Patient information and consent to laparoscopic cholecystectomy

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 read this information carefully,** you and your health professional will sign it to document your consent.
- **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.
- **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. If you have diabetes please ask for specific individual advice to be given on your medication at your Pre-Operative Assessment appointment.
- If you have any other concerns about this procedure after reading this guide, please contact Mercers Ward Sister or Matron on Tel: 0207 288 5481

Cambridge University Hospitals NHS
NHS Foundation Trust

With thanks to Cambridge University Hospitals for the use of their content

Important things you need to know

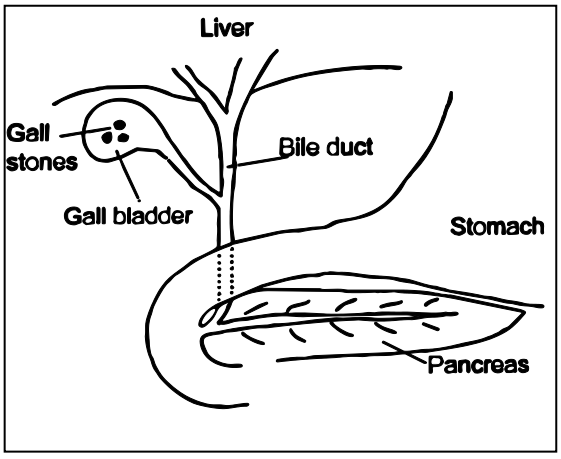
Patient choice is an important part of your care. You have the right to change your mind at any time, even after you have given consent and the procedure has started (as long as it is safe and practical to do so). If you are having an anaesthetic you will have the opportunity to discuss this with the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

What is the gall bladder?

Your liver has many functions, one of which is to produce a substance called bile. This green liquid drains from the liver to the intestine via the bile duct (see diagram below). The gall bladder is a small reservoir attached to the side of the bile duct where bile can be stored and concentrated between meals. When we eat, particularly fatty foods, the gall bladder contracts and empties extra bile into the bile duct and then into the intestine to mix with the food. Bile has many functions, one of which is to allow us to absorb fat. The gall bladder sits just under the liver, which is in the right upper part of the abdomen, just under the ribs.



Why will I need my gall bladder removed?

Usually this is because it is giving you pain due to gall stones. These small stones form in the gall bladder and can cause a range of problems including pain, jaundice, infection and pancreatitis. They are very common but do not always cause symptoms. Gall stones that are not causing trouble can be left alone.

Intended benefits

The gallbladder and gallstones are removed to prevent pain and/or complications of these.

Who will perform my procedure?

This procedure will be performed by a suitably qualified and experienced surgeon, or a trainee surgeon under the direct supervision of a suitably qualified and experienced surgeon.

Before your procedure

Most patients attend a pre-admission clinic, when you will meet a member of the team who will be looking after you. At this clinic, we will ask for details of your medical history and carry out any necessary clinical examinations and investigations. You will also be informed by the doctor you see about where your operation will be carried out. 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 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. They will review your medical history. In particular, you will be asked about your medications and any health problems that you have. They will also ask you about previous anaesthetics you have had and whether you had any problems with these (for example, nausea). You will be asked if you are allergic to anything. They will also want to know about your teeth, whether you wear dentures, have caps or a plate. Your anaesthetist may examine your heart and lungs.

Occasionally you may be prescribed medication that you will be given shortly before your operation – this is known as ‘the pre-medication’ or 'pre-med'. They relax you and may send you to sleep

Most people who have this type of procedure will not need to stay in hospital overnight and the procedure is performed as a day case, although this may not be suitable for everyone. Whether your procedure will be carried out as a day case or not, you will almost always be admitted to hospital on the day of your operation. Your doctor will discuss the length of stay with you.

During surgery it is very unlikely you may lose blood. If you lose a considerable amount of blood your doctor may want to replace the loss with a blood transfusion as significant blood loss can cause you harm. The blood transfusion can involve giving you other blood components such as plasma and platelets which are necessary for blood clotting. Your doctor will only give you a transfusion of blood or blood components during surgery, or recommend for you to have a transfusion after surgery, if you need it.

Compared to other everyday risks the likelihood of getting a serious side effect from a transfusion of blood or blood component is very low. Your doctor can explain to you the benefits and risks from a blood transfusion. Your doctor can also give you information about whether there are suitable alternatives to blood transfusion for your treatment. There is a patient information leaflet

for blood transfusion available for you to read on request; please do not hesitate to ask for it.

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 (i.e. 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.
- Four small holes (between 0.5cm- 1cm long each) are made in the tummy wall. Through these, we inflate your tummy up with carbon dioxide gas which is completely harmless.
- We then use special long instruments to free up the gall bladder with its stones from underneath the liver and it is completely removed. This is all visualised on a TV screen by a miniature camera inserted through one of the four key-holes. In addition, it is sometimes necessary to perform a special X-ray during the operation called a cholangiogram. This is used to check for stones in the bile duct.
- At the end of the operation, before you wake up, all the puncture sites in your abdomen will be treated 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.
- The cuts we have made will be covered with small waterproof dressings or absorbable glue.

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.

Most patients go home on the same day as the operation. You will be informed by your surgical team if they are planning to send you home or admit you overnight.

After certain more complicated 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. You will be able to drink immediately after the operation and if this is all right and 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. Avoid heavy lifting, strenuous activity and contact sports for 4-6 weeks after the operation to allow the wounds to heal properly.

Leaving hospital. You will be reviewed by the doctors and nursing staff on the ward after your operation. You will be allowed home after you have had something to drink and eat. We will also check that you are not feeling sick and have been able to pass urine. You will be given a supply of simple painkillers to take home. We recommend that you take these regularly for the first couple of days at home after your operation. You may feel discomfort for seven to ten days after, 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 as you feel comfortable.

Special measures after the procedure.
What happens with my dressing? 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. If you have any worries about your wounds, you should contact your GP. If you have glue then you can have a shower the following day and a bath four days after the procedure and the glue will dissolve/ disappear over the coming weeks.

Check-ups and results: Before you leave hospital you will be advised about your expected recovery. We do not need to see you routinely for a check-up in the clinic but are always happy to do so if you have any problems.

How is this different from the traditional operation for gall bladder problems?

The actual operation is the same. The only thing that differs is the way in which we get to the gall bladder to remove it. Traditionally, we make a cut underneath the ribs (15cm long). This takes longer to heal than the four little holes of keyhole surgery and the recovery is slower.

Is there a guarantee that keyhole surgery can be done?

No, there is no guarantee that the operation can be completed by keyhole surgery. If there is some technical difficulty with removing the gall bladder then a traditional cut would be needed to remove it. The time in hospital would be a little longer (about three to five days) and the recovery at home would be between six to eight weeks. The risk of having to convert to open surgery is small, about 5%.

Can I manage without my gall bladder?

Yes. The gall bladder is a reservoir for bile and we are able to manage without it. Rarely patients notice that their bowels are a little looser than before the operation but this is uncommon. You will be able to eat a normal diet after your operation, assuming that there is nothing else wrong with you.

Significant, unavoidable or frequently occurring risks of this procedure

Removal of the gallbladder is a very common and a very safe procedure. However, like all operations there are small risks involved. We believe that it is very important that you are fully aware of these risks as this is important in your understanding of what the operation involves. The possible complications below are particularly important as they can mean that you need to stay in hospital for longer and that further operations or procedures are required.

- **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 will require a further operation to stop it. This can usually be done through the same keyhole scars as your first operation.

- **Infection** – this can affect your scars (‘wound infection’) or can occur inside your tummy. Again this can happen after any type of abdominal operation. Simple wound infections can be easily treated with a short course of antibiotics that can be obtained from your GP. Infection inside your tummy will also usually settle with antibiotics. Occasionally, it may be necessary to drain off infected fluid from inside your tummy. This is most frequently performed under a local anaesthetic by our colleagues in the X ray department.

- **Leakage of bile** – When we remove the gallbladder, we put special clips on the tube that connects the gallbladder to the main bile duct draining the liver. Despite this, sometimes bile fluid leaks out. If this does occur, we have a number of different ways of dealing with this. Sometimes the fluid can simply be drained off by our colleagues in the X-ray

department. In other cases we will ask some other colleagues to perform a special test called an ERCP. This is a procedure where you are made very sleepy (using sedative injections) and a special flexible camera ('an endoscope') is passed down your gullet and stomach to allow the doctor to see the lower end of your bile duct. The doctor then injects a special dye that allows them to see where the bile has leaked from. If they see where the bile is leaking from, they will insert a plastic tube (called a 'stent') into your bile duct to allow the bile to drain internally. This stent is usually removed six to eight weeks after it is put in. Rarely, if a patient develops a bile leak, an operation is required to drain the bile and wash out the inside of the abdominal cavity. This can usually be performed as a keyhole procedure.

- **Injury to bile duct** – Injury to the main bile duct draining bile from the liver to your intestine is a rare (1 per 400 cases) complication of gallbladder surgery. We use a number of techniques during the operation to prevent this happening. If an injury occurs, it requires immediate repair so that you recover smoothly from the operation. Repair of this injury requires an open cut to be made under your ribs. You might need to be transferred to another hospital for specialists to treat this injury.

- **Injury to intestine, bowel and blood vessels** – Injury to these structures can, rarely, occur during the insertion of the keyhole instruments and during the freeing up of the gallbladder particularly if it is very inflamed. Usually this injury can be seen and repaired at the time of the operation, but occasionally may only become clear in the early postoperative period. If we suspect that you may have sustained such an injury, a further operation will be required. This will be performed as a keyhole operation but will need conversion to an open operation if necessary.

