



Health Research
Authority

North West - Haydock Research Ethics Committee

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19 January 2023

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

Dear Prof Griffiths

Study title: British Association of Dermatologists Biological Interventions Register
REC reference: 07/MRE08/9
EudraCT number: not applicable
Amendment number: Substantial Amendment 13
Amendment date: 01 August 2022
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 [Amendment Tool for BADBIR Substantial Amendment 13]	1.6	01 August 2022
Non-validated questionnaire [Patient Baseline Questionnaire]	6	01 August 2022
Non-validated questionnaire [Under 16 Patient Baseline]	2	01 August 2022

Questionnaire]		
Non-validated questionnaire [Patient Follow-up Questionnaire]	7	01 August 2022
Non-validated questionnaire [Clinical Baseline Questionnaire]	11	01 August 2022
Non-validated questionnaire [Clinical Follow-up Questionnaire]	11	01 August 2022
Non-validated questionnaire [TRACKED_CHANGES Patient Baseline Questionnaire]	6	01 August 2022
Non-validated questionnaire [TRACKED_CHANGES Clinical Follow-up Questionnaire]	11	01 August 2022
Non-validated questionnaire [TRACKED_CHANGES Patient Follow-up Questionnaire]	7	01 August 2022
Non-validated questionnaire [TRACKED_CHANGES Under 16 Patient Baseline Questionnaire]	2	01 August 2022
Non-validated questionnaire [TRACKED_CHANGES Clinical Baseline Questionnaire]	11	01 August 2022
Other [D1 Chief Investigator Declaration_Richard Warren]	1	27 October 2022
Other [Patient Portal Invitation Letter]	1	01 August 2022
Other [TRACKED_CHANGES Patient Portal Invitation Letter]	1	01 August 2022
Participant consent form [Patient Assent Form]	5.3	01 August 2022
Participant consent form [Parent or Guardian Consent Form]	5.3	01 August 2022
Participant consent form [Patient Consent Form]	5.3	01 August 2022
Participant consent form [TRACKED_CHANGES Patient Assent Form]	5.3	01 August 2022
Participant consent form [TRACKED_CHANGES Patient Consent Form]	5.3	01 August 2022
Participant consent form [TRACKED_CHANGES Parent or Guardian Consent Form]	5.3	01 August 2022
Participant information sheet (PIS) [BADBIR Very Young Childrens_Info_Sheet]	2.2	01 August 2022
Participant information sheet (PIS) [Patient Information Sheet]	5.3	01 August 2022
Participant information sheet (PIS) [BADBIR Children's Information Sheet]	2.2	01 August 2022
Participant information sheet (PIS) [Young Persons Information Sheet]	2.2	01 August 2022
Participant information sheet (PIS) [TRACKED_CHANGES Childrens Information Sheet]	2.2	01 August 2022
Participant information sheet (PIS) [TRACKED_CHANGES Very Young Childrens Information Sheet]	2.2	01 August 2022
Participant information sheet (PIS) [TRACKED_CHANGES Patient Information Sheet]	5.3	01 August 2022
Participant information sheet (PIS) [TRACKED_CHANGES Young Persons Information Sheet]	2.2	01 August 2022
Research protocol or project proposal [BADBIR Protocol (Clean)]	20	01 August 2022
Research protocol or project proposal [TRACKED CHANGES BADBIR Protocol]	20	01 August 2022
Summary CV for Chief Investigator (CI) [CV of New Chief Investigator Professor R Warren]	1	04 August 2022

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,

Aoife Harrington

pp

Mr Stephen Edgar
Chair

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

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

Copy to: 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 17 January 2023

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>
Miss Aoife Harrington	Approvals Administrator