

# HORIZONS

Insert logos and  
letterhead here

Central Research Office Tel: 023 8059 6885

Chief Investigator: Professor Claire Foster; Tel: 023 8059 6885

Local Principal Investigator: *[insert name and contact telephone here]*

## Participant Information Sheet

### Macmillan HORIZONS Study: Understanding the impact of cancer diagnosis and treatment on everyday life

#### 1. We invite you to take part in a study

- We would like to invite you to take part in the Macmillan HORIZONS study. Before you decide we would like you to understand why the research is being done and what it would involve.
- The research nurse or member of your clinical team will go through the information sheet with you and answer any questions you have. This will take about 10 minutes. Please take the information sheet away with you and you can talk to your friends, family or GP about the study if you wish. Take time to make your decision.
- This study will follow a large group of patients over time who have had a diagnosis of cancer. **We will be asking participants to complete questionnaires to find out how people's health and well-being is after diagnosis and treatment.**
- We understand that this invitation comes at a time when you have a lot to deal with already, but we need to find out how you are before your treatment, so that we can find out how your health and well-being changes over time.

#### 2. Why are we doing this study?

- A growing number of people are living for many years after cancer treatment but we don't yet know all the ways to support them to ensure the best possible recovery.
- We will be recruiting approximately 3,000 patients over 3 years. Patients will have a diagnosis of either breast cancer who are under 50 years old, gynaecological cancer or non-Hodgkin lymphoma. Recruitment will take place prior to treatment from hospitals across the UK.
- We are interested in how a diagnosis of cancer and its treatment affects a person's life over time.
- Other studies collect data about people from their medical and hospital records, but we believe it is important to find out about your health and wellbeing from your perspective through your responses to questionnaires.
- Understanding what is important to people with cancer during their treatment and in the months and years afterwards will help inform support services in the future.

### 3. Why have I been asked to take part?

- You have been asked to take part in the study because you are awaiting treatment for either breast cancer, gynaecological cancer or non-Hodgkin lymphoma.

### 4. What would taking part involve?

- After you have read the information sheet and have had your questions answered, you will be asked whether you are happy to take part in the study.
- If you would like to take part you will be given a consent form to complete with the nurse or researcher and a questionnaire to fill in. You can complete the questionnaire during your hospital visit and hand it to the nurse or researcher or you can take it home to complete and return in the pre-paid envelope.
- You will be asked to fill in questionnaires before your treatment starts and then again in 3 months, 9 months, 12 months, 15 months and 2 years. After that point, you will be sent questionnaires once a year.
- You can complete the study questionnaires on paper or online. You will receive the first questionnaire on paper and the second one in the post to your home address and this will give you details of how to complete it online if you prefer. Pre-paid envelopes will be provided for return of paper questionnaires.
- If we do not receive your completed questionnaires within two weeks we will contact you to remind you. If we have not received your questionnaire after another two weeks, we will send you a new one.

- We would also like to ask your permission to gather information that is routinely collected about you by the NHS, such as your clinical and treatment details both through your medical records and national databases such as the Health and Social Care Information Centre and other central UK bodies.
- If you choose not to complete the study questionnaires, but would like to contribute to the study, you can give your permission for the research team to look at these routine medical details.
- You do not have to take part in this study and your clinical care will not be affected by your decision. If you decide to take part but change your mind in the future you can withdraw at any time.
- If you choose not to take part in the study you will be asked to provide some anonymous details on your background. This will be useful to the researchers in helping look at the patient population. You do not have to provide these details.

### 5. What are the possible benefits of taking part?

- We cannot promise that taking part in this study will help you personally. Some patients may find it helpful to think about issues related to their cancer. We hope that the information you provide in your questionnaires will help us understand people's experiences following diagnosis and treatment for cancer.

