(To be printed on local hospital headed paper)

SPRUCE

A study of electronic versus paper healthcare questionnaire completion

PARTICIPANT INFORMATION SHEET

ICR The Institute of Cancer Research

CANCER RESEARCH UK

We are inviting you to take part in a research study called SPRUCE

- SPRUCE is a study which runs within an existing clinical trial that you have either already joined or are considering taking part in – this is called a 'host trial' in this information sheet.
- Before you decide if you would like to take part, it is important for you to understand why this research is being done and what happens if you decide to take part.
- Please take time to read the following information carefully. Discuss it with friends and relatives if you wish. Take time to decide if you would like to take part.
- You are free to decide if you want to take part in this research study. If you choose not to take part, this will not affect the standard of care you receive from your medical team in any way.
- You can decide to stop taking part in the study at any time without giving a reason.
- The following information is designed to be read in addition to discussions with your medical team. Ask your hospital SPRUCE study contact if anything is not clear or if you would like more information.

Thank you for reading this information and considering taking part in our research.

Contents

How to contact us

This study and all host trials are coordinated by the research centre at The Institute of Cancer Research Clinical Trials and Statistics Unit (ICR-CTSU).

If you have any questions about this research study, please talk to your hospital SPRUCE study contact or a member of the ICR-CTSU SPRUCE team. Their details are given on page 9 of the information sheet.

Part One

1 What is the SPRUCE study about?

What is the purpose of this study?

Within health care and clinical trials, questionnaires are used to collect information from patients about the impact that treatments and health conditions may be having upon their life. This information is known as patient reported outcomes, and is collected using quality of life questionnaires. These questionnaires can include general questions about mobility and tiredness, as well as more disease or treatment specific questions such as those about bowel movements or sexual function.

Traditionally, clinical trial participants complete these questionnaires on paper, either during clinic visits or at home. Questionnaires are then posted to the research team running the clinical trial for the information to be added to a database. Technology development means that it is now possible to offer trial participants the opportunity to complete these questionnaires electronically over the internet.

The Clinical Trials and Statistics Unit at the Institute of Cancer Research (ICR-CTSU) is considering introducing electronic questionnaires for its clinical trial participants. Before this is introduced routinely, we want to check whether electronic questionnaires are as reliable as paper questionnaires to collect information, and that participants are happy with their experience completing questionnaires electronically. This is the purpose of the SPRUCE study.

The results of this study will also be used as part of a PhD project looking at the collection of information on side effects of treatments in clinical trials.

You can find a summary of all of the questions we are hoping to answer within the study on page 10.

Why am I being invited to take part?

You are being invited to take part in the SPRUCE study because you have consented to take part in a clinical trial run by the ICR-CTSU which includes the completion of quality of life questionnaires. This trial will be referred to as a "host trial" in this information sheet. Approximately 350 people from around 20 UK hospitals who are taking part in a host trial will be invited to participate in SPRUCE.

Do I have to take part?

No, it is up to you to decide whether or not to take part in SPRUCE. Your participation is entirely voluntary and you will be given sufficient time to decide if you wish to participate. Whether or not you decide to take part will not affect the standard of care you receive. If you choose not to take part in SPRUCE you will still be able to complete paper quality of life questionnaires within the host trial you are participating in.

If you do agree to participate in SPRUCE, you are free to decide to end your participation at any time and you do not have to give a reason.

2 What happens if I decide to take part?

Everyone who agrees to take part in SPRUCE will have already completed their first questionnaire on paper, which was handed out by their hospital's medical team.

Everyone will then be included in one of two groups:

Group 1: Completion of paper questionnaire booklets

If you are in this group, you will continue to receive your questionnaires on paper. The questionnaire booklets will be sent directly to your home address by the ICR-CTSU. When completed, they will need to be posted back to ICR-CTSU in the postage paid envelope which will be provided (at no cost to you).

Example section of a paper questionnaire:*

13. How big a problem **during the last 4 weeks**, if any, has each of the following been for you?
(Circle one number on each line)

	No Problem	Very Small Problem	Small Problem	Moderate Problem	Big Problem
a. Hot flashes.....	0	(1)	2	3	4
b. Breast tenderness/enlargement..	(0)	1	2	3	4
c. Feeling depressed.....	0	(1)	2	3	4
d. Lack of energy.....	0	1	(2)	3	4
e. Change in body weight.....	(0)	1	2	3	4

Group 2: Completion of electronic questionnaires on a website

If you are in this group, you will be asked to complete the remaining questionnaires on a secure online website. You will receive an email to ask you to complete the questionnaires at the appropriate times using your own electronic device (e.g. laptop/tablet/smartphone).

