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
16 February 2017
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 SA~~015~~ 16:

pp Carver 18 Apr 17

1. Addition of patient identification centres:
   Solent NHS Trust
   Ipswich and East Suffolk CCG

   Please find statement of activities and schedule of events enclosed.

2. Change of PI at secondary care sites:
   Dr Rosalind Garr will resume her duties as PIS at St Helens & Knowsley Teaching Hospital, replacing Dr Ijaz Ahmad

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

Primary Health Care Archie

From: Karen Melham
Sent: 17 February 2017 14:12
To: Primary Health Care Archie
Cc: rpm@oxfordjro.org
Subject: Sponsor authorisation for ARCHIE SA 16

Follow Up Flag: Follow up
Flag Status: Flagged

Dear Sharon and Tricia,

Thank you for sending for our review the amendment proposed to the ARCHIE trial to change PI at one site, and add two PICs.
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-A024-SP001

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:	2013-002822-21
B.3 Full title of the trial:	The early use of Antibiotics for at Risk CHildren with InfluEnza in primary care (ARCHIE): a double-blind randomised placebo-controlled trial
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:	University 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.ox.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	Nuffield Department of Primary Care Health Sciences
Town/city	ROQ, Woodstock Rd, Oxford
Post code	OX26GG
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_SA16
Version:
Date: 2017/02/20

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:
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:
Addition of Patient Identification Centres

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)*

Addition of the following organisations as Patient Identification Centres:

Solent NHS Trust

Ipswich and East Suffolk CCG

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

G.1.2 Removal of an existing site

G.1.2.1 Principal investigator (provide details below)

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

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	Rosalind
Middle name(if applicable)	
Family name	Garr
Qualification (MD...)	MD
Professional address	St Helens & Knowsley Teaching Hosptial

G.1.4.6 Indicate the name of the previous principal investigator:
Dr Ijaz Ahmad

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 20/02/2017 13:17.

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.

Health Research Authority

HRA Statement of Activities

for Participating NHS Organisations in England (template version 4.0)

For non-commercial studies, one Statement of Activities should be completed as a template for each site type in the study. Each Statement of Activities should be accompanied by a completed HRA Schedule of Events, as part of the submission via IRAS for HRA Approval.

Blue shaded fields (also marked with an asterisk) should be completed by the sponsor/applicant prior to submission to the HRA.*
Where appropriate, for the purpose of confirming capacity and capability, green shaded fields (also marked with a caret^) should be completed by the participating organisation before returning the document to the sponsor.
Other questions may be completed either by the sponsor/applicant or participating organisation (or collaboratively between both parties), as appropriate.

For participating organisations in Northern Ireland, Scotland or Wales, the sponsor should transfer a Site Specific Information Form to each local research team for completion and submission to their research management support function.

To provide an answer in the form, click in a box with the blue text and over-write this text, or select the relevant option if presented with drop-down text. A separate guidance document is provided and should be consulted prior to completion of this template. Please also read the question specific guidance where present.

IRAS ID*	121769
Short Study Title*	The early use of Antibiotics in at Risk CHildren with InfluEnza-ARCHIE
Full Study Title*	The early use of Antibiotics for at Risk CHildren with InfluEnza in primary care (ARCHIE): a double-blind randomised placebo-controlled trial
Contact details of sponsor, or delegated point of contact, for questions relating to study set-up*	Sharon Tonner sharon.tonner@phc.ox.ac.uk 01865 617836
Site Type*	Participant Identification Centre *Select one option. If 'Other', give details.* If 'Other', insert details here

Name of Participating Organisation	*Where this statement is to be used as the agreement between sponsor and participating organisation, the name of the participating organisation should be entered here prior to agreement. If this Statement is being agreed to cover multiple separate entities (e.g. multiple GP practices within a single LCRN geography) please make this clear here.* Enter name of participating organisation

Date *HRA Office Use Only*	*Date template assessed by HRA*
Version Number *HRA Office Use Only*	Applicant version assessed by HRA

1. Does the sponsor intend that this document forms the agreement between itself and the participating organisation/s in England?*

For non-commercial studies other than clinical trials and clinical investigations, the HRA encourages use of the Statement of Activities as the only form of agreement between sponsor and an English participating organisation, in place of bespoke agreements created by sponsors. For research in primary care settings, the Statement may be used for a geographical area, e.g. at the LCRN level, although agreement should be between the sponsor and independent legal entity (e.g. GP Practice). For clinical trials and clinical investigations the HRA expects that sponsors will use the relevant model agreement, where one exists.

