

**DAY 28 POST RANDOMISATION FOLLOW-UP**

**CONFIDENTIAL**

<b>Study number</b>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>	<input type="text"/>
<b>Infant initials</b>	<input type="text"/>	<input type="text"/>	<input type="text"/>		

<b>Name of nurse completing this questionnaire</b>	<input style="width: 100%;" type="text"/> <i>please print name</i>						
<b>Signed</b>	<input style="width: 100%;" type="text"/>						
<b>Date</b>	<table border="1" style="width: 100%; text-align: center;"> <tr> <td style="width: 16.6%;">D</td> <td style="width: 16.6%;">D</td> <td style="width: 16.6%;">M</td> <td style="width: 16.6%;">M</td> <td style="width: 16.6%;">Y</td> <td style="width: 16.6%;">Y</td> </tr> </table>	D	D	M	M	Y	Y
D	D	M	M	Y	Y		

**Notes for completing this form**

*Explanatory text and instructions for completion of the questions are in italics in a separate box before each set of questions. All questions in the grey boxes should be completed. Unless stated otherwise, please complete all questions on the form. In certain circumstances some questions may not be applicable and where this is the case there are instructions on exactly what information may be missed.*

*Please complete the information in the required format (as specified in the form). For questions with a Yes/No answer, please mark the relevant Yes/No box with a 'X' (i.e. if the answer to a question is 'yes', the yes box should be crossed and the no box should be left blank).*

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**SpO<sub>2</sub> Measurement**

Before asking the follow-up questions, please explain to the parent that the child's oxygen saturation will be measured. Please explain that the measurement is being taken for the study only, and should not cause any concern over child's health etc. If you are worried by the oxygen saturation measurement please refer to the BIDS PI, or advise the parent/carer to attend GP/hospital (as appropriate).

SpO<sub>2</sub>  %

Time  hh:mm

**1. Resolution of cough**

Before asking the questions below please refer back to the answers given to section 1 at the day 14 follow-up call. If the cough had stopped and parent/carer felt that the child was back to normal by day 14 please do not ask these questions and score through this section. If the cough was still present and the parent/carer did not feel that the child was back to normal please ask both questions. The resolution of cough guidance sheet should be used to help the parent/carer answer the questions and provide accurate dates. If cough has not resolved yet, please mark as no, remind parents that you will be asking about this again at the 6 month follow-up call and suggest they record date cough stopped in advance of next follow-up.

Has your child stopped coughing?  Y  N

Date cough stopped  D  D  M  M  Y  Y

Do you feel that your child is 'back to normal'?  Y  N

Date back to normal  D  D  M  M  Y  Y

**Please remember to record any adverse events (AEs) and serious adverse events (SAEs) when asking how the child has been feeling since discharge. AEs should be recorded on the BIDS AE log. Any AEs that meet the criteria for 'serious' should be recorded on the BIDS SAE form and faxed to ECTU (refer to protocol section 11 for guidance)**

**2. Healthcare utilisation**

Please ask if the child has seen a doctor since the last follow-up. All visits to see a doctor should be recorded, even those visits that were for symptoms not related to this episode of bronchiolitis.

Have you taken your child to see a doctor since the last follow-up?  Y  N

If yes, please complete the details below

How many visits to GP

How many visits to hospital (OPD)

How many visits to see A&E

If admitted to hospital, how many nights? (admission means overnight stay)

**If child admitted, please complete a BIDS SAE form and fax to ECTU on 0131 537 3851**

If the child was taken to the doctor, please ask the parent to give an estimate of the total travel expenses incurred. If the parent is unsure, please encourage them to guess by prompting on the mode of travel and average cost of journey (for example, if they travelled by bus ask them how much a bus fare is etc)

Estimate of costs (total costs if multiple visits) £

Study number

Infant initials

### 3. Time off work and missed activities

Please refer back to question 7 in the admission questionnaire (occupational status of parents/lead carers) before asking the following questions. The questions below should be asked for each parent/carer, if one parent/carer is absent (identified from the admission questionnaire) please score through relevant table and mark as NK.

#### Mother/lead carer

From the admission questionnaire, is the Mother/lead carer employed?  Y  N

If yes, please ask questions 1 AND 2. If no, please ask only question 2 and score through question 1.

