Patient information and consent to mastectomy and sentinel lymph node (SLN) biopsy +/- axillary clearance

Breast Side: .................................................................

Key messages for patients

- Please read your admission letter carefully. It is important to follow the instructions we give you about not eating or drinking or we may have to postpone or cancel your operation.

- Please bring with you any medications you use (including patches, creams and herbal remedies) and any information that you have been given relevant to your care in hospital, such as x rays or test results.

- Take your medications as normal on the day of the procedure unless you have been specifically told not to take a drug or drugs before or on the day by a member of your medical team. Do not take any medications used to treat diabetes.

- Please call a member of the breast specialist nurses on 01223 596291 or 01223 216313 if you have any questions or concerns about this procedure. Other contact numbers are listed in the information section of this leaflet.

- Important - please bring this form with you to the hospital on the day of your procedure. Please read this information carefully, you and your health professional will sign it to document your consent.

After the procedure we will file the consent form in your medical notes and you may take this information leaflet home with you.

Important things you need to know
Patient choice is an important part of your care. You have the right to change your mind at any time, even after you have given consent and the procedure has started (as long as it is safe and practical to do so). If you are having an anaesthetic you will have the opportunity to discuss this with the anaesthetist, unless the urgency of your treatment prevents this.

We will also only carry out the procedure on your consent form unless, in the opinion of the responsible health professional, a further procedure is needed in order to save your life or prevent serious harm to your health. However, there may be procedures you do not wish us to carry out and these can be recorded on the consent form. We are unable to guarantee that a particular person will perform the procedure. However the person undertaking the procedure will have the relevant experience.

All information we hold about you is stored according to the Data Protection Act 1998. Mastectomy and SLN biopsy +/- axillary clearance, CF341, v7, May 2016
About mastectomy and sentinel lymph node (SLN) biopsy +/- axillary clearance

You have been recommended to have a mastectomy and removal of lymph glands in the armpit (axilla) as the surgical treatment for your breast cancer. This will be performed under general anaesthetic. The operation usually lasts up to one to two hours and you are usually able to be discharged home the same day.

**Intended benefits**
- To remove the cancer in the breast
- To assess the sentinel lymph glands under the armpit to help us to plan the next stage of your treatment. To help prevent recurrence and improve your outcome.

**Who will perform my procedure?**
This procedure will be performed by a breast surgeon who is a member of the breast team.

**Before your procedure**
You will attend a pre-admission clinic, when you will meet a member of the pre assessment team. At this clinic, we will ask for details of your medical history and carry out any necessary clinical examinations and investigations.

We will ask if you take any tablets or use any other types of medication either prescribed by a doctor or bought over the counter in a pharmacy. Please bring any packaging with you.

This procedure involves the use of anaesthesia. We explain about the different types of anaesthesia or sedation we may use at the end of this leaflet. You will see an anaesthetist before your procedure.

You will normally be admitted to hospital on the day of surgery. If you have any questions about your procedure, please contact one of the breast specialist nurses.

**During the procedure**
At the start of your procedure, you will be given the necessary anaesthetic and/or sedation - see below for details of this.

**Mastectomy**
This involves making incisions around the breast, removing most of the breast tissue, including the nipple and areola (dark skin around the nipple), and some of the breast skin, which leaves a scar that is flat against the chest wall. The mastectomy will usually be performed in conjunction with the removal of the lymph glands from under your arm.
**Sentinel lymph node biopsy**

This involves making a small incision in the armpit (axilla) and removing about one to four lymph nodes. The information obtained from this procedure will help us plan the next stage of your treatment.

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. We call the first lymph nodes draining the breast, sentinel lymph nodes (SLNs). If there are no cancer cells present in these sentinel lymph nodes, we can be reasonably certain that the remaining lymph nodes in the axilla are also free of tumour cells.

A few hours (usually between 2 to 24 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, we may not be able to identify your sentinel lymph nodes, or alternatively it may be apparent that the SLNs are affected by cancer. This happens overall in 4-5% of cases. 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.

