



**Health Research Authority**  
**National Research Ethics Service**

**NRES Committee North West - Haydock**

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28 December 2012

**Professor Christopher EM Griffiths**  
**Professor of Dermatology**  
**The University of Manchester**  
**Dermatopharmacology Unit**  
**Irving Building**  
**Salford Royal Teaching Hospital**  
**M6 8HD**

Dear Professor Griffiths,

**Study title:** **British Association of Dermatologists Biological Interventions Register**  
**REC reference:** **07/MRE08/9**  
**Amendment number:** **Amendment seven 05/21/2012**  
**Amendment date:** **14 December 2012**

The above amendment was reviewed by the Sub-Committee in correspondence.

**Ethical opinion**

The amendment (Amendment 10, 14 Dec 12) sought approval to extend the period of study recruitment and/or follow-up, so that a) the primary endpoints can be evaluated, and b) there is an increased likelihood of identifying adverse events which may have greater latency. This extension would affect the yearly costs of the study. The end date of July 2018 would remain the same.

Approval was also requested for a patient poster that has been developed for outpatient waiting rooms so that interested patients would have the opportunity to ask the BADBIR research team for further information.

The amendment also includes the following revisions:

- The discontinuation of data collection at various follow ups for the purpose of refining data collection to improve patient retention, as completion of the questionnaires is one of the main reasons for withdrawal of consent.
- Certain procedures that have been developed to deal with patient participation in clinical trials transfer to other hospitals, missed follow ups, and withdrawals.
- Some minor textual changes made to the Protocol for the purpose of clarification.
- To reduce patient fees (from year 4 to the end of follow up) from £30 to £15 per follow up visit.

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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:

Document	Version	Date
Covering Letter: from Kathy McElhone		17 December 2012
Notice of Substantial Amendment (non-CTIMPs): Amendment seven 05/21/2012		14 December 2012
Protocol	14	12 December 2012
Advertisement: Patient Poster	1	16 July 2012

### Membership of the Committee

The members of the Committee who took part in the review 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 and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

<b>07/MRE08/9:</b>	<b>Please quote this number on all correspondence</b>
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Yours sincerely



On behalf of  
**Professor Ravi S Gulati**  
**Chair**

**E-mail:** nrescommittee.northwest-haydock@nhs.net

**Enclosures:** List of names and professions of members who took part in the review

**Copy to:** Dr Karen Shaw  
Head of the University Research Office  
Oxford Road  
M13 9PL

## NRES Committee North West - Haydock

### Attendance at Sub-Committee of the REC meeting on 27 December 2012

Name	Profession	Capacity
Professor Ravi S Gulati	Consultant Physician	Expert
Dr Tim S Sprosen	Epidemiologist	Expert