

Patient agreement to investigation or treatment

Breast Surgery: Sentinel lymph node (SLN) biopsy +/- axillary clearance

Authors: Cambridge Breast Unit

Brief description:

- You have been recommended a biopsy of lymph glands in the armpit (axilla) as part of the surgical treatment for your breast cancer. This will be performed under general anaesthetic.
- The operation usually lasts up to one hour. This can be done as a day case or as an overnight stay.
- Here, we explain some of the aims, benefits, risks and alternatives to this procedure (operation/treatment). We want you to be informed about your choices to help you to be fully involved in making any decisions.
- Please ask about anything you do not fully understand or wish to have explained in more detail.
- If you would like this information in another format or language or would like help completing the form, please ask a member of our staff.

Please bring this form with you to hospital

- You will be asked to read this form carefully, and you and your doctor (or other appropriate healthcare professional) will sign it to document your consent.
- All our consent forms are available on the Addenbrooke’s website:
<http://www.addenbrookes.org.uk/consent>
- Remember, you can change your mind about having the procedure at any time even after you have signed the form.

For staff use:

Does the patient have any special requirements? (For example: requires an interpreter or other additional communication method)

.....
.....

Breast Surgery – Sentinel lymph node biopsy +/- axillary clearance

Breast Side:

Before your procedure

- You will be seen at the pre-admission clinic by members of the Surgical Breast Team.
- At this clinic, we shall ask you for details of your medical history and carry out any necessary clinical examinations and investigations. This is a good opportunity for you to ask us any questions about the procedure, but please feel free to discuss any concerns you might have at any time.
- You will be asked if you are taking any tablets or other types of medication - these might be ones prescribed by a doctor or bought over the counter in a pharmacy. It helps us if you bring with you details of anything you are taking (for example bring the packaging with you).
- You will normally come into hospital on the day of your surgery.
- This procedure involves the use of general anaesthesia, which means you will not be conscious during the surgery.
- The anaesthetist will see you before the procedure to assess your state of health and discuss the details with you.

During the procedure

- **Sentinel lymph node biopsy:** This involves making a small incision in the armpit (axilla) and removing about one to four lymph nodes.
- Lymph nodes ('glands') are concentrations of immune cells within the lymphatic system. Lymph draining from the tissues passes through them. Cancer cells can also escape from a tumour and lodge in lymph nodes. This information will help us plan the next stage of your treatment.
- In the past, surgery involved removing most of these lymph nodes, even though we know that cancer cells affect lymph nodes in only a third of all patients. A new technique has recently been developed that allows us to examine the first lymph nodes that drain the breast and using this information, remove only the lymph nodes that are affected.
- We call the first lymph nodes draining the breast, sentinel lymph nodes (SLNs). Approximately two hours before your surgery, a small amount of radioactive tracer will be injected. Immediately before your operation and under general anaesthesia, blue dye will be injected around the areola (the pigmented area around the nipple). Both the radioactive tracer and the blue dye will help us to identify the SLNs during the operation, which are then removed, and sent to the pathology department for analysis.

- Very rarely during the operation, it will be obvious by eye, that the SLNs are affected by cancer. If this is the case, we will remove the remaining lymph glands in your armpit. This is called axillary clearance.
- In all other cases, we will do no further surgery to the armpit. After your operation, we will need to wait for the result of the detailed pathological analysis. This will show us whether the SLNs have cancer cells in them. If we find cancer cells in the SLNs, you will be offered a second operation to remove further lymph nodes in the armpit. This second operation will usually take place approximately two weeks after your pathology results are available.
- Sometimes during the first operation we cannot identify the SLNs. This is for technical reasons - neither dye nor tracer has reached the lymph nodes in the armpit. This occurs in approximately 4 to 5% of patients. If this happens, we will take a cautious route and remove the majority of the remaining lymph glands, ie axillary clearance.

