

***Information about a research study***

***(For patients aged 13 – 15 years)***

# Summary of the study

* We are inviting you to take part in a research study called ICONIC because you have osteosarcoma, or a similar bone cancer.
* Please read this information carefully and talk to your parents (or carer) and doctor about this study. Ask us if you want to know more about the study or if there is anything you do not understand.
* It is up to you and your parents (or carer) to decide if you want to take part in this study. If you don’t take part you will be looked after by your doctor just the same.
* You and your parents (or carer) can decide to stop taking part in the study at any time without giving a reason.
* This is an observational study. It is not a study looking at a new treatment.
* We want to understand more about   
  what causes osteosarcoma and how osteosarcoma changes with treatment and over time.
* This will help us to decide what types of treatment are most likely to work best, allowing us to develop better clinical trials of new treatments.

# What is involved if you take part?

* We will take extra blood samples at up to   
  12 different times in addition to your routine blood tests. Where possible, these will be taken when you have your routine bloods so no additional visits should be required.
* We may ask you to have a biopsy that you wouldn’t have routinely. This biopsy is optional and you don’t have to agree to have the extra biopsy to take part in the study. This is entirely up to you and your parents (or carer).
* We’ll ask you to complete some questionnaires about your health and wellbeing. This is something that you wouldn’t need to do if you weren’t on the study.

# Will you have to visit hospital more often if you take part?

* You do not have to make any extra visits to the hospital if you take part in this study unless you agree to have the extra biopsy.

## Why are we doing this study?

We are doing this study to collect high quality medical information about osteosarcoma patients of all ages, such as information about the size of the disease and where it is at diagnosis, what treatments were given and how osteosarcoma responds to the treatments. We will also collect blood and tissue samples for analysis in research laboratories.

By looking at the results of the laboratory findings and the medical information together, we can start to answer questions about why some people get osteosarcoma, what makes osteosarcoma spread, and why some patients respond to treatment better than others.

We plan to use this information to develop clinical trials of new treatments.

Also, we want to find out more about how osteosarcoma and its treatments affect the lives of osteosarcoma patients. This will help us to provide the most appropriate care and support to meet the needs of each patient.

The more we understand about how and why osteosarcoma happens, the better we can decide what treatments are most likely to work best.

## Do you have to take part?

**No. This is up to you and your parents (or carer) to decide.**

If you decide to take part:

* We will ask your parents (or carer) to sign a form to say they agree for you to take part (the consent form)
* If you want, you can sign this consent form as well
* We’ll give you this information sheet and a copy of the consent form to keep.
* If you decide not to take part, or withdraw from the study later, you will still receive the best possible care.

## What will happen if you take part?

### Treatment

If you decide to take part in this study, **you   
will receive routine treatment** for your osteosarcoma.

Depending on your treatment plan, you may have one or more of the following:

* Chemotherapy
* Surgery
* Radiotherapy

As part of your routine care, we will explain what treatment you will receive. **Your treatment will not be affected by taking part in this study.**

### Tests and investigations

You will have all the routine tests and investigations that you would have even if you weren’t taking part in this study. These include blood tests, scans and biopsies if required.

If you take part, you’ll have some extra tests and investigations. These are described below. The number and timing of extra samples depends on which treatments you have.

If you choose to be part of this study we will monitor you at least annually according to routine practice for up to two years. After this, we may continue to collect routine clinical data from your medical records (long term follow up) but you won’t need to attend any study specific visits for this.

We have a flowchart showing the different treatment pathways at the end of this information sheet.

#### Blood Samples

We will always aim to take study samples at the same time you are having routine blood samples so no extra jabs are required.

**Germline DNA:** To see if we can find any genes linked to your osteosarcoma we will need one sample. Usually, this sample will be taken when you join the study..

**Circulating Tumour Cells (CTCs):** If your first treatment is chemotherapy and to see if we can detect any tumour cells in the blood stream we will need samples at the following times:

* Before you start your chemotherapy,
* After chemotherapy, before you have surgery (if this is part of your treatment)
* If your cancer comes back or spreads after treatment.

**Circulating Tumour DNA (ctDNA):** To see if we can detect any DNA leaked from tumour cells into the blood we will need samples at the following times:

* Before, or shortly after, you start your chemotherapy.
* After chemotherapy, before you have surgery (if this is part of your treatment)
* At the end of your treatment,
* Routine follow up clinic visits, no more than 6 monthly, after that.
* If your cancer comes back or spreads after treatment.

These will be optional so you don’t have to consent to these blood samples if you don’t want to.

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**Peripheral blood mononuclear cells (PBMCs):** To see if we can detect any PBMCs, which are cells that destroy other foreign cells (e.g. cancer cells) we will take samples at the following times:

* Before, or shortly after, you start your chemotherapy
* After chemotherapy, before you have surgery
* At the end of your treatment
* If your cancer comes back or spreads after treatment.

We’ll collect these blood samples from about 20 patients taking part in the ICONIC study.

These will be optional so you don’t have to consent to these blood samples if you don’t want to.

Over the course of the study we may take bloods at up to 12 time points. In total, this will be up to about 200mL of blood.

The amount of blood that we take will not affect you in any way.

#### Tissue samples and biopsies

We will collect tissue samples for use in this research at the time of your diagnosis and at your surgery. The tissue will be removed during routine procedures so you will not have to have any extra procedures for this.

We would also like to collect some tissue if your cancer comes back or spreads after treatment.