Yes

2. **Date this Statement of Activities confirmed by participating organisation, if applicable.^**

Enter date confirmed

3. Confirmation on behalf of participating organisation provided by (insert name and job title), if applicable.^

Enter name and job title

It is not intended that this confirmation requires wet-ink signatures, or a passing of hard copies between the sponsor and participating organisation. Instead, sponsors are expected to accept confirmation by email from an individual empowered by the participating organisation to agree to the commencement of research (including any budgetary responsibility, where the study involves the transfer of funds).

4. If this Statement is not intended to form the agreement with the participating organisation/s in England, will the sponsor be using an unmodified model non-commercial agreement?*

Select 'yes' or 'no'

5. If no, please provide details of the modifications made to the model agreement and the reasons for them. If the sponsor intends to use an agreement not based on the model agreement, please provide detailed justification for this (templates of all 'site agreements' to be used, including for sites in the devolved administrations (where applicable) should be provided as part of the submission for HRA Approval).*

6. Predicted Participant Recruitment, if applicable.

This is recruitment or identification at participating organisation, not overall for the study. Please clarify if this refers to participants, samples or data. Please clearly state if this is per month, per year, overall etc. Leave blank if not applicable to this site type.

N/A

7. Proposed start date of research/participant identification activity at participating organisation.

Where it might otherwise be open to interpretation, please specify whether this date refers to the commencement of screening, the recruitment of the first participant, etc.

(01/March/2017)

Distributing information leaflets to potentially eligible patients

8. Predicted end date of research/participant identification activity at participating organisation.

Where it might otherwise be open to interpretation, please specify whether this date refers to the recruitment of the final participant, the final visit of the final participant, database lock, etc.

(30/April/18)

Projected end of study recruitment

9. Person responsible for research activities at site.*

Local Collaborator

The HRA expects Principal investigators to be in place at participating organisations where locally employed staff take responsibility for research procedures. Where this is not the case, the HRA expects Local Collaborators to be in place where central study staff will be present at site to undertake research procedures (the role of the Local Collaborator is to support practical arrangements for the presence of research staff under Letters of Access or Honorary Research Contracts). Where existing data is being provided for research purposes without additional research procedures and without the presence of central research team members at site, the HRA does not expect that a Principal Investigator or Local Collaborator is appointed and you should select Chief Investigator.

10. Are you requesting support to identify a Principal Investigator or Local Collaborator?*

Please indicate whether support from the host organisation is being requested to identify a Principal Investigator/Local Collaborator and provide further information on expectations below. Where a Principal Investigator or Local Collaborator has already been identified, their details appear on Part C of the IRAS Form.

No

11. Further Information (where applicable).*

Please provide further information on sponsor expectations for a Principal Investigator/Local Collaborator, to help participating organisations identify an appropriate individual if required (e.g. Profession, specialty, seniority etc.)

12. The following capabilities and capacity are needed locally in order to deliver the study, e.g. specific equipment, patient/participant groups, service support nursing time, excess treatment costs, etc.*

Any funding or support from the sponsor/funder to the participating organisation is set out in the Finance Schedule.

Access to paediatric population who may be at risk of complications of influenza like illness

13. Projected NHS Treatment Cost savings at this site type, if applicable.*

Although many studies incur Excess Treatment Costs (see AcoRD for information on cost attribution) many studies also give rise to treatment cost savings during the study (e.g. a two armed study comparing standard care to a less intensive, and less expensive, alternative treatment). Please describe below any projected treatment cost savings, so your participating organisations may include this information when considering the overall treatment costs/cost savings of their portfolio of research. Any funding or support from the sponsor/funder to the participating organisation is set out in the Finance Schedule. Excess Treatment Costs will be indicated above (question 12) and in the HRA Schedule of Events.

N/A

14. The following training for local staff will be provided by the sponsor. Where only specific team members (e.g. the Principal Investigator) will receive this training, this is described below.*

No training is necessary

15. In addition to the above training, to be provided by the sponsor, the sponsor also expects that the following local research team members will undertake the following training.*

It would not be usual for the sponsor to expect study specific training additional to that which it will provide, this section does however allow sponsors to state that they will accept, for example, NIHR CRN training in Good Clinical Practice where the study is a Clinical Trial of an Investigational Medicinal Product etc.

N/A.

