Guidance for recruiting care home residents

**PRINCIPLE TRIAL** aims to find treatments that improve symptoms and reduce hospital admission for older people with COVID-19. Any healthcare professional can facilitate recruitment of care home residents, by guiding patients/their legal representative through consent and registration.

Who are we recruiting?
* Those aged 65 and over
* Or aged 18-64 with shortness of breath due to COVID-19
* Or aged 18-64 with any known comorbidities including:
  - Weakened immune system due to serious illness or medication (e.g. chemotherapy)
  - Asthma or lung disease
  - Heart disease and/or high blood pressure
  - Known diabetes
  - Stroke or neurological problems
  - Liver disease

Presenting any of the symptoms below (within 14 days of onset):
- New continuous cough
- High temperature
- Change/loss of smell/taste
- Or confirmed COVID-19 with any symptoms

**IMPORTANT** – those who have had a COVID-19 vaccine or a flu vaccine are still eligible to take part in the study.

**Recruiting into the study and obtaining informed consent**

Residents **with capacity** have three options:

1. **Recruit patient yourself.** Go to [www.principletrial.org](http://www.principletrial.org) and click ‘Enrol a patient button’
   - Patient Information Sheet provided to go through with patient before completing consent form.
   - Nb. You are verbally supporting someone to self-consent to the study and transcribing this information into the online system – Good Clinical Practice (GCP) therefore not required.

2. **Refer patient to study team:** 0800 138 0880, to help guide patient through enrolment process

3. **Self-enrolling patient** go to: [https://www.principletrial.org/participants/how-to-join-the-trial](https://www.principletrial.org/participants/how-to-join-the-trial)

Residents **without capacity**:

1. Contact patient’s legal representative (ideally family member or next of kin) to confirm if they are willing for the patient to take part in the study. Can email/telephone to discuss the study and role of the legal representative (approved legal representative letter available)

2. Complete the screening, consent and baseline information online with the legal representative to register patient for the study: Go to [www.principletrial.org](http://www.principletrial.org) and click ‘Enrol a patient button’

**What happens next?**

Patients will be automatically randomised to receive usual care or a treatment arm, and a study pack with the relevant information is couriered directly to the care home.

**For further information or support:** Email: principle@phc.ox.ac.uk Tel: 0800 138 0880

GPs providing information to confirm a patient’s eligibility will be reimbursed £50 per patient