Consent Form 1

Department of Health

THE ROYAL MARSDEN NHS FOUNDATION TRUST

Radical Hysterectomy and Bilateral Pelvic Lymphadenectomy

Patient Agreement to Investigation or Treatment

Patient's surname/family name

Patient's first names

Date of birth

Health professional seeking consent

Job title

NHS number (or other identifier)

☐ Female

Special requirements
(e.g. other language/other communication method)

Name of proposed procedure (include brief explanation if medical term not clear)

☐ **Radical hysterectomy: removal of womb, cervix, surrounding tissue (parametrium) and top part of vagina** Your womb, cervix, approximately 2 cm of surrounding tissue and upper 1-2 cm (less than half an inch to one inch) of the vagina is removed. The top of your vagina is then stitched closed.

☐ **Bilateral pelvic lymphadenectomy** Lymph nodes (or glands) are small, bean-like structures that are part of the body's lymphatic system. The lymphatic system is one of the body's natural defenses against infection. Cancers may spread via lymph nodes. This involves removing the lymph nodes near to your womb in the pelvis to find out if the cancer has spread.

☐ **Para-aortic lymph node sampling** This involves removing some the lymph nodes near the large blood vessels (aorta and vena-cava) that run at the back of you abdomen to find out if the cancer has spread.

☐ **Keyhole (laparoscopic) approach** The procedure is done through three or four small cuts in your abdomen (a keyhole approach). Surgical instruments and a laparoscope (a telescope with a camera on the end) are inserted via these cuts. The womb, cervix and surrounding tissues are removed via your vagina.

☐ **Robotic-assisted Laparoscopic (keyhole) approach**
The procedure is done through three or four small cuts in your abdomen (a keyhole approach). Surgical instruments and a laparoscope (a telescope with a camera on the end) are inserted via these cuts. The instruments are controlled by the surgeon using a console and a specifically designed robot. The womb, cervix and surrounding tissues are removed via your vagina.

☐ **Open approach (laparotomy)** The procedure is done via a cut across your abdomen, just above the pubic hair. Alternatively, we may need to cut downwards from the belly button to the pubic hair; this cut may need to extend round and slightly above your belly button. We remove the womb, cervix, and surrounding tissues by lifting them out through the cut in your abdomen.

Other procedures

☐ **Bilateral salpingo-oophorectomy** Removal of both fallopian tubes and ovaries

☐ **Bilateral salpingectomy** Removal of both fallopian tubes

☐ **Indocyanine sentinel node sampling**
A substance called indocyanine green is injected into the neck of the womb. This sometimes assists the surgeon in locating the lymph glands during the operation as well as the first gland (called a sentinel lymph node) that a cancer might spread to.

☐ **Ovarian transposition**
If during the operation if becomes apparent that you will definitely need radiotherapy to treat the cancer, we can stich your ovaries up and out of your pelvis. This means that they are less likely to be affected (stop working) due to future radiotherapy.

☐ A catheter will be placed into your bladder through the urethra and will remain in place for 3 to 5 days to drain the urine. After the catheter is removed we will record the volume of urine passed on 3 occasions. The nursing staff will also perform an ultrasound scan of your bladder to make sure amount of urine left in your bladder (residual volume) is less than 150ml. The scan involves placing a portable probe over the lower portion of the abdomen. If the residual volumes are less than 150ml on 3 occasions then no further assessments of your bladder need to be made. If the volume remaining in your bladder is more than 150mls we will need to replace the catheter for normally 2-3 weeks. We will remove the catheter and check the residual volumes again.

Other procedures (to be specified)

☐
……
……

☐
……
……

Statement of health professional seeking consent (to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in consent policy)

I have explained the procedure to the patient. In particular, I have explained:

The intended benefits:

☐ To treat the cervix cancer

☐ To determine as to whether any further treatment should be considered after surgery

Significant, unavoidable or frequently occurring risks/side effects:

☐ **Infertility** (all patients if your ovaries were functioning before the operation)

☐ **Menopause** (all patients if ovaries removed and functioning before the operation)

☐ **Bleeding** (less than 1 in100 risk)

☐ **Infection** of wound, pelvis, chest or urine. To reduce this risk, we give you antibiotics during, and sometimes for one or two days after your operation (less than 5 in 100 risk)

☐ **Injury to nearby structures**; blood vessels, bladder, ureter (tube from kidney to bladder), bowel and nerves. If this occurs we repair it (less than 5 in 100 risk).