You might not normally have a routine procedure to remove tissue at this time. In this case, we would ask for your and your parents/ carers permission for you to have an extra biopsy**. The extra biopsy is also optional** so you do not have to have the extra biopsy if you don’t want to.

The type of imaging used to help collect this biopsy will be decided by your doctor who will discuss any potential risks with you before you decide to have the biopsy.

#### Questionnaires

We’ll ask you to complete some questionnaires about your symptoms, diagnosis, health and general wellbeing. The questionnaires should take less than 40 minutes to do. You’ll get them:

* At study entry
* At the end of treatment (not applicable   
  if treatment isn’t given for any reason)
* At 12, 24, 36 and 48 months

We’ll ask you to complete another questionnaire just after you start treatment. This one aims to get a better understanding of your pathway, from symptoms and diagnosis to treatment for osteosarcoma patients.

If you agree to complete these, you will help   
us see changes in quality of life due to osteosarcoma, research into osteosarcoma patient experiences and look into the process of diagnosis for osteosarcoma. In addition, and with your and your parents/carers consent, we will also ask your GP to complete a parallel questionnaire.

### Data collection

With your permission we will collect information from your medical records about your general health, your cancer, your treatment and tests including routine blood tests and scans. We will pass this information on to CRUK & UCL Cancer Trials Centre (UCL CTC) which is the organisation running the study. See Section [7](#Ref524609392) for more information about how your data will be handled.

## What are the possible advantages and disadvantages of taking part?

### Advantages

You will not benefit directly from taking part   
in this study. However by taking part you will be contributing to the further understanding of osteosarcoma which may help future patients.

### Disadvantages

There are very few disadvantages to taking part. You may need to spend a bit of extra time at the hospital when you visit for your appointments to complete the study questionnaires or have the extra blood tests.

It is possible you may have extra jabs if, for some reason, we cannot take the research blood samples at the same time as your routine blood tests.

If you have the extra biopsy for research, you may need to come for an extra visit.

## What if there is a problem or something goes wrong?

Tell us (or your parents/carer) if there is a problem and we will try to sort it out straight away.

Your parents/carers also have information on who to contact and what to do if you are not happy the way you have been treated.

## Will anyone else know you are doing this?

The doctors and nurses treating you will know you are taking part in the study. Your name will not be published in medical papers or on the internet.

## What will happen to samples you give?

#### Blood and tissue samples collected for research

The blood and tissue samples collected for research will be sent to laboratories in the UK, and possibly outside the UK. They will be used for research to help scientists learn more about osteosarcoma. This includes trying to find ways to predict who is going to respond to treatment, understanding more about what causes osteosarcoma to grow and how the cells may change after treatment.

#### Future research

We would like your permission to store some of your tissue and blood samples for use in future research projects. Any future research involving your stored tissue or blood samples will take place only after it has received appropriate Ethical approval.

If you do not want to give permission for the use of your tissue and blood samples in future research, you can still take part in this study.

### Will any genetic tests be done?

**Yes: Genetic testing is an important part of this research.**

We will look at genes that will help us to understand the causes of osteosarcoma and what treatments work best. This is an important part of this research.

**If you do not want to have any genetic testing, you will not be able to take part in the study.**

Results of genetic tests may include chance findings about your health, or the health of your blood relatives.

You can tell us on the consent form whether or not you want us to tell you about any chance findings. However, we will always tell you about any findings that could affect the way we treat your cancer.

If we do tell you about a chance finding, we will refer you (and your family if necessary) to a genetic counsellor who will give you information and advice.

## What will happen to the results of the study

When the study has finished we will present our findings to other doctors and will publish the results in medical journals. Your name will never be mentioned. You can find out about the results from your doctor.

## Who is organising and funding this research?

The Cancer Research UK and University College London Cancer Trials Centre (UCL CTC) are organising the study and it is funded by a charity called the Bone Cancer Research Trust.

## Who has reviewed the study?

All research in the NHS is looked at by an independent group, called a Research Ethics Committee, to protect the interests of any patients that may take part. This study has been reviewed and approved by the London – Camden and King’s Cross Research Ethics Committee (REC) and has also been approved by the Health Research Authority (HRA).

## Contacts for more information

You may want to contact one of the following organisations that are independent of the hospital where you are being treated:

#### Cancer Research UK

Cancer Research UK provides information for people with cancer. Their contact details are:

Freephone: 0808 800 4040 (Mon-Fri 9am-5pm)

Or visit their website at:

<https://www.cancerresearchuk.org/about-cancer>

#### Macmillan Cancer Support

Macmillan is a charity which provides support and counselling to help people live with cancer. They can be contacted at:

Freephone: 0808 808 0000 (8am-8pm seven days a week)

<https://www.macmillan.org.uk/information-and-support>

#### Bone Cancer Research Trust

The Bone Cancer Research Trust is the leading charity dedicated to fighting primary bone cancer. Their mission is to save lives and improve outcomes for people affected by primary bone cancer through research, information, awareness and support.

<https://www.bcrt.org.uk/information/>

### Thank you for taking the time to read this leaflet and to consider this study.

Please discuss any questions you may have with us. Contact details are given at the end of this sheet. There is also space at the end of the Patient Information Sheet for you to write down any questions and comments occurring to you as you read about the study.



### Your treatment team’s contact details

|  |  |
| --- | --- |
| Your doctor’s name: |  |
| Phone number: |  |
| Your research/ specialist nurse’s name: |  |
| Phone number: |  |

**Questions/Comments**

The space below is for you to write down any questions you would like to ask your Doctor or Research Nurse about taking part in the study

**Study Flowchart**

