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)
COVER: COvid-19 Vascular sERvice Study

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. Please answer the following question(s):

a) Will you be processing identifiable data at any stage of the research (including in the identification of participants)? ( ) Yes (●) No

b) Please confirm that you will be processing only anonymised or pseudonymised data:

(●) Yes, only anonymised or pseudonmyised data ( ) No

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

☑ 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
- [ ] Confidentiality Advisory Group (CAG)
- [ ] Her Majesty's Prison and Probation Service (HMPPS)

Most research projects require review by a REC within the UK Health Departments' Research Ethics Service. Is your study exempt from REC review?

( ) 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

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

Integrated Research Application System
Application Form for Study limited to working with data (specific project only)

IRAS Form (project information)

Please refer to the E-Submission and Checklist tabs for instructions on submitting this application.

The Chief Investigator should complete this form. Guidance on the questions is available wherever you see this symbol displayed. We recommend reading the guidance first. The complete guidance and a glossary are available by selecting Help.

Please define any terms or acronyms that might not be familar to lay reviewers of the application.

Short title and version number: (maximum 70 characters - this will be inserted as header on all forms)
COVER: COvid-19 Vascular sERvice Study

Please complete these details after you have booked the REC application for review.

REC Name:

REC Reference Number:

Submission date:
30/03/2020

PART A: Core study information

1. ADMINISTRATIVE DETAILS

A1. Full title of the research:

The COVID-19 Vascular sERvice Study

A3-1. Chief Investigator:

Title	Forename/Initials	Surname
Professor	Christopher	Imray

Post	Professor of Vascular Surgery, consultant vascular and transplant surgeon
Qualifications	PhD FRCS FRCP FRGS
ORCID ID	0000 0001 9889 6308
Employer	University Hospital Coventry and Warwickshire
Work Address	University Hospital of Coventry and Warwickshire Clifford Bridge Road Coventry
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Work E-mail	christopher.imray@uhcw.nhs.uk
* Personal E-mail	christopher.imray@uhcw.nhs.uk
Work Telephone	02476965222

* Personal Telephone/Mobile 07531418104
Fax

** This information is optional. It will not be placed in the public domain or disclosed to any other third party without prior consent.*
A copy of a current CV (maximum 2 pages of A4) for the Chief Investigator must be submitted with the application.

A4. Who is the contact on behalf of the sponsor for all correspondence relating to applications for this project?
This contact will receive copies of all correspondence from REC and HRA/R&D reviewers that is sent to the CI.

	Title	Forename/Initials	Surname
	Miss	Becky	Haley
Address	Research and Development		
	University Hospitals Coventry & Warwickshire NHS Trust		
	Clifford Bridge Road, Coventry		
Post Code	CV2 2DX		
E-mail	Becky.Haley@uhcw.nhs.uk		
Telephone	02476 966198		
Fax			

A5-1. Research reference numbers. *Please give any relevant references for your study:*

Applicant's/organisation's own reference number, e.g. R & D (if available):	RB485520
Sponsor's/protocol number:	1.0
Protocol Version:	1.0
Protocol Date:	27/03/2020
Funder's reference number (enter the reference number or state not applicable):	NA

Project website: vascular-research.net/projects

Additional reference number(s):

Ref.Number Description	Reference Number

Registration of research studies is encouraged wherever possible. You may be able to register your study through your NHS organisation or a register run by a medical research charity, or publish your protocol through an open access publisher. If you have registered your study please give details in the "Additional reference number(s)" section.

A5-2. Is this application linked to a previous study or another current application?

○ Yes ◉ No

Please give brief details and reference numbers.

2. OVERVIEW OF THE RESEARCH

To provide all the information required by review bodies and research information systems, we ask a number of specific questions. This section invites you to give an overview using language comprehensible to lay reviewers and members of the public. Please read the guidance notes for advice on this section.

A6-1. Summary of the study. *Please provide a brief summary of the research (maximum 300 words) using language*

easily understood by lay reviewers and members of the public. Where the research is reviewed by a REC within the UK Health Departments' Research Ethics Service, this summary will be published on the Health Research Authority (HRA) website following the ethical review. Please refer to the question specific guidance for this question.

The Coronavirus Disease 2019 (COVID-19) pandemic has resulted in the postponement and cancellation of routine and urgent vascular work in favour of disaster-mitigation. Emergency work is ongoing, but national guidance has been provided by vascular organisations recommending endovascular treatments rather than open where possible, alternative follow up regimes and increasing use of non-clinician teams. The aim is to reduce reliance on general anaesthetic and high-dependency care post-operatively. This is a significant deviation from pre-COVID practice. It will create a backlog of work, or lead to treatments with less evidence base.

All this is vital to adapt to current circumstances, but will have a major impact on vascular clinicians and patients in the coming months. The majority of patients with vascular disease are elderly and co-morbid making them the highest risk group for COVID-19-related mortality.

There is an urgent need to quantify the impact of the pandemic on the provision of vascular and endovascular surgery and the adjustments made to standard vascular practice. The COvid-19 Vascular sERvice (COVER) study is a three-tiered study designed to capture global data on vascular practices during the pandemic.

