

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)

RECOVERY-Supportive Care

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. Will the study involve the use of any medical device without a CE Mark, or a CE marked device which has been modified or will be used outside its intended purposes?

Yes No

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)

4a. Will you be seeking data from Hospital Episode Statistics (HES) or the Secondary Uses Service (SUS)?

- Yes No

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	Gavin	Perkins
Work Address	Warwick Clinical Trials Unit		
	The University of Warwick		
	Gibbet Hill Road		
PostCode	CV4 7AL		
Email	g.d.perkins@warwick.ac.uk		
Telephone	02476 750479		
Fax			

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

Full title of study:	Ventilation Strategies in COVID-19; CPAP, High-flow, and standard care
Lead sponsor:	University of Warwick
Name of REC:	Brighton and Sussex
REC reference number:	20/HRA/1696

International Standard Randomised Controlled Trial Number (ISRCTN):	ISRCTN00000000
ClinicalTrials.gov Identifier (NCT number):	

Additional reference number(s):

Ref.Number	Description	Reference Number

Name of lead R&D office:	University Hospital Birmingham NHS Foundation Trust
Date study commenced:	03-Apr-2020
Protocol reference (if applicable), current version and date:	v3.1 24-Apr-2020
Amendment number and date:	3.0 29-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.

- Contact names and numbers – TSC and DMC sections updated
- Trial summary - Updated secondary outcomes with ICU admission
- Trial Flow Diagram - Update to the trial flow diagram to bring in line with changes from SA1 and SA3
- Section 2.4.1 – Primary – removed collection of ethnicity as a primary outcome
- Section 2.4.1 - Secondary outcomes – updated to include admission to ICU and data could be collected via data linkage as well as hospital records
- Section 2.5.1 amended inclusion criteria to allow for inpatients with suspected or proven Covid-19, not only those admitted with
- Section 2.8.1 - Update to consent process for Northern Ireland to bring protocol in line with Northern Ireland regulations
- Section 2.8.1 - Added CHI number for Scottish sites
- Section 2.9.1 – included reference to an back up randomisation system
- Section 4.1.3 - Clarification of which SAEs need reporting to remove contradiction
- Section 5.1 – Added collection of socioeconomic status and the use of data linkage. Added email address.
- Section 6.1 - Changes to timeline for interim analysis as agreed by DMC rather than fixed timepoints
- Section 6.2.4 – minor clarification
- Correction to typos and grammar where required

(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.

Update to Consent Form Consultee

5. formatting update

7. To include NHS digital and electronic Data Research & Innovation Service (eDRIS)

Footer – to clarify that this document is only applicable for use in England, Wales and Northern Ireland

Update to Consultee Cover Letter

Footer – to clarify that this document is only applicable for use in England, Wales and Northern Ireland

Patient Information Sheet

PIS on Commencement

Short Patient Information Sheet

Short PIS on Commencement

All include clarification that the Secretary of State’s for Health and Social Care (England) advice is not applicable to data from Northern Ireland patients

Addition of a new Easy Read PIS (print & screen).

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.

This amendment is mainly;

- 1) to bring the protocol and study documentation in line with regulations in Northern Ireland. As part of this, we are removing the use of the assent form in Northern Ireland. Sites in Northern Ireland will use the deferred consent form and consultee route.
- 2) Amendment to the secondary outcomes to include ICU admission and to add the use of data linkage to assist with data collection.
- 3) There are minor clarifications and updates throughout the protocol as detailed above.
- 4) This amendment is to add an Easy Read PIS (print & screen) to improve the accessibility of the trial for patients and consultees.

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

<i>Document</i>	<i>Version</i>	<i>Date</i>
Protocol	4.0	29/05/2020
Consent Form Consultee	3.0	29/05/2020
Consultee cover letter	2.0	29/05/2020
Patient Information Sheet	4.0	29/05/2020
PIS on commencement	2.0	29/05/2020
Short PIS	4.0	29/05/2020
Short PIS on commencement	2.0	29/05/2020
Easy Read PIS (print)	1.0	29/05/2020
Easy Read PIS (screen)	1.0	29/05/2020

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 Prof Gavin Perkins on 01/06/2020 10:02.

Job Title/Post: CI
 Organisation: University of Warwick
 Email: g.d.perkins@warwick.ac.uk

Declaration by the sponsor's representative

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

This section was signed electronically by Mrs Jane Prewett on 01/06/2020 10:04.

Job Title/Post: Head of Research Governance

Organisation: University of Warwick

Email: jane.prewett@warwick.ac.uk