Consent Form 1

Patient's surname/family name

Patient's first names

Date of birth

THE ROYAL MARSDEN NHS FOUNDATION TRUST

Health professional seeking consent

Job title

Pelvic lymphadenectomy and radical trachelectomy

NHS number (or other identifier)

☐ Female

Patient Agreement to Investigation or Treatment

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

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

☐ **Radical trachelectomy (removal of cervix and surrounding tissues, 2cm of vagina, and placement of a stitch at the isthmus)**

The neck of the womb (cervix) is removed as well as the top 2cm of vagina and the tissue around the cervix (parametrium). A permanent stitch is placed at the remaining portion of the womb (isthmus) and a small opening is left for menstruation. The remaining portion of the uterus is then stitched to the vagina. It is important that you use contraception whilst undergoing treatment and for 6 months following completion of treatment.

☐ **Keyhole (laparoscopic) 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 procedure involves removing the lymph nodes near to your womb in the pelvis to find out if the cancer has spread. The procedure is done through three or four small cuts in your abdomen (a keyhole approach). Surgical instruments and a telescope with a camera on the end (a laparoscope) are inserted via these cuts. The lymph glands are removed through one of these small cuts in your abdomen.

☐ **Robotic-assisted keyhole (laparoscopic) approach**

The procedure is done through three or four small cuts in your abdomen (a keyhole approach). Surgical instruments and a telescope with a camera on the end (a laparoscope) are inserted via these cuts. The instruments are controlled by the surgeon using a console and a specifically designed robot.

To be retained in patient's notes

☐ **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.

Other procedures

☐ A urethral catheter will be placed in order to drain urine from your bladder through the urethra and may be kept in place for between 3 and 5 days. The catheter may need replacing if you are unable to pass urine. After the catheter is removed we may record the volume of urine passed on a number of occasions. The nursing staff may 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 of urine are less than 150ml on 3 occasions, you can be discharged from hospital.

☐ A catheter may also be placed in your vagina and inserted at the site of the stitch ‘cerclage at the level of the isthmus’ and remain for 3 days.

☐ A vaginal pack, which is like a large tampon, may be placed in the vagina for 24 hours to help stop any bleeding.

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:

☐ Treatment for cervical cancer

☐ To preserve fertility i.e. your womb is retained

☐ To find out how advanced (what stage) the cancer is and help decide whether other treatments should be considered

Significant, unavoidable or frequently occurring risks/side effects:

☐ **Bleeding** (less than 1 in 100 risk)

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

☐ **Injury to nearby structures**; blood vessels, bladder, tube which takes the urine from the kidney to the bladder (ureter), bowel and nerves (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) (1 in 400 risk).

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

☐ **Lymphocyst or lymphoedema** (if planned for lymph node dissection). 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 six months after your operation to reduce the risk of lymphoedema. Lymphoedema can occur many months after your operation (less than 5 in 100 risk) with an associated risk of cellulitis. You will be contacted by a lymphoedema nurse for support.

☐ **Numbness** (Paraesthesia) occurs in approximately 4 in a 100 women who have undergone this procedure. Numbness may occur over an area of skin on your thigh and may be associated with lymphoedema. This is usually temporary.

☐ **Incisional hernia** arising from the port sites (i.e. belly button and supra-pubic or the midline laparotomy). 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 laparotomy required, less than 3 in 100 if laparoscopy).

☐ **Isthmic narrowing (stenosis)** occurs in approximately 5 in 100 women who have undergone this procedure. This is when the opening at the level of the stitch has closed over, mainly due to scar tissue, and may lead to painful periods (dysmenorrhoea) and sometimes no periods (amenorrhoea).

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

☐ **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).

☐ The overall risk of **serious complication** (i.e. bleeding, damage to nearby structures etc.) is 4 in 100; this includes a very rare risk of death within six weeks (overall average figure of less than 1 in 100 risk).

☐ There may be a need for further treatment i.e. a more extensive hysterectomy (removal of womb) or a need for a combination of chemotherapy and radiotherapy.

☐ There is a 4 in 100 chance that the cancer will come back.

☐ **Implications for pregnancy.** Careful antenatal care is necessary but needs to be discussed with the supervising obstetrician. Weakness (incompetence) is a risk, either of any remaining cervix or of the isthmus (neck of the womb). If you do become pregnant, there is the risk of miscarriage during the first 14 weeks (1st trimester) in approximately 7 out of 100 women who have undergone this procedure. If you go beyond, then there is approximately a 1 in 4 chance of premature labour.

☐ **Mode of delivery.** Your baby will need to be delivered by 'classical caesarean section' (a vertical incision on the uterus; the skin incision will be horizontal)

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.

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	☐

To be retained in patient's notes

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

☐ …….... (version no_____)

☐ …….... (version no_____)

This procedure will involve:

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

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) ……..……

To be retained in patient's notes

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