# Prophylactic Therapy in Care Homes Trial (PROTECT-CH)

## Legal Representative Informed Consent Form

**Final v2.0, 01-Jul-2021**

**IRAS Project ID: 294832**

**Name of Participant:**

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

| | | Please mark each box |
|---|---|---|
| **1.** | I confirm that the care home and the research team have discussed the PROTECT-CH trial with me and given me the Legal Representative 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| **2.** | I understand that taking part is voluntary for the person I am representing and that I can request they are withdrawn at any time, without giving any reason. Their medical care or legal rights will not be affected. I understand that if I withdraw them, the information collected so far cannot be deleted and may still be used in the trial. | |
| **3.** | I understand that if the care home of the person I am representing is allocated to give usual care or the care home is allocated to give a trial medication that the person I am representing cannot take, they will not receive the trial medication. They will continue receiving their usual care.<br>I agree to questionnaires being completed about the health of the person I am representing during the trial whether they are allocated to usual care or usual care plus medication. | |
| **4.** | I agree to the GP of the person I am representing being informed of their participation in this trial. I agree to the research team contacting their GP for further information regarding their medical history and current medications. | |
| **5.** | I understand that relevant sections of the medical notes of the person I am representing 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 them taking part in this trial. I | |

| | | |
|---|---|---|
| | give permission for these individuals to have access to the records of the person I am representing and for the NCTU to have a copy of this signed Consent Form. | |
| **6.** | I give permission for the NCTU, the Sponsor, trusted third parties and the research team to collect, store, analyse and publish information obtained from participation in this trial by the person I am representing. I understand that their 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 the care home, GP, trusted third parties, NHS Digital and other central UK NHS bodies in order to help contact the person I am representing or provide information about their health status. | |
| **8.** | I understand that the anonymised information collected about the person I am representing may be used to support other research in the future and may be shared with other researchers. | |
| **9.** | I give permission for the NCTU, the Sponsor and the research team to collect and store my contact details to discuss trial treatment options with me for the person I am representing. I understand my personal details will be kept confidential. | |
| **10.** | In my opinion, the person I am representing would have no objection to taking part in the above trial. | |

**Optional consent**

| | | |
|---|---|---|
| **11.** | I agree to be approached about the person I am representing 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. | |

I confirm I am the Legal Representative for the participant named above.

_____
Relationship to participant

| _____ | _____ | _____ |
|---|---|---|
| Name of Legal Representative | Date | Signature |

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