Schedule 1 (Finance) (template version 4.0)

Please select one of the following*	
There are no funds/resources/equipment, etc. being provided to this/these organisation/s by the sponsor. *This schedule should be left blank.**	☐
The following funding/resources/equipment, etc. is to be provided to this/these local participating organisation/s. However, the finance schedule to cover such transfer is detailed in a separate agreement. *Please complete the information below but leave the schedule blank and submit your separate agreement to the HRA.**	☐
The following funding/resource/equipment, etc. is to be provided to this local participating organisation. This Statement of Activities is intended by the sponsor to form the agreement between them and the participating organisation. The finance schedule below details the funds to be provided to the site by the sponsor. *Please complete the information and the schedule below.**	☒
Promotional materials (posters, leaflets, postcards) will be provided for local distribution	

1 Payment Schedule (i.e. frequency or trigger for payments)*

Enter details of payment schedule

2 Area of Cost (e.g. set-up, procedure, overall cost, etc.)*

Enter details on area of cost

Payment Details:

If VAT is payable, then the Sponsor shall pay the VAT in addition to the payment on presentation of a VAT invoice. If VAT is not payable, then the Sponsor shall issue a VAT exemption certificate.

3 Invoices to be submitted to (insert job title, name of body and address)*

Enter address details

4 Payment to be made by cheque to^

Enter cheque payable details

4.1 AND remitted to (insert job title/position and address)

Enter job title/position and address

OR

5 Arrange BACS transfer to: Bank Name

Enter bank name

5.1 Sort Code

Enter sort code

5.2 Account Number

Enter account number

5.3 And send the relevant paper work to the following address

Enter address details

Invoices should be presented promptly. No payment shall be made in the case where invoices are not presented in a complete, accurate and timely fashion and funding from an external funding body has been irrecoverably reclaimed by such external funding body as a result of such delay or inadequacy.

Schedule 2 (Material Transfer Provisions)

(template version 4.0)

These provisions do not remove the responsibility for a sponsor to clearly lay out in their protocol (and to potential participants in the patient information sheet/s) at a minimum the following information for all human biological material taken: 1) The nature of the materials, 2) The reason that the material is being taken, 3) where the material is to be sent, 4) what will happen to any remaining material once it has been processed/analysed, etc. for the purposes of this study (e.g. return, retention or destruction).

Detailed guidance on what information should be included in a protocol may be found on the HRA website http://www.hra.nhs.uk

Please select one of the following*	
This study does not involve the transfer of human biological material from this participating organisation to the sponsor or its agents. ***This schedule does not form part of this agreement.****	☒
The Sponsor has separately provided to the HRA and participating organisation an agreement for the transfer of human biological material. ***This schedule does not form part of this agreement.****	☐
These provisions form part of the agreement between the sponsor and this participating organisation. ***Select this option if no other agreement is provided, and the terms below constitute the arrangements for this study.****	☐

1 Where the protocol requires the participating organisation to supply material to the sponsor/joint sponsor(s)/either of the co-sponsors, these provisions shall apply if stated above.

2 In accordance with the protocol, the participating organisation shall send material to the sponsor/joint sponsor(s)/a co-sponsor or, in accordance with provision 8 below, a third party nominated by the sponsor/joint sponsor(s)/either of the co-sponsors.

3 The participating organisation warrants that all material has been collected with appropriate informed consent and has been collected and handled in accordance with applicable law (including, without limitation, the Human Tissue Act 2004 or the Human Tissue (Scotland) Act 2006 (as the case may be)) and as required by the protocol.

4 Subject to provision 3 above, the materials are supplied without any warranty, expressed or implied including as to their properties, merchantable quality, fitness for any particular purpose, or that the materials are free of extraneous or biologically active contaminants which may be present in the Materials.

5 The sponsor/joint sponsor(s)/one of the co-sponsors shall ensure, or procure through an agreement with the sponsor/joint sponsor(s)/co-sponsors nominee as stated in provision 2 above that.

5.1 the material is used in accordance with the protocol, the consent of the participant, and the HRA Approval for the Study,

5.2 the material is handled and stored in accordance with applicable law,

5.3 the material shall not be redistributed or released to any person other than in accordance with the protocol or for the purpose of undertaking other studies approved by an appropriate ethics committee and in accordance with the participant's consent, and

5.4 no alteration shall be made to the title, coding or acronym of the material.

6 The parties shall comply with all relevant laws, regulations and codes of practice governing the research use of human biological material.

7 The participating organisation and the sponsor/joint sponsors(s)/a co-sponsor shall each be responsible for keeping a record of the material that has been transferred according to these provisions.

8 To the extent permitted by law the participating organisation and its staff shall not be liable for any consequences of the supply to or the use by the sponsor/joint sponsors//co-sponsor of the material or of the supply to or the use by any third party to whom the sponsor/joint sponsors/co-sponsor subsequently provides the material or the Sponsor's/Joint Sponsors/Co-Sponsor's nominee as stated in provision 2 above, save to the extent that any liability which arises is a result of the negligence of the participating organisation.

9 The sponsor/joint sponsors/co-sponsor undertake(s) that, in the even that material is provided to a third party in accordance with provision 2 above, it/they shall require that such third party shall undertake to handle any data and Material related to the Study in accordance with all applicable statutory requirements and codes of practice and under terms no less onerous than those set out in these provisions.

