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

Email: approvals@hra.nhs.uk

11 August 2023

Dear Professor Sharp

HRA and Health and Care Research Wales (HCRW) Approval Letter

Study title:	**Supporting Women with adhErence to hormonE Therapy following breast cancer (SWEET)**
IRAS project ID:	**330129**
Protocol number:	**1.0**
REC reference:	**23/SC/0254**
Sponsor	**The Newcastle upon Tyne Hospitals NHS Foundation Trust**

I am pleased to confirm that **HRA and Health and Care Research Wales (HCRW) Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications received. You should not expect to receive anything further relating to this application.

Please now work with participating NHS organisations to confirm capacity and capability, in line with the instructions provided in the "Information to support study set up" section towards the end of this letter.

How should I work with participating NHS/HSC organisations in Northern Ireland and Scotland?

HRA and HCRW Approval does not apply to NHS/HSC organisations within Northern Ireland and Scotland.

If you indicated in your IRAS form that you do have participating organisations in either of these devolved administrations, the final document set and the study wide governance report

(including this letter) have been sent to the coordinating centre of each participating nation. The relevant national coordinating function/s will contact you as appropriate.

Please see IRAS Help for information on working with NHS/HSC organisations in Northern Ireland and Scotland.

How should I work with participating non-NHS organisations?
HRA and HCRW Approval does not apply to non-NHS organisations. You should work with your non-NHS organisations to obtain local agreement in accordance with their procedures.

What are my notification responsibilities during the study?
The standard conditions document "*After Ethical Review – guidance for sponsors and investigators*", issued with your REC favourable opinion, gives detailed guidance on reporting expectations for studies, including:

- Registration of research
- Notifying amendments
- Notifying the end of the study

The HRA website also provides guidance on these topics, and is updated in the light of changes in reporting expectations or procedures.

Who should I contact for further information?
Please do not hesitate to contact me for assistance with this application. My contact details are below.

Your IRAS project ID is **330129**. Please quote this on all correspondence.

Yours sincerely,

Sarah Prothero
Approvals Specialist

Email: approvals@hra.nhs.uk

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

List of Documents

The final document set assessed and approved by HRA and HCRW Approval is listed below.

Document	*Version*	*Date*
Contract/Study Agreement template [mNCA_SWEET (11.07.2023)]	1.0	11 July 2023
GP/consultant information sheets or letters [SWEET_GPletter-UsualCare_2.0 07.08.2023]	2.0	07 August 2023
GP/consultant information sheets or letters [SWEET_GPletter (usual care) 2.0 07.08.2023 TC]	2.0	07 August 2023
GP/consultant information sheets or letters [SWEET_GPletter-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
Organisation Information Document [SWEET_OID_27.06.2023]	1.0	27 June 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_RemoteVerbalConsentForm_07.08.2023 2.0]	2.0	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 information sheet (PIS) [PROPEL_PatientInformationSheet_2.0 09.05.2023 tracked changes]	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
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
Schedule of Events or SoECAT [SoECAT (All WPS)]	1.0	28 November 2018
Schedule of Events or SoECAT [HRA SoECAT Export]	1.0	30 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

IRAS project ID	330129

Information to support study set up

The below provides all parties with information to support the arranging and confirming of capacity and capability with participating NHS organisations in England and Wales. This is intended to be an accurate reflection of the study at the time of issue of this letter.

Types of participating NHS organisation	Expectations related to confirmation of capacity and capability	Agreement to be used	Funding arrangements	Oversight expectations	HR Good Practice Resource Pack expectations
Research activities and procedures as per the protocol and other study documents will take place at participating NHS organisations.	Research activities should not commence at participating NHS organisations in England or Wales prior to their formal confirmation of capacity and capability to deliver the study in accordance with the contracting expectations detailed.	An Organisation Information Document has been submitted but the sponsor is intending to use a separate agreement. The sponsor has supplied the unmodified model agreement and intends to use this with participating NHS organisations.	Study funding arrangements are detailed in the Organisation Information Document.	A Principal Investigator should be appointed at participating NHS organisations .	No Honorary Research Contracts, Letters of Access or pre-engagement checks are expected for local staff employed by the participating NHS organisations. Where arrangements are not already in place, research staff not employed by the NHS host organisation undertaking any of the research activities listed in the research application would be expected to obtain a Letters of Access based on standard DBS checks and occupational health clearance.

Other information to aid study set-up and delivery

This details any other information that may be helpful to sponsors and participating NHS organisations in England and Wales in study set-up.
The applicant has indicated that they intend to apply for inclusion on the NIHR CRN Portfolio.