



Health Research Authority

North West - Lancaster Research Ethics Committee

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27 July 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 Road, 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
Amendment number: 1
Amendment date: 19 July 2016
IRAS project ID: 202342

Submission of the pilot phase baseline questionnaire.
HRA approval amendments.
Addition of 16 sites in September/October.

The above amendment was reviewed by the Sub-Committee in correspondence.

Ethical opinion

The members of the Committee taking part in the review gave a favourable ethical opinion of the amendment on the basis described in the notice of amendment form and supporting documentation.

The members had no ethical issues with this amendment.

Approved documents

The documents reviewed and approved at the meeting were:

<i>Document</i>	<i>Version</i>	<i>Date</i>
Covering letter on headed paper		18 July 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
Participant information sheet (PIS) [Clean]	1.1	05 July 2016

Membership of the Committee

The members of the Committee who took part in the review are listed on the attached sheet.

R&D approval

All investigators and research collaborators in the NHS should notify the R&D office for the relevant NHS care organisation of this amendment and check whether it affects R&D approval of the research.

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.

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
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Yours sincerely



Dr Lisa Booth
Chair

E-mail: nrescommittee.northwest-lancaster@nhs.net

Enclosures: List of names and professions of members who took part in the review

*Copy to: Mrs Sharon Davies-Dear, University Hospital Southampton NHS Foundation Trust
Miss Becci Petch*

North West - Lancaster Research Ethics Committee**Attendance at Sub-Committee of the REC meeting on 27 July 2016****Committee Members:**

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Dr Lisa Booth	Senior Lecturer / Chair	Yes	
Professor Jois Stansfield	Professor of Speech Pathology	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Mrs Carol Ebenezer	REC Manager