Data Access Policy for the Head and Neck 5000 Study Resource

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Introduction

This document sets out the data access policy for the resource arising from the study entitled “Head and Neck 5000”. This is a UK based study of people with head and neck cancer. It was set up to investigate the factors that influence cancer survival and the psychological impact of living with head and neck cancer. 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) and at 4 months, 12 months and at 3-5 years post diagnosis. A 10 year questionnaire is in progress. Samples of blood and saliva were collected at baseline and formalin fixed paraffin embedded (FFPE) biopsy material retrieved from either a diagnostic or therapeutic procedure. For participants who have died we have collected information on the date and cause of death The original study protocol, questionnaires, consent form and patient information leaflet, along with the 10 year follow up were approved by the Southwest-Frenchay Ethics Committee (original approval 5th November 2010), the 3- 5 year follow up study was approved by HSC REC B (Office for Research Ethics Committees Northern Ireland) on the 4th August 2016. Copies of the study protocol and documentation are available on the study website (http://www.headandneck5000.org.uk).

Study Methods

All people aged 16 and over with a new diagnosis of head and neck cancer were eligible to join the study. Diagnoses included cancers in the pharynx, mouth, larynx, salivary glands and thyroid. People with head and neck lymphoma, skin cancers, primaries that were not head and neck cancer, and recurrence of a previous head and neck cancer were excluded from the study. People were recruited before starting treatment unless the cancer treatment also formed part of their diagnostic procedure. Details of methodology can be found 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 AR et al, BMC Cancer.2014, 14:973 http://www.biomedcentral.com/content/pdf/1471-2407-14-973.pdf and of the recruitment process in "*Recruitment response rates and characteristics of 5511 enrolled in a perspective clinical cohort study head & neck 5000*" Ness AR, et al. Clinical Otolaryngology 2015; 41: 804-809. https://onlinelibrary.wiley.com/doi/full/10.1111/coa.12548

Resource Management

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 and input from other key individuals. The Head and Neck 5000 Executive meet regularly to consider proposals and papers. The final decision lies with the study Chief Investigator, Dr Miranda Pring.

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. A Data Manual is available in PDF format on the website. Only anonymised data will be shared with researchers.

Linked biological samples are available in the form of blood, saliva, FFPE blocks (including representative digital H+E images); germline DNA can be requested. Release of material that may result in exhaustion of part of the bioresource is at the discretion of the Head and Neck 5000 Executive. NHS REC approval is required for all studies requiring samples.

A range of data derived from biological data is available for sharing with researchers including representative digital H+E slides, some digitalised IHC slides (common biomarkers such as P16), germline genetic data (array genotypes and imputed data), methylation data and NMR metabolomic data. These data will not require NHS REC approval but due to the digital size of the data may attract additional costs.

External researchers do not need to seek REC approval for the use of anonymised data provided from the H&N5000 study; however researchers must follow their own institutions policies relating to the secondary use of anonymised data (e.g. registration of their research project, university ethics approval) and it is their responsibility to ensure that these policies are adhered to.

Submitting a proposal

You will need to complete and submit the Head and Neck 5000 research proposal form which can be found on the study website. Please contact a member of the Head and Neck 5000 Executive if you would like to discuss a proposal ahead of submission.

Please note that the lay summary you provide will be added to the Head and Neck 5000 website and made available to our study participants. Please ensure that language and wording are appropriate.

The Executive will aim to review all documentation and advise of the outcome (accept, reject, request additional information) within a month. Details of any costings will be provided. The Head and Neck 5000 Executive reserve the right to impose additional restrictions as appropriate.

Successful applicants will receive contact details of an appropriate link person from the Head and Neck 5000 Executive to liaise with for the duration of their study.

Data Provision

Following approval a dataset will be made available. This is usually within a month of all paperwork being completed however some types of data may take longer. The study does not routinely provide statistical, methodological or other support without prior agreement. The Head and Neck 5000 Executive will publish abstracts 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 prevent duplication of research.

Data, samples and digital images are provided for the project specified on the application form and must not to be used outside of the project specified.

Derived Variables

Any derived variables (such as data obtained as part of a new data collection exercise, newly derived variables coming from secondary analyses, or data derived from samples) 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 resource and made available to other researchers. Failure to return derived variables may risk your future access to the resource.

Paper submission and Publication

At least one member of the Head and Neck 5000 Executive should be included within authorship of papers utilising data and/or samples from Head and Neck 5000. The Head and Neck 5000 link person will ensure that input of other executive members and study collaborators, is appropriately recognised within authorship. The link person will be responsible for circulating draft papers for wider review as required and will ensure that the study and the study sponsor are referenced correctly, and that the publication will not bring the study into disrepute.

The final draft must be approved by an appropriate member of the Head and Neck 5000 Executive prior to journal submission. There is a papers checklist describing the requirements for papers, along with some accompanying notes explaining these requirements, and containing

appropriate text to insert 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 an electronic copy of the author accepted manuscript. 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 these policies are adhered to, Head and Neck 5000 cannot contribute to publication costs.

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 study should be seen and approved by the Head and Neck 5000 Executive (headandneck5000@uhbw.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 in future applications for core support.

Intellectual property

Intellectual property in the data and samples that make up the Head and Neck 5000 resource is vested in University Hospitals Bristol and Weston NHS Foundation Trust 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 University Hospitals Bristol and Weston NHS Foundation Trust.

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 and Care 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. Core funding was also provided through awards from Above and Beyond, University Hospitals Bristol and Weston Research Capability Funding, the NIHR Senior Investigator award to Professor Andy Ness. Work on the 3 – 5 year follow up was also supported by Cancer Research UK C18281/A29019'. The 10 year follow up questionnaire has been funded by a grant from Cancer Research UK (CRUK ref: PRCPJT-Nov22/100020)".

The following funder acknowledgement statement(s) may be required if relevant.

If using serology data:
"Human papillomavirus (HPV) serology was supported by a Cancer Research UK Programme Grant, the Integrative Cancer Epidemiology Programme (grant number: C18281/A19169)"

If using germline genotype data:
"Round 1 genotyping was funded by US National Institute of Dental and Craniofacial Research (NIDCR) grant 1X01HG007780-0. Round 2 genotyping was funded by World Cancer Research Fund Pilot Grant (grant number: 2018/1792), Above and Beyond, Wellcome Trust Research Training Fellowship (201237/Z/16/Z) and Cancer Research UK Cancer Research UK Programme Grant, the Integrative Cancer Epidemiology Programme (grant number: C18281/A19169)."

If using HPV / p16 data from Predictr2
"We acknowledge the PredicTR research programme, led by the Institute of Head and Neck Studies and Education (InHANSE), University of Birmingham, UK, and funded by Cancer Research UK and the UKRI Medical Research Council, for performing p16 and HPV status data of the Head & Neck 5000 cohort."

If using digital pathology images
"The digital imaging project was supported by the Showering Fund (Project ref: SF 127)"
A copy of the published paper is to be sent to the Chairman of the Trustees.