

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 11 |
| Sponsor Amendment Notification date: | 03/05/2018 |
| 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 | Document | Version | |
| 1 | Addition of Royal Cornwall Hospitals NHS Trust as a recruiting site | England | Royal Cornwall Hospitals NHS Trust | IRAS Form – Non SA 11 | 1.0 | |
| 2 | Following a trust merger a previously recorded site's name and PI has been updated - Manchester University NHS Foundation Trust PI - Simon Watt | England | Manchester University NHS Foundation Trust | IRAS Form – Non SA 11 | 1.0 | |

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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: CLARKE.....

Print name: CLARKE FOSTER

Date: 3/5/18.....

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: [Signature].....

Print name: Sharon SCODDS-DEE

Post: Research Coordinator

Organisation: University Hospital Southampton NHS Foundation Trust

Date: 8 May 2018.....