Author's response to reviews

Title: Randomized, controlled, parallel-group prospective study to investigate the clinical effectiveness of early insulin treatment in patients with latent autoimmune diabetes in adults.

Authors:

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Version: 5 Date: 18 June 2008

Author's response to reviews: see over
17 June 2008

Dr Sinead Brophy
Lecturer in Epidemiology and Public Health
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Dear Dr Brophy

**Study title:** Randomized, controlled, parallel-group study to investigate the clinical effectiveness of early insulin treatment in patients with latent autoimmune diabetes in adults [LADA]

**REC reference:** 07/MRE09/8
**Amendment number:** Amendment 2
**Amendment date:** 01 May 2008

The above amendment was reviewed at the meeting of the Sub-Committee of the REC held on 06 June 2008.

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:

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<thead>
<tr>
<th>Document</th>
<th>Version</th>
<th>Date</th>
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<tbody>
<tr>
<td>Notice of Substantial Amendment (non-CTIMPs)</td>
<td>Amendment 2</td>
<td>01 May 2008</td>
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</table>

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

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/MRE09/8: Please quote this number on all correspondence

Yours sincerely

Dr. Gordon Taylor
Chairman
E-mail: corinne.scott@bsc.wales.nhs.uk

Enclosures
List of names and professions of members who were present at the meeting and those who submitted written comments

Copy to: ms Jemma Hughes, Swansea NHS Trust

REC for Wales

Attendance at Sub-Committee of the REC meeting on 06 June 2008

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<thead>
<tr>
<th>Name</th>
<th>Profession</th>
<th>Capacity</th>
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<tbody>
<tr>
<td>Dr Maurice Buchalter</td>
<td>Alternate Vice Chairman / Hospital Consultant (Cardiologist)</td>
<td>Expert</td>
</tr>
<tr>
<td>Dr Gordon Taylor</td>
<td>Chairman / Statistician</td>
<td>Expert</td>
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