



Health Research Authority

London - Stanmore Research Ethics Committee

Ground Floor
NRES/HRA
80 London Road
London
SE1 6LH

Please note: This is the favourable opinion of the REC only and does not allow the amendment to be implemented at NHS sites in England until the outcome of the HRA assessment has been confirmed.

27 July 2021

Dr Alice Turner
Consultant Chest Physician/Reader in Respiratory Medicine
University of Birmingham
Institute for Applied Health Research
University of Birmingham
Birmingham B15 2TT

Dear Dr Turner

Study title: The use of a personalised early warning decision support system with novel saliva bio-profiling to predict and prevent acute exacerbations of Chronic Obstructive Pulmonary Disease - 'Predict & Prevent AECOPD'

REC reference: 19/LO/1939

Protocol number: RG_19-050

Amendment number: SA04

Amendment date: 02 June 2021

IRAS project ID: 261576

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	Version	Date
Completed Amendment Tool [SA04 Amendment tool]	1.0	12 July 2021
GP/consultant information sheets or letters [Predict and prevent GP letter]	3.0	04 June 2021

GP/consultant information sheets or letters [PREDICT PREVENT_GP letter v2.1 Tracked changes]	2.1	28 May 2021
Other [Predict and prevent recruitment poster for hospitals v1.0]	1.0	04 June 2021
Participant consent form [PredictPrevent Healthcare Professional Information Study and Audio-recording Consent Form Final]	2.0a	28 May 2021
Participant consent form [Predict and prevent ICF]	4.0	04 June 2021
Participant consent form [PredictPrevent Healthcare Professional Information Study and Audio-recording Consent Form_V2.0a Vd28-May-2021 Tracked changes]	2.0a	28 May 2021
Participant consent form [PredictPrevent_ICFv3.1 Vd28-May-2021 Tracked changes]	3.1	28 May 2021
Participant information sheet (PIS) [Predict and prevent PIS Final]	6.0	04 June 2021
Participant information sheet (PIS) [PredictPrevent Trial PIS V5.1 Vd 28-May-2021Tracked changes]	5.1	28 May 2021
Research protocol or project proposal [Protocol v7.0]	7.0	05 July 2021
Research protocol or project proposal [Protocol v6.1]	6.1	28 May 2021

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

Amendments related to COVID-19

We will update your research summary for the above study on the research summaries section of our website. During this public health emergency, it is vital that everyone can promptly identify all relevant research related to COVID-19 that is taking place globally. If you have not already done so, please register your study on a public registry as soon as possible and provide the HRA with the registration detail, which will be posted alongside other information relating to your project.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at: <https://www.hra.nhs.uk/planning-and-improving-research/learning/>

IRAS Project ID - 261576:	Please quote this number on all correspondence
----------------------------------	---

Yours sincerely

Wai Yung

PP - Mrs Sunder Chita
Chair

E-mail: stanmore.rec@hra.nhs.uk

Enclosures: *List of names and professions of members who took part in the review*

Copy to: *Dr Birgit Whitman*

London - Stanmore Research Ethics Committee

Attendance at Sub-Committee of the REC

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Ms Sunder Chita	Health Research Manager and PPI Lead	Yes	
Dr Anthony Kaiser	Consultant Neonatologist	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Mr Wai Yeung	Approvals Administrator