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)
Paediatric Oximetry Algorithms

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 investigation for CE marking purposes (includes investigation of a CE marked device outside its current intended purposes or in modified form)
( ) Combined clinical investigation for CE marking purposes and clinical trial of an investigational medicinal product
( ) Post-market clinical study of one or more CE marked devices within intended purposes, involving a change to standard care or randomisation between groups

- (●) Registry of a CE marked device in clinical use, involving no change to standard care or randomisation
- ( ) Performance evaluation of an in vitro diagnostic device (PEIVDD)

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
d) Will the study involve any other clinical procedures with participants (e.g. MRI, ultrasound, physical examination)?	( ) Yes (●) No

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

- [x] 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?

IMPORTANT: If your project is taking place in the NHS and is led from England select 'IRAS Form'. If your project is led from Northern Ireland, Scotland or Wales select 'NHS/HSC Research and Development Offices' and/or relevant Research Ethics Committee applications, as appropriate.

- [x] IRAS Form
- [ ] Confidentiality Advisory Group (CAG)
- [ ] National Offender Management Service (NOMS) (Prisons & Probation)

For NHS/HSC R&D Offices in Northern Ireland, Scotland and Wales the CI must create NHS/HSC Site Specific Information forms, for each site, in addition to the study wide forms, and transfer them to the PIs or local collaborators.

For participating NHS organisations in England different arrangements apply for the provision of site specific information. Refer to IRAS Help for more information.

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 Biomedical Research Unit, NIHR Collaboration for Leadership in Health Research and Care (CLAHRC), NIHR Patient Safety Translational Research Centre or a Diagnostic Evidence Co-operative 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

Integrated Research Application System
Application Form for Medical Device Study

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)
Paediatric Oximetry Algorithms

PART A: Core study information

1. ADMINISTRATIVE DETAILS

A1. Full title of the research:

PAEDIATRIC OXIMETRY ALGORITHMS – NORMATIVE DATA COLLECTION

A3-1. Chief Investigator:

	Title	Forename/Initials	Surname
	Prof	Heather	Elphick

Post	Consultant in Paediatric Respiratory Medicine
Qualifications	MB ChB, MRCP, MRCPCH, MD
ORCID ID	
Employer	Sheffield Children's NHS Foundation Trust
Work Address	Western Bank Sheffield
Post Code	S10 2TH
Work E-mail	heather.elphick@sch.nhs.uk
* Personal E-mail	
Work Telephone	01142717400
* Personal Telephone/Mobile	
Fax	01142717672

** 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	Samya	Armoush

Address	Sheffield Children's NHS Foundation Trust

	Western Bank
	Sheffield
Post Code	S10 2TH
E-mail	
Telephone	
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):	
Sponsor's/protocol number:	
Protocol Version:	1.0
Protocol Date:	05/01/2017
Funder's reference number:	
Project website:	

Registry reference number(s):
The Department of Health's Research Governance Framework for Health and Social Care and the research governance frameworks for Wales, Scotland and Northern Ireland set out the requirement for registration of trials. Furthermore: Article 19 of the World Medical Association Declaration of Helsinki adopted in 2008 states that "every clinical trial must be registered on a publicly accessible database before recruitment of the first subject"; and the International Committee of Medical Journal Editors (ICMJE) will consider a clinical trial for publication only if it has been registered in an appropriate registry. Please see guidance for more information.

International Standard Randomised Controlled Trial Number (ISRCTN):

ClinicalTrials.gov Identifier (NCT number):

Additional reference number(s):

Ref.Number Description	Reference Number

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.*

Children with long-term respiratory conditions such as chronic lung disease of prematurity and muscular dystrophy need frequent monitoring of their blood oxygen concentrations to assess levels of treatment required (e.g. oxygen therapy, ventilation). Such conditions can lead to severe illness or death if oxygen levels are not monitored and appropriate action taken. Currently, blood oxygen levels are monitored at home using pulse oximetry with monitors that are cumbersome and not optimised for movement and paediatric reference values. This leads to inaccurate readings, especially at times when oxygen may be needed most, for example, during feeding and activity. Accurate monitoring

will allow targeted treatment when children most need it.

There is no pulse oximeter currently available which can accurately monitor patients able to ambulate and which uses bespoke paediatric algorithms to obtain accurate results from children of different sizes.

