Hannover Medical School

PATIENT INFORMATION AND DECLARATION OF CONSENT

For the use of **biomaterials** and associated data

as part of the study

„A randomized clinical trial comparing laparoscopic or robot-assisted radical/simple hysterectomy versus abdominal radical/simple hysterectomy in patients with early-stage cervical cancer“

Short title

German-funded Laparoscopic Approach to Cervical Cancer (G-LACC)

Address of study site: **<Individual data>**

Clinic

Department

Street No.

PLZ City

Phone number:

_____

Investigator:

_____

_____

Dear patient,

You have consented to participate in the "G-LACC" study (hereinafter referred to as the main study).

We would like to ask you whether you are willing to provide samples of body fluids (specifically blood, cervical smear), as well as, if possible, samples of tumor material and lymph nodes for additional examinations. These various aspects will be discussed in the following text. The samples are called biomaterials for simplicity.

This additional sample collection is voluntary and will only take place if you give your written consent. Even if you don't agree here, you can still take part in the main study. If you do not wish to participate or wish to revoke your consent later, this will not result in any disadvantages for you.

Below we will inform you about the objectives of sample collection, the procedures and the measures to protect your personal data, so that you can form your own opinion and make a decision on this basis.

1. Why are the samples collected?

The examination of human biomaterials has become an important tool for medical research. The aim of this research is not to diagnose you or other people or to prove predispositions that cause illness. Rather, biomedical connections should be determined in the comparative study of larger groups of people. To describe it more specifically, we want to find out afterwards which of our patients responded particularly well to the therapy. We hope that the comparison to patients who did not respond well will provide important insights so that we can improve therapeutic decisions in the future.

2. What type of biomaterial is it?

In addition to collecting clinical data, we are investigating the significance of different biological markers in the tumor and sentinel lymph nodes in order to gain better insight into the development, spread, prediction and treatment of cervical cancer. The collection of the samples does not involve any additional pain or risks as it is already performed as part of the follow-up examinations. The following materials are required for these examinations:

- Cervical swabs/pap smear (preoperative)
- Urine sample (preoperative)

- Blood samples (preoperative)
- Tissue sections from the tumor and lymph nodes (intraoperative)

In case your disease will reoccur, although this is not expected, another blood sample will be taken.

3. How are the biomaterials and data used?

We are asking you for very broad permission to use your biomaterials and data. These are made available for medical research to improve the prevention, detection, and treatment of diseases. They are intended to be used for many different medical research purposes in order to maximize the benefit to the general public. They may relate to specific disease areas (e.g. cervical carcinoma) or genetic associations that are not yet understood. Because new questions continually arise in research, it is possible that your samples and data will also be used for medical research projects that cannot yet be foreseen. However, your biomaterials and data will never be used for research projects that are considered unethical by the ethics committee evaluating the project (see section 7c below).

The biomaterials and data will be stored indefinitely and made available for medical research.

For logistical reasons, it is not possible to make individual restrictions (e.g. exclusion of certain research, exclusion of the materials from being passed on to third parties). If you do not fully agree with the described type and duration of use, you should not give your consent.

4. What risks are associated with your donation?

a. Health risks

Patients with cervical cancer receive structured follow-up care after surgery in accordance with corresponding national guidelines. Follow-up care includes a physical and gynecological examination, a medical consultation, and other optional procedures (e.g. tumor marker determination or wet smear of the cervix). If there are abnormal findings during the examination or if there is clinical suspicion of recurrence of the disease, diagnostic imaging should be carried out. Since taking a cervical swab is recommended as part of routine follow-up care, there is no additional risk to you. In justified cases, taking blood samples may also be recommended as part of follow-up care and, also does not pose any additional risk to you.

b. Further risks

There is a hypothetical risk of accidentally disclosing your identity every time data concerning your identity is stored or transmitted as part of research projects. These risks cannot be completely ruled out and they increase in case you yourself publish genetic data on the Internet (e.g. for genealogy research). Under point 7 "What happens to your biomaterials and data and how are they protected?" we explain in more detail how your privacy is protected.

5. What are the benefits for you personally?

Personally, you cannot expect any immediate benefit or advantage from donating your samples and data. Their evaluation is used exclusively for research purposes and not to draw conclusions about your health.

However, in individual cases a researcher may come to the conclusion that certain results are important for you to know about your health. This is particularly the case if there is an urgent suspicion of a serious, previously possibly unrecognized illness that could be treated or the outbreak of which could be prevented. In such a case, feedback can be sent to you (see point 9 below).

