

headandneck
5000

Newsletter 12 June 2015

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Amendments 9 & 10 now have Ethics approval

Amendment 9 allows us to collect postcode data where this was not given to us in the questionnaire. As we already have a lot of this data we will be in touch to let you know if you need to collect any postcodes for us.

Amendment 10 allows us to do some further testing on the blood, saliva and tissue samples that have been collected. This amendment does not have an impact on the H&N5000 sites.

Please ensure that you file the notice of substantial amendment, the REC approval and your local R&D approval in your H&N5000 site file (sections 7 & 8)

H&N5000 Further Follow Up Study

We are setting up a follow up study to H&N5000.

Patients who were recruited to H&N5000 over three years ago will be eligible. There will be a questionnaire for patients to complete and a short data capture form to be completed by site staff.

This will be submitted as a new study so there will be portfolio funding attached.

Watch this space and we will let you know more when it is ready for submission to the REC and R&D departments.

Follow Up Data Capture Forms

It is vital to the study that we get as much follow up data as possible.

If one of your participants has moved to another area do let us know. If they are being followed up at a site that is taking part in the study then we may be able to put you in touch with someone who can help with data collection.

Four Month Follow Up Data Capture Forms

Please can you ensure that your four month follow up Data Capture Forms are completed and sent in to us by the end of July 2015.

Don't forget that if the patient has had surgery we will need the pathology staging from the operation. If you are having trouble with this please ask your pathologist to help, or send us an anonymised copy of the pathology report from the operation so that we can allocate the staging.

Twelve Month Follow Up Data Capture Forms

Please don't forget that it is the treatments that have started after month 4 that we need you to record in B2.

If a patient has been on outpatient follow up only then this is coded as 'Active Monitoring'. For these cases please tick either 'ongoing' or 'N/A' in B12b . If you tick 'yes' we will think that the patient has stopped having outpatient follow up.

If you complete and send your forms in late please add a comment to tell us that you have only collected data up to the 12 month time point.

If you are ever unsure about what to record, do get in touch with us, we are always happy to help.

Data Queries

Thank you to everyone who has sent back their data queries. We are very grateful for their speedy return.

If you are having trouble working your way through them or have any questions regarding the queries do let us know. We can help to clarify and to prioritise the questions.

Tissue samples

We are still chasing up tissue blocks - we do need these in as soon as possible so if you haven't been in touch with your pathology team to request any outstanding samples please would you do so.

We also have a large number of invoices outstanding!!! Don't forget that we pay £30 per patient for the tissue blocks that we receive. If you are not sure if you are up to date with samples and invoicing just ask Christine or Katrina and we will let you know.

We will have some queries being sent out soon that relate to the pathology reports. These need to be answered by your head and neck pathology consultant, so we will be in touch to check their contact details if required.

**Thank you all very much for your ongoing support for
Head & Neck 5000**