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	02380597951		

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:	5 23/06/2017

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.

A6-2 Summary of main issues - Reduced consent option and completion of demographic forms no longer an option
Section A13 Please summarise your design and methodology – changes to the questionnaire time points.
Section A17-1 Please list the principal inclusion criteria. – Removal of reduced consent wording.
Section A18 Give details of all non-clinical intervention(s) or procedure(s) that will be received by participants as part of the research protocol. – changes to the questionnaire time points.

(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 v3.0 (19/06/2017) 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.

HORIZONS - Participant Letter Questionnaire Timepoints V1.0 19.06.2017.docx
HORIZONS - Participant Letter Reduced Consent V1.0 19.06.2017.docx
HORIZONS - Follow up online questionnaire letter V1.0 09.06.2017.docx
HORIZONS - PIS V2.0 19.06.2017.docx
HORIZONS - PIS V2.0 19.06.2017 tracked.docx
HORIZONS - Patient Invitation Letter V2.0 19.06.2017.docx
HORIZONS - Patient Invitation Letter V2.0 19.06.2017 tracked.docx
HORIZONS - GP Letter V2.0 19.06.2017.docx
HORIZONS - GP Letter V2.0 19.06.2017 tracked.docx
HORIZONS Flyer for waiting room V2.0 19.06.2017 clean.pptx
HORIZONS Flyer for patient pack V2.0 19.06.2017 clean.pptx
HORIZONS Flyer for waiting room V2.0 19.06.2017 tracked.pptx
HORIZONS - Participant Letter Questionnaire Timepoints V1.0 19.06.2017.docx
HORIZONS - Participant Letter Reduced Consent V1.0 19.06.2017.docx
HORIZONS - Follow up online questionnaire letter V1.0 09.06.2017.docx
HORIZONS - PIS V2.0 19.06.2017.docx
HORIZONS - PIS V2.0 19.06.2017 Tracked Changes.docx
HORIZONS - Patient Invitation Letter V2.0 19.06.2017.docx
HORIZONS - Patient Invitation Letter V2.0 19.06.2017 Tracked Changes.docx
HORIZONS - GP Letter V2.0 19.06.2017.docx
HORIZONS - GP Letter V2.0 19.06.2017 Tracked Changes.docx
HORIZONS Flyer for waiting room V2.0 19.06.2017 Clean.pptx
HORIZONS Flyer for patient pack V2.0 19.06.2017 Clean.pptx
HORIZONS Flyer for waiting room V2.0 19.06.2017 Tracked Changes.pptx
HORIZONS Flyer for patient pack V2.0 19.06.2017 Tracked Changes.pptx
HORIZONS 202342 12 Month Questionnaire Breast V1.0 12.06.2017
HORIZONS 202342 12 Month Questionnaire NHL V1.0 12.06.2017
HORIZONS 202342 12 Month Questionnaire Cervical V1.0 12.06.2017
HORIZONS 202342 12 Month Questionnaire Endometrial V1.0 12.06.2017
HORIZONS 202342 12 Month Questionnaire Ovarian V1.0 12.06.2017

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.

Summary of main changes to the Protocol

• Changes to the Study Staff section of the Protocol, including the removal of Becci Petch, Trial Coordinator and Chris May, Patient and Public Involvement Lead, and the addition of Sophia Taylor, Senior Research Assistant, Nicole Tipler, Trial Administrator and Fabia Le Moignan, Trial Coordinator.
• Updated text within the Patient and Public Involvement (PPI) and User Reference Group (URG) sections of the Protocol.
• Removal of any reference to the pilot phase from the Protocol. The pilot phase of the study is now finished.
• Removal of any reference to the reduced consent option and the decliners' demographics forms from the Protocol. Following review of these study options by the HORIZONS Programme Management Group, they will no longer be offered to participants.
• Inclusion of a demographic anonymous aggregate log for sites to complete periodically. This will replace the decliners' demographics form, which is being removed from the study (as mentioned in the previous point)
• Restructuring of the questionnaire time points from baseline, 3 months, 9 months, 12 months, 15 months, 24 months then annually to baseline, 3 months, 12 months and 18 months, 24 months and then annually. This follows a review of the questionnaire time points by the HORIZONS Programme Management Group.

Summary of main changes to the supporting documents

• Changes to the wording regarding questionnaire time points and the removal of references to reduced consent and the decliners' demographic forms from the Patient Information Sheet, full consent form, GP letter and patient invitation letter.
• Rewording of the HORIZONS patient pack and waiting room flyers: "uterine" has been changed to "endometrial".
• Creation of a letter including instructions on how to complete the online follow-up questionnaires for patients who do not wish to supply an email address.
• Creation of a patient letter for reduced consent participants, to explain the removal of this consent option and their withdrawal from the study. This letter is for sites to send to participants who gave reduced consent.
• The creation of a patient letter for full consent patients, to explain the restructure of the questionnaire time points.
• The 12-month time point questionnaire is submitted for review, along with a contents page of measures selected.

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 V3.0 19.06.2017 Clean	3.0	19/06/2017
HORIZONS Protocol V3.0 19.06.2017 Tracked Changes	3.0	19/06/2017
HORIZONS - PIS V2.0 19.06.2017	2.0	19/06/2017
HORIZONS - PIS V2.0 19.06.2017 Tracked Changes	2.0	19/06/2017
HORIZONS - Full Consent V2.0 19.06.2017	2.0	19/06/2017
HORIZONS - Full Consent V2.0 19.06.2017 Tracked Changes	2.0	19/06/2017
HORIZONS - Patient Invitation letter V2.0 19.06.2017	2.0	19/06/2017
HORIZONS - Patient Invitation letter V2.0 19.06.2017 Tracked Changes	2.0	19/06/2017
HORIZONS - Participant Letter Questionnaire Timepoints V1.0 19.06.2017	1.0	19/06/2017
HORIZONS - Participant Letter Reduced Consent V1.0 19.06.2017	1.0	19/06/2017
HORIZONS - Follow up online questionnaire letter V1.0 09.06.2017	1.0	09/06/2017
HORIZONS - GP Letter V2.0 19.06.2017	2.0	19/06/2017

HORIZONS - GP Letter V2.0 19.06.2017 Tracked Changes	2.0	19/06/2017
HORIZONS Flyer for waiting room V2.0 19.06.2017 Clean	2.0	19/06/2017
HORIZONS Flyer for waiting room V2.0 19.06.2017 Tracked changes	2.0	19/06/2017
HORIZONS Flyer for patient pack V2.0 19.06.2017 Clean	2.0	19/06/2017
HORIZONS Flyer for patient pack V2.0 19.06.2017 Tracked Changes	2.0	19/06/2017
HORIZONS 202342 12 Month Questionnaire Breast V1.0 12.6.2017	1.0	12/06/2017
HORIZONS 202342 12 Month Questionnaire NHL V1.0 12.06.2017	1.0	12/06/2017
HORIZONS 202342 12 Month Questionnaire Cervical V1.0 12.06.2017	1.0	12/06/2017
HORIZONS 202342 12 Month Questionnaire Endometrial V1.0 12.06.2017	1.0	12/06/2017
HORIZONS 202342 12 Month Questionnaire Ovarian V1.0 12.06.2017	1.0	12/06/2017

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 23/06/2017 13:02.

Job Title/Post:	Director of MSRG and Professor of Psychological Oncology
Organisation:	University of Southampton, Faculty of Health Sciences
Email:	

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 26/06/2017 10:27.

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