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05 May 2011

Kathy McElhone
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Dear Ms McElhone

Study title:	**British Association of Dermatologists Biological Interventions Register**
REC reference:	**07/MRE08/9**
Amendment number:	**Amendment Five 24/02/11**
Amendment date:	**11 April 2011**

The above amendment was reviewed at the meeting of the Sub-Committee held on 26 April 2011.

Ethical opinion

The amendment (Amendment Five 24/02/11) sought approval to make a number of changes to the approved Protocol as follows:-

1. To allow nurses from the Clinical Research Network to post a letter of invitation along with the Participant Information Sheet and Consent Form to potentially suitable patients followed up by a discussion of the study over the telephone. All nurses from the Clinical Research Network are fully trained in taking consent for participation in research.

2. To allow potential participants less than 24 hours to provide informed consent. At the time of the original application it was not anticipated that management of biologic and conventional patients would vary across the regions. In some centres, commencement of these therapies is not a 'long and considered' process, as described in the original application but varies depending on prescribing practice or local service provision. In such situations, the requirement to wait for 24 hours to elapse before obtaining consent is problematic. As BADBIR is an observational study, the Trial Steering Committee – which includes a patient representative – propose to allow patient to provide informed consent as soon as they have had sufficient time to consider the whether or not to take part in the study, i.e. less than 24 hours. Patients will still be given as much time as they require, but it is hoped that a simpler recruitment process will aid recruitment.

3. To revise payments to centres from: £100 for each baseline registration to £120, and from £50 for each follow-up to £30 for each follow-up.

4. To provide investigators with a standard operating procedure for measurement of waist circumference.

A comprehensive rationale had been submitted in support of each of the proposed changes.

The Sub-Committee agreed that the whilst the intention to allow patients less than 24 hours to provide informed consent wasn't considered to be the norm, it appeared that in this instance it could be justified given both the circumstances outlined above and the fact that the proposal had been endorsed by the Trial Steering Committee.

The members of the Committee taking part in the review 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, BADBIR Study Co-ordinator, University of Manchester		12 April 2011
Notice of Substantial Amendment (non-CTIMPs): Amendment Five 24/02/11		
Letter of invitation to participant: BADBIR Patient Invitation	1	25 February 2011
Standard Operating Procedure Waist Circumference Measurement		

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 (July 2001) and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

Yours sincerely

P.P. **Professor Ravi S Gulati**
Chair

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

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