1. Evaluation of structure, processes and interventions at a unit level during the pandemic. We will report results 'live' using web-hosting, and feedback to those creating relevant guidelines. Results are anonymous, and will be reported on a regional level. No patient data will be collected.

2. Collect prospectively, all vascular operations/procedures undertaken during the COVID-19 crisis. We will capture early, mid and late outcomes for these patients.

3. Information regarding the fate of consecutive vascular referrals (limb ischaemia, carotid disease, aneurysmal disease, acute aortic syndromes) during the pandemic. This is to see how patients cope with delayed procedures, and the effect on their condition and late outcomes.

A6-2. Summary of main issues. *Please summarise the main ethical, legal, or management issues arising from your study and say how you have addressed them.*

Not all studies raise significant issues. Some studies may have straightforward ethical or other issues that can be identified and managed routinely. Others may present significant issues requiring further consideration by a REC, HRA, or other review body (as appropriate to the issue). Studies that present a minimal risk to participants may raise complex organisational or legal issues. You should try to consider all the types of issues that the different reviewers may need to consider.

This study does not include any patient identifiable data, and will use a secure database for data entry.

However, individual centres will need to maintain a list of patients uploaded onto RedCap in order to permit follow up for late outcomes at 6 months and 1 year. This will require review of electronic records, or paper records, depending on the centres practice.

Ethical issues: The study will not contain any identifiable data. Therefore patient consent will not be sought for upload onto the database. However individual centres will need to have a record of patients locally and securely, as per their own regulations.

3. PURPOSE AND DESIGN OF THE RESEARCH

A7. Select the appropriate methodology description for this research. *Please tick all that apply*:

- ☐ Case series/ case note review
- ☐ Case control
- ☑ Cohort observation
- ☐ Controlled trial without randomisation
- ☐ Cross-sectional study
- ☐ Database analysis

- ☐ Epidemiology
- ☐ Feasibility/ pilot study
- ☐ Laboratory study
- ☐ Metanalysis
- ☐ Qualitative research
- ☑ Questionnaire, interview or observation study
- ☐ Randomised controlled trial
- ☐ Other (please specify)

A10. What is the principal research question/objective? *Please put this in language comprehensible to a lay person.*

The study is in three parts. The primary objectives for each part are as follows:

Part 1: To objectively capture the changes made to the structure and delivery of vascular surgery at unit level throughout the COVID-19 pandemic, and compare it to the guidance provided by the VSGBI as well as other national/international committees (e.g. the Society for Vascular Surgery, the European Society for Vascular Surgery).

Part 2: To capture data on all vascular and endovascular interventions being undertaken throughout the COVID-19 pandemic. It is anticipated that the type and nature of vascular procedures performed will change due to the pressures on the wider healthcare service and rationing of resources or in-patient beds.

Part 3: To identify how the management of all referred urgent vascular cases changes throughout the COVID-19 pandemic. This is to identify the many anticipated deviations from pre-pandemic best practice or pre-defined standards for acute/urgent cases due to healthcare pressures in the form of delays to treatment. This will focus on chronic limb-threatening ischaemia, symptomatic carotid disease, acute aortic syndromes and aneurysmal disease.

A11. What are the secondary research questions/objectives if applicable? *Please put this in language comprehensible to a lay person.*

Parts 2 and 3 will include follow up of mid- and late condition related events, at 6 months and 1 year. These will include amputation free survival, overall mortality, aortic specific morbidity, aortic/aneurysm specific mortality, major stroke or stroke related mortality.

A12. What is the scientific justification for the research? *Please put this in language comprehensible to a lay person.*

The Coronavirus Disease 2019 (COVID-19) pandemic is having a profound impact on our healthcare systems. The pace of change has been unexpected. For vascular patients, this has meant their operations are being delayed and cancelled. For vascular surgeons, it has meant patients coming to hospital later than usual. They are facing huge pressures, and major decisions on who to treat and who to delay. These are not unique to vascular teams. It has also meant they have been helping their medical colleagues to look after patients with COVID-19. This will likely persist long after the peak of the pandemic has passed.

We know that vascular conditions are often slow to build, and cause chronic pain, a decline in physical fitness, repeat infections, or unexpected strokes. Vascular patients often have lots of other medical issues, which makes their risk of having an anaesthetic and operation, higher that average. They are also amongst the highest risk group for COVID-19-related mortality.

There is a need to gather information on 1. How the vascular patients who do receive an emergency operation are managed, and their outcomes; this will show us if the surgical risks have increased dramatically, and if so, if they are now greater than surgery for some of our most common procedures. 2. How the patients experiencing delays and deferrals to their procedures will do over the coming months.

Results will inform planning for the coming months, and may lead to a change in what we know about the outcomes from delays in surgery for specific conditions in the era of improved best medical therapy.

A13. Please summarise your design and methodology. *It should be clear exactly what will happen to the research participant, how many times and in what order. Please complete this section in language comprehensible to the lay person. Do not simply reproduce or refer to the protocol. Further guidance is available in the guidance notes.*

Design:
A prospective study
Methodology:
Prospective recruitment of consecutive patients onto a RedCap data collection tool.
Clinicians will be asked to enter every patients operated on (stage 2) or referred to the vascular team (stage 3) onto a bespoke, secure database.We anticipate that stage 2 will take place over 3 moths, and stage 3, 1 month.

The database has been designed by the VERN collaborative and approved by the Vascular Society.
It is possible that data collected may change as the study evolves, and we receive feedback from participating centres. Approval for this will be sought as appropriate. Patient identifiable data will NEVER be collected.

Analysis:
Interim analyses will be performed periodically to inform data collection and provide participating centres with up to date information on the impact of the pandemic. The first analysis will be performed once 50 patients have been entered onto the database, and the frequency of subsequent analyses will be agreed based on the findings. Hospital-level data will not be released or published by the VERN team, but individual centres will have full access to their own data.

4. RISKS AND ETHICAL ISSUES

RESEARCH PARTICIPANTS

A15. What is the sample group or cohort to be studied in this research?

Select all that apply:

- [ ] Blood
- [ ] Cancer
- [x] Cardiovascular
- [ ] Congenital Disorders
- [ ] Dementias and Neurodegenerative Diseases
- [ ] Diabetes
- [ ] Ear
- [ ] Eye
- [ ] Generic Health Relevance
- [ ] Infection
- [ ] Inflammatory and Immune System
- [ ] Injuries and Accidents
- [ ] Mental Health
- [ ] Metabolic and Endocrine
- [ ] Musculoskeletal
- [ ] Neurological
- [ ] Oral and Gastrointestinal
- [ ] Paediatrics
- [ ] Renal and Urogenital
- [ ] Reproductive Health and Childbirth
- [ ] Respiratory
- [ ] Skin
- [ ] Stroke

Gender:	Male and female participants
Lower age limit: 18	Years
Upper age limit: 100	No upper age limit

A17-1. Please list the principal inclusion criteria (list the most important, max 5000 characters).

1. Any patient being referred the vascular team
2. Any patient being operated on by a member of the vascular team

A17-2. Please list the principal exclusion criteria (list the most important, max 5000 characters).

1. A patient who is referred to the vascular team, who is judged not to have a vascular condition
2. A patient being operated on by the vascular team, in whom the primary pathology isn't a vascular condition

RECRUITMENT AND INFORMED CONSENT

In this section we ask you to describe the recruitment procedures for the study. Please give separate details for different study groups where appropriate.

A27-1. How will potential participants, records or samples be identified? Who will carry this out and what resources will be used?*For example, identification may involve a disease register, computerised search of GP records, or review of medical records. Indicate whether this will be done by the direct healthcare team or by researchers acting under arrangements with the responsible care organisation(s).*

The vascular team at each participating centre will identify consecutive patients from their referrals and operating lists.

The type of medical records used i.e. digital or paper will depend on each hospital's practice. Hospitals will be expected to obtain onsite approvals before uploading data.

Each centre will be asked to maintain a record of patients included in their centre's database. This list should be kept securely, and will not be shared with anyone else. This is to permit medium and late follow up.

A33-2. What arrangements will you make to comply with the principles of the Welsh Language Act in the provision of information to participants in Wales?

We will comply with Welsh language requirements and the patient information sheet, consent form and any other required documents will be available in wels if requested. Patients will be offered a Welsh language interpreter during ay relevant discussions around the study. however all documents used for data collection will remain in English.

CONFIDENTIALITY

In this section, personal data means any data relating to a participant who could potentially be identified. It includes pseudonymised data capable of being linked to a participant through a unique code number.

A37. Please describe the physical security arrangements for storage of personal data during the study?

All data collected by the VERN study team will be electronic. Any paper copies of the data collection form used by the individual centres will not contain any patient identifiable data.
Centres will be asked to keep an electronic record of patients included on the database, to permit follow up at 6 months and 1 year. This follow up will use electronic health records.
Any paper copies of patient numbers, or data collections sheets before upload onto RedCap must be kept in a secure locked office. We will expect each centre to have their own standards in place, in accordance with UK guidance and regulations.

Storage and use of data after the end of the study

A41. Where will the data generated by the study be analysed and by whom?

The data will be stored by the University of Birmingham GlobalSurg team. Once 50 patients have been uploaded, the data will be analysed by members of the VERN team. Raw data will not be released to any other individual or team.
At the time of writing, there is no access to university computers for any members of the team.
The data will be anonymised. Therefore it will be sent to members using secure email, and analysed on NHS computers.

A42. Who will have control of and act as the custodian for the data generated by the study?

Title	Forename/Initials	Surname
Mr	Aneel	Bhangu

Post	Senior Lecturer in Colorectal and General surgery
Qualifications	Clinician Scientist in Global Surgery, FRCS, PhD, MBChB
Work Address	Second Floor Institute of Translational Medicine Heritage Building University of Birmingham
Post Code	B15 2TH
Work Email	a.a.bhangu@bham.ac.uk
Work Telephone	
Fax	

A44. For how long will you store research data generated by the study?