**After the procedure**

Once your surgery is completed you will usually be transferred to the recovery ward where you will be looked after by specially trained nurses, under the direction of your anaesthetist. The nurses will monitor you closely until the effects of any general anaesthetic have adequately worn off and you are conscious. They will monitor your heart rate, blood pressure and oxygen levels too. You may be given oxygen via a facemask, fluids via your drip and appropriate pain relief until you are comfortable enough to return to your 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.
When you wake up, you may have a drain (plastic tube) coming from your wound. The drain collects tissue fluid in a small collecting chamber, which is monitored daily. When there is less than a certain amount (usually 50mls) of fluid collected in the drain over 24 hours, the drainage tube will be removed, which is a simple procedure. It might be possible for you to be discharged on the day of your surgery, with your drain in place. Your district nurse will take over your care and remove the drain. Occasionally it may be possible to avoid the use of drains.

After certain major operations you may be transferred to the intensive care unit (ICU/ITU), high dependency unit (HDU), intermediate dependency area (IDA) or fast track/overnight intensive recovery (OIR). These are areas where you will be monitored much more closely because of the nature of your operation or because of certain pre-existing health problems that you may have. If your surgeon or anaesthetist believes you should go to one of these areas after your operation, they will tell you and explain to you what you should expect.

**If there is not a bed in the necessary unit on the day of your operation, your operation may be postponed as it is important that you have the correct level of care after major surgery.**

**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.

**Getting about after the procedure.** We will help you to become mobile as soon as possible after the procedure. This helps improve your recovery and reduces the risk of certain complications. The breast specialist nurses will also give you information on arm exercises for after your surgery.

**Leaving hospital.** The time that you stay in hospital will depend on how you are feeling after your operation, the type of operation, and your doctor's opinion.

**Resuming normal activities including work.** You can usually begin gentle work within a week 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 specialist nurse if you feel you need more psychological support.

**Special measures after the procedure:** We will give you detailed information about any special measures you need to take after the procedure. We will also give you information about things to watch out for that might be early signs of problems (for example, 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 may have some surgical wound glue on top of your wound which helps the wound to heal and acts as waterproof protection. The wound may be secured with steri-strips which are like small pieces of tape. They help to heal and support the wound. These will gradually come off in the bath or the shower.

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 breast specialist nurses will contact you at home the day following your surgery to discuss the care of your wound.

**Check-ups and results:** You will be given a date to return to clinic for the results of your surgery. By then the tissue removed at the operation will have examined and your results discussed by the Breast Care Team. Any further treatment, if recommended, will be discussed with you then.

Before you leave the ward, you will be given two temporary prostheses ‘comfies’. You will be contacted about arrangements for being fitted with a longer-term prosthesis. The fitting will be about six to eight weeks after your operation and the service is provided free of charge.

**Significant, unavoidable or frequently occurring risks of this procedure**

**Mastectomy**

**Altered sensation:** you might have tingly feelings or shooting pain where the breast was removed, this can last for six months or longer. Additionally, some women notice a change in their balance due to the loss of the breast weight. Wearing a prosthesis helps with this problem.

**Seroma** is a collection of fluid under your chest scar after surgery. It is relatively common after mastectomy and axillary clearance, but is easily treated by drainage through a small needle. Draining is a very simple procedure that can be done by a member of the Breast Team.

**Sentinel node biopsy**

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 remaining 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 (ie in 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**

**Numbness**: you may experience numbness and discomfort in the armpit and upper arm. The numbness usually lessens slowly, after treatment, but might not resolve completely

**Shoulder stiffness**: the shoulder may become stiff and painful after your operation. Performing shoulder exercises (taught to you after the operation) improves mobility.

**Lymphoedema** is a swelling 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 specialist nurse.

**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%.

**Post surgical treatment**

When deciding if you need post-surgical treatment (called adjuvant therapy) your team will assess several factors, including the risk of the cancer recurring, the characteristics of the cancer, and how much the treatment will benefit you. This will be discussed with you by a member of the Breast Team.

**Alternative procedures that are available**

In some cases it is possible to treat cancer by removing part of the breast only.

The axilla can be assessed and treated by axillary clearance. However, the present recommendation by the Breast Team is that in your case, mastectomy and axillary clearance is the best form of treatment at this stage.

Other forms of treatment may be utilised in the treatment of 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). These will be discussed with you if and when appropriate.

