

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 13 (14/05/2009)
Amendment number and date:	Amendment Five 24/02/11

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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

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

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) MREC application form

Section A26

The project was adopted onto the NIHR UK Clinical Research Network portfolio of studies in April 2010. Subsequently, at some centres, research nurses from the Clinical Research Network (fully trained in taking consent for participation in research) are available to recruit participants to the study. In order to fully maximise the use of this valuable resource, the principal investigators would like to make an addition to the statement in Section A26 as follows:

“Research nurses (fully trained in taking consent for participation in research) may also (in some cases) post a letter of invitation along with the information sheet and consent form to potentially suitable patients (identified by case notes review) followed up by discussion of the study over the telephone”.

If the potential participant is interested in being involved in the study, the consent form could be signed and returned by post or the consent could be taken by the appropriate person when the participant is next in clinic for a routine appointment dependant on which is more convenient for the patient.

A draft template of the Letter Inviting Participation has been attached for consideration by the Ethics Committee.

Section A28.

Current statement

At least 24 hours, as usually the decision to start biological treatment/conventional therapy will be a long and considered process

Problem

At the time of ethics application, it was not anticipated that management of biologic and conventional patients would vary significantly across regions. In some centres, commencement of these therapies is not a ‘long and considered process’ as described in the above statement. This may be for a variety of reasons such as prescribing practice or local service provision (rural areas where patients have to travel long distances to get to clinic). In such situations, the requirement for 24 hours to have elapsed between provision of study information to the potential participant and them signing the consent form is problematic. We have been informed that at some sites the patients wish to provide consent as soon as they have read the information sheet and do not require the 24 hours to decide. As BADBIR is an observational study only using relatively simple questionnaires, the Steering Committee (which includes a patient representative) propose to allow patients to sign the consent form as soon as they feel they have had sufficient time to consider if they would like to participate. This would eliminate the need for 24 hours to elapse in all cases. We would therefore like to request the permission of the Ethics Committee to change this statement, as described below:

Proposed change

“The participant will be given as much time as they require in which to make a decision regarding participation in this research study”

Positive aspects to proposed change in methodology

1. This will allow the participant to decide to sign the consent form immediately if they so wish whilst not in any way detracting from the rights of those patients who wish to take longer to consider participation. This will not increase the risk to patients as all patients can continue to consider participation for as long as they feel is necessary.
2. The recruitment process would be simpler thus potentially allowing for improved recruitment levels

Section A34

The BAD have revised the payments to centres from: £100 for each baseline registration to £120 and from £50 for each follow up to £30 for each follow-up.

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
Letter of Invitation to Patient	1	25/02/2011
Reference: Waist Circumference, The National Obesity Forum http://www.nationalobesityforum.org.uk/ accessed 04.05.10		

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: CEM GURUTH ..

Date of submission: 11 April 2011