Welcome to the Integrated Research Application System

IRAS Project Filter

The integrated dataset required for your project will be created from the answers you give to the following questions. The system will generate only those questions and sections which (a) apply to your study type and (b) are required by the bodies reviewing your study. Please ensure you answer all the questions before proceeding with your applications.

Please complete the questions in order. If you change the response to a question, please select 'Save' and review all the questions as your change may have affected subsequent questions.

Please enter a short title for this project (maximum 70 characters)
HORIZONS: Understanding the impact of cancer diagnosis and treatment

1. Is your project research?

(●) Yes ( ) No

2. Select one category from the list below:

( ) Clinical trial of an investigational medicinal product

( ) Clinical investigation or other study of a medical device

( ) Combined trial of an investigational medicinal product and an investigational medical device

( ) Other clinical trial to study a novel intervention or randomised clinical trial to compare interventions in clinical practice

( ) Basic science study involving procedures with human participants

(●) Study administering questionnaires/interviews for quantitative analysis, or using mixed quantitative/qualitative methodology

( ) Study involving qualitative methods only

( ) Study limited to working with human tissue samples (or other human biological samples) and data (specific project only)

( ) Study limited to working with data (specific project only)

( ) Research tissue bank

( ) Research database

If your work does not fit any of these categories, select the option below:

( ) Other study

2a. Please answer the following question(s):

a) Does the study involve the use of any ionising radiation?	( ) Yes	(●) No
b) Will you be taking new human tissue samples (or other human biological samples)?	( ) Yes	(●) No
c) Will you be using existing human tissue samples (or other human biological samples)?	( ) Yes	(●) No

3. In which countries of the UK will the research sites be located? *(Tick all that apply)*

☑ England
☑ Scotland

☐ Wales
☐ Northern Ireland

3a. In which country of the UK will the lead NHS R&D office be located:

◉ England
○ Scotland
○ Wales
○ Northern Ireland
○ This study does not involve the NHS

4. Which applications do you require?

☑ IRAS Form
☐ Confidentiality Advisory Group (CAG)
☐ Her Majesty's Prison and Probation Service (HMPPS)

Most research projects require review by a REC within the UK Health Departments' Research Ethics Service. Is your study exempt from REC review?

○ Yes ◉ No

5. Will any research sites in this study be NHS organisations?

◉ Yes ○ No

5a. Are all the research costs and infrastructure costs (funding for the support and facilities needed to carry out research e.g. NHS Support costs) for this study provided by a NIHR Biomedical Research Centre, NIHR Collaboration for Leadership in Health Research and Care (CLAHRC), NIHR Patient Safety Translational Research Centre or Medtech and In Vitro Diagnostic Cooperative in all study sites?

Please see information button for further details.

○ Yes ◉ No

Please see information button for further details.

5b. Do you wish to make an application for the study to be considered for NIHR Clinical Research Network (CRN) Support and inclusion in the NIHR Clinical Research Network Portfolio?

Please see information button for further details.

◉ Yes ○ No

The NIHR Clinical Research Network provides researchers with the practical support they need to make clinical studies happen in the NHS e.g. by providing access to the people and facilities needed to carry out research "on the ground".

If you select yes to this question, you must complete a NIHR Clinical Research Network (CRN) Portfolio Application Form (PAF) immediately after completing this project filter question and before submitting other applications. Failing to complete the PAF ahead of other applications e.g. HRA Approval, may mean that you will be unable to access NIHR CRN Support for your study.

6. Do you plan to include any participants who are children?

○ Yes ◉ No

7. Do you plan at any stage of the project to undertake intrusive research involving adults lacking capacity to consent for themselves?

○ Yes ◉ No

Answer Yes if you plan to recruit living participants aged 16 or over who lack capacity, or to retain them in the study following loss of capacity. Intrusive research means any research with the living requiring consent in law. This includes use of identifiable tissue samples or personal information, except where application is being made to the Confidentiality Advisory Group to set aside the common law duty of confidentiality in England and Wales. Please consult the guidance notes for further information on the legal frameworks for research involving adults lacking capacity in the UK.

8. Do you plan to include any participants who are prisoners or young offenders in the custody of HM Prison Service or who are offenders supervised by the probation service in England or Wales?

○ Yes ◉ No

9. Is the study or any part of it being undertaken as an educational project?

○ Yes ◉ No

10. Will this research be financially supported by the United States Department of Health and Human Services or any of its divisions, agencies or programs?

○ Yes ◉ No

11. Will identifiable patient data be accessed outside the care team without prior consent at any stage of the project (including identification of potential participants)?

○ Yes ◉ No

NOTICE OF SUBSTANTIAL AMENDMENT

Please use this form to notify the main REC of substantial amendments to all research other than clinical trials of investigational medicinal products (CTIMPs).
The form should be completed by the Chief Investigator using language comprehensible to a lay person.