☐ **Blood clots** They most commonly form in the calf causing lower leg swelling and pain or in the lung causing shortness of breath or chest pain. Blood clots can be life threatening and are treated with blood thinning drugs. I have advised the patient to seek medical advice immediately if they have any of the above symptoms and are concerned they may have a blood clot. Airline travel and long journeys where one has to remain seated are also associated with an increased risk. Therefore, I have advised that it is important to seek medical advice about any plans to travel while on treatment (Deep vein thrombosis (DVT) or pulmonary embolism (PE) (less than 1 in 400 risk).

☐ **Lymphocyst or lymphoedema** Lymphocyst is a collection of lymphatic fluid in the pelvis that may cause pelvic discomfort or pain. Lymphoedema is swelling of the legs. We will give you supportive stockings to wear for 6 months after your operation to reduce the risk of lymphoedema. Lymphoedema can occur many months after your operation. The swelling could be localised to a specific part of your leg or the vulva. Additionally, it may be different from one leg to the other (less than 5 in 100). You will be contacted by a lymphoedema nurse for support.

☐ **Conversion to** an open operation (laparotomy) involving a cut in your abdomen, if planned for laparoscopic approach) if it is not possible to complete the surgery via laparoscopy or in order to repair injury to nearby structures (less than 5 in 100 risk).

☐ **Incisional hernia** A weakness in your abdominal wall at the site of the cut. This may not be apparent until a few months after your operation. If troublesome this can be repaired by an operation (less than 15 in 100 risk if midline laparotomy and 3 in 100 risk if key hole surgery).

☐ **Change in bladder function** Urinary incontinent or difficulty in passing urine. Some women may have difficulty passing urine once their catheter has been removed. Others feel that they are not able to empty their bladder completely. This is almost always a temporary effect, and the catheter usually needs to stay in for 2-3 weeks until normal bladder function returns (less than 1 in 100 risk).

To be retained in patient's notes

☐ **Shorter vagina than before**, which is not usually a problem. It is safe to start having sex again once your wounds have completely healed, which usually takes about 6-8 weeks. However, many women need longer than this to feel physically or emotionally ready for sex. Your clinical nurse specialist (CNS) will talk to you about this in more detail before, and/or after your operation if you want.

☐ **Changes in body image, feelings about femininity and sexual function.**

☐ **Abandon procedure** if during the surgery there is evidence of cancer in your pelvic or para-aortic lymph nodes. Para-aortic lymph nodes are those near the large blood vessels (aorta and vena-cava) that run at the back of you abdomen. If this is the case we would not usually proceed to the hysterectomy as it is better to have radiotherapy treatment for the cancer in this situation.

☐ **Return to theatre** (immediate or late) to stop bleeding, repair injured structures, or for management of post-operative complication (less than 1 in 100 risk).

☐ **Slow recovery.** Recovery time from this sort of major operation is variable; usually women go home after 3 to 7 days. A few women have a prolonged stay in hospital. Full recovery back to your level of well- being prior to the operation will take between 3 and 6 months, in part this will depend on whether you need any other sort of treatment.

☐ The overall risk of **serious complication** is approximately 1 in 50; this includes a very rare risk of death within 6 weeks (less than 1 in 200 risk).

Any other risks:

☐ ……

☐ ……..

☐ ……..

Any extra procedures which may become necessary during the procedure:

☐ blood transfusion

☐ other procedure (please specify): ……..……..……..……..

……..……..……

Use of medical images or recordings

I hereby give consent for medical images or recordings taken during the procedure to be used for one or more of the purposes listed below:

I understand in all cases the images will be anonymised (i.e. there will be no means of identifying me).

