National Patient Safety Agency

National Research Ethics Service

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.nres.npsa.nhs.uk/applicants/review/after/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 11 (30/11/2007)
Amendment number and date:	Amendment Three 13/05/08

Type of amendment (indicate all that apply in bold)

(a) Amendment to information previously given on the NRES 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

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.

Section A40 of the MREC application form
We would like to amend this section to more accurately reflect the description of the database

"All identifiable information is stored in a secure database. Patient identifiable information is stored in separate tables to that of clinical data. All data sent to us over the internet is encrypted during transmission. The encryption method used is the Secure Socket Layers

protocol thus converting the data into an unreadable format during transmission between the dermatology centres and the University of Manchester. Access to the database is password protected and limited to BADBIR staff and research team employees".

The protocol has been amended (amended text in bold font) for three reasons

1.To concur with the MREC application form

2.To include suggestions from the Steering Group

3.To provide clarification on sections related to a)audit and b)relationships with interested parties e.g. BAD and Pharmaceutical Companies

1.The following amendments have been made to correct omissions and inaccuracies in the protocol and align discrepancies between the MREC application and the protocol.

The following pages have been amended:

a)page 6

i)Section 3.2.1 Inclusion Criteria

" Aged 16 years or older" has been added

ii)Section 3.2.2 Inclusion Criteria

"Aged 16 years or older" has been added

b)page 10

i)Study flow sheet has been amended

ii)Section 7, Baseline data, 1st line "all possible" deleted and replaced by "potential"

c)page 13

i)Section 8.1 "Other" has been added to the list of options

2) The following changes have been suggested by the Steering Group

a)Page 6

i)Section 3.2.1 Inclusion Criteria

"Patients commencing treatment with a biological agent in the previous six months for their psoriasis"

ii)Dermatologists in the Republic of Ireland have expressed an interest in participating in BADBIR therefore "Republic of Ireland" has been added

iii)Section 3.2.2 Inclusion Criteria

"for therapy of their psoriasis" has been added

3) To provide clarification on sections related to a)audit and b)relationships with interested parties e.g. BAD and Pharmaceutical Companies

a) page 9

i) Section 5, Sub section d, Auditing the conduct of the study and research governance

"ongoing analyses will be conducted for any outliers between centres" has been deleted

ii) Sub section e "End point evaluation for serious adverse events (SAEs) will be validated by obtaining copies of medical records" amended to "Selected serious adverse events (SAEs) will be checked against a set of pre-defined validation criteria" and this is now sub-section d

b) The following sections have been completely revised to reflect current agreements between the BAD, the participating pharmaceutical companies, BADBIR and University of Manchester.

page 15

i)Section 9.3, Interim analysis

ii)Section 10, Roles of interested parties

page 16

i)Section 10, 1 Role of the Pharmaceutical companies section

ii)Section 10.2, Role of BAD-revised

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

Document	*Version*	*Date*
BADBIR	12	13/03/08

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: ……