Health Research Authority

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29 July 2016

Dear Professor Foster

Letter of HRA Approval

Study title:	**HORIZONS: a cohort study to explore recovery of health and well-being in adults diagnosed with cancer**
IRAS project ID:	**202342**
Protocol number:	**RHM CAN1199**
REC reference:	**16/NW/0425**
Sponsor	**University Hospital Southampton NHS Foundation Trust**

I am pleased to confirm that **HRA Approval** has been given for the above referenced study, on the basis described in the application form, protocol, supporting documentation and any clarifications noted in this letter.

Participation of NHS Organisations in England

The sponsor should now provide a copy of this letter to all participating NHS organisations in England.

Appendix B provides important information for sponsors and participating NHS organisations in England for arranging and confirming capacity and capability. **Please read *Appendix B* carefully**, in particular the following sections:

- *Participating NHS organisations in England* – this clarifies the types of participating organisations in the study and whether or not all organisations will be undertaking the same activities
- *Confirmation of capacity and capability* - this confirms whether or not each type of participating NHS organisation in England is expected to give formal confirmation of capacity and capability. Where formal confirmation is not expected, the section also provides details on the time limit given to participating organisations to opt out of the study, or request additional time, before their participation is assumed.

- *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* - this provides detail on the form of agreement to be used in the study to confirm capacity and capability, where applicable.

Further information on funding, HR processes, and compliance with HRA criteria and standards is also provided.

It is critical that you involve both the research management function (e.g. R&D office) supporting each organisation and the local research team (where there is one) in setting up your study. Contact details and further information about working with the research management function for each organisation can be accessed from www.hra.nhs.uk/hra-approval.

Appendices

The HRA Approval letter contains the following appendices:

- A – List of documents reviewed during HRA assessment
- B – Summary of HRA assessment

After HRA Approval

The 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.

In addition to the guidance in the above, please note the following:

- HRA Approval applies for the duration of your REC favourable opinion, unless otherwise notified in writing by the HRA.
- Substantial amendments should be submitted directly to the Research Ethics Committee, as detailed in the *After Ethical Review* document. Non-substantial amendments should be submitted for review by the HRA using the form provided on the HRA website, and emailed to hra.amendments@nhs.net.
- The HRA will categorise amendments (substantial and non-substantial) and issue confirmation of continued HRA Approval. Further details can be found on the HRA website.

Scope

HRA Approval provides an approval for research involving patients or staff in NHS organisations in England.

If your study involves NHS organisations in other countries in the UK, please contact the relevant national coordinating functions for support and advice. Further information can be found at http://www.hra.nhs.uk/resources/applying-for-reviews/nhs-hsc-rd-review/.

If there are participating non-NHS organisations, local agreement should be obtained in accordance with the procedures of the local participating non-NHS organisation.

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 email the HRA at hra.approval@nhs.net. Additionally, one of our staff would be happy to call and discuss your experience of HRA Approval.

HRA Training

We are pleased to welcome researchers and research management staff at our training days – see details at http://www.hra.nhs.uk/hra-training/

Your IRAS project ID is **202342**. Please quote this on all correspondence.

Yours sincerely

Gemma Oakes
Assessor

Email: hra.approval@nhs.net

Copy to: *Miss Becci Petch, University of Southampton [Sponsor Contact]*
horizons@soton.ac.uk
Mrs Sharon Davies-Dear, University Hospital Southampton NHS Foundation Trust [Lead NHS R&D Contact]
sharon.davies-dear@uhs.nhs.uk
NIHR CRN Portfolio Applications Team
portfolio.applications@nihr.ac.uk

