NUFFIELD DEPARTMENT OF PRIMARY CARE HEALTH SCIENCES

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ARCHIE

+44 (0)1865 617 842• archie@phc.ox.ac.uk

Mrs Glenys Hunt
Chair, NRES Committee North West – Liverpool East
HRA NRES Centre Manchester
Barlow House, 3rd Floor
4 Minshull Street
Manchester
M1 3DZ
10 November 2016

Dear Mrs Hunt,

Study title: The early use of Antibiotics for at Risk CHildren with InfluEnza in primary care (ARCHIE): a double-blind randomised placebo-controlled trial
REC reference: 13/NW/0621
Protocol number: ARCHIE001
EudraCT number: 2013-002822-21
IRAS project ID: 121769

With reference to the above study we would like to submit a substantial amendment SA015:

1. Addition of new secondary care sites
2. Change of PI at secondary care sites/walk in centre

We would also like to inform you of the following notifications:
1. Identification of individual primary care sites and PI's
2. Change of PI at open primary care sites
3. Closure of primary care sites.

Tricia Carver
Senior Trial Manager
on behalf of Chief Investigator, Dr Kay Wang

Appendix 1 – Addition of sites as part of SA 15

Site	Principal Investigator	CRN
University of South Manchester NHS Foundation Trust	Dr Asim Ahmed	Greater Manchester
St Georges University Hospitals NHS Foundation Trust	Professor Paul Heath	South London
Oxford Health NHS Foundation Trust	Dr Merlin Wilcox	Thames Valley & South Midlands

Appendix 2 – Removal of Existing Sites as part of SA 15

Site	Principal Investigator	CRN
Derby Teaching Hospitals NHS Foundation Trust	Dr Julia Surridge	East Midlands
University of Coventry & Warwickshire NHS Trust	Dr Marius Holmes	West Midlands

Appendix 3 – Change of PI at sites as part of SA 15

Site	Principal Investigator	Previous Principal Investigator
Royal Cornwall Hospital NHS Trust	Dr Anne Prendiville	Dr Yadlapalli Kumar
Taunton & Somerset NHS Foundation Trust	Dr Alex Powell	Dr Rebecca Mann
Smithdown Children's Walk in Centre – Liverpool Community Health NHS Trust	Claire Griffiths	Dr M.G Semple
St Helens & Knowsley Teaching Hospitals NHS Trust	Dr Ijaz Ahmad	Dr Roasline Garr

Appendix 4 – New sites identified in Primary Care

Site	Local Lead	CRN
Hillcrest Surgery, W3 9RA	Venetta Norgrove	North West London
Fulham Medical Practice, SW6 1BG	Dr Libby Pearson	North West London
Akysr Medical, Preston Hill Surgery, HA3 9SN	Dr Rakshan Syed	North West London
Gosford Hill Medical Practice, OX5 2NS	Dr Matt Wallard	Thames Valley & South Midlands
Summertown Health Centre, OX2 7BS	Dr Kyle Knox	Thames Valley & South Midlands
Berinsfield Medical Centre, OX10 7NE	Dr Jonathan Crawshaw	Thames Valley & South Midlands
Bedford Street Surgery, MK2 2TX	Dr Motaz Muhderbashi	Thames Valley & South Midlands
Morland House Surgery, OX33 1YJ	Dr David Copping	Thames Valley & South Midlands
Milton Keynes Family Practice, MK10 9BQ	Dr Darren Moore	Thames Valley & South Midlands

Appendix 5 – Changes of PI in Primary Care

Site	Local Lead	Previous Local Lead	CRN
Wellspring Surgery, BS5 9QY	Dr Will Klinkenberg	Dr Trevor Thompson	West of England
Wymondham Medical Centre, NR18 0RF	Dr Phillip Pinney	Dr Stephen Thurston	Eastern

