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6<sup>th</sup> October 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

**Sponsor:** University of Birmingham

I am writing on behalf of the Chief Investigator, Professor Alice Turner, to inform you of a substantial amendment. The documents that have been added in the SA02 are listed below...

- **Predict and Prevent AECOPD Qualitative Patient Consent Form V1.0 Vd31-Aug-2020**
- **Predict and Prevent AECOPD Qualitative Patient Information Sheet V1.0 Vd31-Aug-2020**

The protocol has also been amended to compensate for the withdrawal from the qualitative aspect of the study and the review of concomitant medications at each hospital visit.

- **Predict and prevent\_v5.0 Vd06-Oct-2020**

This amendment is to also inform you that due to the COVID-19 outbreak we have made the difficult decision to pause the saliva collection element of the study until further notice.

We have not activated a site for the trial as of yet, but site staff will be notified of this pause prior to site activation. This pause will be implemented for all sites on the same day of first site activation.

We will continue to assess the situation and will inform you once saliva collection has been deemed safe to continue. If you require any further information please do not hesitate to contact me.

Yours sincerely,



Dalbir Kaur on behalf of Professor Alice Turner

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