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Anaesthesia

Anaesthesia means ‘loss of sensation’. There are three types of anaesthesia: general, regional and local. **The type of anaesthesia chosen by your anaesthetist depends on the nature of your surgery as well as your health and fitness.** Sometimes different types of anaesthesia are used together.

Before your operation

Before your operation you will meet an anaesthetist who will discuss with you the most appropriate type of anaesthetic for your operation, and pain relief after your surgery. To inform this decision, he/she will need to know about:

- your general health, including previous and current health problems
- whether you or anyone in your family has had problems with anaesthetics
- any medicines or drugs you use
- whether you smoke
- whether you have had any abnormal reactions to any drugs or have any other allergies
- your teeth, whether you wear dentures, or have caps or crowns.

Your anaesthetist may need to listen to your heart and lungs, ask you to open your mouth and move your neck and will review your test results.

Pre-medications

You may be prescribed a ‘premed’ prior to your operation. This a drug or combination of drugs which may be used to make you sleepy and relaxed before surgery, provide pain relief, reduce the risk of you being sick, or have effects specific for the procedure that you are going to have or for any medical conditions that you may have. **Not all patients will be given a premed or will require one and the anaesthetist will often use drugs in the operating theatre to produce the same effects.**

Moving to the operating room or theatre

You will usually change into a gown before your operation and we will take you to the operating suite. When you arrive in the theatre or anaesthetic room, monitoring devices may be attached to you, such as a blood pressure cuff, heart monitor (ECG) and a monitor to check your oxygen levels (a pulse oximeter). An intravenous line (drip) may be inserted and you may be asked to breathe oxygen through a face mask.

It is common practice nowadays to allow a parent into the anaesthetic room with children; as the child goes unconscious, the parent will be asked to leave.

**Before starting your anaesthesia the medical team will perform a check of your name, personal details and confirm the operation you are expecting.**
General anaesthesia

During general anaesthesia you are put into a state of unconsciousness and you will be unaware of anything during the time of your operation. Your anaesthetist achieves this by giving you a combination of drugs.

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 at the correct level of unconsciousness for the period of the surgery. 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.

Regional anaesthesia

Regional anaesthesia includes epidurals, spinals, caudals or local anaesthetic blocks of the nerves to the limbs or other areas of the body. Local anaesthetic is injected near to nerves, numbing the relevant area and possibly making the affected part of the body difficult or impossible to move for a period of time. Regional anaesthesia may be performed as the sole anaesthetic for your operation, with or without sedation, or with a general anaesthetic. Regional anaesthesia may also be used to provide pain relief after your surgery for hours or even days. Your anaesthetist will discuss the procedure, benefits and risks with you.

Local anaesthesia

In local anaesthesia the local anaesthetic drug is injected into the skin and tissues at the site of the operation. The area of numbness will be restricted and some sensation of pressure may be present, but there should be no pain. Local anaesthesia is used for minor operations such as stitching a cut. Usually a local anaesthetic will be given by the doctor doing the operation.

Sedation

Sedation is the use of small amounts of anaesthetic or similar drugs to produce a ‘sleepy-like’ state. Sedation may be used as well as a local or regional anaesthetic. The anaesthesia prevents you from feeling pain, the sedation makes you drowsy. Sedation also makes you physically and mentally relaxed during an investigation or procedure which may be unpleasant or painful (such as an endoscopy) but where your co-operation is needed. You may remember a little about what happened but often you will remember nothing. Sedation may be used by other professionals as well as anaesthetists.

What will I feel like afterwards?

How you will feel will depend on the type of anaesthetic and operation you have had, how much pain relieving medicine you need and your general health.
Most people will feel fine after their operation. Some people may feel dizzy, sick or have general aches and pains. Others may experience some blurred vision, drowsiness, a sore throat, headache or breathing difficulties.

You may have fewer of these effects after local or regional anaesthesia although when the effects of the anaesthesia wear off you may need pain relieving medicines.

**What are the risks of general or regional 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 performed in an emergency.