Appendix 5 – Sites closed/scheduled to close in Primary Care

Site	Local Lead	CRN
Ascot Medical Centre, SL5 8AA	Dr Edouard Williams	Thames Valley & South Midlands
Evergreen Practice, RG12 1LH	Dr G P Nelli	Thames Valley & South Midlands
Langley Health Centre, SL3 8LE	Dr Sajid Ali	Thames Valley & South Midlands
New Wokingham Road Surgery, RG45 6JL	Dr Edmond Chau	Thames Valley & South Midlands
Wokingham Medical Centre, RG40 1XS	Dr Zishan Ali	Thames Valley & South Midlands
Brownlow Group Practice, L69 3GF	Dr Diane Exley	North West Coast
Claughton Medical Centre, CH41 0DD	Dr Peter Arthur,	North West Coast
Wingate Medical Centre, L33 6YJ	Dr Chris Mimnagh	North West Coast
Abbeywell Surgery, Nightingale site, SO51 7QN	Dr Tracey Ryan	Wessex
Vine Medical Group (formerly Forest End), PO7 7AH	Dr Olivia Boocock	Wessex
Oaklands Health Group (formerly Oaklands Practice) GU46 7LS	Dr Gareth Robinson	Wessex
Trafalgar Medical Group (formerly Osborne Practice) PO5 3ND	Dr Serge Macanovic	Wessex
Wareham Surgery BH20 4PG	Dr James Bennett	Wessex
Friarsgate Practice.	Dr Stephen Fowler	Wessex

SO22 6EL		
Acorn Surgery , PE29 7HN	Dr Gysbert Fourie	Eastern
Cornerstone Practice, PE15 9BF	Dr Peter Winfrey	Eastern
Danetre Surgery, NN11 4DY	Dr Lesley Jeffers	East Midlands
Kingsthorpe Surgery, NN2 7JN	Dr. Aboo Thamby	East Midlands
Mundesley Medical Centre, NR11 8AR	Dr Angela Hallatt	Eastern
Roundwell Medical Centre. NR5 0GB	Dr Chaminda Dooldeniya	Eastern
Saffron Group Practice, LE2 6UL	Dr. Stephanie Short	East Midlands
Wansford and Kings Cliffe Practice, PE8 6PL	Dr Amrit Takhar	Eastern
Nelson Medical Practice, NR31 0DW	Dr T Mirza	Eastern
Lawson Road Surgery, NR3 4LE	Dr Alice Shiner	Eastern
Castle Mead Medical Centre, LE10 1DS	Dr Dave Tull	East Midlands
Castle Partnership, NR4 7QX	Dr Mercedes Perez-Morales	Eastern
Lakeside Healthcare, NN17 2UR	Dr Amardeep Heer	East Midlands

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 complete the questions in order. If you change the response to a question, please select 'Save' and review all the questions as your change may have affected subsequent questions.

Please enter a short title for this project (maximum 70 characters)
The early use of Antibiotics in at Risk Children with InfluEnza-ARCHIE

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. Is this a commercially sponsored Phase 1 or Phase 1/2a trial involving healthy volunteers?

( ) Yes (●) No

2b. Will the study involve the use of any medical device without a CE Mark, or a CE marked device which has been modified or will be used outside its intended purposes?

( ) Yes (●) No

2c. Please answer the following question:

Is this trial subject to advice from the Expert Advisory Group on Clinical Trials and the Commission on Human Medicine prior to authorisation from MHRA? ○ Yes ◉ No

2d. Please answer the following question:

Is this a trial of a gene therapy medicinal product? ○ Yes ◉ No

2e. 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)*

- ☑ 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 applications do you require?

IMPORTANT: If your project is taking place in the NHS and is led from England select 'IRAS Form'. If your project is led from Northern Ireland, Scotland or Wales select 'NHS/HSC Research and Development Offices' and/or relevant Research Ethics Committee applications, as appropriate.

- ☐ IRAS Form
- ☑ NHS/HSC Research and Development offices
- ☐ Social Care Research Ethics Committee
- ☑ Research Ethics Committee
- ☑ Medicines and Healthcare products Regulatory Agency (MHRA) – Medicines
- ☐ Gene Therapy Advisory Committee (GTAC)
- ☐ Confidentiality Advisory Group (CAG)
- ☐ National Offender Management Service (NOMS) (Prisons & Probation)

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

For participating NHS organisations in England different arrangements apply for the provision of site specific information. Refer to IRAS Help for more information.

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

(●) Yes ( ) No

5a. Are all the research costs and infrastructure costs (funding for the support and facilities needed to carry out research e.g. NHS Support costs) for this study provided by a NIHR Biomedical Research Centre, NIHR Biomedical Research Unit, NIHR Collaboration for Leadership in Health Research and Care (CLAHRC), NIHR Patient Safety Translational Research Centre or a Diagnostic Evidence Co-operative in all study sites?

