Head and neck cancer survivorship needs in regional/remote areas: Perceptions of patients and GPs

PARTICIPANT INFORMATION SHEET – GENERAL PRACTITIONERS

Title	Head and neck cancer survivorship needs in regional/remote areas: Perceptions of patients and GPs
Short Title	Survivorship needs in head and neck cancer
Protocol Number	X23-0027
Project Sponsor	Chris O'Brien Lifehouse
Coordinating Principal Investigator/ Principal Investigator	Dr Rebecca Venchiarutti
Associate Investigator(s)	Miss Poorva Pradhan, Ms Ashleigh Sharman, A/Prof Judith Lacey, Professor Jonathan Clark, Dr Raymond Wu
Location	Chris O'Brien Lifehouse

1. Introduction

You are invited to take part in a research study exploring the survivorship needs of patients with head and neck cancer across the whole care continuum, from diagnosis, pre-treatment assessment, treatment, and post-treatment. The aim of the study is to evaluate the survivorship needs of patients with head and neck cancer residing in regional/rural areas. You have been asked to participate because you have been involved with patients who have been diagnosed with head and neck cancer and are practicing as a GP in regional/rural areas of NSW.

This study is being conducted by the researchers listed above. This Participant Information Sheet (PIS) will tell you what is involved in the study and help you decide whether or not you wish to take part. Please read this information carefully. If there is anything you do not understand or if you feel you need more information about anything, please ask. Before you make a decision, please feel free to talk things over with a colleagues or the researchers named above.

The study is being conducted by Helen Hughes as part of the requirements for a Master of Public Health degree under the supervision of Dr Rebecca Venchiarutti.

2. Study Procedures

If you agree to participate in this study, you will be asked to sign the Participant Consent Form prior to participating in a maximum 60mins audio-recorded interview. The interview will be conducted by videoconferencing (Zoom) by researchers Miss Poorva Pradhan or Ms Ashleigh Sharman. This audio-recording will then be transcribed and will not contain any details that will identify you. Due to the anticipated length of the interview, you will be able to schedule the interview at a time that suits you and it may be conducted over more than one session. This will be discussed with a member of the study team.

If the study data will be used for future research purposes and / or shared with national and international collaborators, Ethics Approval will be required to be sought prior to access any data. You will also be provided with the opportunity to receive a summary of the study results when they are available, as well as to review a transcript of the recording. You can indicate your preferences to these at the end of the interview.

3. Risks

The risks of participating in this study are minimal. You may feel that some of the questions we ask are stressful or upsetting. If you do not wish to answer a question, you may skip it and go to the next question, or you may stop immediately. If you become upset or distressed as a result of your participation in the research project, the research team will be able to arrange for counselling or other appropriate support. Any counselling or support will be provided by qualified staff who are not members of the research team. This counselling will be provided free of charge.

4. Benefits

While we intend that this research study furthers medical knowledge and may improve survivorship experiences of people residing in regional/rural areas in the future, it may not be of direct benefit to you. However, possible benefits may include better identification of unmet survivorship needs for patients who have been diagnosed with head and neck cancer.

5. Costs

Participation in this study will not cost you anything, nor will you be paid.

6. Voluntary Participation

Participation in this study is entirely voluntary. You do not have to take part in it. If you do take part, you can withdraw at any time without having to give a reason by contacting Dr Rebecca Venchiarutti on 02 8514 0866.

If you decide to withdraw from the study, we will not collect any more study-related information from you. If you want to withdraw, please let us know and tell us what you would like us to do with the information we have collected from you up till then. If you wish, your information will be removed from our study records. It will not be included in the study results, unless we have analysed and published the results.

7. Confidentiality

All the information collected from you for the study will be treated confidentially and will be stored on a research database at Chris O'Brien Lifehouse. Only the researchers named on this Information Sheet will have access to the data. The research database is called Research Electronic Data Capture (REDCap), which is password protected.

The data will be analysed by the researchers at Chris O'Brien Lifehouse. All data for use in journal publications and presentations will be de-identified*. The files will be retained for five years from the day the study is completed. Once the retention expires the files will be disposed of.

Data collected up until the time you withdraw may be included in the study. If you do not want them to do this, you must tell the researchers at the time of your withdrawal. The study results may be presented at a conference or in a scientific publication, but individual participants will not be identifiable in such a presentation.

*de-identified data means that you/your information will not be identifiable

Re-identifiable data will be stored on an online secure password protected research database accessed within the Head and Neck Research Department at Chris O'Brien Lifehouse supported by Chris O'Brien Lifehouse Clinical Informatics and Technology Service.

8. Future use of Data

The data collected in this project may also be used in future research studies. The results of this study and de-identified data may be shared in the future with national and international collaborators. Any data that is used for related or future research will first be reviewed and approved by an appropriately constituted Ethics Committee. You can indicate your agreement to this on the Participant Consent Form.

9. Further Information

When you have read this information, Miss Poorva Pradhan or Ms Ashleigh Sharman will discuss it with you further and answer any questions you may have. If you would like to know more at any stage, please feel free to contact the research team on 02 8514 0866.

This information sheet is for you to keep.

10. Ethics Approval and Complaints

This study has been approved by the Ethics Review Committee (RPAH Zone) of the Sydney Local Health District. Any person with concerns or complaints about the conduct of this study should contact the Executive Officer on 02 9515 6766 and quote protocol number X23-0027.

The conduct of this study at Chris O'Brien Lifehouse has been authorised by the Sydney Local Health District. Any person with concerns or complaints about the conduct of this study may also contact the Research Governance Officer, Ms Anna Swanson on 02 8514 0410 and quote protocol number X23-0027.