At a recent Technology Innovation Transforming Child Health (TITCH) Network meeting the above problems were identified and a collaborative team was set up. This working group consists of Viamed; a medical device company who have worked in the field of pulse oximetry for 40 years, Medilink Yorkshire and Humber; who will provide the project management along with innovation and commercialisation expertise; and the Respiratory and Sleep team at Sheffield Children's Hospital (SCH) who will provide the clinical and research expertise. The team have recently been successful in being awarded £93,318 for 6 month phase 1 funding from the Small Business Research Initiative Scheme (SBRI). The key end point and key output of phase 1 is to design a wearable paediatric oximetry probe.

The first stage of this project is to collect clinical data from children undergoing oximetry monitoring to be able to create bespoke paediatric algorithms. This protocol outlines the normative data collection process of existing clinical algorithms using existing oximetry technology.

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, R&D office 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.

Oximetry data will be collected from children already having an oximetry test for clinical reasons. The study will involve collection of data from a second oximeter in order to produce a paediatric algorithm. The data from both oximeters will be collected on an SD card. All data recorded into an oximeter is anonymous. When the oximeter data is downloaded to a PC, this is the point that information about the patient is added. So in the case of this validation work, no identifiable information will be added, just a study ID number.

The data will be collected via a data logger. The data logger is battery powered and connected to the isolated serial interfaces of both oximeters, therefore safe as there is no direct connection to patients. The test oximeter (VM2160 with SMARTsat), is a medical device with interfaces that pass all tests according to IEC60601-1 3rd edition. Therefore it is given that the applied part (sensor), the internal battery and serial interface fulfil all requirements for electrical safety.

Some demographic data for each child will also be collected on a data collection sheet, but this will be ananymised by the clinical team prior to passing it on to the research team.

If, for any reason, either of the oximeters fail to collect data, the patient's clinical care will not be affected. The patient will be withdrawn from the study and the clinical oximetry only will be repeated, in accordance with Trust clinical guidlines.

The study will be conducted in compliance with the NHS Research Ethics Committee favourable opinion, Health Research Authority approval and Confirmation of Capacity & Capability at all participating sites.

The study will also be conducted in accordance with the International Conference for Harmonisation of Good Clinical Practice (ICH GCP), and the Research Governance Framework for Health and Social Care (2nd Edition). The study will also be submitted to the Research Ethics Committee at Sheffield Hallam University for review.

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
- [x] Feasibility/ pilot study
- [ ] Laboratory study
- [ ] Metanalysis
- [ ] Qualitative research
- [ ] Questionnaire, interview or observation study
- [ ] Randomised controlled trial
- [ ] Other (please specify)

Collection of normative data for use to develop a paediatric algorithm.

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

The primary objective of the project will be to obtain oximetry data from our paediatric sleep and respiratory patients to determine normative values with which to develop paediatric oximetry algorithms in children with long-term respiratory conditions.

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

Not applicable

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

Hypothesis
Obtaining clinical paediatric oximetry data on a wide age range of children undergoing clinical oximetry for respiratory conditions will provide data to determine paediatric software algorithms.

The design of the next phase of the project is to develop a wearable, self-adjustable wireless probe that is supported by clinical evidence (current protocol) to support product claims.

Paediatric Pulse Oximetry
Pulse oximetry is frequently used in clinical practice as a simple, non-invasive measure of oxygen saturation. This technique estimates arterial oxygen saturation with reasonable accuracy. However, this technique can only be used safely if the user is aware of the following limitations1,2:
• Motion artefacts
• Poor perfusion
• Irregular pulse rhythms
• Influence of ambient light
• Electromagnetic interference
• Skin pigmentation
• Tissue perfusion
• Nail polish
• Calibration assumptions
• Probe positioning
• Sample rate time
• Intravenous dyes
• Presence of abnormal haemoglobin molecules
• Night to night variability3

There are differences in oxygenated (oxyhaemoglobin) and deoxygenated blood (deoxyhaemoglobin) in terms of the amount of red and infrared light absorption. These differences in light absorption ratios are measured by transmission pulse oximeters. Within the microprocessor of an oximeter are stored calibration algorithms. These algorithms are used to calculate the SpO2. Most oximeters have algorithms for neonates and adults, however there are no algorithms written specifically for paediatrics.

Within the paediatric community of the South Yorkshire and Humber region, there are over 100 patients who are supported by Sheffield Children's Hospital community paediatric home oxygen and home ventilation team. This team

regularly monitor patients with long-term respiratory conditions in terms of pulse oximetry in the home environment. In addition, Sheffield Children's Hospital Sleep Unit and community sleep team undertakes approximately 400 pulse oximetry studies a year to investigate and monitor sleep-disordered breathing in children. Accurate pulse oximetry is required to measure hypoxaemia in all of these paediatric patient groups. Current oximeters are not adapted for accurate continuous perfusion monitoring in patients that are able to ambulate. There remains a gap in the market for a device which can take accurate readings from young children whilst the patient is moving, and which can interpret the data and deliver back to the patient clear indications on when to seek the advice of a medical professional. Such a device would allow these children to live more independently and without the need for the current level of medical care, representing an improvement in overall care provision.

The role of the Phase 1 SBRI study is to
a. explore some of the limitations of current oximetry technology and
b. to develop a wearable paediatric probe and paediatric algorithms.
The data obtained from the study described in this protocol will provide data using existing technology to inform the development of the paediatric algorithm.

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.*

The study design is outlined in Figure 1 and explained below.

Following ethics and HRA approval, we will identify 10-20 suitable children who are under the care of the sleep and respiratory team Sheffield Children's Hospital Sleep Unit and are due to undergo an overnight or daytime oximetry recording.

Following consent, RK will complete a data sheet [Appendix 1]. This information does not contain any identifiable information. The data collection sheet contains information that will be needed by Viamed to calculate the algorithms: date of test; age; gender; weight; height; ethnicity; comorbidities; the type of saturation probe which was worn; where the probe was attached; the algorithms used. Rather than obtaining the date of birth, RK will calculate the age in years and months at the time of the oximetry. This means that no identifiable information will be passed onto Viamed.

Each patient will undergo the standard clinical diagnostic / monitoring pulse oximetry recording using a Masimo oximeter as part of their clinical care. Masimo oximeters are the current oximeter brand used by the respiratory team at the hospital. In this study, we are going to use the Masimo Radical 7 oximeter as the gold standard reference oximeter.

In addition to the clinical Masimo oximeter, the participant will also wear a second Viamed oximeter because the data from this oximeter will be used to develop the algorithm. Both oximeters will be connected to a single battery powered data logger. A diagram of the set up is included in appendix 2. The data logger will allow both oximeters to use the same time stamp and store anonymous clinical data on an SD card. RK will label the SD card with the research ID that she has allocated to anonymise the data.

Following on from the oximetry recording, the clinical Masimo oximeter data will be downloaded, interpreted, reported and stored as per usual clinical purposes. If the Masimo oximeter failed to work for some reason during the study, the patient would be withdrawn from the study and the Masimo recording repeated alone, in accordance with Trust clinical guidelines.

The data from the Masimo and Viamed oximetry data stored on the SD card will be given by hand to Viamed along with the data collection sheet. The data on the SD card consists of voltage numbers and time stamp and will contain overnight values for oxygen saturation levels, artefact and pulse oximetry. There is no patient identifiable information on the SD card. The Masimo data will act as the gold standard reference and allow the team to synchronise the data and compare alarm status and recovery periods.

A14-1. In which aspects of the research process have you actively involved, or will you involve, patients, service users, and/or their carers, or members of the public?

- [x] Design of the research
- [ ] Management of the research
- [ ] Undertaking the research
- [x] Analysis of results

- [x] Dissemination of findings
- [ ] None of the above

Give details of involvement, or if none please justify the absence of involvement.
A parent/carer and patient focus group is planned for February 28th. this group will explore the optimum strategy for phases 1 and 2 of this project. The focus group will be organised by Medilink, with patients to be identified by Heather Elphick.

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
- [ ] 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
- [x] Paediatrics
- [ ] Renal and Urogenital
- [ ] Reproductive Health and Childbirth
- [x] Respiratory
- [ ] Skin
- [ ] Stroke

Gender:	Male and female participants
Lower age limit: 1	Months
Upper age limit: 16	Years

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

• All children who have consented to the study and are undergoing overnight oximetry
• Age 1 month -16 years.

