Patient information and consent to staging laparoscopy

<table>
<thead>
<tr>
<th>Key messages for patients</th>
</tr>
</thead>
<tbody>
<tr>
<td>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.</td>
</tr>
<tr>
<td>Please read this information carefully, you and your health professional will sign it to document your consent.</td>
</tr>
<tr>
<td>It is important that you bring the consent form with you when you are admitted for surgery. You will have an opportunity to ask any questions from the surgeon or anaesthetist when you are admitted. You may sign the consent form either before you come or when you are admitted.</td>
</tr>
<tr>
<td>Please bring with you all of your medications and its packaging (including inhalers, injections, creams, eye drops, patches, insulin and herbal remedies), a current repeat prescription from your GP, any cards about your treatment and any information that you have been given relevant to your care in hospital, such as x rays or test results.</td>
</tr>
<tr>
<td>Simple painkillers such as paracetamol and ibuprofen may be required after surgery. Simple bowel medication such as senna and lactulose may be required after surgery. It is suggested that you discuss with your pharmacist and have a seven day supply of these medications at home to take as you need according to the instructions.</td>
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<tr>
<td>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. If you have diabetes please ask for specific individual advice to be given on your medication at your pre-operative assessment appointment</td>
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<tr>
<td>If you have any concerns requiring urgent medical advice please call the nurse specialist during working hours on 01223 596383 or through the hospital contact centre on 01223 245151 and ask for pager 154-348. During evenings or weekends please call Upper GI Enhanced recovery unit (ward M4) via contact centre.</td>
</tr>
</tbody>
</table>

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 health professional responsible for your care, 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.

About staging laparoscopy
This is a key-hole operation that allows us to see inside your abdominal cavity to assess the extent of your cancer. It is the most accurate way of detecting any spread of cancer around the abdominal cavity.

Why do I need a staging laparoscopy?
Before we can discuss the options for treating your cancer, we need to thoroughly assess its extent (also known as its “stage”). The CT body scan and PET scan in the X-ray department is good at detecting the spread of cancer in the liver and lungs. However, it cannot detect tiny deposits of cancer spread inside the abdominal cavity. That is why we recommend that you undergo a staging laparoscopy procedure.

The results of this procedure will allow us to fully discuss and plan treatment with you. Laparoscopy (or “key hole”) surgery allow us to see inside your abdomen without having to make large incisions. This is a major advantage to you in getting over the procedure. This procedure is performed while you are under a general anaesthetic.

Intended benefits
To accurately detect any spread of cancer around the abdominal cavity.

Who will perform my procedure?
This procedure will be performed by a consultant surgeon or under the direct supervision of the consultant by a surgeon in training who works in the team.
Before your procedure

Most patients attend a pre-admission clinic, when you will meet a member of the team. At this clinic, we will ask for details of your medical history and carry out any necessary clinical examinations and investigations. Please ask us any questions about the procedure, and feel free to discuss any concerns you might have at any time.

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 all your medications and any packaging (if available) with you. Please tell the ward staff about all of the medicines you use. If you wish to take your medication yourself (self-medicate), please ask your nurse. Pharmacists visit the wards regularly and can help with any medicine queries.

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.

We aim to do it as a daycase however you might have to stay in hospital for a day or longer afterward the operation. If at all possible, we will allow you home in the evening after your operation. Sometimes we can predict whether you will need to stay for longer than usual and your doctor will discuss this with you before you decide to have the procedure.

Hair removal before an operation

For most operations, you do not need to have the hair around the site of the operation removed. However, sometimes the healthcare team need to see or reach your skin and if this is necessary they will use an electric hair clipper with a single-use disposable head, on the day of the surgery. Please do not shave the hair yourself or use a razor to remove hair, as this can increase the risk of infection. Your healthcare team will be happy to discuss this with you.

During the procedure

Before your procedure, you will be given a general anaesthetic. This is usually performed by giving you an injection of medication intravenously (into a vein) through a small plastic cannula (commonly known as a drip), placed usually in your arm or hand.

