Study Title: TRUTH – TRu-cut biopsy in Tumor cHaracterisation Utilization of tru-cut biopsy in the diagnosis and specification of gynecological malignancies Research

Institution: Department of Gynecology, Obstetrics, and Neonatology, 1st Faculty of Medicine and General University Hospital, Apolinářská 18, Prague 2 – 128 08

Ethics Committee: Ethics Committee of the General University Hospital
Responsible Physician: Dr. Renata Poncová

Dear Miss/Madam,

We would like to invite you to participate in an observational clinical study, which involves only standard medical procedures. Thus, the same treatment approach would be used regardless of your potential participation. We only request your consent for the collection of data from your medical records and their subsequent comparison with data from other patients receiving similar treatment, followed by statistical analysis. All data will be used for research purposes. No alternative diagnostic or monitoring procedures will be proposed than those commonly used in clinical practice, and we simply aim to contact you via phone with few questions.

We would like to acquaint you with the organizational aspects of this study so that you can make a voluntary decision regarding your participation. Please allocate sufficient time to read this information. If anything is unclear or if you require clarification, feel free to contact your attending physician responsible for leading the study, who will gladly explain everything and address your questions.

Key information about the study:
• The treatment proposed by your physician aligns with current recommendations. Your participation in the study will not alter this.
• The study has been approved by the ethics committee.
• The decision to participate is entirely voluntary, and no one will coerce you in any way. If you decide to participate, you will be asked to sign an informed consent form. You are free to withdraw from the study at any time without providing a reason.
• Your health data collected as part of the study is confidential. When research results are published, your data will be pseudonymized.
• If you need further information about the study, you can always contact your attending physician or a member of the study team.

Study Procedure and Objectives:
We propose your participation in this clinical study because your doctor has recommended a transvaginal, transrectal, or transabdominal tru-cut biopsy. Tru-cut biopsy is a routine procedure that has been performed in the Czech Republic for many years.

This clinical study is organized to evaluate the safety of the examination and the diagnostic effectiveness of tru-cut biopsy in a large group of patients with tumors of unknown origin. During ultrasound-guided transvaginal tru-cut biopsy, the needle is inserted through the vagina into the lesion to obtain several tissue samples for examination. In the case of ultrasound-guided transrectal or transabdominal tru-cut biopsy, access is through the anal canal or abdominal wall, respectively. The result of this examination will assist your attending physician in determining your further treatment.

The obtained tumor tissue will be further examined for research purposes using modern methods, including molecular-genetic analysis and examination of the tumor's immunological

environment. Some findings from this analysis may also be relevant for planning further treatment or may reveal an increased risk of hereditary predisposition to cancer.

The indication and method of performing the biopsy will not differ for you, whether you participate in the study or not. It is also important to note that there will be no additional biopsies performed as part of this clinical study compared to standard clinical practice.

A total of 250 patients will participate in this clinical study.

Our study also includes monitoring of your overall well-being, discomfort, or pain, and other possible issues, which we will inquire about at the following time points:

- 0-72 hours after the procedure (in person or via phone)

Additionally, we will request the use of your medical records to obtain necessary information (age, medication, medical history) for the evaluation of this study. The data will be stored in pseudonymized form.

Description of Risks and Benefits of the Study
As mentioned above, the treatment proposed to you and the procedures for determining your diagnosis and subsequent monitoring are in accordance with standard medical practice. Your participation in this study poses no health risks.

By consenting to this study, you will enable us to better understand the safety and accuracy of biopsies guided by gynecological ultrasound, and thus suggest possible modifications in the future. Our further goal is to verify the possibility of performing modern examinations from the obtained tissue, including immunohistochemical examination, immune profiling, and molecular-genetic examination known as NGS, and potentially compare changes in these tumor characteristics during treatment.

Withdrawal of Consent
Your participation in the study is entirely voluntary, and therefore, you have the right to withdraw your consent without providing a reason. If you withdraw your consent, the data collected about you will only be retained until your withdrawal, ensuring that the study is properly conducted and valid.

If you decide to participate in this study, we kindly ask you to:

- fully cooperate in the proper conduct of the study
- not withhold any information about your health status, medications, or symptoms you experience
- inform your attending physician about any participation in other studies so that they can discuss with you whether you can participate in these studies or whether your participation in this study should be terminated
- allow your attending physician to contact you at predetermined times (0-72 hours after the biopsy) for a brief telephone conversation regarding any pain, discomfort, and overall experience with the procedure.

Reimbursement of Costs Associated with Study Participation:
Basic examinations, treatment procedures, and study procedures are covered by health insurance. Special new methods for examining tumor tissue will be covered by a grant. No

special expenses are expected for patients participating in the study. No financial compensation will be provided for participating in the study.

Data Protection:
All records will be kept and handled in accordance with the applicable legislation of the Czech Republic, including the General Data Protection Regulation (GDPR). The information on the processing of personal data is a separate document that you will receive. Only your attending physician, persons authorized by national regulatory authorities, and members of the ethics committee, i.e., persons responsible for monitoring the progress of the clinical evaluation, have access to your personal records in medical documentation. These individuals are bound by confidentiality. The processing of your personal data will be carried out for the purpose of enabling the analysis of results while respecting data confidentiality and confidentiality conditions. Your personal data will be pseudonymized for the purpose of conducting this study.

You have the right to ask your attending physician what data about you have been collected and how they are used in connection with the study. These data relate to your current clinical situation, as well as your medical history and examination results that have been performed for the treatment of your health condition according to applicable standards of care. You have the right to review and, if inaccurate, correct this data. The attending physician is obliged to treat these collected data as confidential. This means that they never undertake to disclose your name in connection with publication or conference and to encode your data. We undertake to use the collected data only in connection with this study. If you withdraw your consent to participate in the study, coded data collected prior to your withdrawal will be retained to ensure the validity of the study.

Information on Protection and Rights of Clinical Evaluation Participants:
This study has been evaluated by an independent ethics committee of the General University Hospital in Prague, which issued a favorable opinion. The task of ethics committees is to protect individuals participating in clinical studies. They ensure that your rights as a patient and study participant are respected and that the study is scientifically relevant and ethically justified. A positive opinion from the ethics committees should not be considered as an invitation to participate in this study under any circumstances.

Contact:
If you would like further information or need to address any concerns or issues, you can contact the attending physician or a member of the study team at the following number:

Dr. Renata Poncová
Dr. Bc. Filip Frühauf, Ph.D.

Phone during working hours: 224 96 7451
Phone outside working hours: 224 96 7440

If you have any questions regarding your rights as a study participant, you can contact the ethics committee of the General University Hospital.