Appendix A - List of Documents

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

Document	*Version*	*Date*
Contract/Study Agreement [Schedule of Events]	1	22 June 2016
Contract/Study Agreement [Statement of Activities]	1	22 June 2016
Contract/Study Agreement [mNCA (for use in Scotland)]		07 July 2016
Copies of advertisement materials for research participants [HORIZONS flyer for waiting room V1.0 20.04.2016]	1.0	20 April 2016
Covering letter on headed paper [HORIZONS 202342 REC cover letter]	1.0	12 May 2016
Covering letter on headed paper [HORIZONS 202342 REC 16.NW.0425 response cover letter]	1.0	17 June 2016
Covering letter on headed paper		18 July 2016
Evidence of Sponsor insurance or indemnity (non NHS Sponsors only) [HORIZONS Indemnity Statement UoS 10.05.2016]	1.0	10 May 2016
GP/consultant information sheets or letters [HORIZONS - GP letter V1.0 20.04.2016]	1.0	20 April 2016
IRAS Application Form [IRAS_Form_12052016]		12 May 2016
IRAS Application Form XML file [IRAS_Form_12052016]		12 May 2016
IRAS Checklist XML [Checklist_17052016]		17 May 2016
Letter from funder [HORIZONS funding confirmation letter]	1.0	10 March 2016
Letter from sponsor [UHS Sponsorship letter - 31-03-2016]	1.0	31 March 2016
Letters of invitation to participant [HORIZONS - Patient Invitation Letter V1.0 20.04.2016]	1.0	20 April 2016
Notice of Substantial Amendment (non-CTIMP)	1	19 July 2016
Other [baseline questionnaire BREAST]	1	07 July 2016
Other [baseline questionnaire GYNAE]	1	07 July 2016
Other [baseline questionnaire Pilot]	1	07 July 2016
Other [HORIZONS phase 2 sites]	1	18 July 2016
Other [HORIZONS flyer for pt pack V1.0 20.04.2016]	1.0	20 April 2016
Other [HORIZONS - Participant Contact details sheet V1.0 20.04.2016]	1.0	20 April 2016
Other [HORIZONS - Baseline Reminder letter V1.0 20.04.2016]	1.0	20 April 2016
Other [HORIZONS - Follow up questionnaire letter V1.0 20.04.2016]	1.0	20 April 2016
Other [HORIZONS - Post treatment questionnaire Reminder letter V1.0 20.04.2016]	1.0	20 April 2016
Other [HORIZONS - Missing page letter V1.0 20.04.2016]	1.0	20 April 2016
Other [HORIZONS - Withdrawal cover letter V1.0 20.04.2016]	1.0	20 April 2016
Other [HORIZONS - Withdrawal Form V1.0 20.04.2016]	1.0	20 April 2016
Other [HORIZONS - Demographics reduced consent V1.0 20.04.2016]	1.0	20 April 2016
Other [HORIZONS - Demographics decliners V1.0 20.04.2016]	1.0	20 April 2016
Other [HORIZONS 202342 no-material-ethical-issues-tool]	1.0	12 May 2016
Other [HORIZONS 202342 REC questionnaire cover letter]	1.0	13 May 2016
Other [PPI review of consent timings]	1.0	11 April 2016
Participant consent form [HORIZONS - Consent Form V1.0 20.04.2016]	1.0	20 April 2016

Participant information sheet (PIS) [Tracked]	1.1	05 July 2016
Participant information sheet (PIS) [Clean]	1.1	05 July 2016
Research protocol or project proposal [HORIZONS Protocol V1.0 050516_202342_FINAL]	1.0	05 May 2016
Summary CV for Chief Investigator (CI) [Professor Claire Foster short CV 040416]	1.0	04 April 2016

Appendix B - Summary of HRA Assessment

This appendix provides assurance to you, the sponsor and the NHS in England that the study, as reviewed for HRA Approval, is compliant with relevant standards. It also provides information and clarification, where appropriate, to participating NHS organisations in England to assist in assessing and arranging capacity and capability.

For information on how the sponsor should be working with participating NHS organisations in England, please refer to the, *participating NHS organisations*, *capacity and capability* and *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* sections in this appendix.

The following person is the sponsor contact for the purpose of addressing participating organisation questions relating to the study:

Becci Patch (Tel: 02380 596885 horizons@soton.ac.uk)

HRA assessment criteria

Section	HRA Assessment Criteria	Compliant with Standards	Comments
1.1	IRAS application completed correctly	Yes	The applicant has confirmed that IRAS [A36] is incorrect and visual/audio recordings will not be used in this study.
2.1	Participant information/consent documents and consent process	Yes	No Comments.
3.1	Protocol assessment	Yes	No Comments.
4.1	Allocation of responsibilities and rights are agreed and documented	Yes	The statement of activities and the schedule of events will act as the agreement between the sponsor and participating NHS organisations in England. The sponsor has confirmed no other agreement will be used.
4.2	Insurance/indemnity arrangements assessed	Yes	Where applicable, independent contractors (e.g. General Practitioners) should ensure that the professional indemnity provided by their medical defence organisation covers the

