*To be printed on hospital headed paper*

**PARTICIPANT INFORMATION SHEET**

**13-15 YEARS OF AGE**

rEECur

**International Randomised Controlled Trial of Chemotherapy for the Treatment of Recurrent and Primary Refractory Ewing Sarcoma**

Dear …………………………………………………

We would like to invite you to take part in a research study called rEECur. Before you decide whether you want to take part, it is important that you understand why the research is being done and what it involves. Please take time to read the following information sheet carefully and discuss it with your family. Your family has been given more details about this study. Ask us if there is anything that is not clear or if you would like more information.

This document is provided to help you understand what treatment will be given to you, and will provide answers to the following questions:

* **Section 1 – What is the standard treatment for Ewing sarcoma that has not responded to treatment or has come back after treatment has finished?**

This section explains what the standard treatment for Ewing sarcoma in these situations involves.

* **Section 2 – Why is the research being done and what does it involve?**

This section explains why the study is being done, and what it involves.

* **Section 3 – What else do I need to know about taking part in the study?**

This section answers any additional questions you may have about taking part in this study.

# Section 1: What is the standard treatment for Ewing sarcoma that has not responded to treatment or has come back after treatment has finished?

There is no standard treatment for Ewing sarcoma that has not responded to treatment or has come back after treatment has finished. In deciding on the best treatment doctors think about things such as how much time has passed since you first started treatment for your tumour, whether it has spread anywhere and how well you are. Treatment can involve medicines (including chemotherapy), radiotherapy and surgery. However, there are several ‘regimens’ (mixtures) of chemotherapy drugs that are used in this situation and not much information to help doctors to decide which one is the best. Because of that, different doctors around the UK and around Europe use different treatments, with some treatments being used more frequently in one hospital or one country than others.

# Section 2: Why is the research being done and what does it involve?

**Why are we doing this research study?**

Research studies help us to find new treatments and new ways to use existing treatments. It is through research that we are able to improve your care and the care of other children and young people with cancer. In this study (called the ‘rEECur’ study) we want to compare different regimens of chemotherapy (chemo) to find out which is best.

The best way of testing this is by doing a randomised study. ‘Randomised’ means that a computer will decide by chance which treatment you have. This study contains one randomisation at the beginning of the study.

The computer will divide all of the participants taking part in the study into groups. Each group will be treated with one of the available chemo regimens. Although these chemo regimens are used a lot in people with Ewing sarcoma that has either not responded to initial treatment or has come back, we do not know which is best. A randomised study will allow us to fairly compare the regimens.

**Why have I been invited to take part?**

You have been invited to take part in this study because you have Ewing sarcoma. About 500 children and adults in the UK and around the world will take part in this study.

**Do I have to take part?**

No. It is up to you and your family. We will describe the study and talk through this information sheet with you. This information sheet is yours to keep. You are free to stop taking part at any time during the study without giving a reason. If you decide to stop, this will not affect the care you receive. If you decide not to take part in this study, your doctors will decide which chemo regimen to give you.

**What will happen to me if I take part?**

If you agree to take part, the doctor will look at the results of the tests that have been done to confirm that you are able to take part in the study. You will then be entered into the study and the computer will decide which of the chemo regimens you will receive. Each regimen involves being given between 3 and 5 days of chemo every three weeks. Every 3-week round of chemo is called a ‘cycle’. The available chemo regimens are:

|  |  |
| --- | --- |
| **IFOS** | Four cycles of chemotherapy with a drug called  **ifosfamide**.  Each cycle will involve 5 days of chemotherapy. |

OR

|  |  |
| --- | --- |
| **CE** | Six cycles of chemotherapy with two drugs called  **carboplatin** and **etoposide**.  Each cycle will involve 3 days of chemotherapy. |

**How will the doctor know if things are going well?**

During treatment, you will have routine tests to check how well the chemo is working, including physical check-ups, blood tests and scans.

**What are the side effects of chemo?**

Chemo works by killing tumour cells, but it can also damage normal healthy cells in the body. Side effects happen when healthy cells are damaged.

Common side effects of chemo are:

* Hair falling out, but it will grow back again after the chemo has finished
* Feeling sick or being sick
* Diarrhoea or constipation
* Feeling tired
* Your blood cells are affected by chemo and as a result you may find that if you hurt yourself you bleed or bruise a bit more than usual. This is because the platelet cells which help the blood to clot are affected by the chemo. If you notice this please tell your family or doctor.
* Your white blood cells, which help you fight infections, will also be low. You may catch a cold or cough more easily and you may need to come into hospital to treat any infections.

