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)*

[x] England
[x] 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)
☐ National Offender Management Service (NOMS) (Prisons & Probation)

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 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:	2.0 21/12/2016
Amendment number and date:	3 21/12/2016

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.

A22. What are the potential risks and burdens for research participants and how will you minimise them?
A36. Will you be undertaking any of the following activities at any stage (including in the identification of potential participants)?
A38. How will you ensure the confidentiality of personal data?

Answers to A22, A36 and A38 reference “Participant contact details will be transferred by sites to the Coordinating Centre by secure means such as safe haven fax”, the answers are to be updated to include the option for this transfer to be safe haven fax or nhs.net to nhs.net email.

A5-1. Research reference numbers
Project website: www.HORIZONS-HUB.ac.uk
This is now http://www.horizons-hub.org.uk/

(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.

Protocol version v2.0 (21/12/2016) clean and tracked changes

(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.

Consent form v1.0 (21/12/2016) full consent (tracked changes on original combined full and reduced consent form, and clean version of the separate full consent)
Consent form v1.0 (21/12/2016) reduced consent
Contact details form v1.1 (21/12/2016) changes highlighted

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.

Protocol amendments;
Administrative updates have been made to reflect the present or past tense of initial processes and applications.
The inclusion and exclusion criteria for the three cohorts; breast cancer, gynaecological cancer and non-Hodgkin lymphoma have been clarified given advice from the Tumour Specific Expert Panels for their respective cohorts. In particular the gynaecological criteria are now separated in to ovarian, endometrial and cervical. The eligible patients meet the same criteria as those recruited to date but the clarification is provided to sites for their recruitment.
Throughout the protocol references to the Advisory group structure and study staff have been updated to reflect current status of these members
The reference to the short form questionnaire at baseline has been removed as this will not be an option at this timepoint. Given the importance of understanding all relevant factors at baseline in order to understand change over time these need to be captured at this timepoint in full.
Reference to the research data management system, Edge, has been removed as this will no longer be used by the HORIZONS Coordinating Centre. Participating sites may use the system in line with their Trust policy but the HORIZONS Coordinating Centre will not have access to data on this platform.
Supporting documents:
Participants who offer reduced consent in the pilot phase have been asked to complete certain points of the full consent form and there have been some inconsistencies with this. Therefore, under this amendment, we introduce a

reduced consent form and the protocol is update to reflect separate reduced consent form process for reduced consent participants
A separate reduced consent form is to be used for participants offering reduced consent. This is a new document and the full consent form is amended to remove the reference to the reduced consent option.
The contact details form has been update to include GP telephone and fax numbers.
The original application was for the pilot sites. The HORIZONS Coordinating Centre have selected the NHS Secondary Care sites to participate in the full HORIZONS study from those that expressed interest. In line with the protocol the sites selected offer a geographical spread and population diversity across the UK.
Update to data transfer information in IRAS:
Some sites governance offices, particularly in the devolved nations have indicated they do not consider faxing patient details confidential and have requested to transfer these via nhs.net to nhs.net email accounts. The HORIZONS Coordinating Centre have set up an nhs.net account for these purposes. Therefore, references to “Participant contact details will be transferred by sites to the Coordinating Centre by secure means such as safe haven fax” in the IRAS form should be updated to include the option for this transfer to be safe haven fax or nhs.net to nhs.net email.

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*
HORIZONS Protocol V2.0 211216_202342 clean	2.0	21/12/2016
HORIZONS Protocol V2.0 211216_202342 tracked changes	2.0	21/12/2016
HORIZONS - Full Consent Form V1.0 21.12.2016 TC	1.0	21/12/2016
HORIZONS - Full Consent Form V1.0 21.12.2016	1.0	21/12/2016
HORIZONS - Reduced Consent Form V1.0 21.12.2016	1.0	21/12/2016
HORIZONS - Participant Contact details sheet V2.0 21.12.2016	2.0	21/12/2016
HORIZONS 202342 REC 16 NW 0425 SA3 cover letter	1.0	21/12/2016

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 21/12/2016 10:20.

Job Title/Post:	Director Macmillan Survivorship Research Group
Organisation:	University of Southampton
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 22/12/2016 10:28.

Job Title/Post:	Research Governance Officer
Organisation:	University Hospital Southampton NHS Foundation Trust
Email:	sharon.davies-dear@uhs.nhs.uk