



Health Research Authority

South Central - Hampshire B Research Ethics Committee

2 Redman Place
Stratford
London
E20 1JQ

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.

05 June 2024

Miss Laura Frisby
The Newcastle upon Tyne Hospitals NHS Foundation Trust
Regent Point, Regent Farm Road, Gosforth
Newcastle
NE3 3HD

Dear Miss Frisby

Study title: Supporting Women with adherence to hormone Therapy following breast cancer (SWEET)
REC reference: 23/SC/0254
Protocol number: 1.0
Amendment number: SA001
Amendment date: 02 May 2025
IRAS project ID: 330129

The above amendment was reviewed at the meeting of the Sub-Committee held by 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 [10534 - Amendment Tool - SA01 - Locked For Submission - 2024-05-02]	1.6	06 December 2021

Copies of materials calling attention of potential participants to the research [SWEET_Recruitment Animation Script_v1.0_Feb2024]	v1.0	01 February 2024
Copies of materials calling attention of potential participants to the research [SWEET_StudyPoster_v1.0_05Mar24]	v1.0	05 March 2024
Copies of materials calling attention of potential participants to the research [SWEET_StudyBanner_v1.0_05Mar24]	v1.0	05 March 2024
Covering letter on headed paper [SA01 Cover Letter_v1.0_08Apr2024]	v1.0	08 April 2024
GP/consultant information sheets or letters [SWEET_GPLetter Usual Care_v4.0_08Apr2024]	v4.0	08 April 2024
GP/consultant information sheets or letters [SWEET_GPLetter HTMe arm_v4.0_08Apr2024]	v4.0	08 April 2024
Other [SWEET_Website_v1.0_28Feb2024]	v1.0	28 February 2024
Other [SWEET_Consultation Follow Up Text_v1.0_03Apr24]	v1.0	03 April 2024
Other [SWEET_BaselineCoverLetter_v1.0_03Apr24]	v1.0	03 April 2024
Other [SWEET_FollowUpCoverLetter_v1.0_03Apr24]	v1.0	03 April 2024
Other [SWEET_E Pro Text_v1.0_01Mar2024]	1.0	01 March 2024
Other [SWEET_Initial Appt Conf letter_v2.0_08Apr2024]	v2.0	08 April 2024
Other [SWEET_FollowUpApptConfletter_v2.0_08Apr2024]	v2.0	08 April 2024
Participant consent form [SWEET_InformedConsentForm_v4.0_03Apr2024]	v4.0	03 April 2024
Participant information sheet (PIS) [SWEET_PatientInformationSheet_v4.0_03Apr2024]	v4.0	03 April 2024
Research protocol or project proposal [SWEET_Protocol_v4.0_08Apr2024]	v4.0	08 April 2024
Summary, synopsis or diagram (flowchart) of protocol in non technical language [SWEET_ProtocolSummary_v2.0_08Apr2024]	v2.0	08 April 2024
Validated questionnaire [SWEET_FollowUpQuestionnaire_v3.0_08Apr2024]	v3.0	08 April 2024

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

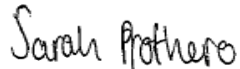
We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at: <https://www.hra.nhs.uk/planning-and-improving-research/learning/>

IRAS Project ID - 330129:

Please quote this number on all correspondence

Yours sincerely

pp



**Honorary Associate Professor Brian Birch
Chair**

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

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

Copy to: Professor Linda Sharp, Newcastle University

South Central - Hampshire B Research Ethics Committee

Attendance at Sub-Committee of the REC meeting by correspondence

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>
Honorary Associate Professor Brian Birch (Chair)	Consultant Urological Surgeon	Yes
Mrs Alison Rapley	Semi-retired medical writer/ manager	Yes

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Miss Sarah Prothero	Approvals Specialist