

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 enter a short title for this project (maximum 70 characters)

The Paediatric Observation Priority Score (POPS)

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 taking new samples primarily for research purposes (i.e. not surplus or existing stored samples), including any removal of organs or tissue from the deceased? Yes No
- b) Will you be using surplus tissue or existing stored samples identifiable to the researcher? Yes No
- c) Will you be using only surplus tissue or existing stored samples not identifiable to the researcher? Yes No
- d) Will you be processing identifiable data at any stage of the research (including in the identification of participants)? Yes No
- e) Please confirm that you will be processing only anonymised or effectively pseudonymised data:
 Yes, only anonymised or pseudonymised data No

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

- England
 Scotland
 Wales
 Northern Ireland

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

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

4. Which review bodies are you applying to?

- NHS/HSC Research and Development offices
 Social Care Research Ethics Committee
 Research Ethics Committee
 National Information Governance Board for Health and Social Care (NIGB)
 Ministry of Justice (MoJ)
 National Offender Management Service (NOMS) (Prisons & Probation)

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

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

- Yes No

5a. Do you want your NHS R&D application(s) to be processed through the NIHR Coordinated System for gaining NHS Permission?

- Yes No

If yes, you must complete and submit the NIHR CSP Application Form immediately after completing this project filter, before proceeding with completing and submitting other applications.

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 Research limited to working with human tissue samples and/or data

NHS/HSC R&D Form (project information)

Please refer to the *Submission and Checklist* tabs for instructions on submitting R&D applications.

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 familiar to lay reviewers of the application.

Short title and version number: (maximum 70 characters - this will be inserted as header on all forms)
 The Paediatric Observation Priority Score (POPS)

PART A: Core study information
1. ADMINISTRATIVE DETAILS
A1. Full title of the research:

An evaluation of the Paediatric Observation Priority Score in predicting appropriate admission and safe discharge from a Children's Emergency Department.

A3-1. Chief Investigator:

	Title Forename/Initials Surname
	Dr Damian Roland
Post	NIHR Doctoral Research Fellow
Qualifications	BMedSci, BMBS, MRCPCH
Employer	Leicester University
Work Address	Emergency Medicine Academic Group
	Jarvis Building
	LRI, Leicester
Post Code	LE1 5WW
Work E-mail	dr98@le.ac.uk
* Personal E-mail	dr98@le.ac.uk
Work Telephone	01162586397
* Personal Telephone/Mobile	07727158213
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 R&D reviewers that is sent to the CI.

	Title Forename/Initials Surname
	Mr Graham Hewitt
Address	College of Medicine University of Leicester Leicester
Post Code	LE1 7RH
E-mail	gjh13@le.ac.uk
Telephone	0116 223 1262
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:

Protocol Date:

Funder's reference number: N/A

Project website:

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 website of the National Research Ethics Service following the ethical review.*

Six million children use Urgent Care Services every year. National scoring systems such as the Modified Early Warning Score (MEWS) exist to recognise sick and deteriorating adults. No validated tool exists for children in emergency departments. The Confidential Enquiry into Maternal and Childhood Health (CEMACH) report "Why Children Die" indicated death could be prevented if doctors were better at recognising ill children, with the National Patient Safety Agency (NPSA) also reporting similar findings. Both identified illness scoring systems as a key area of development. The pilot of a locally developed "Paediatric Observation Priority Score" (POPS) showed it allows healthcare professionals of any level of experience to assess the acuity of children. POPS was popular, easy to use, and discriminated between children of low and high acuity and is now the standard assessment tool in the Leicester Royal Infirmary children's Emergency Department. This study will determine appropriate cut off points for the POPS score to predict appropriate admission and safe discharge.

Once this work has been performed we hypothesise POPS will enable a quantification of the level of resources a particular child requires as those being admitted are by definition more ill than those being discharged. This would subsequently allow decisions on the number of health care professional staff and their skill mix requirements to be made based on the intensity of acuity of all children in a department. This will ultimately be used to facilitate resource management and would be the basis for a future study.

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.

This study will collect POPS scores and the physiological (e.g. Heart Rate) and observational features (e.g. such as appears unwell to a health care professional) which make up the score and test whether they are predictive of admission and safe discharge. These values are currently routinely collected as part of standard care within Emergency Departments. A secondary aim of this study will be to determine whether the POPS score is predictive of resource utilisation. Resources can be physical (need for blood or urine test), time-based (length of time in the department) or population (seniority of attending doctor) attributes. These resources are routinely recorded in the Emergency Department Information System and are readily accessible.

Data will be collected prospectively by inputting patient de-identified information (as above) with resource utilisation and outcome into an NHS password protected computer located in a locked office. This data will be used to create prediction models to map the POPS score against the selected proxies for resource allocation. Data collection is in keeping with the Caldicott Principles and has been confirmed by the Ethics and Confidentiality Committee of the NIGB that section 251 support is not required. No new data, technique or intervention is being utilised as part of this study so specific patient consent is not being requested.

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.*

What are appropriate cut off points on the POPS score to determine appropriate admission to the childrens hospital and safe discharge.

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

Does the POPS system predict resource use (that is the time of staff or the use of medical interventions) in the Emergency Department?

Whether POPS is predictive of the presence of a serious bacterial illness?

Does POPS predict which children require admission for greater than 24 hours?

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

Illness scoring systems such as the Modified Early Warning Score (MEWS) exist to recognise sick and deteriorating adults. These translate commonly recorded physiological parameters (e.g. heart rate) into an integer (whole number) score. On reaching a predefined value the score would trigger a response such as a medical review or admission to a high dependency area. Despite the fact six million children use Urgent Care Services every year no validated tool exists for children in emergency departments. The Confidential Enquiry into Maternal and Childhood Health (CEMACH) report "Why Children Die" indicated death could be prevented if clinicians were better at recognising ill children, with the National Patient Safety Agency (NPSA) also reporting similar findings. Both identified illness scoring systems as a key area of development.

The pilot of a locally developed "Paediatric Observation Priority Score" (POPS) showed it allows healthcare professionals of any level of experience to assess the acuity of children and is currently undergoing a service evaluation. The POPS score defined in more detail below is a score from 0-16. This research project is to define the which scores in the POPS system best predict appropriate admission and safe discharge

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.

This study involves creating a predictive model to link POPS to the eventual decision on admission or discharge for the patient.

Definitions used:

POPS - POPS is the Paediatric Observation Priority Score. It is a checklist of variables which include heart rate, respiratory rate and temperature and also some comments on the appearance of the child (such as work of breathing and level of alertness). Each of the variables has a score between 0-2 assigned to it (i.e a normal heart rate for the child's age would score 0, a very high rate would score 2). There are 8 variables which are considered leading to a score between 0-16.

The POPS system is employed when a child initially presents to the Children's Emergency Department of the Leicester Royal Infirmary. The POPS system has been awarded a Da Vinci Health Care Technology award.

Appropriate Admission - If a child is admitted to the Children's Assessment Unit they are not discharged within 4 hours of arrival. The Children's Assessment Unit at the Leicester Royal Infirmary is a specialist unit run by paediatricians which also takes referrals direct from GPs and Urgent Care centres throughout Leicester City.

Safe Discharge - If a child is discharged they do not return to the Emergency Department and be subsequently admitted within 7 days. This duration is has been chosen as it has recently been accepted by the College of Emergency Medicine as a quality indicator for Emergency Departments nationally. It is currently not possible to determine if the child represents to another health care provider however admission back to the Leicester Royal Infirmary Children's Assessment Unit following discharge from the ED can be determined.

Study Design:

This study will for a defined period prospectively analyse the outcome of children (admission or discharge) against their result at presentation.

During the study period all children who present to the Leicester Royal Infirmary Emergency Department will have a POPS recorded and stored electronically (i.e the data fields are inputted directly into a computer). This recording system does not record patient identifiable data but is able to also record the eventual outcome (disposition) of the patient according the admission and discharge definitions above.

The POPS system is utilized by staff at the Leicester Royal Infirmary who all have training in the recording of observations in children.

This process is no different to current practice at the Leicester Royal Infirmary Emergency Department except from the electronic recording of data. No data is being collected that would not already be obtained from patients.

Study Methodology:

The Emergency Department sees over 30000 patients per year of which at least 10000 have a medical problem for which they would be assessed with a POPS score. A sample size of 5000 patients (discussed with a medical statistician) would make this the largest series of its kind and enable model development and external validation. Because of technical reasons (computer shut downs and downtime) and use of the electronic recording by staff it is not feasible to obtain data on all 10000 potential subjects although it is feasible at least 80% of attendees will have data sets recorded.

This work will enable a rationalization of the POPS tool and development of a model. Guidance on the assessing the performance of Prediction models has been published and this will form the basis for this work (Steyerberg 2010). In summary the overall score will be plotted against the outcomes of appropriate admission and safe discharge and relevant cut off points selected.

Secondary outcomes

1) Whether POPS is predictive of the presence of a serious bacterial illness as defined by a growth of an organism in the urine, blood stream or cerebral spinal fluid (fluid around the brain).

2) Whether there is any relationship between overall POPS and the total resource utilisation based on the following each having a unit score of 1.

- require an early medical intervention (defined as immediate cannula insertion, intravenous antibiotic prescribing, immediate delivery of an inhaled or nebulised medication, request for a portable CXR, transfer to the resuscitation area))

- require senior clinician involvement
- to be admitted to Children's Intensive Care
- to have longer stay in the ED (over 3 hours)

3) Whether POPS predicts which children require admission for greater than 24 hours?

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
 Paediatrics
 Renal and Urogenital
 Reproductive Health and Childbirth
 Respiratory
 Skin
 Stroke

Gender: Male and female participants

Lower age limit: 0 Years

Upper age limit: 15 Years

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

1) Children assessed at the Leicester Royal Infirmary Children's Emergency Department.

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

Patients over the age of 15

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).

On a prospective basis the physiological observations and other relevant non-identifiable patient data of the those children presenting to the Leicester Royal Infirmary Emergency Department will be recorded in an electronic form.

The following system has been agreed by the NIGB as not requiring consent from patients. The POPS system is currently in use in the Emergency Department - no information is collected in this research which is not currently occurring.

- 1) A patient books into the Emergency Department at the Leicester Royal Infirmary.
- 2) They have an assessment within 15 minutes of arriving in the department (current departmental standard) which includes a POPS score. This is the current standard of care. This occurs via the triage or assessment nurse on duty.
- 3) This score is put on an electronic proforma and data relevant to the research (which does not include the patients name or any demographic information) and stored in secure encrypted computer database. The electronic proforma is printed off as per current practice and this is used in the patients normal clinical care. The serial number of the patient is coded and scrambled and then linked to the information in the encrypted database. It can then be used to match the outcomes required via the Emergency Department Information System. This process occurs automatically.
- 4) Data analysis which will not include identifiable data will be analysed by the principal Investigator (who is not part of the patients care team).

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?

Data will be placed on an electronic database held on an NHS password protected computer in locked office.

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 analysed on site by the principal investigator.

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

	Title Forename/Initials Surname
	Dr Damian Roland
Post	NIHR Doctoral Research Fellow
Qualifications	BMedSci, BMBS, MRCPCH
Work Address	Emergency Medicine Academic Group
	Jarvis Building
	LRI, Leicester
Post Code	LE1 5WW
Work Email	dr98@le.ac.uk
Work Telephone	01162586397
Fax	

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

Years: 7

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.