10 Any surplus material that is not returned to the participating organisation or retained for future research (in line with participant consent) shall be destroyed in accordance with applicable law (including, without limitation, the Human Tissue Act 2004).

Schedule 3 (Confidentiality, Data Protection and Freedom of Information) (template version 4.0)

Please select one of the following*	
This study does not involve the transfer of Personal Data from this participating organisation to the sponsor or its agents, nor is there transfer of confidential information between the parties. *This schedule does not form part of this agreement.**	☒
The Sponsor has separately provided to the HRA and participating organisation another agreement for the transfer of data. *This schedule does not form part of this agreement.**	☐
These provisions form part of the agreement between the sponsor and this participating organisation. *Select this option if no other agreement is provided, and the terms below constitute the arrangements for this study.**	☐

1. Participant Confidentiality
   - 1.1. The parties agree to adhere to all applicable statutory requirements and mandatory codes of practice in respect of confidentiality (including medical confidentiality) in relation to participants
   - 1.2. Personal Data shall not be disclosed to the sponsor by the participating organisation, save where this is required directly or indirectly to satisfy the requirements of the Protocol, or for the purpose of monitoring or reporting adverse events, or in relation to a claim or proceeding brought by a participant in connection with the study.
   - 1.3. Neither the sponsor nor the participating organisation shall disclose the identity of participants to third parties without the prior written consent of the participant except in accordance with applicable statutory requirements and codes of practice, including HSCIC Code of Practice on Confidential Information.
   - 1.4. The sponsor agrees to act as Data Controller in relation to any processing of Personal Data under this agreement. This extends to all processing that would not have taken place but for this agreement regardless where that processing takes places. In particular, it extends to processing by the participating organisation where that processing is undertaken solely for the purposes of the study.
   - 1.5. The sponsor agrees to comply with the obligations placed on a Data Controller by the Data Protection Act 1998. This is not limited to, but includes, ensuring that:
     - 1.5.1. Personal Data shall be obtained only for one or more specified and lawful purposes, and shall not be further processed in any manner incompatible with that purpose or those purposes
     - 1.5.2. Personal Data are adequate, relevant and not excessive in relation to the purpose or purposes described within the protocol.
     - 1.5.3. Personal Data shall be accurate and, where necessary, kept up to date.
     - 1.5.4. Personal Data shall be processed in accordance with the rights of data subjects under the Data Protection Act 1998.
   - 1.6. The Sponsor agrees to ensure appropriate training. In particular:
     - 1.6.1. To ensure that any persons (excluding employees, honorary employees, students, researchers, consultants and subcontractors of the Participating Site) processing Personal Data are subject to annual mandatory training in the information

governance responsibilities and have appropriate contracts including sanctions, including for breach of confidence or misuse of data;

1.6.2. To ensure that the Senior Information Risk Owners, e.g. Caldicott Guardians, senior partners and board members of the sponsor (or organisational equivalent of each of these) complete additional data security training annually.

1.7. The participating organisation agrees to ensure that its employees, honorary employees, students, researchers, consultants and subcontractors processing Personal Data are subject to annual mandatory training in the information governance responsibilities and have appropriate contracts including sanctions, including for breach of confidence or misuse of data;

1.8. The sponsor agrees to use Personal Data solely in connection with the operation of this agreement and the study and not otherwise. In particular;

1.8.1. Not to disclose Personal Data in whole or in part to any person without the participating organisation's prior written consent;

1.8.2. Not to disclose other than pursuant to a data sharing agreement that conforms to the requirements set out in the Information Commissioner's data sharing code of practice.

1.9. The sponsor agrees to proactively prevent data security breaches and to respond appropriately to incidents or near misses.

1.10. The sponsor agrees to ensure data are processed using secure and up to date technology. In particular,

1.11. The participating organisation agrees to act as Data Processor on behalf of the sponsor as Data Controller for processing undertaken under this agreement solely for the purposes of the study. The participating organisation agrees to comply with the obligations placed on it as the data controller by the seventh data protection principle ("the Seventh Principle") set out in the Data Protection Act 1998, namely:

1.11.1. to maintain technical and organisational security measures sufficient to comply at least with the obligations imposed on the Data Controller by the Seventh Principle;

1.11.2. only to process Personal Data for and on behalf of the Data Controller, in accordance with the instructions of the Data Controller and for the purpose of the study and to ensure the Data Controller's compliance with the Data Protection Act 1998;

1.11.3. to allow the sponsor to audit the participating organisation's compliance with the requirements of this clause on reasonable notice and/or to provide the Data Controller with evidence of its compliance with the obligations set out in this clause;

1.11.4. the participating organisation shall obtain prior agreement of the sponsor to store or process Personal Data at sites outside the European Economic Area (comprising the countries of the European Community, Norway, Iceland and Liechtenstein).