Example section of an electronic questionnaire:*

Question 13. How big a problem during the last 4 weeks, if any, has each of the following been for you?

	No problem	Very Small Problem	Small Problem	Moderate Problem	Big Problem
a. Hot flashes	○ Reset	◉	○	○	○
b. Breast tenderness/enlargement	◉ Reset	○	○	○	○
c. Feeling depressed	○ Reset	◉	○	○	○
d. Lack of energy	○ Reset	○	◉	○	○
e. Change in body weight	◉ Reset	○	○	○	○

*Example questions from the EPIC-26 questionnaire looking at quality of life in people with prostate cancer.

Who decides what questionnaire group I will be in?

If you are happy to complete questionnaires either on paper or electronically, you will be put into a group by a process called randomisation. This uses a computer program to randomly assign people between one of the two groups. This is to make sure that the people in the two groups are as similar as possible. Using randomisation helps us to be sure that if there are differences in the way questionnaires are completed between the two groups, it is because of the completion method and not because the participants in the two groups are different from each other.

However, if you wish to take part in SPRUCE and have a strong preference for the way in which you complete the questionnaires i.e. via paper or electronically, then you can still join the study and you will be allocated to the group of your choice rather than be randomly assigned. We will use the information gained about how questionnaires are completed by people who choose their questionnaire format to support the analysis of the randomised comparison.

In order to be randomised to electronic or paper questionnaires, or to choose the electronic questionnaire method, you will need an email address and a device that can access the internet, for instance a smartphone, computer or tablet.

If you are in the electronic questionnaires group, you will be given a guidance document to explain more about how to use the electronic system.

How do I join the study?

If you decide to participate in SPRUCE, you will be asked by your medical team to sign a consent form. Your medical team will then telephone the research centre responsible for coordinating the study (ICR-CTSU). Your details will be recorded and your medical team will be informed which group you will be in and provide a unique number called a Study ID. Your medical team will then let you know as soon as possible which group you are in.

3 What happens during the study?

What will taking part in SPRUCE involve?

If you decide to participate in SPRUCE, you will be asked to complete the same questionnaires using the same timings as those within the host trial. This timing is described in the host trial's patient information sheet which you were given when you agreed to join that trial.

You will not be asked to complete questionnaires for both the host trial and SPRUCE. Instead, the information from the questionnaires you complete for SPRUCE will also be used for analysis in the host trial.

If you take part in SPRUCE, you will only be asked to complete two additional questionnaires.

The first is a questionnaire to find out a bit more about you. This is to see if there are any differences between the types of people who prefer using electronic questionnaires to paper questionnaires. We also want to make sure we are including people from all backgrounds and life

experiences in our questionnaire studies. You will be sent this either on paper or electronically, depending on how you are completing your other questionnaires.

The other additional questionnaire is a short paper survey which you will be sent 14 months after joining the study. This is to collect your feedback on how you have found completing questionnaires within SPRUCE.

What happens if I want to stop taking part in the SPRUCE study?

You can stop taking part in SPRUCE at any time. You do not have to give a reason and your future treatment and participation in your host clinical trial will not be affected by your decision. Information collected before you stopped taking part in SPRUCE will be kept and used in the study analysis, as described below here.

What happens if I stop taking part in the host clinical trial I am already participating in?

If you stop taking part in your host trial, or the questionnaire study within your host trial, you will automatically stop taking part in the SPRUCE study. You do not have to give a reason and your future treatment will not be affected by your decision. Information collected before you stop taking part will be kept and used in the study analysis, as described in the section below.

4 What are the possible advantages and disadvantages of taking part?

What are the possible advantages of taking part?

There is no guarantee that you will benefit directly from taking part in this study. If you have a strong preference for a particular method (paper or electronic), you will be able to choose to complete the questionnaires via that method.

The information we get from this study will help in deciding if routinely offering electronic questionnaire completion will be helpful for future trial participants, and what the impact would be on the amount and quality of information provided.

