Consent Form 1	
	Patient's surname/family name
DH Department of Health	Patient's first names
	Date of birth
THE ROYAL MARSDEN NHS FOUNDATION TRUST	Health professional seeking consent
	Job title
Diagnostic procedures in gynaecological cancer	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).

☐ **Examination under anaesthesia and possibly biopsies.** This includes a vaginal and/or rectal (back passage) examination while you are asleep or under regional or local analgesia. If indicated, small pieces of tissue may be taken for microscopic examination.

☐ **Investigation of the inside of the bladder through a telescope (cystoscopy) and possibly biopsies.** The tube between the bladder and the outside (urethra) is lubricated and the telescope is passed gently into the bladder. Some sterile fluid is run into the bladder to allow the surgeon to inspect the lining fully. If indicated, small pieces of tissue may be taken for microscopic examination.

☐ **Investigation of the inner lining of the lower large bowel with a telescope (sigmoidoscopy) and possibly biopsies.** A lubricated sigmoidoscope is inserted in the back passage (rectum). A sigmoidoscope is a short tube with a bright light which enables the surgeon to have a look at the inner lining of the bowel. If indicated, small pieces of tissue may be taken for microscopic examination.

☐ **Diagnostic laparoscopy (inspection of the abdominal cavity through keyhole), peritoneal washings and possibly biopsies.** This procedure is done through one or two small cuts in your abdomen (a keyhole approach). The abdominal cavity can be inspected and a sample from some water which we will put inside your abdomen (peritoneal washings) will be taken for microscopic examination to assess whether there are any abnormal floating cells. If indicated, small pieces of tissue may be taken for microscopic examination.

To be retained in patient's notes

☐ **Hysteroscopy and possibly biopsies**. This involves inserting a telescope inside the womb through the cervix to examine the inner lining (endometrium). If indicated, small pieces of tissue may be taken for microscopic examination.

☐ **Dilatation and curettage (D&C).** This is sampling (by curettage) the inner lining of the womb (called endometrium) after widening the cervix (dilatation). This is done to confirm if there is any abnormality in the endometrium.

☐ **Other**……
…….
…….

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 assess whether there is abnormal tissue and be able to obtain a diagnosis

☐ To assess how advanced the disease is (the stage)

Significant, unavoidable or frequently occurring risks/side effects:

☐ Passing urine may produce a burning and/or scalding feeling for a few days after the procedure. This usually settles within a few days (approximately 90 in 100 risk)

☐ **Vaginal bleeding or discharge**. This usually settles within a few days (approximately 90 in 100 risk of bleeding occurring)

☐ **Infection** of wound or urinary tract (bladder/kidney) (less than 5 in 100 risk)

☐ **Injury to nearby structures** like blood vessels, bladder, urethra, bowel and tube from kidney to bladder (ureter) (less than 5 in 100 risk). This may need further surgery

☐ **Accidental puncture of the womb or bladder** (less than 1 in 100 risk). This may require further surgery.

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

☐ **Conversion to open approach** (if planned for keyhole 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)

☐ **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 then 1 in 100 risk))

☐ **Changes in body image, feelings about femininity and sexual function** This is very rare following this type of diagnostic procedure

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	☐

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:

☐ …… (version no_____)
☐ …… (version no_____)

This procedure will involve:

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

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