2. Freedom of Information

2.1. Parties to this agreement which are subject to the Environmental Information Regulations 2004 (EIR) and the Freedom of Information Act 2000 (FOIA) or the Freedom of Information (Scotland) Act 2002 (FOI(S)A) and which receive a request under EIR, FOIA or FOI(S)A to disclose any information that belongs to another party shall notify and consult that party, as soon as reasonably practicable, and in any event, not later than seven (7) calendar days after receiving the request.

2.2. The parties acknowledge and agree that the decision on whether any exemption applies to a request for disclosure of recorded information under EIR, FOIA or FOI(S)A is a decision solely for the party responding to the request.

2.3. Where the party responding to an EIR, FOIA or FOI(S)A request determines that it will disclose information it will notify the other party in writing, giving at least four (4) calendar days' notice of its intended disclosure.

3. Confidential information

3.1. The receiving party agrees to take all reasonable steps to protect the confidentiality of the confidential information and to prevent it from being disclosed otherwise than in accordance with this agreement.

3.2. Subject to clause 3.4 below, the participating organisation agrees to treat the results, excluding any clinical data of the study, as confidential information disclosed by the sponsor and the sponsor agrees to treat Personal Data as confidential information disclosed by the participating organisation.

3.3. The receiving party agrees:

3.3.1. To ensure that any of its employees, students, researchers, consultants or sub-contractors who participate in the operation of the study are made aware of, and abide by, the requirement of this clause 3 and, where relevant, clause 2.

3.3.2. To use confidential information solely in connection with the operation of the agreement and not otherwise.

3.3.3. Not to disclose confidential information in whole or in part to any person without the disclosing party's prior written consent.

3.4. The provision of clause 3 shall not apply to the whole or any part of the confidential information that is:

3.4.1. lawfully obtained by the receiving party free of any duty of confidentiality;

3.4.2. already in the possession of the receiving party and which the receiving party can show from written records was already in its possession (other than as a result of a breach of clause 3.1 or 3.2);

3.4.3. in the public domain (other than as a result of a breach of clause 3.1 or 3.2);

3.4.4. independently discovered by employees of the receiving party without access to or use of confidential information;

3.4.5. necessarily disclosed by the receiving party pursuant to a statutory obligation;

3.4.6. disclosed with prior written consent of the disclosing party;

3.4.7. necessarily disclosed by the receiving party by virtue of its status as a public authority in terms of the Freedom of Information Act 2000;

3.4.8. published in accordance with HRA expectations on research transparency.

3.5. The restrictions contained in clauses 2 and 3 shall remain in force without limit in time in respect of Personal Data or which relates to a patient, his or her treatment and/or medical records. Save as aforesaid and unless otherwise expressly set out in this Agreement, these clauses shall remain in force for a period of 10 years after the termination or expiry of this Agreement.

Appendix 1 (Staff signature and delegation log) (template version 4.0)

This Appendix is for use at the discretion of the participating organisation and sponsor, to record the roles and responsibilities of the local research team (where applicable) and the authorisation of the Principal Investigator (PI) for this.

IRAS ID	Name of Participating Organisation
Enter IRAS ID	Enter name of participating organisation

Name of Principal Investigator	PI's Signature[1]	PI's Initials	Start (dd/mmm/yy)	End (dd/mmm/yy)
Enter name			Enter start date	Enter date

[1]My signature confirms/acknowledges that the information contained in this delegation log is accurate and that:

a. I will conduct the study in accordance with the protocol and remain responsible for the overall study conduct at the participating organisation and for the reported data.
b. I will ensure study oversight.
c. I will authorise the delegation of study-related tasks to each individual as listed.
d. The study tasks listed will only be delegated by me to skilled and qualified staff appropriately trained for the role.
e. I will ensure that all personnel assisting in the conduct of the study are informed about their obligations and will not have performed any delegated study-related tasks prior to appropriate delegation and completion of study training appropriate to the role.
f. I will ensure that participating organisation staff receive, in a timely manner, the appropriate information and training.
g. I am not involved in any regulatory or misconduct litigation or investigation by any regulatory authority and no data produced by me in any previous clinical Study has been rejected because of concerns as to its accuracy or because it was generated by fraud.
h. Neither I, nor any dependents, have entered into and will not enter into arrangements, financial or otherwise, with any third party providing support, products and/or services to the study that would present a conflict of interests
i. I will ensure that any and all changes in staff or delegated study-related task will be recorded in a timely manner.
j. I consent to the sponsor, and to any relevant third party providing support, products and/or services to the Study, holding my name and other relevant details on an appropriate database for the purpose of communicating with me in relation to the study.

