Business Services Organisation
Providing Support to Health and Social Care

Office for Research Ethics Committees Northern Ireland (ORECNI)

Customer Care & Performance Directorate
Office Suite 3
Lisburn Square House
Haslem's Lane
Lisburn
Co. Antrim BT28 1TW
Tel: + 44 (0) 28 9260 3107
Fax: + 44 (0) 28 9260 3619
www.orecni.hscni.net

HSC REC 1

COPY

RESEARCH OFFICE
28 JAN 2013
SOUTH EASTERN TRUST

23 January 2013

Dr Ian Ryans
Rheumatology Department
South Eastern HSC Trust
Ulster Hospital
Dundonald
BT16 1RH

Dear Dr Ryans

Study title:	**Treatment of Shoulder Capsulitis by Single or Multiple Corticosteroid Injections**
REC reference:	**07/NIR01/79**
Protocol number:	**10.05.7**
EudraCT number:	**2007-001709-85**
IRAS project ID:	**N/A**

Thank you for notifying the Research Ethics Committee that the above study concluded on 29 June 2010 and the summary of the final research report. I will arrange for the Committee to be notified.

These will be reviewed by the Chair of the Research Ethics Committee, and I will let you know if any further information is requested.

07/NIR01/79: **Please quote this number on all correspondence**

Yours sincerely

Kathryn Taylor

Kathryn Taylor
Committee Administrator
E-mail: Kathryn.Taylor@hscni.net

Copy to: ✓ *Mr Paul Carlin, Research Manager, South Eastern HSC Trust*

Sands, Janice

From:	Ian Ryans [ianryans@me.com]
Sent:	05 December 2012 16:53
To:	Sands, Janice
Subject:	Fwd: 07/NIR01/79
Attachments:	End of Study Report (FINAL) IR-Injection.pdf; ATT00001.htm; MHRA End of Trial.pdf; ATT00002.htm
Follow Up Flag:	Follow up
Flag Status:	Flagged
Categories:	Janice to do

Begin forwarded message:

From: Ian Ryans <ianryans@me.com>
Subject: 07/NIR01/79
Date: 5 December 2012 16:52:19 GMT
To: katheryn.taylor@hscni.net

Dear Kathryn,
Thank you for your letter dated 16th of November 2012 requesting an annual review update on this trial. This trial finished in 2010 due to poor recruitment. I have attached the MHRA acknowledgement of the end of trial and the final trial report. I was under the impression that this had already been reported to you. Sorry for any confusion.

Best regards

Ian Ryans

1/12/12 – File closed today + docs added –
End of study report final version 1.0
MHRA dated 6/7/2010.

28/1/13 – letter from OREC NI dated 23/1/13 recd – summary of final research report. (We have this doc so have just filed this).

Safeguarding public health

Dr I Ryans
SOUTH EASTERN HEALTH AND SOCIAL CARE TRUST
RHEUMATOLOGY DEPARTMENT, ULSTER HOSPITAL
UPPER NEWTOWNARDS ROAD, DUNDONALD
BELFAST
BT16 1RH
UNITED KINGDOM

06/07/2010

Dear Dr I Ryans

THE MEDICINES FOR HUMAN USE (CLINICAL TRIALS) REGULATIONS 2004 S.I. 2004/1031

Our Reference	32029/0001/001-0002
Eudract Number	2007-001709-85
Product	Kenalog Intra-articular
Protocol number	10.05.7

ACKNOWLEDGEMENT OF END OF TRIAL

Thank you for sending your end of trial declaration, received on 06/07/2010.

If you have not already submitted an End of Trial Study Report, we would like to remind you that it should be submitted to the Licensing Authority within one year of the end of the trial.

Yours sincerely,

Submissions
MHRA

Dr Ian Ryan

Proposal to act as consultant for 2 trials on shoulder treatment and 1 preliminary trial.

13/8/2007

CONTENTS

1.	INTRODUCTION	3
2.	CLIENT REQUIREMENTS	4
3.	PROPOSED SERVICE	5
4.	CONSULTANT PROFILE	6
5.	COMMERCIAL PROPOSAL	7

APPENDIX A

CONSULTANT CURRICULUM VITAE

1 1 INTRODUCTION

Dr Annette Harte, School of Health Science, Faculty of Life and Health Science at the University of Ulster is pleased to submit a proposal to assist Dr Ian Ryan to conduct two trials on the management of shoulder pain: Treatment of shoulder capsulitis by single or multiple corticosteroid injections; The treatment of subacromial shoulder pain by individual or group physiotherapy following corticosteroid injection. In addition a preliminary trial will also be conducted on the validation of the inter observer stability of classification of shoulder pain by pattern of restriction in range on movement.

