15 January 2008

Dear Professor Griffiths

Study title: British Association of Dermatologists Biological Interventions Register
REC reference: 07/MRE08/9
Amendment number: Amendment 2
Amendment date: 30 November 2007

The above amendment was reviewed at the meeting of the Sub-Committee of the North West REC held on 08 January 2008.

Ethical opinion

The amendment (2) requested approval for a number of changes to the original approved application, protocol and study documentation, as follows:

1. Minor amendments to information provided on the original REC Application Form including details of the sponsor contact and a change to the project website address.

2. Changes to the protocol (Version 11, dated 30/11/07) including the correction of typographical errors and omissions; the addition of waist circumference measurement; the deletion of "Abnormal LFTs" and "raised creatinine" from the co-morbidity data; and the removal of appendix 5 relating to coding for psoriasis, which was considered confusing as it did not concur with section 7.3 of the protocol.

3. Revisions to supporting study documentation including the Patient Information Sheet (Version 3, dated 30/11/07), the Patient Consent Form (Version 3, dated 30/11/07), the Baseline Clinical Questionnaire (Version 6, dated 30/11/07), and the Baseline Patient Questionnaire (Version 5, dated 30/11/07).

It was noted that full details of, and justification for, each of the proposed changes had been provided, and that revised documentation had been submitted.

The Sub-Committee had no ethical difficulties with the proposed amendment.

This Research Ethics Committee is an advisory committee to North West Strategic Health Authority.

The National Research Ethics Service (NRES) represents the NRES Directorate within the National Patient Safety Agency and Research Ethics Committees in England.
The members of the Committee present gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

Approved documents

The documents reviewed and approved at the meeting were:

<table>
<thead>
<tr>
<th>Document</th>
<th>Version</th>
<th>Date</th>
</tr>
</thead>
<tbody>
<tr>
<td>Covering Letter - from Kathy McElhone, BSRBR Study Co-ordinator</td>
<td></td>
<td>19 December 2007</td>
</tr>
<tr>
<td>Notice of Substantial Amendment (non-CTIMPs)</td>
<td>Amendment 2</td>
<td>30 November 2007</td>
</tr>
<tr>
<td>Protocol</td>
<td>11</td>
<td>30 November 2007</td>
</tr>
<tr>
<td>Questionnaire: Baseline Patient Questionnaire</td>
<td>5</td>
<td>30 November 2007</td>
</tr>
<tr>
<td>Questionnaire: Baseline Clinical Questionnaire</td>
<td>6</td>
<td>30 November 2007</td>
</tr>
<tr>
<td>Participant Information Sheet</td>
<td>3</td>
<td>30 November 2007</td>
</tr>
<tr>
<td>Participant Consent Form</td>
<td>3</td>
<td>30 November 2007</td>
</tr>
</tbody>
</table>

Membership of the Committee

The members of the Committee who were present at the meeting are listed on the attached sheet.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

Statement of compliance

The Committee is constituted in accordance with the Governance Arrangements for Research Ethics Committees (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

07/MRE08/9: Please quote this number on all correspondence

Yours sincerely

Cathie Stokes
Committee Co-ordinator

E-mail: cathie.stokes@northwest.nhs.uk
Enclosure: - List of names and professions of members who were present at the meeting and those who submitted written comments

Copy to: - Dr K Shaw
Head of the University Research Office
The University of Manchester
Oxford Road
MANCHESTER
M13 9PL
North West Research Ethics Committee

Attendance at Sub-Committee of the North West REC meeting on 8 January 2008

<table>
<thead>
<tr>
<th>Name</th>
<th>Profession</th>
<th>Capacity</th>
</tr>
</thead>
<tbody>
<tr>
<td>Dr Donal Manning – Chair</td>
<td>Consultant Paediatrician</td>
<td>Expert</td>
</tr>
<tr>
<td>Mrs Margaret Norval</td>
<td>Chief Pharmacist</td>
<td>Expert</td>
</tr>
</tbody>
</table>

Also in attendance:

<table>
<thead>
<tr>
<th>Name</th>
<th>Position (or reason for attending)</th>
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<tbody>
<tr>
<td>Cathie Stokes</td>
<td>Committee Co-ordinator</td>
</tr>
</tbody>
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