

North West - Haydock Research Ethics Committee

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

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.

26 August 2020

Dear Prof Christopher EM Griffiths,
The University of Manchester

Study title: British Association of Dermatologists Biological Interventions Register
REC reference: 07/MRE08/9
EudraCT number: not applicable
Amendment number: SA 12
Amendment date: 01.07.20
IRAS project ID: 32990

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

Ethical opinion

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>
Completed Amendment Tool [Completed Amendment Tool]	v1.2 11 Jun 2020	01 July 2020
Copies of advertisement materials for research participants [Patient Post v2]	2	01 June 2020
Letters of invitation to participant [Participant Invitation Letter]	2	01 June 2020
Non-validated questionnaire [Clinical Baseline Questionnaire v10_For Ethics_changes_highlighted]	10	01 June 2020
Non-validated questionnaire [Clinical Follow-up Questionnaire v10 changes_highlighted]	10	01 June 2020

Other [2020 03 09 SLSP_BADBIR_v3.]	v3	10 December 2018
Other [BADBIR_Patient_Assent_Form_V5.2 draft]	v5.2	01 June 2020
Participant consent form [Parent or Guardian Consent Form]	5.2	01 June 2020
Participant consent form [Consent Form v5.2]	5.2	01 June 2020
Participant information sheet (PIS) [PIS v5.2]	5.2	01 June 2020
Research protocol or project proposal [Protocol with tracked changes]	19	01 June 2020

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.

Amendments related to COVID-19

We will update your research summary for the above study on the research summaries section of our website. During this public health emergency, it is vital that everyone can promptly identify all relevant research related to COVID-19 that is taking place globally. If you have not already done so, please register your study on a public registry as soon as possible and provide the HRA with the registration detail, which will be posted alongside other information relating to your project.

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.

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at: <https://www.hra.nhs.uk/planning-and-improving-research/learning/>

IRAS Project ID - 32990:

Please quote this number on all correspondence

Yours sincerely



pp
Chair

E-mail: haydock.rec@hra.nhs.uk

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

review

Copy to:

*Prof 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 18 August 2020

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Mr Stephen Edgar (Chair)	Designer	Yes	
Dr Ezzat Kozman	Consultant Gynaecologist	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Dr Keith Haylock	Approvals Administrator
Miss Laura Howe	Approvals Officer