Data will be maintained on a password protected NHS computer of which only the principal investigator has access. The ethics committee will be informed if either the dataset is no longer required for any future meta-analysis or the principal investigator changes his location of work.

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.

There is no relevant register for this type of research at present however the results of the work will be widely disseminated.

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?

No identifiable personal data will be used.

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:

The project has been previously submitted to the University of Leicester's MD Degree Board and felt to be suitable for registration.

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
	Dr	Nick	Taub
Department	Phd		
Institution	Leicester University		
Work Address	Department of Health Sciences		
	Leicester University		
	Leicester		
Post Code	LE1 6TP		
Telephone	0116-252-5416		
Fax			
Mobile			
E-mail	nat2@le.ac.uk		

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

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

Which are the appropriate cut off points of an illness identification system (the Paediatric Observation Priority Score) in predicting

- (1) Which children are admitted to a specialist paediatric unit for greater than four hours
- (2) Which are potentially suitable for safe discharge .

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

Does the POPS system predict resource use (that is the time of staff or the use of medical interventions) in the Emergency Department?

Whether POPS is predictive of the presence of a serious bacterial illness?

DOes POPS predict which children require admission for greater than 24 hours?

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: 8000
 Total international sample size (including UK):
 Total in European Economic Area:

Further details:

The number needed is 5000 which is easily achievable in a one year period given the total numbers of children presenting the Leicester Royal Infirmary Emergency Department (>35000/year) of whom 10000 would be eligible for inclusion. The number above represents total potential data capture taking into account difficulties with electronic data collection processes.

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.

In regard to determining appropriate admission:

The feasibility study of POPS (942 patients) has demonstrated a 36% admission rate from those with assigned POPS scores. This is a much higher than average admission rate although for this work those with POPS scores were a self selecting high risk group. For this study the admission rate is likely to be around 10%.

In regard to determining safe discharge:

In a population of 5000 a 3% re-attendance rate would detect the sensitivity of a POPS score greater than zero to within a precision of 8% either way with reference to the 95% Confidence Interval for this estimate.

This sample size is would also make it the largest published series of its kind.

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.

ROC curves will be used to examine the effect that different choices for the cut point would have on the sensitivity and specificity to predict appropriate admission and safe discharge (admission for greater than four hours to the Children's Assessment Unit and discharge without return within 7 days) as outcomes. The final decision will be based on appropriate best practice in paediatric emergency care. This work will be performed with the assistance of a medical statistician.

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
	Prof Timothy Coats
Post	Professor of Emergency Medicine
Qualifications	BSc MB BS FRCS FFAEM MD
Employer	Leicester University
Work Address	Emergency Department Leicester Royal Infirmary
Post Code	LE1 5WW
Telephone	

Fax
 Mobile
 Work Email tc61@leicester.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 Leicester University
 Given name Graham
 Family name Hewitt
 Address College of Medicine
 Town/city University of Leicester
 Post code LE1 7RH
 Country
 Telephone 0116 223 1262
 Fax
 E-mail gjh13@le.ac.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?

- 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:

Please give details of funding applications.

Organisation College of Emergency Medicine
 Address Churchill House
 35 Red Lion Square
 London
 Post Code WC1R 4SG
 Telephone 020 7067 1263
 Fax 020 7067 1267
 Mobile
 Email Chris.Walsh@collemergencymed.ac.uk

Funding Application Status: Secured In progress

Amount: £5250

Duration

Years: 2

Months: 0

If applicable, please specify the programme/ funding stream:

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

CEM research grants awarded within the UK have been approved as NIHR portfolio studies. The study should will be registered under the Injuries and Emergencies, or critical care theme, of the local Comprehensive Research Network (CRN).