I understand that this will in no way affect my treatment.

I understand I am free to withdraw my consent at any time without giving any reason, and will do so by informing medical team.

To be retained in patient's notes

Please tick every box to which you give consent	**Tick to give consent**
Research and audit, for example evaluating new planning methods and technologies. This may involve researchers outside the Royal Marsden and the Institute of Cancer Research including workers in commercial companies (for example equipment manufacturers), or other health and research organisations.	☐
Teaching and/or training of healthcare staff This may include books, articles, CD ROMs, videos, presentations and/or lectures. Digital images, teaching slides and CD-ROMs may be accessible via computers for online and internet publications.	☐
Publication in the hospital's newsletters or promotional literature	☐

I have also discussed what the procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of this patient.

The following leaflet has been provided as part of the patient's information prescription:

☐ Macmillan Cervical Cancer

https://www.macmillan.org.uk/information-and-support/cervical-cancer/understanding-cancer

☐ Jo's Cervical Cancer is a registered charity for women with cervical cancer

www.jostrust.org.uk

☐ Menopause matters is an award winning, independent website providing up-to-date, accurate information about the menopause, menopausal symptoms and treatment options.

https://www.menopausematters.co.uk

☐ The Daisy Network Premature Menopause Support Group is a registered charity for women who have experienced a premature menopause

www.daisynetwork.org.uk

☐…….. (version no_____)

☐…… (version no_____)

This procedure will involve:

☐ general and/or regional anaesthesia ☐ local anaesthesia ☐ sedation

☐ After this operation you will be normally cared for in our Critical Care Unit. You may possibly be kept anaesthetised or sedated for a longer period, such as overnight or longer if this is needed. This is to let you to recover from surgery at your own pace, and allow the Critical Care staff to support you fully. Your anaesthetist will explain more about what your care after surgery may involve.

To be retained in patient's notes

Signed: …… Date ……

Name (PRINT) …… Job title ……

☐ I am capable of performing this procedure or prescribing this treatment.

☐ I am trained and authorised to obtain consent for this procedure or treatment which I cannot perform or prescribe by myself. I have been delegated to take your consent by …… (name of supervising consultant).

While under the care of The Royal Marsden you will be treated by a team of healthcare professionals (clinicians), working with the consultant(s) responsible for your care. Team members may include registered nurses, allied health professionals and qualified doctors in training.

All clinical procedures or treatments will be performed by clinicians who are fully competent to do so, but they may also be supervising team members who are in training. The presence of any particular clinician at any given time cannot be guaranteed.

Contact details (if patient wishes to discuss options later) ……
……
……

Statement of interpreter (where appropriate)

I have interpreted the information above to the patient to the best of my ability and in a way in which I believe s/he can understand.

Signed …… Date ……

Name (PRINT) ……

Statement of patient

Patient identifier/label

Please read this form carefully. If your treatment has been planned in advance, you should already have your own copy of page 2 which describes the benefits and risks of the proposed treatment. If not, you will be offered a copy now. If you have any further questions, do ask – we are here to help you. You have the right to change your mind at any time, including after you have signed this form.

I agree to the procedure or course of treatment described on this form.

I understand that you cannot give me a guarantee that a particular person will perform the procedure. The person will, however, have appropriate experience.

I understand that I will have the opportunity to discuss the details of anaesthesia with an anaesthetist before the procedure, unless the urgency of my situation prevents this. (This only applies to patients having general or regional anaesthesia.)

I understand that any procedure in addition to those described on this form will only be carried out if it is necessary to save my life or to prevent serious harm to my health.

I have been told about additional procedures which may become necessary during my treatment. I have listed below any procedures **which I do not wish to be carried out** without further discussion. ……
……
……
……..

Please indicate your preference with a cross against one of the following two options:

☐ **I will accept** the offer of a copy of this consent form to keep, when it is signed by me.

☐ **I will <u>not</u> accept** the offer of a copy of this consent form to keep, when it is signed by me.

