

North West - Preston Research Ethics Committee

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03 September 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
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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:	10
Amendment date:	12 July 2019
IRAS project ID:	202342

The above amendment was reviewed at the meeting of the Sub-Committee held on 31 July 2019.

Summary

The amendment proposes the submission of the questionnaires to be sent to HORIZONS participants at the 36 month, 48 month and 60 month follow-up time points. The amendment also includes an amended Reply Slip for participants who would like to take part in an interview as part of the qualitative phase of the HORIZONS study.

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 [HORIZONS 202342 REC 16 NW 0425 SA10 cover letter]		26 July 2019
Notice of Substantial Amendment (non-CTIMP) [Amendment Form]	10	12 July 2019
Other [Contents of HORIZONS 202342 Annual Assessment Qs]		27 June 2019
Other [HORIZONS 202342 annual assessment Cervical]	1.0	27 June 2019
Other [HORIZONS 202342 annual assessment Endometrial]	1.0	27 June 2019
Other [HORIZONS 202342 annual assessment NHL]	1.0	27 June 2019
Other [HORIZONS 202342 annual assessment Ovarian]	1.0	27 June 2019
Other [HORIZONS 202342 annual assessment Vulval]	1.0	27 June 2019
Other [HORIZONS Qualitative Reply Slip-Clean]	2.0	09 July 2019
Other [HORIZONS Qualitative Reply Slip-Tracked Changes]	2.0	09 July 2019
Validated questionnaire [HORIZONS 202342 annual assessment Breast]	1.0	27 June 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
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Yours sincerely



**Signed on behalf of;
Professor Karen Wright
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 31 July 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	Principal Lecturer, Postgraduate Programmes	Yes	Vice Chair

Also in attendance:

<i>Name</i>	<i>Position (or reason for attending)</i>
Miss Nafeesa Khanam	Approvals Administrator
Miss Damilola Odunlami	Approvals Officer