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)*

- [x] England
- [ ] Scotland
- [x] Wales
- [x] 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?

- [x] IRAS Form
- [x] 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:	
REC reference number:	

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:	v3.0
Amendment number and date:	1.0 21-Apr-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.

Clarification of resource account details throughout (recovery-rs@warwick.ac.uk)
Trial summary: Update to the Trial Title: RECOVERY-RS Respiratory Support: Respiratory Strategies in COVID-19; CPAP, High-flow, and standard care
Updates throughout to reference that the trial will also be open in Scotland (section 1.5, 2.1) IRAS Filter Question 3, A6.2, A30-1, A40, A50, A71-2, A72 and B11
Section 1.5 – update to reflect the consent procedures in England, Wales and Northern Ireland (IRAS A6-2, A29, A30-1, A31, B2, B7, B8, B7-2, B8-2, B11) and updated to include Scotland.
Figure 1 – updated to include consent possible after screening
Section 2.4.1 – updated to reflect appropriate data linkage (IRAS A6-2) and that ethnicity as well as all-cause mortality will be collected via data linkage
Section 2.4.1 – addition of secondary outcome 'duration of invasive ventilation' (IRAS A-11)
Section 2.5.1 – clarification that patients will be eligible with FiO2 more than or equal to 0.4 and SpO2 less than or equal to 94%. (IRAS A17-1)
Section 2.8 – Section updated to include Scotland consent processes. England, Wales and Northern Ireland section amended to reflect new consent approach in these nations (IRAS A6-2, A29, A30-1, A31, B2, B7, B8, B7-2, B8-2, B11)
Table 1 – updated to reflect amended consent approach in England, Wales and Northern Ireland. (IRAS A6-2, A29, A30-1, A31, B2, B7, B8, B7-2, B8-2, B11)
Section 2.9.1 – reference to online randomisation removed and inclusion of the interactive voice response system. (IRAS A-61)
Section 2.10.1 – clarification of initial CPAP settings that are being collected on the CRF. (IRAS A-13)
Section 2.10.2 – clarification of the initial HFNO settings that are being collected on the CRF. (IRAS A-13)
Section 2.11.2 – removal of reference that CTU staff will be blind to the study arm
Table 2 – removal of Visit 2 Day 2 for clarity for sites.
Section 4.1.1 – deletion of AE 'hypercapnia' and inclusion of 'respiratory acidosis with pH <7.25 prior to intubation
Sections 4.1.3, 4.1.4 and 4.2 – clarification added to the SAE review process
Section 5.1 – Detail added to clarify the data collected following randomisation. Clarification that ethnicity and mortality will be collected via data linkage. Updated to reflect appropriate data linkage across the devolved nations. Reference to onsite monitoring removed.
Section 6.2 – removal of detail regarding interim analyses and inclusion of reference to statistical analysis plan for formal stopping rules.

Minor clarifications and typo corrections throughout.

(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.

Addition information sheets and consent form at trial commencement to be included.

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.

The main changes proposed in this amendment are
1) the inclusion of Scotland as a participating nation, the purpose of including Scotland is this allows for additional sites to be set-up to recruitment and will aid the trial in recruiting to time and target.
2) Amendments to the consent procedures. Information has been added to reflect the consent procedures applicable for Scotland as per the Adults with Incapacity (Scotland) Act 2000. The consent procedure for Scotland details that patients with capacity will review the trial information and provide verbal consent prior to entering the trial. If a patient lacks capacity they will not be randomised. We have updated the England, Wales and Northern Ireland consent procedures to align with this approach, patients with capacity to provide informed verbal consent upfront, though the trial is maintaining the option for emergency waiver when a patient lacks capacity due to a number of reasons including the perceived delay to administering urgent treatment whilst identifying a personal/professional consultee.
3) Clarification has been added to the eligibility criteria to confirm that patients would be eligible with FiO2 more than or equal to 0.4 and SpO2 less than or equal to 94%. It was the intention that these patients would be included and was missed in the initial protocol. This update also brings the criteria in line with national guidelines.
There are minor clarifications and updates throughout as detailed in the protocol section above.

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*
Patient Information Sheet at Commencement	v1.0	21/04/2020
Short Patient Information Sheet at Commencement	v1.0	21/04/2020
Consent Form at Commencement	v1.0	21/04/2020
Recovery-RS Protocol Tracked	v2.1	21/04/2020
RECOVERY-RS Protocol Clean	v3.0	21/04/2020

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 21/04/2020 13:41.

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 21/04/2020 13:52.

Job Title/Post:	Head of Research Governance
Organisation:	University of Warwick
Email:	jane.prewett@warwick.ac.uk