Years: 25
Months: 0

A45. Please give details of the long term arrangements for storage of research data after the study has ended. *Say where data will be stored, who will have access and the arrangements to ensure security.*

The data will be stored on systems managed by the University of Birmingham. After the study has ended, this will continue for a minimum of five years. If there is a need to keep the research data for any longer, we will apply for permission.

INCENTIVES AND PAYMENTS

A47. Will individual researchers receive any personal payment over and above normal salary, or any other benefits or incentives, for taking part in this research?

○ Yes ◉ No

A48. Does the Chief Investigator or any other investigator/collaborator have any direct personal involvement (e.g. financial, share holding, personal relationship etc.) in the organisations sponsoring or funding the research that may give rise to a possible conflict of interest?

○ Yes ◉ No

NOTIFICATION OF OTHER PROFESSIONALS

PUBLICATION AND DISSEMINATION

A50. Will the research be registered on a public database?

○ Yes ◉ No

Please give details, or justify if not registering the research.
Study will be registered with the R&D departments and will be available on the HRA website

Registration of research studies is encouraged wherever possible.
You may be able to register your study through your NHS organisation or a register run by a medical research charity, or publish your protocol through an open access publisher. If you are aware of a suitable register or other method of publication, please give details. If not, you may indicate that no suitable register exists. Please ensure that you have entered registry reference number(s) in question A5-1.

A51. How do you intend to report and disseminate the results of the study?*Tick as appropriate:*

- ☑ Peer reviewed scientific journals
- ☐ Internal report
- ☑ Conference presentation
- ☑ Publication on website
- ☐ Other publication
- ☐ Submission to regulatory authorities
- ☐ Access to raw data and right to publish freely by all investigators in study or by Independent Steering Committee on behalf of all investigators
- ☐ No plans to report or disseminate the results
- ☐ Other (please specify)

A52. If you will be using identifiable personal data, how will you ensure that anonymity will be maintained when publishing the results?

NA

5. Scientific and Statistical Review

A54. How has the scientific quality of the research been assessed?*Tick as appropriate:*

- ☑ Independent external review
- ☐ Review within a company
- ☐ Review within a multi−centre research group
- ☑ Review within the Chief Investigator's institution or host organisation
- ☑ Review within the research team
- ☐ Review by educational supervisor
- ☐ Other

Justify and describe the review process and outcome. If the review has been undertaken but not seen by the researcher, give details of the body which has undertaken the review:
This has been a rapid process. The protocol and data collection tools have been extensively reviewed by all members of the VERN executive committee.

It has been reviewed externally and independently by members of the Vascular Society of Great Britain and Ireland.

It has also been reviewed by the sponsor.

For all studies except non-doctoral student research, please enclose a copy of any available scientific critique reports, together with any related correspondence.

For non-doctoral student research, please enclose a copy of the assessment from your educational supervisor/ institution.

A56. How have the statistical aspects of the research been reviewed? *Tick as appropriate:*

- ☐ Review by independent statistician commissioned by funder or sponsor
- ☐ Other review by independent statistician
- ☐ Review by company statistician
- ☐ Review by a statistician within the Chief Investigator's institution
- ☑ Review by a statistician within the research team or multi−centre group
- ☐ Review by educational supervisor
- ☐ Other review by individual with relevant statistical expertise
- ☐ No review necessary as only frequencies and associations will be assessed – details of statistical input not required

In all cases please give details below of the individual responsible for reviewing the statistical aspects. If advice has been provided in confidence, give details of the department and institution concerned.

	Title Forename/Initials Surname
Department	Department of population health sciences
Institution	Bristol Medical School
Work Address	39 Whatley Road Bristol
Post Code	BS8 2PS
Telephone	
Fax	
Mobile	
E-mail	

Please enclose a copy of any available comments or reports from a statistician.

A57. What is the primary outcome measure for the study?

There are three parts of the study, with a primary outcome measure for each, detailed below:

1. To objectively capture the changes made to the structure and delivery of vascular surgery at unit level throughout the COVID-19 pandemic, and compare it to the guidance provided by the VSGBI as well as other national/international committees (e.g. the Society for Vascular Surgery, the European Society for Vascular Surgery).

2. To document all vascular surgery and interventional procedures performed throughout the COVID-19 pandemic across participating centres.

3. To document and quantify deviation from "best vascular practice" and the impact on patient care, specifically focusing on:
- Chronic Limb Threatening Ischaemia (CLTI):
- Symptomatic carotid disease
- Abdominal Aortic Aneurysm (AAA)
- Acute Aortic syndrome (AAS)

A58. What are the secondary outcome measures?*(if any)*

Part 1 does not have any secondary outcomes.

The secondary outcome measures for parts 2 and 3 of the study are as follows:

2. Outcomes following intervention. These will be reviewed at 6 and 12 months following intervention. They will focus on re-admissions, re-intervention, all cause mortality, operation specific morbidity, morbidity and if COVID-19 +ve, respiratory outcomes and admission to intensive care unit.

