



Patient Information Sheet

The Pathobiology of Neoplastic and Non-Neoplastic Diseases of Bone, Joint and Soft Tissue and Cellular Mechanisms of Pathological Bone Resorption **(CR01.070/CR01.071)**

We are inviting you to take part in a research project. Before you decide whether to take part it is important for you to know why the research is being done and what it will involve for you. Please take time to read the following information carefully and to decide whether or not you wish to take part. Please talk to others about the study if you wish.

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

Part 1

What is the Research Project about?

As you may be aware there is currently a lot of research being carried out worldwide into musculoskeletal diseases such as osteoporosis, Paget's disease, arthritis and bone tumours. The aim of this research is to gain a better understanding of the disease mechanisms underlying these orthopaedic conditions in order to develop new methods of diagnosis and treatment.

The Orthopaedic Tissue Bank is a tissue resource for a number of research projects that study diseases of bone, joint and related soft tissues. Samples of blood, and samples of diseased and normal tissues of patients are studied in order to gain direct knowledge of the cellular mechanisms that cause musculoskeletal disease. Samples collected from patients looked after at the Nuffield Orthopaedic Centre NHS Trust are used for research carried out at the Nuffield Orthopaedic Centre in Oxford and in other research centres in the UK and other countries. These studies are ongoing and require the collection and storage of tissue and blood samples over many years to provide a useful tissue resource.

Why have I been chosen to take part?

Patients in Oxford, who are being investigated or treated for a musculoskeletal disease, may be invited to take part.

Do I have to take part?

No. The choice to allow us to collect samples of your tissue and blood for this project is entirely yours. If you decide to take part you can keep this information sheet and you will also be asked to sign a consent form releasing the tissue sample for research use; this forms part of the operation consent form. You are still free to change your mind at any time and without saying why. Whatever your decision, it will not affect your surgery, treatment or any other part of the care you will receive in this hospital or any future care

What will it involve if I decide to take part?

You will need to sign a consent form to allow us to keep a small part of your tissue that is removed during your operation in order to provide a tissue diagnosis; this tissue is normally discarded once a diagnosis has been made. There is no need to take any additional tissue from you, and only tissue that would otherwise be disposed of is retained for research use. You would have exactly the same operation as if you had decided not to take part in the study. Samples of blood taken during routine tests or clinic appointments may also be requested [approximately 10-20ml (2-4 teaspoons)]. We require your signed specific consent for blood collection.

What are the advantages and disadvantages of taking part?

There are no disadvantages in contributing to this study. Blood samples are usually taken at the time of routine investigation/follow up and tissue samples are sent for analysis as part of your operation. The tissue samples used for research are only taken from the diseased tissue that is being removed in the normal course of surgical treatment: no additional tissue is removed.

There are no advantages to you, but the results of the research using your samples of tissue taken from you and others may help patients in the future. You are asked to donate your tissue freely for research and you will not receive a financial reward either now or in the future. Your samples will not be sold for profit to other researchers. Your samples may be used for research that may lead to the development of new drugs or therapies, which may eventually be marketed, and companies may sell these drugs for profits.

What if there is a problem?

Any complaint regarding the way you have been treated during the project will be addressed – more detailed information is available in Part 2. Please address complaints/concerns to: Professor N. Athanasou on **01865 38139**

Will my taking part in the project be kept confidential?

Yes, all the information about your participation in this project will be kept confidential. Further details are included in Part 2.

Contact details

If you would like further information or you have concerns about this project you can either:

- Ask the person who has provided the leaflet to you
- Write to Professor Athanasou at:

**Department of Histopathology,
Nuffield Orthopaedic Centre
Windmill Road
Headington
Oxford
OX3 7LD**

- Contact Professor Athanasou on: **01865 738139**

This completes part 1 of the information sheet.

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

Part 2

What will happen if I don't want to carry on with the study?

You are free to withdraw your samples from the resource at any time and without saying why and we will destroy all of your samples. However if you change your mind a long time after the operation, your tissue and blood components may already have been used for research.

What if there is a problem?

If you have a concern about any aspect of this project, you should speak to the researchers who will do their best to answer your questions (Professor Athanasou: **01865 738139**)

The study involves no more than your usual hospital care and normal NHS complaints procedures will apply. In the unlikely event that you are harmed as a result of an accidental injury and as a direct result of your participation in the study compensation may be available from the University of Oxford.

