# Quick guide for Home Visit Recruitment

| ACTIVITIES PRIOR TO DIRECT NURSE INVOLVEMENT | |
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| **CHECKLIST ITEM** | **ASSESSMENT BY GP OR NURSE** |
| **Patient identification** | The GP or nurse will identify the patient opportunistically when they consult for flu-like illness and determine that the patient does not require immediate antibiotics or hospitalisation. If parent/guardian is willing to consider allowing their child to participate in the ARCHIE study, the GP or nurse will give them a study PIL and contact the ARCHIE Trial Office on **01865 617858.** |
| **Eligibility Assessment** | The ARCHIE Trial Office will complete the eligibility for home visit assessment form with the GP/nurse over the phone while they are with the patient. This form will include the full set of study eligibility criteria, as well as contact information, brief clinical details (date of birth, weight, 'at risk' category, seasonal influenza vaccination status, heart rate, respiratory rate) and details of any special considerations (e.g. whether the standard BNF dosing regimen for co-amoxiclav would apply for this patient). The ARCHIE Trial Office will then contact the relevant area nurse. |
| **Your recruitment pack contains all the paper case report forms (CRFs) needed for the study apart from Withdrawal and Serious Adverse Event (SAE) forms. Instructions for obtaining these are detailed at the end of this guide. Completed patient CRFs should be filed in the GP surgery's ISF.** | |
| **BASELINE ACTIVITIES DIRECTLY INVOLVING NURSE** | |
| **CHECKLIST ITEM** | **ARRANGING HOME VISIT BASELINE ASSESSMENT (ELIGIBLE CHILDREN ONLY)** |
| **Proceed to Home Visit** | For eligible patients, you will receive the completed home visit eligibility assessment form by email via NHS.net. A text will also be sent as a notification. |
| **Arrange visit appointment** | Please contact the parent/guardian directly to discuss the study and arrange the home visit to enter patient into the study.<br>• **The visit must occur within 24 hrs**<br>• **Parent/Guardian must be present to give consent**<br>Please let the GP surgery and ARCHIE Trial Office know that the visit has been arranged. |
| **Screening & Recruitment Status log completion** | Please record the potential patient on a **site screening & recruitment status log,** (one for each GP surgery or nurses office), to track their progress through the study or on a combined excel worksheet. |
| | **STUDY ENTRY/DAY 1 – BASELINE, CONSENT & RANDOMIZATION** |
| **PIL Booklets Video**<br><br>**Consent Form**<br><br><br><br>**ARCHIE ID**<br><br>**Assent Form (optional)** | **Introductory Pack, clear pocket**<br>1. Please use the study PIL in the Introductory Pack or show the videos found on the www.archiestudy.com to explain the study.<br>2. Complete and sign the Consent Form with the child's parent/guardian, ensuring they initial in the boxes. If you do not wish to recruit participants into the follow-up throat swabs portion of the study please cross through item 8 on the consent form.<br>3. Assign an ARCHIE ID. This is comprised of the sites ID number and the recruitment pack number. Stickers are available to be used. Each pack has a sheet of recruitment pack stickers but you will need to write in the site ID (first 3 digits).<br>4. If appropriate please complete an Assent Form with the child. |
| **Baseline Assessment**<br><br><br><br><br>**Swabs:**<br>– **Nasal**<br>– **Throat** | **Recruiter Pack, blue pocket (use the appropriate Site ID and ARCHIE ID stickers for documents)**<br>5. Complete the **Baseline Assessment Form** noting the following instructions:<br>a. You may measure the child's temperature using an electronic tympanic or axillary thermometer, remember to note the time. **Parent to only take axillary temperature**.<br>b. Please take a nasal swab from EVERY child. Place stickers on plastic bag. **Note: If you cannot obtain a nasal swab, please DO NOT allocate study medication to the child**. Please tick 'NO' in response to 'nasal swab taken?' and return any completed study documents to the CTU, University of Oxford in the prepaid envelope provided. Thank the parent / child for their |

