

## 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?**

*IMPORTANT: If your project is taking place in the NHS and is led from England select 'IRAS Form'. If your project is led from Northern Ireland, Scotland or Wales select 'NHS/HSC Research and Development Offices' and/or relevant Research Ethics Committee applications, as appropriate.*

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

*For NHS/HSC R&D Offices in Northern Ireland, Scotland and Wales the CI must create NHS/HSC Site Specific Information forms, for each site, in addition to the study wide forms, and transfer them to the PIs or local collaborators.*

*For participating NHS organisations in England different arrangements apply for the provision of site specific information. Refer to IRAS Help for more information.*

**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 Biomedical Research Unit, NIHR Collaboration for Leadership in Health Research and Care (CLAHRC), NIHR Patient Safety Translational Research Centre or a Diagnostic Evidence Co-operative 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 Road, Southampton		
PostCode	SO17 1BJ		
Email	C.L.Foster@soton.ac.uk		
Telephone	02380 594006		
Fax	023 8059 7967		

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

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

**Additional reference number(s):**

Ref.Number	Description	Reference Number

<b>Name of lead R&amp;D office:</b>	University Hospital Southampton NHS Foundation Trust
<b>Date study commenced:</b>	29.07.2016
<b>Protocol reference (if applicable), current version and date:</b>	4.0 27.11.2017
<b>Amendment number and date:</b>	7 - 12.02.2018

**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.*

The 18 month breast, NHL, endometrial, ovarian, cervical and vulval time point questionnaires are submitted for review, along with a contents page of measures selected.

This change will not affect the recruiting sites as all follow up questionnaires are sent by the coordinating centre.

**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**

<i>Document</i>	<i>Version</i>	<i>Date</i>
HORIZONS 202342 18 month Questionnaire Breast V1.0 09.02.2018	1.0	09/02/2018
HORIZONS 202342 18 month Questionnaire NHL V1.0 09.02.2018	1.0	09/02/2018
HORIZONS 202342 18 month Questionnaire Ovarian V1.0 09.02.2018	1.0	09/02/2018
HORIZONS 202342 18 month Questionnaire Endometrial V1.0 09.02.2018	1.0	09/02/2018
HORIZONS 202342 18 month Questionnaire Cervical V1.0 09.02.2018	1.0	09/02/2018
HORIZONS 202342 18 month Questionnaire Vulval V1.0 09.02.2018	1.0	09/02/2018
Contents of HORIZONS 18 month Breast, NHL, Endometrial, Cervical, Ovarian and Vulval Questionnaires	1.0	09/02/2018

**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 12/02/2018 11:13.

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 13/02/2018 08:59.

Job Title/Post: Research Coordinator

Organisation: University Hospital Southampton NHS Foundation Trust

Email: sharon.davies-dear@uhs.nhs.uk