



Health Research Authority

North West - Preston Research Ethics Committee

Barlow House
3rd Floor
4 Minshull Street
Manchester
M1 3DZ

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.

01 December 2019

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: Amendment 11
Amendment date: 17 October 2019
IRAS project ID: 202342

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.

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		17 October 2019
Letters of invitation to participant [Follow up questionnaire letter - Clean]	v3.0	08 October 2019
Letters of invitation to participant [Follow up questionnaire letter - Tracked Changes]	v3.0	08 October 2019
Notice of Substantial Amendment (non-CTIMP)	Amendment 11	17 October 2019
Other [Email from UHSFT (sponsor)]	V1.0	10 October 2019
Other [GP Status Check Card]	v1.0	10 October 2019
Other [3-12 month Questionnaire Reminder Letter - Clean]	V4.0	08 October 2019
Other [3-12 month Questionnaire Reminder Letter - Tracked Changes]	V4.0	08 October 2019
Other [18 month onwards Questionnaire Reminder Letter - Clean]	v4.0	08 October 2019
Other [18 month onwards Questionnaire Reminder Letter - Tracked Changes]	v4.0	08 October 2019
Other [Patient Study newsletter]	v1.0	10 October 2019
Other [PPI Comments on flyer wording and status checks]	v1.0	10 October 2019
Other [PPI comments on questionnaire reminder frequency]	v1.0	10 October 2019
Other [No status check available information flyer (clean)]	v1.1	29 November 2019
Other [No status check available information flyer (TC)]	v1.1	29 November 2019
Research protocol or project proposal [Protocol - Clean]	V6.0	10 October 2019
Research protocol or project proposal [Protocol - Tracked Changes]	v6.0	10 October 2019

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.

HRA Learning

We are pleased to welcome researchers and research staff to our HRA Learning Events and online learning opportunities– see details at: <https://www.hra.nhs.uk/planning-and-improving-research/learning/>

16/NW/0425:

Please quote this number on all correspondence

Yours sincerely

A handwritten signature in black ink that reads "Mark Thompson". The signature is written in a cursive style and is centered within a light gray rectangular box.

**On behalf of Dr. Karen Rouse
Vice-Chair**

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

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

Copy to: Mr Richard Brooks

North West - Preston Research Ethics Committee

Attendance at Sub-Committee of the REC meeting on 15 November 2019

Committee Members:

<i>Name</i>	<i>Profession</i>	<i>Present</i>	<i>Notes</i>
Professor Carol Haigh	Professor of Nursing	Yes	
Dr Karen Rouse (Vice-Chair)	Principal Lecturer, Postgraduate Programmes	Yes	

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Mark Thompson	Approvals Officer