Partner Organisations:

Health Research Authority, England NHS Research Scotland

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

HSC Research & Development, Public Health Agency, Northern Ireland

# 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 <a href="http://www.hra.nhs.uk/research-community/during-your-research-project/amendments/">http://www.hra.nhs.uk/research-community/during-your-research-project/amendments/</a>
- 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 <a href="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/">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/</a>. 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 2
Sponsor Amendment Notification date:	05/06/2017
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 delete as appropriate	England
If England led is the study going through CSP? delete as appropriate	Yes
Name of lead R&D office:	University Hospitals Southampton NHS Foundation Trust

# Partner Organisations:

NISCHR Permissions HSC Research & Development, Public Health Agency, Northern Ireland Health Research Authority, England

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

2. Summary of amendment(s)

# 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.

o N	No. Brief description of amendment (please enter each separate amendment in a new row)	Amendme (delete/ list as	Amendment applies to (delete/ list as appropriate)	List relevant supporting document(s), including version numbers (please ensure all referenced supporting documents are	ent(s), cuments are	R&D category of amendment (category A, B, C)
		Nation	Sites	Submitted with this form) Document	Version	For office use only
_	Addition of a further site to participant in the	Wales	University	HORIZONS IRAS Form 202342	_	
11	HORIZONS study.		Hospital of	Non SA 2 additional sites.pdf		
			Wales			*)
7						
3						
4						
2						
	[Add further rows as required]					

[Add further rows as required]

Partner Organisations:

Health Research Authority, England NHS Research Scotland

**Declaration by Chief Investigator** 

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

HSC Research & Development, Public Health Agency, Northern Ireland

## 3. Declaration(s)

•	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: CLARE FOSTER

Date: 6 JUNE 2017

# 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: SHAROW DAVIES-DEAR

Post: Research coordinate.

Organisation University Hospital Southernpton of Foundation

Date: 7 June 2617