

Adele Moores

From: haydock.rec@hra.nhs.uk <noreply@harp.org.uk>
Sent: 05 January 2023 17:08
To: Christopher Griffiths; ian.evans@outlook.com
Cc: Kathleen Mcelhone; Adele Moores
Subject: IRAS 32990. Substantial Amendment valid for REC review

Dear Prof Griffiths,

Study title: British Association of Dermatologists Biological Interventions Register
REC reference: 07/MRE08/9
IRAS project ID: 32990
Amendment number: Substantial Amendment 13
Amendment date: 01 August 2022

Thank you for submitting the above amendment, which was received on 03.01.22. I can confirm that this is a valid notice of a substantial amendment and will be reviewed by the Sub-Committee at its next meeting.

Documents received

The documents to be reviewed are as follows:

<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 Questionnaire]	2	01 August 2022
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	2.2	01 August 2022

Very Young Childrens Information Sheet]		
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

Notification of the Committee's decision

The Committee will issue an ethical opinion on the amendment within a maximum of 35 days from the date of receipt.

Kind regards,

Aoife

Aoife Harrington

Approvals Administrator

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