



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:

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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:	16/08/07
Protocol reference (if applicable), current version and date:	BADBIR Study Protocol – Version 10 (05/12/2006)

Amendment number and date:

Amendment Two 30/11/07

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

Yes

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

Yes

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.

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

i) Amendment to Section A59 of the application form

Sponsor Contact should be Dr Karen Shaw, Head of the University Research Office, The University of Manchester, Oxford Road Manchester, M13 9PL

Email: research-governance@manchester.ac.uk

ii) Amendment to Section A65 of the application form

The project website address is changed to www.badbir.org.uk

b) The investigators propose amending BADBIR Protocol Version 10 dated December 5th 2006 in the following manner:

1) Correct typographical errors/omissions

a) Typographical errors

i) Protocol Section 4 (page 8)

After discussion with sponsors, industry, health administration and opinion leaders we feel over 5 years collecting 4000 patients in the psoriasis and control cohorts is likely to be achievable.

Should read

After discussion with sponsors, industry, health administration and opinion leaders we feel over 5 years collecting 4000 patients in each of the biological intervention arms and in the control cohort is likely to be achievable.

ii) Protocol Section 7.8 (page 12)

Co-morbidity yes/no

Should read

Co-morbidity including

iii) Protocol Section 7.10 (page 13)

Transaminase AAT

Should read

Transaminase ALT

iv) Protocol page 23 - Appendix 4

While the total PASI score may range from 0 - 72, most cases fall in the range of 0 – 25

Should read

While the total PASI score may range from 0 - 72, most cases fall in the range of 0 – 25

b) Correct four omissions/errors

i) Fumaric acid esters have been added to Section 3.2.2 (page 7) of the protocol as a conventional therapy. This drug was already included as conventional therapy in the MREC application form

ii) Section 6.6 Prior therapy (page 12) add “biologicals group only” in brackets after adalimumab

iii) Section 9.3 (page 15) Analytic approach “e.g. malignancy” has been added to line 7

iv) The EuroQol questionnaire included in the protocol as Appendix 3 (page 22 and 23) has an item missing from the text. A corrected version has now been included with this item highlighted in yellow.

2) The investigators wish to measure and record waist circumference (WC) in addition to height and weight as current research suggests that while the waist-to-hip ratio is the preferred clinical measure of obesity for predicting all cause and CVD mortality, WC is a practical alternative.

References:

Gisondi, P. et al. “Prevalence of metabolic syndrome in patients with psoriasis: a hospital-based case-control study”. Br J Dermatol. 2007 July; 157(1):68-73

Welborn, T.A. and Dhaliwal S.S., “Preferred clinical measures of central obesity for predicting mortality” Eur J Clin Nutr 2007 Feb 14; [Epub] 61, 1373 -1379

3) Protocol Section 7.8 (page 12) “Abnormal LFTs” and “raised creatinine” have been deleted from this list

4) Remove Appendix 5 “Coding for psoriasis”

The Steering Committee members found it confusing as it did not concur with Section 7.3 (page 11) of the protocol. The consultant baseline questionnaire has been altered (page 2) to reflect psoriasis classification as recommended by Griffiths et al. (2007).

Reference

Griffiths, C.E.M., et al, “A classification of psoriasis vulgaris according to phenotype” Br J Dermatol 156 (2007) 258-262

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

- i) The Patient Information Sheet has been amended (Version 3, dated 30/11/07) to reflect the fact that the data will be captured via a web based system
- ii) A revised Patient Consent Form (Version 3, dated 30/11/07) to reflect the changed Patient Information Sheet
- iii) The format and wording of the Baseline Consultant and Patient Baseline questionnaires have been revised (highlighted in yellow) to reflect changes in the protocol and recommendations from clinicians.

Baseline Consultant Questionnaire

Title changed to “BAD Biologic Intervention Register Baseline Clinical Questionnaire”.

Item number	Reason for change
1	Reflect psoriasis classification as recommended by Griffiths et al. (2007) and protocol change
2	Feedback from clinicians
5	Feedback from clinicians
6	Feedback from clinicians
7	Feedback from clinicians
8	Reflect REC application form
9	Feedback from clinicians
10	Feedback from clinicians
11a	Feedback from clinicians
11c	Transferred to Patient Baseline Questionnaire
11d	Transferred to Patient Baseline Questionnaire
12	Feedback from clinicians
13	Feedback from clinicians
15	Reflect addition of waist circumference record and protocol change

Baseline Patient questionnaire

The question “Do you drink alcohol” has been clarified by the following statement: “If yes, how many units do you drink in an average week? For guidance please refer to the table below”

In addition an alcohol unit table has been included (page 2)

The following items have been transferred from the Baseline Consultant Questionnaire:

“Do you have an occupation or hobby which is mainly outdoors”? (page 2)

“Have you ever lived in tropical/subtropical countries”? (page 2)

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>
BADBIR Protocol	11	30/11/2007
Baseline Clinical Questionnaire	6	30/11/2007
Baseline Patient Questionnaire	5	30/11/2007
Patient Information Sheet	3	30/11/2007
Patient Consent form	3	30/11/2007

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: