



**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 you to start your study at NHS sites in England until you receive HRA Approval

11 August 2023

Professor Linda Sharp
Professor of Cancer Epidemiology/Honorary Research Contract (NuTH)
Newcastle University
Level 5, Sir James Spence Institute
Royal Victoria Infirmary
Queen Victoria Road
NE1 4LP

Dear Professor Sharp

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

Thank you for your letter of , responding to the Research Ethics Committee's (REC) request for further information on the above research and submitting revised documentation.

The further information has been considered on behalf of the Committee by the Alternate Vice-Chair.

Confirmation of ethical opinion

On behalf of the Committee, I am pleased to confirm a favourable ethical opinion for the above research on the basis described in the application form, protocol and supporting documentation as revised, subject to the conditions specified below.

Good practice principles and responsibilities

The [UK Policy Framework for Health and Social Care Research](#) sets out principles of good practice in the management and conduct of health and social care research. It also outlines the responsibilities of individuals and organisations, including those related to the four elements of [research transparency](#):

1. [registering research studies](#)
2. [reporting results](#)
3. [informing participants](#)
4. [sharing study data and tissue](#)

Conditions of the favourable opinion

The REC favourable opinion is subject to the following conditions being met prior to the start of the study.

Confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or NHS management permission (in Scotland) should be sought from all NHS organisations involved in the study in accordance with NHS research governance arrangements. Each NHS organisation must confirm through the signing of agreements and/or other documents that it has given permission for the research to proceed (except where explicitly specified otherwise).

Guidance on applying for HRA and HCRW Approval (England and Wales)/ NHS permission for research is available in the Integrated Research Application System.

For non-NHS sites, site management permission should be obtained in accordance with the procedures of the relevant host organisation.

Sponsors are not required to notify the Committee of management permissions from host organisations

Registration of Clinical Trials

All research should be registered in a publicly accessible database and we expect all researchers, research sponsors and others to meet this fundamental best practice standard.

It is a condition of the REC favourable opinion that **all clinical trials are registered** on a publicly accessible database within six weeks of recruiting the first research participant. For this purpose, 'clinical trials' are defined as:

- clinical trial of an investigational medicinal product
- clinical investigation or other study of a medical device
- combined trial of an investigational medicinal product and an investigational medical device
- other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice.

Failure to register a clinical trial is a breach of these approval conditions, unless a deferral has been agreed by the HRA (for more information on registration and requesting a deferral see: [Research registration and research project identifiers](#)).

If you have not already included registration details in your IRAS application form you should notify the REC of the registration details as soon as possible.

Publication of Your Research Summary

We will publish your research summary for the above study on the research summaries section of our website, together with your contact details, no earlier than three months from the date of this favourable opinion letter.

Should you wish to provide a substitute contact point, make a request to defer, or require further information, please visit:

<https://www.hra.nhs.uk/planning-and-improving-research/application-summaries/research-summaries/>

N.B. If your study is related to COVID-19 we will aim to publish your research summary within 3 days rather than three months.

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 haven't already done so, please register your study on a public registry as soon as possible and provide the REC with the registration detail, which will be posted alongside other information relating to your project. We are also asking sponsors not to request deferral of publication of research summary for any projects relating to COVID-19. In addition, to facilitate finding and extracting studies related to COVID-19 from public databases, please enter the WHO official acronym for the coronavirus disease (COVID-19) in the full title of your study. Approved COVID-19 studies can be found at: <https://www.hra.nhs.uk/covid-19-research/approved-covid-19-research/>

It is the responsibility of the sponsor to ensure that all the conditions are complied with before the start of the study or its initiation at a particular site (as applicable).

After ethical review: Reporting requirements

The attached document "After ethical review – guidance for researchers" gives detailed guidance on reporting requirements for studies with a favourable opinion, including:

- Notifying substantial amendments
- Adding new sites and investigators
- Notification of serious breaches of the protocol
- Progress and safety reports
- Notifying the end of the study, including early termination of the study
- Final report
- Reporting results

The latest guidance on these topics can be found at <https://www.hra.nhs.uk/approvals-amendments/managing-your-approval/>.

Ethical review of research sites

NHS/HSC sites

The favourable opinion applies to all NHS/HSC sites taking part in the study, subject to confirmation of Capacity and Capability (in England, Northern Ireland and Wales) or management permission (in Scotland) being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" below).

Non-NHS/HSC sites

I am pleased to confirm that the favourable opinion applies to any non-NHS/HSC sites listed in the application, subject to site management permission being obtained prior to the start of the study at the site.

Approved documents

The final list of documents reviewed and approved by the Committee is as follows:

<i>Document</i>	<i>Version</i>	<i>Date</i>
GP/consultant information sheets or letters [SWEET_GPIletter-UsualCare_2.0 07.08.2023]	2.0	07 August 2023
GP/consultant information sheets or letters [SWEET_GPIletter (usual care) 2.0 07.08.2023 TC]	2.0	07 August 2023
GP/consultant information sheets or letters [SWEET_GPIletter-HT&Me_2.0 07.08.2023]	2.0	07 August 2023
GP/consultant information sheets or letters [SWEET_GP letter HT&Me arm_2.0 07.08.2023 TC]	2.0	07 August 2023
Interview schedules or topic guides for participants [SWEET_HCPTopicGuide_1.0 26.06.2023]	1.0	26 June 2023
Interview schedules or topic guides for participants [SWEET_ParticipantTopicGuide_1.0 26.06.2023]	1.0	26 June 2023
IRAS Application Form [IRAS_Form_30062023]		30 June 2023
Letter from funder [SWEET_FundingLetter]	1.0	18 April 2019
Letters of invitation to participant [SWEET_InvitationLetter_1.0 23.05.2023]	1.0	23 May 2023
Letters of invitation to participant [SWEET_InitialAppointmentConf.Letter 1.0 23.05.2023]	1.0	23 May 2023
Letters of invitation to participant [SWEET_FollowUpAppointmentConf.Letter 1.0 23.05.2023]	1.0	23 May 2023
Other [SWEET_Protocol_2.0 02.08.2023 tracked changes]	2.0	02 August 2023
Other [SWEET_REC feedback]	1.0	07 August 2023
Participant consent form [SWEET_HCP process evaluation ICF_1.0 24.05.2023]	1.0	24 May 2023
Participant consent form [SWEET_HCP process evaluation Remote Verbal ICF_1.0 24.05.2023]	1.0	24 May 2023
Participant consent form [SWEET_InformedConsentForm_2.0 07.08.2023]	2.0	07 August 2023

Participant consent form [SWEET_InformedConsentForm_2.0 07.08.2023]	2.0	07 August 2023
Participant consent form [SWEET_RemoteVerbalConsentForm_2.0 07.08.2023]	2.0	07 August 2023
Participant consent form [SWEET_RemoteVerbalConsentForm_07.08.2023 2.0]	2.0	07 August 2023
Participant information sheet (PIS) [SWEET_HCP process evaluation PIS_1.0 15.06.2023]	1.0	15 June 2023
Participant information sheet (PIS) [SWEET_PatientInformationSheet_2.0 07.08.2023 clean]	2.0	07 August 2023
Participant information sheet (PIS) [PROPEL_PatientInformationSheet_2.0 09.05.2023 tracked changes]	2.0	07 August 2023
Research protocol or project proposal [SWEET_Protocol_2.0 02.08.2023 clean]	2.0	02 August 2023
Sample diary card/patient card [SWEET_HT&Me Login Card_1.0 28.06.2023]	1.0	28 June 2023
Sample diary card/patient card [SWEET_HT&Me How to guide]	1.0	15 June 2023
Summary CV for Chief Investigator (CI) [SWEET_CI CV _31.05.2023]	1.0	31 May 2023
Validated questionnaire [SWEET_HealthResourceUseQuestionnaire-Baseline 1.0 31.05.2023]	1.0	31 May 2023
Validated questionnaire [SWEET_FollowUpQuestionnaire_1.0 22.06.2023]	1.0	22 June 2023
Validated questionnaire [SWEET_Baseline_1.0 22.06.2023]	1.0	22 June 2023
Validated questionnaire [SWEET_HealthResourceUseQuestionnaire-Follow Up 1.0 31.05.2023]	1.0	31 May 2023

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.

User Feedback

The Health Research Authority is continually striving to provide a high quality service to all applicants and sponsors. You are invited to give your view of the service you have received and the application procedure. If you wish to make your views known please use the feedback form available on the HRA website:

<http://www.hra.nhs.uk/about-the-hra/governance/quality-assurance/>

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

With the Committee's best wishes for the success of this project.

Yours sincerely

A handwritten signature in black ink, appearing to read 'Mannery', written in a cursive style.

pp.

Mrs Samantha Trace
Chair

Email: hampshireb.rec@hra.nhs.uk

Enclosures: "After ethical review – guidance for
researchers"

Copy to: Miss Laura Frisby, The Newcastle upon Tyne Hospitals NHS Foundation
Trust

Lead Nation

England: approvals@hra.nhs.uk