

Data Access Policy for the Head and Neck 5000 Study Resource

Version 1.6 9th March 2017

Head and Neck 5000 Executive (in alphabetical order):

Ms Katrina Hurley (Programme Manager)
Dr Vanessa Marshall (Manager, Bristol Nutrition Biomedical Research Unit)
Professor Andy Ness (Professor of Epidemiology)
Dr Christopher Penfold (Research Associate in Statistics)
Dr Miranda Pring (Consultant Senior Lecturer in Oral Maxillofacial Pathology)
Professor Steven Thomas (Professor in Oral and Maxillofacial Surgery)
Mr Stu Toms (Database Manager)
Dr Andrea Waylen (Senior Lecturer in Social Sciences)

NIHR Biomedical Research Unit in Nutrition, Diet and Lifestyle
Level 3, University Hospitals Bristol Education Centre
Upper Maudlin Street
Bristol BS2 8AE
Fax: 0117 342 4843

Introduction

This document sets out the data access policy for the resource arising from the study entitled "Head and Neck 5000". This is a large study of people with head and neck cancer across the UK. It was set up to investigate the factors that influence cancer survival in the UK, and the psychological impact that living with head and neck cancer can have on people. Detailed information has been collected using a series of questionnaires, which include questions about health and lifestyle and quality of life. These were given out after diagnosis (but before treatment started), at 4 months and at 12 months. Samples of blood and saliva at baseline and tissue at diagnosis or treatment were obtained. Information on the date, cause and place of death for any participants who died are collected. The study protocol, questionnaires, consent form and patient information leaflet were approved by the local research ethics committee (South West-Frenchay Ethics Committee original approval 5th November 2010) and subsequently approved by the research and development departments for all participating hospitals. Copies of the study protocol and all documents described below are available on the study website (<http://www.headandneck5000.org.uk>).

Study Methods

All people with a new diagnosis of head and neck cancer were eligible to join the study. People with cancers in the pharynx, mouth, larynx, salivary glands and thyroid were all included. People with lymphoma, tumours of the skin, primary tumours elsewhere or a recurrence of a previous head and neck cancer were excluded from the study. People had to be recruited before their treatment started unless their cancer treatment was also their diagnostic procedure. A detailed description of the study methods is contained in the paper "*Establishing a large contemporary clinical cohort in people with head and neck cancer as a biomedical resource: Head and Neck 5000*" Ness et al, BMC Cancer.2014, 14:973 <http://www.biomedcentral.com/content/pdf/1471-2407-14-973.pdf>

Resource Management

Professor Andy Ness is the Director of the resource. The management of the resource is the responsibility of the Head and Neck 5000 Executive. From time to time the Head and Neck 5000 Executive may seek advice from other key individuals. The Head and Neck 5000 Executive meets every month to consider proposals and papers. The final decision lies with the Director.

Sharing data with researchers

The resource is set up as a supported access resource rather than as an open access resource. The following sections describe the information available on the resource, the process of accessing and sharing different types of data and the procedures in place to monitor output. We may charge investigators for cost incurred in providing a dataset or samples.

The study website <http://www.headandneck5000.org.uk/> describes the resource and the types of data available. There is also a copy of the protocol paper "*Establishing a large contemporary clinical cohort in people with head and neck cancer as a biomedical resource*", updated tables of recruitment and follow up and the study protocol (that includes questionnaires, data abstraction forms and consent forms). These documents should help you decide whether this data would be potentially valuable in addressing your research question. Our Data Dictionary is also available in PDF format on the website. Only fully anonymised data will be shared with researchers.

Biological samples will be provided in principle to researchers with participants enrolled in our study and another study they lead. Please note that the last or only sample will not normally be provided. Blood, saliva, tissue or germline DNA can be requested. GWAS data and mortality data may need to be analysed in Bristol.

Submitting a proposal

If you decide that you would like to access the resource you should contact the Head and Neck 5000 Executive on headandneck5000@uhbristol.nhs.uk. We welcome informal enquiries before submission of formal proposals. Once you are ready to submit a formal proposal you should complete the proposal form. This will ask you to state the aims, hypothesis and variables you require. All proposals need to be for ethically approved studies and in the proposal form we will ask for evidence of ethical approval. The Head and Neck 5000 Executive will reply within one month to inform you of the outcome and to provide advice on the next stages. The Head and Neck 5000 Executive will also estimate the cost of sharing data if applicable. The Head and Neck 5000 Executive also reserve the right to impose additional restrictions as appropriate.

Data Provision

When the Head and Neck 5000 Executive have approved your project, a standard dataset will be provided to you usually within a month of all paperwork being completed; however some types of data may take longer. You will not be provided with statistical, methodological or other support without prior agreement. Upon access to data being granted, you will have a year to work on this data from point of receipt of dataset, after which others may apply to perform the same analysis. The Head and Neck 5000 Executive will publish a searchable abstract of approved research proposals utilising the resource on the website. The Head and Neck 5000 Executive may put you in touch with other groups working in the same area to reduce overlaps in order to prevent duplication.

Derived Variables

Any derived variables (such as data obtained as part of a new data collection exercise or newly derived variables coming from secondary analyses) created as part of any research project must be returned to the Head and Neck 5000 Executive with appropriate documentation. These will be incorporated into the main resource made available to all researchers once the protected period of approved use has ended. Failure to return derived variables may risk your future access to the resource.

Paper submission and Publication

The Director and/ or one or more nominated member(s) of the Head and Neck 5000 Executive should also be included as an author on papers using data from Head and Neck 5000 resource. The designated author from the Head and Neck 5000 Executive will read all papers to check confidentiality is protected and to ensure that the paper will not bring the study into disrepute. The Head and Neck 5000 Executive member will also provide advice and feedback.

All full papers must be sent to the Head and Neck 5000 Executive for approval (headandneck5000@uhbristol.nhs.uk) along with a completed papers checklist prior to journal submission. The checklist of requirements for papers along with some accompanying notes explaining these requirements and containing appropriate text to insert is available on the Head and Neck 5000 website. The Head and Neck 5000 Executive expect to process all papers within one month of receipt

Researchers should let the Head and Neck 5000 Executive know when a paper is accepted and send through an electronic copy of the final published version. If your work on the resource was funded by bodies that require open access to publications arising from their funding it is your responsibility to ensure papers are freely available.

All papers submitted will be sent to the National Institute of Health Research (NIHR) as per the programme regulations. We will maintain a list of papers arising from the resource on the study website. We request that we are provided with an electronic copy of any reports and other publications that use the Head and Neck 5000 resource as soon as possible. We request that we are provided with an electronic copy of any theses that use the Head and Neck 5000 resource as soon as possible after a degree is awarded. We do not need to see conference submissions prior to submission but a copy should be sent to the Head and Neck 5000 Executive once submitted.

Publicity policy

All press releases on research arising from the resource should be seen and approved by the Head and Neck 5000 Executive (headandneck5000@uhbristol.nhs.uk). We may write press releases on certain articles and expect the lead author on the paper and host organisation's public relations team to be available to deal with media enquiries and interviews. We may also ask authors to prepare a précis of important papers to include in reports to funders and future applications for future core support.

Intellectual property

Intellectual property in the data and samples that make up the Head and Neck 5000 resource is vested in UHBristol and managed by the Head and Neck 5000 Executive. As such any requests to access the data and/or samples must be made through the Head and Neck 5000 Executive. Any data generated through an approved project must be made available to the Head and Neck 5000 Executive where it will form part of the Head and Neck 5000 resource to enable it to be used by the research community. Any intellectual property generated using the Head and Neck 5000 resource ("Foreground IP") will belong to UHBristol.

Acknowledgements

The following is a standard acknowledgements section that should be included in all papers:

"This publication presents data from the Head and Neck 5000 study. The study was a component of independent research funded by the National Institute for Health Research (NIHR) under its Programme Grants for Applied Research scheme (RP-PG-0707-10034). The views expressed in this publication are those of the author(s) and not necessarily those of the NHS, the NIHR or the Department of Health. Human papillomavirus (HPV) serology was supported by a Cancer Research UK Programme Grant, the Integrative Cancer Epidemiology Programme (grant number: C18281/A19169)."