## MONITORING LOG

Principal Investigator: ___________________________  Centre no: ___________

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<th>Date of visit</th>
<th>Name of Monitor</th>
<th>Signature of Site Personnel</th>
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British Association of Dermatologists’ Biologic Intervention Register

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   b) Have amended documents been filed in site file and old documents superseded?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)

Signature of Monitor: ___________________________  Date of Visit: ___________
British Association of Dermatologists’ Biologic Intervention Register

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 continue on another sheet if required)

Signature of Monitor: ___________________________    Date of Visit: ___________
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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Instructions for monitor:
Please complete at each visit.
Fax one copy to BADBIR Office (0161 603 7731) and store one copy in Investigator Site file.

Signature of Monitor: ___________________________    Date of Visit: ______ D ______ M ______ Y ______