Our proposal is in response to your brief dated November 2006.

Should you have any queries relating to this proposal, please do not hesitate to contact Dr Annette Harte who can be reached on
90366650, or via e-mail at aa.harte@ulster.ac.uk.

2 2 CLIENT REQUIREMENTS

2.1 Your Terms of Reference for this Project

To give advice on:

- Development of final clinical trial protocol
- Physiotherapy intervention for subacromial trial
- Data collection sheet design
- Development of SPSS database for data collection
- Analysis and study write up
- Assist with training needs for research therapist and physiotherapists working within the trial protocol

3 3 WORK PROGRAMME

3.1 Project Description

3 trials will be undertaken
1. A validation of the inter observer stability of classification of shoulder pain on restriction in range of movement. This study is a preliminary study for both studies below. It will look at the validation of a system of classification of shoulder movement restriction to identify patients with capsulitis and subacromial impingement. This study will recruit 85 patients who will be assessed by two independent and blinded examiners and findings will be analysed in order to estimate the agreement between examiners.

2. Treatment of shoulder capsulitis by single or multiple corticosteroid injection. A double blind randomised. The aim of this study is to determine if repeated injections (3) are more effective than a single injection in the treatment of shoulder capsulitis. 150 subjects will be randomly assigned to one of the two treatment groups (3 or 1 injection) and outcomes will be recorded at baseline, 12, 18 and 26 weeks.

3. Treatment of subacromial shoulder pain by individual or group physiotherapy following corticosteroid injection. The aim of this study is to determine if a course of rotator cuff rehabilitation classes is as effective as individual physiotherapy in the treatment of shoulder pain due to subacromial pain. 200 patients will be randomly assigned to each group after corticosteroid injection. Outcomes will be recorded at 12, 26, 52 weeks.

3.2 Work Programme

- Advice for general running and final design of the trial
- Development of data collection sheets
- Development of patient advice sheets and consent forms
- Training and assistance for research therapist e.g. setting up SPSS data files, developing training for intervention physiotherapists prior to trial commencement
- Reviewing articles etc for publication and conference submission

3.3 Deliverables

Development of final research proposal
Development of data collection forms
Development of patient information sheets
Development of SPSS spread sheet
Reviewing of papers, reports, presentations etc
Support for research therapist
Training of physiotherapists applying interventions

4 4 CONSULTANT PROFILE

4. 1 Consultant Profile

Dr Annette Harte is a lecturer in the School of Health Science, Faculty of Life and Health Science at the University of Ulster. She has more than 20 years' clinical experience in the field of musculoskeletal management and also has 6 years experience in the area of research.

Dr Harte has a BSc (Hons) in physiotherapy from the University of Ulster (1982), a postgraduate certificate in Research studies (2000) and recently obtained a PhD also from the university of Ulster (2006).

Dr Harte has completed a PhD which included conducting a randomised controlled trial and has experience of running a trial, developing protocols and data collection sheets, recruiting and screening patients and analysing data.
She also has considerable experience with writing and publishing papers related to her work, presenting at conferences and poster presentations.
In addition her strong clinical background in the area of musculoskeletal management makes her ideally placed to advise re physiotherapy interventions. Her teaching and research experience also place her to assist with training of staff who will be applying interventions and in supporting the research therapist in her role.

5 5 COMMERCIAL PROPOSAL

5.1 Commercial Fee Quotation

To undertake the programme of work described we will spend a total of 18 days. This produces a fee of **£11,700**.

No additional expenses e.g. travelling will be charged for these days.
We will recharge expenses at cost. Expenses will be limited to a maximum of 5% of the professional fees incurred.

VAT will also be charged for this project at the standard rate of 17.5%. The maximum cost for the total of the work involved will be:

Consulting Fee	£11,700
Expenses	£x
Sub-Total	£x
VAT at 17.5%	£2047.5
Total Cost	£13747.5

The University of Ulster's wholly owned subsidiary UUTech Limited kindly requests payment within 30 days of date of invoice.

5.2 Project Timing

Project started in November 2006 with work ongoing until approximately Dec 2011.
Dr Ian Ryan suggested that I would be required 1 day per month for the first 6 months to:

- finalise the protocol - completed
- physiotherapy intervention - completed
- develop data collection sheets - completed
- SPSS database – ongoing
- assist with training of research therapist and intervention therapists - ongoing

Total of 5 days has been completed.

