

**Partner Organisations:**

Health Research Authority, England

NHS Research Scotland

HSC Research &amp; Development, Public Health Agency, Northern Ireland

NIHR Clinical Research Network, England

NISCHR Permissions Co-ordinating Unit, Wales

**Notification of Non-Substantial/Minor Amendments(s) for NHS Studies**

This template **must only** be used to notify NHS/HSC R&D office(s) of amendments, which are **NOT** categorised as Substantial Amendments.

**If you need to notify a Substantial Amendment to your study then you MUST use the appropriate Substantial Amendment form in IRAS.**

**Instructions for using this template**

- For guidance on amendments refer to <http://www.hra.nhs.uk/research-community/during-your-research-project/amendments/>
- This template should be completed by the CI and optionally authorised by Sponsor, if required by sponsor guidelines.
- This form should be submitted according to the instructions provided for NHS/HSC R&D at <http://www.hra.nhs.uk/research-community/during-your-research-project/amendments/which-review-bodies-need-to-approve-or-be-notified-of-which-types-of-amendments/>. If you do not submit your notification in accordance with these instructions then processing of your submission may be significantly delayed.

**1. Study Information**

<b>Full title of study:</b>	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 - 'Predict & Prevent AECOPD
<b>IRAS Project ID:</b>	261576
<b>Sponsor Amendment Notification number:</b>	01
<b>Sponsor Amendment Notification date:</b>	12-Feb-2020
<b>Details of Chief Investigator:</b>	
Name [first name and surname]	Alice Turner
Address:	UNIVERSITY HOSPITALS BIRMINGHAM NHS FOUNDATION TRUST TRUST HQ, PO BOX 9551 QUEEN ELIZABETH MEDICAL CENTRE EDGBASTON BIRMINGHAM WEST MIDLANDS
Postcode:	B15 2TH
Contact telephone number:	0121 414 8590
Email address:	a.m.turner@bham.ac.uk
<b>Details of Lead Sponsor:</b>	

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Name:	University of Birmingham
Contact email address:	<a href="mailto:predictandprevent@trials.bham.ac.uk">predictandprevent@trials.bham.ac.uk</a> <a href="mailto:researchgovernance@contacts.bham.ac.uk">researchgovernance@contacts.bham.ac.uk</a>
<b>Details of Lead Nation:</b>	
Name of lead nation <i>delete as appropriate</i>	England
If England led is the study going through CSP? <i>delete as appropriate</i>	No
<b>Name of lead R&amp;D office:</b>	University Hospitals Birmingham NHS Foundation Trust

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**2. Summary of amendment(s)**

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If you need to notify a **Substantial Amendment** to your study then you **MUST** use the appropriate **Substantial Amendment form** in IRAS.

No.	Brief description of amendment (please enter each separate amendment in a new row)	Amendment applies to (delete/ list as appropriate)		List relevant supporting document(s), including version numbers (please ensure all referenced supporting documents are submitted with this form)		R&D category of amendment (category A, B, C) For office use only			
		Nation	Sites	Document	Version				
1	Addition of site <table><tr><td>Site</td><td>PI</td></tr><tr><td>Queen Elizabeth Hospital</td><td>Davinder Dosanjh</td></tr></table>	Site	PI	Queen Elizabeth Hospital	Davinder Dosanjh	England	Queen Elizabeth Hospital	CV and CGP for Davinder Dosanjh	
Site	PI								
Queen Elizabeth Hospital	Davinder Dosanjh								

[Add further rows as required]

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**3. Declaration(s)****Declaration by Chief Investigator**

- I confirm that the information in this form is accurate to the best of my knowledge and I take full responsibility for it.
- I consider that it would be reasonable for the proposed amendment(s) to be implemented.

Signature of Chief Investigator: .....



Print name: .....

A. TURNER

Date: .....

12/2/20

**Optional Declaration by the Sponsor's Representative (as per Sponsor Guidelines)**

*The sponsor of an approved study is responsible for all amendments made during its conduct.*

*The person authorising the declaration should be authorised to do so. There is no requirement for a particular level of seniority; the sponsor's rules on delegated authority should be adhered to.*

- I confirm the sponsor's support for the amendment(s) in this notification.

Signature of sponsor's representative: .....

Print name: .....

Post: .....

Organisation: .....

Date: .....