

North West – Preston (formerly Lancaster) Research Ethics Committee

Barlow House
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Tel: 020 71048008

Please note: This is the favourable opinion of the REC only and does not allow the amendment to be implemented at NHS sites in England until the outcome of the HRA assessment has been confirmed.

12 December 2017 amended

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: 6
Amendment date: 27 November 2017
IRAS project ID: 202342

Staff changes, change to inclusion and exclusion criteria, rewording of and new patient facing documents, questionnaires, additional site.

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		04 December 2017
Non-validated questionnaire [follow up on line questionnaire letter]	2	27 November 2017
Non-validated questionnaire [3 month questionnaire vulval]	1	18 October 2017
Non-validated questionnaire [12 month questionnaire vulval]	1	18 October 2017
Non-validated questionnaire [baseline questionnaire vulval]	1	18 October 2017
Notice of Substantial Amendment (non-CTIMP)	6	27 November 2017
Other [contents of vulval cancer questionnaires]	1	
Other [follow up questionnaire letter]	2	27 November 2017
Other [flyer for patient pack]	3	27 November 2017
Other [flyer for waiting room]	3	27 November 2017
Other [withdrawal form]	2	27 November 2017
Other [Newsletter issue 1]	1	23 November 2017
Participant consent form	3	27 November 2017
Research protocol or project proposal	4	27 November 2017

Membership of the Committee

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

Working with NHS Care Organisations

Sponsors should ensure that they notify the R&D office for the relevant NHS care organisation of this amendment in line with the terms detailed in the categorisation email issued by the lead nation for the study.

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 Research Ethics 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 Rob Monks
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
Mr Richard Brooks*

North West – Preson (formerly Lancaster) Research Ethics Committee
Attendance at Sub-Committee of the REC meeting on 12 December 2017

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Professor Carol Haigh	Professor of Nursing	Yes	
Dr Rob Monks	Principal Lecturer in Nursing, Research and Innovation Lead	Yes	

Also in attendance:

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