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?

☑ 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:	11 17/10/2019

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.

Section A18: The original IRAS form states that we will wait 2 weeks after sending a questionnaire at a follow up time point before sending a duplicate questionnaire. We have found that, in practice, 2 weeks is not enough time for patients to receive and complete our questionnaires. We propose changing the time interval to 3 weeks.

(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.

Revised protocol (version 6, 10/10/2019) submitted, clean and tracked versions

(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.

Revised documents
HORIZONS - Follow up questionnaire letter V3.0 2019-10-08 (clean and tracked versions)
HORIZONS 3-12 Month Post Treatment Questionnaire Reminder Letter V4.0 2019-10-08 (clean and tracked versions)
HORIZONS 18 Month Onwards Post Treatment Questionnaire Reminder Letter V4.0 2019-10-08 (clean and tracked versions)
New documents
GP Status Check Card V1.0 10-10-2019
HORIZONS - No status check available information flyer V1.0 2019-10-10
HORIZONS Patient Newsletter Issue 2 V1.0 2019-10-10
Non-study documents providing evidence to support this amendment
Email from UHSFT (sponsor)V1.0 2019-10-10
PPI Comments on flyer wording and status checks V1.0 2019-10-10
PPI comments on questionnaire reminder frequency V1.0 2019-10-10

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. Brief summary of the main changes proposed
1.1 Changes to the protocol
I. The names of staff involved in the HORIZONS study have been updated [pages 8-13]
II. The name, roles and responsibilities of the HORIZONS Data Monitoring Committee have been updated [pp 19, 53]
a) The Data Monitoring Committee (DMC) is now called the Data Sharing Panel (DSP)
b) The roles of the DSP will not include monitoring recruitment progress and data quality or advising on data handling, which were roles of the DMC
III. The process of sending follow-up questionnaires to HORIZONS participants has been changed
a) Before a follow-up questionnaire is sent, recruiting hospitals will be asked to check whether a participant is alive and living at the same address but not whether there have been any changes, such as a change in a participant's mental capacity, which would make it inappropriate to send a questionnaire [flow diagram on p 28]
b) If a recruiting hospital is unable to confirm that a participant is alive and living at the same address, despite their best efforts to obtain this information, a follow-up questionnaire will be sent to that participant together with a

flyer/notice explaining that a status check was not possible [p 43 – please see rationale below]
IV. The process of sending duplicate questionnaires and reminders to participants from whom no questionnaire has been received has been changed. Instead of sending participants a follow-up questionnaire, then a reminder letter, then a second/duplicate questionnaire, we will send the follow-up questionnaire, then a reminder letter and duplicate questionnaire together [flow diagram on p 28 and p 49]

1.2 Changes to the supporting documents
I. A flyer/card to be sent to the GP practices of HORIZONS participants has been produced. This is to alert GP practices to the fact that staff from hospitals who recruited HORIZONS participants may be in contact with them to ask whether those participants are alive and living at the same address. NB Patients have already consented for their GP to be informed of their involvement in HORIZONS
II. A flyer/notice to be sent to HORIZONS participants for whom the study team have been unable to get a status update check prior to sending a follow up questionnaire has been produced. The flyer/notice will be sent with the follow up questionnaire. It states that, although every effort to check that the patient is alive and living at the same address has been made, it has not been possible on this occasion. To enable the patient to continue participating in HORIZONS, the follow up questionnaire is being sent even though no status update was possible
III. The letters sent to participants with follow-up questionnaires have been changed. The letters make it clearer that only one questionnaire should be completed at each time point; if a participant has completed a questionnaire but received a duplicate (sent by the HORIZONS study team in case the original was lost), that duplicate should be ignored

