Study ID ☐☐☐☐☐☐ **Initials** ☐☐☐

H&N5000 FOLLOW UP STUDY DATA CAPTURE FORM

Please read the H&N5000 Follow-up Study Data Capture Form Completion Guidelines before filling in the Data Capture Form (DCF). If you have any questions regarding the Data Capture Form please contact the Head & Neck 5000 team on (0117) 342 9536 or (0117) 342 9531 before completing the DCF.

- This form is to be completed with reference to the head and neck cancer that was diagnosed at recruitment to the study and listed on the Baseline DCF.
- If the patient has had a new head & neck primary tumour since Month 12 please record the details in question 6 and ensure that the new primary box is ticked in the relevant treatment section(s).
- Please complete the Data Capture Form (DCF) with data to the current date, or as close to this as possible.
- Please note that apart from the comorbidity section we are only collecting information on head and neck cancers. For example: treatment for a breast cancer primary would be noted in the comorbidity section but not recorded elsewhere.
- If a patient has had several head and neck tumours and you are unsure which tumour and treatments to record please contact the Head & Neck 5000 team.

- Please ensure all questions are completed accurately in black or dark blue ballpoint pen.
- Please ensure that the participants study ID and initials are clearly written at the top of each page.
- If any data are unknown please enter NK for 'not known'.
- To make corrections cross out the error with a single line and record the correction next to the original entry, then date and initial the change.
- If a question asks you to make a choice, please indicate the correct box with a tick or a cross.
- Please remember to sign the final page of the form. Unsigned forms will result in a data query.

Please return this form within the timelines agreed at site initiation. If you are having difficulty in meeting the deadlines for your site, please inform the Head & Neck 5000 team.

Please return completed Data Capture Forms to:
Head & Neck 5000 Office
First Floor
Bristol Dental Hospital
Bristol
BS1 2LY

Pre-paid return envelopes are supplied by the Head & Neck 5000 team.

Study ID ☐☐☐☐☐☐ **Initials** ☐☐☐

1. THE DATE UP TO WHICH DATA HAS BEEN COLLECTED ☐☐/☐☐/☐☐

Please record the **date to which the data has been collected** rather than the date that you complete the form. For example if you complete the form on the 1st September 2016, but the last entry in the patient notes used for data collection is 01 Feb 2016, please enter 01/02/16.

1a. If the date recorded above is more than 8 months ago or less than 3 years after consent please tell us why:

_____

2. IS THE PATIENT ALIVE? Yes ☐ No ☐

2a. IF NO, PLEASE GIVE DATE OF DEATH ☐☐/☐☐/☐☐

If the patient has died please complete the rest of the Data Capture Form with data up to the date of death.

3. CANCER CARE PLAN INTENT

Please let us know the intent of the ***current*** cancer care plan for the patient's head and neck cancer. If the treatment intent has altered since month 12 please give details of the previous plan(s) as well.

Please record the date of the MDT or clinic where the decision was made to alter the treatment intent; this will not necessarily be the same as the date of treatment. For example; if the decision was made on 04/04/15 that a patient's pathway was to become palliative, but the patient did not start palliative radiotherapy until 06/07/15 you would record the date of the palliative pathway as 04/04/15. Treatment dates are recorded later in question 7.

If you are unsure of the intent, or the date that the decision was made, please try asking a member of the patient's clinical team or contact the Head & Neck 5000 team for advice.

☐ **Curative.** Considered to be cancer free or eligible for treatment that intends, however slight the chance of success, to cure.

☐ **Palliative.** Treatments such as chemotherapy, radiotherapy or surgery are given but it is known that the cancer cannot be cured.

☐ **Supportive.** Treatments to reduce symptoms are given but the cancer cannot be cured. Often called 'Best Supportive Care'. These treatments are less aggressive than 'Palliative'

☐ **No Specific Anti-Cancer.** Patient has refused all input from the head and neck clinical team. If this pathway applies please give an explanation of the circumstances in the Comments section on page 14.

3a. If the current pathway has been ongoing since the month 12 DCF please tick here ☐ and go to question 4.

3b. If there has been a different pathway before the current one please record the previous pathways and dates:

Previous Pathway 1: _____ Date pathway started: ____/____/_____

Previous Pathway 2: _____ Date pathway started: ____/____/_____

Previous Pathway 3: _____ Date pathway started: ____/____/_____

Study ID ☐☐☐☐☐☐ **Initials** ☐☐☐

4. DOES THE PATIENT HAVE ANY RESIDUAL HEAD & NECK TUMOUR? Yes ☐ No ☐

Residual tumour is the head and neck tumour recorded on the Baseline DCF that is still present following the initial treatment(s) recorded on the Month 4 and 12 DCFs. Cancer that has recurred after being tumour free is recorded in question 5, and any new head and neck cancer that has been diagnosed is recorded in question 6.

5. HAS THE HEAD & NECK TUMOUR RECURRED SINCE MONTH 12? Yes ☐ No* ☐

Recurrence is return of the cancer listed on the Baseline DCF after the original treatment(s) and following a period of at least six months of being tumour free.

**If 'No' please go to question 6*

5a. If YES please give the staging of the recurrence:

T ☐☐ **N** ☐☐ **M** ☐ **Not recorded** ☐

5b. WHEN WAS THE RECURRENCE CONFIRMED? ☐☐/☐☐/☐☐
(Please give as accurate a date as possible)

5c. PLEASE GIVE THE LOCATION OF THE RECURRENCE:
Please give as much detail as possible (for example: recurrence at tongue base with single 2cm neck node on left or multiple bilateral neck nodes and widespread liver metastases):

_____

_____

If there has been more than one confirmed espisode of recurrence and you need more space please continue here or in section the Comments section on page 14, or add a new sheet of paper:

6. SINCE MONTH 12 HAS THERE BEEN A NEW HEAD & NECK PRIMARY CANCER? Yes ☐ No* ☐

Please record any new head and neck primary tumour(s) diagnosed since completion of the Month 12 Data Capture Form. These are head and neck cancers that are not connected to the tumour listed on the Baseline DCF.

**If 'No' please go to question 7*

1	**Location of new primary** (please give as detailed a description as possible eg: left floor of mouth): _____ _____ **Date diagnosis confirmed by MDT:** _____/_____/_____ **Staging of new primary:** **T** ☐☐ **N** ☐☐ **M** ☐ Please record the treatment(s) given in section 7 and ensure that you tick the box marked 'new primary'.

Please send an anonymised copy of the histopathology report(s) from diagnosis and surgery for the new primary head and neck cancer(s).

Diagnostic report(s)enclosed: Yes ☐ No ☐

Surgery report(s) enclosed: Yes ☐ No ☐ Not applicable ☐

Study ID ☐☐☐☐☐☐ **Initials** ☐☐☐

7. TREATMENTS RECEIVED SINCE THE MONTH 12 TIMEPOINT.
Please record the ***treatments given for Head & Neck cancer*** since month 12. ***For each treatment please answer 'Yes' or 'No' and if 'Yes' please complete the remaining questions for that treatment***. If there have been a lot of treatments and there is not enough space to record them all please ask the H&N5000 team and we will send you some additional pages. If unsure whether a treatment or procedure should be included please contact the H&N5000 team for advice.

7a. Surgery *Yes ☐ No ☐ *If Yes please complete a section below for each operation for head and neck cancer.

1

Name of operation (include primary tumour site, neck dissection and name of flap reconstruction as applicable): _____
_____
_____

Date: _____/_____/_____ **Was this laser surgery?** Yes ☐ No ☐ **Treatment Intent:** Curative ☐ Palliative ☐

Reason for treatment: Residual H&N tumour ☐ Recurrent H&N tumour ☐ Distant metastases ☐ New H&N primary ☐

Pathology staging from the operation: pT ____ pN____ pM____ **Histology** (eg: squamous cell carcinoma, papillary, benign): _____

Has an anonymized copy of the pathology report from the operation been sent to the Head & Neck 5000 team? Yes / No (please delete as appropriate)
If 'No' please let us know if this will be sent later:_____

2

Name of operation (include primary tumour site, neck dissection and name of flap reconstruction as applicable): _____
_____
_____

Date: _____/_____/_____ **Was this laser surgery?** Yes ☐ No ☐ **Treatment Intent:** Curative ☐ Palliative ☐

Reason for treatment: Residual H&N tumour ☐ Recurrent H&N tumour ☐ Distant metastases ☐ New H&N primary ☐

Pathology staging from the operation: pT ____ pN____ pM____ **Histology** (eg: squamous cell carcinoma, papillary, benign): _____

Has an anonymized copy of the pathology report from the operation been sent to the Head & Neck 5000 team? Yes / No (please delete as appropriate)
If 'No' please let us know if this will be sent later:_____

Study ID ☐☐☐☐☐☐ **Initials** ☐☐☐

7b. Radiotherapy *Yes ☐ No ☐ *If Yes please complete a section below for each course of radiotherapy to the head and neck cancer. **Please record radioiodine in section 7g.**

1

Type: Intensity Modulated (IMRT) Static field or rotational arc ☐ External Beam (Not IMRT) ☐ Brachytherapy ☐ Other ☐ Please state:_____

Dose received: _____ Gy _____ Fractions over _____ weeks **Treatment intent:** Curative ☐ Palliative ☐

Reason for treatment: Residual H&N tumour ☐ Recurrent H&N tumour ☐ Distant metastases ☐ New H&N primary ☐

Location of treatment (eg: ribs, cervical spine): _____

Start Date: ____/____/____ **End Date:** ____/____/____ **If course not completed please give reason:** _____

2

Type: Intensity Modulated (IMRT) Static field or rotational arc ☐ External Beam (Not IMRT) ☐ Brachytherapy ☐ Other ☐ Please state:_____

Dose received: _____ Gy _____ Fractions over _____ weeks **Treatment intent:** Curative ☐ Palliative ☐

Reason for treatment: Residual H&N tumour ☐ Recurrent H&N tumour ☐ Distant metastases ☐ New H&N primary ☐

Location of treatment (eg: ribs, cervical spine): _____

Start Date: ____/____/____ **End Date:** ____/____/____ **If course not completed please give reason:** _____

3

Type: Intensity Modulated (IMRT) Static field or rotational arc ☐ External Beam (Not IMRT) ☐ Brachytherapy ☐ Other ☐ Please state:_____

Dose received: _____ Gy _____ Fractions over _____ weeks **Treatment intent:** Curative ☐ Palliative ☐

Reason for treatment: Residual H&N tumour ☐ Recurrent H&N tumour ☐ Distant metastases ☐ New H&N primary ☐

Location of treatment (eg: ribs, cervical spine): _____

Start Date: ____/____/____ **End Date:** ____/____/____ **If course not completed please give reason:** _____

Study ID ☐☐☐☐☐☐ **Initials** ☐☐☐

7c. Chemotherapy, Biological & Immunotherapy *Yes ☐ No ☐ *If Yes please complete a section below for each treatment for the head & neck cancer

1

Treatment name: _____ **Treatment intent:** Curative ☐ Palliative ☐

Initial dose per cycle: _____ **Given (please circle as appropriate):** Daily / Once weekly / Once every 3-4 weeks **Number of cycles:** _____

Duration of treatment in weeks if given daily _____ **Was this treatment combined with radiotherapy?** Yes ☐ No ☐

Reason for treatment: Residual H&N tumour ☐ Recurrent H&N tumour ☐ Distant metastases ☐ New H&N Primary ☐

Start Date: ____/____/____ **End Date:** ____/____/____ **If not completed please give the reason:** _____

2

Treatment name: _____ **Treatment intent:** Curative ☐ Palliative ☐

Initial dose per cycle: _____ **Given (please circle as appropriate):** Daily / Once weekly / Once every 3-4 weeks **Number of cycles:** _____

Duration of treatment in weeks if given daily _____ **Was this treatment combined with radiotherapy?** Yes ☐ No ☐

Reason for treatment: Residual H&N tumour ☐ Recurrent H&N tumour ☐ Distant metastases ☐ New H&N Primary ☐

Start Date: ____/____/____ **End Date:** ____/____/____ **If not completed please give the reason:** _____

3

Treatment name: _____ **Treatment intent:** Curative ☐ Palliative ☐

Initial dose per cycle: _____ **Given (please circle as appropriate):** Daily / Once weekly / Once every 3-4 weeks **Number of cycles:** _____

Duration of treatment in weeks if given daily _____ **Was this treatment combined with radiotherapy?** Yes ☐ No ☐

Reason for treatment: Residual H&N tumour ☐ Recurrent H&N tumour ☐ Distant metastases ☐ New H&N Primary ☐

Start Date: ____/____/____ **End Date:** ____/____/____ **If not completed please give the reason:** _____

Study ID ☐☐☐☐☐☐ **Initials** ☐☐☐

7d. Hormone Therapy *Yes ☐ No ☐ *If Yes please complete a section below for each course of hormone treatment for the head and neck cancer

1

Drug name: _____ **Dose:** _____ **Start Date:** ____/____/____ **End Date:** ____/____/____ or **ongoing** ☐

Reason for treatment: Residual H&N tumour ☐ Recurrent H&N tumour ☐ New H&N Primary ☐ Ongoing from thyroid surgery ☐

Treatment intent: Curative ☐ Palliative ☐ Supportive ☐

2

Drug name: _____ **Dose:** _____ **Start Date:** ____/____/____ **End Date:** ____/____/____ or **ongoing** ☐

Reason for treatment: Residual H&N tumour ☐ Recurrent H&N tumour ☐ New H&N Primary ☐ Ongoing from thyroid surgery ☐

Treatment intent: Curative ☐ Palliative ☐ Supportive ☐

7e. Specialist Palliative (input from the palliative care team for the H&N cancer) *Yes ☐ No ☐ *If Yes please give details below

Start Date: ____/____/_____

Please give a brief description of the input given: _____

_____

_____

7f. Active monitoring (Outpatient follow-up) Please tick the answer that applies to the patients Head & Neck cancer follow-up:

Ongoing hospital follow-up by Head & Neck clinicians ☐ (This includes follow up by oncologists or surgeons at any hospital, NHS or private)

Patient has been discharged from hospital to GP care ☐ Date of letter discharging patient from H&N follow up to GP care: _____/_____/_____

Other (please state) ☐ _____

Study ID ☐☐☐☐☐☐ **Initials** ☐☐☐

7g. Other (eg: radioiodine / blinded drug trial) *Yes ☐ No ☐ *If Yes please complete a section below for each treatment given for the head and neck cancer

1

Treatment name: _____ **Start Date:** ____/____/____ **End Date:** ____/____/____ or **ongoing** ☐

Reason for treatment: Residual H&N tumour ☐ Recurrent H&N tumour ☐ Distant metastases ☐ New H&N Primary ☐

Treatment intent: Curative ☐ Palliative ☐ Supportive ☐

Please record any other information regarding the treatment (if applicable please give the short name of the drug trial):

_____

_____

_____

2

Treatment name: _____ **Start Date:** ____/____/____ **End Date:** ____/____/____ or **ongoing** ☐

Reason for treatment: Residual H&N tumour ☐ Recurrent H&N tumour ☐ Distant metastases ☐ New H&N Primary ☐

Treatment intent: Curative ☐ Palliative ☐ Supportive ☐

Please record any other information regarding the treatment (if applicable please give the short name of the drug trial):

_____

_____

_____

Study ID ☐☐☐☐☐☐ **Initials** ☐☐☐

8. CO-MORBIDITY INDEX

<u>Please tick ALL the relevant boxes below</u> to indicate the patients medical history. Please complete all medical history regardless of the scoring with the following exception.

- **Do not include the head & neck cancer recorded in A5 on the Baseline Data Capture Form, or any recurrence of this cancer, when scoring the section on malignancy**. In the section on malignancy only record any previously diagnosed cancer or any other newly diagnosed cancer (eg prostate, lung, or other head and neck primary cancer).

For the section on end stage renal disease please note that it uses the measurement mg%. Mg% is the same as mg/dL. If your hospital measures creatinine in umol/L then take the result in umol/L and divide it by 88.4 to get mg%.

If you are unsure how to record information in this section please contact the H&N5000 team in Bristol (Tel: 0117 3429536 or 0117 3429531)

Please record here any medical history or illnesses that you are unsure how to record or that are not covered by the comorbidity list below. Please give the date and name of the illness / procedure:

Please complete the comorbidity questions below by ticking all the relevant boxes.

If the participant has no comorbidities at all please tick here ☐ and go to question 9.

Cogent comorbid ailment	Grade 3 Severe Decompensation	Grade 2 Moderate Decompensation	Grade 1 Mild Decompensation
Cardiovascular system			
Myocardial Infarct	☐ MI ≤ 6 months	☐ MI > 6 months ago	☐ MI by ECG only, age undetermined
Angina / Coronary Artery Disease	☐ Unstable angina	☐ Chronic exertional angina ☐ Recent (≤ 6 months) Coronary Artery Bypass Graft (CABG) or Percutaneous Transluminal Coronary Angioplasty(PTCA) ☐ Recent (≤ 6 months) coronary stent	☐ ECG or stress test evidence or catheterization evidence of coronary disease without symptoms ☐ Angina pectoris not requiring hospitalization ☐ CABG or PTCA (>6 mos.) ☐ Coronary stent (>6 mos.)
Congestive Heart Failure (CHF)	☐ Hospitalized for CHF within past 6 months ☐ Ejection fraction < 20%	☐ Hospitalized for CHF >6 months prior ☐ CHF with dyspnoea which limits activities	☐ CHF with dyspnoea which has responded to treatment ☐ Exertional dyspnoea ☐ Paroxysmal Nocturnal Dyspnoea (PND)
Arrhythmias	☐ Ventricular arrhythmia ≤ 6 months	☐ Ventricular arrhythmia > 6 months ☐ Chronic atrial fibrillation or flutter ☐ Pacemaker	☐ Sick Sinus Syndrome ☐ Supraventricular tachycardia
Hypertension	☐ DBP>130 mm Hg ☐ Severe malignant papilledema or other eye changes ☐ Encephalopathy	☐ DBP 115-129 mm Hg ☐ DBP 90-114 mm Hg while taking antihypertensive medications ☐ Secondary cardiovascular symptoms: vertigo, epistaxis, headaches	☐ DBP 90-114 mm Hg while not taking antihypertensive medications ☐ DBP <90 mm Hg while taking antihypertensive medications ☐ Hypertension, not otherwise specified

Cogent comorbid ailment	Grade 3 Severe Decompensation	Grade 2 Moderate Decompensation	Grade 1 Mild Decompensation
Cardiovascular system continued			
Venous Disease	☐ Recent PE (≤ 6 mos.) ☐ Use of venous filter for PE's	☐ DVT controlled with Coumadin or heparin ☐ Old PE > 6 months	☐ Old DVT no longer treated with Coumadin or Heparin
Peripheral Arterial Disease	☐ Bypass or amputation for gangrene or arterial insufficiency < 6 months ago ☐ Untreated thoracic or abdominal aneurysm (>6 cm)	☐ Bypass or amputation for gangrene or arterial insufficiency > 6 months ago ☐ Chronic insufficiency	☐ Intermittent claudication ☐ Untreated thoracic or abdominal aneurysm (< 6 cm) ☐ s/p abdominal or thoracic aortic aneurysm repair
Respiratory System			
	☐ Marked pulmonary insufficiency ☐ Restrictive Lung Disease or COPD with dyspnoea at rest despite treatment ☐ Chronic supplemental O2 ☐ CO2 retention (pCO2 > 50 torr) ☐ Baseline pO2 < 50 torr ☐ FEV1 (< 50%)	☐ Restrictive Lung Disease or COPD (chronic bronchitis, emphysema, or asthma) with dyspnoea which limits activities ☐ FEV1 (51%-65%)	☐ Restrictive Lung Disease or COPD (chronic bronchitis, emphysema, or asthma) with dyspnoea which has responded to treatment ☐ FEV1 (66%-80%)
Gastrointestinal System			
Hepatic	☐ Portal hypertension and/or oesophageal bleeding ≤ 6 mos. (Encephalopathy, Ascites, Jaundice with Total Bilirubin > 2)	☐ Chronic hepatitis, cirrhosis, portal hypertension with moderate symptoms "compensated hepatic failure"	☐ Chronic hepatitis or cirrhosis without portal hypertension ☐ Acute hepatitis without cirrhosis ☐ Chronic liver disease manifested on biopsy or persistently elevated bilirubin (>3 mg/dl)
Stomach / Intestine	☐ Recent ulcers(≤ 6 months ago) requiring blood transfusion	☐ Ulcers requiring surgery or transfusion > 6 months ago	☐ Diagnosis of ulcers treated with meds ☐ Chronic malabsorption syndrome ☐ Inflammatory bowel disease (IBD) on meds or h/o with complications and/or surgery
Pancreas	☐ Acute or chronic pancreatitis with major complications (phlegmon, abscess, or pseudocyst)	☐ Uncomplicated acute pancreatitis ☐ Chronic pancreatitis with minor complications (malabsorption, impaired glucose tolerance, or GI bleeding)	☐ Chronic pancreatitis w/o complications
Renal System			
End-stage renal disease	☐ Creatinine > 3 mg% with multi-organ failure, shock, or sepsis ☐ Acute dialysis	☐ Chronic Renal Insufficiency with creatinine >3 mg% ☐ Chronic dialysis	☐ Chronic Renal Insufficiency with creatinine 2-3 mg%.
Endocrine System (Code the comorbid ailments with the (*) in both the Endocrine system and other organ systems if applicable)			
Diabetes Mellitus	☐ Hospitalization ≤ 6 months for DKA ☐ Diabetes causing end-organ failure ☐ retinopathy ☐ neuropathy ☐ nephropathy* ☐ coronary disease* ☐ peripheral arterial disease*	☐ IDDM without complications ☐ Poorly controlled AODM with oral agents	☐ AODM controlled by oral agents only
Neurological System			
Stroke	☐ Acute stroke with significant neurologic deficit	☐ Old stroke with neurologic residual	☐ Stroke with no residual ☐ Past or recent TIA
Dementia	☐ Severe dementia requiring full support for activities of daily living	☐ Moderate dementia (not completely self-sufficient, needs supervising)	☐ Mild dementia (can take care of self)
Paralysis	☐ Paraplegia or hemiplegia requiring full support for activities of daily living	☐ Paraplegia or hemiplegia requiring wheelchair, able to do some self care	☐ Paraplegia or hemiplegia, ambulatory and providing most of self care

Study ID ☐☐☐☐☐☐ **Initials** ☐☐☐

Cogent comorbid ailment	Grade 3 Severe Decompensation	Grade 2 Moderate Decompensation	Grade 1 Mild Decompensation
Neurological System continued			
Neuromuscular	☐ MS, Parkinson's, Myasthenia Gravis, or other chronic neuromuscular disorder and requiring full support for activities of daily living	☐ MS, Parkinson's, Myasthenia Gravis, or other chronic neuromuscular disorder, but able to do some self care	☐ MS, Parkinson's, Myasthenia Gravis, or other chronic neuromuscular disorder, but ambulatory and providing most of self care
Psychiatric			
	☐ Recent suicidal attempt ☐ Active schizophrenia	☐ Depression or bipolar disorder uncontrolled ☐ Schizophrenia controlled w/ meds	☐ Depression or bipolar disorder controlled w/ medication
Rheumatologic (Incl. Rheumatoid Arthritis, Systemic Lupus, Mixed Connective Tissue Disorder, Polymyositis, Rheumatic Polymyositis)			
	☐ Connective Tissue Disorder with secondary end-organ failure (renal, cardiac, CNS)	☐ Connective Tissue Disorder on steroids or immunosuppressant medications	☐ Connective Tissue Disorder on NSAIDS or no treatment
Immunological System (AIDS should not be considered a comorbidity for Kaposi's Sarcoma or Non-Hodgkin's Lymphoma)			
AIDS	☐ Fulminant AIDS w/KS, MAI, PCP (AIDS defining illness)	☐ HIV+ with h/o defining illness. CD4+ < 200/μL	☐ Asymptomatic HIV+ patient. ☐ HIV+ w/o h/o AIDS defining illness. CD4+ > 200/μL
Malignancy (Excluding Cutaneous Basal Cell Ca., Cutaneous SCCA, Carcinoma in-situ, and Intraepithelial Neoplasm)*****			
Solid Tumour including Melanoma*	☐ Uncontrolled cancer***** ☐ Newly diagnosed but not yet treated ☐ Metastatic solid tumour*****	☐ Any controlled solid tumour without documented metastases, but initially diagnosed and treated within the last 5 years*****	☐ Any controlled solid tumour without documented metastases, but initially diagnosed and treated > 5 years ago*****
*** do not include the head & neck cancer with which this patient was recruited to the study, or any recurrence of this cancer, in the comorbidity chart. However, if the patient has had a new head and neck primary please score the new primary. If there was a synchronous primary cancer at baseline please contact the H&N5000 team for advice.**			
Leukaemia and Myeloma	☐ Relapse ☐ Disease out of control	☐ 1st remission or new dx <1yr ☐ Chronic suppressive therapy	☐ H/o leukaemia or myeloma with last Rx > 1 yr prior
Lymphoma	☐ Relapse	☐ 1st remission or new dx <1yr ☐ Chronic suppressive therapy	☐ H/o lymphoma w/ last Rx >1 yr prior
Substance Abuse (Must be accompanied by social, behavioural, or medical complications			
Alcohol	☐ Delirium tremens	☐ Active alcohol abuse with social, behavioural, or medical complications	☐ H/o alcohol abuse but not presently drinking
Illicit Drugs	☐ Acute Withdrawal Syndrome	☐ Active substance abuse with social, behavioural, or medical complications	☐ H/o substance abuse but not presently using
Body Weight			
Obesity		☐ Morbid (i.e., BMI ≥ 38)	

There is no need to give the overall comorbidity score as you have ticked every box that applies and given any further information in the section on page 9.

Study ID ☐☐☐☐☐☐ **Initials** ☐☐☐

9. DOES THE PATIENT HAVE A FEEDING TUBE? A. Yes ☐ B. No ☐

9a. IF YES, APPROXIMATELY HOW MUCH DIETARY INTAKE IS THROUGH THE FEEDING TUBE?

A. None ☐ B. < 20% ☐ C. 20 – 80% ☐ D. > 80% ☐

If the feeding tube has been inserted for a reason not related to the H&N tumour recorded on the Baseline DCF please give the reason for insertion: _____

_____

10. DOES THE PATIENT HAVE A TEMPORARY TRACHEOSTOMY? A. Yes ☐ B. No ☐

11. DOES THE PATIENT HAVE A PERMANENT LARYNGEAL STOMA? A. Yes ☐ B. No ☐

If the tracheostomy has been inserted for a condition other than head & neck cancer please let us know the reason for insertion:_____

_____

12. AT THE TIME OF COMPLETING THIS FORM DOES THE PATIENT HAVE RESIDUAL HEAD & NECK TUMOUR OR ARE THEY CONSIDERED TO BE FREE OF HEAD AND NECK CANCER?

Residual tumour is cancer remaining following the initial treatment(s). If this has not been recorded in the notes please ask advice from the Head & Neck clinical team. If you are not sure how to record the information from the clincial notes please contact the Head & Neck 5000 team on 0117 342 9531 for advice.

a.	Residual tumour remaining from the initial H&N cancer diagnosis	Yes ☐	No ☐
b.	Residual tumour remaining from recurrence of the H&N cancer	Yes ☐	No ☐
c.	Residual tumour remaining from a new H&N primary cancer	Yes ☐	No ☐
d.	Considered to be tumour free from H&N cancer	Yes ☐	No ☐
e.	Is the participant under investigation for a suspicious H&N lesion?	*Yes ☐	No ☐

*If question 'e' has been answered 'Yes' please give details here:

If the patient is still alive please go to the signature section on page 14.

If the patient has died please complete as much as you can of the Mortality Questions on page 13 before signing the form.

Study ID ☐☐☐☐☐☐ **Initials** ☐☐☐

Head & Neck 5000 Mortality Questions

If the following information is not available from the patient's hospital notes we would be grateful if you could contact an appropriate clinician e.g. their Head and Neck Clinical Nurse Specialist / Consultant to provide answers to the following questions:

Q1 Was death caused by head and neck disease? Yes ☐ No ☐ Not Known ☐

Q2 Mode of death (please tick one):

Gradual Deterioration (>1 week) ☐

Rapid Deterioration (<1week) ☐

Q3 Please record cause of death as reported on the patient's death certificate:

1a)_____

1b)_____

1c)_____

2)_____

Q4 Did this patient have a catastrophic bleed as a terminal event? Yes ☐ No ☐ Not Known ☐

Q5 Did this patient have an airway obstruction as a terminal event? Yes ☐ No ☐ Not Known ☐

Q6 Did this patient have any aggressive interventions e.g. emergency tracheostomy in the last 48 hours before their death? Yes ☐ No ☐ Not Known ☐

Q7 Did this patient receive continuous sedation for the relief of difficult respiratory symptoms at the end of life? Yes ☐ No ☐ Not Known ☐

Q8 Where was the place of death?

Home ☐

Hospice ☐

Hospital ☐

Care Home ☐

Other ☐ Please state:_____

Q9 If the patient did not die at home, was this because their care needs could not be met at home? Yes ☐ No ☐ Not Known ☐

Study ID ☐☐☐☐☐☐ **Initials** ☐☐☐

COMMENTS: Please add here any information that you feel may help to clarify the answers given on the Data Capture Form.

SIGNATURE:	
Please sign below to confirm that you have checked that this form is complete and that the data is accurate to the best of your knowledge. The name of the person signing this form must appear on the site signature & delegation log and be delegated to this duty by the study Principal Investigator.	
Name of person completing form (please print):	
Signature of person completing form:	
Date:	

Thank you for completing the Data Capture Form.

Please return the completed Data Capture Form to the Head & Neck 5000 team at:
Head & Neck 5000 team
Bristol Dental Hospital
Bristol BS1 2LY