



# Health Research Authority

## North West – Preston Research Ethics Committee

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

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.**

30 June 2017

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

|                          |  |
|--------------------------|--|
| <b>Study title:</b>      | <b>HORIZONS: a cohort study to explore recovery of health and well-being in adults diagnosed with cancer</b> |
| <b>REC reference:</b>    | <b>16/NW/0425</b>  |
| <b>Protocol number:</b>  | <b>RHM CAN1199</b>   |
| <b>Amendment number:</b> | <b>5</b>   |
| <b>Amendment date:</b>   | <b>23 June 2017</b>  |
| <b>IRAS project ID:</b>  | <b>202342</b>  |

Changes to protocol

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>  |
|--|----------------|--------------|
| Copies of advertisement materials for research participants [flyer for patient pack] | 2              | 19 June 2017 |
| Copies of advertisement materials for research participants [flyer for waiting room] | 2              | 19 June 2017 |
| Covering letter on headed paper  |                | 29 June 2017 |
| GP/consultant information sheets or letters  | 2              | 19 June 2017 |
| Letters of invitation to participant   | 2              | 19 June 2017 |
| Non-validated questionnaire [12 month Breast]  | 1              | 12 June 2017 |
| Non-validated questionnaire [12 month cervical]                                      | 1              | 12 June 2017 |
| Non-validated questionnaire [12 month endometrial]                                   | 1              | 12 June 2017 |
| Non-validated questionnaire [12 month NHL]   | 1              | 12 June 2017 |
| Non-validated questionnaire [12 month ovarian]                                       | 1              | 12 June 2017 |
| Notice of Substantial Amendment (non-CTIMP)  | 5              | 23 June 2017 |
| Other [contents of HORIZONS 12 month questionnaires]                                 |                |              |
| Other [follow up on line questionnaire letter]                                       | 1              | 19 June 2017 |
| Other [Participant Letter Reduced Consent]   | 1              | 19 June 2017 |
| Other [Decliners log]  | 1              | 19 June 2017 |
| Other [Participant Letter Questionnaire Timepoints]                                  | 1              | 19 June 2017 |
| Participant consent form [full]  | 2              | 19 June 2017 |
| Participant information sheet (PIS)  | 2              | 19 June 2017 |
| Research protocol or project proposal  | 3              | 19 June 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/>

|  |
|--|
| <b>16/NW/0425:</b> <b>Please quote this number on all correspondence</b> |
|--|

Yours sincerely

  
pp.

**Dr Rob Monks**  
**Chair**

E-mail: [nrescommittee.northwest-lancaster@nhs.net](mailto: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*

**North West - Lancaster Research Ethics Committee****Attendance at Sub-Committee of the REC meeting on 30 June 2017****Committee Members:**

| <i>Name</i>           | <i>Profession</i> | <i>Present</i> | <i>Notes</i> |
|-----------------------|-------------------|----------------|--------------|
| Professor Carol Haigh |                   | Yes            |              |
| Dr Rob Monks          | Senior Lecturer   | Yes            |              |

**Also in attendance:**

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