2. Rationale for changes to the protocol III a) and III b)
We currently check with our recruiting hospitals whether HORIZONS participants are alive, living at the same address and that it is appropriate to send them a questionnaire (for example, there have not had any changes in mental capacity) before we send any follow-up questionnaires. However, we are finding two problems with this system. Firstly, staff in our recruiting hospitals are often unable to provide us with information about participants' mental capacity etc., so we want to stop asking them this question. Secondly, as time passes, participants whose treatment finished many months ago are likely to have been discharged from the hospital where they were recruited. Staff in our recruiting hospitals are, therefore, unable to give us up to date information on the health status and address of participants who have not attended hospital recently. We do not want participants who have consented to take part in HORIZONS to be denied the opportunity to complete a questionnaire just because they have not had a recent hospital appointment. However, where possible, we want to avoid sending questionnaires to patients who have died or to a wrong address if they have moved.
In our original IRAS application, approved in 2016, we stated that status checks with recruiting hospitals would be made by the HORIZONS team before sending questionnaires to participants. We will continue to do this. However, with increasing time since treatment, it may not be possible for hospitals to give us an up to date status check. For example, if the patient pathway changes and a patient is discharged, the recruiting hospital will no longer have access to up to date information about that patient. In these cases, we have proposed a strategy that recruiting hospitals should follow to check with patients' GPs and with other hospitals involved in patients' care. However, if, after trying all available options for checking a patient's status, it is still not possible to find out if a patient is alive and living at the same address, the HORIZONS study team in Southampton will send the questionnaire to the participant together with a flyer/notice explaining that we have made every effort to check their status but on this occasion have not been able to do so.

In summary, in order to ensure HORIZONS participants who have consented to take part in the study are not denied the opportunity to take part at the follow-up time points, we propose the following strategy:
1. Alert participants' GP practices to the fact that HORIZONS recruiting hospitals may contact them to ask for participant status checks
2. When hospital staff do not have up to date information for a participant and the participant has not been transferred to another hospital, ask them to contact the participant's GP practice to check the participant's status
3. When hospital staff know that a participant has been transferred to another hospital, ask them to contact that hospital to check the participant's status
4. If no answer is given by the participant's GP practice or the transferred to hospital, the HORIZONS study team in Southampton will send the questionnaire to the participant together with a flyer/notice explaining that we have made every effort to check their status but on this occasion have not been able to do so.

3. Supporting documents for changes to the protocol and supporting documents
a) Changes to the protocol 1.1.III b): We sought the views of our User Reference Group and our Sponsor Representative on these proposed changes. Please see documents:
PPI Comments on flyer wording and status checks.pdf
Email from UHSFT (sponsor).pdf
b) Changes to the protocol 1.1.IV: We sought the views of our User Reference Group on how many reminders/duplicates questionnaires we should send at each follow-up time point. Please see documents
PPI comments on questionnaire reminder frequency.pdf

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*
GP Status Check Card	1.0	10/10/2019
HORIZONS - Follow up questionnaire letter [clean]	3.0	08/10/2019
HORIZONS - Follow up questionnaire letter [tracked]	3.0	08/10/2019
HORIZONS - No status check available information flyer	1.0	10/10/2019
HORIZONS - 3-12 Month Post Treatment Questionnaire Reminder Letter [clean]	4.0	08/10/2019
HORIZONS - 3-12 Month Post Treatment Questionnaire Reminder Letter [tracked]	4.0	08/10/2019
HORIZONS - 18 Month Onwards Post Treatment Questionnaire Reminder Letter [clean]	4.0	08/10/2019
HORIZONS - 18 Month Onwards Post Treatment Questionnaire Reminder Letter [tracked]	4.0	08/10/2019
HORIZONS Patient Newsletter Issue 2	1.0	10/10/2019
HORIZONS Protocol [clean]	6.0	10/10/2019
HORIZONS Protocol [tracked]	6.0	10/10/2019
Email from UHSFT (sponsor)	1.0	10/10/2019
PPI Comments on flyer wording and status checks	1.0	10/10/2019
PPI comments on questionnaire reminder frequency	1.0	10/10/2019

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 18/10/2019 16:44.

Job Title/Post:	Director of MSRG and Professor of Psychosocial Oncology
Organisation:	University of Southampton, School of Health Sciences
Email:	clf1@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 21/10/2019 08:58.

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