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 or clinical investigation
(●) 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, other human biological samples and/or 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?

- ☑ 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)

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

● Yes ○ No

5a. Do you want your application 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 participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research 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 the study, being undertaken as an educational project?

● Yes ○ No

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 clinical care team without prior consent at any stage of the project (including identification of potential participants)?

○ Yes ◉ No

Site-Specific Information Form

Is the site hosting this research a NHS site or a non-NHS site? *NHS sites include Health and Social Care organisations in Northern Ireland. The sites hosting the research are the sites in which or through which research procedures are conducted. For NHS sites, this includes sites where NHS staff are participants.*

- (●) NHS site
- ( ) Non-NHS site

This question must be completed before proceeding. The filter will customise the form, disabling questions which are not relevant to this application.

One Site-Specific Information Form should be completed for each research site and submitted to the relevant R&D office with the documents in the checklist. See guidance notes.

The data in this box is populated from Part A:

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

Short title: Evaluating outcomes of interventions that change practice

Chief Investigator:

Title	Forename/Initials	Surname
Dr	Damian	Roland

Name of NHS Research Ethics Committee to which application for ethical review is being made:
NRES COMMITTEE EAST MIDLANDS – DERBY 1 RESEARCH ETHICS COMMITTEE

Project reference number from above REC: 11/EM/0186

1-1. Give the name of the NHS organisation responsible for this research site

University Hospitals of Leicester NHS Trust

1-2. In which country is the research site located?

- (●) England
- ( ) Wales
- ( ) Scotland
- ( ) Northern Ireland

1-3. Is the research site a GP practice or other Primary Care Organisation?

( ) Yes (●) No

2. Who is the Principal Investigator or Local Collaborator for this research at this site?

Select the appropriate title: (•) Principal Investigator ( ) Local Collaborator

	Title	Forename/Initials	Surname
	Dr	Damian	Roland
Post	NIHR Doctoral Research Fellow		
Qualifications	BMedSci, BMBS, MRCPCH		
Organisation	Leicester University		
Work Address	Emergency Medicine Group		
	Room 003A, RKCS Building		
	LRI, Leicester		
PostCode	LE1 5WW		
Work E-mail	dr98@le.ac.uk		
Work Telephone	01162523263		
Mobile	07727158213		
Fax			

a) Approximately how much time will this person allocate to conducting this research? *Please provide your response in terms of Whole Time Equivalents (WTE).*
1.0

b) Does this person hold a current substantive employment contract, Honorary Clinical Contract or Honorary Research Contract with the NHS organisation or accepted by the NHS organisation? (•) Yes ( ) No

A copy of a current CV for the Principal Investigator (maximum 2 pages of A4) must be submitted with this form.

3. Please give details of all locations, departments, groups or units at which or through which research procedures will be conducted at this site and describe the activity that will take place.

Please list all locations/departments etc where research procedures will be conducted within the NHS organisation, describing the involvement in a few words. Where access to specific facilities will be required these should also be listed for each location.

Name the main location/department first. Give details of any research procedures to be carried out off site, for example in participants' homes.

	Location	Activity/facilities
1	Emergency Department Seminar Room	Focus Group and Semi-structured Interviews
2	Emergency Department	Observation of doctors consultations with patients

5. Please give details of all other members of the research team at this site.

6. Does the Principal Investigator or any other member of the site research team have any direct personal involvement (e.g. financial, share-holding, personal relationship etc) in the organisation sponsoring or funding the research that may give rise to a possible conflict of interest?

( ) Yes (•) No

7. What is the proposed local start and end date for the research at this site?

Start date:	01/11/2010
End date:	03/09/2013
Duration (Months):	34

8-1. 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.)*

Columns 1-4 have been completed with information from A18 as below:

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

Please complete Column 5 with details of the names of individuals or names of staff groups who will conduct the procedure at this site.

Intervention or procedure	1	2	3	4	5
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	

8-2. Will any aspects of the research at this site be conducted in a different way to that described in Part A or the protocol?

○ Yes ◉ No

If Yes, please note any relevant changes to the information in the above table.

Are there any changes other than those noted in the table?

10. How many research participants/samples is it expected will be recruited/obtained from this site?

A maximum of 35

11. Give details of how potential participants will be identified locally and who will be making the first approach to them to take part in the study.

Potential participants are all junior doctors who have arrived in the Emergency Department as a foundation trainee or Specialty Doctor 1 since August 2010. The Prinicipal Investigator will make the first approach to include them in the study.

12. Who will be responsible for obtaining informed consent at this site? What expertise and training do these persons have in obtaining consent for research purposes?

Name	Expertise/training
Dr. Damian Roland	GCP up-to-date. Consent training for Magnetic Trial (Magnesium in Children)and consented patients into trial on regular basis. Gained consent for 50 children recruited into study on dehydration

15-1. Is there an independent contact point where potential participants can seek general advice about taking part in research?

Only new starting junior doctors in the Emergency Department will be eligible to partake in the study. Information for junior doctors in the Emergency Department regarding research is availble from Prof. Tim Coats via his secretary.

15-2. Is there a contact point where potential participants can seek further details about this specific research project?

Only new starting junior doctors in the Emergency Department will be eligible to partake in the study. Junior Doctors may contact Dr. Damian Roland with regard to further information.

16. Are there any changes that should be made to the generic content of the information sheet to reflect site-specific issues in the conduct of the study? *A substantial amendment may need to be discussed with the Chief Investigator and submitted to the main REC.*

No

Please provide a copy on headed paper of the participant information sheet and consent form that will be used locally. Unless indicated above, this must be the same generic version submitted to/approved by the main REC for the study while including relevant local information about the site, investigator and contact points for participants (see guidance notes).

17. What local arrangements have been made for participants 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 etc.)*

Only junior doctors will be used - no communication issues are expected.

18. What local arrangements will be made to inform the GP or other health care professionals responsible for the care of the participants?

Not applicable.

19. What arrangements (e.g. facilities, staffing, psychosocial support, emergency procedures) will be in place at the site, where appropriate, to minimise the risks to participants and staff and deal with the consequences of any harm?

Not applicable

20. What are the arrangements for the supervision of the conduct of the research at this site? *Please give the name and*

contact details of any supervisor not already listed in the application.

Supervision will be via local arrangements with the R+D office and Leicester University. This is an educational rather than clinical project.

21. What external funding will be provided for the research at this site?

- ○ Funded by commercial sponsor
- ◉ Other funding
- ○ No external funding

Please give details of the funding:
NIHR Doctoral Research Fellowship (£307000)

Type of funding	Details (including breakdown over years if appropriate)
(i) Block grant	NIHR Doctoral Research Fellowship
(ii) Per participant	
(iii) Other (give details)	

Which organisation will receive and manage this funding?
Leicester University

23. Authorisations required prior to R&D approval

This section deals with authorisations by managers within the NHS organisation. It should be signed in accordance with the guidance provided by the NHS organisation. This may include authorisation by clinical supervisors, line managers, service managers, support department managers, pharmacy, data protection officers or finance managers, depending on the nature of the research. Managers completing this section should confirm in the text what the authorisation means, in accordance with the guidance provided by the NHS organisation.

This section may also be used by university employers or research support staff to provide authorisation to NHS organisations, in accordance with guidance from the university.

1. Type of authorisation:
Clinical Supervisor

	Title	Forename/Initials	Surname
	Prof	Tim	Coats
Post	Professor of Emergency Medicine		
Qualifications	BSc MB BS FRCS FFAEM MD		
Organisation	Leicester University		
Work Address	Emergency Medicine Group		
	Room 003A, RKCS Building		
	LRI, Leicester		
PostCode	LE1 5WW		
Work E-mail	tc61@le.ac.uk		
Work Telephone	01162523263		
Mobile			
Fax			

Signature: .....

Date: .....

Declaration by Principal Investigator or Local Collaborator

1. The information in this form is accurate to the best of my knowledge and I take full responsibility for it.
2. I undertake to abide by the ethical principles underpinning the World Medical Association's Declaration of Helsinki and relevant good practice guidelines in the conduct of research.
3. If the research is approved by the main REC and NHS organisation, I undertake to adhere to the study protocol, the terms of the application of which the main REC has given a favourable opinion and the conditions requested by the NHS organisation, and to inform the NHS organisation within local timelines of any subsequent amendments to the protocol.
4. If the research is approved, I undertake to abide by the principles of the Research Governance Framework for Health and Social Care.
5. I am aware of my responsibility to be up to date and comply with the requirements of the law and relevant guidelines relating to the conduct of research.
6. I undertake to disclose any conflicts of interest that may arise during the course of this research, and take responsibility for ensuring that all staff involved in the research are aware of their responsibilities to disclose conflicts of interest.
7. I understand and agree that study files, documents, research records and data may be subject to inspection by the NHS organisation, the sponsor or an independent body for monitoring, audit and inspection purposes.
8. I take responsibility for ensuring that staff involved in the research at this site hold appropriate contracts for the duration of the research, are familiar with the Research Governance Framework, the NHS organisation's Data Protection Policy and all other relevant policies and guidelines, and are appropriately trained and experienced.
9. I undertake to complete any progress and/or final reports as requested by the NHS organisation and understand that continuation of permission to conduct research within the NHS organisation is dependent on satisfactory completion of such reports.
10. I undertake to maintain a project file for this research in accordance with the NHS organisation's policy.
11. I take responsibility for ensuring that all serious adverse events are handled within the NHS organisation's policy for reporting and handling of adverse events.
12. I understand that information relating to this research, including the contact details on this application, will be held by the R&D office and 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.
13. I understand that the information contained in this application, any supporting documentation and all correspondence with the R&D office and/or the REC system relating to the application 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.

This section was signed electronically by Dr Damian Roland on 23/06/2011 08:41.

Job Title/Post:

Organisation:

Email: