


RHiNO			
Standard Operating Procedure			
		SOP Title: Ensuring Staff and Patient Safety when Undertaking Home Visits for the RHiNO Study	
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1. GUIDE

This document (also referred to as a Standard Operating Procedure: SOP) is identified by the code RHINO/3.0/1.0. The code identifies the origin of the document (RHINO study), the number of the document central list SOPs for the RHINO trial, and the version number (1.0). The date when it was last amended is found in the footer and the history can be found in section 9 of the document.

2. LEGAL BASIS AND BACKGROUND

The legal basis for this SOP is the EU Directive 2001/20/EC which establishes specific provisions regarding the conduct of clinical trials, in particular relating to the implementation of Good Clinical Practice (GCP). A key aspect is to have Standard Operating Procedures (SOPs) covering activities of the RHINO study.

3. PURPOSE

This SOP details the necessary procedures required to ensure that strategies are in place to reduce the risk of lone working in line with the Cardiff and Vale Health Board Lone worker Policy and the All Wales NHS Violence and Aggression Training Passport and Information Scheme.

4. LINKS TO OTHER SOPs AND RHINO DOCUMENTS

Buddy System Rota.

5. DEFINITIONS

Buddy	Research team member who is responsible for supporting and checking on the safety of the team member undertaking the home visit.
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CI	Chief Investigator.
Datex Form	Cardiff and Vale University Health Board online incident reporting form.
Lone worker	“those who work by themselves without close or direct supervision”. (Health and Safety Executive)

6. SCOPE AND RESPONSIBILITIES

This SOP is applicable to:

6.1. Chief Investigator

Responsible for ensuring that staff have completed relevant training to ensure SOP is instigated appropriately. Responsible for ensuring that relevant risk assessment strategies and associated equipment are in place to reduce risk and protect staff undertaking home visits.

6.2. Senior Research Nurse/Clinical Fellow

To ensure that research staff are aware of this SOP and its implementation into practice. To ensure that staff undertake and complete the relevant risk assessments related to home visits and comply with and document activities related this SOP. To support staff if concerns and issues are identified. To ensure that relevant training is completed and documented.

6.3. All Research Team Members

To ensure that they have successfully undertaken relevant training. To ensure they are conversant with this SOP and its use. To ensure that equipment relevant to this SOP are maintained and in good working order. To ensure that risk assessments and mandatory documentation related to this SOP are completed. To ensure that each

member of the team ensures that they take responsibility for their own and other team members safety.

7. PROCEDURE

Preparation for Visit

7.1 Pre-visit risk assessment is undertaken

7.1.1. Risk assessment of the family is undertaken via contact with GP practice

Having completed the survey and identified their willingness to participate in the trial, a letter shall be sent to the practice manager of the child's GP. This letter will contain details of the RHiNO trial and request information related to the appropriateness of lone visits being undertaken (Appendix I). It is anticipated that this form is faxed back to the research team where it will form part of the pre-visit risk assessment. In the event that the practice manager does not complete the form a member of the RHiNO team shall telephone the practice manager and request this information verbally. He/she should be asked to repeat the information to a second member of the research team. This information will be documented and signed by both research team members. In the event that the practice manager does not agree to give information verbally, or the child does not have a GP, the case will be discussed with the CI who will make a decision on the most appropriate way forward.

7.1.2. Undertaking telephone risk assessment

Telephone the participant's family and use your clinical judgement to sense whether there may be issues related to risk in terms of the lone worker or capacity. Any concerns must be raised and discussed with the Senior Research Nurse/Medical Fellow who will in turn discuss with the CI.

During this telephone call the home visit telephone call visit pro-forma (Appendix II) will need to be completed in full. It will identify additional risk factors such as pets in the home which will need to be placed into a separate room for the visit and outline

available parking near the home. The name of the visiting team member will be shared with the family. They will also be informed that the staff member will be carrying identification which can be checked on arrival.

7.2. Pre-visit organisation

Visits will be arranged by the responsible team member. An appropriate risk assessment will have been undertaken prior to the visit.

A two person buddy system rota will be developed and maintained by the senior research nurse/clinical fellow. This will involve each member of the research team. This system will ensure the safety of the visiting team member when undertaking the visit. In the first instance the visiting team member will contact their first allocated buddy. A second buddy is in place in case of problems contacting the first buddy. Team members' details (home address, home and personal mobile telephone number and car details – make and license plate number) will be kept within the RHiNO office in line with the Data Protection Act (1998). This information will be accessed if concerns about the team member arise during a home visit.

A home visit itinerary will be completed (Appendix III) by the visiting team member. This form will detail the visiting team member's name and contact details (RHiNO mobile telephone number), the participant's name, contact details and address, anticipated times of arrival at participant's house, duration of visit and time of return to CRF or home address. The original form will be left within the RHiNO office visit diary. Three further copies of this form will be made for reference by the visiting team member and the two allocated buddies. These additional forms will be shredded once the visit has been completed and the original form fully completed. This original form will be placed with the participant's CRF.

The RHiNO mobile phone allocated to the visiting team member must be fully charged and in good working order. All RHiNO staff member's mobile, work and home numbers will be pre-programmed onto the mobile phone. They will also ensure that the mobile phone has the participant's contact details inputted. This will be

checked by the visiting team member prior to the visit. Information related to the participant will be removed once the visit has been completed.

7.3. The visit day

The home visit checklist will be completed prior to departure (Appendix IV).

In addition to a fully charged RHiNO trail mobile phone staff members must ensure that they are carrying the Skyguard personal safety device. This GPS device enables the user to call for emergency assistance in the event of an incident whilst undertaking a home visit. It has a two way audio ability allowing a controller to listen to the events and talk to the user when safe to do so.

The visiting team member will telephone the participant and their family on the day of the visit detailing the anticipated time of arrival. Any delays will be conveyed to the family and the first buddy as soon as practically possible.

The visiting team member will telephone their designated first buddy on arrival to the house. Direct contact with the buddy is mandatory. Texting and leaving messages on an answerphone are unacceptable.

In the case of no mobile reception, the participant will ask to utilise the landline within the property. The visiting team member will call the first buddy and inform of no mobile reception and give the landline details. The buddy will then convey this information to the research office.

During the visit the buddy will contact the visiting team member 20 minutes into the call and ask "Are you OK. Do you need to leave?" If the visiting team member feels they need to leave, the buddy will ask for their presence back at the hospital/office, providing the nurse with the opportunity to leave.

On leaving, the visiting team member will telephone their allocated first buddy and inform them of the estimated time that they will arrive at the research office. Upon

reaching the research office the participant will again contact their allocated first buddy to indicate that they are safe.

All telephone calls will be documented on the home visit itinerary form (Appendix III).

Any issues and subsequent actions during the visit will be documented in the individual participant visit file.

7.4. Concerns about participant behaviour

Safety of the staff member is paramount. Staff who are concerned about participant behaviour must curtail the visit as soon as possible. Staff should leave equipment if its' collection is deemed to place the staff member at risk. Collection can be arranged for another time. Once safe, the staff member's buddy must be informed, a clinical incident report must be completed on the online Datex form and a report sent to the CI.

Concerns about child protection must be assessed at the time. Unless threats to the child's safety are imminent the staff member must end the visit and leave the premises to gain further help. They will be contact with their buddy when in a safe environment in the first instance to discuss and decide upon the most appropriate action in line with the All Wales Child Protection Procedures.

Where the threat to the staff member or child participating in the trial is imminent, an emergency call shall be initiated through use of the Skyguard system through which attendance of the emergency services shall be requested.

Any issues and subsequent actions during the visit will be documented in the individual participant visit file.

7.5. Concerns about staff member undertaking visit

Staff should maintain contact with their allocated buddy as detailed above. If this does not happen then the buddy will contact them to assess their safety and well-

being. If fifteen minutes have passed since the visit was expected to finish and there has been no response from the individual, the buddy will call them on the trial mobile phone. They will try to use this contact on three occasions. Following this, if there is no response the buddy will try the team member's personal mobile on three occasions. If there is no answer, the visiting team member's home contact number will be tried. In the case when no contact is gained the Senior Nurse/Clinical Fellow on the RHiNO trial must be informed. Following this, the Senior Manager on Duty within the Trust must be contacted via the UHW switch board and informed of the situation. They will inform the UHB security team or police.

General Security Issues

All staff will have completed the UHB violence and aggression training modules A, B and C prior to undertaking any lone visits.

All research team members will ensure that their vehicle is in good working order and is fully insured.

Uniforms will not be worn during home visits to reduce potential risk.

