

London - Stanmore Research Ethics Committee

2nd Floor 2 Redman Place Stratford London E20 1JQ

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.

22 April 2022

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: SA-06

Amendment date: 03 March 2022

IRAS project ID: 261576

The above amendment was reviewed at the meeting of the Sub-Committee held on 28 March 2022 via 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 [SA06 amendment tool] | 1.0 | 03 March 2022 |
| GP/consultant information sheets or letters [PREDICT PREVENT_GP letter4.0 Vd03-Mar-2022 Tracked changes] | 4.0 Tracked changes | 03 March 2022 |
| GP/consultant information sheets or letters [PREDICT PREVENT_GP letter4.0 Vd03-Mar-2022 Clean] | 4.0 Clean | 03 March 2022 |
| Participant information sheet (PIS) [PredictPrevent Trial PIS V7.0 Vd11-Feb-2022 Tracked changes] | 7.0 Tracked changes | 11 February 2022 |
| Participant information sheet (PIS) [PredictPrevent Trial PIS V7.0 Vd11-Feb-2022 Clean] | 7.0 | 11 February 2022 |
| Research protocol or project proposal [Predict and prevent_v9.0 03-Mar-2022 Clean] | 9.0 | 03 March 2022 |
| Research protocol or project proposal [Predict and prevent_v9.0 03-Mar-2022 Tracked changes] | 9.0 Tracked | 03 March 2022 |

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

pp.



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 meeting on 28 March 2022 via correspondence

Committee Members:

| Name | Profession | Present | Notes |
|-------------------------|---|---------|-------|
| Ms Sunder Chita (Chair) | Health Research Manager and PPI Lead | Yes | |
| Miss Zin Mon | Project Manager | Yes | |

Also in attendance:

| Name | Position (or reason for attending) |
|-----------------|------------------------------------|
| Mr Richard Reed | Approvals Administrator |