

Consent and Randomisation Form

To randomise a patient please call 0800 953 0274 between 9am-5pm, Monday to Friday

Section 1 - Participant Details

Initials: <i>First, Middle, Last</i> <input type="text"/> <input type="text"/> <input type="text"/>	Site Name: <input type="text"/>
Date of birth: <i>E.g. 31-Dec-2017</i> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Patient Gender: <i>Please tick one</i> <input type="radio"/> Male <input type="radio"/> Female

Section 2 - Eligibility Checklist

Inclusion checklist:

Aged 18 or over? <i>Tick one</i>	<input type="radio"/> No <input type="radio"/> Yes
Clinically diagnosed COPD, confirmed by post-bronchodilator spirometry and defined as FEV1/FVC<0.7 and lower limit of normal for age post bronchodilator use? <i>Tick one</i>	<input type="radio"/> No <input type="radio"/> Yes
Has the patient had ≥ 1 AECOPD in any 12-month period within the last 2 years or ≥ 1 hospital admission for AECOPD in the previous two years? <i>Tick one</i>	<input type="radio"/> No <input type="radio"/> Yes
Willing and able to comply with completion of questionnaires out to 12 months post-randomisation ? <i>Tick one</i>	<input type="radio"/> No <input type="radio"/> Yes
Ability to use intervention as judged by the investigator at screening, upon demonstration of the system to the patient <i>Tick one</i>	<input type="radio"/> No <input type="radio"/> Yes
State version of informed consent form signed by patient: <i>e.g. 1.0, 2.0 etc</i> <input type="text"/> <input type="text"/>	

Exclusion checklist:

Is the patient unable to consent to research? <i>Tick one</i>	<input type="radio"/> No <input type="radio"/> Yes
Life expectancy <12 months from a condition other than COPD? <i>Tick one</i>	<input type="radio"/> No <input type="radio"/> Yes
Patients with active infection, unstable co-morbidities at enrolment or very severe comorbidities such as grade IV heart failure, renal failure on haemodialysis or active neoplasia or significant cognitive impairment <i>Tick one</i>	<input type="radio"/> No <input type="radio"/> Yes

Please note: if any of the **shaded boxes** above are ticked then the patient is **ineligible** to take part in Predict&Prevent AECOPD

Section 3 - Co-enrolment

Has the patient, or is the patient intending to co-enrol into another trial/study? <i>Tick one</i>	<input type="radio"/> No <input type="radio"/> Yes
If Yes , specify: <input type="text"/>	

Section 4 - Randomisation

Recruitment setting? <i>Tick one</i>	<input type="radio"/> At discharge from hospital <input type="radio"/> Out-patients/invited from database list
Age	<input type="radio"/> <60 years <input type="radio"/> ≥ 60 years
Was shortness of breath assessed? <i>If yes please indicate status below</i>	<input type="radio"/> No <input type="radio"/> Yes
Shortness of breath category <i>Tick one</i>	
<input type="radio"/> Category 0, No dyspnoea <input type="radio"/> Category 1, Slight degree of dyspnoea (troubled by shortness of breath when hurrying on the level or walking up a slight hill) <input type="radio"/> Category 2, Moderate degree of dyspnoea (walks slower than people of the same age on the level because of breathlessness) <input type="radio"/> Category 3, Moderately severe degree of dyspnoea (has to stop because of breathlessness when walking at own pace on the level) <input type="radio"/> Category 4, Severe degree of dyspnoea (stops for breath after walking about 100 yards or after a few minutes on the level) <input type="radio"/> Category 5, Very severe degree of dyspnoea (too breathless to leave the house or breathless when dressing or undressing)	
What was the patient's CAT score? <i>Please take the score from the COPD CAT baseline booklet</i> <input type="text"/> <input type="text"/>	
How many exacerbations has the patient in the last year? <input type="text"/> <input type="text"/>	
Patient Trial Number: <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>	Date randomised: <i>e.g. 31-JAN-2017</i> <input type="text"/> <input type="text"/> <input type="text"/> - <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>

Time randomised: 24hr Intervention Allocation: *Tick one*☐ COPDinCheck App☐ Standard self-management

Section 5 - Form Completion Details

Form completed by:

Signature:

Date: *e.g. 31-JAN-2017* - -

Principal Investigator Name:

Principal Investigator Signature:

Date: *e.g. 31-JAN-2017* - -