3. To collect longitudinal data to identify condition-specific outcomes for these patients at 6 months and 1 year.

A59. What is the sample size for the research? *How many participants/samples/data records do you plan to study in total? If there is more than one group, please give further details below.*

Total UK sample size: 200
Total international sample size (including UK): 400
Total in European Economic Area:

Further details:
Stages 2 and 3 combined, across all UK centres have to be estimated, as we have no idea how the situation will impact numbers of patients seen and managed.

Numbers will be much lower than normal due to the planned cancellation of non-emergency surgery, and changing ways of managing acute conditions, as per emerging guidelines.

A60. How was the sample size decided upon? *If a formal sample size calculation was used, indicate how this was done, giving sufficient information to justify and reproduce the calculation.*

It has been necessary to estimate the number. We have no idea how the COVID-19 outbreak has impacted UK numbers, only that anecdotal evidence suggests operating is minimal. There is no calculation available.

A61. Will participants be allocated to groups at random?

○ Yes ◉ No

A62. Please describe the methods of analysis (statistical or other appropriate methods, e.g. for qualitative research) by which the data will be evaluated to meet the study objectives.

A detailed statistical analysis plan will be written. Reports will include description of the primary and secondary outcomes in the cohort using statistical methods appropriate for the data i.e. distribution, variability, categorical or continuous variables.

Interim analyses will be performed periodically to inform data collection and provide participating centres with up to date information on the impact of the pandemic. The first analysis will be performed once 50 patients have been entered onto the database, and the frequency of subsequent analyses will be agreed based on the findings.

Country-level analyses will only be conducted with permission of lead investigators from each participating country.

6. MANAGEMENT OF THE RESEARCH

A63. Other key investigators/collaborators. *Please include all grant co−applicants, protocol co−authors and other key members of the Chief Investigator's team, including non-doctoral student researchers.*

	Title	Forename/Initials	Surname
	Miss	Ruth	Benson
Post	Clinical lecturer and SPR in vascular surgery		
Qualifications	BSc MBChB PhD		
Employer	University of Birmingham		
Work Address	Department of Institute of Cancer and Genomic Sciences Institute of Translational Medicine University of Birmingham		
Post Code	B15 2TH		
Telephone			
Fax			
Mobile	07810674667		
Work Email	r.a.benson@bham.ac.uk		

	Title	Forename/Initials	Surname
	Mr	Sandip	Nandhra
Post	NIHR Academic Clinical Lecturer / Specialist Vascular Registrar		
Qualifications	MBBS PGCDI MD FRCS FHEA		
Employer	Newcastle University		
Work Address	Northern Vascular Centre Freeman Newcastle		
Post Code	NE77DN		
Telephone			
Fax			
Mobile			
Work Email	sjnandhra@gmail.com		

	Title	Forename/Initials	Surname
	Mr	Joseph	Shalhoub
Post	Consultant Vascular Surgeon, Honorary Clinical Senior Lecturer		
Qualifications	BSc MBBS FHEA PhD MEd FRCS FEBVS		
Employer	Imperial College Healthcare NHS Trust		
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Post Code	W2 1NY		
Telephone			
Fax			
Mobile			
Work Email	j.shalhoub@imperial.ac.uk		

	Title	Forename/Initials	Surname
	Mr	Athanasios	Saratzis
Post	Assistant Professor of Vascular surgery, consultant vascular surgeon		
Qualifications			
Employer	University of Leicester Department of Cardiovascular Sciences		
Work Address	NIHR Leicester Biomedical Research Centre British Heart Foundation (BHF) Cardiovascular Research Facility		

	Glenfield Hospital, Leicester
Post Code	LE39QP
Telephone	07531418104
Fax	
Mobile	
Work Email	as875@le.ac.uk

Title	Forename/Initials	Surname
Mr	Dave	Bosanquet

Post	Consultant Vascular surgeon, honorary senior lecturer
Qualifications	
Employer	Aneurin Bevin University Health Board
Work Address	Cromwell Road
	Risca
Post Code	NP11 6YF
Telephone	01495745865
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Mobile	
Work Email	david.bosanquet@wales.nhs.uk

Title	Forename/Initials	Surname
Miss	Rachael	Forsythe

Post	Specialty Registrar in Vascular Surgery
Qualifications	MBChB PhD MRCS
Employer	Scotland deanery
Work Address	
Post Code	
Telephone	
Fax	
Mobile	
Work Email	rachael.forsythe@ed.ac.uk

Title	Forename/Initials	Surname
Miss	Sarah	Onida

Post	NIHR clinical lecturer in vascular surgery
Qualifications	
Employer	Imperial College
Work Address	Academic section, Vascular surgery dept
	Imperial College London
	Charing Cross Road
Post Code	W68RF
Telephone	
Fax	
Mobile	
Work Email	s.onida@imperial.ac.uk