**Very common (1 in 10 people) and common side effects (1 in 100 people)**
- Feeling sick and vomiting after surgery
- Sore throat
- Dizziness, blurred vision
- Headache
- Bladder problems
- Damage to lips or tongue (usually minor)
- 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
- Muscle pains
- Slow breathing (depressed respiration)
- Damage to teeth
- An existing medical condition getting worse
- Awareness (becoming conscious during your operation)

**Rare (1 in 10,000 people) and very rare (1 in 100,000 people) complications**
- Damage to the eyes
- Heart attack or stroke
- Serious allergy to drugs
- Nerve damage
- Death
- Equipment failure

Deaths caused by anaesthesia are very rare. There are probably about five deaths for every million anaesthetics in the UK.
Information and support

We will give you a Patient Information Breast Care Pack which will give you additional information and your care plan. Do feel free to speak to the breast specialist nurses if you have any questions or anxieties. The breast care nurses can be contacted on: 0800 -1700 Monday – Friday:

01223 596291  01223 216313
01223 586960  01223 348272  01223 586573

Further information is also available from:
- [www.breastcancercare.org.uk](http://www.breastcancercare.org.uk)
- [www.breastcancernow.org](http://www.breastcancernow.org)

Privacy & dignity

Same sex bays and bathrooms are offered in all wards except critical care and theatre recovery areas where the use of high-tech equipment and/or specialist one to one care is required.

We are now a smoke-free site: smoking will not be allowed anywhere on the hospital site. For advice and support in quitting, contact your GP or the free NHS stop smoking helpline on 0800 169 0 169.

Other formats:

If you would like this information in another language, large print or audio, please ask the department where you are being treated, to contact the patient information team: [patient.information@addenbrookes.nhs.uk](mailto:patient.information@addenbrookes.nhs.uk).

Please note: We do not currently hold many leaflets in other languages; written translation requests are funded and agreed by the department who has authored the leaflet.

Document history

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Information about important questions on the consent form

1 Creutzfeldt Jakob Disease (‘CJD’)

We must take special measures with hospital instruments if there is a possibility you have been at risk of CJD or variant CJD disease. We therefore ask all patients undergoing any surgical procedure if they have been told that they are at increased risk of either of these forms of CJD. This helps prevent the spread of CJD to the wider public. A positive answer will not stop your procedure taking place, but enables us to plan your operation to minimise any risk of transmission to other patients.

2 Photography, Audio or Visual Recordings

As a leading teaching hospital we take great pride in our research and staff training. We ask for your permission to use images and recordings for your diagnosis and treatment, they will form part of your medical record. We also ask for your permission to use these images for audit and in training medical and other healthcare staff and UK medical students; you do not have to agree and if you prefer not to, this will not affect the care and treatment we provide. We will ask for your separate written permission to use any images or recordings in publications or research.

3 Students in training

Training doctors and other health professionals is essential to the NHS. Your treatment may provide an important opportunity for such training, where necessary under the careful supervision of a registered professional. You may, however, prefer not to take part in the formal training of medical and other students without this affecting your care and treatment.

4 Use of Tissue

As a leading bio-medical research centre and teaching hospital, we may be able to use tissue not needed for your treatment or diagnosis to carry out research, for quality control or to train medical staff for the future. Any such research, or storage or disposal of tissue, will be carried out in accordance with ethical, legal and professional standards. In order to carry out such research we need your consent. Any research will only be carried out if it has received ethical approval from a Research Ethics Committee. You do not have to agree and if you prefer not to, this will not in any way affect the care and treatment we provide. The leaflet ‘Donating tissue or cells for research’ gives more detailed information. Please ask for a copy.

If you wish to withdraw your consent on the use of tissue (including blood) for research, please contact our Patient Advice and Liaison Service (PALS), on 01223 216756.
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A Patient's side left / right or N/A

Consultant or other responsible health professional

Name and job title: .................................................................

☐ Any special needs of the patient (e.g. help with communication)? ......................................................

Please use 'Procedure completed' stamp here on completion: .................................................................