Please see information button for further details.

(●) Yes ( ) No

Please see information button for further details.

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 Confidentiality Advisory Group 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

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

SUBSTANTIAL AMENDMENT FORM [1]

NOTIFICATION OF A SUBSTANTIAL AMENDMENT TO A CLINICAL TRIAL ON A MEDICINAL PRODUCT FOR HUMAN USE TO THE COMPETENT AUTHORITIES AND FOR OPINION OF THE ETHICS COMMITTEES IN THE EUROPEAN UNION

For official use:

Date of receiving the request:	Grounds for non acceptance/negative opinion:
	Date:
Date of start of procedure:	Authorisation/ positive opinion:
	Date:
Competent authority registration number of the trial:	Withdrawal of amendment application:
Ethics committee registration number of the trial:	Date:

To be filled in by the applicant:

*This form is to be used both for a request to the Competent Authority for authorisation of a **substantial** amendment and to an Ethics Committee for its opinion on a **substantial** amendment. Please indicate the relevant purpose in Section A.*

A TYPE OF NOTIFICATION

A.1 Member State in which the substantial amendment is being submitted:

United Kingdom

A.2 Notification for authorisation to the competent authority: ☐

A.3 Notification for an opinion to the ethics committee: ☑

(1) Cf. Section 3.7.b of the Detailed guidance on the request to the competent authorities for authorisation of a clinical trial on a medicinal product for human use, the notification of substantial amendments and the declaration of the end of the trial (OJ, C82, 30.3.2010, p.1) hereinafter referred to as 'detailed guidance CT-1'.

B TRIAL IDENTIFICATION *(When the amendment concerns more than one trial, repeat this form as necessary.)*

B.1 Does the substantial amendment concern several trials involving the same IMP? [2] ○ Yes ◉ No

B.2 EudraCT number:	201300282221
B.3 Full title of the trial:	The early use of Antibiotics for at Risk CHildren with InfluEnza in Primary Care
B.4 Sponsor's protocol code number:	ARCHIE001
B.4 Sponsor's protocol version number:	v2
B.4 Sponsor's protocol date:	12/02/2014

(2) Cf. Section 3.7. of the detailed guidance CT-1

C IDENTIFICATION OF THE SPONSOR RESPONSIBLE FOR THE REQUEST

C.1 Sponsor

Organisation:	Univeristy of Oxford
Contact Given name:	Heather
Contact Family name:	House
Address:	Joint Research Office, Block 60, Churchill Hospital
Town/city:	Headington, Oxford
Post code:	OX3 7LE
Telephone:	
Fax:	01865572228
E-mail:	ctrg@admin.ax.ac.uk

C.2 Legal representative [3] of the sponsor in the European Union for the purpose of this trial (if different from the sponsor)

Name of organisation:
Contact Given name:
Contact Family name:
Address:
Town/city:
Post code:
Telephone:
Fax:
E-mail:

(3) As stated in Article 19 of Directive 2001/20/EC.

D APPLICANT IDENTIFICATION, (please tick the appropriate box)

D1. Request for the competent authority

D.1.1 Sponsor ☐
D.1.2 Legal representative of the sponsor ☐
D.1.3 Person or organisation authorised by the sponsor to make the application. ☐
D.1.4 Complete below:

Name of organisation
Contact Given name
Contact Family name
Address
Town/city
Post code

Telephone
Fax
E-mail

D2. Request for the Ethics Committee

D.2.1 Sponsor ☐
D.2.2 Legal representative of the sponsor ☐
D.2.3 Person or organisation authorised by the sponsor to make the application. ☑
D.2.4 Investigator in charge of the application if applicable[4]:
- Co-ordinating investigator (for multicentre trial): ☐
- Principal investigator (for single centre trial): ☐

D.2.5 Complete below:

Name of organisation	University of Oxford
Given name	Tricia
Family name	Carver
Address	Nuffled Department of Primary Health Care Sciences
Town/city	Radcliffe Observatory Quarter, Woodstock Rd
Post code	OX2 6GG
Telephone	01865617842
Fax	
E-mail	Tricia.Carver@phc.ox.ac.uk

(4) According to national legislation.

E SUBSTANTIAL AMENDMENT IDENTIFICATION

E.1 Sponsor's substantial amendment information for the clinical trial concerned:

Code Number: ARCHIE_SA015
Version:
Date: 2015/11/01

E.2 Type of substantial amendment

E.2.1 Amendment to information in the CT application form ○ Yes ◉ No
E.2.2 Amendment to the protocol ○ Yes ◉ No
E.2.3 Amendment to other documents appended to the initial application form ○ Yes ◉ No
If yes specify:
E.2.4 Amendment to other documents or information: ◉ Yes ○ No
If yes specify:
Addition of new NHS Sites
Change of PI at NHS sites
E.2.5 This amendment concerns mainly urgent safety measures already implemented[5]: ○ Yes ◉ No
E.2.6 This amendment is to notify a temporary halt of the trial[6]: ○ Yes ◉ No

E.2.7 This amendment is to request the restart of the trial[7]:	○ Yes	◉ No

(5) Cf. Section 3.9. of the detailed guidance CT-1.
(6) Cf. Section 3.10. of the detailed guidance CT-1
(7) Cf. Section 3.10. of the detailed guidance CT-1

E.3 Reasons for the substantial amendment:

E.3.1 Changes in safety or integrity of trial subjects	○ Yes	◉ No
E.3.2 Changes in interpretation of scientific documents/value of the trial	○ Yes	◉ No
E.3.3 Changes in quality of IMP(s)	○ Yes	◉ No
E.3.4 Changes in conduct or management of the trial	○ Yes	◉ No
E.3.5 Change or addition of principal investigator(s), co-ordinating investigator	◉ Yes	○ No
E.3.6 Change/addition of site(s)	◉ Yes	○ No
E.3.7 Other change	○ Yes	○ No
E.3.7.1 If yes specify:		
E.3.8 Other case	○ Yes	◉ No
E.3.8.1 If yes specify:		

E.4 Information on temporary halt of trial:[8]

E.4.1 Date of temporary halt		
E.4.2 Recruitment has been stopped	○ Yes	○ No
E.4.3 Treatment has been stopped	○ Yes	○ No

E.4.4 Number of patients still receiving treatment at time of the temporary halt in the MS concerned by the amendment

E.4.5 Briefly describe:

Justification for a temporary halt of the trial *(free text)*:

The proposed management of patients receiving treatment at time of the halt *(free text)*:

The consequences of the temporary halt for the evaluation of the results and for overall risk benefit assessment of the investigational medicinal product *(free text)*:

(8) Cf. Section 3.10. of the detailed guidance CT-1

F DESCRIPTION OF EACH SUBSTANTIAL AMENDMENT[9]

Please use this section to detail each substantial amendment which is being notified. If you are notifying more than one substantial amendment, please use the "Add Amendment" button as required

Substantial amendment 1

Previous and new wording:*(tracked)*

New wording:

Comments/ explanation/ reasons for substantial amendment:

(9)Cf. Section 3.7.c. of the detailed guidance CT-1. The sponsor may submit this documentation on a separate sheet.

G CHANGE OF CLINICAL TRIAL SITE(S)/INVESTIGATOR(S) IN THE MEMBER STATE CONCERNED BY THIS AMENDMENT

Type of change:

G.1.1 Addition of a new site

G.1.1.1 Principal investigator (provide details below)

Given name	Asim
Middle name(if applicable)	
Family name	Ahmed
Qualification (MD...)	MD
Professional address	Univeristy Hosptial South Manchester NHS Foundation Trust
Given name	Paul
Middle name(if applicable)	
Family name	Heath
Qualification (MD...)	MD
Professional address	St George's University Hospitals NHS Foundation Trust
Given name	Merlin
Middle name(if applicable)	
Family name	Wilcox
Qualification (MD...)	MD
Professional address	Oxford Health NHS Foundation Trust

G.1.2 Removal of an existing site

G.1.2.1 Principal investigator (provide details below)

Given name	Marius
Middle name(if	

applicable)	
Family name	Holmes
Qualification (MD...)	MD
Professional address	University of Coventry and Warwickshire NHS Trust
Given name	Julia
Middle name(if applicable)	
Family name	Surridge
Qualification (MD...)	MD
Professional address	Derby Teaching Hospitals NHS Foundation Trust

G.1.3 Change of co-ordinating investigator (provide details below of the new coordinating investigator)

