Quick guide for GP recruitment

Your recruitment pack contains all the paper case report forms (CRFs) needed for the study apart from a Serious Adverse Event (SAE) form. Instruction for the SAE form are detailed in section 6. **If you use the paper eligibility form, you will need to arrange to enter the data into the online form and archive the completed hard copy in your Investigator Site File (ISF).**	
CHECKLIST ITEM	**SECTION 1: ELIGIBILITY AND CONSENT**
Eligibility Assessment **Site recruitment status log (not found in this section)**	Complete the **Eligibility Assessment Form (paper or online at www.archiestudy.com)** Examples of risk categories and a reminder of contraindications to co-amoxiclav are included in the pack for your reference. There is no longer a screening log to be completed as we will generate this from the data you complete online. Please use the **Site recruitment status log** to track their progress through the study. You can complete this electronically (word doc available from the website) or on paper (in trial medication document wallet)
Information Booklets **Consent Form** **Assent Form (optional)** **Post forms**	**Introductory Pack, clear pocket** Please use the study **Information Booklets** in the **Introductory Pack** to explain the study. Complete and sign the **Consent Form** with the child's parent/guardian. Write the ARCHIE ID on the form and ensure the adult initials in the boxes. If appropriate, please also complete an **Assent Form** with the child. If your sites does not wish to recruit participants into the follow-up throat swabs portion of the study please cross through item 8 on the consent form. A prepaid envelope to return the completed bottom copy of the forms is provided in **section 2, baseline assessment** (**blue Recruiter Pack**).
	SECTION 2: BASELINE ASSESSMENT (ELIGIBLE CHILDREN ONLY) – DAY 1
Baseline Assessment **Swabs:** – **High Nasal** – **Throat** **Medication** **Contact Card**	**Recruiter Pack, blue pocket (use the appropriate ARCHIE ID stickers for documents)** 1. Complete the **Baseline Assessment Form** noting the following instructions: a. You may measure the child's temperature using an electronic tympanic or axillary thermometer. **Parent to only take axillary temperature**. Please remember to note the time you took the child's temperature. b. Please take a high nasal swab from EVERY child. Place stickers on plastic bag. **Note: If you cannot obtain a high nasal swab, please DO NOT allocate study medication to the child**. Please tick 'NO' in response to 'High nasal swab taken?' and return any completed study documents to the University of Oxford in the prepaid envelope provided. Thank parent / child for their time and explain why they cannot remain in the trial. c. Use Sortition to allocate the medication and the allocation report can be printed, signed and filed as the drug accountability documentation. Alternatively complete the accountability log in the medication document wallet. 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. Note: To save time, while you collect the medication ask the adult to complete the participant questionnaires (yellow pocket). 2. Complete the **ARCHIE Study Contact Card** and give the card to the parent/guardian. Please write your surgery contact telephone number in the space next to 'Local Investigator'.

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Contact Information Questionnaires **Thermometer Diary** – **Parent** – **Child** **Follow-up /Reminders**	**Participant Questionnaire Pack, yellow pocket (Stickers provided for ARCHIE ID)** 3. Please ask the child's parent/guardian to fill in the following forms: a. **Contact information form** (you may keep this or return it to us) b. **EQ-5D-Y proxy questionnaire** c. **CARIFS questionnaire** d. If appropriate, please ask the child to complete the **EQ-5D-Y questionnaire**. This is OPTIONAL. **Participant Pack** (in the front pocket of the pack, by the swabs) 4. 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**. 5. Fill in the details on the front page of each weekly **Study Diary.** 6. If appropriate, explain and fill in the details on the front page of the study diary for children (OPTIONAL). **Follow-up arrangements and reminders** 7. Arrange times for the week 1 and week 2 follow-up telephone calls. 8. Set up mobile phone text reminders if the child's parent/guardian wishes to receive these (days 4, 7, 14, 21, 28).
Post forms	**Post documents** 9. **Post** the following **completed documents** to the University of Oxford in the prepaid envelope provided: a. Consent form (bottom copy) b. Assent form, if completed (bottom copy) c. Baseline Assessment form (keep a copy for you own records e.g. scan or photocopy) d. Contact information form (GP practices consenting patients from their practice may keep this form for their records) e. EQ-5D-Y proxy questionnaire f. CARIFS questionnaire **g.** EQ-5D-Y questionnaire, if completed
Special Instructions Consent **Site recruitment status log**	**Special Instructions:** 10. Please scan a copy of the consent +/- assent form into the child's electronic medical record. 11. Please keep a copy of the Baseline Assessment form for your records. 12. Add the participant to your **Site recruitment status log** to help you track progression through the study
File Documents	13. Please make a copy of the baseline form. 14. Please file any documents which you retain in your ISF, i.e. consent form +/- assent form, paper Eligibility and copy of Baseline Assessment