	Title	Forename/Initials	Surname
	Mr	George	Dovell
Post	NIHR academic clinical fellow, ST5 in Vascular surgery		
Qualifications			
Employer	University of Bristol		
Work Address	Canynge Hall		
	Bristol Medical School		
	Bristol		
Post Code	BS82PS		
Telephone			
Fax			
Mobile			
Work Email	gd17321@bristol.ac.uk		

	Title	Forename/Initials	Surname
	Miss	Louise	Hitchman
Post	NIHR Academic clinical fellow		
Qualifications			
Employer	Hull university teaching hospital		
Work Address	Hull royal infirmary		
	Anlaby Road		
	Hull		
Post Code	HU32JZ		
Telephone			
Fax			
Mobile			
Work Email	louisehhitchman@gmail.com		

	Title	Forename/Initials	Surname
	Mr	Nikesh	Dattani
Post	ST8 in Vascular Surgery		
Qualifications			
Employer	Queen Elizabeth Hospital		
Work Address	QE Hospital		
	Edgebaston		
	Birmingham		
Post Code	B152TH		
Telephone			
Fax			
Mobile			
Work Email	nikeshdattani@nhs.net		

	Title	Forename/Initials	Surname
	Mr	Ryan	Preece
Post	Core surgical trainee		
Qualifications			
Employer	Cheltenham General Hospital		
Work Address	Cheltenham General Hospital		
	Sandford Road		

Post Code	GL537AN
Telephone	
Fax	
Mobile	
Work Email	ryan.preece1@nhs.net

Title	Forename/Initials	Surname
Mr	Graeme	Ambler

Post	NIHR Academic Clinical Lecturer in Vascular Surgery
Qualifications	MB BChir BSc (hons) PhD MRCS
Employer	University of Bristol
Work Address	Canynge Hall University of Bristol medical school Whatley road
Post Code	BS82PS
Telephone	
Fax	
Mobile	
Work Email	Graeme.ambler@bristol.ac.uk

A64. Details of research sponsor(s)

A64-1. Sponsor

Lead Sponsor

Status:
- (●) NHS or HSC care organisation
- ( ) Academic
- ( ) Pharmaceutical industry
- ( ) Medical device industry
- ( ) Local Authority
- ( ) Other social care provider (including voluntary sector or private organisation)
- ( ) Other

Commercial status: Non-Commercial

If Other, please specify:

Contact person

Name of organisation	University Hospital of Coventry and Warwickshire NHS Trust
Given name	Becky
Family name	Haley
Address	Research & Development, 4th Floor Rotunda
Town/city	Coventry
Post code	CV2 2DX
Country	UNITED KINGDOM
Telephone	02476 966198

Fax	
E-mail	Becky.Haley@uhcw.nhs.uk

A65. Has external funding for the research been secured?

Please tick at least one check box.

- [ ] Funding secured from one or more funders
- [ ] External funding application to one or more funders in progress
- [x] No application for external funding will be made

What type of research project is this?

- ○ Standalone project
- ○ Project that is part of a programme grant
- ○ Project that is part of a Centre grant
- ◉ Project that is part of a fellowship/ personal award/ research training award
- ○ Other

Other – please state:

A66. Has responsibility for any specific research activities or procedures been delegated to a subcontractor (other than a co-sponsor listed in A64-1) ? *Please give details of subcontractors if applicable.*

○ Yes ◉ No

A67. Has this or a similar application been previously rejected by a Research Ethics Committee in the UK or another country?

○ Yes ◉ No

Please provide a copy of the unfavourable opinion letter(s). You should explain in your answer to question A6-2 how the reasons for the unfavourable opinion have been addressed in this application.

A68-1. Give details of the lead NHS R&D contact for this research:

	Title	Forename/Initials	Surname
	Miss	Sonia	Kandola
Organisation	University Hospital Coventry and Warwickshire NHS Trust		
Address	University Hospital of Coventry and Warwickshire		
	Clifford Bridge Road		
	Coventry		
Post Code	CV2 2DX		
Work Email	sonia.kandola@uhcw.nhs.uk		
Telephone	02476 966195		
Fax			
Mobile			

Details can be obtained from the NHS R&D Forum website: http://www.rdforum.nhs.uk

A68-2. Select Local Clinical Research Network for NHS Organisation identified in A68-1:

West Midlands

For more information, please refer to the question specific guidance.

A69-1. How long do you expect the study to last in the UK?

Planned start date: 15/04/2020
Planned end date: 16/06/2021
Total duration:
Years: 1 Months: 2 Days: 2

A71-1. Is this study?

- ○ Single centre
- ◉ Multicentre

A71-2. Where will the research take place? *(Tick as appropriate)*

- ☑ England
- ☑ Scotland
- ☑ Wales
- ☑ Northern Ireland
- ☐ Other countries in European Economic Area

Total UK sites in study >10

Does this trial involve countries outside the EU?

