Written participant information about participation in a scientific experiment

"Removal of uterus and fallopian tubes / possibly ovaries, using either laparoscopy surgery or robot-assisted surgery"

You have, in consultation with your doctor, planned to have your your uterus remove and possibly also the fallopian tubes / ovaries. In this connection, we ask you if you want to participate in a health research project carried out at the Gynecological Obstetrics Department, Herning Regional Hospital.
Before you decide to participate, we will orally and in writing inform you about the project and why we want to implement it. We therefore ask you to read this participant information thoroughly.

The purpose
The purpose of the project is to determine whether there are differences between the two methods of operation in relation to the scarring (appearance and durability) and in relation to which of the two methods has the least complications.

The difference between the two types of operation
When your doctor considers that you are eligible to participate in the project, you will be assigned one of the two methods of surgery by random distribution. During surgery, exactly what you have agreed with your doctor will be done, namely removal of your uterus and possibly the fallopian tubes / ovaries - just the way we do the surgery and the technical equipment will be different to whether we use ordinary laparoscopy (routine surgery) or robot-assisted surgery.
In general laparoscopy, the instruments are inserted into the stomach via 4 small (5 mm) holes, distributed over the lower part of the stomach. For robot-assisted surgery, all instruments are entered via an approx. 2.5 cm wide hole at the navel and the instruments connect to the robot. The movement of the instruments in both cases is controlled by the surgeon. In both cases the wounds are sewn together by soluble thread.
You will be asked to fill out a questionnaire before and after the operation regarding your personal assessment of cosmetic conditions in your body and your assessment of the scars. We will then send you a questionnaire in the e-box 1, 3 and 6 months after the operation with similar questions and if we do not hear from you we will try to contact you by telephone. It takes less than 5 minutes to complete the questionnaire. At the same time, we will ask for permission to retrieve operational information from your journal and your own doctor for up to 12 months after your surgery.

Anonymity
Personal data are treated confidentially and information about participants is subject to professional secrecy. You may at any time withdraw your participation and withdraw from the project without affecting your current or future treatment.
Information about economic conditions
The project does not support commercial financial resources. There will be sought financial support from private funds and contributions will be deposited in a research account.
Result of the project
The project is expected to last 2 years after which the results in anonymous form will be compiled and published in scientific journals and research databases in order to get as widely a dissemination as possible for use by others.
Experienced persons' rights
We hope that with this information you have gained insight into what it means to participate in the experiment and that you feel prepared to make the decision about your possible participation. If you want to know more about the experiment, you are welcome to contact the project managers by e-mail or make a message in the secretariat for a call If you are interested, we will hand over the "Science as a subject in a biomedical research project" by the Central Science Ethics Committee's "

Declaration of consent / authorization
"Removal of uterus and possibly fallopian tubes / ovaries, using either ordinary laparoscopy surgery or robot-assisted surgery"
I hereby confirm that after receiving information, both verbally and in writing, I agree to participate in the study described. I am informed that it is voluntary to participate and that at any time, I can withdraw my commitment to participate without affecting my current or future treatment at the department. I authorize my journal to be viewed by specially authorized persons associated with the investigation for up to 15 years after the end of the investigation (see section 20 of the Law on Patients' Status, Act No. 482). I am informed that all information will be treated confidentially. This power of attorney only applies to information relating to the investigation and may be revoked at any time.
(to be signed by patient and surgeon)