Consent Form 1	
DH Department of Health	Patient's surname/family name
	Patient's first names
	Date of birth
THE ROYAL MARSDEN NHS FOUNDATION TRUST	Health professional seeking consent
	Job title
Surgery for cancer of the vulva	NHS number (or other identifier)
	☐ Female
	Special requirements (e.g. other language/other communication method)
Patient Agreement to Investigation or Treatment	

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

The aim of your surgery is to remove all of the cancer affecting the vulva. This is done by taking away the area of skin where the cancer is, and a border (margin) of healthy tissue all around it. The type of operation you need depends on the size and position of the cancer. If the cancer is very small, it may be possible to remove only a small area of the vulva, but if the cancer is larger a more major operation will be needed. We will use the diagram on page 3 to explain to you where your cancer is and what type of operation you need.

☐ Wide local excision

This involves removing the cancer (or the scar if you have had a previous operation that removed the cancer) and a margin of healthy tissue, usually 1-2 cm, all around the cancer. The margin of healthy skin and tissues under the skin to be removed should be at least 1cm (less than half an inch) and up to a 2cm margin. We then stitch the remaining skin together with dissolvable stitches. The reason we need to remove healthy tissue is to reduce the chance of the cancer coming back on the same site on the vulva. We cannot see individual cancer cells at the time of surgery and when tissues are examined under the microscope often there are cancer cells beyond the edge of the cancer which cannot be seen by the naked eye. We aim to preserve as much normal-appearing vulval skin as possible.

☐ Radical partial vulvectomy

This operation removes part of the vulva. Which part of your vulva is removed will depend on where on the vulva the cancer is. This may include removing part or all of the inner and outer labia and/or the clitoris. We can then often stitch the remaining skin together with dissolvable stitches, if this is not possible you will have plastic surgery reconstruction of

your vulva (see below). Usually this operation is performed when the cancer is visibly on one side of the vulva, thereby preserving normal skin tissue.

☐ Radical vulvectomy

This operation removes the entire vulva, including the inner and outer labia and the clitoris. Usually the defect in the vulval area requires a plastic surgery reconstruction of your vulva (see below).

☐ Reconstruction

If it is not possible to stitch the skin back together in the usual manner – that is, the skin edges are too far apart - you will need plastic surgery reconstruction with a skin flap or flaps. A skin flap is made from a piece of skin and some of the underlying tissue close to the vulva; usually from the inner thigh or buttock crease. This is referred to as a 'donor site'. The flap of skin is moved (rotated) onto the vulval area to cover the wound. Often if you need a reconstruction a plastic surgeon will be involved in your surgery. You will meet the plastic surgeon in his/her clinic before surgery.

☐ Unilateral (right or left side) or bilateral (both right and left side) inguinal (groin) lymph node dissection

Lymph nodes (or glands) are small, bean-like structures that are part of the body's lymphatic system. We have lymph nodes in many different parts of our body eg in the neck, under the arm and in the groins. The lymphatic system is one of the body's natural defences against infection. Lymph nodes in the groin are usually the first place that vulval cancer spreads to. Having these lymph nodes removed will not affect the body’s ability to fight infection.

Your groin lymph nodes will be removed through a cut 5 (2-3 inches) to 10cm (5-6 inches) in the skin of the groin. Your skin will be closed with stitches or staples. You will have a thin tube called a drain going into your groin. This is to drain any fluid that may collect there. The drain is connected to a small suction bottle. It will be removed when most of the excess fluid has been drained off - usually this is within about seven days.

Other procedures (to be specified)

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☐ ……
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☐ ……
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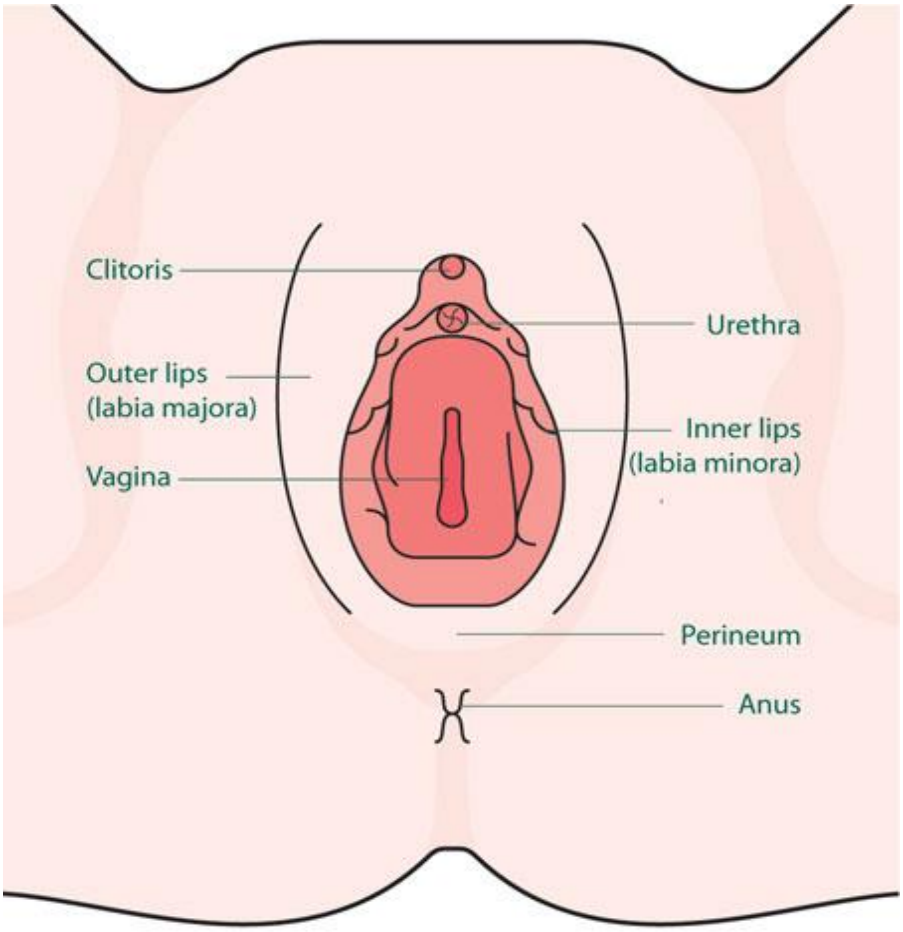

Statement of health professional seeking consent (to be filled in by health professional with appropriate knowledge of proposed procedure, as specified in consent policy)

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

The intended benefits:

☐ To remove the vulval cancer

☐ 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:

These risks apply to all types of vulva surgery:

☐ **Infection** of wounds (vulval, groins, flap sites), urine, chest, blood (1 in 5 risk). To reduce this risk we give you antibiotics during, and often for one or two days after your operation. To reduce the risk of the vulval wounds getting an infection they will be kept clean by being gently rinsed with water (vulval douching). This is usually done three times a day while in hospital and may be continued at home until the area has completely healed. We will show you how to keep the area clean and dry yourself. If necessary, we will arrange for a district nurse to visit you at home to help with rinsing the area and keeping it clean.

- ☐ **Bleeding** If the bleeding from the operation site is significant you may need a blood transfusion during or after your operation (1 in 10 risk).
- ☐ **Blood clots in legs or lungs** These are called deep vein thrombosis (DVT) or pulmonary embolism (PE). They most commonly form in the calf (DVT) or pelvis causing lower leg swelling and pain or in the lung (PE) 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. To reduce the risk of blood clots you will have supporting stockings to wear and have an injection once a day to thin your blood while in hospital and continuing usually until 28 days after your operation. If you had surgery in your groin you will be advised not to have this injection in your leg (1 in 400 risk).
- ☐ **Wound separation or breakdown** The wounds on your vulva are particularly prone to separating or breaking down. If this does occur it is usually managed with regular vulval douching and letting the wound heal by granulation from the edges and base of the wound. It is very rare to need to go back to theatre to have another operation to have a wound re-stitched. (Wound separation 1 in 2 risk, major wound breakdown 1 in 10 risk).
- ☐ **Effects on nerves** There may be numbness or altered sensation around the operation site, and /or on the front of your thigh if you have had a groin node dissection after surgery. This is due to the effects of the surgery on the nerves close by. It usually diminishes over a few months (1 in 10 risk). Some patients (less than 1 in 20) report continued numbness in or around the scar(s)
- ☐ **Difficulty sitting for a long time** After extensive vulva surgery some women find they have difficulty and pain in sitting for long periods (1 in 20 risk). This typically improves with time (3-6 months).
- ☐ **Changes in body image, feelings about femininity and sexual function** There will be a scar on your vulva and your vulva will look different to how it did before your operation. If your clitoris is removed this will be associated with diminution or loss of sexual function. It is safe to start having sex again once your wound has 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.
- ☐ **Return to theatre** for another operation (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** is 5 to 10 in 100; this includes a very rare risk of death within six weeks (overall average figure of less than 1 in 100 risk).

