



Central Office for Research Ethics Committees (COREC)

NOTICE OF SUBSTANTIAL AMENDMENT

For use in the case of all research other than clinical trials of investigational medicinal products (CTIMPs). For substantial amendments to CTIMPs, please use the EU-approved notice of amendment form (Annex 2 to ENTR/CT1) at <http://eudract.emea.eu.int/document.html#guidance>.

To be completed in typescript by the Chief Investigator in language comprehensible to a lay person and submitted to the Research Ethics Committee that gave a favourable opinion of the research ("the main REC"). In the case of multi-site studies, there is no need to send copies to other RECs unless specifically required by the main REC.

Further guidance is available at <http://www.corec.org.uk/applicants/apply/amendments.htm>.

Details of Chief Investigator:

Name:	Professor Christopher EM Griffiths
Address:	Dermatology Centre Hope Hospital Stott Lane Salford
Telephone:	0161 206 4392
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Fax:	0161 206 1095

Full title of study:	British Association of Dermatologists Biological Interventions Register
Name of main REC:	North West England
REC reference number:	07/MRE08/9
Date study commenced:	Recruitment has not commenced
Protocol reference (if applicable), current version and date:	BADBIR Study Protocol – Version 10 (05/12/2006)
Amendment number and date:	Amendment One 04/04/07

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Type of amendment (indicate all that apply in bold)

(a) Amendment to information previously given on the REC application form

Yes

If yes, please refer to relevant sections of the REC application in the “summary of changes” below.

(b) Amendment to the protocol

No

If yes, please submit either the revised protocol with a new version number and date, highlighting changes in bold, or a document listing the changes and giving both the previous and revised text.

(c) Amendment to the information sheet(s) and consent form(s) for participants, or to any other supporting documentation for the study

No

If yes, please submit all revised documents with new version numbers and dates, highlighting new text in bold.

Is this a modified version of an amendment previously notified to the REC and given an unfavourable opinion?

No

Summary of changes

Briefly summarise the main changes proposed in this amendment using language comprehensible to a lay person. Explain the purpose of the changes and their significance for the study. In the case of a modified amendment, highlight the modifications that have been made.

If the amendment significantly alters the research design or methodology, or could otherwise affect the scientific value of the study, supporting scientific information should be given (or enclosed separately). Indicate whether or not additional scientific critique has been obtained.

This amendment relates to Part B: Section 1.

In order to achieve the anticipated recruitment of patients to this study the following additional research sites are proposed.

Name of the research site: Wroughtington, Wigan and Leigh NHS Trust (Leigh)

Principal Investigator for the study at this site:

Title: Dr **Forename:** Denise **Surname:** Ramlogan

Post: Consultant Dermatologist:

Address: Department of Dermatology

Leigh Infirmary

The Avenue

Leigh

Lancashire

Postcode: WN7 1HS

Name of the research site: East Cheshire NHS Trust

Principal Investigator for the study at this site:

Title: Dr **Forename:** Tamara **Surname:** Griffiths

Post: Consultant Dermatologist:

Address: Department of Dermatology

Macclesfield District General Hospital

Victoria Road

Macclesfield

Cheshire

SK10 3BL

Name of the research site: The Newcastle upon Tyne NHS Hospitals Trust

Principal Investigator for the study at this site:

Title: Professor **Forename:** Nicholas J **Surname:** Reynolds

Address: Department of Dermatology

Royal Victoria Infirmary

Queen Victoria Road

Newcastle Upon Tyne

Tyne and Wear

NE1 4LP

Name of the research site: Guys and St Thomas's NHS Foundation Trust

Principal Investigator for the study at this site:

Title: Professor **Forename:** Jonathan **Surname:** Barker

Address: St John's Institute of Dermatology

St Thomas's Hospital

Lambeth Palace Road

London SE1 7EH

Name of the research site: Salford Royal NHS Foundation Trust

Principal Investigator for the study at this site:

Title: Professor **Forename:** Christopher EM **Surname:** Griffiths

Address: Department of Dermatology

Hope Hospital

Stott Lane

Salford

M6 8HD

Name of the research site: Grampian NHS
Principal Investigator for the study at this site:

Title: Dr **Forename:** Anthony **Surname:** Ormerod
Address: Department of Dermatology
 Aberdeen Royal Infirmary
 Foresterhill
 Aberdeen
 Scotland
 AB25 2ZN

Any other relevant information

Applicants may indicate any specific ethical issues relating to the amendment, on which the opinion of the REC is sought.

List of enclosed documents

<i>Document</i>	<i>Version</i>	<i>Date</i>

Declaration

- I confirm that the information in this form is accurate to the best of my knowledge and I take full responsibility for it.
- I consider that it would be reasonable for the proposed amendment to be implemented.

Signature of Chief Investigator:

Print name:

Date of submission: