





**MONITORING CHECKLIST**

Principal Investigator: \_\_\_\_\_ Centre no: \_\_\_\_\_

Instructions for monitor:  
Please complete at each visit and fax one copy to the BADBIR Office and store one copy in Site file

**GENERAL MONITORING Checks**

1. Have all consent forms been checked to ensure that consent has been correctly provided by patients/investigator for the trial?  
Yes  No  Outstanding  (If no or outstanding, please document in report)

2. Have all SAEs and CV outcomes that occurred since the last visit been documented and sent off to the BADBIR Office?  
Yes  No  Outstanding  (If no or outstanding, please document in report)

3. Are all essential documents correctly filed in the Site Investigator File (SIF)?  
Yes  No  (If yes, please answer Q3a and 3b, If no, document in report)

a) Have any new amendments occurred since last visit? Yes  No   
b) Have amended documents been filed in site file and old documents superseded? Yes  No  N/A

4. Has the patient log been updated since the last visit and does this correspond with the information provided by the BADBIR office monthly report?  
Yes  No  Outstanding  (If no or outstanding, please document in report)

5. Has the delegation log been updated and does it correspond with the CVs in the SIF?  
Yes  No  Outstanding  (If no or outstanding, please document in report)

<b>Signature of Monitor:</b> _____	<b>Date of Visit:</b> <table border="1" style="display: inline-table; border-collapse: collapse; text-align: center; width: 100px;"> <tr> <td style="width: 15px; height: 15px;">D</td> <td style="width: 15px; height: 15px;">D</td> <td style="width: 15px; height: 15px;">M</td> <td style="width: 15px; height: 15px;">M</td> <td style="width: 15px; height: 15px;">Y</td> <td style="width: 15px; height: 15px;">Y</td> <td style="width: 15px; height: 15px;">Y</td> <td style="width: 15px; height: 15px;">Y</td> </tr> </table>	D	D	M	M	Y	Y	Y	Y
D	D	M	M	Y	Y	Y	Y		



**MONITORING REPORT PROFORMA**

Principal Investigator: \_\_\_\_\_ Centre no: \_\_\_\_\_

Please provide a brief outline of your monitoring plan for this visit:  
Study initiation

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Please provide comments you may have regarding outstanding information or data?

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(Please continue on another sheet if required)

<b>Signature of Monitor:</b> _____	<b>Date of Visit:</b>							
	D	D	M	M	Y	Y	Y	Y



**MONITORING REPORT PROFORMA**

Principal Investigator: \_\_\_\_\_ Centre no: \_\_\_\_\_

Please state any recommendations that you have suggested to the centre at this visit:

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Have all previous queries from previous visit been resolved?

Yes  No  If no, please provide comments

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Fax one copy to BADBIR Office (0161 603 7731) and store one copy in Investigator Site file.

Signature of Monitor: \_\_\_\_\_ Date of Visit: 

D	D	M	M	Y	Y	Y	Y
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