After the procedure

- After your operation, you will wake up in the recovery room. You might have an oxygen mask on your face to help you breathe. You might also wake up feeling sleepy.
- You will have a small, plastic tube in one of the veins in your arm. This may be attached to a bag of fluid (called a drip), which keeps you hydrated until you are awake enough to eat and drink by yourself.
- While you are in the recovery room, a nurse will check your pulse and blood pressure regularly. When you are well enough to be moved, you will be taken to the ward. Sometimes, people feel sick after an operation and might vomit. If you feel sick, please tell a nurse and you will be offered medicine to make you feel more comfortable.
- **Eating and drinking:** After the operation, you will be able to eat and drink when you are awake again. This usually takes two to four hours. How quickly you return to a normal diet will depend on how you feel. Most patients recover their appetite very quickly.
- **Mobile again:** Generally, it is best to get out of bed as soon as you feel you can.
- We might arrange for the physiotherapist to visit you on the ward to give advice and exercises, depending on the type of axillary surgery you have had.
- We advise you to bring a supportive and well-fitting bra into the ward with you. This may be put on after your surgery, providing support and comfort to the wound. The nursing staff will advise you when to put the bra on.
- **When you can leave hospital:** The time that you stay in hospital will depend on how you are feeling; you can usually go home the same day.
- **When you can resume normal activities including work:** You can usually begin gentle work within a day or two, but you might need to wait a little longer for more vigorous activity.
- It is not uncommon to feel a bit 'down' after any operation, so do ask your doctor or breast care nurse if you feel you need more psychological support.

- **Special measures you need to take after the procedure:** You will be given more detailed information about any special measures you need to take after the procedure. You will also be given information about things to watch out for that might be early signs of problems (for example an infection).
- Experienced staff are available to help you. Please tell your nurses or doctors about any concerns that you have, they will try to help you resolve them.
- The skin stitches are dissolvable and will not need to be removed. You will have a light dressing covering your wound to keep it clean, and this will usually be in place for the first day or so. The wound may be secured with steri-strips which are like small pieces of tape. They help healing and support the wound. These will gradually come off in the bath or the shower.
- **Check-ups and results:** You will be given a date to return to clinic for the results of your surgery in about two weeks. By then the tissue removed at the operation will have been examined and your results discussed by the Breast Care Team. Any further treatment, if recommended, will be discussed with you then.

Intended benefits of the procedure

- To biopsy the sentinel lymph glands in the armpit. This will help us to plan the next stage of your treatment.

Who will perform my procedure?

- This procedure will be performed by a breast surgeon who is a member of the Breast Team.

Alternative procedures that are available

- Other forms of treatment may be utilised in the treatment of your cancer such as radiation therapy (using high-dose x-rays to kill cancer cells), chemotherapy (using drugs to kill cancer cells), and hormone therapy (using hormones to stop the cells from growing). However, the present recommendation by the Breast Team is that in your case, surgery is the best form of treatment at this stage.

Serious or frequently occurring risks

- **Surgery:** All operations have a small risk of side effects, such as pain, bleeding and infection. The risks associated with general anaesthesia include potential breathing and heart problems, as well as possible reactions to medications. For a woman who is otherwise in good health, the risk of a serious complication due to general anaesthesia is less than 1%.
- **Sentinel node biopsy:** Worldwide, this more 'conservative' approach has been studied and we have found that there is a small possibility when we remove only one or two nodes that an occasional node containing cancer cells might be left behind. This occurs in less than 5% of all patients who have diseased lymph glands in the armpit.

