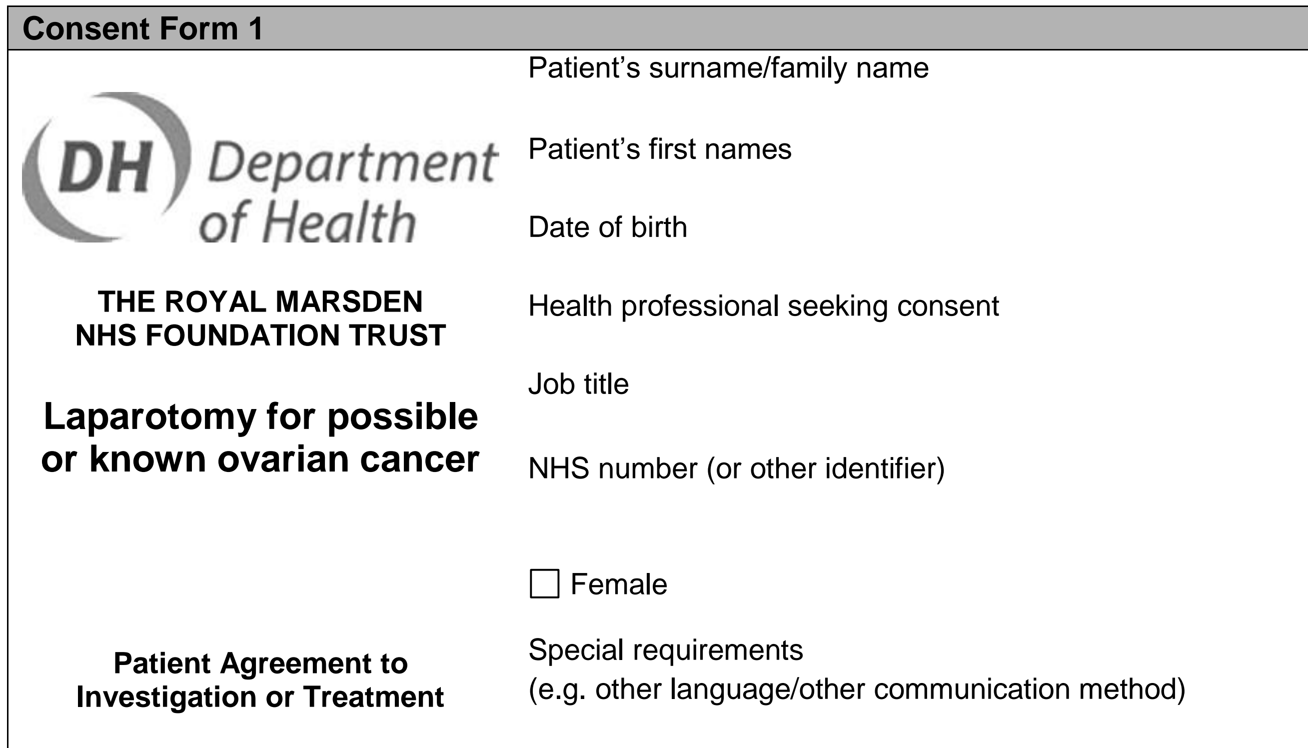

**Consent Form 1**

Department of Health

**THE ROYAL MARSDEN**
**NHS FOUNDATION TRUST**

**Laparotomy for possible or known ovarian cancer**

**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)

### ☐ Midline open approach (laparotomy)

The procedure is done via a cut in your abdomen, downwards from the belly button to the pubic hair; this cut may need to extend round your belly button up towards your breast bone. We will perform your operation through the smallest incision possible.

### ☐ Total (abdominal) hysterectomy, bilateral salpingo-oophorectomy (removal of womb, cervix, fallopian tubes and ovaries) with removal of the pelvic mass

Your womb, cervix, tubes and ovaries are removed. We remove the womb, cervix, tubes and ovaries by lifting them out through the cut in your abdomen. The top of your vagina is then stitched closed. If there is a "pelvic mass" (tumour) separate to your ovaries this is removed together with your womb, cervix, tubes and ovaries.

### ☐ Peritoneal washings or removal of ascites

We take a sample from some saline which we will put inside your abdomen (peritoneal washings). This is to assess whether there are any abnormal floating cells. If there is fluid inside your abdomen (ascites), at the beginning of your operation, we remove this and send a sample to assess if there are any abnormal floating cells. This part of your operation is done before the hysterectomy.

### ☐ Frozen section

A "frozen section" is when the pathologist gives an initial report on a biopsy of the mass or of the whole mass that has been removed surgically while you are still asleep. One, or both, of your ovaries or the pelvic mass are sent to the pathologist (the doctor who looks at the specimen down the microscope). The pathologist gives an initial report, while you are still under anaesthetic, to say if your specimen is benign (not cancer), borderline (between benign and cancer), or cancer. This then determines what else should be done during your

operation. The frozen section is in agreement with the final pathology report 95 out of 100 times. The frozen section report takes about 40 minutes; the final pathology report is usually available 10 to 14 days after your operation.

## ☐ Omental biopsy or omentectomy

The omentum is an apron of fatty tissue that lies in the upper abdomen attached to part of the colon. It helps support the organs nearby, but it's not essential to us. A small portion may be removed (biopsy), or all of it removed (omentectomy), to find out if the cancer has spread.

