Prophylactic Therapy in Care Homes Trial (PROTECT-CH)
Informed Consent Form

Final v1.0, 18-May-2021

IRAS Project ID: 294832

Participant Trial ID: | | | | | | | |

		Please mark each box
1.	I confirm that my care home and the research team have discussed the PROTECT-CH trial with me and given me the Participant Information Sheet dated: <insert date>, version: <insert version>, which I have read and understood. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2.	I understand that taking part is voluntary and that I can withdraw at any time, without giving any reason. My medical care or legal rights will not be affected. I understand that if I withdraw, the information collected so far cannot be deleted and may still be used in the trial.	
3.	I understand that if my care home is allocated to give usual care or my care home is allocated to give a trial medication that I cannot take I will not receive the trial medication. I will continue receiving my usual care. I agree to complete questionnaires about my health during the trial whether I am allocated to usual care or usual care plus medication.	
4.	I agree to my GP being informed of my participation in this trial. I agree to the research team contacting my GP for further information regarding my medical history and current medications.	
5.	I understand that relevant sections of my medical notes and data collected in the trial may be looked at by authorised individuals from the Nottingham Clinical Trials Unit (NCTU), the Sponsor (University of Nottingham), central NHS bodies, trusted third parties, the research team and regulatory authorities where it is relevant to my taking part in this trial. I give permission for these individuals to have access to my records and for the NCTU to have a copy of my signed consent form.	
6.	I give permission for the NCTU, the Sponsor, trusted third parties and the research team to collect, collate, store, analyse and publish	

	information obtained from my participation in this trial. I understand that my personal details will be kept confidential.	
7.	I understand that all information and personal data relevant to the trial will be shared with, stored and maintained by my care home, GP, trusted third parties, NHS Digital and other central UK NHS bodies in order to help contact me or provide information about my health status.	
8.	I understand that the anonymised information collected about me may be used to support other research in the future and may be shared with other researchers.	
9.	I agree that my legal representative can discuss my ongoing involvement in the trial, should I lose capacity to make this decision for myself during the trial.	
10.	I agree to take part in the above trial.	

Optional consent:

11.	I agree to be approached about taking further medications or other treatments as part of this trial in the future.	
12.	I am happy to be contacted about taking part in an interview to talk about my experience of taking part in this trial.	

If the participant can sign consent:

_____	_____	_____
Name of Participant	Date	Signature
_____	_____	_____
Name of person taking consent (You must be on the delegation log)	Date	Signature

If participant is not able to read the text and/or sign for themselves but has capacity to give consent:
I witnessed accurate reading of the consent form to the potential participant, who could ask any questions and got satisfactory replies.

I confirm that they gave their consent freely.

_____	_____	_____
Name of Witness	Date	Signature
_____	_____	_____
Name of person taking consent (You must be on the delegation log)	Date	Signature

Original signed ICF to be kept in the Site File. 1 copy should be given to the participant, and 1 should be sent to the Nottingham Clinical Trials Unit.