Information letter with consent form for children aged 12 to 16 on admission to the Princess Máxima Center.

Dear .....,

You are to be admitted to the Princess Máxima Center for Pediatric Oncology because there is suspicion of a form of cancer, or another condition that is treated in our hospital, for which, for example, treatment with chemotherapy or a stem cell transplant is required. We understand that this is a great shock for you.

The purpose of this letter is to ask you to take part in a medical scientific study. Before you make a decision, it is important that we explain what the study entails. Read this information carefully and discuss it with your parents, friends or family. There is also an independent person who knows a great deal about this study. Do you have any questions after reading the information? Then you can ask your doctor or the research nurse.

Introduction

The Princess Máxima Center for Pediatric Oncology is both a hospital and a scientific research institute. Our scientific research is intended to improve the treatment of children in our hospital. We ask all parents/guardians of children being treated in the Princess Máxima Center if they would like their child to take part in research in our hospital. Children aged 12 and older also give their permission for this themselves.

This letter describes:

1. The biobank
2. The use of data collected in the course of care for scientific research.
3. Other information

Part 1: the BIOBANK

The official title of the biobank protocol in our hospital is: *"Prinses Máxima Centrum Biobank: establishing a biobank for extensive characterization of pediatric malignancies"*

What is a biobank?

For the Princess Máxima Center it is very important that bodily material, such as tumour tissue, blood, bone marrow, bodily fluids such as the cerebrospinal fluid, urine and/or cheek swabs of different groups of patients are collected for future medical scientific research. We call this bodily material. This material is stored in the laboratory. This way, it can be used for future research. We call this a biobank.

What is the purpose of the biobank?

The material from the biobank can be used for scientific research. This should hopefully enable us to improve the treatment of children in the future.

The bodily material may be collected when the diagnosis is first made, on subsequent appointments at the hospital and on other occasions during the treatment.
To be sure of an accurate diagnosis, we always collect more than sufficient bodily material. Typically, not all of this material is used. The bodily material that remains is called residual material. We would like to store this residual material in the biobank.

Besides using this residual material, for some diseases we also wish to collect an extra sample of blood, bone marrow, urine or other bodily material. We always collect these extra samples during routine, planned sample taking. We also sometimes take some extra (tumour) tissue during a biopsy or surgery, but only if it is safe to do so. This means that the biobank uses both residual material and additionally collected material.

In addition to the extraction and collection of bodily material, we would also like to be able to link bodily material to medical data. This is very valuable for scientific research in the field of cancer and/or related conditions.

What kind of research do we perform with material from the biobank?
We do research:

- on the causes of childhood cancer
- or on the diseases related to it
- and to improve the treatment.

With this research, we hope to achieve:

- better diagnostics,
- new treatments,
- a better cure rate and fewer side effects.

We examine the bodily material using various techniques:

- we study cells under the microscope,
- we also perform measurements on different parts of cells, such as DNA or proteins,
- we try to "grow" tumour cells in the laboratory so that more material becomes available for research.

When we store or process material, we usually do not yet know which studies we will use it for. Every study that we (wish to) perform is referred to the scientific committee of the Princess Máxima Center. This is a committee that checks whether material or data from the biobank can be used.

Genetic research and its possible consequences
With material from the biobank, scientific research is also carried out using "genetic analysis". We would like to tell you more about this.

Genetic analysis: research on DNA
DNA is the material of heredity and is found in all cells of the body. DNA consists of small pieces that contain information about bodily characteristics such as the colour of the eyes. We call these bits of DNA genes.

Changes in the DNA in a body cell can cause cancer. These changes are only present in the diseased cells and cause a tumour to grow, for example.

DNA research can teach us a great deal about the causes of cancer and offers opportunities for new treatments.

To find out which DNA abnormalities occur in a tumour, we compare a person's DNA from diseased cells with the DNA of his or her healthy cells. Healthy cells can be obtained from blood, a smear taken from the inside of the cheek, or a piece of skin. A piece of skin can be taken during an operation. We only do this if there is a need for surgery or a procedure in the first place.

What do we do if we find something in the healthy cells that might be important to you?
It is possible that in healthy body cells we discover a change in the DNA that is important for you or your family. A change in healthy body cells can sometimes go hand in hand with a predisposition to cancer or a predisposition to other conditions.

