

Patient Information Leaflet



interNational Anaplastic Thyroid Cancer Tissue Bank and Database Project: Patient Information Leaflet v7

What is this project?

You are being invited to take part in a long term thyroid cancer research project. The project aims to collect a tissue sample from your thyroid cancer, and if possible a blood sample and some information relating to your thyroid cancer diagnosis, investigation and treatment.

The collected samples will be used by scientists who wish to carry out approved research projects that are either investigating the mechanism by which this disease develops and/or investigating potential drug treatments.

As anaplastic thyroid cancer is a rare disease this project will need to be run over a number of years in order to be able to collect enough samples to be studied.

Why have I been chosen?

All patients who have been diagnosed with anaplastic thyroid cancer or who have areas of anaplastic thyroid cancer mixed in with other types of thyroid cancer are being asked if they would like to participate in the project.

Do I have to take part?

No. The decision is completely down to you. If you do wish to take part please keep this information sheet and you will subsequently be asked to sign a consent form to show that you wish to proceed. If you do not want to take part then we will make a note of your decision and not ask you again although if you change your mind you or your medical team can contact us and we can proceed. Whatever your decision, it will not affect your treatment options or the care you receive.

What will happen to me if I take part?

In order to have made your diagnosis you will already have had a biopsy taken from your thyroid gland or a thyroid operation. The tissue samples taken will have already been analysed by your local thyroid cancer team. Often there is some tissue left over which your local team do not need and it is this that would be used for the anaplastic thyroid cancer tissue bank research project.

This tissue will be sent to the Wales Cancer Bank in Cardiff, Wales, UK for storage and future research.

It is quite likely that routine blood tests will be required from you at some point. We would like your consent to take an additional sample (approximately 4-8 teaspoons or 20 to 40mls) that will then be used for our research.

As well as collecting the tissue and blood samples it would be very helpful if we could also look at and collect some medical information. This would include information about the symptoms that lead to you finding out about your diagnosis, the tests you may have undergone and any treatment that you receive. This information would be treated in the strictest confidence and in accordance with the Data Protection Act 1998. The researchers will not be able to identify you from the information they receive and they will not have information such as your name, telephone number or address. We will not disclose any information about you to any third party. Under the Data Protection Act 1998 you are entitled to see what information is recorded about you.

What do I have to do?

You will need to give your written consent in order to donate your tissue, blood and medical information. You have 4 options. i) donate just your thyroid tissue ii) donate your thyroid tissue as well as a blood sample iii) donate your thyroid tissue and give permission for your clinical information to be collected or iv) donate your thyroid tissue, a blood sample and give permission for your clinical information to be used. If however you live outside the UK we may not be able to get your blood sample from your local hospital to storage in the Wales Cancer Bank before the sample deteriorates in which case we would not take any blood from you for the research project. There will be no additional treatment or investigations required as a result of you taking part in this project after the initial samples are collected. If you are willing for your medical information to be collected we would be very interested to collect updates on any additional treatment that you may undergo.

What are the advantages and disadvantages of taking part?

Tissue and blood samples will be taken as part of your routine treatment and care. The samples taken for the research project will only be taken after all of the necessary diagnostic tests have been carried out on them. Therefore taking part in this project will have no disadvantages.

Research project proposals will be reviewed by a multidisciplinary expert panel to ensure these precious tissue and blood samples are used for the best research purposes.

The results of the research using your samples and those from other patients will be used to benefit anaplastic thyroid cancer patients in the future. You are being asked to donate your tissue for research and will not receive a financial reward either now or in the future. Your tissue samples will not be sold for profit to other researchers. Your samples may be used for research purposes that may lead to the development of new drugs or treatments. The research may be carried out in academic institutions, the NHS or commercial companies involved in cancer research. Due to the rarity of this disease and the difficulty in getting large numbers of samples it is quite likely that international researchers may express interest in using the samples.

We would ensure that the research projects with the best chances of providing helpful information on the future treatment of this disease were selected.

What happens if I change my mind?

You can change your mind and withdraw from the project at anytime without giving a reason. If you do this a short time after donating your samples, it will be possible to return your biopsy samples to your local hospital and to destroy any blood samples along with any data associated with them.

However, if you withdraw your consent a long time after donation, it is likely that some of your samples will have already been used for research. However any of your samples remaining at the time you withdraw your consent will be returned or destroyed.

What if new information becomes available as a result of the research?

Results for individual patients will not be relayed back to that individual, their hospital doctor or GP. Your hospital doctor and the wider medical community will be notified of any information that would change current medical practices and improve patient treatments and outcomes.

Will my taking part be confidential?

Yes. All information that is collected about you during the course of the research will be kept strictly confidential. Any information about you that is given to the researchers will have your name and address and any other personal information removed so that you cannot be recognised from it.

What will happen to the results of the research project?

It is expected to take several years to collect sufficient numbers of samples that can then be studied. It is then likely to take several more years before the results of the research are available. Results will be published as appropriate in scientific journals and presented at national/international meetings.

Who is organising and funding the research?

This research project will be run by Dr Laura Moss, Consultant Oncologist at Velindre Cancer Centre, Cardiff, Wales UK in conjunction with the staff of the Wales Cancer Bank, a multidisciplinary steering committee and with the support of the National Cancer Research Institute Thyroid Cancer Subgroup. The project also has the support of the UK Endocrine Pathology Society, the International Rare Cancer Initiative, members of Thyroid Cancer Forum-UK and the European Thyroid Association along with thyroid cancer patient charity support from Thyroid Cancer Support Group-Wales and the Butterfly Thyroid Cancer Trust.

Funding has been provided by Thyroid Cancer Support Group Wales (registered charity number 1113774). The medical team involved in your treatment and care will receive no payment because of your involvement in this project.

Who has approved/reviewed the project?

Velindre NHS Trust as research sponsor has reviewed and approved this project and will be responsible for the management and conduct of the whole project. The

project has also received ethical approval via its submission through the Integrated Research Application System.

If you would like to talk to someone regarding your diagnosis and to get information on support that may be available, you can contact the following patient support groups:

Thyroid Cancer Support Group-Wales

Supporting thyroid cancer patients and families not only in Wales but nationally and internationally. The group is responsible for the entire funding of the iNATT project.

Address: 'Morcote', Sunlea Crescent, New Inn, Pontypool, Gwent, NP4 8AD, South Wales UK

Tel: +44 (0)845 009 2737

Website: www.thyroidsupportwales.co.uk

Email: thyroidgroup@tiscali.co.uk

Butterfly Thyroid Cancer Trust

Butterfly Thyroid Cancer Trust is the first registered charity in the UK dedicated solely to the support of people affected by thyroid cancer.

Address: PO Box 205, Rowlands Gill, Tyne & Wear, NE39 2WX, UK

Tel: +44 (0)1207 545469

Website: www.butterfly.org.uk

Email: enquiries@butterfly.org.uk

**Thank you very much for taking the time to read this information.
Should you agree to take part in this project, your generosity will enable
anaplastic thyroid cancer patients of the future to benefit**

Contact Information:

If you would like further information:

- You can contact the Chief Investigator: Dr Laura Moss at Velindre Cancer Centre, Cardiff, Wales UK
 - By telephone on +44 (0)29 20316205
 - By e-mail laura.moss@wales.nhs.uk
 - By writing to Velindre Cancer Centre, Velindre Road, Whitchurch, Cardiff CF14 2TL Wales, UK
- You can ask the person who has provided this leaflet to you