However, you have the right not to know. Please tick in the declaration of consent whether you would like to receive feedback in such a case (see also point 9 below). You can change your decision for or against a feedback option at any time by notifying your testing center. Please note that you may have to disclose health information that you receive through such feedback to other authorities (e.g. before taking out health or life insurance) and may suffer disadvantages as a result.

It is possible that you will be diagnosed with a reportable disease as part of the scientific examination of your samples. In this case, in accordance with the Infection Protection Act, we are obliged to report this to the authorities and inform you of the result.

6. What are the benefits for the general public?

Medical-scientific research projects aim to improve our understanding of disease development and diagnosis and, on this basis, to develop improved treatment approaches and preventive measures. The knowledge gained could provide an advantage for patients who also suffer from sepsis in the future.

7. What happens to your biomaterials and data and how are they protected?

a. Coding your biomaterials and data

All data that directly identifies you (name, date of birth, address, etc.) will be replaced by a code immediately after the biomaterials have been obtained (this is called pseudonymized). The biomaterial and data will be used for research purpose only.

The data that directly identifies you remains at the facility where the samples and data were obtained and is stored there separately from the biomaterials and medical data. Therefore, the samples and data cannot be assigned to you personally without the cooperation of this institution. Such an assignment is only made to supplement additional data from your medical records or to contact you again if you have agreed to be contacted (see point 9 below). Your personally identifying data will not be passed on to researchers or other unauthorized third parties, such as insurance companies or employers.

b. The storage and distribution of biomaterials and data

The coded biomaterials and medical data collected by the MHH and other participating study sites are stored by the MHH. They may be sent pseudonymized according to previously defined criteria to other institutions such as universities, research institutes and research companies, if necessary for specific medical research purposes. The data may also be linked to other medical databases, provided that the legal requirements are met. Biomaterials and data released to researchers may only be used for the specified research purpose and may not be disclosed by the recipient for any other purpose. Unused material will be returned to the MHH laboratory or destroyed.

Your samples and data may also be passed on to recipients in countries outside the EU if one of the following conditions is met:

- The European Commission has determined that the country has an adequate legal level of data protection,
  or, if this has not been done,
- The MHH agrees contractual data protection clauses with the research partners that have been decided or approved by the European Commission or the responsible supervisory authority. You can obtain a copy of these data protection clauses from MHH.

In addition, samples and data may be passed on to research partners in third countries for which neither of these two requirements is met. These countries **may have lower levels of data protection** than the EU. In these cases, the MHH guarantees that the research partners will contractually oblige to comply with the EU data protection level as far as legally possible. However, there is a risk that government or private entities will access your data, even though

this would not be permitted under European data protection law. In addition, you may have fewer or less enforceable data subject rights and there is no independent supervisory authority that could support you in enforcing your rights. **In this case, your samples and data can only be passed on if you have expressly agreed to this. You can do this by checking the appropriate box on the consent form.**

c. Evaluation by an ethics committee

The prerequisite for the use of biomaterials and data for a specific medical research project is that the research project has been evaluated by an independent ethics committee.

d. Publications

Scientific publications of results are only carried out anonymously, i.e. in a form that does not allow any conclusions to be drawn about you personally. This is particularly true for genetic information. However, it is possible to include genetic information in specially protected scientific databases that are not accessible to the general public.

8. Do you gain financial benefit from using your biomaterials and data?

When the biomaterials are transferred to MHH, they become the property of MHH. You also authorize MHH to use your data. You will not receive any payment for providing your biomaterials and data. If a commercial benefit is achieved from the research, you will not be involved.

Your biomaterials and data will be used exclusively for scientific purposes. The samples and data will not be sold.

9. Will you be contacted again?

In order to obtain your medical history, you might be contacted at a later date to request additional information and/or biomaterials from you. During this contact you might be asked for consent to obtain further medical data from other databases or to give you/your treating physicians/study doctor/family doctor feedback on results relevant to your health (see point 5 and point above 7a). Contact will be made in writing by the study doctor.

Please tick in the declaration of consent whether you would like to be contacted again in these cases or not.

10. What does your right of withdrawal include?

You may revoke your consent to the storage and use of your samples and data at any time without giving reasons and without any negative consequences for you. However, the legality of the use of the samples and data until revocation remains unaffected.