B Statement of health professional (details of treatment, risks and benefits)

1 I confirm I am 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:

a) the intended benefits of the procedure (please state)
   - To remove the cancer in the breast
   - To assess the sentinel lymph glands under the armpit to help us to plan the next stage your treatment. To help prevent recurrence and improve your outcome.

b) the possible risks involved. Addenbrooke's always ensures any risks are minimised. However all procedures carry some risk and I have set out below any significant, unavoidable or frequently occurring risks including those specific to the patient
   - Altered sensation, seroma, numbness, shoulder stiffness, lymphoedema, pain, bleeding, infection.
   - There is a small possibility when we remove only one or two nodes that an occasional node containing cancer cells might be left behind.
   - Blue discolouration of your urine. The remaining skin of the breast can also stay blue for several months.
   - 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.

c) what the treatment or procedure is likely to involve, the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of this patient:
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d) any extra procedures that might become necessary during the procedure such as:

☐ Blood transfusion  ☐ Other procedure (please state)

The following information leaflet has been provided:
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or  ☐ I have offered the patient information about the procedure but this has been declined.

3 This procedure will involve:

☐ General and/or regional anaesthesia  ☐ Local anaesthesia  ☐ Sedation  ☐ None

Signed (Health professional): ___________________________ Date: _______ / _______ / _______.

Name (PRINT): ___________________________ Time (24hr): _______ / _______

Designation: ___________________________ Contact/bleep no: ___________________________

C Consent of patient / person with parental responsibility

I confirm that the risks, benefits and alternatives of this procedure have been discussed with me and that my questions have been answered to my satisfaction and understanding.

Important: please read the patient information about this procedure and then put a tick in the relevant boxes for the following questions:

1 Creutzfeldt Jakob disease (CJD)
Have you ever been notified that you are at risk of CJD or variant CJD for public health purposes? If yes, please inform your health professional.

☐ Yes ☐ No

2 Photography, Audio or Visual Recording
a) I agree to the use of any of the above type of recordings for the purpose of diagnosis and treatment.

☐ Yes ☐ No

b) I agree to unidentified versions of any of the above recordings being used for audit and medical teaching in a healthcare setting.

☐ Yes ☐ No

3 Medical Training
I agree to the involvement of trainee medical and other students as part of their formal training.

☐ Yes ☐ No
Consent Form

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4 Use of Tissue
a) I agree that tissue (including blood) not needed for my own diagnosis or treatment can be used and stored for ethically approved research which may include ethically approved genetic research. □ Yes □ No

b) Where additional clinical information is needed for the purposes of ethically approved research, I agree that relevant sections of my medical record may be looked at by researchers or by relevant regulatory authorities. I give permission for these individuals to have access to my records. □ Yes □ No

I have listed below any procedures that I do not wish to be carried out without further discussion.

I have read and understood the Patient Information about this procedure and the above additional information. I agree to the procedure or treatment.

Signed (Patient): ___________________________ Date: __/__/__
Name of patient (PRINT): ___________________________

If signing for a child or young person; delete if not applicable.
I confirm I am a person with parental responsibility for the patient named on this form.
Signed: ___________________________ Date: __/__/__
Relationship to patient: ___________________________

If the patient is unable to sign but has indicated his/her consent, a witness should sign below.
Signed (Witness): ___________________________ Date: __/__/__
Name of witness (PRINT): ___________________________
Address: ___________________________
Consent Form

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D Confirmation of consent

Confirmation of consent (where the treatment/procedure has been discussed in advance)
On behalf of the team treating the patient, I have confirmed with the patient that she/he has no further questions and wishes the treatment/procedure to go ahead.

Signed (Health professional): ................................................................. Date: ...D.D./M.M./Y.Y.Y.Y....

Name (PRINT): ......................................................................................... Job title: .................................................................

Please initial to confirm all sections have been completed:

E Interpreter’s statement (if appropriate)

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

Signed (Interpreter): ................................................................. Date: ...D.D./M.M./Y.Y.Y.Y....

Name (PRINT): .........................................................................................

Or, please note the language line reference ID number:

F Withdrawal of patient consent

☐ The patient has withdrawn consent (ask patient to sign and date here)

Signed (Patient): ................................................................. Date: ...D.D./M.M./Y.Y.Y.Y....

Signed (Health professional): ................................................................. Date: ...D.D./M.M./Y.Y.Y.Y....

Name (PRINT): ......................................................................................... Job title: .................................................................