Given name	
Middle name(if applicable)	
Family name	
Qualification (MD...)	
Professional address	

G.1.3.6 Indicate the name of the previous co-ordinating investigator:

G.1.4 Change of principal investigator at an existing site (provide details below of the new principal investigator)

Given name	Ijaz
Middle name(if applicable)	
Family name	Ahmad
Qualification (MD...)	MD
Professional address	St Helen's & Knowsley Teaching Hospitals NHS Foundation Trust

G.1.4.6 Indicate the name of the previous principal investigator:
Dr Rosaline Garr

Given name	Anne
Middle name(if applicable)	
Family name	Prendiville
Qualification (MD...)	MD
Professional address	Royal Cornwall Hosptial NHS Foundation Trust

G.1.4.6 Indicate the name of the previous principal investigator:
Dr Yadlapalli Kumar

Given name	Alex
Middle name(if applicable)	
Family name	Powell
Qualification (MD...)	MD
Professional address	Taunton & Somerset NHS Foundation Trust

G.1.4.6 Indicate the name of the previous principal investigator:
Dr Rebecca Mann

Given name	Claire
Middle name(if applicable)	
Family name	Griffiths
Qualification (MD...)	RN
Professional address	Smithdown Chilldren's Walk In Centre - Liverpool Health Community NHS Trust

G.1.4.6 Indicate the name of the previous principal investigator:
Dr M.G Semple

H CHANGE OF INSTRUCTIONS TO CA FOR FEEDBACK TO SPONSOR

H.1 Change of e-mail contact for feedback on application*

H.2 Change to request to receive an .xml copy of CTA data ○ Yes ◉ No

H.2.1 Do you want a .xml file copy of the CTA form data saved on EudraCT? ○ Yes ◉ No

H.2.1.1 If yes provide the e-mail address(es) to which it should be sent (up to 5 addresses):

H.2.2 Do you want to receive this via password protected link(s)[10]? ○ Yes ◉ No

If you answer no to question H.2.2 the .xml file will be transmitted by less secure e-mail link(s)

H.2.3 Do you want to stop messages to an email for which they were previously requested? ○ Yes ◉ No

H.2.3.1 If yes provide the e-mail address(es) to which feedback should no longer be sent:

(*This will only come into effect from the time at which the request is processed in EudraCT).

(10) This requires a EudraLink account. (See eudract.emea.europa.eu for details)

I LIST OF THE DOCUMENTS APPENDED TO THE NOTIFICATION FORM (cf. Section 3.7 of detailed guidance CT-1)

Please submit only relevant documents and/or when applicable make clear references to the ones already submitted. Make clear references to any changes of separate pages and submit old and new texts. Tick the appropriate box(es).

I.1 Cover letter ☑

I.2 Extract from the amended document in accordance with Section 3.7.c. of detailed guidance CT-1 (if not contained in Part F of this form) ☐

I.3 Entire new version of the document[11] ☐

I.4 Supporting information ☐

I.5 Revised .xml file and copy of initial application form with amended data highlighted ☐

I.6 Comments on any novel aspect of the amendment if any :

(11) Cf. Section 3.7.c. of the detailed guidance CT-1

J SIGNATURE OF THE APPLICANT IN THE MEMBER STATE

Please submit only relevant documents and/or when applicable make clear references to the ones already submitted. Make clear references to any changes of separate pages and submit old and new texts. Tick the appropriate box(es).

J.1 I hereby confirm that/ confirm on behalf of the sponsor that (delete which is not applicable)

- The above information given on this request is correct;
- The trial will be conducted according to the protocol, national regulation and the principles of good clinical practice; and
- It is reasonable for the proposed amendment to be undertaken.

J.2 APPLICANT OF THE REQUEST FOR THE COMPETENT AUTHORITY*(as stated in section D.1):* ☐

J.2.1 Signature [12]: .....

J.2.2 Print name:

J.2.3 Date:

J.3 APPLICANT OF THE REQUEST FOR THE ETHICS COMMITTEE *(as stated in section D.2)***:** ☐

J.3.1 Signature [13]: .....

J.3.2 Print name:

J.3.3 Date:

This section was signed electronically by Mrs Tricia Carver on 10/11/2016 14:37.