Section	HRA Assessment Criteria	Compliant with Standards	Comments
			activities expected of them for this research study.
4.3	Financial arrangements assessed	Yes	The study is funded by Macmillan Cancer Support. The sponsor has confirmed that funding will not be provided to participating NHS organisations.
5.1	Compliance with the Data Protection Act and data security issues assessed	Yes	No Comments.
5.2	CTIMPS – Arrangements for compliance with the Clinical Trials Regulations assessed	Not Applicable	No Comments.
5.3	Compliance with any applicable laws or regulations	Not Applicable	No Comments.
6.1	NHS Research Ethics Committee favourable opinion received for applicable studies	Yes	REC Favourable Opinion was issued on 20 June 2016. A substantial amendment was submitted to the REC to bring the study in line with HRA Standards. REC Favourable opinion for the substantial amendment was issued by the REC on 27 July 2016.
6.2	CTIMPS – Clinical Trials Authorisation (CTA) letter received	Not Applicable	No Comments.
6.3	Devices – MHRA notice of no objection received	Not Applicable	No Comments.
6.4	Other regulatory approvals and authorisations received	Not Applicable	No Comments.

Participating NHS Organisations in England

This provides detail on the types of participating NHS organisations in the study and a statement as to whether the activities at all organisations are the same or different.
There is one site type participating in this study. Study activity is the same at all participating NHS organisations. A statement of activities and schedule of events will act as the agreement for participating NHS organisation in England. The sponsor has confirmed that no other agreement will be used. The Chief Investigator or sponsor should share relevant study documents with participating NHS organisations in England in order to put arrangements in place to deliver the study. The documents should be sent to both the local study team, where applicable, and the office providing the research management function at the participating organisation. For NIHR CRN Portfolio studies, the Local LCRN contact should also be copied into this correspondence. For further guidance on working with participating NHS organisations please see the HRA website. If chief investigators, sponsors or principal investigators are asked to complete site level forms for participating NHS organisations in England which are not provided in IRAS or on the HRA website, the chief investigator, sponsor or principal investigator should notify the HRA immediately at hra.approval@nhs.net. The HRA will work with these organisations to achieve a consistent approach to information provision.

Confirmation of Capacity and Capability

This describes whether formal confirmation of capacity and capability is expected from participating NHS organisations in England.
Participating NHS organisations in England that are **will be expected to formally confirm their capacity and capability to host this research**. • Following issue of this letter, participating NHS organisations in England may now confirm to the sponsor their capacity and capability to host this research, when ready to do so. How capacity and capacity will be confirmed is detailed in the *Allocation of responsibilities and rights are agreed and documented (4.1 of HRA assessment criteria)* section of this appendix. • The Assessing, Arranging, and Confirming document on the HRA website provides further information for the sponsor and NHS organisations on assessing, arranging and confirming capacity and capability.

Principal Investigator Suitability

This confirms whether the sponsor position on whether a PI, LC or neither should be in place is correct for each type of participating NHS organisation in England and the minimum expectations for education, training and experience that PIs should meet (where applicable).
The sponsor has confirmed that a Local Principal Investigator would be required at each participating NHS organisation and these have already been identified. Training - The sponsor has confirmed that training will be delivered both through study launch days and site invitation visits.

The sponsor has further confirmed that study launch days will involve all sites, and that all members of the research team may attend however it is expected that at least one member of the team attends.

GCP training is not a generic training expectation, in line with the HRA statement on training expectations.

HR Good Practice Resource Pack Expectations

This confirms the HR Good Practice Resource Pack expectations for the study and the pre-engagement checks that should and should not be undertaken
The sponsor has confirmed that local staff will be undertaking all research activities at sites and access arrangements are therefore not required in this case.

Other Information to Aid Study Set-up

This details any other information that may be helpful to sponsors and participating NHS organisations in England to aid study set-up.
• The applicant has indicated that they intend to apply for inclusion on the NIHR CRN Portfolio. • Please note the final list of documentation does not match with the final list of REC approved documentation. This is due to the submission of a substantial amendment in order to bring the study in line with HRA Standards.