- We do not expect any risks or side effects from the low-dose radioactive tracer because the total amount of radiation that you receive is less than you would receive from the environment over three months.
- The blue dye itself is not known to be harmful. You might, however, notice some blue discolouration of your urine for a few days following the operation. The skin of the breast can also stay blue for several months after the operation (sometimes up to 12 months), fading gradually over time. Mild allergic reactions to the blue dye can occur in 1.8 % of patients. More severe allergic reactions are rare and can occur in 0.2 % of patients (this means for every two patients for every 1000 patients treated).
- It is hoped that the complications and side-effects of the sentinel node biopsy will be minimal, but it is possible that you may experience some of those associated with axillary clearance.
- **Axillary clearance:** If it has been necessary to proceed to axillary clearance, you may experience numbness and discomfort in the armpit and upper arm, as well as shoulder stiffness. The numbness usually lessens slowly, after treatment, but might not resolve completely. Performing shoulder exercises (taught to you after the operation) improves mobility.
- When you wake up from the operation, you may have tubes (drains) coming from your wound. (This only applies if you have had an axillary clearance) These drains collect tissue fluid in a small collecting chamber, which is monitored daily. When the amount of fluid reaches a certain level (less than 50 ml per 24 hours), the drains will be removed, this is a simple procedure. It might be possible for you to be discharged with your drain in place after 48 hours. If not, you will stay in hospital until the drain is removed, this will be up to a maximum of three days after surgery. In a number of patients it may be possible to avoid the use of drains.
- **Seroma:** Seroma is a collection of fluid under the arm after surgery. This fluid may need to be drained through a needle. Draining is a very simple procedure that can be done by a member of the Breast Team.
- **Lymphoedema:** Lymphoedema is a possible complication of axillary clearance. Swelling occurs in the tissue below the skin caused by lymph fluid which cannot drain away. This can occur when the lymph glands are removed (by surgery) or blocked (by radiotherapy) secondary to scar tissue formation. The hand and or arm may swell at any time after the surgery. It can affect about 15 to 20% of women but only around 5% to a significant degree. There are certain precautions you need to take to prevent lymphoedema, these will be discussed with you by the Breast Care Nurse.

Information and support

Additional information will be given to you in the form of a Patient Resource Pack. Do feel free to speak to a member of staff if you have any questions or anxieties.

Breast Care Nurses:

Tel: 01223 216313/586756/586960/586573/596291/348272/586573

Further information:

Cancer BACKUP

Tel: Freeline 0808 800 1234

www.cancerbackup.org.uk

Breast Cancer Care

Nationwide Free Call: 0808 800 6000

www.breastcancercare.org.uk

General Anaesthesia

Before your operation

Before your operation your anaesthetist will visit you in the ward, although occasionally this will happen in a pre-anaesthetic assessment clinic. If you are a day case patient it may not be until just before your operation. The anaesthetist who looks after you on the day of your operation is the one who is responsible for making the final decisions about your anaesthetic. He or she will need to understand about:

- your general health
- any medication that you are taking
- any past health problems that you have had.

Additionally your anaesthetist will want to know whether:

- you are a smoker
- whether you have had any abnormal reactions to any of the drugs
- or if you have any allergies.

They will also want to know about your teeth:

- whether you wear dentures
- have caps
- or a plate.

Your anaesthetist needs to know all these things so that he or she can assess how to look after you in this vital period. Your anaesthetist may examine your heart and lungs.

Before your operation, you will usually be changed into a gown and wheeled to the operating suite into an anaesthetic room. This is an ante-room outside the theatre. The anaesthetist, his or her assistant and nurses are likely to be present. An intravenous line (drip) may be inserted. Monitoring devices may be attached to you, such as a blood pressure cuff or a pulse oximeter. A pulse oximeter is usually a little red light in a small box, which is taped to your finger. It shows how much oxygen you have in your blood and is one of the vital monitors that an anaesthetist uses during your operation to ensure that you remain in the best of health. You may be given some oxygen to breathe.

During your operation

While you are unconscious and unaware your anaesthetist remains with you at all times. He or she monitors your condition and administers the right amount of anaesthetic drugs to maintain you in the correct level of unconsciousness for the period of the surgery. Your anaesthetist is constantly aware of your condition and trained to respond. Your anaesthetist will be monitoring such factors as heart rate, blood pressure, heart rhythm, body temperature and breathing. He or she will also constantly watch your need for fluid or blood replacement. If you have any other medical conditions, your anaesthetist will know of these from your pre-operative assessment and be able to treat them during surgery.

After your operation

After your operation your anaesthetist continues to monitor your condition carefully. You will probably be transferred to a recovery ward where specially trained nurses, under the direction of anaesthetists, will look after you. Your anaesthetist and the recovery nurses will ensure that all the anaesthetic effects are reversed and that you are closely monitored as you return to full consciousness. You may be given some oxygen to breathe in the recovery area, and may find that intravenous drips have been inserted whilst you are unconscious in theatre and that these will be replacing fluids that you might require. You will be given medication for any pain that you might feel.

