Health Research Authority
North West - Lancaster Research Ethics Committee
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Telephone: 020 71048008

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

20 June 2016

Professor Claire Foster
Professor of Psychosocial Oncology & Director of Macmillan Survivorship Research Group
University of Southampton
Faculty of Health Sciences, Building 67
Highfield Campus, University of Southampton
University Raod, Southampton
SO17 1BJ

Dear Professor Foster

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

Thank you for responding to the Proportionate Review Sub-Committee's request for changes to the documentation for the above study.

The revised documentation has been reviewed and approved by the sub-committee.

We plan to publish your research summary wording for the above study on the HRA website, together with your contact details. Publication will be no earlier than three months from the date of this favourable opinion letter. The expectation is that this information will be published for all studies that receive an ethical opinion but should you wish to provide a substitute contact point, wish to make a request to defer, or require further information, please contact the REC Manager Mrs Carol Ebenezer, nrescommittee.northwest-lancaster@nhs.net. Under very limited circumstances (e.g. for student research which has received an unfavourable opinion), it may be possible to grant an exemption to the publication of the study.

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.

Conditions of the favourable opinion

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

Management permission must be obtained from each host organisation prior to the start of the study at the site concerned.

Management permission 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 Approval (England)/ NHS permission for research is available in the Integrated Research Application System, www.hra.nhs.uk or at http://www.rdforum.nhs.uk.

Where a NHS organisation's role in the study is limited to identifying and referring potential participants to research sites ("participant identification centre"), guidance should be sought from the R&D office on the information it requires to give permission for this activity.

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 clinical trials (defined as the first four categories on the IRAS filter page) must be registered on a publically accessible database. This should be before the first participant is recruited but no later than 6 weeks after recruitment of the first participant.

There is no requirement to separately notify the REC but you should do so at the earliest opportunity e.g. when submitting an amendment. We will audit the registration details as part of the annual progress reporting process.

To ensure transparency in research, we strongly recommend that all research is registered but for non-clinical trials this is not currently mandatory.

If a sponsor wishes to request a deferral for study registration within the required timeframe, they should contact hra.studyregistration@nhs.net. The expectation is that all clinical trials will be registered, however, in exceptional circumstances non registration may be permissible with prior agreement from the HRA. Guidance on where to register is provided on the HRA website.

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).

Ethical review of research sites

The favourable opinion applies to all NHS sites taking part in the study, subject to management

permission being obtained from the NHS/HSC R&D office prior to the start of the study (see "Conditions of the favourable opinion" above).

Approved documents

The documents reviewed and approved by the Committee are:

Document	*Version*	*Date*
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
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
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 Invitiation Letter V1.0 20.04.2016]	1.0	20 April 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 [000 - Questionnaire Contents]	1.0	13 May 2016
Other [A01 - Front & Back Cover Text]	1.0	13 May 2016
Other [B01 - Demographic questions]	1.0	13 May 2016
Other [C01 - Smoking Self-assessment]	1.0	13 May 2016
Other [C02 - Alcohol intake Self-assessment]	1.0	13 May 2016
Other [C03 - Godin Leisure-Time Exercise]	1.0	13 May 2016
Other [C04 - Resistance Exercise Measure]	1.0	13 May 2016
Other [C05 - Fruit and Vegetables Screening Log]	1.0	13 May 2016
Other [D01 - EuroQoL EQ-5D-5L & Visual Scale]	1.0	13 May 2016
Other [D02 - Quality of Life in Adult Cancer Survivors (QLACS) Pt1]	1.0	13 May 2016
Other [D03 - Personal Well-being Index (PWI)]	1.0	13 May 2016
Other [E01 - EORTC QLQ-C30]	1.0	13 May 2016

Other [E02B - EORTC QLQ-BR23]	1.0	13 May 2016
Other [E02GC - EORTC QLQ-CX24]	1.0	13 May 2016
Other [E02GE - EORTC QLQ-EN24]	1.0	13 May 2016
Other [E02GO - EORTC QLQ-OV28]	1.0	13 May 2016
Other [E02NHL - EORTC QLQ-NHL-HG29]	1.0	13 May 2016
Other [E03 - Body Image Scale]	1.0	13 May 2016
Other [E04 - Hospital Anxiety and Depression Scale (HADS)]	1.0	13 May 2016
Other [F01 - Health Education Impact Questionnaire (heiQ)]	1.0	13 May 2016
Other [G01 - Health Literacy]	1.0	13 May 2016
Other [G02 - Self-Efficacy for Managing Chronic Disease (LORIG)]	1.0	13 May 2016
Other [G03 - Connor-Davidson Resilience Scale (CD-RISC2)]	1.0	13 May 2016
Other [G04 - Spirituality Questions]	1.0	13 May 2016
Other [H01 - Medical Outcomes Study (MOS)]	1.0	13 May 2016
Other [H02 - Your Social Network (Adapted UCNET)]	1.0	13 May 2016
Other [I01 - Life Events & Open ended question]	1.0	13 May 2016
Other [J01 - Participant feedback questions]	1.0	13 May 2016
Other [PPI review of consent timings]	1.0	17 June 2016
Other [C01b - eCigarette additional questions]	1.0	17 June 2016
Other [B01 - Demographic questions v2.0 (clean format)]	2.0	17 June 2016
Participant consent form [HORIZONS - Consent Form V1.0 20.04.2016]	1.0	20 April 2016
Participant information sheet (PIS) [HORIZONS - PIS V1.0 20.04.2016]	1.0	20 April 2016
Research protocol or project proposal [HORIZONS Protocol V1.0 050516_202342_FINAL]	1.0	05 May 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

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.

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

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

Feedback

You are invited to give your view of the service that you have received from the National Research Ethics Service 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

We are pleased to welcome researchers and R & D staff at our NRES committee members' training days – see details at http://www.hra.nhs.uk/hra-training/

16/NW/0425	**Please quote this number on all correspondence**

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

Yours sincerely

pp.

Dr Lisa Booth
Chair

Email: nrescommittee.northwest-lancaster@nhs.net

Enclosures: *"After ethical review – guidance for researchers"*

Copy to: *Miss Becci Petch*

Mrs Sharon Davies-Dear, University Hospital Southampton NHS Foundation Trust