Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please complete the questions in order. If you change the response to a question, please select 'Save' and review all the questions as your change may have affected subsequent questions.

Please enter a short title for this project (maximum 70 characters)
Predict&Prevent AECOPD

1. Is your project research?

(●) Yes ( ) No

2. Select one category from the list below:

( ) Clinical trial of an investigational medicinal product
(●) Clinical investigation or other study of a medical device
( ) Combined trial of an investigational medicinal product and an investigational medical device
( ) Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice
( ) Basic science study involving procedures with human participants
( ) Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology
( ) Study involving qualitative methods only
( ) Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)
( ) Study limited to working with data (specific project only)
( ) Research tissue bank
( ) Research database

If your work does not fit any of these categories, select the option below:

( ) Other study

2a. Is the study sponsored or funded by a device manufacturer or other commercial company?

( ) Yes (●) No

Please select one of the following:

( ) Clinical study of a non-CE marked device where commercialisation of the product is intended
( ) Clinical study of a non-CE marked device for use within the institution, where commercialisation is not intended
( ) Clinical study of one or more CE marked devices for an off-label indication
(●) Clinical study of one or more CE marked devices for a labelled indication, involving a change to standard care or randomisation between groups

◯ Clinical study of one or more CE marked devices for a labelled indication, involving *no* change to standard care or randomisation between groups

◯ Pre-clinical device development or performance testing

2b. Please answer the following question(s):

a) Does the study involve the use of any ionising radiation? ◯ Yes ◉ No

b) Will you be taking new human tissue samples (or other human biological samples)? ◉ Yes ◯ No

c) Will you be using existing human tissue samples (or other human biological samples)? ◯ Yes ◉ No

3. In which countries of the UK will the research sites be located?*(Tick all that apply)*

☑ England
☐ Scotland
☐ Wales
☐ Northern Ireland

3a. In which country of the UK will the lead NHS R&D office be located:

◉ England
◯ Scotland
◯ Wales
◯ Northern Ireland
◯ This study does not involve the NHS

4. Which applications do you require?

☑ IRAS Form
☐ Confidentiality Advisory Group (CAG)
☐ Her Majesty's Prison and Probation Service (HMPPS)

5. Will any research sites in this study be NHS organisations?

◉ Yes ◯ No

5a. Are all the research costs and infrastructure costs (funding for the support and facilities needed to carry out research e.g. NHS Support costs) for this study provided by a NIHR Biomedical Research Centre, NIHR Collaboration for Leadership in Health Research and Care (CLAHRC), NIHR Patient Safety Translational Research Centre or Medtech and In Vitro Diagnostic Cooperative in all study sites?

Please see information button for further details.

◯ Yes ◉ No

Please see information button for further details.

5b. Do you wish to make an application for the study to be considered for NIHR Clinical Research Network (CRN) Support and inclusion in the NIHR Clinical Research Network Portfolio?

Please see information button for further details.

(•) Yes ( ) No

The NIHR Clinical Research Network provides researchers with the practical support they need to make clinical studies happen in the NHS e.g. by providing access to the people and facilities needed to carry out research "on the ground".

If you select yes to this question, you must complete a NIHR Clinical Research Network (CRN) Portfolio Application Form (PAF) immediately after completing this project filter question and before submitting other applications. Failing to complete the PAF ahead of other applications e.g. HRA Approval, may mean that you will be unable to access NIHR CRN Support for your study.

6. Do you plan to include any participants who are children?

( ) Yes (•) No

7. Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?

( ) Yes (•) No

Answer Yes if you plan to recruit living participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research with the living requiring consent in law. This includes use of identifiable tissue samples or personal information, except where application is being made to the Confidentiality Advisory Group to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service or who are offenders supervised by the probation service in England or Wales?

( ) Yes (•) No

9. Is the study or any part of it being undertaken as an educational project?

( ) Yes (•) No

10. Will this research be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs?

( ) Yes (•) No

11. Will identifiable patient data be accessed outside the care team without prior consent at any stage of the project (including identification of potential participants)?

( ) Yes (•) No

NOTICE OF SUBSTANTIAL AMENDMENT

Please use this form to notify the main REC of substantial amendments to all research other than clinical trials of investigational medicinal products (CTIMPs).
The form should be completed by the Chief Investigator using language comprehensible to a lay person.

Details of Chief Investigator:

	Title	Forename/Initials	Surname
	Professor	Alice	Turner
Work Address	Institute for Applied Health Research		
	University of Birmingham		
	Birmingham		
PostCode	B15 2TT		
Email	a.m.turner@bham.ac.uk		
Telephone	01214240325		
Fax			

For guidance on this section of the form refer to the guidance

Full title of study:	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'
Lead sponsor:	University of Birmingham
Name of REC:	London - Stanmore
REC reference number:	19/LO/1939

International Standard Randomised Controlled Trial Number (ISRCTN):	
ClinicalTrials.gov Identifier (NCT number):	

Additional reference number(s):

Ref.Number Description	Reference Number

Name of lead R&D office:	University Hospitals Birmingham NHS Foundation Trust
Date study commenced:	30-Jan-2020
Protocol reference (if applicable), current version and date:	V3.0 Vd13-Jan-2020
Amendment number and date:	SA01 12-May-2020

Type of amendment

(a) Amendment to information previously given in IRAS

○ Yes ◉ No

If yes, please refer to relevant sections of IRAS in the "summary of changes" below.

(b) Amendment to the protocol

◉ Yes ○ No

If yes, please submit either the revised protocol with a new version number and date, highlighting changes in bold, or a document listing the changes and giving both the previous and revised text.

Updated Protocol submitted

(c) Amendment to the information sheet(s) and consent form(s) for participants, or to any other supporting documentation for the study

◉ Yes ○ No

If yes, please submit all revised documents with new version numbers and dates, highlighting new text in bold.

Updated PIS submitted
New Consent video submitted

Is this a modified version of an amendment previously notified and not approved?

○ Yes ◉ No

Summary of changes

Briefly summarise the main changes proposed in this amendment. Explain the purpose of the changes and their significance for the study.
If this is a modified amendment, please explain how the modifications address the concerns raised previously by the ethics committee.
If the amendment significantly alters the research design or methodology, or could otherwise affect the scientific value of the study, supporting scientific information should be given (or enclosed separately). Indicate whether or not additional scientific critique has been obtained.

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. This will in turn decrease the number of home visits (nhs limitation) by the community team without effecting the integrity of the study.

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.

Any other relevant information

Applicants may indicate any specific issues relating to the amendment, on which the opinion of a reviewing body is sought.

List of enclosed documents

Document	*Version*	*Date*
Protocol	3.1	24/04/2020
Protocol	4.0	05/05/2020
Patient Information Sheet	3.1	24/04/2020
Patient Information Sheet	4.0	05/05/2020
Consent Video	1.0	12/05/2020

Declaration by Chief Investigator

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

This section was signed electronically by Dr Alice Turner on 22/05/2020 15:11.

Job Title/Post:

Organisation:

Email:

Declaration by the sponsor's representative

I confirm the sponsor's support for this substantial amendment.

This section was signed electronically by Dr Birgit Whitman on 22/05/2020 10:24.

Job Title/Post:	Research Governance Manager
Organisation:	University of Birmingham
Email:	researchgovernance@contacts.bham.ac.uk