1. Have you had to take any time off work since the last follow-up call to look after your child?  Y  N

If yes, how many hours have they taken off work?  hours

2. Have you had to miss any of your normal activities since the last follow-up to look after your child? (normal activities include shopping, meeting friends, exercising)  Y  N

If yes, how many hours have they missed?  hours

#### Father/second carer

From the admission questionnaire, is the Father/second carer employed?  Y  N

If yes, please ask questions 1 AND 2. If no, please ask only question 2 and score through question 1.

1. Has your husband/wife/partner (or other) had to take any time off work since the last follow-up call to look after your child?  Y  N

If yes, how many hours have they taken off work?  hours

2. Has your husband/wife/partner (other) had to miss any of their normal activities since the last follow-up to look after your child? (normal activities include shopping, meeting friends, exercising)  Y  N

If yes, how many hours have they missed?  hours

### 4. Childcare

Please refer back to question 9 in the admission questionnaire (childcare) before asking the following questions. The following questions should only be asked if the child normally attends paid or unpaid childcare.

From the admission questionnaire, does the child regularly attend paid or unpaid childcare?  Y  N

If yes, please ask the following. If NO, please score through the following questions

Has the child been well enough since the last follow-up call to attend normal childcare?  Y  N

If no, how many hours the child has missed?  hours

Study number

Infant initials

### 5. Medications

Please ask the parent/carer if they have had to get any extra medications for the child since the last follow-up. Extra medications mean any additional medications that were bought (over the counter) or prescribed. It does not include medications taken from a supply that the parents already have. Please complete all dates where possible. Where part of the date is not known, please mark as NK and complete the rest of the date field.

Have you had to get any extra medications for your child since the last follow-up?

 Y

 N

If yes, please complete details below

Medication name	Indication	Prescription		Over-the counter medication		Start date		Continuing?		End date (if not continuing)								
		Y	N	Y	N	D	D	M	M	Y	Y	D	D	M	M	Y	Y	
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**6. Anxiety questions**

The following section is a series of standard questions to measure anxiety levels of the person answering the questions. Before asking these questions please explain to the parent/carer the type of questions that will be asked and the reasons that they are being asked. The following points should be used as a guide for the information given to the parent/carer.

Please make the parent/carer aware of the following:

- These questions are being asked as part of the study only. These questions are not being asked because of their child's illness or treatment, their behaviour or actions
- All answers given will be kept confidential but will be collated and anonymised as part of the study analysis
- There is no 'correct answer', parents/carers should answer honestly and be reassured that the answers will not be recorded in the medical notes, or be made available to their doctor
- The purpose of these questions is to measure if parents (in a general way) are anxious when their child is admitted with bronchiolitis, and to see if/how this anxiety changes over time (up to the 6 months)
- When answering the questions the parent/carer should give their immediate response and should be based on how they feel at that particular moment, rather than spending a long time thinking about their answer

If you are concerned or worried by the responses to the following questions please make the ward nurses and/or the BIDS PI aware of this. Please record this in the BIDS ISF by completing a file note describing the actions taken and any follow-up required.

**I feel tense or 'wound up'**1. Most of the time 2. A lot of the time 3. From time to time, occasionally 4. Not at all **I get a sort of frightened feeling as if something awful is about to happen**1. Very definitely and quite badly 2. Yes, but not too badly 3. A little, but it doesn't worry me 4. Not at all **I can sit at ease and feel relaxed**1. Definitely 2. Usually 3. Not often 4. Not at all **Worrying thoughts go through my mind**1. A great deal of the time 2. A lot of the time 3. Not too often 4. Very little *continued on the next page*

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**I get a sort of frightened feeling like 'butterflies' in the stomach**

1. Not at all

2. Occasionally

3. Quite often

4. Very often

**I feel restless as if I have to be on the move**

1. Very much indeed

2. Quite a lot

3. Not very much

4. Not at all

**I get sudden feelings of panic**

1. Very often indeed

2. Quite often

3. Not very often

4. Not at all

**Please remind parents that you will be calling them for the last time in 5 months for the 6 month follow-up call (please use actual scheduled date when discussing with the parent/carer). Please confirm the best number to call them on and try and agree a suitable time for the call.**

**Please photocopy the completed form and send the copy back to:**

**Fiona Sloan  
BIDS Trial Manager  
Edinburgh Clinical Trials Unit (ECTU)  
OPD 2, 2<sup>nd</sup> Floor  
Western General Hospital  
Crewe Road South  
Edinburgh  
EH4 2XU**

**Tel: 0131 537 2516**

**The original questionnaire should be retained in the BIDS participant file**

**To be completed by ECTU only**

Data entered by (initials)

Date