We would like to invite you to take part in a research study. Before you decide you need to understand why the research is being done and what it would involve for you.

Please take time to read the following information carefully. Talk to others about the study if you wish.

(Part 1 tells you the purpose of this study and what will happen to you if you take part. Part 2 gives you more detailed information about the conduct of the study).

Ask us if there is anything that is not clear or if you would like more information. Once you have done this please take some time to decide whether or not you wish to take part.

You do not have to take part in this study. You will be treated to the very best of our ability whether you take part or not.

PART 1

What is the purpose of the study?
This study is a research project that is trying to find new ways to diagnose thyroid cancer from blood samples. If successful, the hope is that thyroid cancer could be diagnosed with simple tests like the ones used for diabetes and cholesterol. This would allow thyroid cancer to be detected earlier and more easily with less intrusion and discomfort.

Why have I been chosen?
You have been chosen because you are attending a clinic that deals with thyroid cancer.

Do I have to take part?
It is up to you to decide. We will describe the study and go through this information sheet, we will then ask you to sign a consent form. You are free to withdraw at any time, without giving a reason. This would not affect the standard of care you receive.
What will happen to me if I take part?
There will be no changes to your treatment. We would like to collect some additional information and a blood sample from you.

Whilst at the clinic you will be asked to provide a small blood sample and asked some questions about any medications you are on and some medical history. Wherever possible the blood sample will be taken at the same time as any sample taken as part of the standard clinical assessment.

When you leave the clinic you will be given a lifestyle questionnaire to fill in at home and post back in the envelope provided. This should take less than half an hour. This questionnaire is optional and will be used to inform part of a larger study. There is also an online version that can be filled in over the internet if that is more convenient. Please note that some of the questions in this questionnaire are personal. If you prefer, you may wish not to answer some of the questions.

What is the study trying to test?
Some conditions, for example diabetes, can already be diagnosed from blood. This study is trying to create more tests for thyroid cancer.

What are the possible disadvantages and risks of taking part?
There should be no disadvantages or risks to taking part. Your treatment will be unaffected. The blood sample is a small amount and in the worst case you may experience some slight bruising from where the sample was taken. Wherever possible the sample will be taken at the same time as you provide samples during your clinical assessment and so should involve no additional risks or discomfort.

What are the possible benefits of taking part?
The trial will not help you personally but it could help improve the diagnosis and treatment of thyroid cancer in the future.

What if there is a problem?
Any complaint about the way you have been dealt with during the study or any possible harm you might suffer will be addressed. The detailed information on this is given in Part 2.

Will my taking part in the study be kept confidential?
Yes. We will follow ethical and legal practice and all information about you will be handled in confidence. The details are included in Part 2.

If the information in Part 1 has interested you and you are considering participation, please read the additional information in Part 2 before making any decision.

PART 2

What will happen if I don't want to continue with the study?
You can withdraw from the study at any time and without giving a reason. If you withdraw from the study, we will destroy all your identifiable samples, but we will need to use the data collected up to your withdrawal.
What if there is a problem?
If you have a concern about any aspect of this study, you should ask to speak to the researchers who will do their best to answer your questions:

**Research Nurse:** Lesley Naik  
**Primary Investigator:** Dr. Petros Perros, Consultant Endocrinologist, 0191 282 0590

If you remain unhappy and wish to complain formally, you can do this through the NHS Complaints Procedure by contacting:

   The Patient Advisory Service, Tel: 0800 032 0202

If something does go wrong and you are harmed during the research and this is due to someone’s negligence then you may have grounds for legal action for compensation against the NHS Trust but you may have to pay your legal costs. The normal National Health Service complaints mechanisms will still be available to you (if appropriate).

There is a small chance that results from this study will suggest you have a condition of which you are unaware. This will not be a diagnosis but it may suggest further standard clinical tests should be run just to be sure. In such circumstances you will be referred to the appropriate specialist in consultation with your general practitioner, if that is what you would like. Such detection has the benefit of starting treatment early but in a small number of cases may have implications for future employment and insurance.

Will my taking part in this study be kept confidential?
There are very strict rules about collecting medical research information under the 1998 Data Protection Act. We must comply with this act and keep your information safe. Any Information that leaves the hospital will have your name and address removed.

Your medical notes include details about your name, date of birth and hospital number. The information accessed for the research will be about your diagnosis and long term state of health. In order to check that the study is being carried out correctly and the information accurate the trials team may wish to see your medical records.

Your GP will not normally be notified that you are taking part in this study, but a member of the medical team would be happy to do so if you so wish. All information which is collected about you during the course of the research will be kept strictly confidential, and any information about you which leaves the hospital will have your name and address removed so that you cannot be identified.

What will happen to the samples I give?
The blood sample will be sent anonymously to a laboratory and processed. The result of the processing is to measure relative quantities of many thousands of constituents of your blood. We will keep your samples until the genetic testing is completed, after which the samples will be destroyed.
The blood sample will also be used to check genetic markers in the blood stream that may indicate whether there is thyroid cancer or not in the body. These genetic tests will not check whether you have an inherited predisposition to cancer or any other conditions or diseases.

The blood sample will not be used to create cell lines or for animal experimentation.

**What will happen to the results of the research study?**
- The results will be published in a scientific journal.
- If diagnostic signatures of disease are validated they will be commercialised and put into standard clinical practice as soon as is practical.

An overview of results of the research will also be presented on the sponsor's website [http://www.biosignatures.com/RVIEndocrinology/](http://www.biosignatures.com/RVIEndocrinology/) to allow participants to follow overall progress.

**Who is organising and funding the research?**
The study is funded by the Strategic Health Authority (which is part of the NHS) and a company: Biosignatures Ltd. - Biosignatures is a small team based in Newcastle.

This study has been designed by the research team, which consists of senior doctors and academics based at the Royal Victoria Infirmary, Northern Centre for Cancer Care, the University of Newcastle upon Tyne and scientists from Biosignatures Ltd.

The funder is paying the hospital to employ a full time research nurse and to have some time from the medical experts in the clinic. There is no patient payment or incentives for any of the medical staff. Biosignatures Ltd staff do not work in the clinic and everyone you will meet will be employed, trained and managed by the hospital.

**Who has reviewed this study?**
All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and given favourable opinion by Northern and Yorkshire Research Ethics Committee. The study has also been reviewed by independent experts.

This study has also been reviewed and approved by the Newcastle Upon Tyne Hospitals NHS Foundation.

*Thank you for reading this information leaflet. If you have problems or questions now or during your treatment, please do not hesitate to get in touch.*
Clinical team:

Research Nurse: Lesley Naik
Chief Investigator: Dr. Petros Perros, tel: 0191 282 0590
Address: Department of Endocrinology, Royal Victoria Infirmary, Newcastle Upon Tyne, NE1 4LP

Additional and updated information is available here: http://www.biosignatures.com/RVIEndocrinology/
PARTICIPANT INFORMATION SHEET
DIAGNOSING THYROID CANCER USING A BLOOD TEST

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**PART 2**

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