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| **Randomisation Medication** | time and explain why they cannot remain in the trial.<br>c. Once swabs obtained, Call the trial office on<br>**01865 617 842 or 01865 617 836**<br>to randomise and have the medication allocated. You will need to provide patient age, weight and vaccination status. The trial office will then tell you which bottle to dispense and the appropriate dose. Please take a photo of the bottle you dispense.<br>Complete the accountability log in the medication document wallet.<br>Complete stickers and place one on **medication bottle (a second med ID sticker is for the week one diary).** Full details can be found on the back of blue pack cover sheet again and there is a brief review inside of medication box.<br>**Note:** To save time, while you arrange the medication ask the parent/guardian to complete the participant questionnaires (yellow pocket). |
| **Contact Card** | 6. Complete the **ARCHIE Study Contact Card** and give the card to the parent/guardian. Please write the recruiting surgery contact telephone number in the space next to 'Local Investigator'. You will find this on the Home Visit Eligibility Assessment form. |
| **Contact Information Questionnaires** | **Participant Questionnaire Pack, yellow pocket (Stickers provided for Site ID and ARCHIE ID)**<br>7. Please ask the child's parent/guardian to fill in the following forms:<br>a. **Contact information form** (Keep this securely so you are able to perform follow-up and notes review. You may also complete this form for the parent whilst they are completing the remaining paper work.)<br>b. **EQ-5D-Y proxy questionnaire**<br>c. **CARIFS questionnaire**<br>d. If appropriate, please ask the child to complete the **EQ-5D-Y questionnaire**. This is OPTIONAL. |
| **Thermometer**<br>**Diary**<br>– **Parent**<br>– **Child**<br><br>**Follow-up /Reminders** | **Participant Pack** (in the front pocket of the pack, by the swabs)<br>8. Explain to the child's parent/guardian how to use the **armpit thermometer** and how to complete the **Study Diary** using the **Study Diary Instructions and Overview**.<br>9. Fill in the details on the front page of each weekly **Study Diary.**<br>10. If appropriate, explain and fill in the details on the front page of the study diary for children (OPTIONAL).<br>**Follow-up arrangements and reminders**<br>11. Arrange times for the week 1 and week 2 follow-up telephone calls.<br>12. Set up mobile phone text reminders if the child's parent/guardian wishes to receive these (days 4, 7, 14, 21, 28). |
| **Copy forms** | Please take a copy of the **signed consent+/- assent** form (top sheet), if possible send a scan to the GP surgery for their electronic records. |
| **Post forms** | **Post documents**<br>13. **Post** the following completed documents to the CTU, **University of Oxford** in the prepaid envelope provided:<br>a. Consent form (**bottom copy**)<br>b. Assent form, if completed (**bottom copy**)<br>c. Baseline Assessment form (**top copy**)<br>d. EQ-5D-Y proxy questionnaire<br>e. CARIFS questionnaire<br>f. EQ-5D-Y questionnaire, if completed |
| **File forms** | 14. File retained copies of consent+/- assent, baseline assessment, and eligibility in site ISF when convenient. |