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

• Families who do not understand written or verbal English.
• Children who do not attend with their parent /legal guardian and so are therefore unable to give informed consent.
• The research oximetry kit is in use on another patient and so not available for a suitable patient
• Patients deemed too unwell, or unsuitable, by the clinical team

RESEARCH PROCEDURES, RISKS AND BENEFITS

A18. Give details of all non-clinical intervention(s) or procedure(s) that will be received by participants as part of the research protocol. *These include seeking consent, interviews, non-clinical observations and use of questionnaires.*

Please complete the columns for each intervention/procedure as follows:

1. Total number of interventions/procedures to be received by each participant as part of the research protocol.
2. If this intervention/procedure would be routinely given to participants as part of their care outside the research, how many of the total would be routine?
3. Average time taken per intervention/procedure (minutes, hours or days)
4. Details of who will conduct the intervention/procedure, and where it will take place.

Intervention or procedure	1	2	3	4
Consent	1	0	30 minutes	Dr Ruth Kingshott
Oximetry using Viamed oximeter	1	0	8-24 hours	Dr Ruth Kingshott

A21. How long do you expect each participant to be in the study in total?

Up to 24 hours. The duration of an oximetry is usually about 8-10 hours, but can occasionally be for a 24 hour period.

A22. What are the potential risks and burdens for research participants and how will you minimise them?

For all studies, describe any potential adverse effects, pain, discomfort, distress, intrusion, inconvenience or changes to lifestyle. Only describe risks or burdens that could occur as a result of participation in the research. Say what steps would be taken to minimise risks and burdens as far as possible.

Each participant will already be having an oximetry test using the usual clinical oximeter (Masimo). In addition, they will have a second oximetry using the research oximeter (Viamed). The oximetry involves attachment of a probe, usually to the foot or toe. For the research study the participant will have two probes attached instead of one. The distress caused by this will be minimal as the participants will be familiar with the procedures which are already used as part of their clinical monitoring.

A24. What is the potential for benefit to research participants?

No benefit to research participants.

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 social care or GP records, or review of medical records. Indicate whether this will be done by the direct care team or by researchers acting under arrangements with the responsible care organisation(s).*

Patients will be identified and recruited from three different locations:
1) Sheffield Children's Hospital Sleep Unit
Potential participants who are undergoing overnight oximetry using a Masimo oximeter will be identified by specialist sleep nurses on arrival to the sleep unit.
2) Sheffield Children's Hospital Wards
Potential participants who are undergoing overnight oximetry using a Masimo oximeter will be identified by specialist sleep nurses who set up the overnight oximetry studies on the hospital wards.
3) Home oximetry monitoring
Potential participants who are undergoing overnight oximetry using a Masimo oximeter will be identified by specialist home oxygen nurse or specialist home ventilation nurse.

A27-2. Will the identification of potential participants involve reviewing or screening the identifiable personal information of patients, service users or any other person?

○ Yes ◉ No

Please give details below:
Heather Elphick and/or Ruth Kingshott will discuss eligibility for the study with their clinical team, usually the specialist nurse. No other members of the research team will be involved in screening patient information. Participants will be given a unique ID code for the purposes of analysing the research data.

A28. Will any participants be recruited by publicity through posters, leaflets, adverts or websites?

○ Yes ◉ No

A29. How and by whom will potential participants first be approached?

In the case of patients attending the sleep unit for an overnight oximetry, information sheets will be included in the appointment letter for the sleep unit.

In the case of ward patients, information sheets will be given to the patient by a member of the healthcare team during a ward round.

In the case of patients to be monitored at home, information sheets will be given to the parents by their specialist outreach nurse, or by their consultant in a clinic.

A30-1. Will you obtain informed consent from or on behalf of research participants?

◉ Yes ○ No

If you will be obtaining consent from adult participants, please give details of who will take consent and how it will be done, with details of any steps to provide information (a written information sheet, videos, or interactive material). Arrangements for adults unable to consent for themselves should be described separately in Part B Section 6, and for children in Part B Section 7.

If you plan to seek informed consent from vulnerable groups, say how you will ensure that consent is voluntary and fully informed.

Consent will be taken from parents on behalf of children. Assent will be taken if appropriate.

If you are not obtaining consent, please explain why not.

Please enclose a copy of the information sheet(s) and consent form(s).