## 6. What are the possible disadvantages and risks of taking part?

- We do not anticipate that there will be any risks to you in taking part in the study, but if you have any concerns about your health as a result you should contact your doctor or nurse.
- Sometimes people find it difficult to talk or write about their experiences. We will be asking you about your emotional health, for example, how you are coping. You do not have to answer any questions that you do not want to.
- If you return a questionnaire with missing information, we will contact you just to check if this information has been missed by accident or not. We will only ask you for information that you are happy to give us.
- If you are finding any aspect of your experience difficult, we can also provide you with details of where you might get more support. For example: Maggie's Centres ([www.maggiescentres.org](http://www.maggiescentres.org)) or Macmillan Cancer Support ([www.macmillan.org.uk](http://www.macmillan.org.uk)). You may also want to talk to your GP or hospital clinical team if you have more specific questions.

## 7. What will happen if I don't want to carry on with the study?

- You are free to withdraw from the study at any time without giving a reason. A decision not to take part, or to withdraw at any time, will not affect the care you receive.

- You can withdraw by telephoning us on 023 8059 6885 – Monday to Friday 9:00 – 17:00 or by emailing [HORIZONS@soton.ac.uk](mailto:HORIZONS@soton.ac.uk). This will allow us to discuss your concerns with you and determine the level of withdrawal with you.

The options for withdrawal are;

- You may choose not to receive further questionnaires but are happy for us to use the answers you have given us so far and for us to continue to access your medical records

Or

- You may prefer for the researchers to no longer contact you or access your medical records in the future but use the information provided so far

Or

- You may prefer the researchers to no longer contact you or use the information collected previously

## 8. Will my taking part in this study be kept confidential?

- All information which is collected about you during the course of the research will be kept strictly confidential.
- We will ask you for your contact details so that the questionnaires can be posted out to you. These questionnaires will not have your name on. We will use a study ID number on questionnaires, which will not personally identify you.
- In the consent form we will ask if you are happy for us to use direct, anonymous, quotations from the questionnaires in any reports or publications we write. We will never use your name.

- We will also ask you in the consent form if the information collected in this research may be shared anonymously with other researchers to support research in the future. Before the data are shared, anything that identifies you personally will be removed.
- Any medical information about you which leaves your hospital will have your name and address removed so that you cannot be recognised. This anonymous medical data will be sent in the post from your hospital to the HORIZONS researchers at the University of Southampton.
- If you have agreed for us to collect routine NHS data this will be tracked using your NHS and hospital numbers, but your name will be removed so that it does not identify you.
- If you have agreed to answer the background questions for the study your answers are completely anonymous and do not include either your name or any other way of identifying you.
- All data stored at the University of Southampton will be kept in locked filing cabinets in a secure office, accessible only by the HORIZONS research team. The answers that you give in the questionnaires will be kept separately from your name and other identifiable information.
- The HORIZONS research team will send your anonymous answers to an approved external company for data entry.
- The HORIZONS research team will keep the study data securely for 10 years after the end of the study.

## 9. Involvement of your General Practitioner/ Family doctor (GP)

- We will inform your GP that you are taking part in this study, and may contact your GP before mailing out the follow up questionnaire in case your details have changed or you have moved.

## 10. What will happen to the results of this study?

- Details of the study and its progress can be found on the HORIZONS website: [www.HORIZONS-hub.org.uk](http://www.HORIZONS-hub.org.uk).
- To keep you updated throughout the study we will also send you newsletters by post or email
- You will be sent a short summary of the study findings, if you request this and a summary of the results will be made available on the HORIZONS website.
- During the study our funders, Macmillan Cancer Support, will receive reports of the study findings. The results of this study will be made available to all participating hospital specialists, will be published in health care journals and presented at national and international conferences.

## 11. Who is organising and funding the research?

- This research is being organised by the Faculty of Health Sciences, University of Southampton and University Hospitals Southampton NHS Foundation Trust.
- The research has been funded by Macmillan Cancer Support.
- The Chief Investigator for this study is Professor Claire Foster