## ☐ Bilateral pelvic lymph node sampling or lymphadenectomy

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, e.g. in the neck, under the arm and in the pelvis. 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 to them. They may all be removed (called lymphadenectomy) or just some of them may be removed (lymph node sampling). Having some or all of these lymph nodes removed will not affect the body’s ability to fight infection. There is variation in practice whether to sample or remove all the lymph nodes, the reasons for this will be discussed with you.

## ☐ Para-aortic lymph node sampling or dissection

This involves removing the lymph nodes near the large blood vessels (aorta and vena-cava) that run at the back of you abdomen. There is variation in practice whether to sample or remove all the lymph nodes, the reasons for this will be discussed with you.

## ☐ Appendicectomy

The appendix is a part of the bowel that serves no function. Cancer of the ovary can spread to the appendix, and/or be associated with a cancer that originates in the appendix. Your appendix is removed to find out if it is involved in the cancer.

## ☐ Bowel resection with or without re-joining of the bowel (anastomosis), with or without stoma formation

If you have a cancer from the ovary, the aim of your operation is to remove, when possible, all visible sites of cancer. Cancer from the ovary can spread to the surface of the bowel. Your pre-operative scans give us an idea of the likely areas of cancer but are not completely accurate. If we find that there is cancer on the surface of your bowel we would advise, when technically possible, the removal of the involved portion of your bowel if doing so (together with other parts of the operation), would remove all visible disease. When we remove a length of bowel we would aim to re-join the bowel (anastomosis). If it is not technically possible to form an anastomosis, we instead need to form a stoma. A stoma is when the bowel comes to the surface of your stomach and your stool is collected in a bag rather than coming out of the back passage. If you need to have a stoma we will teach you how to look after it before you leave hospital. A temporary stoma may be formed to allow an anastomosis to heal without stool passing along that section of bowel. A stoma may be temporary or permanent. If you have a temporary or a permanent stoma you will be referred to the local stoma nurse who will support you after discharge from hospital. A temporary stoma is reversed some months later, usually by a minor operation, after which you would pass stool normally through the back passage.

### ☐ Removal of any other sites of visible disease

If you have a cancer from the ovary, the aim of your operation is to remove, when possible, all visible sites of cancer. Cancer from the ovary can spread anywhere within your abdominal cavity. Your pre-operative scans give us an idea of the likely areas of cancer but are not completely accurate. If we find that there is cancer on any other area we would advise, when technically possible, removing it.

## Other procedures (to be specified)

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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:**

☐ Remove your ovaries and/or the “pelvic mass” (tumour) and improve any symptoms

☐ To make a diagnosis, and if it is a cancer from the ovary, to find out how advanced (what stage) the cancer is and help decide whether other treatments should be considered

☐ If it is cancer, this operation is all or some of the treatment you need with the aim to cure the cancer

☐ If it is a cancer of the ovary, to remove, when technically possible, all visible disease

**Significant, unavoidable or frequently occurring risks/side effects:**

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

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

☐ **Bleeding** If the bleeding is significant you may need a blood transfusion during or after your operation (less than 5 in 100 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).
- ☐ **Blood clots in legs or lungs** They most commonly form in the calf (DVT) 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. Deep vein thrombosis (DVT) or pulmonary embolism (PE) (1 in 400 risk). To reduce the risk of blood clots you will have supportive 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.
- ☐ **Injury to nearby structures**; blood vessels, bladder, tube which takes the urine from the kidney to the bladder (ureter), bowel and nerves. If any damage occurs we repair it (less than 5 in 100 risk).
- ☐ **Lymphocyst or lymphoedema** (if 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). You will be contacted by a lymphoedema nurse for support.
- ☐ **Anastomosis leak** (If bowel resection with re-joining (anastomosis) performed) A leak of bowel contents from the area where your bowel was re-joined together. If this occurs, it is managed with a combination of antibiotics, a drain inserted into the area, and/or going back to theatre. This will delay your discharge from hospital. If this does occur, it is within 2 weeks of the operation (less than 5 in 100 risk).
- ☐ **Stoma prolapse, hernia or narrowing (stenosis)** (If bowel resection with stoma performed). The stoma may protrude out from your stomach wall (prolapse) or there may be a weakness in the abdominal wall around the stoma (hernia) or the opening of your bowel to the skin may be too tight (stenosis). These problems can occur many months after the operation and can, if troublesome, be repaired by a minor operation (less than 1 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).
- ☐ **Return to theatre** (immediate or late) to stop bleeding, repair injured structures, or for management of a post-operative complication (less than 1 in 100 risk).
- ☐ **Changes in body image, feelings about femininity and sexual function**
- ☐ **Slow recovery.** Recovery time from this sort of major operation is variable; usually women go home after 5 to 10 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 10 in 100; this includes a very rare risk of death within six weeks (overall average figure of less than 1 in 100 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.<br>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**<br>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 Ovarian Cancer
https://www.macmillan.org.uk/information-and-support/ovarian-cancer

☐ 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

☐ Pre-operative practice pack

For stomas

☐ ……………………………………………………………………………………………………

☐ ……………………………………………………………………………………………………

**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.

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**



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