

# STANDARD OPERATING PROCEDURE

## CONDUCT OF HOME VISITS S23

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UNDER REVIEW

**DISCLAIMER**

This generic R&D Standard Operating Procedure (SOP) must be followed unless;

- A study specific SOP exists
- A departmental SOP dictates a different working practice

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**VERSION HISTORY LOG**

This area should detail the version history for this document. It should detail the key elements of the changes to the versions.

<b>VERSION</b>	<b>Date Implemented</b>	<b>Details of significant changes</b>
2.0	20 March 2014	SOP reviewed and changed so that it covers all home visits and not those just related to vaccine studies.
2.1	22 October 2015	SOP re-numbered from S01 to S23, as per request by Claire Ridler, RM&G Manager. No other changes

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CONTENTS

Section		Page
1	Background	5
2	Purpose	5
3	Scope	5
4	Responsibilities	5
5	Procedure	5
6	Further reading	6

UNDER REVIEW

## 1. **BACKGROUND**

This SOP covers the general aspects of home visit conduct. For further details and/or study specific instructions, please refer to:

- SOP's for specific procedures (as referenced below)
- Study Protocol
- Study-specific sample handling/processing instructions

## 2. **PURPOSE**

- To ensure consistency and quality of home visit procedures across clinical trials.
- To highlight other relevant SOP's and sources of information.

## 3. **SCOPE**

Home visits to patients in their own homes may be carried out as part of a research project. It is the employer's duty to assess the level of risk to staff carrying out home visits and take steps to minimise or control the risk where necessary.

## 4. **RESPONSIBILITIES**

Home visits will be undertaken by suitably qualified, trained and experienced staff who have been assigned study-related tasks as documented on the delegation log for the study prior to carrying out any procedures. It is the responsibility of staff undertaking home visits to ensure that they are aware of and follow the guidance in the Lone Worker SOP – R&D/Lone Worker/S16.

## 5. **PROCEDURES**

### **Consent**

Written informed consent will be obtained before any study procedures are conducted, and verbal consent will be sought from the subject and/or parent/legally authorised representative (LAR) prior to commencement of any procedure(s). Consent will be obtained as described in R&D/Informed Consent/S15.

If the study involves taking a blood sample in children, with the verbal consent of the participant and/or parent/LAR, anaesthetic cream may be applied (to numb the skin for venepuncture) prior to obtaining written informed consent, provided this is permitted by the study protocol and Research Ethics Committee.

### **Immunisation**

For home visits which involve administration of vaccine(s), procedures for cold chain maintenance (as described in R&D/Transportation of Vaccines/S45) will be followed, and vaccines administered (as described in R&D/Administration of Vaccines/S44) in accordance with instructions from the supplier.

### **Obtaining a Blood Sample**

If a home visit involves taking a blood sample, the sample(s) will be obtained according to procedures described in R&D/Venepuncture in Infants and Small Children/S39 and R&D/Spillages of Blood, Saliva or Sputum/S46 will be followed.

### **Transportation of Clinical Sample(s)**

If a home visit involves taking a clinical sample, the sample(s) will be transported back to site according to study protocol and procedures described in R&D/Storage and Transportation of Clinical Samples/S42.

#### **Centrifuging & Storage of Blood Samples**

If a home visit involves taking a blood sample, the sample(s) will be centrifuged once back at the hospital site according to the study laboratory manual and procedures described in R&D/Spinning & Storage of Blood Samples/S36.

#### **Source Data & Record Keeping**

Completion of relevant sections of the subject's case report form will be undertaken throughout the course of the visit. This data will then be transcribed to the e-CRF (where required for a study) as soon as possible on return to the office, and the source data stored securely.

### **6. FURTHER READING**

R&D/Informed Consent/S15

R&D/Lone Worker/S16

R&D/Spinning & Storage of Blood Samples/S36

R&D/Venepuncture in Infants and Small Children/S39

R&D/Storage and Transportation of Clinical Samples/S42

R&D/Administration of Vaccines/S44

R&D/Transportation of Vaccines/S45

R&D/Spillages of Blood, Saliva or Sputum/S46