandemic Illnesses - PRINCIPLE

REC Number: 20/SC/058 **IRAS Number: 281958** **EudraCT Number: 2020-001209-22**

Chief Investigator: Professor Christopher Butler **Participant ID:**

CONSENT FORM

Thank you for completing the screening questionnaire, you have passed the screening stage for the trial.

Please read the Participant Information Sheet if you haven't already done so, and if you are willing to participate please select 'Yes', TYPE your FIRST and LAST names below and then click Submit

If you agree, please select 'Yes' to confirm that you have read and understood the following:

		YES	NO
1	I confirm I have read and understood the information sheet version number ____-_____dated __ __ / __ __ __ / __ __ __ __ for the above study. I have had the opportunity to ask questions and had these answered satisfactorily.		
2	I understand my participation is voluntary and that I am free to withdraw at any time, without giving any reason, and without my medical care or legal rights being affected.		
3	I understand that if I chose to withdraw data already collected will continue to be used and I or my GP may be contacted if there are further questions regarding side effects from trial medications.		
4	I understand that I will be randomised to receive either: standard care plus a trial treatment or standard care, and that I will not be able to choose which I will receive.		
5	I understand that relevant sections of my GP and Hospital medical notes and data collected during the study may be looked at by members of the research team and individuals from University of Oxford, both during and for up to 10 years after the scheduled follow-up period. It may also be reviewed by relevant people from regulatory authorities and from the NHS Trust(s). I give permission for these individuals to have access to my records.		
6	I understand that members of the research team may view my Summary Care Record (SCR) to check my medication, allergies, adverse reactions and additional information to make sure that it is safe for me to take trial medication. I give permission for these individuals to access my SCR for this purpose.		
7	I consent to being contacted by the research team for the purposes of trial follow up for 28 days from randomisation (and for long-term follow-up contact after 3, 6 and 12 months; up to 3 months after each time-point). I understand that this will require me to provide my contact details to the research team.		
8	I consent to my GP and/or Care Home being informed of my participation within the study and I understand that the trial team may contact my GP about my ongoing participation in the trial.		

9	I agree to take part in the study.		
10	I understand that the information collected about me may be shared in a form that cannot identify me with commercial companies to support the licensing of trial treatments, within the UK and abroad.		
11	For women of child-bearing potential only: I agree to take the urine pregnancy test provided on Day 1 of the trial and confirm my test result to the trial team.		
	ADDITIONAL (optional, not required for study participation)	**YES**	**NO**
1	*I agree to provide the research team with the contact details of my Trial Partner. I confirm my Trial partner is aware of their role and willing to answer questions.*		
2	*I am happy to be contacted by the research team to be invited to a telephone interview at the end of the study.* *(Taking part in the interview is optional and will not affect your study participation. If you agree to be contacted, the research team will contact you with details of the interview in approximately 28 days. You can then decide whether you want to take part or not.)*		

If you are the participant completing the consent form, please provide your signature below

Participant Signature:

First Name: _____ Last Name: _____

Date: __ __ / __ __ / __ __ __ __

If the participant has provided verbal consent, but they are unable to complete the consent form due to lack of online access, too unwell, too frail or consent is completed via the telephone (the participant must have capacity), please provide:

1. Name of the participant
First Name: _____ Last Name: _____

Date: __ __ / __ __ / __ __ __ __

2. Signature of person completing the form
First Name: _____ Last Name: _____
Role: Study Partner/Trial Team Member/Health Care Professional

Date: __ __ / __ __ / __ __ __ __

If participant lacks capacity to give consent:
I have read the information (or had it read to me) and had an opportunity to ask questions.

Participant:

Name: _____ Date: __ __ / __ __ / __ __ __ __

I believe that if they were able to, the patient would wish to take part in this study.

…….	…….	……../……../……
PRINTED name of Legal Representative	Signature	Today's date

……
Relationship to participant

You will have the opportunity to print a copy of the consent form after submission. Please contact the study team if you would like a copy sent to you

By submitting, I confirm that I am the person whose name is stated above.

If you have any questions about this or any other part of the study please contact the study team:

Tel: 0800 138 0880 Email principle@phc.ox.ac.uk