

Checklist for papers on the Biomedical Resource “Head and Neck 5000”

All papers from the Biomedical Resource “Head and Neck 5000” (henceforth referred to as the ‘Resource’) must be submitted to a representative of the Head and Neck 5000 Executive for approval *prior* to journal submission. We expect to process all papers within one month of receipt. We read all papers to check confidentiality is protected and to ensure that the paper will not bring the Resource into disrepute. We also provide advice and feedback to authors where we feel this may be helpful. Below is a checklist of requirements for papers along with some accompanying notes either explaining these requirements and/or containing appropriate text to insert. A signed and completed checklist must be included with each paper submitted for approval. Please send to headandneck5000@uhbw.nhs.uk

CHECKLIST FOR PAPERS			
Name of corresponding author			
Head & Neck 5000 Project number			
Title of paper			
Funding Body			
I have included an accurate description of the study numbers ¹ (including version of dataset used) and I have included a reference to the Study Protocol Paper ²			<input type="checkbox"/>
I have included an accurate description of the ethical approval ³			<input type="checkbox"/>
I have included an accurate acknowledgements section ⁴			<input type="checkbox"/>
I have not used the term statistical significance ⁵ (optional)			<input type="checkbox"/>
I will return any derived variables and accompanying documentation ⁶			<input type="checkbox"/>
I will send a copy of the final submitted manuscript and revised versions			<input type="checkbox"/>
I will let the Head and Neck 5000 Executive know when the paper is accepted for publication			<input type="checkbox"/>
I will send through a paper and electronic copy of the final paper			<input type="checkbox"/>
I will liaise with Head and Neck 5000 Executive over media coverage ⁷			<input type="checkbox"/>
Signature:		Date:	

1. Description of study numbers

The study website <http://www.headandneck5000.org.uk/> includes updated tables of recruitment and follow up and a copy of the study manual.

2. Study Protocol Paper

“Establishing a large contemporary clinical cohort in people with head and neck cancer as a biomedical resource: Head and Neck 5000”, Ness AR, Waylen A, Hurley K, Jeffreys M, Penfold M, Pring M, Leary S, Allmark C, Toms C, Ring S, Peters TJ, Hollingworth W, Worthington H, Nutting C, Fisher S, Rogers SN and Thomas SJ, The Head and Neck 5000 Study Team, BMC Cancer.2014, 14:973

3. Ethical approval

Head and Neck 5000 was reviewed by the South West – Frenchay REC and initial approval was given on the 5th November 2010. The study REC reference number is: 10/H0107/57.

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. The follow up study was submitted as a new study for administrative reasons but forms part of the same cohort research.

4. Acknowledgements section

The following funder acknowledgement to be included in all publications:

“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)”.

Additional funder acknowledgement statement(s) may be inserted here 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.

5. Statistical significance

We discourage the use of the term “statistical significance” and encourage authors to describe the observed effect sizes and the strength of the evidence that supports these effect size estimates. For a detailed justification see: Sterne JAC, Davey Smith G. Sifting the evidence—what's wrong with significance tests? *British Medical Journal* 2001; 322; 226-231.

6. Final dataset of derived variables

By derived variables we mean new variables that have been derived using at least two existing variables, (rather than simple recodes) or other variables that do not currently exist in the Study resource that may be of use to other collaborators. Derived variables will be archived by the Head and Neck 5000 Executive will ultimately be made available to future data users. This will be followed up on approval of your manuscript. A copy of the final data set should be returned to the Head and Neck 5000 Executive.

7. Media coverage of publications

Where appropriate we encourage media coverage of papers arising from the resource to raise its profile and in particular to show participants that the study is producing interesting and valuable outputs. Please inform the Head and Neck 5000 Executive if you know there is going to be a press release and let us know about any coverage arising from this.

Head and Neck 5000 Executive
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