- **Blood clots in the legs (DVT)** – Before your operation, you will be fitted with some stockings that you wear during your operation to help prevent blood clots developing in the veins of your legs. You may also be given an injection in the skin of your tummy - this is a blood thinning medicine (Heparin) that also helps prevent blood clots.

- **Chest infection and atelectasis (lung collapse) –** After any operation involving a general anaesthetic and especially on the abdomen, there is a risk of chest infection. This is improved by ensuring you take regular deep breaths, and regular coughing. You will be given pain killers to ensure that this is possible. If you develop an infection after the operation, you may be treated with antibiotics.

Alternative procedures that are available

Unfortunately no alternative exists. The only successful treatment is to remove the gall bladder and gall stones completely. The results of this operation are very good and most patients can then return to eating a normal diet.

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) will be inserted. If a regional anaesthetic (a spinal or an epidural) 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. 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 when you are asleep to help with pain relief after the operation. 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 and 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

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

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

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.

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 0300 123 1044

Patient advice and liaison service (PALS)

If you have a question, compliment, comment or concern please contact our PALS team on 020 7288 5551 or whh-tr.whitthealthPALS@nhs.net

If you need a large print, audio or translated copy of this leaflet please contact us on 020 7288 3182. We will try our best to meet your needs.

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Patient agreement to investigation or treatment where patient has capacity to consent

Patient's surname..... Patient's first names .....
Date of birth ..... NHS / hospital number ..... .
Male Female Special requirement (language/communication method)
.....
Responsible health professional .....
Job title .....

Proposed procedure or course of treatment (include brief explanation if medical term not clear). .....
Laparoscopic cholecystectomy +/- open +/- on table cholangiogram
.....
.....

Statement of health professional (who has appropriate knowledge of proposed procedure as specified in the consent policy)
I have explained the procedure to the patient. In particular I have explained:
The intended benefits ..... Treat gallstones, prevent complications .....
.....
serious or frequently occurring' risks ..... Chronic pain, bleeding, infection, collection, bile leak injury to bile duct, retained stones, damage to other organs - stomach, small bowel, large bowel, liver, blood vessels, wound hernias, scarring, blood clots (DVT/PE), heart attack, stroke, chest infection, atelectasis (lung collapse)

The procedure will involve:
☒ general anaesthesia ☐ regional anaesthesia ☒ local anaesthesia ☐ sedation

Any extra procedures that may become necessary during the procedure
☐ Blood transfusion .....
☐ Other .....

☒ **A leaflet/tape** has been provided (name & code) ..... S&C/GralSurg/PI&CLapCholec/01 .....
☒ **Consenting to treatment leaflet** has been provided .....

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 the patient.

Signed ..... **Date** .....
Name (PRINT) ..... **Job title** ..... Consultant / Registrar / SHO .....
Contact details .....

Statement of interpreter, (where appropriate). I have interpreted the information above to the patient to the best of my ability and in a way, which I believe she/he can understand.

Signed ..... **Date** .....
Name (PRINT) .....

Top copy accepted by patient: Yes/No (Please ring)

Patient Copy

Statement of patient

Identifier label

Please read this form carefully and make sure that you understand the benefits and risks of the proposed treatment. If you have any further questions please 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.

As this is a teaching hospital, medical and nursing students may accompany the consultant during your treatment for training purposes. If you have any objection to this, please tell your doctor/nurse. This decision will not affect your treatment or care.

I agree to the procedure or course of treatment that is 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 the appropriate experience.

I understand that I will have the opportunity to discuss the details of general or regional anaesthesia with an anaesthetist before that procedure, unless the urgency of the procedure prevents this.

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 understand that human tissue (such as skin, muscle, organs) removed during the procedure may be sent to the laboratory for tests. Only with my express consent may any of the remains of these tissues be used for research or education. **(see signature below)**

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 to be carried out** without further discussion.

.....

.....

.....

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

Name (PRINT) .....

Signed consent for research on removed tissue .....

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).

Signed ..... **Date** .....

Confirmation of consent (to be completed by a health professional when a patient is admitted for a 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 she/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 directive/living will (e.g. Jehovah's Witness form)
- ☐ Patient has withdrawn consent (ask patient to sign/date here)

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-memoir to health professionals and patients, by providing a checklist 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.doh.gov.uk/consent).

Who can give consent?

Everyone aged 16 or more is presumed to be competent to give consent for him or herself, 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 counter sign as well. If the child is not able to give consent for himself or herself, someone 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 him 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 is not legally competent to give consent, you should use form 4 (form for adults who are unable to consent to investigation or treatment) instead of this form. A patient will not be legally competent to give consent if:

they are unable to comprehend and retain information material to the decision and/or

they are unable to weigh and use this information in coming to a decision.

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 this form on behalf of an adult who is not legally competent to consent for him or herself.

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 the reverse of this page of the form or in the patient' s notes.