Developing a core outcome set (COS) for adolescents and young adults with cancer: measuring outcomes that matter

Health Professional interview Information Sheet

### **We invite you to take part in a research study to help us understand which issues and outcomes are important to adolescents and young adults with cancer. Before you decide we would like you to understand why the study is being done and what it will involve. Please take time to make your decision. If you wish, the researcher can contact you by telephone or email in 1 or 2 days.**

### ****Do I have to take part?****

### **No, it is up to you.**

### ****What will happen if I agree to take part?****

### **Taking part involves answering some questions about how adolescent and young adults have been affected by cancer and its treatment.**

### Why do we want to know this?

We are working with young people and others to develop a list of outcomes which matter the most. By outcome, we mean the way in which cancer and its treatment has had an impact on the young person. Outcomes can include feeling anxious, experiencing pain, changes in relationships, and any physical changes. We want to make sure that we can develop a core set of outcomes that matter to them and others.

### ****Who can take part?****

We are asking health professionals who provide care for adolescents and young adults with cancer.

### ****How to contact us****

**If you have any questions, please contact Nicole Collaço, the researcher who is organising the study.**

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 **n.b.collaco@soton.ac.uk**

**What happens next?**

* If you do not want to take part, you do not need to do anything. If you choose to take part, you will be asked to provide verbal consent. By giving your consent, you are saying that you are happy to take part.
* We will arrange a time to talk to you, via an online platform (such as Microsoft Teams) or talk to you on the telephone.
* First, the researcher will ask you a few questions about yourself. We will ask you how cancer and the treatment impacts adolescents and young adults with cancer. We will ask you what you think are the most important outcomes to measure.
* The study involves a one-off conversation with a researcher. There will be no follow ups and is likely to take up to 20 minutes but no longer than 45 minutes.
* With your permission, the discussion might be audio-recorded and transcribed. The recorder can be stopped at any time. Once we have listened to the recording, it will be safely deleted.
* The information collected about you will be securely sent to the University of Southampton for analysis. Before we send this information, we will make sure that we remove any names or information that could be linked back to you.
* We hope that you will find taking part in the research interesting, but you are free to stop at any time, and you will not need to explain why.

### What data will be collected?

### We will talk about important outcomes. We would also like to collect some general background details about you.

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

Yes, all information collected about you during the study will be kept strictly confidential. For the purposes of this study, you will be given a unique numbered code. Some of the words you use may be taken as direct quotes and included in reports or publications. These quotes will be completely anonymous so no one will be able to tell the words came from you. Only members of the research team and responsible members of the University of Southampton may be given access to data about you for monitoring purposes and/or to carry out an audit of the study to ensure that the research is complying with applicable regulations. Individuals from regulatory authorities (people who check that we are carrying out the study correctly) may require access to your data. All of these people have a duty to keep your information, as a research participant, strictly confidential.

All electronic data will be stored on a secure, password-protected University of Southampton database server, accessible only to the research team.

**Data Protection Privacy Notice**

The University of Southampton conducts research to the highest standards of research integrity. As a publicly funded organisation, the University has to ensure that it is in the public interest when we use personally identifiable information about people who have agreed to take part in research. This means that when you agree to take part in a research study, we will use information about you in the ways needed, and for the purposes specified, to conduct and complete the research project. Under data protection law, ‘Personal data’ means any information that relates to and is capable of identifying a living individual. The University’s data protection policy governing the use of personal data by the University can be found on its website (https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page).

This Participant Information Sheet tells you what data will be collected for this project and whether this includes any personal data. Please ask the research team if you have any questions or are unclear what data is being collected about you.

Our privacy notice for research participants provides more information on how the University of Southampton collects and uses your personal data when you take part in one of our research projects and can be found at <http://www.southampton.ac.uk/assets/sharepoint/intranet/ls/Public/Research%20and%20Integrity%20Privacy%20Notice/Privacy%20Notice%20for%20Research%20Participants.pdf>

Any personal data we collect in this study will be used only for the purposes of carrying out our research and will be handled according to the University’s policies in line with data protection law. If any personal data is used from which you can be identified directly, it will not be disclosed to anyone else without your consent unless the University of Southampton is required by law to disclose it.

Data protection law requires us to have a valid legal reason (‘lawful basis’) to process and use your Personal data. The lawful basis for processing personal information in this research study is for the performance of a task carried out in the public interest. Personal data collected for research will not be used for any other purpose.

For the purposes of data protection law, the University of Southampton is the ‘Data Controller’ for this study, which means that we are responsible for looking after your information and using it properly. The University of Southampton will keep identifiable information about you for 10 years after the study has finished after which time any link between you and your information will be removed.

To safeguard your rights, we will use the minimum personal data necessary to achieve our research study objectives. Your data protection rights – such as to access, change, or transfer such information - may be limited, however, in order for the research output to be reliable and accurate. The University will not do anything with your personal data that you would not reasonably expect.

If you have any questions about how your personal data is used, or wish to exercise any of your rights, please consult the University’s data protection webpage (https://www.southampton.ac.uk/legalservices/what-we-do/data-protection-and-foi.page) where you can make a request using our online form. If you need further assistance, please contact the University’s Data Protection Officer (data.protection@soton.ac.uk).

### What are the possible risks of taking part?

You will be asked to think about things relating to adolescents and young adults with cancer and how their life is impacted. Some people may find this upsetting. If you do become upset at any time, we can stop the study.

**What are the benefits of taking part?**

It is hoped that the information you provide will help us understand what is important to adolescents and young adults with cancer.

**What will happen to the results of the study?**

The study results are likely to be published in a scientific journal and presented at national and international conferences. The results will also be used to collect information from adolescents and young adults with cancer in clinical practice. This will be done to improve care for adolescents and young adults with cancer.

**Who is organising and funding this study?**

This study is part of a larger study which aims to improve care for adolescents and young adults (AYAs) with cancer. The Chief Investigator for this part of the study is Professor Anne-Sophie Darlington. The study is sponsored by the University of Southampton. Funding has been received from the European Union (EU) and from UK Research and Innovation (UKRI)

**Who has checked this study?**

Before any research is allowed to happen, it must be checked by a group of people called a Research Ethics Committee. This study has been checked and approved by *the Faculty Research Ethics Committee.*

**What if there is a problem?**

If you are unhappy with anything about this study, please let us know. If you have any concerns, you may also contact:

**Research Governance Office**

**University of Southampton**

**Building 28, Room 2027**

**University Road**

**Highfield**

**Southampton, SO17 1BJ**

**023 8059 5058**

**Rgoinfo@soton.ac.uk**