What are the possible disadvantages of taking part?

You will not be asked to complete more quality of life questionnaires than you have already agreed to complete within the clinical trial you have consented to, however you may not like the method of completion you have been assigned to. If you are unhappy with the way in which you are having to complete the questionnaires, you can ask to change to the alternative method.

You will be asked to complete two extra short questionnaires regarding your background and experience of completing the study questionnaires if you agree to join SPRUCE.

This completes Part 1 of the Information Sheet.

If the information in Part 1 has interested you and you are considering taking part in the SPRUCE study, please continue to read the additional information in Part 2 before making any decision.

PART 2

1 Confidentiality

Who will have access to my data?

The Institute of Cancer Research is the sponsor for this study based in the United Kingdom. We will be using your information from you and your medical records in order to undertake this study and will act as the data controller for this study. This means that we are responsible for looking after your information and using it properly. The Institute of Cancer Research will keep identifiable information about you for at least five years after the study has finished.

The Institute of Cancer Research's lawful basis for processing your information is for the performance of a task carried out in the public interest and it is necessary to process sensitive health and genetic information for the purposes of scientific research with appropriate safeguards in place to protect personal information, as required by the United Kingdom General Data Protection Regulation (UKGDPR).

Your rights to access, change, or move your information are limited, as we need to manage your information in specific ways in order for the research to be reliable and accurate. If you withdraw from the study, we will keep the information about you that we have already obtained. To safeguard your rights, we will use the minimum personally identifiable information possible.

You can find out more about how we use your information at www.icr.ac.uk/our-research/centres-and-collaborations/centres-at-the-icr/clinical-trials-and-statistics-unit/transparency.

[Insert appropriate name for NHS site] will collect information from you and/or your medical records for this research study in accordance with our instructions.

[Insert appropriate name for NHS site] will use your full name, hospital number, date of birth, postcode and NHS number (or Community Health Index (CHI) and/or hospital number in Scotland) to contact you about the research study, and make sure that relevant information about the study is recorded for your care, and to oversee the quality of the study.

After you have enrolled in the study The Institute of Cancer Research will contact you directly at your home address or email address to send you questionnaires to complete either on paper or electronically, depending which group you are in.

Will my taking part in this study be kept confidential?

All information which is collected about you during the study will be kept strictly confidential. When you join SPRUCE, your full name, date of birth, address, and email address will be passed to the Clinical Trials and Statistics Unit at the Institute of Cancer Research (ICR-CTSU) where the study is being coordinated. You will be given a unique study ID number, which will be used together with your initials and date of birth on questionnaires and any information that the research staff at your hospital need to send to ICR-CTSU.

All information about you will be stored securely and the online system used for the electronic questionnaires has been assessed to make sure it meets data security requirements by the Institute

of Cancer Research. Information will be treated as strictly confidential and nothing that might identify you will be revealed to any third party. Only members of the research teams at your hospital and the ICR-CTSU will have access to the information that could allow this study ID number to be linked to you.

Representatives from the ICR-CTSU, the NHS Trust relevant to your taking part in research and third parties approved by ICR-CTSU may need to see your hospital or clinic records to the extent permitted by applicable laws and regulations to make sure the information received is correct. All information will be kept confidential.

[Insert appropriate name for NHS site] will keep identifiable information about you from this study for 5 years after the study has finished.

Will information about me be shared with other researchers?

When you agree to take part in a research study, the information about your health and care may be provided to researchers running other research studies in this organisation and in other organisations now or in the future. These organisations may be universities, NHS organisations or companies involved in health and care research in this country or abroad. Your information will only be used by organisations and researchers to conduct research in accordance with the UK Policy Framework for Health and Social Care Research.

Your information could be used for research in any aspect of health or care, and could be combined with information about you from other sources held by researchers, the NHS or government. Where this information could identify you, the information will be held securely with strict arrangements about who can access the information. The information will only be used for the purpose of health and care research, or to contact you about future opportunities to participate in research. It will not be used to make decisions about future services available to you, such as insurance.

Where there is a risk that you could be identified your data will only be used in research that has been independently reviewed by an ethics committee.

