The subject's explanation and consent form.

A prospective randomized clinical study to compare the sample removal method through vagina after laparoscopic resection of kidney and the sample removal method through conventional additional abdominal incision.

I ask you to participate in this study. Before deciding to participate in this study, it is important to understand exactly why this study is conducted and what and how it will be done.

The contents below are designed to explain the contents of this study, the role you will play, and the progress of the study if you participate in this study. Take enough time to read the manual of the person you saw, and if you want, you can discuss it with your family or someone else. Also, if you have any questions, please ask the person in charge of the test or another person in charge of the test and consider it carefully to decide whether to participate in this study.

The purpose of the study: You were proposed to participate in this study as a person who will undergo total or partial resection of large organs such as kidneys through laparoscopic surgery. Currently, when the organ is resected by laparoscopic surgery and the resected organ is taken out of the body, the laparoscopic incision, which is 1-1.5 cm long, is additionally incised to 5-7 cm long. The purpose of this study is to prove the usefulness and stability of removing samples through vagina without additional abdominal incisions in minimizing postoperative pain and abdominal scars. This study is conducted for academic purposes.

As previously described, the conventional sample removal method through additional abdominal incision requires an additional 5-7 cm incision only to take the resected organ out of the body, although the organ resection is completed through an incision of about 1 cm. This is the main factor in reducing the advantages of laparoscopic surgery, "small wounds and postoperative pain reduction and rapid recovery through them." To overcome this, female patients have often been used to take out samples through vagina without additional incision in the abdomen, and various institutions at home and abroad have reported their stability and excellence. Therefore, the researchers planned this study to prove the usefulness of the sample removal method through quality using the same method in this institution.

Participation procedures, progress of research, duration of participation: If you decide to participate in this study, you will first fill out a consent form. One of the two signed consent forms will be given to you, and the first will be kept by the researcher. You will undergo a gynecological examination to see if it is possible to remove samples through vagina, and if it is possible, you will participate in the study. In the same way as those who did not participate in the study, laparoscopic resection is performed, and according to the assigned group, samples are removed through additional abdominal incision or by gynecologist's quality. In the process of removing samples

through vagina, an incision of an appropriate length is applied to the uppermost part of the vagina, and then the sample is induced into the vagina using a laparoscopic instrument and pulled out of the body. After that, the upper vaginal incision is sutured to complete the operation. The time required to remove samples through vagina may vary depending on the type of sample and the width of the vagina, but most of them are about 20 minutes, which does not increase significantly compared to the conventional sample removal method through additional abdominal incision. After surgery, the degree of reduction in anemia levels, pain, addition and opening of surgical scars, and subjective scar satisfaction are measured. Participation in this study will be terminated after four surveys of pain during the postoperative hospitalization period, a survey of scars 1 week and 8 weeks after discharge, and a survey of sexual life evaluation 6 months later. The total number of participants in this study is 180, and the total study period is 2 years.

Except for the pain level assessment and the survey on scars and sexual life, there is nothing different from participation in this study. This study includes a variety of surgeries to resect large organs, including stomach, kidneys, colon, and spleen, making it difficult to mention the exact cost of surgery, but the additional cost of participating in this study is expected to be about 38,000 won, including the cost of obstetric consultation. This cost will be borne by the research cost of this study and there is no additional cost that the patient has to the patient. Accurate surgical costs may vary from individual to individual depending on the instruments and drugs used at the time of surgery.

Predicted risks or discomfort: complications commonly reported in laparoscopic surgery include vascular or organ damage (1%), subcutaneous emphysema (1%), bladder damage (1%), postoperative organ damage, bleeding, intestinal obstruction, postoperative fever, wound, and conversion to open surgery. These complications are common complications following general laparoscopic surgery, and additional complications or side effects expected from sample removal through vaginal incision are very rare. The removal of samples through vagina is done through the innermost incision of the vagina, and this part is pain-free, so you don't have to worry about additional pain caused by resection of the vaginal opening after surgery. However, there may be short-term discomfort, and although it is a small amount, blood may come out. In addition, very rarely, inflammation or fistula in the pelvis may occur due to vaginal incision, but the frequency is extremely rare, and has not been reported in the organ surgery you will receive. The additional surgery time required to remove samples through vagina is about 20 minutes, which is not much different from the time required for the surgery you will receive. Preoperative gynecological examination evaluates the possibility of removal through organ vagina, but if it is deemed impossible or inappropriate to remove the sample removed during surgery through vagina, it can be removed through additional abdominal incisions.