Study Task Key:

The sponsor may detail in the below key the main study activities that the PI can delegate to staff at the participating organisation. The task list and delegation log are intended to be maintained as an up to date document throughout the duration of the study at the participating organisation.

1. Screens/recruits study subjects	6.	11. Enter other task here	16. Enter other task here
2. Obtains Informed Consent	7.	12. Enter other task here	17. Enter other task here
3. Confirms eligibility (Inclusion/Exclusion)	8.	13. Enter other task here	18. Enter other task here
4.	9. Enter other task here	14. Enter other task here	19. Enter other task here
5.	10. Enter other task here	15. Enter other task here	20. Enter other task here

Name	**Signature[2]**	**Initials**	**Study Role**	**Study Task(s) (Select from key)**	**Start of task(s)** (dd/mmm/yy)	**PI Initials**	**End of task(s)** (dd/mmm/yy)	**PI Initials**

[2]My signature confirms/acknowledges that I accept the assigned study task/s and that:

- I am not involved in any regulatory or misconduct litigation or investigation by any regulatory authority, and no data produced by me in any previous clinical Study has been rejected because of concerns as to its accuracy or because it was generated by fraud.
- I consent to the sponsor, and to any relevant third party providing support, products and/or services to the study, holding my name and other relevant details on an appropriate database for the purpose of communicating with me in relation to the study.

I confirm that the information contained in this delegation log is accurate and complete. (To be completed by the PI at the end of the study).

PI name: Signature: Date:

User Feedback (template version 4.0)

Please complete this form with your comments on the usability of the Statement of Activities and return by email to: hra.approvalprogramme@nhs.net

Comments

Enter comments here

What we will do with your response?

The HRA has a commitment to transparency. We will analyse the comments we receive, and publish a report on our website explaining how we will address the themes raised. The published report will compare the views of different organisations and groups of individuals.

Organisational responses: In the interest of transparency, all comments made on behalf of an organisation will normally be published and attributed unless an explanation is provided with your response as to why you consider the information should not be. (Please note the Confidentiality of Information section below.)

Individual responses:

Comments will be summarised in a way that does not identify individual respondents unless we have your permission to identify you.

Are you responding in an organisation or personal capacity?

Organisation Capacity ☐

Personal Capacity ☐

If you are replying in an organisational capacity, please note that your response may be published and quoted in the final report.

Organisational responses only

If you do not wish your organisational response, and any quotes used from it, to be identified in any consultation report and any future HRA publications, or published once the consultation has ended.

Please provide explanation of why you do not wish us to publish your organisational response

Individual responses only

I am responding primarily as a: (please check only one box):

Research Team Member	☐	NHS Staff	☐
Member of the public	☐	Industry	☐
REC Member	☐	Phase 1 Company	☐
REC Staff	☐	Regulatory Body	☐
R&D Community	☐	Academic	☐
Other (Please specify)	☐		

Please specify if answered 'Other'

I am willing for my response, and quotes used from it, to be used in non-identifiable form in any consultation report and any future HRA publications:

I am willing for my response, and quotes used from it, to be made identifiable in any consultation report and any future HRA publications:

Select 'yes' or 'no'

All responses

I am willing to be contacted by the HRA for further information in relation to this consultation or future consultations.

Select 'yes' or 'no'

If ‘yes’, please provide your contact details below. By providing these contact details, you are giving your consent for a member of HRA staff to contact you about your submission. The HRA takes data protection very seriously. We promise we will not pass your details on to any other organisations or use them for any other purposes.

Contact Name:

Enter contact name

Email:

Enter email address

Confidentiality of Information

The HRA will process your personal data in accordance with the DPA and in most circumstances this will mean that your personal data will not be disclosed to third parties without your permission or unless required by law. Information we receive, including personal information, may be published or disclosed in accordance with the access to information regimes (primarily the Freedom of Information Act 2000 (FOIA), the Data Protection Act 1998 (DPA) and the Environmental Information Regulations 2004). If you want the information that you provide to be treated as confidential, please be aware that, under the FOIA, there is a statutory Code of Practice with which public authorities must comply and which deals, amongst other things, with obligations of confidence. In view of this it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the HRA.

General Activities

Guidance
This tab should be completed for the 'site-type' covered by this Schedule of Events, including only those activities relevant to the organisations covered by this document (e.g. if the organisations will not be recruiting participants, do not include the activities related to participant recruitment). All activities should be given a cost attribution, in line with the DH AcoRD guidance. https://www.gov.uk/government/publications/guidance-on-attributing-the-costs-of-health-and-social-care-research

Please refer to the Hints and Tips tab before completing this section.