Our main privacy policy can be found at https://www.icr.ac.uk/legal/privacy. If you have any questions about your rights under the UKGDPR or how we use your information please contact our Data Protection Officer at dataprotectionofficer@icr.ac.uk.

2 Further useful information

Who is funding and organising this research?

The study was designed by investigators at the Institute of Cancer Research and is funded by Cancer Research UK. The study is coordinated by the ICR-CTSU. None of the researchers or doctors at the hospitals taking part will receive personal payments from this funding.

What will happen to the results of the study?

The results will be published in a scientific journal and shared with study participants as soon as there is enough information to be sure the results are reliable. You will not be identified in any report or publication. The results will help to decide if electronic completion of quality of life questionnaires is a suitable alternative to paper based questionnaires for clinical trial participants.

Who has reviewed the study?

All research in the NHS is reviewed by an independent group of people, called a Research Ethics Committee, to protect participants' interests. This study has been reviewed and approved by the **West Midlands - Coventry and Warwickshire Research Ethics Committee**. Their approval means:

- They are satisfied that your rights will be respected,
- That any risks have been reduced to a minimum and balanced against possible benefits, and
- That you have been given the right information to decide whether to take part.

This study has also been reviewed and approved by the Health Research Authority (HRA) and by the Committee for Clinical Research (CCR) at The Institute of Cancer Research.

3 What happens next?

Your medical team will be happy to answer any questions you may have about this study.

Once you have decided whether or not to take part in SPRUCE, please let your medical team know. If you decide to join the SPRUCE study, you will be asked to sign the consent form at the end of this information sheet. Once signed, you will be given a copy of the form to keep together with the information sheet.

4 Useful contact information

Who can I contact for further information?

You have the right to ask questions about this study at any time.

Please contact the ICR-CTSU study co-ordination team if you have any questions about SPRUCE or about your participation in this study.

ICR-CTSU SPRUCE team email address: SPRUCE-icrctsu@icr.ac.uk

ICR-CTSU SPRUCE team phone number: 020 3437 6869

ICR-CTSU SPRUCE Study Contacts:

Study team names: XXXX

For any medical questions, or questions about the host trial you are also taking part in, please contact your hospital medical team.

Your hospital study contact is: xxx

Contact phone numbers: xxxx

Out of hours number: xxxx

Who else can I contact for support?

Your hospital Patient Advice and Liaison Service (PALS) (delete if not applicable): xxxx

