



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

6 September 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 SA013:

- Addition of new NHS Sites - Secondary Care. (Table A attached)
- Addition of new NHS Sites – Primary Care (Table B attached)

Many thanks,

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

Attached:  
ARCHIE SA13 Amendment form  
ARCHIE SA13 IRAS Export  
Sponsor confirmation



Table A – Secondary Care

<b>Site</b>	<b>PI</b>	<b>CRN</b>
West Suffolk NHS Foundation Trust	Dr Arun Saraswatula	Eastern
University Hospitals Southampton NHS Foundation Trust	Dr Katrina Cathie	Wessex
Torbay and South Devon NHS Foundation Trust	Dr Mala Raman	South West Peninsula

Table B – Primary Care

<b>CRN</b>	<b>PI</b>
Kent, Surrey & Sussex (All CCG's & former PCT's)	Dr Kay Wang
Greater Manchester (All CCG's & former PCT's)	Dr Kay Wang
West Midlands (All CCG's & former PCT's)	Dr Kay Wang
North East & North Cumbria (All CCG's & former PCT's)	Dr Kay Wang
Yorkshire & Humber (All CCG's & former PCT's)	Dr Kay Wang

## Primary Health Care Archie

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**From:** Karen Melham  
**Sent:** 01 September 2016 17:23  
**To:** Primary Health Care Archie  
**Cc:** Research.Portfolio@ouh.nhs.uk  
**Subject:** Sponsor authorisation for substantial amendment 13 to ARCHIE trial

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

Dear Sharon,

Thank you for sending for our review the amendment proposed to ARCHIE to add new sites. I can confirm that we as sponsor representative are content for this to be sent to the relevant REC for review and approval.

Please remember correspondence and any final, REC-approved documents to [karl.shepherd@admin.ox.ac.uk](mailto: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](mailto:karen.melham@admin.ox.ac.uk) T: 01865 227093

[www.admin.ox.ac.uk/researchsupport](http://www.admin.ox.ac.uk/researchsupport)

PID:8801

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 <sup>1</sup>**

**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:**

*(<sup>1</sup>) 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?** <sup>2</sup>  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:** Sponsor protocol ref 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: 01865572228  
Fax:  
E-mail: ctrg@admin.ox.ac.uk

**C.2 Legal representative <sup>3</sup> 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<sup>4</sup>:
- 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

<sup>(4)</sup> According to national legislation.

**E SUBSTANTIAL AMENDMENT IDENTIFICATION**

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

Code Number: ARCHIE\_SA013

Version:

Date: 2016/08/30

**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<sup>5</sup>:  Yes  No
- E.2.6 This amendment is to notify a temporary halt of the trial<sup>6</sup>:  Yes  No
- E.2.7 This amendment is to request the restart of the trial<sup>7</sup>:  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:<sup>8</sup>**

- 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*):

<sup>(8)</sup>Cf. Section 3.10. of the detailed guidance CT-1

**F DESCRIPTION OF EACH SUBSTANTIAL AMENDMENT<sup>9</sup>**

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 Kay  
 Middle name(if applicable)  
 Family name Wang  
 Qualification (MD...) BA,BM BCh, MA, DRCOG, DCH, MRCGP, DPhil  
 Professional address PCT/CCG's covered by Kent, Surrey & Sussex CRN

Given name Kay  
 Middle name(if applicable)  
 Family name Wang  
 Qualification (MD...) BA,BM BCh, MA, DRCOG, DCH, MRCGP, DPhil  
 Professional address PCT/CCG's covered by West Midlands CRN

Given name Arun  
 Middle name(if applicable)  
 Family name Saraswatula  
 Qualification (MD...)  
 Professional address West Suffolk NHS Foundation Trust

Given name Katrina  
 Middle name(if applicable)  
 Family name Cathie  
 Qualification (MD...)

Professional address University Hospital Southampton NHS Foundation Trust

Given name Mala

Middle name(if applicable)

Family name Raman

Qualification (MD...)

Professional address Torbay and South Devon NHS Foundation Trust

Given name Kay

Middle name(if applicable)

Family name Wang

Qualification (MD...) BA,BM BCh, MA, DRCOG, DCH, MRCGP, DPhil

Professional address PCT/CCG's covered by Yorkshire & Humber CRN

Given name Kay

Middle name(if applicable)

Family name Wang

Qualification (MD...) BA,BM BCh, MA, DRCOG, DCH, MRCGP, DPhil

Professional address PCT/CCG's covered by North East and North Cumbria CRN

Given name Kay

Middle name(if applicable)

Family name Wang

Qualification (MD...) BA,BM BCh, MA, DRCOG, DCH, MRCGP, DPhil

Professional address PCT/CCG's covered by Greater Manchester CRN

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

G.1.4.6 Indicate the name of the previous principal investigator:

**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)<sup>10</sup>?**

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](http://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).*

- |  |                                     |
|--|-------------------------------------|
| <b>I.1 Cover letter</b>  | <input checked="" type="checkbox"/> |
| <b>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)</b> | <input type="checkbox"/>            |
| <b>I.3 Entire new version of the document<sup>11</sup></b>   | <input type="checkbox"/>            |
| <b>I.4 Supporting information</b>  | <input type="checkbox"/>            |
| <b>I.5 Revised .xml file and copy of initial application form with amended data highlighted</b>  | <input type="checkbox"/>            |
| <b>I.6 Comments on any novel aspect of the amendment if any :</b>  |                                     |

*(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 <sup>12</sup>: .....

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 <sup>13</sup>: .....

J.3.2 Print name:

J.3.3 Date:

This section was signed electronically by Mrs Tricia Carver on 05/09/2016 10:42.

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.*

13 September 2016

**Ms Sharon Tonner**  
**Assistant Trial manager**  
**Clinical Trials Unit**  
**Nuffield Department of Primary Care Health Sciences**  
**Radcliffe Observatory Quarter**  
**Woodstock Road**  
**Oxford**  
**OX2 6GG**

Dear Ms Tonner

**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:** Substantial Amendment 013

**Amendment date:** 30 August 2016

**IRAS project ID:** 121769

Thank you for submitting the above amendment, which was received on 06 September 2016.

<i>Research site</i>	<i>Principal Investigator / Local Collaborator</i>
PCT/CCG's covered by Kent, Surrey & Sussex CRN	Dr Kay Wang
PCT/CCG's covered by West Midlands CRN	Dr Kay Wang
West Suffolk NHS Foundation Trust	Dr Arun Saraswatula
University Hospital Southampton NHS Foundation Trust	Dr Katrina Cathie
Torbay and South Devon NHS Foundation Trust	Dr Mala Rahman
PCT/CCG's covered by Yorkshire & Humber CRN	Dr Kay Wang
PCT/CCG's covered by North East and North Cumbria CRN	Dr Kay Wang
PCT/CCG's covered by Greater Manchester CRN	Dr Kay Wang

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



**Ewa Grzegorska**  
**REC Assistant**

**Email:** [nrescommittee.northwest-liverpooleast@nhs.net](mailto:nrescommittee.northwest-liverpooleast@nhs.net)

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

## Primary Health Care Archie

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**From:** LiverpoolEast NRESCCommittee.NorthWest- (HEALTH RESEARCH AUTHORITY)  
<nrescommittee.northwest-liverpooleast@nhs.net>  
**Sent:** 13 September 2016 11:07  
**To:** Primary Health Care Archie  
**Cc:** Kay Wang  
**Subject:** Re: 13/NW/0621 [IRAS ID: 121769]. Confirmation of Amendment Categorisation as Category B  
**Attachments:** 2016.09.13 Wang 13-0621 Acknowledge Sites.pdf  
**Follow Up Flag:** Follow up  
**Flag Status:** Flagged

Dear Sharon,

<b>IRAS Project ID:</b>	<b>121769</b>
<b>Short Study Title:</b>	<b>The early use of Antibiotics in at Risk Children with Influenza-ARCHIE</b>
<b>Date complete amendment submission received:</b>	<b>06 September 2016</b>
<b>Amendment No./ Sponsor Ref:</b>	<b>Substantial Amendment 013</b>
<b>Amendment Date:</b>	<b>30 August 2016</b>
<b>Amendment Type:</b>	<b>Substantial</b>

Thank you for submitting the above referenced 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](#).

Subject to the same four conditions, you will be able to implement your amendment at participating organisations in Northern Ireland, Scotland or Wales on 11 October 2016.

- You may not implement this amendment until and unless you receive all required regulatory approvals, including REC favourable opinion where applicable, (for participating organisations in

England, please see 'Confirmation of Assessment Arrangements' below). 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, please see 'Confirmation of Assessment Arrangements' below) 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.

### **Participating NHS Organisations in England – Confirmation of Assessment Arrangements**

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

Ewa



Miss Ewa Grzegorska | REC Assistant  
 North West – Greater Manchester South  
 North West – Bloomsbury  
**Health Research Authority**  
 HRA RES Centre Manchester  
 3<sup>rd</sup> Floor, Barlow House, 4 Minshull Street, Manchester, M1 3DZ  
 E: [ewa.grzegorska@nhs.net](mailto:ewa.grzegorska@nhs.net) | T: 0207 104 8002  
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**IMPORTANT** – [Click here](#) for the latest details of the roll-out of HRA Approval in England

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

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