You are likely to feel drowsy and sleepy at this stage. Some patients feel sick, others may have a sore throat related to the insertion of the breathing tube during surgery. During this time it is important that you relax as much as you can, breathe deeply, do not be afraid to cough, and do not hesitate to ask the nursing staff for any pain relief, and about any queries you may have. You are likely to have hazy memories of this time and some patients experience vivid dreams. Once you are fully awake you will be returned to the ward, and if you are a day patient will be allowed to go to the waiting area to fully recover before you are accompanied home. Do not expect to feel completely normal immediately!

What are the risks of general anaesthesia?

In modern anaesthesia, serious problems are uncommon. Risks cannot be removed completely, but modern equipment, training and drugs have made it a much safer procedure in recent years. The risk to you as an individual will depend on; whether you have any other illness, personal factors (such as smoking or being overweight) or surgery which is complicated, long or done in an emergency. Please discuss any pre-existing medical condition with your anaesthetist.

- Very common and common side effects (1 in 10 or 1 in 100 people)
Feeling sick and vomiting after surgery, sore throat, dizziness, blurred vision, headache, itching, aches, pains and backache, pain during injection of drugs, bruising and soreness, confusion or memory loss.
- Uncommon side effects and complications (1 in 1000 people)
Chest infection, bladder problems, muscle pains, slow breathing (depressed respiration), damage to teeth, lips or tongue, an existing medical condition getting worse, awareness (becoming conscious during your operation).
- Rare or very rare complications (1 in 10,000 or 1 in 100,000)
Damage to the eyes, serious allergy to drugs, nerve damage, death, equipment failure.



We are currently working towards a smoke free site. Smoking is only permitted in the designated smoking areas.

For advice and support in quitting, contact your GP or the free NHS stop smoking helpline on 0800 169 0 169

Help with this leaflet:



If you would like this information in another language, large print or audio format, please ask the department to contact Patient Information: 01223 216032 or patient.information@addenbrookes.nhs.uk

Polish

Jeżeli chciałbyś uzyskać te informacje w innym języku, w dużej czcionce lub w formacie audio, poproś pracownika oddziału o kontakt z biurem Informacji Pacjenta (Patient Information) pod numerem telefonu: 01223 216032 lub pod adresem patient.information@addenbrookes.nhs.uk

Portuguese

Se precisar desta informação noutra língua, em impressão de letras grandes ou formato áudio, por favor peça ao departamento que contacte a secção de Informação aos Doentes (Patient Information) pelo telefone 01223 216032 ou através do e-mail patient.information@addenbrookes.nhs.uk

Arabic

إذا كنت تود الحصول على هذه المعلومات بلغة أخرى، بالأحرف الكبيرة أو بشكل شريط صوتي، يمكنك أن تطلب من القسم الاتصال بمعلومات المريض على الرقم: 01223216032 أو عبر البريد الإلكتروني: patient.information@addenbrookes.nhs.uk

Cantonese

如您需以另一語言版本、特大字體或錄音形式索取本資料，請要求部門聯絡病人諮詢服務：電話 01223 216032，電郵地址 patient.information@addenbrookes.nhs.uk

Turkish

Eğer bu bilgileri başka bir dilde veya büyük baskılı veya sesli olarak isterseniz, lütfen bulunduğunuz bölümdeki görevlilere söyleyin Hasta Bilgilendirme servisini arasinlar: 01223 216032 veya patient.information@addenbrookes.nhs.uk

Urdu

اگر آپ کو یہ معلومات کسی دیگر زبان میں، بڑے الفاظ میں یا آڈیو طریقہ سے درکار ہوں تو برائے مہربانی اس شعبہ سے پیشمنت انفارمیشن سے ذیل کے ذریعہ رابطہ کرنے کی درخواست کریں: patient.information@addenbrookes.nhs.uk یا 01223 216032

