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:	5.1 21.01.2019
Amendment number and date:	9 21.01.2019

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.

A4. Who is the contact on behalf of the sponsor for all correspondence relating to applications for this project?
This should now be:
Dr Rebecca Foster
School of Health Sciences
University of Southampton
SO17 1BJ
023 8059 6885

A5-1. Research reference numbers
Protocol version = 5.1
Protocol date = 21.01.2019

(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.

HORIZONS Protocol V5.1 21.01.2019 (document submitted)

Summary of changes to the Protocol
1. Updates to names of Study Staff
2. Removal of any references to a short version of the HORIZONS questionnaire
3. Removal of the NOMAD tool as a proposed questionnaire measure
4. Change in the number of recruiting centres from 50 to 78
5. Changes to reflect the introduction of the General Data Protection Regulations
6. Addition of Appendix 11.5 containing the protocol for the qualitative phase of the HORIZONS study. Addition of Appendix 11.6 containing the interview schedule for the qualitative phase of the HORIZONS study.
7. MODIFICATION OF AMENDMENT 9 – Removed reference to use of a decliner form, section 5.5, page 70

(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.

1. HORIZONS 3-12 Month Post Treatment Questionnaire Reminder Letter v3.0 16.10.2018 (clean and tracked)
2. HORIZONS 18 Month Onwards Post Treatment Questionnaire Reminder Letter v3.0 16.10.2018 (clean and tracked)
3. HORIZONS Baseline Reminder Letter V2.0 20.08.2018 (clean and tracked)
4. HORIZONS Data Protection Statement V1.0 30.11.2018 (clean)
5. HORIZONS Flyer for Online Completion of Questionnaires v2.0 16.10.2018 (clean and tracked)
6. HORIZONS Follow up online questionnaire letter no email V1.0 16.10.2018 (clean)
7. HORIZONS Follow up Online Questionnaire Letter V3.0 16.10.2018 (clean and tracked)
8. HORIZONS Full Consent Form v4.0 29.11.2018 (clean and tracked)
9. HORIZONS Notice about Data Protection Statement v1.0 19.10.2018 (clean)
10. HORIZONS Online Questionnaire Nonresponse Reminder Letter V1.0 20.08.2018 (clean)
11. HORIZONS Online Questionnaire Partial Completion Letter v1.0 20.08.2018 (clean)
12. HORIZONS Participant Contact Details Sheet V3.0 21.11.2018 (clean and tracked)
13. HORIZONS PIS v3.0 30.11.2018 (clean and tracked)
14. HORIZONS Qualitative Consent Form V1.0 12.09.2018 (clean)
15. HORIZONS Qualitative Letter Introducing Sociogram v1.0 12.09.2018 (clean)
16. HORIZONS Qualitative Patient Invitation Letter V1.1 18.01.2010 (clean and tracked)
17. HORIZONS Qualitative PIS V1.1 21.01.2019 (clean and tracked)
18. HORIZONS Qualitative Reply Slip v1.0 12.09.2018 (clean)
19. HORIZONS Qualitative Sociogram Instructions v1.0 12.09.2018 (clean)
20. HORIZONS Recruitment Update Flyer for Waiting Room v1.0 20.08.2018 (clean)
21. HORIZONS Site Thank You Card v1.0 03.09.2018 (clean)
22. HORIZONS Your Answers Matter Postcard v6.0 03.09.2018 (clean)

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.

Changes to the protocol:
1. Updates to names of HORIZONS study staff
2. Removal of any references to a short version of the HORIZONS questionnaire
3. Removal of the NOMAD tool as a proposed questionnaire measure
4. Change of the number of recruiting centres from 50 to 78
5. Changes to reflect the introduction of the General Data Protection Regulations
6. Addition of Appendix 11.5 containing the protocol for the qualitative phase of the HORIZONS study. Addition of Appendix 11.6 containing the interview schedule for the qualitative phase of the HORIZONS study.
7. MODIFICATION OF AMENDMENT 9 - Reference to the use of a Decliner Form removed from the protocol: Section 5.5, page 70

Summary of main changes to the supporting documents
• Removal of the reference to a short version of the questionnaire. This includes removal of the term in the protocol, baseline reminder letter and post treatment questionnaire reminder letter. A shorter version of the questionnaire was used in another study conducted by the research group. It was decided that this option would not be used in this study due to low return rates and implications for statistical analysis.
• Creation of a follow-up letter for participants who opt to complete online questionnaires but do not provide an email address to the co-ordinating centre. The mailed letter describes how to access the online questionnaires and requests participants to contact the co-ordinating centre to update email details.
• Creation of a reminder email/letter to online questionnaire participants who have not responded and therefore are being sent a paper duplicate. This letter includes details of how to access the online questionnaires and informs them that our previous email may have been sent to their spam folder instead of their main inbox
• Creation of a reminder email/letter to online questionnaire participants who have partially completed an online questionnaire to prompt them to complete the questionnaire. It also informs participants that data from the partially completed questionnaire are saved into our database and can still be used as part of the study
• Changes to the follow-up letter for online questionnaire completion and the flyer promoting the online questionnaires. They inform participants that data from the partially completed questionnaire are saved into our database and can still be used as part of the study
• Changes to the follow up patient letters from 18 month time point onwards. They inform participants of a change in questionnaire layout. Essential measures have been moved to the front of the questionnaires and patients are encouraged to complete as many questions as possible.
• Changes to improve the clarity of the consent form and the PIS. These are based on the new GDPR requirements. They also cover returned forms and site feedback.
• Changes to improve the clarity of the participant contact details sheet. It is now clear that a postcode is required as part of a participants' address. It is also now clear that we are asking for an email address to allow a participant to receive online questionnaires should they wish to do so
• Inclusion of a Data Protection Statement for the HORIZONS study, which will be made available on the study website.
• The creation of a letter to patients already participating in HORIZONS sign-posting them to the Data Protection Statement
• The creation of a patient postcard and patient waiting room flyer to boost retention of participants at questionnaire follow up points. They update patients about the HORIZONS study and emphasise that all data are useful.
• The creation of a site thank you card to boost retention of participants at questionnaire follow up points by updating HORIZONS sites about study progress overall and at a site level
• A protocol for the qualitative phase of HORIZONS is submitted for review. The qualitative work will help to answer the original research questions proposed by the study. The qualitative work was mentioned in the original IRAS application and protocol. The protocol for the qualitative work is included in V5.0 of the HORIZONS study protocol as Appendix 11.5. The interview schedule for the qualitative work is included in V5.0 of the HORIZONS study protocol as Appendix 11.6. Other patient facing documents related to the qualitative work are as follows:
o Consent Form
o Decliner Form
o Letter Introducing Sociogram
o Patient Invitation Letter
o PIS
o Reply Slip