# Quick guide for Home Visit Recruitment

| FOLLOW UP ACTIVITIES DIRECTLY INVOLVING NURSE | |
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| **CHECKLIST ITEM** | **WEEK 1 FOLLOW-UP (TELEPHONE)** |
| **Week 1 Follow-up CRF** | 1. Contact the child's parent/guardian by telephone and complete the **week 1 follow-up CRF**. This follow-up can be done from day 7 to day 10 inclusive (day 1=date of randomisation). |
| **Unable to contact** | 2. Indicate this and return the signed and dated form |
| **Adverse Event Report** | 3. Please remember to complete **Adverse Event/Serious Adverse Event** documentation if necessary (see section 6). |
| **Diary Reminder** | 4. Remind parent/guardian to return completed week 1 study diary by post. Please check that the parent/guardian has completed the following items in the week 1 diary:<br>• Daily pages, days 1 to 7 inclusive (symptoms, temperature, study medication, other medication).<br>• Day 4 study questionnaire.<br>• Day 7 study questionnaires 1 and 2.<br>• End of week questions (potential side-effects of study medication, daily activities and childcare, health service contacts). |
| **Post form** | 5. Please **post** the top copy of the **signed and dated completed form** to the CTU, University of Oxford in the prepaid envelope provided. On completion of patient follow up calls your retained copy should be filed in the site ISF. |
| | **WEEK 2 FOLLOW-UP (TELEPHONE)** |
| **Week 2 Follow-up CRF** | 1. Contact the child's parent/guardian by telephone and complete the **week 2 follow-up CRF**. This follow-up can be done from day 14 to day 17 inclusive (day 1=date of randomisation). |
| **Unable to contact** | 2. Indicate this and return the signed and dated form |
| **Adverse Event Report** | 3. Please remember to complete **Adverse Event/Serious Adverse Event** documentation if necessary (see section 6). |
| **Diary Reminder** | 4. Remind parent/guardian to return completed week 2 study diary by post. Please check that the parent/guardian has completed the following items in the week 2 diary:<br>• Daily pages, days 8 to 14 inclusive (symptoms, temperature, study medication, other medication).<br>• Day 14 study questionnaire.<br>• End of week questions (potential side-effects of study medication, daily activities and childcare, health service contacts). |
| **Post form** | 5. Please **post** the top copy of the **signed and dated completed form** to the CTU, University of Oxford in the prepaid envelope provided. On completion of patient follow up calls your retained copy should be filed in the site ISF. |
| | **MEDICAL NOTES REVIEW** |
| **Notes review** | Your regional coordinator will remind you to make arrangements for completing the medical notes review at the child's GP practice. This will occur no sooner than 3 months after study entry and will cover the child's medical history leading up to study entry and any consultations in the 28-day period after study entry. OpenClinica is used for direct online data entry and training will be provided. |
| **Optional - Nested study involving further throat swabs and medical notes review** | |
| **NURSE** | **Optional - Further throat swabs** |
| **3, 6 and 12 months follow-up throat swab** | A follow-up kit containing three swab kits will be sent to you. A covering letter will provide the due dates for the swabs which are due 3, 6 and 12 months after study entry (+/- 2 weeks). You will also receive electronic reminders. |
| **NURSE** | **Optional - Further medical notes review** |
| **Antibiotic use** | Collect data on antibiotics prescribed during the 12-month period after study entry or until the last follow-up throat swab was obtained. Enter this directly into OpenClinica. |

# Quick guide for Home Visit Recruitment

| ACTIVITIES THAT MAY REQUIRE BOTH GP & NURSE INVOLVEMENT | |
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| **CHECKLIST ITEM** | **WITHDRAWAL FORM** |
| **Withdrawal** | The healthcare professional or parent/guardian may elect to withdraw the patient from the study.<br>Please request a withdrawal form from the trial office.<br>Please note that treatment may be stopped without the patient being withdrawn.<br>Please discuss this with the trial team if you are not clear on the terms of withdrawal. |
| **Post form** | Retain a copy for the ISF and post the completed form to the CTU, University of Oxford in the prepaid envelope provided. |
| | **SAFETY REPORTING INSTRUCTIONS AND FORMS** |
| **Adverse Event (AE) Report Form** | Please record an **Adverse Event** on the participant's **Adverse Event Report Log.**<br><br>Send a copy of the **Adverse Event Report Log** after adding a new event(s) to the trial office using a prepaid envelope or by email to: **archie@phc.ox.ac.uk.**<br>A copy should also be forwarded to the child's GP for filing in the ISF.<br><br>Please note that you do NOT need to report the following adverse events unless they are severe (based on clinician's assessment) or result in a serious adverse event: diarrhoea, nausea, vomiting, thrush.<br><br>Please discuss any queries about completing the form with the lead investigator at the site where the patient was initially assessed or with the University of Oxford Primary Care Clinical Trials Unit (PC CTU) (01865 617842 or 01865 617 836). |
| **Serious Adverse Event (SAE) Report Form** | If an adverse event is **SERIOUS**<br><br>• Download a **Serious Adverse Event (SAE) Report Form** from www.archiestudy.com or make a copy of the master form provided in the investigator site file.<br><br>• **Consult with the site PI or medically qualified delegate** to complete the **SAE Report Form** and submit it to PC CTU by fax (01865 617 939) or email (archie@phc.ox.ac.uk) within 24 hours of becoming aware of the event.<br><br>• The PC CTU will contact you for further information. Please contact ARCHIE Oxford Trial Office on 01865 617842/01865 617836 **if you have not been contacted** within one working day of submitting the SAE Report form.<br><br>• For each SAE, please also record the event on the Adverse Event Report Log per above and supply a copy to the trial office. Please retain a copy for filing in the site ISF. |