IRAS Reference Number:	121769

Area of Activity (Select this first. You can insert free text if the drop-down options are not suitable)	Specific Activity (drop down only present when Area of Activity selected first - or use free text if the drop-down options are not suitable)	Duration (Minutes)	Undertaken by (drop down or free text)	Day -x to -y	Day 0	Day x	Day x2	Day x3	Day x4	Day x5	Day x6	Day x7	Day x8	Day x9	Day x10	Day x11	Day x12	Day x13	Day x14	Day x15	Day x16
				Screen	Base	Visit 1	Visit 2	Visit 3	Visit 4	Visit 5	Visit 6	Visit 7	Visit 8	Visit 9	Visit 10	Visit 11	Visit 12	Visit 13	Visit 14	Visit 15	Visit 16
Distrubution of study promotional materials	promotional materials (colouring pages for example)	5	Local Clinical Nurse Specialist																		

General Activities

Guidance
This tab should be completed for the 'site-type' covered by this Schedule of Events, including only those activities relevant to the organisations covered by this document (e.g. if the organisations will not be recruiting participants, do not include the activities related to participant recruitment). All activities should be given a cost attribution, in line with the DH AcoRD guidance. https://www.gov.uk/government/publications/guidance-on-attributing-the-costs-of-health-and-social-care-research

Please refer to the Hints and Tips tab before completing this section.

IRAS Reference Number:	121769

Area of Activity (Select this first. You can insert free text if the drop-down options are not suitable)	Specific Activity (drop down only present when Area of Activity selected first - or use free text if the drop-down options are not suitable)	Duration (Minutes)	Undertaken by (drop down or free text)	Day x17	Day x18	Day x19	Day x20	Day x21	Day x22	Day x23	Day x24	Day x25	Day x26
				Visit 17	Visit 18	Visit 19	Visit 20	Visit 21	Visit 22	Visit 23	Visit 24	Visit 25	Visit x
Distrubution of study promotional materials	promotional materials (colouring pages for example)	5	Local Clinical Nurse Specialist										

Health Research Authority

North West - Liverpool East Research Ethics Committee

Barlow House
3rd Floor
4 Minshull Street
Manchester
M1 3DZ

Tel: 02071048127

22 February 2017

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:	**SA16**
Amendment date:	**20 February 2017**
IRAS project ID:	**121769**

Thank you for submitting the above amendment, which was received on 21 February 2017. I can confirm that this is a valid notice of a substantial amendment and will be reviewed by the Sub-Committee of the REC at its next meeting.

Documents received

The documents to be reviewed are as follows:

Document	*Version*	*Date*
Covering letter on headed paper [Cover Letter]		16 February 2017
Letter from sponsor [Sponsor Acknowledgement]		17 February 2017
Notice of Substantial Amendment (CTIMP) [NoSA]		

Notification of the Committee's decision

The Committee will issue an ethical opinion on the amendment within a maximum of 35 days from the date of receipt.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval for the research.

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

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

Yours sincerely

Matt Rogerson
REC Manager

Email: nrescommittee.northwest-liverpooleast@nhs.net

Copy to: *R&D Department, Oxford Health NHS Foundation Trust*
Dr Kay Wang, University of Oxford

North West - Liverpool East Research Ethics Committee

Barlow House
3rd Floor
4 Minshull Street
Manchester
M1 3DZ

Please note: This is the favourable opinion of the REC only and does not allow the amendment to be implemented at NHS sites in England until the outcome of the HRA assessment has been confirmed.

10 March 2017

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:	
Amendment date:	
IRAS project ID:	**121769**

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Covering letter on headed paper [Cover Letter]		16 February 2017
Letter from sponsor [Sponsor Acknowledgement]		17 February 2017
Notice of Substantial Amendment (CTIMP) [NoSA]		

Membership of the Committee

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

Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

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.

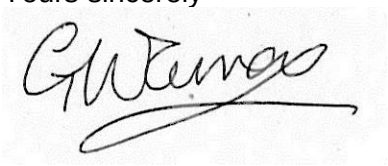
The Committee is fully compliant with the Regulations as they relate to ethics committees and the conditions and principles of good clinical practice.

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.

We are pleased to welcome researchers and R & D staff at our Research Ethics Committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

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

Yours sincerely



Mrs Glenys J Hunt
Chair

E-mail: nrescommittee.northwest-liverpooleast@nhs.net

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

Copy to: *R&D Department, Oxford Health NHS Foundation Trust*
Dr Kay Wang, University of Oxford

North West - Liverpool East Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 06 March 2017

Committee Members:

Name	*Profession*	*Present*	*Notes*
Mrs Glenys J Hunt	Solicitor	Yes	
Dr Peter Walton	Retired Lay Member	Yes	

Also in attendance:

Name	*Position (or reason for attending)*
Mr Matthew Rogerson	REC Manager

North West - Liverpool East Research Ethics Committee

Barlow House
3rd Floor
4 Minshull Street
Manchester
M1 3DZ

Please note: This is the favourable opinion of the REC only and does not allow the amendment to be implemented at NHS sites in England until the outcome of the HRA assessment has been confirmed.