A30-2. Will you record informed consent (or advice from consultees) in writing?

◉ Yes ○ No

A31. How long will you allow potential participants to decide whether or not to take part?

At least 24 hours

A32. Will you recruit any participants who are involved in current research or have recently been involved in any research prior to recruitment?

- ○ Yes
- ○ No
- ◉ Not Known

If Yes, please give details and justify their inclusion. If Not Known, what steps will you take to find out?

Parents will be asked whether they are currently taking part in any other research. If they are willing to participate then consent will be taken as usual.

A33-1. What arrangements have been made for persons who might not adequately understand verbal explanations or written information given in English, or who have special communication needs?*(e.g. translation, use of interpreters)*

As this is a feasibility study, participants for whom an interpreter would be required will not be included.

A35. What steps would you take if a participant, who has given informed consent, loses capacity to consent during the study? *Tick one option only.*

- ○ The participant and all identifiable data or tissue collected would be withdrawn from the study. Data or tissue which is not identifiable to the research team may be retained.
- ◉ The participant would be withdrawn from the study. Identifiable data or tissue already collected with consent would be retained and used in the study. No further data or tissue would be collected or any other research procedures carried out on or in relation to the participant.
- ○ The participant would continue to be included in the study.
- ○ Not applicable – informed consent will not be sought from any participants in this research.
- ○ Not applicable – it is not practicable for the research team to monitor capacity and continued capacity will be assumed.

Further details:

If you plan to retain and make further use of identifiable data/tissue following loss of capacity, you should inform participants about this when seeking their consent initially.

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.

Storage and use of personal data during the study

A36. Will you be undertaking any of the following activities at any stage (including in the identification of potential participants)?*(Tick as appropriate)*

- ☐ Access to medical records by those outside the direct healthcare team
- ☐ Access to social care records by those outside the direct social care team
- ☐ Electronic transfer by magnetic or optical media, email or computer networks
- ☐ Sharing of personal data with other organisations
- ☐ Export of personal data outside the EEA

- ☐ Use of personal addresses, postcodes, faxes, emails or telephone numbers
- ☐ Publication of direct quotations from respondents
- ☐ Publication of data that might allow identification of individuals
- ☐ Use of audio/visual recording devices
- ☐ Storage of personal data on any of the following:
  - ☐ Manual files (includes paper or film)
  - ☑ NHS computers
  - ☐ Social Care Service computers
  - ☐ Home or other personal computers
  - ☐ University computers
  - ☐ Private company computers
  - ☐ Laptop computers

Further details:
Medical records will be accessed by RK or HE, who are both members of the healthcare team, to obtain the necessary patient information, but this information will be anonymised prior to use for data analysis. Personal details will be stored on an NHS computer for 6-12 months but will not be accessible by the research team.

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

Storage will be in locked cabinets and cupboards in a secure area at Sheffield Children's NHS Foundation Trust. Access will only be to members of the research team and those involved in the running and supervision of the study. Electronic data will be held on password protected computers in a secure area of Sheffield Children's NHS Foundation Trust. Data stored on portable devices, such as laptop computers and memory sticks will be password protected and encrypted. A secure email address has been set-up for data transfer, according to the data sharing agreement.

A38. How will you ensure the confidentiality of personal data?*Please provide a general statement of the policy and procedures for ensuring confidentiality, e.g. anonymisation or pseudonymisation of data.*

Study participants will be given a unique study number and all study information will be coded and stored on password protected computers in secure locations at Sheffield Children's NHS Foundation Trust.

A40. Who will have access to participants' personal data during the study? *Where access is by individuals outside the direct care team, please justify and say whether consent will be sought.*

RK and HE are members of the direct respiratory care team and will have access to personal data via the medical files but these will only be used for identification and eligibility purposes and for obtaining demographic data which be anonymised prior to sharing any data with the rest of the research team.

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 clinical oximetry data recorded on the Masimo pulse oximeter will be handled by clinical staff in the usual manner.

In addition, the data from the Masimo oximeter and the Viamed oximeter will be recorded onto an SD card. This, with the data collection sheet will be analysed by Viamed.

