

## North West Research Ethics Committee

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14 March 2007

**Professor C E M Griffiths**  
**Professor of Dermatology**  
**The University of Manchester**  
**Dermatology Centre**  
**Hope Hospital**  
**Stott Lane**  
**SALFORD M6 8HD**

RECEIVED  
16 MAR 2007

Dear Professor Griffiths

**Full title of study:** British Association of Dermatologists Biological Interventions Register  
**REC reference number:** 07/MRE08/9

Thank you for your letter of 05 March 2007, responding to the Committee's request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Chair (Dr Donal Manning) and Mr James Bruce (Consultant Surgeon).

### Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation [as revised].

### Ethical review of research sites

The Committee has not yet been notified of the outcome of any site-specific assessment (SSA) for the research site(s) taking part in this study. The favourable opinion does not therefore apply to any site at present. We will write to you again as soon as one Research Ethics Committee has notified the outcome of a SSA. In the meantime no study procedures should be initiated at sites requiring SSA.

### Conditions of approval

The favourable opinion is given provided that you comply with the conditions set out in the attached document. You are advised to study the conditions carefully.



## Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Application	5.2	18 December 2006
Investigator CV - for Professor C E M Griffiths		19 December 2006
Protocol	10	05 December 2006
Covering Letter		19 December 2006
Peer Review - from Professor Nils Feltenius, Director of ARTIS registry, Karolinska University Hospital Solna - August 2006		
Statistician Comments - Letter from Dr Chris Roberts, Senior Lecturer in Medical Statistics, The University of Manchester		25 October 2006
Questionnaire: Patient baseline questionnaire	4	08 December 2006
Questionnaire: Consultant 6-monthly follow-up questionnaire	4	08 December 2006
Questionnaire: Consultant baseline questionnaire	4	08 December 2006
Questionnaire: Patient 6-monthly follow-up questionnaire	4	08 December 2006
Questionnaire: Psoriasis Area and Severity Index - PASI (validated)		
Questionnaire: Dermatology Life Quality Index - DLQI (validated)		
Questionnaire: CAGE Questionnaire (validated)		
Questionnaire: Generic Health Utility Index - Patient Baseline EuroQol (validated)		
Questionnaire: Health Assessment Questionnaire (HAQ) - rheumatoid arthritis only) (validated)		
Questionnaire: BAD Biological Interventions Register - Patient 6-monthly diary	4	08 December 2006
Questionnaire: Serious Adverse Event Further Information Form: Serious Infections (excluding TB)	1	08 December 2006
Questionnaire: Serious Adverse Event Further Information Form: Lymphoproliferative tumours	1	08 December 2006
Questionnaire: Serious Adverse Event Further Information Form: Congestive Heart Failure	1	08 December 2006
Questionnaire: Serious Adverse Event Further Information Form: Central demyelinating disease	1	08 December 2006
Questionnaire: Serious Adverse Event Further Information Form: Aplastic anaemia / pancytopenia	1	08 December 2006
Questionnaire: Control Patient follow-up questionnaire	4	08 December 2006
Questionnaire: Pregnancy Outcome Questionnaire	1	08 December 2006
Questionnaire: Serious Adverse Event Further Information Form: Tuberculosis	1	08 December 2006
Participant Information Sheet	1	08 December 2006
Participant Information Sheet	2	
Participant Consent Form	1	08 December 2006
Response to Request for Further Information - From Professor EM Griffiths		05 March 2007
Patient Follow-up Flow Chart		
Website content		
Letter from funder - British Association of Dermatologists		07 December 2006



**R&D approval**

The study should not commence at any NHS site until the local Principal Investigator has obtained final approval from the R&D office for the relevant NHS care organisation.

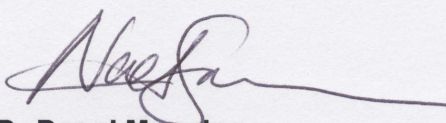
**Statement of compliance**

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.

**07/MRE08/9****Please quote this number on all correspondence**

With the Committee's best wishes for the success of this project

Yours sincerely

  
Dr Donal Manning  
Chair

**Email:** northwest.mrec@northwest.nhs.uk

**Enclosures:** Standard approval conditions

**Copies to: -** Dr K D Watson  
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R&D Department for NHS care organisation at lead site: -

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