The only additional thing added by participation in this study is the evaluation of the degree of

pain and a survey on scars. Therefore, the risks and inconveniences caused by this study itself are expected to be very rare.

Foreseen Benefits: There is no benefit directly returning to you from this study. However, there is an indirect cost benefit by exempting the cost of other medical consultation incurred by requesting a gynecological examination before participating in this study and the cost of examination and ultrasound (worth about 150,000 won). As a reward for participating in additional clinical trials, we will pay you 50,000 won for transportation (expected once before surgery, one week after surgery, eight weeks after surgery, and six months after each outpatient visit.

Furthermore, participation in the study will contribute to the establishment of methods that can be performed with smaller wounds and less pain in large organ removal methods, which will contribute to the development of medicine.

Identification: Information that can verify your identity will be confidential. Even if the results of this study are published, your identity will remain confidential.

Compensation for unexpected damage: Participating in this study is considered extremely unlikely to cause unexpected damage to you, and there is no separate compensation for possible complications caused by laparoscopic surgery. However, the medical staff will do their best to protect your safety during clinical research and will take quick and appropriate measures in case of serious complications to minimize the damage caused by them as much as possible.

Access to records: Monitoring personnel, inspectors, review committees, and the Minister of Food and Drug Safety can directly access your medical records to verify the reliability of clinical trial procedures and data to the extent prescribed by relevant regulations, and by signing the subject's signature agreement.

Notice of New Facts: Once new information is collected that may affect the continuation of your participation in this study, the researcher will immediately inform you of that information.

Suspension of the study: If the researcher determines that this study is difficult to achieve its intended purpose, this study may be discontinued without your consent, even while you are participating in this study. In addition, your physician may drop you out for medical reasons or other reasons if you fail to comply with your instructions.

If you don't participate in the study: your participation in this study is entirely up to you. If you listen to the explanation of the clinical study and agree to participate in this study, it is not a problem at all. In addition, even after agreeing to participate in the study, you can withdraw your consent at any time if you wish, and you will not suffer any disadvantages or damages.

If you have any questions about the study, you or the subject's agent can have a phone interview at any time, and the following are the people you can contact.

- Contact number of the person in charge to discuss problems, concerns, and questions arising from clinical research. (research coordinating professor and CRC's tel number)

You can get information on the subject's rights and interests, or contact us below if you have any questions.

- IRB (Bioethics Review Committee) or Subject Protection Center: 031-787-1376-9 to be discussed when there are questions, concerns, or questions about the rights and interests of the study subjects.

- If you want to participate in this study after hearing the introduction of this study so far, you can write down the date and name in your handwriting on a separate consent form and sign it.

- In the case of therapeutic or non-therapeutic clinical studies that require consent from the subject's understanding and guardian, the research manager and research manager must give the subject information on clinical studies to the extent that they can understand, and if possible, sign the consent form and write the date.

- If the subject or his agent is unable to read the consent form, the study subject's manual, or other documented information, the observer must attend all courses with consent.

- A copy of the explanation manual and the signed consent form will be provided to you.

Research Title: A prospective clinical study of Transvaginal Versus Transabdominal Extraction of Laparoscopically-excised Kidney Specimen RCT

1. I heard a detailed explanation from the doctor in charge of all the information on this study and fully understood it.

2. I have also read the subject consent manual, fully understood the contents, and know that this study is conducted for research purposes.

3. I know that my decision to participate in the study is voluntary and that I can refuse or freely stop participating in the study due to personal reasons at any time during the study period, and that I am not subject to medical treatment or other disadvantages.

4. I know that if there is damage due to adverse reactions caused by clinical trial drugs, the "responsible researcher" will bear the damage compensation protocol.

5. If you have any questions about the study, you can contact the researcher at any time, and I agree to view my medical records directly only for research purposes.

Therefore, I agree to participate in this study according to my free will.

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<tr><th></th><th>Name</th><th>Signature</th><th>Signature date</th></tr>
<tr><td>Subject</td><td></td><td></td><td>yyyy/mm/dd</td></tr>
<tr><td rowspan="2">Agent of subject
(If applicable)</td><td></td><td></td><td>yyyy/mm/dd</td></tr>
<tr><td colspan="3">Relationship with a subject:_____
Specific reasons:_____</td></tr>
<tr><td>Responsible researcher (or co-researcher)</td><td></td><td></td><td>yyyy/mm/dd</td></tr>
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	Name	Signature	Signature date
Observer			yyyy/mm/dd