We know that about 10-15% of children with cancer have a genetic predisposition to cancer or other conditions. In some of these cases, other family members may also have a greater risk of this condition. If so, we will always discuss it with you. We will then make an appointment for you with a doctor specializing in inherited conditions. Together with your parents you will be given an explanation about this and about the possible consequences and available support.

There is more information about this topic in the information given to your parents.

Here at the Princess Máxima Center we also do scientific research into (new) genetic causes of your disease. In such a case, we will first ask you and your parents for permission again. This kind of research cannot take place on material from the biobank without you first being informed about it.

Rules for the management and use of the biobank
There are rules for the management of the biobank. These are documented in writing. We will only use bodily material and data in the way described in this letter and in the regulation.

PART 2: THE USE OF DATA COLLECTED IN THE COURSE OF MEDICAL CARE

Data
By "data collected in the course of medical care" we mean all your medical data from the time you are diagnosed: the history of the disease, the results, the treatment and the possible side effects of the treatment.

This also includes:

- answers to questionnaires from the KLIK portal that you have completed. These questionnaires cover development and quality of life,
- information collected in a cooperating hospital (e.g. shared care),
- information from your home pharmacy and
- data from your general practitioner's treatment file.

This data can be used for scientific research and to improve the care and treatment of children with cancer and related conditions.

PART 3: OTHER INFORMATION

Who will do research using your data and bodily material?
The (processed) bodily material and the data are used for scientific research by the Princess Máxima Center or other research institutes. Sometimes we work together with other researchers outside our hospital. We only do this if this use is compatible with the mission of the Princess Máxima Center.

Confidentiality of data and bodily material
We will encrypt your data and bodily material. Your name and other data that can directly identify you will be kept separate. Only with the encryption key will it be possible for this data to be traced back to you. The encryption key will be kept securely stored in our hospital. A trusted intermediary manages the codes.

Therefore, if there is a reason to, we can trace the code back to you and contact you.
Any data and bodily material that is sent to other people, will only contain the code and not your name or other information via which you can be identified. The data cannot be traced back to you in reports and publications about research either.

Access to your data
Some people and authorities may have access to all your data in our hospital, including to the unencrypted data. This is necessary in order to be able to check whether the study is good and reliable. These people are:

- the safety committee monitoring the study,
- a monitor hired by the research sponsor,
- national and international supervisory authorities, for example, the Inspectorate of Healthcare and Youth,
- the treatment team.

They will keep this information confidential. We're asking for your permission for these people to access your data. If you do not wish them to access your data, none of your bodily material or data will be stored in the biobank.

Retention period for data and bodily material
Your data will be kept in our hospital for an indefinite period of time.

Withdrawing consent
You can withdraw your consent to participation at any time. The research data that has been collected up to the time that you withdraw your consent will still be used by us. The bodily material will be destroyed. If measurements have already been conducted using that bodily material, the results will still be used for research. If you wish all your data to be deleted, you can request this. Discuss this with your doctor.

Transfer to countries outside the European Union (EU)
Sometimes we wish to send the encrypted data and bodily material to countries outside Europe, because we work with researchers from those countries. In those countries there are different rules. However, the data will be protected at an equivalent level. We will only do this if it is necessary for the study and the data is sufficiently protected by encryption.

More information about your rights with regard to the processing of your data
If you have any questions or complaints about the processing of personal data, please contact the Data Protection Officer of the Princess Máxima Center (fg@prinsesmaximacentrum.nl)
More information about your rights with regard to the processing of your personal data can be found on the website of the Data Protection Authority.

Registration of the study
Information about the biobank is also included in an overview of clinical trials, available at: www.trialregister.nl. This website does not contain any information that can be traced back to you. You can find this information under number NL7744.

What are the possible advantages and disadvantages of taking part in the biobank?
You yourself will not benefit directly from taking part in the biobank of the Princess Máxima Center. The purpose of the biobank is to improve the future treatment of childhood cancer. A possible disadvantage is that extra blood or biopsies or other bodily material may be collected. However, we will always combine this with scheduled sample taking that is necessary for routine care. The doctor or research nurse will inform you in advance.

Voluntary participation
If you decide to take part in the biobank and agree to the use of data collected in the course of medical care, we ask you to sign the accompanying consent form. We will keep it in your file. If you decide not to take part, you do not have to do anything else. You do not have to sign anything. You do not have to explain why you do not want to take part.

