



**Health Research Authority**  
Research Ethics Service

**North West - Haydock Research Ethics Committee**

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Tel: 0207 104 8012

28 September 2015

Ian Evans  
BADBIR Assistant Study Manager  
The University of Manchester  
Unit 1 Rutherford House  
Manchester Science Park  
M15 6SZ

Dear Ian

**Study title:** British Association of Dermatologists Biological Interventions Register  
**REC reference:** 07/MRE08/9  
**EudraCT number:** not applicable  
**Amendment number:** 8  
**Amendment date:** 01 July 2015  
**IRAS project ID:**

The above amendment was reviewed by the Sub-Committee in correspondence.

**Favourable opinion**

Approval was sought to extend the study end date for another 10 years to 31 July 2028. Approval was also sought to remove the minimum age limit for patients joining the BADBIR study.

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:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Notice of Substantial Amendment (non-CTIMP)	8	01 July 2015
Other [Patient Assent Form]	4	14 May 2009
Other [System level security policy]	2	01 July 2015

Other [Conventional Cohort Switches to Biologic cohort]		
Other [Biologic interventions register baseline]	8	01 July 2015
Participant consent form [Parent or guardian]	4	14 May 2009
Participant information sheet (PIS) [for very young children]	1	01 July 2015
Participant information sheet (PIS) [for young children]	1	01 July 2015
Participant information sheet (PIS) [for young children]	1	01 July 2015
Research protocol or project proposal [Tracked]	15	01 July 2015
Validated questionnaire [EQ-5D-Y]		
Validated questionnaire [Childhood health assessment questionnaire]		
Validated questionnaire [Biologic interventions register baseline (follow up)]	8	01 July 2015
Validated questionnaire [Children's dermatology life quality Index]		
Validated questionnaire [Children's dermatology life quality Index cartoon version]		

### 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 and complies fully with the Standard Operating Procedures for Research Ethics Committees in the UK.

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at <http://www.hra.nhs.uk/hra-training/>

<b>07/MRE08/9:</b>	<b>Please quote this number on all correspondence</b>
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Yours sincerely

**Dr Tim S Sprosen**  
**Chair**

E-mail: nrescommittee.northwest-haydock@nhs.net

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

*Copy to: Prof Christopher EM Griffiths, The University of Manchester*

**North West - Haydock Research Ethics Committee**

**Attendance at Sub-Committee of the REC meeting on 22 September 2015**

**Committee Members:**

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Dr Ezzat Kozman	Consultant Gynaecologist	Yes	
Dr Tim S Sprosen	Epidemiologist	Yes	

**Also in attendance:**

<i>Name</i>	<i>Position (or reason for attending)</i>
Ms Rachel Katzenellenbogen	REC Manager