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CHECKLIST ITEM	SECTION 3: WEEK 1 FOLLOW-UP (TELEPHONE)
Follow-up swab consent	1. Before you contact the child's parent/guardian please check whether they agreed to point 8 on the **Consent form** (follow-up throat swabs). The **Consent form** can be found in the Investigator Site File and in the GP electronic medical records. If consent has already been given tick "not applicable" to question 4.
Week 1 Follow-up Form	2. Contact the child's parent/guardian by telephone and complete the **week 1 follow-up form** (paper or online at www.archiestudy.com). This follow-up can be done from day 7 to day 10 inclusive (day 1=date of randomisation).
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: • Daily pages, days 1 to 7 inclusive (symptoms, temperature, study medication, other medication). • Day 4 study questionnaire. • Day 7 study questionnaires 1 and 2. • End of week questions (potential side-effects of study medication, daily activities and childcare, health service contacts).
Post form	5. Please **post** the **completed form** to the University of Oxford in the prepaid envelope provided.
CHECKLIST ITEM	**SECTION 4: WEEK 2 FOLLOW-UP (TELEPHONE)**
Follow-up swab consent	1. Before contacting the child's parent/guardian for the week 2 follow-up, check whether they agreed to follow-up throat swabs (point 8 on the **Consent form** or point 4 on the **week 1 follow-up form**). If consent has already been given tick "not applicable" to question 4.
Week 2 Follow-up Form	2. Contact the child's parent/guardian by telephone and complete the **week 2 follow-up form** online. This follow-up can be done from day 14 to day 17 inclusive (day 1=date of randomisation).
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: • Daily pages, days 8 to 14 inclusive (symptoms, temperature, study medication, other medication). • Day 14 study questionnaire. • End of week questions (potential side-effects of study medication, daily activities and childcare, health service contacts).
Post form	5. Please **post** the **completed form** to the University of Oxford in the prepaid envelope provided.
CHECKLIST ITEM	**SECTION 5: DISCONTINUATION FORM (LOST TO FOLLOW-UP / WITHDRAWAL)**
Discontinuation Form **Withdrawal** **Lost to Follow-up**	Please complete discontinuation information Complete either the **WITHDRAWAL portion** OR **LOST TO FOLLOW-UP portion** as appropriate.
Post form	Please **post** the **completed form** to the University of Oxford in the prepaid envelope provided.

CHECKLIST ITEM	SECTION 6: SAFETY REPORTING INSTRUCTIONS AND FORMS
Adverse Event (AE) Report Form	Please record the **Adverse Event** on the participant's **Adverse Event Report Log.** 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** 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. Please discuss any queries about completing the form with the lead investigator at your site or with the University of Oxford Primary Care Clinical Trials Unit (PC CTU) (01865 617842).
Serious Adverse Event (SAE) Report Form	If an adverse event is **SERIOUS** • 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. • 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. The PC CTU will contact you for further information. Please contact Tricia Carver (ARCHIE trial manager) on 01865 617842 **if you have not been contacted** within one working day of submitting the SAE Report form. • For each SAE, please also record the event on the Adverse Event Report Log and supply a copy to the trial office.
CHECKLIST ITEM	**Medical notes review – Primary outcome measure**
Note review	Contact your regional coordinator to make arrangements for completing the medical notes review. This will involved access to OpenClinica for direct online data entry.
Optional - Nested study involving further throat swabs and medical notes review	
CHECKLIST ITEM	**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 for each participant consenting to participate in this portion of the study. A covering letter will provide the due dates for the swabs which are due 3, 6 and 12 months after study entry (+/- 2 weeks)
CHECKLIST ITEM	**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