○ Yes ◉ No

A72. Which organisations in the UK will host the research?*Please indicate the type of organisation by ticking the box and give approximate numbers if known:*

☑ NHS organisations in England	8
☑ NHS organisations in Wales	2
☑ NHS organisations in Scotland	2
☑ HSC organisations in Northern Ireland	1
☐ GP practices in England	
☐ GP practices in Wales	
☐ GP practices in Scotland	
☐ GP practices in Northern Ireland	
☐ Joint health and social care agencies (eg community mental health teams)	
☐ Local authorities	

☐ Phase 1 trial units
☐ Prison establishments
☐ Probation areas
☐ Independent (private or voluntary sector) organisations
☐ Educational establishments
☐ Independent research units
☐ Other (give details)

Total UK sites in study: 13

A73-1. Will potential participants be identified through any organisations other than the research sites listed above?

○ Yes ◉ No

A74. What arrangements are in place for monitoring and auditing the conduct of the research?

The study may be monitored by the Research and Development Department at UHCW as representatives of the Sponsor, to ensure that the study is being conducted as per protocol, adhering to Research Governance and GCP. The approach to, and extent of, monitoring will be specified in a trial monitoring plan determined by the risk assessment undertaken prior to the start of the study.

A76. Insurance/ indemnity to meet potential legal liabilities

***Note:** in this question to NHS indemnity schemes include equivalent schemes provided by Health and Social Care (HSC) in Northern Ireland*

A78. Could the research lead to the development of a new product/process or the generation of intellectual property?

○ Yes ◉ No ○ Not sure

PART C: Overview of research sites

Please enter details of the host organisations (Local Authority, NHS or other) in the UK that will be responsible for the research sites. *For further information please refer to guidance.*

Investigator identifier	Research site		Investigator Name	
IN1	◉ NHS/HSC Site ○ Non-NHS/HSC Site		Forename Middle name Family name Email	Athanasios Saratzis as875@le.ac.uk
	Organisation name	UNIVERSITY HOSPITALS OF LEICESTER NHS TRUST	Qualification (MD...)	
	Address	LEICESTER ROYAL INFIRMARY INFIRMARY SQUARE LEICESTER LEICESTERSHIRE	Country	UNITED KINGDOM
	Post Code	LE1 5WW		
	Country	ENGLAND		
IN2	◉ NHS/HSC Site ○ Non-NHS/HSC Site		Forename Middle name Family name Email	Graeme Ambler Graeme.ambler@bristol.ac.uk
	Organisation name	UNIVERSITY HOSPITALS BRISTOL NHS FOUNDATION TRUST	Qualification (MD...)	
	Address	MARLBOROUGH STREET BRISTOL AVON	Country	
	Post Code	BS1 3NU		
	Country	ENGLAND		
IN3	◉ NHS/HSC Site ○ Non-NHS/HSC Site		Forename Middle name Family name Email	David Bosanquet davebosanquet@hotmail.com
	Organisation name	ANEURIN BEVAN UNIVERSITY LHB	Qualification (MD...)	
	Address	HEADQUARTERS - ST CADOC'S HOSPITAL LODGE ROAD CAERLEON NEWPORT GWENT	Country	

Post Code	NP18 3XQ
Country	WALES

IN4

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Forename	Joseph
Middle name	
Family name	Shalhoun
Email	j.shalhoub@imperial.ac.uk
Qualification (MD...)	
Country	

Organisation name	IMPERIAL COLLEGE HEALTHCARE NHS TRUST
Address	THE BAYS ST. MARYS HOSPITAL SOUTH WHARF ROAD LONDON
Post Code	W2 1BL
Country	ENGLAND

IN5

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Forename	Sandip
Middle name	
Family name	Nandhra
Email	sjnandhra@gmail.com
Qualification (MD...)	
Country	

Organisation name	THE NEWCASTLE UPON TYNE HOSPITALS NHS FOUNDATION TRUST
Address	FREEMAN HOSPITAL FREEMAN ROAD HIGH HEATON NEWCASTLE-UPON-TYNE TYNE AND WEAR
Post Code	NE7 7DN
Country	ENGLAND

IN6

◉ NHS/HSC Site
○ Non-NHS/HSC Site

Forename	Rachel
Middle name	
Family name	Forsythe
Email	rachaelforsythe@doctors.org.uk
Qualification (MD...)	
Country	

Organisation name	NHS Lothian
Address	Waverley Gate 2-4 Waterloo Place Edinburgh Scotland
Post Code	EH1 3EG
Country	SCOTLAND

IN7

(●) NHS/HSC Site

( ) Non-NHS/HSC Site

Organisation name	UNIVERSITY HOSPITALS COVENTRY AND WARWICKSHIRE NHS TRUST
Address	WALSGRAVE GENERAL HOSPITAL CLIFFORD BRIDGE ROAD COVENTRY WEST MIDLANDS
Post Code	CV2 2DX
Country	ENGLAND

Forename	Christopher
Middle name	
Family name	Imray
Email	Christopher.Imray@uhcw.nhs.uk
Qualification (MD...)	MD
Country	UNITED KINGDOM

PART D: Declarations

D1. Declaration by Chief Investigator

1. The information in this form is accurate to the best of my knowledge and belief and I take full responsibility for it.

2. I undertake to fulfil the responsibilities of the chief investigator for this study as set out in the UK Policy Framework for Health and Social Care Research.