Ongoing input will include1 day approximately every 6 months during recruitment and follow up of patients (6 days) and then 1 day per month for the final 6 months (6 days) to advise on data analysis and write up of papers, conference presentations and posters etc.

6 CONTRACT

To be completed on notification of commission of work

[Signatory's Name] on behalf of [Client Name] confirms the commission of the aforementioned consultancy project, and agrees the project scope and cost as set out in this proposal. I/We agree to honour the payment terms as requested.

Signed by [Signatory's Name] on behalf of [Client Name]

Dated

Joel Ferguson, UUTech Ltd for and on behalf of the University of Ulster

---

Dated

---

copy + file in Ryans projects

Sands, Janice

From: Carlin, Paul
Sent: 22 June 2010 10:07
To: Sands, Janice
Subject: FW: HSC R&D budget - URGENT help required

Importance: High

Hi Janice

can you print this email and file in Ian Ryans

Thanks
Paul

-----Original Message-----
From: Bailie, Janice [mailto:Janice.Bailie@hscni.net]
Sent: 11 June 2010 11:56
To: ianryans@doctors.org.uk
Cc: Carlin, Paul
Subject: HSC R&D budget - URGENT help required
Importance: High

This email is covered by the disclaimer found at the end of this message.

Dear Ian,

As you will probably have heard by now, the HSC R&D budget has been cut by £2M this year. Michael has asked us to check with all investigators whether they will be spending their full budget allowance in 2010-11, to identify any potential slippage that there might be.

As I am sure you can imagine we are trying to juggle with the remaining funds, so it is important to identify any potential underspends early - that way we will a. have the chance of redistributing any unused funds to other areas and b. avoid the embarrassment and misfortune of finding out at year end next March that we have not completely spent all of our reduced allowance.

You had previously indicated that one of your intended studies may not recruit enough subjects and might have to close, but that there would be little impact on staffing levels. Can you please update me on this situation. At present your 2010-11 budget contains a full year's costs for 0.2 WTE for yourself, 0.5 WTE for a Grade 3 secretary, 0.5 WTE for Rhona Galway and £4125 service support costs. Can you please confirm whether you will need to incur all of these costs to complete your RRG project? If not, could you let us know and we can adjust the budget accordingly.

I would be most grateful if you could consider this and come back to me at your earliest convenience.

Office for Research Ethics Committees Northern Ireland (ORECNI)

Office Suite 3
1-4 Haslems Lane
Lisburn
Co. Antrim BT28 1TW
Tel: + 44 (0) 28 9260 3107
Fax: + 44 (0) 28 9260 3619
www.orecni.org.uk

HSC REC 1

13 November 2007

Dr Ian Ryans
Hospital/General Practitioner
Ulster Hospital
Dundonald
Belfast
BT16 0RH

Dear Dr Ryans

Full title of study:	**Treatment of Shoulder Capsulitis by Single or Multiple Corticosteroid Injections**
REC reference number:	**07/NIR01/79**
Protocol number:	**5.0**
EudraCT number:	**2007-001709-85**

Thank you for your letter of 31 October 2007, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information was considered at the meeting of the Sub-Committee of the REC held on 13 November 2007. A list of the members who were present at the meeting is attached.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm **a favourable ethical opinion** for the above research on the basis described in the application form, protocol and supporting documentation as revised.

Ethical review of research sites

The favourable opinion applies to the research sites listed on the attached form.

Conditions of approval

The favourable opinion is given provided that you comply with the conditions set out in the attached document. You are advised to study the conditions carefully.

The sponsor is asked to provide the Committee with a copy of the notice from the MHRA, either confirming clinical trial authorisation or giving grounds for non-acceptance, as soon as this is available.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

Document	*Version*	*Date*
Application		23 July 2007
Application	Updated to include information on exposure to ionising radiation	31 October 2007
Investigator CV	Dr Ian Ryans	
Protocol	5.0	30 September 2007
Protocol	4.1	01 June 2007
Covering Letter		23 July 2007
Summary/Synopsis	2.1	01 June 2007
Letter from Sponsor	Form from Ulster Hospital confirming sponsorship and indemnity arrangements	12 June 2007
Peer Review	Copies of R&D Office Peer Reviews, and researcher's response	06 March 2006
GP/Consultant Information Sheets	1.0	01 July 2007
Participant Information Sheet	2.5	01 June 2007
Participant Information Sheet	3.0	30 September 2007
Participant Consent Form	3.0	30 September 2007
Participant Consent Form	2.5	01 June 2007
Response to Request for Further Information	Covering Letter addressing Committee concerns	31 October 2007
Request form for authorisation from MHRA		26 July 2007
Letters from R&D Office confirming funding		23 June 2006