In the event of revocation, the biomaterials will be destroyed and the data deleted. However, data can only be deleted if this is possible with reasonable technical effort. In addition, data from analyses that have already been carried out can no longer be removed.

Instead of destruction or deletion, you can also agree that the biomaterials and data may be used in anonymized form for scientific purposes. Anonymization means that the identification code is deleted, which can be used to determine which person the sample came from (see point 7a above). However, such anonymization of your biomaterials can never completely rule out a later allocation of the genetic material to you. As soon as anonymization has taken place, targeted destruction based on your decision is no longer possible.

To revoke your consent, please contact:

<site specific entry>
Clinic
Department
Street No., PLZ City
E-mail:
Phone:

11. What other data protection rights do you have?

The legal basis for data processing is your consent in accordance with Article 6 Paragraph 1 Letter a and Article 9 Paragraph 2 Letter a of the General Data Protection Regulation. The responsible party within the meaning of the General Data Protection Regulation is the MHH.

You may request information from MHH concerning the data stored about you within the framework of the legal requirements. You may also request the correction of inaccurate data, the disclosure of data provided by you, and the deletion of data or the restriction of data processing To exercise these rights, you can contact the following study leaders:

Principle investigator	
Name: **Phone.:** **Email:**	Prof. Dr. Peter Hillemanns [redacted]

If you have any concerns about data processing and compliance with data protection, you can also contact the data protection officer: The data protection officer – OE 0007, Carl-Neuberg-Str. 1, 30625 Hannover[redacted]

You also have the right to complain to any data protection supervisory authority. A list of the supervisory authorities in Germany can be found at

https://www.bfdi.bund.de/DE/Infothek/Anschrift_Links/anschrift_links-node.html.

12. Where can I get more information?

If you have any questions, please ask your study doctor before giving your consent. You can also contact your study site at a later date if you have any questions.

DECLARATION OF CONSENT

in the use of **biomaterials** and associated data
as part of the study

"A randomized clinical trial comparing laparoscopic or robot-assisted radical/simple hysterectomy versus abdominal radical/simple hysterectomy in patients with early-stage cervical cancer."

Short title:

German-funded Laparoscopic Approach to Cervical Cancer (G-LACC)

.....
Patient's name in block letters

Date of birth ..... Participant no. .....

Please read the following declaration of consent carefully, tick as appropriate and then sign at the end of this declaration of consent if you agree.

I read the information and had the opportunity to ask questions. I understand that my participation is voluntary and independent of the main study. I can revoke my consent at any time without giving reasons and without incurring any disadvantages. I have the right to request the destruction of my biomaterials and the deletion of my data.

I agree that my biomaterials and data, as described in the information document, will be given to the MHH and used for research purposes. In particular, I agree that, as described in the information document,

- personal data from me, in particular information about my health will be collected during the trial. If necessary personal data will be removed from my medical records and/or stored pseudonymously (i.e. encoded);
- the biomaterials are stored pseudonymously by the MHH. I transfer ownership of the biomaterials to the MHH;

- the biomaterials with the aforementioned data may be passed on pseudonymously to universities, research institutes and research companies for the purpose of medical research.

This may also include the transfer of data for research projects in countries outside the EU. This is generally permitted if there is an adequacy decision from the European Commission or officially approved data protection clauses are applied.

In addition, I consent to the transfer of my biomaterials and data to countries outside the EU, even in cases where there is no adequacy decision from the European Commission and no officially approved data protection clauses are applied. I have been informed about the possible risks of such a transfer (section 7b in the information).

□ **yes** □ **no**

I agree that I may be contacted again at a later date

- for the purpose of obtaining further information/biomaterials

  □ **yes** □ **no**

- for the purpose of obtaining my consent in order to access information from other (medical) databases

  □ **yes** □ **no**

- for the purpose of providing feedback on health-relevant results that are important for me to know (including from genetic analyses)

  □ **yes** □ **no**

This feedback should be provided through the facility where my biomaterials/data were obtained or through the following doctor (if desired, please specify):

Name and address of the study doctor:

.....

Name of the study doctor in block letters

.....

Contact data

I have received a copy of the patient information and consent form. One copy remains at the study site.

....

Patient's name in block letters

....

Place, date (to be entered by the patient), **patient's signature**

I conducted the informed consent interview and obtained the patient's consent.

....

Name of the study doctor providing information in block letters

....

Place, date, **signature of the explanatory study doctor**