These are the main side effects. There are other side effects that can happen with some chemo drugs and your doctor will talk to you and your family about these if you will receive those chemo drugs. Some of the important side effects are as follows. Ifosfamide can occasionally make you feel sleepy and confused and can cause kidney problems. Carboplatin may lead to numbness and pins and needles. It can also cause kidney problems and deafness. Occasionally, some people become allergic to carboplatin. Etoposide can cause kidney and liver problems.

Some side effects can be severe. Before each cycle of chemo, blood tests will be done to check that you are well enough to continue.

*Radiation risk*

As part of this study, you may have bone scans, PET-CT scans and up to five CT scans. You may also have tests of your kidneys called a GFR. All of these tests are to look at how you are responding to treatment. Most of the tests that you will undergo are the same as if you were not taking part in this trial, as they form part of standard practice.  However, the PET-CT scans would not be performed as part of standard practice, but they may provide useful information.  You would only have these scans if the doctor feels that they may be useful, and with you and your families agreement.

All of these tests use ionising radiation, which is thought to be associated with a very small increased risk of developing a second cancer in the future. At present, there are no better ways of imaging the body which avoids this radiation, and the tests are only performed to inform your treatment and management.

*Harm to the unborn child*

Chemo can be dangerous for unborn babies, so your doctors will need to talk about sex and pregnancy with you. Your family can be there if you wish, or you can talk to your doctor on your own.

**What will I have to do?**

If you decide to take part in this research study, you will be asked to:

* Keep all appointments with your doctor
* Tell your doctor about any medicines you take, even if it is medicine you buy without a prescription or is a natural or herbal remedy
* Tell your parent or doctor if you feel ill at all
* If you are sexually active, you must use birth control while receiving treatment and continue to do so for 12 months after the end of treatment.
* Complete the questionnaires when asked to do so

**What other medicines could I have instead?**

The chemo regimens being tested in this study are commonly used regimens. Sometimes doctors use other chemo drugs too. Your doctor may discuss these other chemo drugs with you.

**What are the possible disadvantages and risks of taking part?**

As this is a randomised study you may not get the treatment that you would prefer.

**What are the possible benefits of taking part?**

We cannot promise that this study will help you. It is possible that the chemo drugs that you receive will be the most effective or have the fewest side effects. We will not know this until the results of the study are available. The information gained from this study will help improve treatment for other children and adults with Ewing sarcoma in the future.

**How long will I be involved in the study?**

After treatment has finished, the study team will continue to collect data about your health for at least 5 years. All of this information will be collected during routine clinic appointments.

# Section 3: What else do I need to know about taking part in the study?

**What happens if new information about the medicines comes along?**

If any new information comes along during the study, your treatment will be reviewed and you will be told of any changes.

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

You are free to leave the study at any time without giving a reason and this will not affect your standard of care. If you decide to leave the study, we will ask if you will allow us to continue collecting follow-up data (you will not need to attend more clinic appointments than normal for your condition).

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

If you have any worries about this study, please speak to your family or doctor or nurse.

**Will anyone else know I’m doing this?**

The only people who will know that you are taking part in this study will be the team of doctors, nurses and researchers looking after you, your GP (family doctor) and the national cancer registry where you live.

Information about you will be kept for up to 25 years by the trial organisers and your hospital. You can find out more at our website [www.birmingham.ac.uk/crctu](http://www.birmingham.ac.uk/crctu) .

**What will happen to any samples taken from me?**

Additional samples may be collected for research at the same time as your routine blood tests and examinations.

**Will any genetic tests be done?**

Genetic tests may be done on samples taken from you in order to confirm your diagnosis and for research purposes. No testing for inherited diseases or paternity will be carried out.

**What will happen to the results of the study?**

When the study is complete, the results will be published in a medical journal but no individual participants will be identified. If you would like to get a copy of the published results, please ask your doctor or nurse.

**Who is organising and funding the study?**

This study is being run by the University of Birmingham and is funded by the European Commission and Cancer Research UK.

**Who has reviewed the study?**

Before any research is allowed to start, it has to be checked by a group of people called a Research Ethics Committee. They make sure the research is asking a good question about how to treat Ewing’s sarcoma better.

***Thank you for reading this - please ask any questions if you need to.***