

Partner Organisations:

Health Research Authority, England
 NHS Research Scotland
 HSC Research & Development, Public Health Agency, Northern Ireland

NIHR Clinical Research Network, England
 NISCHR Permissions Co-ordinating Unit, Wales

Notification of Non-Substantial/Minor Amendments(s) for NHS Studies

This template **must only** be used to notify NHS/HSC R&D office(s) of amendments, which are **NOT** categorised as Substantial Amendments.

If you need to notify a Substantial Amendment to your study then you MUST use the appropriate Substantial Amendment form in IRAS.

Instructions for using this template

- For guidance on amendments refer to <http://www.hra.nhs.uk/research-community/during-your-research-project/amendments/>
- This template should be completed by the CI and optionally authorised by Sponsor, if required by sponsor guidelines.
- This form should be submitted according to the instructions provided for NHS/HSC R&D at <http://www.hra.nhs.uk/research-community/during-your-research-project/amendments/which-review-bodies-need-to-approve-or-be-notified-of-which-types-of-amendments/> . If you do not submit your notification in accordance with these instructions then processing of your submission may be significantly delayed.

1. Study Information

Full title of study:	HORIZONS: a cohort study to explore recovery of health and well-being in adults diagnosed with cancer
IRAS Project ID:	202342
Sponsor Amendment Notification number:	Non-substantial Amendment 16
Sponsor Amendment Notification date:	18/01/2019
Details of Chief Investigator:	
Name [first name and surname]	Professor Claire Foster
Address:	University of Southampton Facility of Health Sciences, Building 67, Highfield Campus, University Road, Southampton
Postcode:	SO17 1BJ
Contact telephone number:	02380 594 006
Email address:	C.L.Foster@soton.ac.uk
Details of Lead Sponsor:	
Name:	Mrs Sharon Davies-Dear
Contact email address:	Sharon.davies-dear@uhs.nhs.uk
Details of Lead Nation:	
Name of lead nation <i>delete as appropriate</i>	England
If England led is the study going through CSP? <i>delete as appropriate</i>	Yes
Name of lead R&D office:	University Hospitals Southampton NHS Foundation Trust

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2. Summary of amendment(s)

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No.	Brief description of amendment <i>(please enter each separate amendment in a new row)</i>	Amendment applies to <i>(delete/ list as appropriate)</i>		List relevant supporting document(s), including version numbers <i>(please ensure all referenced supporting documents are submitted with this form)</i>	R&D category of amendment <i>(category A, B, C)</i> <i>For office use only</i>
		Nation	Sites		
1	Change of PI at James Paget University Foundation NHS Trust – Wendy Harrison	England	James Paget University Foundation NHS Trust	IRAS Form – Non SA 16	1.0
2	Change of PI at Gateshead Health NHS FT – Lynsey Robson	England	Gateshead Health NHS FT	IRAS Form – Non SA 16	1.0
3	Change of recruitment end date from 31 st of August 2019 to 31 st of March 2019	England	All sites	IRAS Form – Non SA 16	1.0
		Northern Ireland	All sites		
		Scotland	All sites		
		Wales	All sites		

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3. Declaration(s)

Declaration by Chief Investigator

- I confirm that the information in this form is accurate to the best of my knowledge and I take full responsibility for it.
- I consider that it would be reasonable for the proposed amendment(s) to be implemented.

Signature of Chief Investigator: 

Print name: Claire Foster.....


Date: 18 January 2019.....

Optional Declaration by the Sponsor's Representative (as per Sponsor Guidelines)

The sponsor of an approved study is responsible for all amendments made during its conduct.

The person authorising the declaration should be authorised to do so. There is no requirement for a particular level of seniority; the sponsor's rules on delegated authority should be adhered to.

- I confirm the sponsor's support for the amendment(s) in this notification.

Signature of sponsor's representative: 

Print name: Sarah Davies-Deer.....

Post: Clinical Trials Project manager.....

Organisation: University Hospital Southampton NHS Foundation Trust.....

Date: 21 January 2019.....