Job Title/Post:

Organisation:

Email: tricia.carver@phc.ox.ac.uk

(12) On an application to the Competent Authority only, the applicant to the Competent Authority needs to sign.
(13) On an application to the Ethics Committee only, the applicant to the Ethics Committee needs to sign.

Tricia Carver

From: Karen Melham
Sent: 04 November 2016 14:29
To: Sharon Tonner; Tricia Carver; Primary Health Care Archie
Cc: Ronja Bahadori; 'rpm@oxfordjro.org'
Subject: Sponsor Authorisation for SA 15 to ARCHIE SA 15 trial

Follow Up Flag: Flag for follow up
Flag Status: Flagged

Dear Sharon,

Thank you for sending for our review the amendment proposed to the ARCHIE trial with relation to site openings, closures and PIs.
I can confirm that we as sponsor representative are content for this to be sent to the relevant REC for review and approval.

Please forward correspondence and any final, REC-approved documents to karl.shepherd@admin.ox.ac.uk to ensure ongoing sponsorship and indemnity.

With best wishes,

Karen

Dr Karen Melham
Senior Clinical Research Support Manager | Clinical Trials & Research Governance (CTRG)
University of Oxford
Joint Research Office, Block 60, Churchill Hospital, Headington, Oxford, OX3 7LE
E: karen.melham@admin.ox.ac.uk **T:** 01865 227093
www.admin.ox.ac.uk/researchsupport

PID8801-A022-SP001-AC001

Primary Health Care Archie

From: nrescommittee.northwest-liverpooleast@nhs.net
Sent: 18 November 2016 10:57
To: Kay Wang; ouhtma@nhs.net; CTRG Sponsorship Correspondence; Karl Shepherd; Primary Health Care Archie
Cc: tvclrn@nhs.net
Subject: IRAS 121769. Confirmation of REC Validation and Categorisation of Amendment
Attachments: 121769_13NW0621_Confirmation_of_opinion.pdf

Follow Up Flag: Follow up
Flag Status: Flagged

Dear Ms House,

IRAS Project ID:	**121769**
REC Reference:	**13/NW/0621**
Short Study Title:	**The early use of Antibiotics in at Risk Children with InfluEnza-ARCHIE**
Date complete amendment submission received:	**10 November 2016**
Amendment No./ Sponsor Ref:	**SA 15**
Amendment Date:	**10 November 2016**
Amendment Type:	**Substantial**

Thank you for submitting the above referenced amendment. Please find attached a copy of the confirmation letter.

Categorisation of Amendment

In line with the UK Process for Handling UK Study Amendments I can confirm that this amendment has been categorised as:

- **Category B** - An amendment that has implications for, or affects, SPECIFIC participating NHS organisations

You should now provide this email, together with the amended documentation, to the research management support offices **and** local research teams at your participating NHS organisations in England that are affected by this amendment.

If you have participating NHS organisations in Northern Ireland, Scotland and/or Wales that are affected by this amendment, you should communicate directly with the relevant research teams to prepare them for implementing the amendment, as per the instructions below. You do not need to provide this email or your amended documentation to their research management support offices, as we will pass these to the relevant national coordinating functions who will do this on your behalf.

Subject to the four conditions below, you will be able to implement the amendment at affected participating NHS organisations in England **35 days after you notify them of the amendment.** A template email to notify participating NHS organisations in England is provided here.

- You may not implement this amendment until and unless you receive all required regulatory approvals, including REC favourable opinion (for participating organisations in England, this includes receiving confirmation of HRA Approval for the amendment). You should provide regulatory approvals to the research management support offices and local research teams at your participating NHS organisations in England that are affected by this amendment, plus to local

research teams at any affected participating NHS organisations in Northern Ireland, Scotland or Wales*.
- You may not implement this amendment at any participating NHS organisations which inform you within the 35 day period that they require additional time to consider the amendment, until they notify you that the considerations have been satisfactorily completed.
- You may not implement this amendment at any participating NHS organisation that informs you that it is no longer able to undertake this study.
- For amendments adding new sites, you may not commence research activities at site until the nation specific processes to allow this are concluded, e.g. NHS Permission in Northern Ireland, Scotland or Wales and Confirmation of capacity and capability in England (if this amendment adds new sites in England, the HRA will shortly provide further information on expectations relating to their formal confirmation of capacity and capability).

Note: you may only implement changes described in the amendment notice or letter.

