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12th May 2020

Dear Kathryn,

Full title of study:	A phase III, 2 arm, multi-centre, open label, parallel-group randomised designed clinical investigation of 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
Short Title:	Predict&Prevent AECOPD
REC ref:	19/LO/1939
Protocol Number:	833757
IRAS Project ID:	261576
Chief Investigator:	Professor Alice Turner
Sponsor:	University of Birmingham

I am writing to inform you that the following documents have been amended and form substantial amendment 01.

- Protocol V4.0 Vd04-May-2020
- Patient Information Sheet V4.0 Vd04-May-2020

The major change outlines that there will only be two CRP samples collected during the baseline period to form a baseline state as opposed to three.

In addition, to these documents, a consent video has been prepared; this video answers queries that arise during the consent process. The video will be used across several platforms as a tool for patients to address concerns before giving consent. This is to streamline the consent process however, it will not replace it entirely.

Yours sincerely,

Professor Alice Turner,

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