Bengali

আপনি যদি এই তথ্য অন্য কোন ভাষায়, বড় অক্ষরে বা অডিও রেকর্ডিং পেতে চান তাহলে 'প্যাশেন্ট ইনফরমেশান' এর সঙ্গে 01223 216032 নম্বরে ফোন করে বা patient.information@addenbrookes.nhs.uk ঠিকানায় ই-মেইল করে যোগাযোগ করার জন্য ডিপার্টমেন্টটিতে অনুরোধ জানান।

Document history

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Contact number	01223 245151
Published/Review date	November 2009/November 2012
File name	CF344_br_slncbiop_axil.doc
Version number/Ref	3/CF344

Consent form 1

Patient agreement to investigation or treatment

For staff use only:
Surname:
First names:
Date of birth:
Hospital no:
Male/Female:
(Use hospital identification label)

Responsible health professional/job title

.....

Special requirements.....
(For example, other language/other communication method)

Name of proposed procedure or course of treatment

Sentinel lymph node (SLN) biopsy+/- axillary clearance

Side (left/right).....

Statement of health professional

(To be filled in by a health professional with an **appropriate knowledge of the proposed procedure**, as specified in the Hospital's consent policy)

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

- The intended benefits of the procedure
To biopsy the sentinel lymph glands in the armpit.....
- Any serious or frequently occurring risks from the procedures including those specific to the patient
Pain, bleeding and infection.....
- Any extra procedures that might become necessary during the procedure

Blood transfusion Other procedure (please specify)

I have discussed what the treatment / 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 information leaflet has been provided:
..... Version/Date/Ref: 3/November 2009/CF344.....

This procedure will involve:

General and/or regional anaesthesia Local anaesthesia Sedation

Health professional's signature:Date:

Name (PRINT): Job title:

Contact details (if patient wishes to discuss details later)

I have offered the patient information about the procedure but s/he has declined information.

Statement of the interpreter (if appropriate)

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

Interpreter's signature..... Date:

Name (PRINT):.....

Important notes: (tick if applicable)

- The patient has withdrawn consent (ask patient to sign/date here)
- See also advance directive/living will

Copy accepted by patient: yes / no (please circle)

For staff use only:
Surname:
First names:
Date of birth:
Hospital no:
Male/Female:
(Use hospital identification label)

Statement of patient

Please read this form carefully. If your treatment has been planned in advance, you should already have your own copy, which describes the benefits and risks of the proposed treatment. If not, you will be offered a copy now. Do ask if you have any further questions. The staff at Addenbrooke's are here to help you. **You have the right to change your mind at any time before the procedure is undertaken, including after you have signed this form.**

Training doctors and other health professionals is essential to the continuation of the Health Service and improving the quality of care. Your treatment may provide an important opportunity for such training, where necessary under the careful supervision of a senior doctor. You may, however, decline to be involved in the formal training of medical and other students without this adversely affecting your care and treatment.

Please read the following:

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

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 that **I do not wish, without further discussion, to be carried out.**

I understand that any tissue (including blood) removed as part of the procedure or treatment will be anonymised and may be used for teaching or quality control, and stored or disposed of in a manner regulated by appropriate, ethical, legal and professional standards.

I understand that all research will be approved by a research ethics committee and undertaken in accordance with appropriate ethical, legal and professional standards.

I understand that the research may be conducted within a hospital, university, not for profit organisation or a company laboratory.

Please tick boxes to indicate you either agree/disagree to the three points below. Yes No

I agree that tissue (including blood) not needed for my own diagnosis or treatment can be used for **research which may include genetic research.** If you wish to withdraw your consent for the use of your tissue (including blood) for research, please contact the Patient Advice and Liaison Service at Addenbrooke's Hospital.

I agree to the use of photography for the purpose of diagnosis and treatment.

I agree to anonymised photographs being used for medical teaching.

I confirm that the risks, benefits and alternatives of this procedure have been discussed with me and I have read and understood the above and agree to the procedure (or course of treatment) on this form.

Patient's signature:..... **Date:**

Name (PRINT):

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

Witness' signature:..... **Date:**

Name (PRINT):

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.

Signature Date:

Name (PRINT): Job Title: