National Research Ethics Service

**NRES Committee East Midlands - Derby 1**
Research Ethics Office
The Old Chapel
Royal Standard Place
Nottingham
NG1 6FS

Telephone: 0115 8839435
Facsimile: 0115 9123300

02 June 2011

Dr Damian Roland
NIHR Doctoral Research Fellow
Leicester University
Emergency Medicine Group
Room 003A, RKCS Building
LRI, Leicester LE1 5WW

Dear Dr Roland

| | |
|---|---|
| **Study title:** | **Refining evaluation methodologies for interventions that change practice: A model to assess the effectiveness of an e-Learning tool.** |
| **REC reference:** | **11/EM/0186** |

The Proportionate Review Sub-committee of the NRES Committee East Midlands - Derby 1 Research Ethics Committee reviewed the above application on 02 June 2011.

**Ethical opinion**

On behalf of the Committee, the sub-committee gave a favourable ethical opinion of the above research on the basis described in the application form, protocol and supporting documentation, subject to the conditions specified below.

**Ethical review of research sites**

The favourable opinion applies to all NHS sites taking part in the study, subject to management permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

**Conditions of the favourable opinion**

The favourable opinion is subject to the following conditions being met prior to the start of the study.

Management permission or approval must be obtained from each host organisation prior to the start of the study at the site concerned.

*Management permission ("R&D approval") should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements.*

*Guidance on applying for NHS permission for research is available in the Integrated Research Application System or at http://www.rdforum.nhs.uk.*

*Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.*

*For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.*

*Sponsors are not required to notify the Committee of approvals from host organisations.*

**It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).**

**You should notify the REC in writing once all conditions have been met (except for site approvals from host organisations) and provide copies of any revised documentation with updated version numbers. Confirmation should also be provided to host organisations together with relevant documentation.**

**Approved documents**

The documents reviewed and approved were:

| *Document* | *Version* | *Date* |
|---|---|---|
| Evidence of insurance or indemnity | | 13 August 2010 |
| Investigator CV | | |
| Other: Student CV | | |
| Other: Information on Spotting the Sick Child (Press Release) | 1.1 | 12 May 2011 |
| Other: Spotting the Sick Child Patient Safety Award Information | | 01 March 2011 |
| Participant Consent Form | 1.1 | 12 May 2011 |
| Participant Information Sheet | 1.1 | 12 May 2011 |
| Protocol | 1.1 | 12 May 2011 |
| REC application | | 12 May 2011 |
| Referees or other scientific critique report | | 13 October 2010 |

**Membership of the Proportionate Review Sub-Committee**

The members of the Sub-Committee who took part in the review are listed on the attached sheet.

**Statement of compliance**

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

**After ethical review**

Now that you have completed the application process please visit the National Research Ethics Service website > After Review

You are invited to give your view of the service that you have received from the National Research Ethics Service and the application procedure. If you wish to make your views known please use the feedback form available on the website.

The attached document "After ethical review – guidance for researchers" gives detailed

guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Progress and safety reports
- Notifying the end of the study

The NRES website also provides guidance on these topics, which is updated in the light of changes in reporting requirements or procedures.

We would also like to inform you that we consult regularly with stakeholders to improve our service. If you would like to join our Reference Group please email referencegroup@nres.npsa.nhs.uk.

| **11/EM/0186** | **Please quote this number on all correspondence** |
|---|---|

With the Committee's best wishes for the success of this project

Yours sincerely

pp. JRlea

**Mr Peter Korczak**
**Chair**

Email: jennifer.lea@nottspct.nhs.uk

*Enclosures:* *List of names and professions of members who took part in the review*

*"After ethical review – guidance for researchers"*

*Copy to:* *Mr Graham Hewitt*
*Leicester University, College of Leicester, Leicester LE1 7RH*

*Ms Sharon Turner, University Hospitals of Leicester NHS Trust*
*R&D Office, Leicester General Hospital, Gwendolen Road, LE5 4PW*

Professional Risks
Dawson House
5 Jewry Street
London EC3N 2PJ
Tel: +44 (0)20 7488 2345
Fax: +44 (0)20 7481 0511
www.miller-insurance.com

**VERIFICATION OF INSURANCE**

**To Whom It May Concern**

We, the undersigned Insurance Brokers hereby confirm that the following described Insurance **is in force at this date.**

**CLINICAL TRIALS NO FAULT COMPENSATION & LEGAL LIABILITY INSURANCE**

| | |
|---|---|
| **Insured:** | University of Leicester and/or subsidiary companies and/or any officer or members of the Council or the Senate or a committee whilst acting on behalf of the Assured |
| **Period of Insurance:** | From: 1st August 2010<br>To: 31st July 2011 |
| **Interest:** | To indemnify the Assured in respect of claims for compensation first made in writing against the Assured during the period of the Policy in respect of all trials undertaken. |
| **Limit of Indemnity:** | GBP 10,000,000 any one event and in all in the Period of Insurance plus costs and expenses |
| **Conditions:** | As per Policy, plus:<br>Excess: GBP5,000 any one event including costs and expenses increasing to GBP12,000 any one event including costs and expenses in respect of Children's Cancer and Leukaemia Group trials sponsored by the University of Leicester |
| **Insurers:** | Novae Insurance Company Limited (50%) and Brit Insurance (50%) |
| **Policy No.:** | B0621PUNI03610 |

This document is furnished to you as a matter of information only.

The issuance of this document does not make the person or organisation to whom it has been issued an additional Assured, nor does it modify in any manner the contract of insurance between the Assured and Underwriters. Any amendment, change or extension of such contract can only be effected by specific endorsement.

Should the above mentioned contract of insurance be cancelled, assigned or changed during the above policy period in such manner as to affect this document, no obligation to inform the Holder of this document is accepted by the undersigned Insurance Brokers.

**Signed** .....  **Dated** 13th August 2010

**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. 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 12/05/2011 09:57.

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

NHS
National Institute for Health Research

Trainees Coordinating Centre

NIHR Trainees Coordinating Centre
Leeds Innovation Centre
103 Clarendon Road
Leeds LS2 9DF
Tel: 0113 346 6262
Fax: 0113 346 6272
Email: karen.fernando@nihrtcc.org.uk

13th October 2010

Dr. Damian Roland
Academic Clinical Fellow in Paediatric Emergency Medicine
Emergency Department
University Hospitals of Leicester NHS Trust

Dear Damian

**NIHR Fellowship Scheme – Round 3 Doctoral Research Fellowship**
**Application: NIHR-DRF-2010-03-119**
**Refining evaluation methodologies for interventions that change practice.**

Thank you for submitting an application to the third round of the NIHR Fellowship scheme (NIHR Doctoral Research Fellowship). As you should already have been informed, your application for funding was successful.

Please find attached copies of the anonymised assessment forms concerning your application. You should particularly note that this scheme is highly competitive and it is possible for assessment forms to not be supportive of your application even though it has been successful. It is important to note that your application was considered and discussed by all of the Panel members at the meeting, before making their final recommendations.

In discussing your application at the Panel meeting, the Panel identified the following points:

- Good presentation and excellent discussion
- Important, timely and realistic project; could produce findings with broader applicability
- Training and development looks appropriate and targeted
- Query patient benefit from this project?

No further information concerning your application is held and, consequently, the NIHR TCC is not able to enter into further communication concerning your proposal or this feedback.

May I once again thank you for your application. I hope you find this feedback constructive.

Yours sincerely
KFernando

**Karen Fernando**
Programme Manager

The Faculty of Pharmaceutical Medicine has accredited this course for 9 Continuing Professional Development credits.

**GCP web-based training course designed and developed by**

INFONETICA

Ashford and St. Peter's Hospitals NHS
NHS Trust

# *Certificate Of Achievement*

This is to certify that

**Damian Roland**

of University Hopsitals of Leicester NHS Trust

has successfully passed a web-based examination covering all aspects of the International Conference on Harmonisation – Good Clinical Practice Guideline Course

22 October 2009

(Recommended renewal date: 22 October 2011)

Certificate No: 5760-1-7243

Course Director

Dr Isaac John, Hon Lecturer
Royal Holloway, University of London
Assistant Director Research & Development
Ashford & St Peter's Hospitals NHS Trust

Royal Holloway University of London

Endorsed by

Professor George Dickson
Head, School of Biological Sciences
Royal Holloway, University of London