Will my taking part in the study be kept confidential?

If you consent to take part in this project we would need to record some details of your medical history for the purpose of analysing the research results. This information will of course be strictly confidential and the researchers will not be able to identify you from the information they receive. You would also be anonymous if we need to publish results, or share data or samples with other laboratories for research purposes.

What will happen to any samples that I give?

We will store the tissue and blood samples in a central laboratory using a code, not your name, to tell us which sample is which. Samples and data will be used by researchers for various projects, many of which are not yet known and will depend on the development of new research techniques in the future. However all research projects will be subject to approval by a Research Ethics Committee and access to samples and data will be controlled. Scientists who are experts in genetics may perform tests on your samples – the results of these tests may provide information on which genes cause arthritis, osteoporosis, Paget's disease, bone cancer and other musculoskeletal diseases. Samples and data collected may be transferred for the purpose of research and analysis to associated investigators within/outside the European Economic Area. Some countries outside Europe may not have laws which protect your privacy to the same extent as the data protection act in the UK or European Law. The University will take all reasonable steps to protect your privacy.

What will happen to the results of the research?

The results of investigations that we obtain will add to our overall understanding of musculoskeletal diseases. This information may help in the design of new ways to diagnose or treat in the future. Since the results we get will not change the treatment that you as an individual will get after surgery, you would not receive any of the individual research results that we find. However, the overall findings of our studies will be available to you through public sources, since we will publish the results of our research in leading medical journals.

Who is organising and funding the research Project?

The study is being organised by the Nuffield Department of Orthopaedic Surgery, which is part of the University of Oxford (the sponsors). The lead researcher is Professor N. Athanasou who is a consultant specialising in the diagnosis of patients with musculoskeletal diseases and who works with other clinicians and scientists in the Nuffield Department of Orthopaedic Surgery and the Nuffield Orthopaedic Centre. The project is currently funded by the European Commission.

Who has reviewed the project?

This study was given a favourable ethics opinion for conduct in the NHS by the Central Oxford Research Ethics Committee (COREC).
Reference Number: C01.070/ C01.071

Contact for Further Information

If you would like further information you can either:

- Ask the person who has provided the leaflet to you
- Write to Professor Athanasou at :

**Department of Histopathology,
Nuffield Orthopaedic Centre
Windmill Road
Headington
Oxford
OX3 7LD**

- Contact Professor Athanasou on: **01865 738139**

Thank you very much for taking the time to read this information.



Consent Form

Thank you for reading the information about our research project. If you would like to take part, please read and sign the form.

Title of Project: **Pathobiology of neoplastic and non-neoplastic diseases of bone, joint and soft tissue**
Centre: **OXFORD**

Reference: COREC C01.070/C01.071

Name of Researchers: Professor N. Athanasou

1. I confirm that I have read, understood and have had time to consider the information sheet and have been given a copy to keep. I have had the opportunity to ask questions about this project. ☐
2. I agree to give samples of blood for research in this project as detailed in the patient information sheet. ☐
3. I agree to give samples of tissue for research in this project as detailed in the patient information sheet. ☐
4. I understand how the sample(s) will be collected, that giving sample(s) for this research is voluntary and that I am free to withdraw my approval for use of the sample(s) at any time without giving a reason and without my medical treatment or legal rights being affected. ☐
5. I understand and agree that parts of my medical information may be passed to other organisations involved in the research on the understanding that my personal patient confidentiality will be maintained. This may include countries outside the EEA. ☐
6. I understand that I will not benefit financially if this research leads to the development of a new treatment or medical test. ☐
7. I agree that the sample(s) I have given and the information gathered about me can be stored by the Orthopaedic Tissue Bank for possible use in future projects, as described in the attached information sheet. I understand that some of these projects may be carried out by researchers other than the University of Oxford, including researchers working for commercial companies. ☐
8. I agree that the sample(s) I give may be used for genetic research aimed at understanding which genes might cause cancer or increase the chance of side effects from drugs. I understand that the results of these investigations are unlikely to change my future treatment in any way ☐

Patient's name (PRINT)

Signature

Date

Name of person taking consent

Signature

Date

Name of researcher

Signature

Date