

## **INFORMATION FOR THE PATIENT AND INFORMED CONSENT DOCUMENT**

Patient ID: \_\_\_\_\_

**Study: Multicentre study on cancer during pregnancy: registration study, study on the psychological impact of cancer diagnosis during pregnancy, study on pharmacokinetics of chemotherapeutical agents during pregnancy and on the effects of chemotherapy and/or radiotherapy on mother and child.**

*Title: Registration study: Cancer during pregnancy*

### **Introduction**

You were invited to participate in a clinical study with the aim to enlarge current knowledge on the problem of cancer during pregnancy.

Before you decide whether or not to participate, it is important to understand why this research is performed and what it includes. Take your time to read the following information carefully and if required, discuss it with friends, family or your general practitioner. Ask the study coordinator or study nurse for more information if something is not clear or you want more information. Decide after thorough consultation if you want to take part yes or no. This study is reviewed and approved by the ethical committee of the hospital.

### **The aim of the study**

Since cancer is rarely diagnosed during pregnancy, little information is available about the treatment and outcome of mother and child.

This study aims to register the problem of cancer during pregnancy and the outcome of mother and child.

### **Description of the study**

For this study, medical information concerning the cancer diagnosis, treatment and the outcome of you and your child will be registered as precise as possible based on your medical file.

For this reason, we would like to ask your permission to obtain medical information from your medical file.

No supplemental examinations will be performed for this study.

### **Your participation is voluntary**

It is your choice whether or not to participate in this trial. If you want to take part, you will be asked to sign the informed consent page. You will receive a signed and dated copy of this written approval. You can reconsider your decision at every moment without giving a specific reason.

If you decide not to participate or to stop your participation in the study, this will not affect the quality of your treatment or your medical treatment in the future. You will not lose advantages you are entitled to.

**Reimbursement and compensation for the patient**

There is no compensation from a medical company, nor for the researchers, nor for the hospital department.

Since this study is not sponsored, you cannot receive any compensation for taking part.

**Confidentiality and protection of data**

The information which is obtained concerning your person will be handled as confidential information and will only be used for this study. Your physician is responsible for the protection of the data. To protect your identity, your personal information and data that result from the study will be identified by a unique number. Your name will not be mentioned in publications or reports from this study.

You have the right to ask your physician which data are collected in this study and for which purpose. You also have the right to access your medical file.

**Contact person in case of question:**

If you have questions about the study, now or during your participation, you can always contact:

Study physician \_\_\_\_\_ Telephone: \_\_\_\_\_

Study nurse: \_\_\_\_\_ Telephone: \_\_\_\_\_

## INFORMED CONSENT DOCUMENT FOR THE PATIENT

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- I confirm that I have read the previous pages of the informed consent document. I confirm that I had a satisfying explanation of the study and the examinations that will be performed for this study.
- I confirm that I have had the possibility to ask questions concerning the study and that I received satisfying answers.
- I confirm that I had enough time to read the information attentively, to discuss it with others and to decide whether or not to participate in this trial.
- I understand that I will receive a signed copy of this informed consent document.
- I give access to the following persons/organisations to my medical files: physician, the person responsible for this study and his employees, the ethical committee of the hospital and the competent regulatory government agencies.
- By signing this form I do not renounce the legal rights on which I can normally claim as a participant of a research study.
- By signing this form I agree voluntarily to take part in this study.

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Name patient (in capitals)

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Date

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Signature patient

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Name of the person who obtains the consent (in capitals)

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Date

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Signature of the person who obtains the consent