10 March 2017

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**
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Protocol number:	**ARCHIE001**
EudraCT number:	**2013-002822-21**
Amendment number:	
Amendment date:	
IRAS project ID:	**121769**

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

Document	*Version*	*Date*
Covering letter on headed paper [Cover Letter]	16	16 February 2017
Letter from sponsor [Sponsor Acknowledgement]		17 February 2017
Notice of Substantial Amendment (CTIMP) [NoSA]		

Membership of the Committee

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

Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

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.

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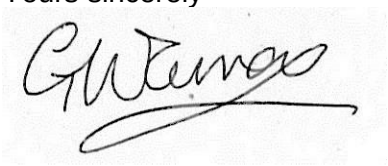
13/NW/0621: Please quote this number on all correspondence

Yours sincerely



Mrs Glenys J Hunt
Chair

E-mail: nrescommittee.northwest-liverpooleast@nhs.net

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

Copy to: *R&D Department, Oxford Health NHS Foundation Trust*
Dr Kay Wang, University of Oxford

North West - Liverpool East Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 06 March 2017

Committee Members:

Name	*Profession*	*Present*	*Notes*	
Mrs Glenys J Hunt	Solicitor	Yes		
Dr Peter Walton	Retired Lay Member	Yes		

Also in attendance:

Name	*Position (or reason for attending)*	
Mr Matthew Rogerson	REC Manager	

Primary Health Care Archie

From: HILL, Stephanie (HEALTH RESEARCH AUTHORITY) <stephanie.hill3@nhs.net>
Sent: 13 March 2017 15:26
To: Kay Wang; Primary Health Care Archie
Cc: CLRN, TV (OXFORD UNIVERSITY HOSPITALS NHS FOUNDATION TRUST); TMA, Ouh (OXFORD UNIVERSITY HOSPITALS NHS FOUNDATION TRUST); CTRG Sponsorship Correspondence; Karl Shepherd
Subject: IRAS ID 121769 Confirmation of Amendment Assessment

Dear Tricia,

Further to the below, I am pleased to confirm that HRA Approval has been issued for the referenced amendment, following assessment against the HRA criteria and standards.

The sponsor should now work collaboratively with participating NHS organisations in England to implement the amendment as per the below categorisation information. This email may be provided by the sponsor to participating organisations in England to evidence that the amendment has HRA Approval.

Please contact hra.amendments@nhs.net for any queries relating to the assessment of this amendment.

Kind regards

Stephanie Hill

Stephanie Hill | HRA Assessment Team
Health Research Authority
Skipton House
80, London Road, London SE1 6LH
E: Stephanie.Hill3@nhs.net

www.hra.nhs.uk

IMPORTANT – **Click here** for the latest details of the roll-out of HRA Approval in England

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From: LIVERPOOLEAST, NRESCommittee.NorthWest- (HEALTH RESEARCH AUTHORITY)
Sent: 10 March 2017 10:24
To: kay.wang@phc.ox.ac.uk; TMA, Ouh (OXFORD UNIVERSITY HOSPITALS NHS FOUNDATION TRUST); ctrg@admin.ox.ac.uk; karl.shepherd@admin.ox.ac.uk; archie@phc.ox.ac.uk
Cc: CLRN, TV (OXFORD UNIVERSITY HOSPITALS NHS FOUNDATION TRUST)
Subject: 121769, Confirmation of favourable opinion for substantial amendment

Dear Tricia,

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:	**21 February 2017**
Amendment No./ Sponsor Ref:	**SA 16**
Amendment Date:	**20 February 2017**
Amendment Type:	**Substantial**

I am pleased to confirm that this amendment has been reviewed by the REC and has received a Favourable Opinion. Please find attached a copy of the Favourable Opinion letter.

Participating NHS Organisations in England – Confirmation of Assessment Arrangements

Further to the details above, I can confirm that this amendment will be assessed by the HRA to confirm that it meets the expected criteria and standards. An Assessor from the HRA will contact you, and you will receive separate notification that the HRA Assessment is complete. You should not implement this amendment at participating NHS organisations in England until the outcome of the HRA assessment is confirmed, and the conditions detailed in the categorisation section above have been met.

If you require further information, please contact hra.amendments@nhs.net

Kind regards

Gemma Warren
REC Manager

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