These risks apply if you are having a lymph node dissection:

- ☐ **Lymphocyst** A lymphocyst is a collection of lymphatic fluid in the groin area. Having a drain in the area for a number of days after your operation reduces the risk of developing a lymphocyst. A lymphocyst is uncomfortable, can be painful and is at risk of infection. We have a number of ways to manage a lymphocyst if it does occur. If you do develop a lymphocyst once resolved it can occasionally recur (1 in 10 risk).

☐ **Lymphoedema** The groin lymph nodes normally help to remove lymph fluid from your legs, taking the lymph nodes can block the flow of lymph fluid. If this happens, fluid will collect in the tissues under your skin, making your vulva, leg and/or legs swell. Lymphoedema can develop any time from a few weeks up to several years after treatment. For most patients with lymphoedema this has developed within one year of treatment. It is difficult to predict how much it will impact on your day to day life. We will give you supportive stockings to wear after your operation and you will see a member of our specialist Lymphoedema team whom will advise you on how to reduce the risk of lymphoedema and how to manage it if it does occur. The risk of developing lymphoedema is greater if radiotherapy is recommended after surgery (2 in 3 risk). You will be contacted by a lymphoedema nurse for support.

☐ **Inguinal or femoral hernia** A weakness in your abdominal wall at the site of the cut used for the groin node dissection. This may not be apparent until a few months after your operation. If troublesome this can be repaired by an operation (less than 1 in 10 risk).

These risks apply if you are having a plastic surgery reconstruction:

☐ **Reconstruction skin flap failure** This is when the skin flap takes longer than normal to heal or fails to heal. The risk of total failure of a reconstruction is small (less than 1 in 50 risk), however the risk of partial loss or failure of reconstructive flaps is higher at 1 in 4. A total loss of reconstructive tissue would necessitate further reconstructive surgery whilst a partial loss can usually be managed by good nursing care whilst the incision line heals.

☐ **Reconstruction skin flap donor site failure** The donor site incision can also be subject to wound healing delay in a small proportion of cases. Typically this type of wound heals over time with good nursing care and does not require further surgery (1 in 10 risk).

Whether or not these risks apply to you depends on which part of your vulva needs to be removed:

☐ **Tightness at the entrance to your vagina (introitus)** A tightening due to scar tissue at the entrance to the vagina can occur after surgery. It can make sex more difficult. If this happens please discuss it with your doctor or Clinical Nurse Specialist (CNS) as there are ways to improve this problem (1 in 20).

☐ **Change in urinary function** The urethra is the tube your urine comes through from your bladder when you pass urine. If you need to have the area of your vulva around the urethra removed you may then have a change in your urinary stream (change in angle of the stream or spraying) or some form of urinary incontinence. If this occurs non-surgical and surgical procedures can be used to improve the symptoms (1 in 10 risk). Women who have urinary problems before surgery are more likely to develop further or worsening problems after surgery. On the other hand, in some women urine problems that were present before surgery are much improved after surgery as the cancer has been removed. Urine problems are more likely to develop, persist or worsen if radiotherapy is given after surgery.

☐ **Passing wind or liquid stool without warning.** These symptoms may occur if surgery has been performed around the anus. These symptoms, if they occur, usually resolve within a few weeks. Constipating measures may be required (1 in 20 risk). Incontinence of wind or stool and other problems with passing stool may develop after surgery. Women who have bowel problems before surgery are more likely to develop further or worsening problems after surgery. On the other hand, in some women bowel problems that were present before surgery are much improved after surgery as the cancer has been removed. Bowel problems are more likely to develop, persist or worsen if radiotherapy is given after surgery.

☐ **Vaginal wall or uterine prolapse** A weakness in your vaginal wall may cause a bulging into your vagina or the neck of the womb (cervix) to fall down your vagina. This can occur a few weeks to many months after your surgery. If this occurs non-surgical and surgical procedures can be used to improve any symptoms (1 in 10 risk).

Any other risks:

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……

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 Vulva Cancer

https://www.macmillan.org.uk/information-and-support/vulva-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 health care 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