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)
Evaluating outcomes of interventions that change practice

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) Does the study involve the use of any ionising radiation?	( ) Yes	(●) No
b) Will you be taking new human tissue samples (or other human biological samples)?	( ) Yes	(●) No
c) Will you be using existing human tissue samples (or other human biological samples)?	( ) Yes	(●) No

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

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

- [x] NHS/HSC Research and Development offices
- [ ] Social Care Research Ethics Committee
- [x] 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

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 NIGB Ethics and Confidentiality Committee 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

Please describe briefly the involvement of the student(s):

9a. Is the project being undertaken in part fulfilment of a PhD or other doctorate?

(●) 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 administering questionnaires/interviews for quantitative analysis or mixed methodology study

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 familar to lay reviewers of the application.

Short title and version number: (maximum 70 characters - this will be inserted as header on all forms)
Evaluating outcomes of interventions that change practice

PART A: Core study information

1. ADMINISTRATIVE DETAILS

A1. Full title of the research:

Refining evaluation methodologies for interventions that change practice: A model to assess the effectiveness of an e-Learning tool.

A2-1. Educational projects

Name and contact details of student(s):

Student 1

	Title	Forename/Initials	Surname
	Dr	Damian	Roland
Address	Emergency Medicine Group		
	Room 003A, RKCS Building		
	LRI, Leicester		
Post Code	LE1 5WW		
E-mail	dr98@le.ac.uk		
Telephone	01162523263		
Fax			

Give details of the educational course or degree for which this research is being undertaken:

Name and level of course/ degree:
PhD

Name of educational establishment:
University of Leicester

Name and contact details of academic supervisor(s):

Academic supervisor 1

	Title	Forename/Initials	Surname
	Prof	Tim	Coats
Address	Emergency Medicine Group		
	Room 003A, RKCS Building		
	LRI, Leicester		
Post Code	LE1 5WW		
E-mail	tc61@le.ac.uk		
Telephone	01162523263		
Fax			

Academic supervisor 2

	Title	Forename/Initials	Surname
	Dr	David	Matheson
Address	Room B94c Medical School		
	Queens Medical Centre		
	Nottingham		
Post Code	NG7 2UH		
E-mail	david.matheson@nottingham.ac.uk		
Telephone	0115 823 0033		
Fax			

Please state which academic supervisor(s) has responsibility for which student(s):
Please click "Save now" before completing this table. This will ensure that all of the student and academic supervisor details are shown correctly.

Student(s)	Academic supervisor(s)
Student 1 Dr Damian Roland	☑ Prof Tim Coats ☑ Dr David Matheson

A copy of a current CV for the student and the academic supervisor (maximum 2 pages of A4) must be submitted with the application.

A2-2. Who will act as Chief Investigator for this study?

- ◉ Student
- ○ Academic supervisor
- ○ Other

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 Group		

	Room 003A, RKCS Building
	LRI, Leicester
Post Code	LE1 5WW
Work E-mail	dr98@le.ac.uk
* Personal E-mail	dr98@le.ac.uk
Work Telephone	01162523263
* 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:
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.*

There are many educational programmes aimed at improving the clinical practice of health care professionals. A number of these programmes are delivered via information technology systems and described as 'e-Learning'. Determing how beneficial they are is difficult as educational outcomes are not always objective or easily measurable.

This study will create a system to test the effeciveness of e-learning packages for health care professionals. A group of junior doctors will undertake an online learning package on dealing with young children with fever. They will all have various aspects of their practice assessed by questionnaire, knowledge testing and direct observation of their consultations.

These methods will be analysed to decide which is most suitable for deciding whether the learning package is useful.

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.

The main phase of this project will be a before and after study. Prior to the proposed intervention (which will be an e-learning package) a group of junior doctors will be assessed in four different ways and will have the same assessments after the intervention. The study will be designed to assess

i) Change in attitude in managing feverish children (via a questionnaire)
ii) Change in performance (via a knowledge test)
iii) Change in adherence with best practice (via observed behaviour)
iv) Change in audited departmental guideline adherence (via review of case notes)

The gold standard approach to determing whether the package is effective would be a randomised control trial. In this approach a group of doctors would be given the e-learning package and another similar group would not. However in order to do this trial the outcomes (or measurements taken during the study) need to be determined. This study aims to clarify which measurements need to be taken, hence the four different approaches above. The published literature is not clear on which is best technique to use however the above assessments are the most commonly used.

The e-learning package itself uses video clips of children to demonstrate features of illness. These images have been consented for and were developed by the Spotting the Sick Child Management team (of which the principal investigator is a member). Spotting the Sick Child is an online educational tool containing clips of children which has won a national patient safety award.

The participants in the study will be junior doctors who are starting work in the Emergency Department in August 2011 and 2012. Points (i) and (ii) above can easily be assessed via the educational website that will be developed to deliver the e-learning package or via case-note review. The educational website will contain a questionnaire and knowledge test which can be repeated at intervals to check progression. Junior Doctors are also assessed in the workplace by seniors using work place based assessment (WPBAs). These are checklists to ensure doctors are performing to a set standard. A WPBA will be developed for doctors examining febrile children. No additional interaction, involvement or invasive procedure is needed or provided to parents or children in this study. A parent and child feedback system is currently being developed as an assessment tool but is still in an early research phase so will not be considered as part of this study. However when the results of this work are fully known and understood they could be used in future work.

3. PURPOSE AND DESIGN OF THE RESEARCH

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

- ☐ Case series/ case note review
- ☐ Case control
- ☑ Cohort observation
- ☐ Controlled trial without randomisation
- ☐ Cross-sectional study
- ☐ Database analysis
- ☐ Epidemiology
- ☑ Feasibility/ pilot study
- ☐ Laboratory study
- ☐ Metanalysis
- ☑ Qualitative research
- ☑ Questionnaire, interview or observation study
- ☐ Randomised controlled trial
- ☐ Other (please specify)

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

The main research question to be addressed is, “Which evaluative methods enable effectiveness of an e-learning intervention to be assessed?”

This project has the following aims:

1. Determination of which outcome methods are currently used to assess a training intervention using audio-visual clips of patients via a literature review.
2. Production of an evidence based online training package using audiovisual descriptions of feverish children.
3. A quantitative (something that can be described in numbers) measure of the training package by observing performance of participants using pre-defined outcome measures.
4. A qualitative (somethings that is descibed with words) description of the effectiveness of the training package via interview of participants at the extremes of performance.

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

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

There are many implementation strategies and educational programmes aimed at improving the clinical practice of health care professionals. An alteration in the ability to integrate evidence based practice into a health care professionals daily work may improve patient safety and clinical outcomes. A number of these strategies are delivered via information technology systems and labeled as ‘e-Health’ or ‘e-Learning’. Assessment of their impact is difficult as clear objective outcomes are not always available and there are often many different reasons why health care professionals change their practice.

A number of methods exist to evaluate an intervention designed to improve performance in a specific are. No single approach has been universally adopted due to the wide range of individual and organisational factors that affect the outcomes before, during and after the intervention. The development of a model which enables the effectiveness (the reasons behind the change in outcomes) to be identified would enable a more systematic evaluation. As e-health care resources become potentially limited in the current economic climate such a tool would provide a way of judging the performance of these interventions and also improving their future production.

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 main phase of this project will be a before and after study. Prior to the intervention (which will be an e-learning package) a group of junior doctors will be assessed in four different ways and will have the same assessments after the intervention. The study will be designed to assess

i) Change in attitude in managing feverish children (via questionnaire)
ii) Change in performance (via knowledge test)
iii) Change in adherence with best practice (via observed behaviour)
iv) Change in audited departmental guideline adherence (via review of case notes)

Phase One

The first phase of the project will be create the assessments and design the e-learning intervention. This has been ongoing from September 2010. A service evaluation of the current use of Spotting the Sick Child in the department for doctors commencing in August 2010 is being undertaken.

Focus groups will be undertaken in order to determine the attitudes and experiences of junior doctors consultations with feverish children. These focus groups will enquire as to how junior doctors feel about managing young children with fever and what language they use to express fears, concerns or confidence etc. Consent will be taken from the junior doctors to record the and write down discussions in the focus groups (Ethical approval for this has already been obtained from the University of Leicester as participants are academic foundation year docotors employed by the University). All notes taken will be anonymised. The key outcomes of these focus groups will be incorporated into a likhart based scale (a range of responses to a question from strongly agreeing to strongly disagreeing). This will enable a change in confidence to be assessed using the language that junior doctors themselves would use.

Phase Two (Pilot Test of Study)

All newly starting doctors in the Leicester Royal Infirmary in August 2011 (approx. 36) will be asked to participate in this work. A brief introduction on the aims of the project will be e-mailed in advance and further information will be provided at induction.

When enrolled the junior doctors will be given access to the educational website. There they will undertake a questionnaire on their experience and attitudes and undertake a knowlege test. This will assess the participants' ability to correctly assign signs and symptoms according to the NICE Feverish illness in children guidelines. The educational website will have secure password protection and the images will only be available to those with pre-defined access. Video recordings of children will be used from a previous project (which had gained consent to show the footage for educational and research purposes). The company supplying this has extensive experience with handling confidential data.

Individual observations of the doctor-patient interaction with reference to the NICE Feverish illness in Children guideline will determine change in behaviour. A checklist of relevant questions and examinations based on the RCPCH Feverish illness in Children Audit will be developed to be used by nursing staff. Nursing staff will observe doctors consulting with feverish children. The observer will not interfere or react to the consultation in anyway and no change in planned care will occur. The doctor will not be doing any more or less to the child than they normally would do in any consultation.

Once observations of interaction, the questionnaire and knowledge test have been completed access to the e-learning package will opened. The junior doctors will have two weeks in which to complete the 45 minute package before undertaking a repeat questionnaire and knowledge test and also undertaking further observations.

In addition departmental audit of guideline compliance using the proformas developed by the RCPCH in their national audit will occur using standard audit protocols. This will encompass both doctors involved in the study and also others employed in the department as part of standard governance procedures.

Phase Three (Before and After Study)

Informed by the above process a formal before and after study will be undertaken. In this phase newly inducted junior doctors (Foundation Year 2 and Specialty Trainee 1 doctors) commencing in the Leicester Royal Infirmary in August 2012 will be recruited to the study with those having completed more than 4 months paediatrics at a post-graduate level or in possession of any part of the DCH or MRCPCH exams excluded. All will undergo the assessment measures prior to undertaking the educational package. They will repeat these measures at two weeks and also at three months.

Phase Four (Interviews)

The principal investigators will undertake semi-structured interviews of participants showing the greatest and least

change as demonstrated by performance in the knowledge test and observation exercise.

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
- [x] Undertaking the research
- [ ] Analysis of results
- [ ] Dissemination of findings
- [ ] None of the above

Give details of involvement, or if none please justify the absence of involvement.
The Project Steering Group will have a patient representative from the Emergency Department involved in its work.

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
- [x] Generic Health Relevance
- [ ] Infection
- [ ] Inflammatory and Immune System
- [x] Injuries and Accidents
- [ ] Mental Health
- [ ] Metabolic and Endocrine
- [ ] Musculoskeletal
- [ ] Neurological
- [ ] Oral and Gastrointestinal
- [x] Paediatrics
- [ ] Renal and Urogenital
- [ ] Reproductive Health and Childbirth
- [ ] Respiratory
- [ ] Skin
- [ ] Stroke

Gender: Male and female participants

Lower age limit: 18	Years
Upper age limit: 60	Years

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

For Focus Group:

Junior Doctor ST2 or below

For Observation pilot testing and main study:

Although the children are not being studied directly themselves the observation of a doctors performance will be on children less than 5 years old who present with a fever or parent reported history of a fever.

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

For main study:

Junior doctor in possession of any part of the MRCPCH

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		15	Principal Investigator will obtain in the Emergency Department
Questionnaire (Development)	1		15 min	The test will be online so can be completed by the participant wherever they have access to a computer
Knowledge Test (Development)	1		30min	The test will be online so can be completed by the participant wherever they have access to a computer
Observation of consultation (Development)	5	5	20min	Consultation will be observed by the principal investigator in the Emergency Department
Questionnnaire (Before and After Study)	2		15 min	The test will be online so can be completed by the participant wherever they have access to a computer
Knowledge Test (Before and After Study)	2		30min	The test will be online so can be completed by the participant wherever they have access to a computer.
Observation of consultation (Before and After Study)	2	2	20min	Consultation will be observed by a research nurse within the Emergency Department
Semi-Structured interview	1		60min	Principal Investigator will perform in a seminar room in Emergency Department

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

Participants will be involved for six months

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.

The focus group, questionnaire and knowledge based testing should cause minimum inconvinience.
Observation of consultation testing and during the main study may cause anxiety but at no greater level than undertaking a Work-Place based assessment which is common place in medical practice. It will be clear to participants that their clinical performance is not being formally tested.
All participants will be given clear feedback on their performance at the end of the study to allay any concerns about individual practice variation.

A23. Will interviews/ questionnaires or group discussions include topics that might be sensitive, embarrassing or upsetting, or is it possible that criminal or other disclosures requiring action could occur during the study?

○ Yes ◉ No

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

- Participants will be able to share experiences about dealing with feverish children (a patient group known to cause anxiety)
- Participants will benefit from a well designed educational programme on feverish children
- Participants will gain individual feedback on their evidence based practice

A26. What are the potential risks for the researchers themselves? *(if any)*

None known

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).*

Junior doctors who are new to the Emergency Department will be identified during the induction programme. They will be recruited by the Principal Investigator seperate from the induction process

Children under 5 with a fever or reported fever who will have consultations observed will be identified by the triage nurse and the prinicipal investigator (during the testing phase) or a research nurse (during the before and after study) informed. They will make themselves available to observe the consultation when the patient is seen by a junior doctor who has been recruited into the study. This process will have no impact on the normal clincal care of the patient in the Emergency Department.

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:

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?

The Principal Investigator will approach participants early in their induction programme. Awareness of the project will be disseminated to all junior doctors when they receive their induction packs.

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.

The Principal Investigator will take individual consent.

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?

Participants will have one week to decide whether to be in the programme or not although they may decide sooner than this.

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)*

Participants will all have good english communicative skills.

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:

Participants are medical professionals.

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
- ☐ 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 including X−rays
  - ☐ NHS computers
  - ☐ Home or other personal computers
  - ☐ University computers
  - ☐ Private company computers
  - ☐ Laptop computers

Further details:
Quotes from the focus groups may be published but these will all be anonymysed.

Audio recordings of the focus groups and semi-structured interviews will take place but will be destroyed when the information has been transcripted.

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

Data will be stored on the online website (questionnaires, knowledge) tests and on university computers for the focus groups, interviews, observation of consultations and case note reviews. The online website will be encypted and password protected and the university computers are on a secure server with password protection.

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.*

All data stored will be with a unique indentifier. The link between indentifier and participant will be held in a secure location in the Emergency Medicine Group office. Basic demographic data is needed for the questionnaire but none of this is indentifiable.

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.*

The prinicipal investigator will have sole access during the study.

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 collated in the Leicester University Emergency Medicine Group office and by analysed by the prinicipal 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 Group		
	Room 003A, RKCS Building		
	LRI, Leicester		
Post Code	LE1 5WW		
Work Email	dr98@le.ac.uk		
Work Telephone	01162523263		
Fax			

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.*

Data will be stored on the Personal computer of the Principal Investigator who has sole access to their terminal. This data would be transferred to an encrypted data storage device if they were to be employed elsewhere. No identifiable data will be stored.

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. Will the research be registered on a public database?

◉ Yes ○ No

Please give details, or justify if not registering the research.
As the princple investigator is funded by the NIHR the results will be available on UK PubMed Central.

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?

N/A

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 have their performance individually fed back to them on completion of the project.

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 NIHR Doctoral Research Fellowship is an annual award given by an independant panel of leading research active health care professionals. A committee has reviewed the award application and interviewed the Prinicipal Investigator.

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	Health Services		
Institution	Leicester University		
Work Address	NIHR RDS East Midlands		
	22-28 Princess Rd West		
	Leicester		
Post Code	LE1 6TP		
Telephone	0116-252-5416		

Fax
Mobile
E-mail nick.taub@leicester.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?

As a before and after study there is no fixed primary outcome.

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: 36
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.*

The sample size is taken from the maximum number of junior doctors commencing in the Emergency Department each year.

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.

There are four outcomes of investigation

1. Attitudinal change via questionnaire:

This will undergo descriptive analysis for demographic details

2. Knoweldge Change via testing

T-tests will be used to define the change in knowledge scores before and after the intervention

3. Behaviour Change via observation

T-tests will be used to define the change in assessment scores before and after the intervention

4. Audit

Departmental adherence to standards defined by NICE will be compared before and after the intervention

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	Tim	Coats
Post	Professor of Emergency Medicine		
Qualifications	BSc MB BS FRCS FFAEM MD		
Employer	Leicester University		
Work Address	Emergency Medicine Group Room 003A, RKCS Building LRI, Leicester		
Post Code	LE1 5WW		
Telephone	01162523263		
Fax			
Mobile			
Work Email	tc61@le.ac.uk		

	Title	Forename/Initials	Surname
	Dr	David	Matheson
Post	Lecturer in Medical Education		
Qualifications	BSc, PGCE, DipEd, MEd, PhD, FRSA		
Employer	Nottingham University		
Work Address	Room B94c Medical School Queens Medical Centre Nottingham		
Post Code	NG7 2UH		
Telephone	0115 823 0033		
Fax			
Mobile			
Work Email	david.matheson@nottingham.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	NIHR
Address	NIHR Trainees Coordinating Centre Leeds Innovation Centre 103 Clarendon Road, Leeds
Post Code	LS2 9DF
Telephone	0113 346 6262
Fax	0113 346 6272
Mobile	
Email	karen.fernando@nihrtcc.org.uk

Funding Application Status: ◉ Secured ◯ In progress

Amount: 303,654.92

Duration

Years: 3

Months: 0

If applicable, please specify the programme/ funding stream:

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

NIHR Doctoral Research Fellowship Award Scheme

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	Sharon	Turner
Organisation	University Hospitals of Leicester NHS Trust		
Address	Research & Development Office		
	Leicester General Hospital		
	Gwendolen Road		
Post Code	LE5 4PW		
Work Email	Sharon.turner@uhl-tr.nhs.uk		
Telephone	0116 258 8351		
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: 01/08/2011

Planned end date: 03/09/2013

Total duration:

Years: 2 Months: 0 Days: 2

A71-1. Is this study?

◉ Single centre

○ Multicentre

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

- [x] 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:*

[x] 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?

Local governance arrangements apply as per Good Clinical Practice Guidance. The Principal Investigator is under the supervision of Prof. Tim Coats who has reserach governance responsibility for the Emergency Department.

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)

The University of Leicester possesses Clinical Trials and Professional Indemnity Insurance which will cover this study

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)

The University of Leicester possesses Clinical Trials and Professional Indemnity Insurance which will cover this study

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

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	University Hospitals of Leicester NHS Trust	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	Derby Hospitals NHS Foundation Trust	Title	Ms
Department name	Emergency Department	First name/ Initials	Coral
Street address	Uttoxeter Road	Surname	Smith
Town/city	Derby		
Post Code	DE22 3DT		
Institution name	University Hospitals Coventry and Warwickshire	Title	Dr
Department name	Emergency Department	First name/ Initials	Magdy
Street address	Clifford Bridge Road	Surname	Sakr
Town/city	Coventry		
Post Code	CV2 2DX		
Institution name	Royal Berkshire NHS Foundation Trust	Title	Dr
Department name	Emergency Department	First name/ Initials	Liza
Street address	London Road	Surname	Keating
Town/city	Reading		
Post Code	RG1 5AN		
Institution name	Northampton General Hospitals NHS Trust	Title	Dr
Department name	Emergency Department	First name/ Initials	Tristan
Street address	Cliftonville	Surname	Dyer
Town/city	Northampton		
Post Code	NN1 5BD		
Institution name	Portsmouth Hospitals NHS Foundation Trust	Title	Ms
Department name	Emergency Department	First name/ Initials	Sarah
Street address	Southwick Hill Road	Surname	Cooke
Town/city	Portsmouth		
Post Code	PO6 3LY		

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 23/06/2011 09:15.

Job Title/Post:

Organisation:

Email:

Signature: .....

Print Name: Damian Roland

Date: 04/05/2011 *(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 23/06/2011 15:25.

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

D3. Declaration for student projects by academic supervisor(s)

1. I have read and approved both the research proposal and this application. I am satisfied that the scientific content of the research is satisfactory for an educational qualification at this level.

2. I undertake to fulfil the responsibilities of the supervisor for this study as set out in the Research Governance Framework for Health and Social Care.

3. I take responsibility for ensuring that this study is conducted in accordance with the ethical principles underlying the Declaration of Helsinki and good practice guidelines on the proper conduct of research, in conjunction with clinical supervisors as appropriate.

4. I take responsibility for ensuring that the applicant is up to date and complies with the requirements of the law and relevant guidelines relating to security and confidentiality of patient and other personal data, in conjunction with clinical supervisors as appropriate.

Academic supervisor 1

This section was signed electronically by Timothy Coats on 18/07/2011 11:33.

Job Title/Post:	Professor of Emergency Medicine
Organisation:	University of Leicester
Email:	tc61@le.ac.uk

Academic supervisor 2

This section was signed electronically by David Matheson on 11/07/2011 10:54.

Job Title/Post:	lecturer in medical education
Organisation:	UoN
Email:	david.matheson@nottingham.ac.uk