All equipment must be locked away in the boot of the car and kept out of sight.

If you are involved with an accident or breakdown notify your buddy and the participant (if you have not visited them yet).

8. REFERENCES

- I. European Commission Directive 2001/20/EC
- II. European Commission Directive 2005/28/EC
- III. ICH Harmonised Tripartite Guidelines for Good Clinical Practice (1996)
- IV. Cardiff and Vale University Health Board Lone Worker Policy (2014)
- V. The Data Protection Act (1998)
- VI. All Wales NHS Violence and Aggression Training Passport and information Scheme

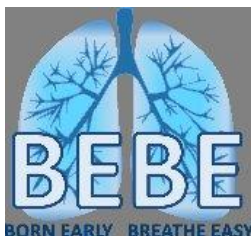
VII. All Wales Child Protection Procedures (2008)

9. DOCUMENT HISTORY

Version number and date	Summary of revisions

10. Appendices

Appendix I	Letter to practice manager of Child's GP
Appendix II	Visit Telephone Call Visit Pro-forma
Appendix III	Home Visit Itinerary
Appendix IV	Home Visit Checklist



RHiNO Trial

Dear Practice Manger,

A patient under the care of your practice by the name of _____ who's DOB is _____ has agreed to participate in the RHiNO trial. This trial aims to examine lung function in children aged 7 – 12 years old living in Wales who were born prematurely. As part of the study they have given consent to allow access to medical records and contact with their GP.

The initial stage of the RHiNO trial involves a home visit from a member of the research team where lung function testing alongside other tests will be conducted. This home visit requires a nurse travelling from Cardiff. We have no current medical or social history for your patient that will allow us to determine the risk of sending a lone nurse to undertake this home visit.

We have generated the attached form which will form part of the assessment of risk prior to the visit. This will also be accompanied by the RHiNO team telephoning the participant's family. It would be of great help to us if you, or a member of your team could complete the form and fax it back to the RHiNO team as soon as possible.

Further information about the study if can be found at www.rhino-health.org. Alternatively you can contact a member of the RHiNO team on 029 2074 4562.

Thank you for your assistance in this matter.



RHiNO Trial

Dear Practice Manager,

A patient under the care of your practice by the name of _____ with the NHS number _____ has agreed to a home visit as part of the RHiNO trial. They have given consent for us to contact you.

Are you aware of any reason that would make it inappropriate for a solo nurse to attend the participant in their own home?

I know of no reason

2 nurses should attend this participant

Not suitable for home visit

I do not wish to answer

Please provide any other comments/additional relevant information on relation to this patient below:

Signed

Date

Please complete and fax to Kylie Hart, Senior Nurse, RHiNO trial. **Fax Number 02920 XXXXXXXX**. If you would like further information please contact the RHiNO team on 029 2074 4562.



Home Visit Telephone Call Pro-forma

Staff Member:

Planned Date and Time of Home Visit:

Participants Name:

Screening Number:

Participants Parents' Names:

Participant Contact Details: Landline :

Mobile:

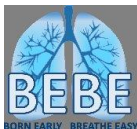
Participants Address:

In terms of the home, what type of home is it and where is it situated?
(Consider situation, need to walk long distances, stairs/lifts etc.)

What type of parking is available?
(Consider escape, distance from home address, lighting, security, need to pay for ticket)

Do you have any pets?
(Please advise dogs etc. be in another room during the visit)

Who will be at the house during the visit?



Home Visit Checklist

Visit Date:
Participant Name:

Staff Member:
Participant Number:

	Yes	No
Have the pre-visit risk assessments been completed; Practice manager/GP assessment form completed? Home visit telephone call pro-forma completed?		
Have any problems been identified? If Yes – what plans are in place to reduce risk?		
Have you completed the home visit itinerary and left it in the RHINO office diary?		
Do you have a copy of the home telephone pro-forma and itinerary?		
Do you have the details of the first and second buddy?		
Do you have the CRF?		
Do you know where you are going?		
Have you contacted the family to inform them of your ETA?		
Do you have a fully charged mobile phone and charger? <small>Working, Fully Charged, Credit on phone, Charger and lead</small>		
Do you have a MicroGuard Personal Safety Device?		
Do you have all the relevant equipment for the home visit? <small>See Equipment Checklist</small>		
Do you have change for a payphone in case of no mobile phone reception?		