If you receive required regulatory approvals (for participating organisations in England, this includes receiving confirmation of HRA Approval for the amendment) after the 35 days have passed you may then immediately implement this amendment at all existing participating NHS organisations that have not requested additional review time, or are no longer able to undertake this study. As above, the 35 days does not apply to opening new sites and nation specific processes should be followed.

For existing participating organisations, there is no need for you to receive a letter of confirmation from the participating organisation that the amendment can be implemented, as the intended date of implementation is communicated through the above process. However, you may be able to implement this amendment ahead of the 35 day deadline, if all necessary regulatory approvals are in place and the participating organisation has confirmed that the amendment may be implemented ahead of the 35 day date.

Further to the details above, I can confirm that no HRA assessment of this amendment is needed.

- If this study has HRA Approval, this amendment may be implemented at participating NHS organisations in England once the conditions detailed in the categorisation section above have been met
- If this study is a pre-HRA Approval study, this amendment may be implemented at participating NHS organisations in England that have NHS Permission, once the conditions detailed in the categorisation section above have been met. For participating NHS organisations in England that do not have NHS Permission, these sites should be covered by HRA Approval before the amendment is implemented at them, please see below;
- If this study is awaiting HRA Approval, I have passed your amendment to my colleague in the assessment team and you should receive separate notification that the study has received HRA Approval, incorporating approval for this amendment.

Please do not hesitate to contact me if you require further information.

Kind regards

Matt Rogerson

REC Manager

Health Research Authority
HRA, Ground Floor, Skipton House, 80 London Road, London, SE1 6LH
E: hra.amendments@nhs.net

www.hra.nhs.uk

The HRA is keen to know your views on the service you received – our short feedback form is available here

Health Research Authority

North West - Liverpool East Research Ethics Committee

Barlow House
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Manchester
M1 3DZ

Telephone: 02071048127

18 November 2016

Ms Heather House
Oxford University NHS Trust
R&D Lead, Research and Development Department, Joint Research Office, Block 60, Churchill Hospital,
Oxford
Old Road
Headington
OX3 7LE

Dear Ms House

Study title:	**The early use of Antibiotics for at Risk CHildren with InfluEnza in primary care(ARCHIE): a double-blind randomised placebo-controlled trial**
REC reference:	**13/NW/0621**
Protocol number:	**ARCHIE001**
EudraCT number:	**2013-002822-21**
Amendment number:	**SA 15**
Amendment date:	**10 November 2016**
IRAS project ID:	**121769**

Thank you for submitting the above amendment, which was received on 10 November 2016.

New Research site	*Principal Investigator / Local Collaborator*
University of South Manchester NHS Foundation Trust	Asim Ahmed
St Georges University Hospitals NHS Foundation Trust	Paul Heath
Oxford Health NHS Foundation Trust	Merlin Wilcox

Research site	*New Principal Investigator / Local Collaborator*
St Helen's & Knowsley Teaching Hospitals NHS Foundation Trust	Ijaz Ahmad
Royal Cornwall Hospital NHS Foundation Trust	Anne Prendville
Taunton & Somerset NHS Foundation Trust	Alex Powell
Smithdown Children's Walk in Centre (Liverpool Health Community NHS Trust	Claire Griffiths

Removal of Research site	*Principal Investigator / Local Collaborator*

Derby Teaching Hospitals NHS Foundation Trust	Julia Surridge
University of Coventry & Warwickshire NHS Trust	Marius Holmes

The amendment relates solely to the addition of new site(s) and/or investigator(s) within the National Health Service (NHS) or Health and Social Care (HSC) in Northern Ireland. Site-specific assessment (SSA) for any site within the National Health Service (NHS) or Health and Social Care (HSC) in Northern Ireland will form part of the nation specific local processes for that site. Guidance on how to work with sites is provided in the IRAS help section at https://www.myresearchproject.org.uk/help/hlpnhshscr.aspx

On behalf of the Committee, I am pleased to confirm the extension of the favourable opinion to the new site(s) and/or investigator(s), subject to management permission being given by the relevant host organisation prior to the study starting at the site.

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 and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

13/NW/0621	**Please quote this number on all correspondence**

Yours sincerely

Matt Rogerson
REC Manager

Email: nrescommittee.northwest-liverpooleast@nhs.net

Copy to: *Dr Kay Wang, University of Oxford*