Details of Chief Investigator:

	Title	Forename/Initials	Surname
	Professor	Claire	Foster
Work Address	Faculty of Health Sciences, Building 67		
	Highfield Campus, University of Southampton		
	University Raod, Southampton		
PostCode	SO17 1BJ		
Email	C.L.Foster@soton.ac.uk		
Telephone	02380 594006		
Fax			

For guidance on this section of the form refer to the guidance

Full title of study:	HORIZONS: a cohort study to explore recovery of health and well-being in adults diagnosed with cancer
Lead sponsor:	University Hospital Southampton NHS Foundation Trust
Name of REC:	North West - Lancaster Research Ethics Committee
REC reference number:	16/NW/0425

Additional reference number(s):

Ref.Number Description	Reference Number

Name of lead R&D office:	University Hospital Southampton NHS Foundation Trust
Date study commenced:	29/07/2016
Protocol reference (if applicable), current version and date:	Version 5.1 21/01/2019
Amendment number and date:	10 12/07/2019

Type of amendment

(a) Amendment to information previously given in IRAS

○ Yes ◉ No

If yes, please refer to relevant sections of IRAS in the "summary of changes" below.

(b) Amendment to the protocol

○ Yes ◉ No

If yes, please submit either the revised protocol with a new version number and date, highlighting changes in bold, or a document listing the changes and giving both the previous and revised text.

(c) Amendment to the information sheet(s) and consent form(s) for participants, or to any other supporting documentation for the study

◉ Yes ○ No

If yes, please submit all revised documents with new version numbers and dates, highlighting new text in bold.

Is this a modified version of an amendment previously notified and not approved?

○ Yes ◉ No

Summary of changes

Briefly summarise the main changes proposed in this amendment. Explain the purpose of the changes and their significance for the study.
If this is a modified amendment, please explain how the modifications address the concerns raised previously by the ethics committee.
If the amendment significantly alters the research design or methodology, or could otherwise affect the scientific value of the study, supporting scientific information should be given (or enclosed separately). Indicate whether or not additional scientific critique has been obtained.

1. Follow-up questionnaires

We submit for review the questionnaires to be sent to HORIZONS participants at the 36 month, 48 month and 60 month follow-up time points. The content of the questionnaires will remain the same for each time point. There are separate questionnaires for participants in each of the HORIZONS cancer cohorts/sub-cohorts:
• Breast
• Cervical
• Endometrial
• NHL • Ovarian
• Vulval

A contents page summarising the validated measures included in these questionnaires is also included. All measures have been psychometrically validated.

Please note that, on the front page of each questionnaire, '<Number>' in grey will be replaced with the word or figures denoting the time point at which that questionnaire is sent, as shown in the table below:

Sixth Questionnaire: 36 month follow-up
Seventh Questionnaire: 48 month follow-up
Eighth Questionnaire: 60 month follow-up

Please also note that these questionnaires include both of the following measures:
• Health Education Impact Questionnaire (heiQ)
• Patient Activation Measure (PAM)

One or both of these measures will be included in the final, printed/online questionnaires.

2. Minor change to the Reply Slip for qualitative interviewees

We also submit for review 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.

The Reply Slip has been changed so that, as well as asking the participant for the best way to contact them, we will now also ask the participant for the best time to contact them.

We are making this change based on our experience of using the original version of the Reply Slip. We often find it difficult to get through to interested participants by telephone. We believe that it will be easier to do this if they can let us know when they are likely to be available. We also feel it will be in participants' best interest to have control over choosing the best time for us to contact them.

3. Implications of the amendment for participating NHS recruiting sites

The changes included in this substantial amendment will not affect the participating NHS sites that recruited HORIZONS participants.

Follow-up questionnaires and interview Reply Slips are sent directly to participants by the HORIZONS Coordinating Centre at the University of Southampton. Completed questionnaires and Reply Slips are sent directly back to the HORIZONS Coordinating Centre at the University of Southampton by participants.

Any other relevant information

Applicants may indicate any specific issues relating to the amendment, on which the opinion of a reviewing body is sought.

List of enclosed documents

Document	*Version*	*Date*
Contents of HORIZONS 202342 Annual Assessment Qs 27-06-2019	1	27/06/2019
HORIZONS 202342 annual assessment Q v1.0 Breast 27-06-2019	1	27/06/2019
HORIZONS 202342 annual assessment Q v1.0 Cervical 27-06-2019	1	27/06/2019
HORIZONS 202342 annual assessment Q v1.0 Endometrial 27-06-2019	1	27/06/2019
HORIZONS 202342 annual assessment Q v1.0 NHL 27-06-2019	1	27/06/2019
HORIZONS 202342 annual assessment Q v1.0 Ovarian 27-06-2019	1	27/06/2019
HORIZONS 202342 annual assessment Q v1.0 Vulval 27-06-2019	1	27/06/2019
HORIZONS Qualitative Reply Slip v2.0 09.07.2019 Clean	2	09/07/2019
HORIZONS Qualitative Reply Slip v2.0 09.07.2019 with tracked	2	09/07/2019

Declaration by Chief Investigator

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

This section was signed electronically by Professor Claire Foster on 24/07/2019 15:09.

Job Title/Post:	Director of MSRG and Professor of Psychological Oncology
Organisation:	University of Southampton, Faculty of Health Sciences
Email:	C.L.Foster@soton.ac.uk

Declaration by the sponsor's representative

I confirm the sponsor's support for this substantial amendment.

This section was signed electronically by Mrs Sharon Davies-Dear on 26/07/2019 15:20.

Job Title/Post:	Clinical Trials Project Manager
Organisation:	University Hospital Southampton NHS Foundation Trust
Email:	sharon.davies-dear@uhs.nhs.uk