

headandneck
5000

FOLLOW-UP STUDY

PARTICIPANT INFORMATION LEAFLET

Why have I been contacted?

You have received this leaflet because you are a participant in the Head and Neck 5000 study, a large UK-wide study of people with head and neck cancer. As part of this study, you were asked to complete a series of questionnaires asking you about your experiences of being diagnosed with and treated for head and neck cancer; you were also asked to provide a blood and saliva sample.

We are now contacting all eligible participants who enrolled in the Head and Neck 5000 study at least three years ago, and are inviting them to take part in a follow-up study. We would like to understand how your life and experiences of cancer have changed since your head and neck cancer diagnosis. By analysing this information, we hope to be able to help other people with head and neck cancer in the future.

What will taking part in the follow-up study involve?

You will be asked to complete a confidential questionnaire which includes questions about your previous medical history, lifestyle, diet, family and mood. The questionnaire should take about 30 - 45 minutes to complete.

Details on any further treatments and follow up that you have had for head and neck cancer will be collected from your medical notes by the research team.

Where you have previously consented to let us link to records already held on existing databases we will ask for an update from the organisations that hold these databases such as Public Health England and the Health and Social Care Information Centre. Public Health England and the Health and Social Care Information Centre are national government organisations that collect data on health.

Do I have to take part?

No, it is up to you to decide whether or not to take part. If you prefer not to take part you do not have to give a reason and your care will not be affected.

If you decide that you would like to take part in the Follow-up Study please complete the enclosed questionnaire and return it to the Bristol office of Head & Neck 5000 in the enclosed reply paid envelope. A stamp is not needed.

If you decide not to complete the questionnaire we will continue to collect data from your medical notes and by linkage to national databases as part of the Head and Neck 5000 study. If you decide that you would prefer us to stop collecting data from your medical notes and from linkage with Public Health England and the Health and Social Care Information Centre please use the enclosed reply paid envelope to let us know this, or you

can get in touch with the study team by telephone or e-mail, the contact details are at the end of this leaflet.

Will my privacy be protected?

As a Head and Neck 5000 participant you will already have been assigned a unique study number. This number and your initials will be the only identifier on the study questionnaire and any data collected from your medical notes.

We store any identifying information (your name, your address, and your consent form to Head and Neck 5000) separately from the samples and information that you have provided. Access to this identifying information is restricted to a small number of people in the study team, who will protect your privacy and confidentiality. No information that could be used to identify you will be included in any report or publication on the results of the study.

How will I find out the results of the study?

We have a Head and Neck 5000 study website which you may like to visit for further information: www.headandneck5000.org.uk. The website also tells you where you can access any publications that have been generated from the study so far.

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

You may withdraw from the study, or part of the study, at any time by contacting the Head & Neck 5000 office; the contact details are at the end of this leaflet. If you choose to withdraw from the Follow-up Study this will not affect your care in any way. We can remove from the Follow-up Study any information that you have provided, and if you prefer, we will not contact you again.

Who is organising and funding this study?

The study is sponsored by University Hospitals Bristol NHS Foundation Trust. It is funded by a National Institute of Health Senior Investigator Award held by Professor Andy Ness, funds from a Research Capability Funding award from University Hospitals Bristol, and a Cancer Research UK grant held by Professor Richard Martin.

Who has reviewed the study?

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee, to protect your interests. This study has been reviewed and given a favourable opinion by the Office for Research Ethics Committees Northern Ireland (HSC REC B). The IRAS (Integrated Research Application System) number for this study is 211454.

If you have a concern about any aspect of this study

If you have any concerns about any aspect of the study in the first instance please contact the Head & Neck 5000 research team who will do their best to answer your questions. If you remain unhappy and wish to complain formally, you can do this by contacting the Patient Support & Complaints Team in Bristol where the study is based.

Patient Support & Complaints Team
Welcome Centre (A201)
Bristol Royal Infirmary
Upper Maudlin Street
Bristol, BS2 8HW
Email: pals@uhbristol.nhs.uk
Tel: 0117 3421050

H&N5000 Study Team Contact Details:

If you have any questions about the study, please feel free to contact the Head and Neck 5000 Study Team directly. The contact details are below.

Lead Researcher for study: Professor Andy Ness

Senior Research Nurse: Miss Katrina Hurley

The Head and Neck 5000 Study Team

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Thank you for taking the time to read this leaflet