o Sociogram Instructions

• MODIFICATION OF AMENDMENT 9; 21/01/2019
o Removal of HORIZONS Qualitative Decliner Form v1.0 12.09.2018
o Removal of reference to use of a Decliner Form in:
o HORIZONS Qualitative Patient Invitation Letter V1.1 18.01.2019
o HORIZONS Qualitative PIS V1.1 21.01.2019

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 3-12 Month Post Treatment Questionnaire Reminder Letter V3.0 16.10.2018.pdf	3	16/10/2018
HORIZONS 3-12 Month Post Treatment Questionnaire Reminder Letter V3.0 16.10.2018 TRACKED.pdf	3	16/10/2018
HORIZONS 18 Month Onwards Post Treatment Questionnaire Reminder Letter V3.0 16.10.2018.pdf	3	16/10/2018
HORIZONS 18 Month Onwards Post Treatment Questionnaire Reminder Letter V3.0 16.10.2018 TRACKED.pdf	3	16/10/2018
HORIZONS Baseline Reminder Letter V2.0 20.08.2018.pdf	2	20/08/2018
HORIZONS Baseline Reminder Letter V2.0 20.08.2018 TRACKED.pdf	2	20/08/2018
HORIZONS Data Protection Statement v1.0 30.11.2018.pdf	1	30/11/2018
HORIZONS Flyer for Online Completion of Questionnaires v2.0 16.10.2018.pdf	2	16/10/2018
HORIZONS Flyer for Online Completion of Questionnaires v2.0 16.10.2018 TRACKED.pdf	2	16/10/2018
HORIZONS Follow up online questionnaire letter no email V1.0 16.10.2018.pdf	1	16/10/2018
HORIZONS Follow up Online Questionnaire Letter V3.0 16.10.2018.pdf	3	16/10/2018
HORIZONS Follow up Online Questionnaire Letter V3.0 16.10.2018 TRACKED.pdf	3	16/10/2018
HORIZONS Full Consent Form V4.0 29.11.2018.pdf	4	29/11/2018
HORIZONS Full Consent Form V4.0 29.11.2018 TRACKED.pdf	4	29/11/2018
HORIZONS Notice About Data Protection Statement v1.0 19.10.2018.pdf	1	19/10/2018
HORIZONS Online Questionnaire Nonresponse Reminder Letter V1.0 20.08.2018.pdf	1	20/08/2018
HORIZONS Online Questionnaire Partial Completion Letter V1.0 20.08.2018.pdf	1	20/08/2018
HORIZONS Participant Contact Details Sheet V3.0 21.11.2018.pdf	3	21/11/2018
HORIZONS Participant Contact Details Sheet V3.0 21.11.2018 TRACKED	3	21/11/2018

HORIZONS PIS v3.0 30.11.2018.pdf	3	30/11/2018
HORIZONS PIS v3.0 30.11.2018 TRACKED.pdf	3	30/11/2018
HORIZONS Protocol V5.1 21.01.2019.pdf	5.1	21/01/2019
HORIZONS Protocol V5.1 21.01.2019 TRACKED.pdf	5.1	21/01/2019
HORIZONS Qualitative Consent Form V1.0 12.09.2018 .pdf	1	12/09/2018
HORIZONS Qualitative Decliner Form V1.0 12.09.2018.pdf	1	12/09/2018
HORIZONS Qualitative Letter Introducing Sociogram V1.0 12.09.2018.pdf	1	12/09/2018
HORIZONS Qualitative Patient Invitation Letter V1.1 18.01.2019	1.1	18/01/2019
HORIZONS Qualitative Patient Invitation Letter V1.1 18.01.2019 TRACKED	1.1	18/01/2019
HORIZONS Qualitative PIS V1.1 21.01.2019	1.1	21/01/2019
HORIZONS Qualitative PIS V1.1 21.01.2019 TRACKED	1.1	21/01/2019
HORIZONS Qualitative Reply Slip V1.0 12.09.2018.pdf	1	12/09/2018
HORIZONS Qualitative Sociogram Instructions V1.0 12.09.2018.pdf	1	12/09/2018
HORIZONS Recruitment Update Flyer for Waiting Room V1.0 20.08.2018.pdf	1	20/08/2018
HORIZONS Site Thank You Card V1.0 03.09.2018.pdf	1	03/09/2018
HORIZONS Your Answers Matter Postcard V6.0 03.09.2018.pdf	6	03/09/2018

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 22/01/2019 16:42.

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 23/01/2019 08:57.

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