Patient's signature …….. Date……..

Name (PRINT) ……

A witness should sign below if the patient is unable to sign but has indicated his or her consent. Young people/children may also like a parent to sign here (see notes).

Signature …… Date ……..……

Name (PRINT) ……..…

To be retained in patient's notes

Confirmation of consent (to be completed by a health professional when the patient is admitted for the procedure, if the patient has signed the form in advance)

On behalf of the team treating the patient, I have confirmed with the patient that s/he has no further questions and wishes the procedure to go ahead.

Signed: ……..…… Date ..……

Name (PRINT) ……..…… Job title ……..……..…

Important notes: (tick if applicable)

☐ See also advance decision to refuse treatment (eg Jehovah's Witness form)

☐ Patient has withdrawn consent (ask patient to sign /date here) ……..……..

To be retained in patient's notes

Guidance to health professionals (to be read in conjunction with consent policy)

What a consent form is for
This form documents the patient's agreement to go ahead with the investigation or treatment you have proposed. It is not a legal waiver – if patients, for example, do not receive enough information on which to base their decision, then the consent may not be valid, even though the form has been signed. Patients are also entitled to change their mind after signing the form, if they retain capacity to do so. The form should act as an *aide-memoire* to health professionals and patients, by providing a check-list of the kind of information patients should be offered, and by enabling the patient to have a written record of the main points discussed. In no way, however, should the written information provided for the patient be regarded as a substitute for face-to-face discussions with the patient.

The law on consent
See the Department of Health's *Reference guide to consent for examination or treatment* for a comprehensive summary of the law on consent (also available at www.dh.gov.uk/consent).

Who can give consent
Everyone aged 16 or more is presumed to be competent to give consent for themselves, unless the opposite is demonstrated. If a child under the age of 16 has "sufficient understanding and intelligence to enable him or her to understand fully what is proposed", then he or she will be competent to give consent for himself or herself. Young people aged 16 and 17, and legally 'competent' younger children, may therefore sign this form for themselves, but may like a parent to countersign as well. If the child is not able to give consent for himself or herself, some-one with parental responsibility may do so on their behalf and a separate form is available for this purpose. Even where a child is able to give consent for himself or herself, you should always involve those with parental responsibility in the child's care, unless the child specifically asks you not to do so. If a patient is mentally competent to give consent but is physically unable to sign a form, you should complete this form as usual, and ask an independent witness to confirm that the patient has given consent orally or non-verbally.

When NOT to use this form
If the patient is 18 or over and lacks the capacity to give consent, you should use the form for adults who lack the capacity to consent to investigation or treatment instead of this form. A patient lacks capacity if they have an impairment of the mind or brain or disturbance affecting the way their mind or brain works and they cannot:
• understand information about the decision to be made
• retain that information in their mind
• use or weigh that information as part of the decision-making process, or
• communicate their decision (by talking, using sign language or any other means).

You should always take all reasonable steps (for example involving more specialist colleagues) to support a patient in making their own decision, before concluding that they are unable to do so. Relatives **cannot** be asked to sign a form on behalf of an adult who lacks capacity to consent for themselves, unless they have been given the authority to do so under a Lasting Power of Attorney or as a court appointed deputy.

Information
Information about what the treatment will involve, its benefits and risks (including side-effects and complications) and the alternatives to the particular procedure proposed, is crucial for patients when making up their minds. The courts have stated that patients should be told about 'significant risks which would affect the judgement of a reasonable patient'. 'Significant' has not been legally defined, but the GMC requires doctors to tell patients about 'serious or frequently occurring' risks. In addition if patients make clear they have particular concerns about certain kinds of risk, you should make sure they are informed about these risks, even if they are very small or rare. You should always answer questions honestly. Sometimes, patients may make it clear that they do not want to have any information about the options, but want you to decide on their behalf. In such circumstances, you should do your best to ensure that the patient receives at least very basic information about what is proposed. Where information is refused, you should document this on page 2 of the form or in the patient's notes.

To be retained in patient's notes