R&D approval

All researchers and research collaborators who will be participating in the research at NHS sites should apply for R&D approval from the relevant care organisation, if they have not yet done so. R&D approval is required, whether or not the study is exempt from SSA. You should advise researchers and local collaborators accordingly.

Guidance on applying for R&D approval is available from http://www.rdforum.nhs.uk/rdform.htm.

Statement of compliance

This Committee is recognised by the United Kingdom Ethics Committee Authority under the Medicines for Human Use (Clinical Trials) Regulations 2004, and is authorised to carry out the ethical review of clinical trials of investigational medicinal products.

The Committee is fully compliant with the Regulations as they relate to ethics committees and the conditions and principles of good clinical practice.

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 Website > After Review

Here you will find links to the following

a) Providing feedback. You are invited to give your view of the service that you have received from the National Research Ethics Service on the application procedure. If you wish to make your views known please use the feedback form available on the website.
b) Progress Reports. Please refer to the attached Standard conditions of approval by Research Ethics Committees.
c) Safety Reports. Please refer to the attached Standard conditions of approval by Research Ethics Committees.
d) Amendments. Please refer to the attached Standard conditions of approval by Research Ethics Committees.
e) End of Study/Project. Please refer to the attached Standard conditions of approval by Research Ethics Committees.

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@nationalres.org.uk .

07/NIR01/79	**Please quote this number on all correspondence**

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

Yours sincerely

Kathryn Taylor

pp **Mr Mark Nelson**
Chair

Email: taylork2@orec.n-i.nhs.uk

Enclosures: *List of names and professions of members who were present at the meeting and those who submitted written comments*
Standard approval conditions
Site approval form

Copy to: Dr David Hill
c/o Mr Paul Carlin
Clinical Trials Research Co-ordinator
Administration and Training Centre
Ulster Hospital
Upper Newtownards Road
Dundonald
BT16 1RH

Clinical Trials Unit
MHRA
Market Towers
1 Nine Elms Lane
London
SW8 5NQ

Office for Research Ethics Committees Northern Ireland (ORECNI)

Office Suite 3
1-4 Haslems Lane
Lisburn
Co. Antrim BT28 1TW
Tel: + 44 (0) 28 9260 3107
Fax: + 44 (0) 28 9260 3619
www.orecni.org.uk

HSC REC 1

30 July 2007

Dr Ian Ryans
Rheumatology Department
Ulster Hospital
Dundonald
Belfast
BT16 0RH

Dear Dr Ryans

Full title of study:	**Treatment of Shoulder Capsulitis by Single or Multiple Corticosteroid Injections**
REC reference number:	**07/NIR01/79**
Protocol number:	**4.1**
EudraCT number:	**2007-001709-85**

Thank you for your application for ethical review, which was received on 30 July 2007. I can confirm that the application is valid and will be reviewed by the Committee at the meeting on 28 August 2007.

Meeting arrangements

The meeting will be held in The Comfort Hotel, Antrim on 28 August 2007. The Committee would find it helpful if you could attend the meeting to respond to any questions from members. Other key investigators and a representative of the sponsor are also welcome to attend. This may avoid the need to request further information after the meeting and enable the Committee to make a decision on the application more quickly.

If you are unable to attend the meeting the Committee will review the application in your absence. If you cannot attend, it would be helpful if you could be available on the telephone at the time of the review.

I will let you know the time of the review and ask you to confirm your availability as soon as the agenda has been finalised.

Committee meetings are occasionally attended by observers, who will have no vested interest in the applications under review or take any part in discussion. All observers are required to sign a confidentiality agreement.