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

	Title	Forename/Initials	Surname
	Prof	Heather	Elphick
Post	Consultant in Paediatric Respiratory Medicine		
Qualifications	MB ChB, MRCP, MRCPCH, MD		
Work Address	Sheffield Children's Hospital		
	Western Bank		
	Sheffield		
Post Code	S10 2TH		
Work Email	heather.elphick@sch.nhs.uk		
Work Telephone	01142717400		
Fax	01142717672		

A43. How long will personal data be stored or accessed after the study has ended?

- ○ Less than 3 months
- ○ 3 – 6 months
- ◉ 6 – 12 months
- ○ 12 months – 3 years
- ○ Over 3 years

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

Years: 5
Months:

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 collected data will be kept at Sheffield Children's Hospital on a password protected computer accessible only by the research team. The identity of subjects will be destroyed in accordance with Standard Operating Procedures so that only the child's care team can identify the subject by considering the allocated numerical labels. The computer used to keep the data has advanced security software to inhibit unauthorised access.

Clinical oximetry data will be collected and entered into a password protected database (Microsoft Excel) and retained in accordance with the Data Protection Act 1998. Study documents (paper and electronic) will be retained in a secure location during and after the study has finished. All source documents will be archived by the Clinical Research Facility once the study has been completed and these records will be retained for 5 years after the last patient visit.

The data collection sheets form part of the clinical data evidence for the ISO auditors. The data collection sheets and the SD cards will be given to Viamed [SN] at the monthly project meetings for analysis. The consent forms will be stored at Sheffield Children's Hospital in the research site file and a copy in the patient's medical notes. The consent form will contain the patient study ID and be the only data source linking the patient to the oximetry data. Data from the SD cards will be transferred to the technical files at Viamed. These files are stored on Viamed servers with two backups at different locations at Viamed as part of the company disaster management policy. The SD cards would then be erased. Any algorithm enhancements that are taken through to market will be recorded in the ISO technical files. Clinical data has to be present and made available within the CE technical files. Viamed already have full approval from their notified body BSI for adult and neonatal algorithms. This process would be to obtain approval and certification for paediatric algorithms. The anonymous data from the data collection sheets will be inputted into the technical files and then the data collection sheets returned to SCH [RK] at the face-to-face meetings for the SCH research team to store with the research site file.

INCENTIVES AND PAYMENTS

A46. Will research participants receive any payments, reimbursement of expenses or any other benefits or incentives for taking part in this research?

○ Yes ◉ No

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

A49-1. Will you inform the participants' General Practitioners (and/or any other health or care professional responsible for their care) that they are taking part in the study?

○ Yes ◉ No

If Yes, please enclose a copy of the information sheet/letter for the GP/health professional with a version number and date.

PUBLICATION AND DISSEMINATION

A50-1. Will the research be registered on a public database?

The Department of Health's Research Governance Framework for Health and Social Care and the research governance frameworks for Wales, Scotland and Northern Ireland set out the requirement for registration of trials. Furthermore: Article 19 of the World Medical Association Declaration of Helsinki adopted in 2008 states that "every clinical trial must be registered on a publicly accessible database before recruitment of the first subject"; and the International Committee of Medical Journal Editors (ICMJE) will consider a clinical trial for publication only if it has been registered in an appropriate registry. Please see guidance for more information.

◉ Yes ○ No

Please give details, or justify if not registering the research.
clinicaltrials.gov.uk

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?

Personal data will not be used or published.

A53. Will you inform participants of the results?

○ Yes ◉ No

Please give details of how you will inform participants or justify if not doing so.
Participants will be informed of their clinical oximetry results as part of usual clinical care. they will not be informed of the results of the second oximeter.

5. Scientific and Statistical Review

A54-1. 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:
The application for SBRI funding was peer reviewed as part of the funding process and 3 members of the research team were interviewed by the SBRI panel.

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
	Prof	Heather	Elphick
Department	Paediatric Respiratory Medicine		
Institution	Sheffield Children's NHS Trust		
Work Address	Western Bank		
	Sheffield		
Post Code	S10 2TH		
Telephone	01142717400		
Fax	01142717672		
Mobile			
E-mail	heather.elphick@sch.nhs.uk		

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

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

The primary outcome of the project will be to obtain oximetry data from our paediatric sleep and respiratory patients to determine normative values with which to develop paediatric oximetry algorithms in children with long-term respiratory conditions.

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

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: 20
Total international sample size (including UK):
Total in European Economic Area:

Further details:

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.*

Feasibility of data collection within a 4 month period as part of a funded project. Sample size calculation not done.

A61-1. 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.

Algorithm development to be carried out by Viamed.

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
		Steven	Nixon
Post			
Qualifications			
Employer			
Work Address			
Post Code			
Telephone			
Fax			
Mobile			
Work Email			

	Title	Forename/Initials	Surname
		Patrick	Trotter
Post			
Qualifications			
Employer			
Work Address			
Post Code			
Telephone			
Fax			
Mobile			
Work Email			

	Title	Forename/Initials	Surname
	Dr	Ruth	Kingshott
Post	Research Paediatric Sleep Physiologist		
Qualifications	PhD, BSc(Hons)		
Employer	Sheffield Children's NHS Foundation Trust		
Work Address	Room E61, E floor, Stephenson Wing Sheffield Children's Hospital Western Bank, Sheffield		
Post Code	S10 2TH		
Telephone	01142717400		
Fax			
Mobile			
Work Email	ruth.kingshott@sch.nhs.uk		

Title	Forename/Initials	Surname
	Tom	Wright

Post
Qualifications
Employer
Work Address

Post Code
Telephone
Fax
Mobile
Work Email

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:

If Other, please specify:

Contact person

Name of organisation	Sheffield Children's Hospital NHS Trust
Given name	Professor Paul
Family name	Dimitri
Address	Sheffield Children's Hospital
Town/city	Sheffield
Post code	S10 2TH
Country	UNITED KINGDOM
Telephone	01142267980
Fax	01142268744
E-mail	paul.dimitri@sch.nhs.uk

Is the sponsor based outside the UK?

( ) Yes (●) No

Under the Research Governance Framework for Health and Social Care, a sponsor outside the UK must appoint a legal representative established in the UK. Please consult the guidance notes.

A65. Has external funding for the research been secured?

- [x] Funding secured from one or more funders
- [ ] External funding application to one or more funders in progress
- [ ] 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:
6 month phase 1 development project to inform application for phase 2, funded by SBRI

Please give details of funding applications.

Organisation Small Business Research Initiative
Address

Post Code
Telephone
Fax
Mobile
Email

Funding Application Status: ◉ Secured ○ In progress

Amount:

Duration
Years:
Months: 6

If applicable, please specify the programme/ funding stream:

What is the funding stream/ programme for this research project?

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
	Mrs	Wendy	Swann
Organisation	Sheffield Children's NHS Foundation Trust		
Address	Dept of Research and Innovation		
	D Floor, Stephenson Wing		
	Sheffield Children's Hospital		
Post Code	S10 2TH		
Work Email	wendy.swann@sch.nhs.uk		
Telephone	01142267980		
Fax	01142267844		
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:

Yorkshire and Humber

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: 06/03/2017
Planned end date: 09/06/2017
Total duration:
Years: 0 Months: 3 Days: 4

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 1

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	1
☐ NHS organisations in Wales	
☐ NHS organisations in Scotland	
☐ HSC organisations in Northern Ireland	
☐ 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: 1

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

○ Yes ◉ No

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**

A76-1. What arrangements will be made for insurance and/or indemnity to meet the potential legal liability of the sponsor(s) for harm to participants arising from the management of the research? *Please tick box(es) as applicable.*

Note: Where a NHS organisation has agreed to act as sponsor or co-sponsor, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For all other sponsors, please describe the arrangements and provide evidence.

☑ NHS indemnity scheme will apply (NHS sponsors only)

☐ Other insurance or indemnity arrangements will apply (give details below)

Please enclose a copy of relevant documents.

A76-2. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of the sponsor(s) or employer(s) for harm to participants arising from the design of the research? *Please tick box(es) as applicable.*

Note: Where researchers with substantive NHS employment contracts have designed the research, indemnity is provided through NHS schemes. Indicate if this applies (there is no need to provide documentary evidence). For other protocol authors (e.g. company employees, university members), please describe the arrangements and provide evidence.

☑ NHS indemnity scheme will apply (protocol authors with NHS contracts only)

☐ Other insurance or indemnity arrangements will apply (give details below)

Please enclose a copy of relevant documents.

A76-3. What arrangements will be made for insurance and/ or indemnity to meet the potential legal liability of investigators/collaborators arising from harm to participants in the conduct of the research?

Note: Where the participants are NHS patients, indemnity is provided through the NHS schemes or through professional indemnity. Indicate if this applies to the whole study (there is no need to provide documentary evidence). Where non-NHS sites are to be included in the research, including private practices, please describe the arrangements which will be made at these sites and provide evidence.

☑ NHS indemnity scheme or professional indemnity will apply (participants recruited at NHS sites only)

☐ Research includes non-NHS sites (give details of insurance/ indemnity arrangements for these sites below)

Please enclose a copy of relevant documents.

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

◉ Yes ○ No ○ Not sure

A79. Please select the level of commercial participation in this project.

○ None

◉ Industry funding, but not industry sponsored

○ Industry funding and industry sponsored

○ Industry sponsored, but not industry funded

A80. Please select the main subject area of research. Additional sub-topics may be selected, if required

☐ Age and Ageing

☐ Anaesthetics

☐ Cancer (includes malignant haematology

☐ Cardiovascular

- [ ] Clinical
- [ ] Critical Care
- [ ] Dementias and Neurodegenerative Diseases
- [ ] Dermatology
- [ ] Diabetes
- [ ] Ear, Nose and Throat
- [ ] Gastrointestinal
- [ ] Genetics
- [ ] Health Services Research
- [ ] Hepatology
- [ ] Immunology and Inflammation
- [ ] Infectious Disease and Microbiology
- [ ] Injuries and Accidents
- [ ] Medicines for Children (does not include Paediatrics)
- [ ] Mental Health
- [ ] Metabolic and Endocrine
- [ ] Musculoskeletal (Rheumatoid Arthritis is a separate category)
- [ ] Nervous System Disorders
- [ ] Non-malignant Haematology
- [ ] Ophthalmology
- [ ] Oral and Dental
- [x] Paediatrics (does not include Medicines for Children)
- [ ] Primary Care
- [ ] Public Health Research
- [ ] Renal
- [ ] Reproductive Health and Childbirth
- [x] Respiratory
- [ ] Rheumatoid Arthritis
- [ ] Stroke
- [ ] Surgery
- [ ] Urogenital

Part B: Section 2

A. General information

Information in this sub-section will be included in applications to the Research Ethics Committee and NHS R & D offices at the research sites.

1-1. Is the manufacturer (or other organisation responsible for developing the device) the same organisation named as lead sponsor for this study?

○ Yes ◉ No

If No, please give details of the manufacturer or other organisation responsible for developing the device below:

Organisation
Address

Post Code
Country
Telephone
Fax
Mobile
E-mail

2. Details of the medical devices to be used in the study

Name of the manufacturer:	Viamed
Manufacturer's trade name for the device:	VM2160 with SMARTsat
Device identification name and/or number:	
Name:	VM2160 with SMARTsat
Number:	
Generic name of device and principal intended use(s):	Pulse oximeter - intended use is to monitor blood oxygen saturation.
Length of time since device came into use:	

3-1. Further details of the purpose of the study

Does the study involve:

- ○ Investigation of a new medical device
- ○ Investigation of new implantable material
- ○ Use of an existing product outside the terms of its CE market intended purpose
- ○ Use of a modified product
- ◉ Use of an existing product within its CE market intended purpose

PART B: Section 7 - Children

1. Please specify the potential age range of children under 16 who will be included and give reasons for carrying out the research in this age group.

1 month to 16 years. This is because there are already established algorithms for analysis of oximetry in neonates (4 weeks and younger) and adults (16 years and over).

2. Indicate whether any children under 16 will be recruited as controls and give further details.

No, each child that is recruited will have oximetry monitored using both devices.

3-2. Please describe the arrangements for seeking informed consent from a person with parental responsibility and/or from children able to give consent for themselves.

Parental consent will be taken for all children recruited into the study. If the child is old enough and has sufficient mental capacity, assent will also be taken.

4. If you intend to provide children under 16 with information about the research and seek their consent or agreement, please outline how this process will vary according to their age and level of understanding.

Information sheets will be provided for parents, and also for children aged under 6, 6-12 years and 12-16 years.

Copies of written information sheet(s) for parents and children, consent/assent form(s) and any other explanatory material should be enclosed with the application.

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