Organisation NIHR
 Address NIHR Trainees Coordinating Centre
 Leeds Innovation Centre, 103 Clarendon Road
 Post Code LS2 9DF
 Telephone 0113 3466277
 Fax
 Mobile
 Email Karen.Fernando@nihrtcc.org.uk

Funding Application Status: Secured In progress

Amount: 307000

Duration

Years: 3

Months:

If applicable, please specify the programme/ funding stream:

What is the funding stream/ programme for this research project?
NIHR Doctoral Research Fellowship

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

	Title Forename/Initials Surname
	Ms Carolyn Maloney
Organisation	
Address	Research & Development Office Leicester General Hospital Gwendolen Road
Post Code	LE5 4PW
Work Email	Sharon.turner@uhl-tr.nhs.uk
Telephone	0116 258 4109
Fax	
Mobile	

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

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

Planned start date: 06/07/2011

Planned end date: 01/04/2013

Total duration:

Years: 2 Months: 0 Days: 0

A70. Definition of the end of trial, and justification in the case where it is not the last visit of the last subject undergoing the trial ⁽¹⁾

Case records obtained in 5000 patients or after one year whichever is the greater.

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

Does this trial involve countries outside the EU?

- Yes No

A72. What host organisations (NHS or other) in the UK will be responsible for the research sites? Please indicate the type of organisation by ticking the box and give approximate numbers of planned research sites:

- 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
 Social care organisations
 Phase 1 trial units
 Prison establishments
 Probation areas
 Independent hospitals
 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

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

The University Hospitals of Leicester NHS Trust will monitor the research as per usual arrangements.

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 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.

The age range will be 0-15.

Illness identification in children has been made a priority area by the National Patient Safety Agency and they have targeted illness identification systems as a way of doing this.

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

Not applicable.

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.

Consent will not 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.

Consent will not be taken.

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 NHS sites, the host organisation is the Trust or Health Board. Where the research site is a primary care site, e.g. GP practice, please insert the host organisation (PCT or Health Board) in the Institution row and insert the research site (e.g. GP practice) in the Department row.

Research site		Investigator/ Collaborator/ Contact	
Institution name	Leicester Royal Infirmary	Title	Dr
Department name	Emergency Department	First name/ Initials	Damian
Street address	Infirmary Square	Surname	Roland
Town/city	Leicester		
Post Code	LE1 5WW		
Institution name	Gloucestershire Royal Hospital	Title	Dr
Department name	Emergency Department	First name/ Initials	Victoria
Street address		Surname	Stacey
Town/city	Gloucester		
Post Code	GL1 3NN		
Institution name	Royal Berkshire NHS Foundation Trust	Title	Ms
Department name	Emergency Department	First name/ Initials	Ellen
Street address		Surname	Bowley
Town/city	Reading		
Post Code	RG1 5AN		
Institution name	Bristol Royal Infirmary Children's Hospital	Title	Dr
Department name	Emergency Department	First name/ Initials	Mark
Street address		Surname	Lyttle
Town/city	Bristol		
Post Code	BS2 8BJ		
Institution name	Royal United Hospital Bath NHS Trust	Title	Dr
Department name	Emergency Department	First name/ Initials	Liz
Street address		Surname	Keating
Town/city	Bath		
Post Code	BA1 3NG		

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 abide by the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research.
3. 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.
4. 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.
5. I undertake to submit annual progress reports setting out the progress of the research, as required by review bodies.
6. 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.
7. I understand that research records/data may be subject to inspection by review bodies for audit purposes if required.
8. 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 1998.
9. 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.
10. 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 1998.
11. 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 below. Publication will take place no earlier than 3 months after issue of the ethics committee's final opinion or the withdrawal of the application.

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

NRES 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

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 Dr Damian Roland on 07/10/2011 09:43.

Job Title/Post:

Organisation:

Email:

Signature:

Print Name: Damian Roland

Date: (dd/mm/yyyy)

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 duties of sponsors set out in the Research Governance Framework for Health and Social Care will be undertaken in relation to this research.
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.

This section was signed electronically by Mr Graham Hewitt on 10/10/2011 12:12.

Job Title/Post: Research Governance Manager
Organisation: University of Leicester
Email: gjh13@le.ac.uk