NHS
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.

11 September 2017

Professor Christopher EM Griffiths
Professor of Dermatology
The University of Manchester
Dermatopharmacology Unit
Irving Building
Salford Royal Teaching Hospital
M6 8HD

Dear Professor Griffiths,

Study title:	**British Association of Dermatologists Biological Interventions Register**
REC reference:	**07/MRE08/9**
EudraCT number:	**not applicable**
Amendment number:	**10**
Amendment date:	**01 August 2017**
IRAS project ID:	**32990**

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

Favourable opinion

This amendment consisted of justified recruiting of a new cohort and the increase of an existing cohort size.

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:

Document	Version	Date
Non-validated questionnaire [Clinical Baseline]	9	01 August 2017
Non-validated questionnaire [Clinical follow-up]	9	01 August 2017
Non-validated questionnaire [Clinical Follow-up Tracked]	9	01 August 2017
Non-validated questionnaire [Clinical Baseline Tracked]	9	01 August 2017
Notice of Substantial Amendment (non-CTIMP)	10	01 August 2017
Other [Section 251 Support]		24 March 2016
Participant consent form	5	01 August 2017
Participant consent form [Assent form]	5	01 August 2017
Participant consent form [Parent/Guardian]	5	01 August 2017
Participant consent form [Parent/Guardian Tracked]	5	01 August 2017
Participant consent form [Assent form Tracked]	5	01 August 2017
Participant consent form [Tracked]	5	01 August 2017
Participant information sheet (PIS)	5	01 August 2017
Participant information sheet (PIS) [under 6]	2	01 August 2017
Participant information sheet (PIS) [6-10]	2	01 August 2017
Participant information sheet (PIS) [11-16]	2	01 August 2017
Participant information sheet (PIS) [Revised]	5	01 August 2017
Participant information sheet (PIS) [11-16 Tracked]	2	01 August 2017
Participant information sheet (PIS) [6-10 Tracked]	2	01 August 2017
Participant information sheet (PIS) [Under 6 Tracked]	2	01 August 2017
Research protocol or project proposal		01 August 2017
Research protocol or project proposal [Tracked]	17	01 August 2017

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/

Yours sincerely

PP **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: Dr Kathleen McElhone, The University of Manchester

North West - Haydock Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 05 September 2017

Committee Members:

Name	Profession	Present	Notes
Mr Charles Otim	Research Support Officer	Yes	
Dr Valerie E Siddall	Retired Senior Manager - Pharmaceutical Industry	Yes	

Also in attendance:

Name	Position (or reason for attending)
Ms Laila Sarwar	REC Assistant