



Health Research  
Authority

## North West - Haydock Research Ethics Committee

3rd Floor - Barlow House  
4 Minshull Street  
Manchester  
M1 3DZ

Tel: 0207 104 8004

**Please note: This is the favourable opinion of the REC only and does not allow the amendment to be implemented at NHS sites in England until the outcome of the HRA assessment has been confirmed.**

25 September 2018 (Revised 25/09/2018)

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

Dear Ian,

<b>Study title:</b>	<b>British Association of Dermatologists Biological Interventions Register</b>
<b>REC reference:</b>	<b>07/MRE08/9</b>
<b>EudraCT number:</b>	<b>not applicable</b>
<b>Amendment number:</b>	<b>Amendment 11</b>
<b>Amendment date:</b>	<b>13 July 2018</b>
<b>IRAS project ID:</b>	<b>32990</b>

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

### **Favourable opinion**

Approval was sought for a change in the study title and the addition of the HADS as an additional reported outcome measure.

No material ethical issues were raised.

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)	Amendment 11	13 July 2018
Participant consent form [Parent]	5.1	01 August 2017
Participant consent form [Assent Form]	5.1	01 August 2017
Participant consent form [Patient]	5.1	01 August 2017
Participant information sheet (PIS) [Children 6-10 years]	2.1	01 August 2017
Participant information sheet (PIS) [Patient]	5.1	01 August 2017
Participant information sheet (PIS) [Young Person (11-16 years)]	2.1	01 August 2017
Participant information sheet (PIS) [Under 6 years]	2.1	01 August 2017
Research protocol or project proposal	18	01 June 2018
Research protocol or project proposal	18 (tracked)	01 June 2018
Validated questionnaire [HADS]		

## Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

## Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

## 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 Research Ethics 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](mailto:nrescommittee.northwest-haydock@nhs.net)

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

Copy to: Professor Christopher EM Griffiths, The University of Manchester  
Dr Kathleen McElhone, The University of Manchester  
Confidentiality Advise Team

**North West - Haydock Research Ethics Committee**

**Attendance at Sub-Committee of the REC meeting on 28 August 2018**

**Committee Members:**

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

**Also in attendance:**

<i>Name</i>	<i>Position (or reason for attending)</i>
Miss Ewa Grzegorska	REC Assistant