HSC REC 1

Attendance at Sub-Committee of the REC meeting on 13 November 2007

Committee Members:

Name	*Profession*	*Present*	*Notes*
Dr Paul Boreland	Consultant Clinical Microbiologist	Yes	
Mr David Hunter	Lecturer in Bioethics	Yes	
Mr Mark Nelson	Senior Pharmaceutical Officer	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Miss Kathryn Taylor	Committee Administrator

email Fri 25/4/08

THIS AGREEMENT IS MADE THIS 27TH DAY OF MAY 2008 (THE "EFFECTIVE DATE") BY AND BETWEEN

Clinical Research Support Centre (CRSC)

Education and Research Centre

The Royal Hospitals

Grosvenor Road

Belfast, BT12 6BA

(hereinafter called the "CRSC")

AND

South Eastern Health and Social Care Trust

Ulster Hospital

Upper Newtownards Road

Dundonald

Belfast, BT16 2LN

(hereinafter called the "Sponsor")

WHEREAS the Sponsor wishes to contract the CRSC to undertake the database development, data entry and statistical analysis for the studies entitled: 'Treatment of Shoulder Capsulitis by Single or Multiple Corticosteroid Injections' and 'Treatment of Subacromial Shoulder Pain by Individual or Group Physiotherapy Following Corticosteroid Injections.'

1.0 OBLIGATIONS OF THE PARTIES

1.1 CRSC will be responsible for the following data management services:

CRF design and production

Database design and validation

Patient registration

Data entry

Data review and validation

Data discrepancy management

Database closure

1.2 CRSC will be responsible for the following statistical services:

Power calculation and statistical aspects of design

Production of a technical report on completion of the study

Response to reviewers comments on statistical issues

2.0 DATA MANAGEMENT AND STATISTICAL ANALYSIS COSTS

Data Manager: Trial set up and closure CRF design, data validation and discrepancy management	£8,931
Database Design and IT Maintenance:	£2,720
Patient Registration and Data Entry:	£3,555
Statistical Aspects of Design and Analysis:	£3,609
STAFF COSTS:	**£18,815**
EE's Costs:	£2,634
Indirect Costs: (40% levied by host organisation)	£8,579
TOTAL STAFF COSTS:	**£30,028**
Consumables (including CRF production):	£2,716.00
TOTAL COST:	**£32,744**

3.0 FINANCIAL ARRANGEMENTS

3.1 The full costs for the data management and statistical analysis as detailed in section 2.0 will be met under the provisions of the core Clinical Research Support Centre grant from the Research & Development Office for Northern Ireland.

4.0 TERMS OF AGREEMENT

4.1 The term of this Agreement shall begin on the Effective Date (27th May 2008) and remain in effect until the completion of the obligations of the parties under this agreement. One copy of this agreement has to be signed and returned to CRSC, otherwise the agreement will lose its validity.

4.2 A party may terminate this agreement on notice to the other party with immediate effect at any time if the other party (the defaulting party) is in breach of any of the defaulting party's obligations (including a failure without just cause to meet a timeline) and fails to remedy such breach where it is capable of remedy within 28 days of a written notice from the terminating party specifying the breach and requiring its remedy.

4.3 Any change in the terms of this agreement shall be valid only if the change is made in writing, agreed and signed by the parties.

5.0 OWNERSHIP OF DATA/CONFIDENTIALITY

5.1 All data and information contained in the computer database created or developed during the course of this agreement shall be the property of the Sponsor. CRSC will provide the Sponsor with the full data set on completion of data entry.

5.2 CRSC undertakes to keep confidential and not reveal or pass on any information to any third party. CRSC further agrees not to use any information for its own purpose and not to permit any third party to use the information unless CRSC obtains prior written approval from the Principal Investigator.

5.3 The confidentiality undertaking and non-use obligation does not extend to
a) Information, which at the time of disclosure is in the public domain;
b) Information, which after disclosure by the Principal Investigator becomes part of the public domain;
c) Information, which CRSC can prove to have had in its possession at the time of disclosure.

STATEMENT

The parties hereto have caused this Agreement to be executed by their duly authorised representatives as of the date first above written.

Signed on behalf of the CRSC:

Name and Position: KAREN BAILIE DIRECTOR

Signature:

Date: 19/5/08

Authorised signatory (Karen Bailie, Director)

Principal Investigator:

Name and Position: _____

Signature: _____

Date: __/__/__

Authorised signatory (Ian Ryans, Principal Investigator)

Signed on behalf of the Sponsor:

Name and Position: PAUL CARLIN

Signature:

Date: 20/9/08

Authorised signatory (Paul Carlin)

This agreement has been signed in two (2) copies.

Please forward the signed agreement along with a copy of all regulatory approval to the:

Clinical Research Support Centre
Education and Research Centre
The Royal Hospitals
Grosvenor Road
Belfast
BT12 6BA