If you take part, you can always change your mind and withdraw your consent at any time without giving reasons. You can discuss this with your doctor. Your decision not to take part or to end your participation in the biobank at some future time will not have any negative consequences for your further treatment and will not affect the care and attention to which you are entitled in our hospital.

Duration of participation
Participation is for an indefinite period of time. The bodily material and medical data collected for the biobank and the use of the data collected in the course of medical care will be stored and used for research for an indefinite time period, or until you withdraw your consent.
If you withdraw your consent, this means that no new bodily material will be stored and no new medical data will be linked to your bodily material that is already stored. The use of data collected in the course of medical care will also be stopped.

In addition, you can choose from two options:

1) Once submitted, the bodily material and the medical data collected up to that point remain available for scientific research as stated in the consent form.

2) You ask for the destruction of the material already collected and ask that medical data is not used for further studies involving the biobank. If any measurements have been made using that bodily material, that data will still be used.

Are there costs involved or payment for taking part?
There are no additional costs or compensation for taking part in the biobank and for the use of data collected in the course of care.

Which medical ethics review committee has agreed to the biobank?
The medical ethics review committee of the Erasmus MC has approved the creation of the biobank.

Is there anything else that you would like to know?
If you have any questions or complaints during the course of your treatment, you can always approach your treating doctor.

If you have any questions or remarks, you can also contact:

- The paediatric oncologist, who can be contacted via the Princess Máxima Center secretariat, on telephone number 06 50 00 65 70

- The research nurses, who can be contacted on telephone number: 06 25 71 05 24 or by email to: researchnurses@prinsesmaximacentrum.nl

If you are unsure about whether or not to participate, you can consult an independent doctor who is not personally involved in the biobank but who is an expert in this area.

- The independent doctor Dr. W. Kollen can be reached on the following telephone number: 06-50 00 61 15.

If, before or during your treatment, you have questions about the biobank that you would rather not ask your doctor or the nurses, you are also welcome to contact the independent doctor.

If, after carefully considering all the information, you decide to take part in future scientific medical research, we ask you to sign and date the consent form, together with your treating doctor. You will receive a copy.

Take the time you need to discuss this information with your parents. Ask your doctor any questions you have.

If you are not satisfied, you can read about the steps you can take in your parents' information leaflet.

With best regards,

the paediatric oncologists and research nurses at the Princess Máxima Center.

Consent form for children between 12-16 years of age on admission to the Princess Máxima Center

I have been asked to give my consent for my child to participate in future scientific research in the Princess Máxima Center comprising the use of data collected in the course of medical care, including data from the KLIK portal and the shared centres, and in the biobank, with official title:*"Prinses Máxima Centrum Biobank, establishing a biobank for extensive characterization of pediatric malignancies".*

Name: _____ Date of birth: ___ / ___ / ___

I have read the information letter for children aged 12 to16. I have had the opportunity to ask any further questions. My questions have been answered sufficiently. I have had ample time to decide if I would like to take part.

I know that participation is completely voluntary. I know I can decide not to take part at any time. I do not have to give a reason for that.

I grant consent for the collected bodily material to be stored indefinitely in the biobank of the Princess Máxima Center.

I consent to the anonymized use of residual material for future scientific research.

I consent to the extraction of a small amount of extra tissue or biopsy and to its use for future scientific research.

I consent to the collection of extra blood, urine or other bodily material and to its use for future scientific research.

I consent to the use of the data collected in the course of medical care (medical data) for future scientific research.

I choose **to be/not to be (*)** informed of any findings of scientific research on the DNA of healthy body cells (genetic predisposition to diseases).

I consent to allow some individuals and authorities approved and trusted by the Princess Máxima Center to access my data. This is necessary to be able to check whether the biobank procedure has been carried out properly and reliably.

I consent to the transfer of my encrypted and anonymized data and bodily material to other countries, including countries outside the EU.

After signing the consent form, I will receive a copy of it.

Name**: ……

Signature: ..... Date: __ / __ / ____

I hereby declare that I have informed the aforementioned person(s) about the biobank of the Princess Máxima Center and about the use of data collected in the course of medical care.

If during scientific research information becomes available that could affect the consent of the person, I will inform him or her in good time.

Name of Doctor: ……..

Signature: ..... Date: __ / __ / ____

*Delete as appropriate.
**For children aged 12 to16 who can make independent decisions for themselves (legally competent), the parents/guardians must also sign a consent form.