Miss Karina Cox
Consultant Breast and Oncoplastic Surgeon/ Honorary
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Email: approvals@hra.nhs.uk

21 August 2020

Dear Miss Cox

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

Study title:	**SENTINUS: Technical feasibility and diagnostic accuracy of intradermal microbubbles and contrast enhanced ultrasound to identify sentinel lymph node metastases in breast cancer patients following training and mentorship of imaging specialists**
IRAS project ID:	**274252**
EudraCT number:	**2020-000819-67**
Protocol number:	**MTW_2020_KC01**
REC reference:	**20/LO/0833**
Sponsor	**Maidstone and Tunbridge Wells NHS 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 **274252**. Please quote this on all correspondence.

Yours sincerely,
Juliana Araujo

Approvals Specialist

Email: approvals@hra.nhs.uk

Copy to: *Ms Hazel Everest*

List of Documents

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

Document	*Version*	*Date*
Clinical Trial Authorisation [MHRA Notice of Amended Request]		28 July 2020
Contract/Study Agreement template [Agreement template]		
IRAS Application Form [IRAS_Form_17072020]		17 July 2020
Letter from funder [Funding]		21 August 2019
Non-validated questionnaire [Procedure Questionnaire]	1.0	25 June 2020
Organisation Information Document	1.0	14 July 2020
Other [Response to REC]	1.0	14 July 2020
Other [Answers to Part B, Section 5]		02 June 2020
Participant consent form [Consent form]	2.0	14 July 2020
Participant information sheet (PIS) [Privacy notice]	1.0	25 June 2020
Participant information sheet (PIS) [PIS]	4.0	25 June 2020
Research protocol or project proposal [Protocol]	4.0	16 July 2020
Schedule of Events or SoECAT [SoECAT]	1.0	22 January 2020
Summary CV for Chief Investigator (CI) [CI CV]		05 May 2020
Summary of product characteristics (SmPC) [Product information]		24 April 2006
Summary, synopsis or diagram (flowchart) of protocol in non technical language [Flow diagram]	1.0	19 December 2019
274252, 20/LO/0833, SE03 HRA Approval Full REC email confirmation template.eml		19 May 2020
274252, 20/LO/0833, SE13 Application valid under consideration - REC review - non-commercial.eml		21May 2020
274252 SL02_Application_Valid.pdf		22 May 2020
274252, 20/LO/0833, SE32 Status Update - Provisional Opinion.eml		17 June 2020
274252 20 LO 0833_Favourable_Opinion_on_Further_Information_22.07.2020.pdf		22 July 2020
274252, 20/LO/0833, SE30 Status Update - Favourable Opinion.eml		22 July 2020

IRAS project ID	274252

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
This is multi-site study. There is therefore one site type.	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.	An Organisation Information Document has been submitted and the sponsor is intending to use a separate site agreement. The agreement is unmodified	The study has secured funding from the Breast Cancer Care and Breast Cancer Now. A copy of the funding award letter was received.	A Principal Investigator will be in place at each participating NHS organisation.	As a contract commercial study undertaken by local staff, it is unlikely that letters of accessor honorary research contracts will be applicable, except where local network staff employed by another Trust (or University) are involved (and then it is likely that arrangements are already in place). Where arrangements are not already in place, network staff (or similar) undertaking any of the research activities listed in A18 or A19 of the IRAS form, would be expected to obtain an honorary research contract from one NHS organisation (if university employed), followed by Letters of Access for subsequent organisations. This would be on the basis of a Research Passport (if university

					employed) or an NHS to NHS confirmation of pre-engagement checks letter (if NHS employed). These should confirm enhanced DBS checks, including appropriate barred list 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.