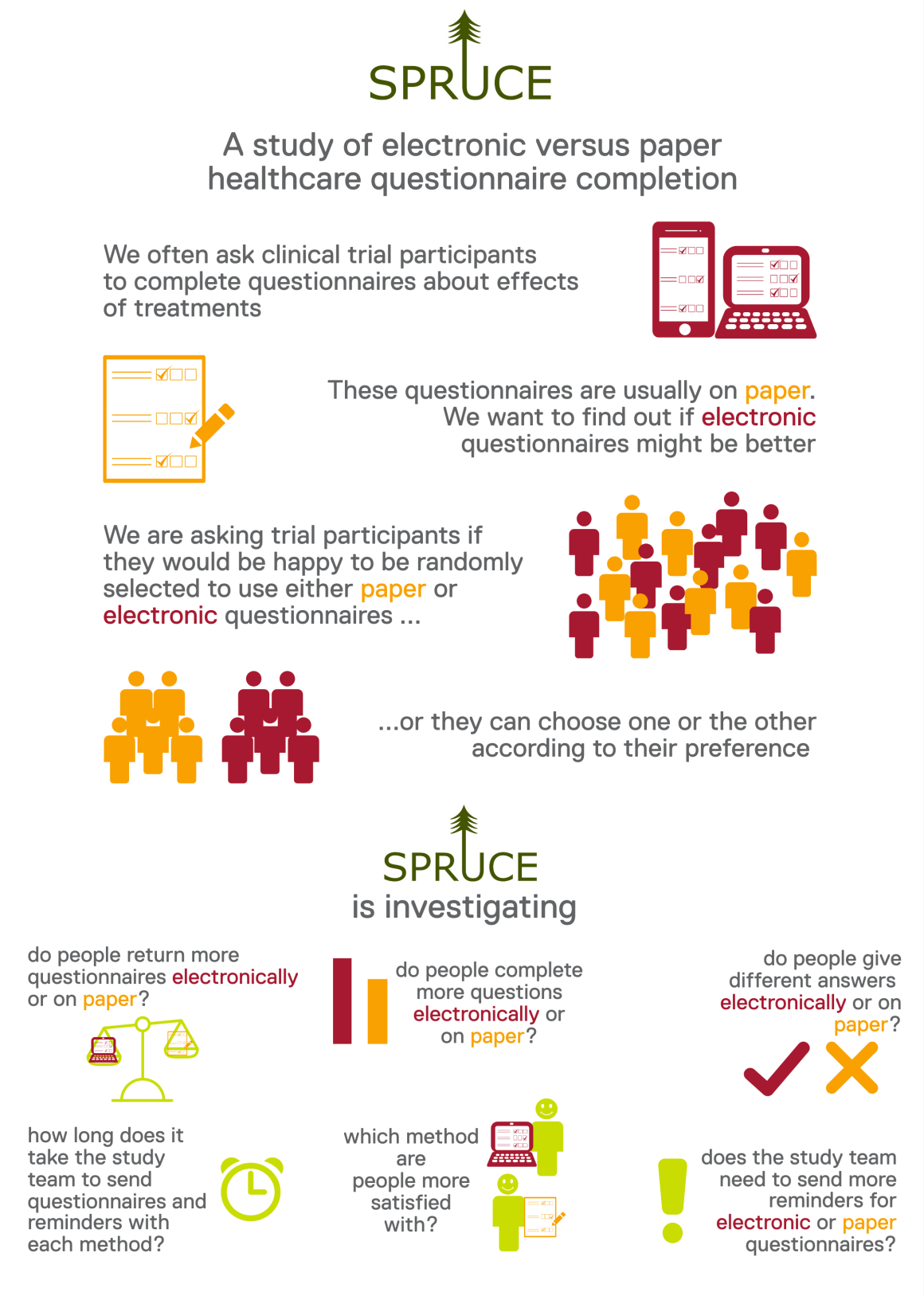
Macmillan Cancer Support is a registered charity providing information, emotional support and publications about all aspects of cancer for cancer participants and their families. You can contact one of their Cancer Information Nurse Specialists on the Macmillan Support Line; Freephone 0808 808 00 00, Monday to Friday, 9.00am to 8.00pm.

In addition to their nurses, the Macmillan Support Line also has other specialist teams that can provide advice and information relating to welfare benefits, financial issues and everyday practical concerns.

You can learn more about clinical trials and research studies on the Cancer Research UK Participant website (www.cancerhelp.org.uk).

Thank you for your interest in our research and for considering taking part in the SPRUCE study.

5 Summary infographic of the SPRUCE study



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CONSENT FORM

Ethics Committee Reference: 21/WM/0223

SPRUCE study ID:
Name of researcher taking consent:

Please write your initials in the box to the right of each statement if you agree, and please sign at the bottom

		Initials
1.	I confirm that I have read and understand the SPRUCE Participant Information Sheet Version 3.1 dated 24/10/2022. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	
2.	I understand that my participation is voluntary and that I am free to stop taking part in the SPRUCE study at any time, without giving any reason and without my medical care or legal rights being affected.	
3.	I agree to my name, date of birth, address and email address (if applicable) being sent to Clinical Trials and Statistics Unit at The Institute of Cancer Research (ICR-CTSU) when I join the SPRUCE study.	
4.	**I agree to participate in SPRUCE AND** *(please initial a <u>or</u> b below)*:	
	a. **I agree to have the format of questionnaires I complete to be decided by randomisation.**	
	OR	**OR**
	b. **I wish to choose what format of questionnaires I will complete (paper or electronic).**	

<u>PART B – OPTIONAL SECTION</u>
<u>Please initial to indicate whether you wish to consent to the following optional item.</u>

5.	Data sharing: I give advance authorisation for the possible future sharing of information collected about me with other organisations, including outside of the UK and European Economic Area (EEA), with the understanding that I will not be identifiable from this information.	

Name of participant	Signature	Date
Name of person taking consent	Signature	Date

Note to hospital staff:

If consent was obtained remotely, enter details of remote consent below and countersign above once form received:

Name of person who took remote consent	Date of remote consent

1 copy for participant; 1 copy for Principal Investigator; 1 copy to be kept with hospital notes