3. I undertake to abide by the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research.

4. If the research is approved I undertake to adhere to the study protocol, the terms of the full application as approved and any conditions set out by review bodies in giving approval.

5. I undertake to notify review bodies of substantial amendments to the protocol or the terms of the approved application, and to seek a favourable opinion from the main REC before implementing the amendment.

6. I undertake to submit annual progress reports setting out the progress of the research, as required by review bodies.

7. I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to security and confidentiality of patient or other personal data, including the need to register when necessary with the appropriate Data Protection Officer. I understand that I am not permitted to disclose identifiable data to third parties unless the disclosure has the consent of the data subject or, in the case of patient data in England and Wales, the disclosure is covered by the terms of an approval under Section 251 of the NHS Act 2006.

8. I understand that research records/data may be subject to inspection by review bodies for audit purposes if required.

9. I understand that any personal data in this application will be held by review bodies and their operational managers and that this will be managed according to the principles established in the Data Protection Act 2018.

10. I understand that the information contained in this application, any supporting documentation and all correspondence with review bodies or their operational managers relating to the application:

    - Will be held by the REC (where applicable) until at least 3 years after the end of the study; and by NHS R&D offices (where the research requires NHS management permission) in accordance with the NHS Code of Practice on Records Management.
    - May be disclosed to the operational managers of review bodies, or the appointing authority for the REC (where applicable), in order to check that the application has been processed correctly or to investigate any complaint.
    - May be seen by auditors appointed to undertake accreditation of RECs (where applicable).
    - Will be subject to the provisions of the Freedom of Information Acts and may be disclosed in response to requests made under the Acts except where statutory exemptions apply.
    - May be sent by email to REC members.

11. I understand that information relating to this research, including the contact details on this application, may be held on national research information systems, and that this will be managed according to the principles established in the Data Protection Act 2018.

12. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the Health Research Authority (HRA) together with the contact point for enquiries named below. Publication will take place no earlier than 3 months after the issue of the ethics committee's final opinion or the withdrawal of the application.

Contact point for publication*(Not applicable for R&D Forms)*

HRA would like to include a contact point with the published summary of the study for those wishing to seek further

information. We would be grateful if you would indicate one of the contact points below.

- ○ Chief Investigator
- ○ Sponsor
- ○ Study co-ordinator
- ○ Student
- ◉ Other – please give details
- ○ None

Title:
Miss
Forename / Initials:
Ruth
Surname:
Benson
Post:
Academic Clinical Lecturer in Vascular Surgery
Work address:
University of Birmingham, Dept of Cancer and Genomics
Work email:
r.a.benson@bham.ac.uk
Work telephone:
07810674667

Access to application for training purposes *(Not applicable for R&D Forms)*

Optional – please tick as appropriate:

☑ I would be content for members of other RECs to have access to the information in the application in confidence for training purposes. All personal identifiers and references to sponsors, funders and research units would be removed.

This section was signed electronically by Mr Christopher Imray on 30/03/2020 11:18.

Job Title/Post:	Professor/Consultant Vascular Surgery
Organisation:	University Hospital Coventry and Warwickshire NHS Trust
Email:	christopher.imray@uhcw.nhs.uk

D2. Declaration by the sponsor's representative

If there is more than one sponsor, this declaration should be signed on behalf of the co−sponsors by a representative of the lead sponsor named at A64-1.

I confirm that:

1. This research proposal has been discussed with the Chief Investigator and agreement in principle to sponsor the research is in place.

2. An appropriate process of scientific critique has demonstrated that this research proposal is worthwhile and of high scientific quality.

3. Any necessary indemnity or insurance arrangements, as described in question A76, will be in place before this research starts. Insurance or indemnity policies will be renewed for the duration of the study where necessary.

4. Arrangements will be in place before the study starts for the research team to access resources and support to deliver the research as proposed.

5. Arrangements to allocate responsibilities for the management, monitoring and reporting of the research will be in place before the research starts.

6. The responsibilities of sponsors set out in the UK Policy Framework for Health and Social Care Research will be fulfilled in relation to this research.

   Please note: *The declarations below do not form part of the application for approval above. They will not be considered by the Research Ethics Committee.*

7. Where the research is reviewed by a REC within the UK Health Departments Research Ethics Service, I understand that the summary of this study will be published on the website of the National Research Ethics Service (NRES), together with the contact point for enquiries named in this application. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

8. Specifically, for submissions to the Research Ethics Committees (RECs) I declare that any and all clinical trials approved by the HRA since 30th September 2013 (as defined on IRAS categories as clinical trials of medicines, devices, combination of medicines and devices or other clinical trials) have been registered on a publically accessible register in compliance with the HRA registration requirements for the UK, or that any deferral granted by the HRA still applies.

This section was signed electronically by - Sponsor Representative on 30/03/2020 11:07.

Job Title/Post:	Sponsor Representative
Organisation:	University Hospitals Coventry and Warwickshire NHS Trust
Email:	R&DSponsorship@uhcw.nhs.uk