While you are unconscious and unaware, your anaesthetist remains with you at all times, monitoring your condition and controlling your anaesthetic. At the end of the operation, your anaesthetist will reverse the anaesthetic and you will regain awareness and consciousness in the recovery room, or as you leave the operating theatre.

While you are asleep we make a small hole by your tummy button (umbilicus) and inflate your tummy up with carbon dioxide gas which is completely harmless.
Through the hole we can use a special long camera to look inside the abdominal cavity. We make two other small holes, one on each side of the abdomen and we pass long instruments through these which move the organs around and allow us to examine them closely.

During the procedure, we frequently take tissue and fluid samples for analysis and to assist in our decision making. We will inform you when we have done this, but may not have the results before you go home.

At the end of the operation, before you wake up, all the port sites in your abdomen will be injected with local anaesthetic so that when you first wake up there should be very little pain. Some patients have some discomfort in their shoulders, but this wears off quite quickly.

**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. 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, especially after a general anaesthetic, and might vomit. If you feel sick, please tell a nurse and you will be offered medicine to make you more comfortable.

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 surgery.

**Eating and drinking.** You will be able to drink immediately after the operation and provided you do not feel sick, then you will be able to eat something.

**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. If you have any mobility problems, we can arrange nursing or physiotherapy help.

**Leaving hospital.** Some patients feel well enough to get home the same day of their procedure, but most people stay one night and then go home the next day after their breakfast. You may feel discomfort for seven to ten days afterwards, but simple painkillers taken by mouth are usually all that people need to enable them to be fully mobile at home.
Resuming normal activities including work. We expect you to return to normal activities in a matter of days following your procedure. You can drive again when you can comfortably make an emergency stop (generally about seven days, but must be checked in stationary car first!). Other more vigorous activities can be resumed after two weeks.

Special measures after the procedure. All the wounds are closed with dissolvable stitches under the skin and therefore nothing needs to be done to these after the operation. Each of the wounds is covered with a small waterproof dressing which we ask you to keep intact for five days if possible. It is shower proof but will come off in a hot bath. We suggest that you get into a hot bath on day five and gently remove the dressings and leave the wound open to the air. If they rub on your clothing you may find it more comfortable to put a small elastoplast dressing over each wound.

Check-ups and results. We are able to give you some information before you go home. If we have taken samples, we will arrange with you how we will communicate the results to you. This may be by telephone or at review in the outpatients clinic. This will be discussed with you before you are discharged home. Clearly it is a time of great anxiety waiting for the results of tests, but it is very important that these tests are performed properly so that the right treatment is chosen for you.

Significant, unavoidable or frequently occurring risks of this procedure

All operations, however minor, have small risks attached to them. A staging laparoscopy is a relatively low risk procedure. However, rare complications can occur and you should ask a member of the team if you have any questions or concerns about the risks of this procedure.

Bleeding – This very rarely occurs after any type of operation. Your pulse and blood pressure are closely monitored after your operation as this is the best way of detecting this potential problem. If bleeding is thought to be happening, you may require a further operation to stop it. This can usually be done through the same scar(s) as your first operation. It is possible that you also may require a blood transfusion.

Damage to major blood vessels - Any major surgery is associated with a small risk of bleeding from a major blood vessel. This is most uncommon. If this were to occur the surgeon would take measures to stop the bleeding and it is possible you would require a blood transfusion.

Damage to the bowel (intestines) - Any surgery inside the abdominal cavity is associated with a very small risk (less than 1 in 500 chance) of damaging other organs, such as the bowel. This is particularly the case if there has been previous surgery with scarring and structures are abnormally stuck to each other. If there is damage to the bowel it can almost always be repaired at the time.
If it is not noticed at the time and you later become unwell a second procedure may be required. This is a more serious situation.

**Perforation** – There is a very small chance that due to the manipulation of the cancer it could perforate (develop a hole). If this were to happen then stomach contents could leak out into the abdominal cavity, causing you to become very sick. If a perforation were to occur this may require urgent, major surgery to remove the cancer and prevent you becoming very unwell. This would require conversion to an open operation with a longer incision made on the tummy.

**Wound haematoma** - Bleeding under the skin can produce a firm swelling of blood clot (haematoma), this may only become apparent several days after the surgery. It is essentially a bruise. This may simply disappear gradually or leak out through the wound without causing any major consequences to you.

**Wound infection** – This affect your scars. If the wound becomes red, hot, swollen and painful or if it starts to discharge smelly fluid then it may be infected. It is normal for the wounds to be a little sore, red and swollen as this is part of the healing process and represents the body’s natural reaction to surgery. It is best to consult your doctor if you are concerned. A wound infection can happen after any type of operation. Simple wound infections are easily treated with a short course of antibiotics.

**Scarring** – Any surgical procedure that involves making a skin incision carries a risk of scar formation. A scar is the body’s way of healing and sealing the cut. It is highly variable between different people. All surgical incisions are closed with the utmost care, usually involving several layers of sutures. The sutures are almost always dissolvable and do not have to be removed. The larger an incision the more prominent it will be. Despite our best intentions, there is no guarantee that any incision (even those only 1-2 cm in length) will not cause a scar that is somewhat unsightly or prominent. Scars are usually most prominent in the first few months following surgery, however, tend to fade in colour and become less noticeable after a year or so.

**Other complications** – We have tried to describe the most common and serious complications that may occur following this surgery. It is not possible to detail every possible complication that may occur following any operation. If another complication that you have not been warned about occurs, we will treat it as required and inform you as best we can at the time. If there is anything that is unclear or risks that you are particularly concerned about, please ask.

**Alternative procedures that are available**

For the particular information we are looking to obtain, there is currently no alternative method to detect spread of cancer within the linings of the abdominal cavity.
Information and support

We may give you some additional patient information before or after the procedure, for example: leaflets that explain what to do after the procedure and what problems to look out for. If you have any questions or anxieties, please feel free to ask a member of staff including your surgeon or one of the senior trainees.

If you have any questions please do not hesitate to call the specialist nurse on 01223 596383 or the consultants on 01223 217421 or 01223 348024.

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-medication

You may be prescribed a 'premed' prior to your operation. This is 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 and before starting your anaesthesia, the medical team will perform a check of your name, personal details and confirm the operation you are expecting.
Once that is complete, 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. If a regional anaesthetic is going to be performed, this may be performed at this stage. If you are to have a general anaesthetic, you may be asked to breathe oxygen through a face mask.

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 and, if you are to have a general anaesthetic as well, whether the regional anaesthesia will be performed before you are given the general anaesthetic.

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, but may also be injected around the surgical site to help with pain relief. 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 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

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Deaths caused by anaesthesia are very rare. There are probably about five deaths for every million anaesthetics in the UK. For more information about anaesthesia, please visit the Royal College of Anaesthetists' website: [www.rcoa.ac.uk](http://www.rcoa.ac.uk)
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.
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 or audio, please contact Interpreting services on telephone: 01223 348043, or email: interpreting@addenbrookes.nhs.uk For Large Print information please contact the patient information team: patient.information@addenbrookes.nhs.uk.

Document history

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Staging laparoscopy

Patient Information

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To accurately detect any spread of cancer around the abdominal cavity.

Full details are set out in the information leaflet and include:

- bleeding
- infection
- damage to viscera.

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

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 accurately detect any spread of cancer around the abdominal cavity.

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

Full details are set out in the information leaflet and include:

- bleeding
- infection
- damage to viscera.

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:
Consent Form

Staging laparoscopy

2 The following information leaflet has been provided: 

Staging laparoscopy

Version, reference and date: CF195, Version 4, September 2018

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: D.D./M.M./Y.Y.Y.Y.

Name (PRINT): ...................................................................................... Time (24hr): H.H.:M.M.

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 Students in training
I agree to the involvement of medical and other students as part of their formal training.

□ Yes □ No
**Consent Form**

**Staging laparoscopy**

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.  

**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.

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

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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): ..........................................................

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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**:

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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**:

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Patient safety – at the heart of all we do

Addenbrooke's Hospital | Rosie Hospital

Staging laparoscopy, CF195, v4, September 2018
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: ..................................................................................................................