Patient Information and Consent to:
Spinal Cord Stimulation Trial
Spinal Cord Stimulation Full Implant

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 the information in this document carefully, you and your health professional will sign it to confirm your consent.

- It is important that you bring this 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 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.

- Laxatives and painkillers may be required after your hospital stay; please ensure you have appropriate supplies at home.

- 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 questions or concerns about this procedure or your appointment, please call the Spinal Cord Stimulator (SCS) Nurses on telephone number 01223 216993.

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 Spinal Cord Stimulation (SCS)

Spinal cord stimulation (SCS) is a treatment for chronic neuropathic pain which may be considered after standard treatments have not proved to be effective. Chronic neuropathic pain conditions that may be suitable for treatment by SCS include failed back surgery syndrome (FBSS) and complex regional pain syndrome (CRPS).

- **Chronic pain** is defined as pain that persists for more than three to six months, or beyond the normal course of a disease or expected time of healing.

- **Neuropathic pain** (nerve pain) is a type of chronic pain which is initiated by, or caused by, damage to a nerve or a dysfunction of the nervous system.

- **FBSS** occurs when surgery to the lumbar spine, despite being anatomically successful, results in a person continuing to have significant back and/or leg pain.

- **CRPS** is a chronic form of neuropathic pain syndrome which most commonly affects one of the limbs (arms, legs, hands, or feet), usually after an injury or trauma to that limb. CRPS is believed to be caused by damage to, or malfunction of, the peripheral and central nervous systems. The central nervous system is composed of the brain and spinal cord, and the peripheral nervous system involves nerve signalling from the brain and spinal cord to the rest of the body. CRPS is characterized by prolonged or excessive pain and mild or dramatic changes in skin colour, temperature, and/or swelling in the affected area. There are two types called CRPS-I and CRPS-II, with the same symptoms and treatments. CRPS-I is the classification given when there is no confirmed nerve injury and CRPS-II is the classification used when nerve injury is known to have occurred or been confirmed.

Over the past fifty years SCS has been used to deliver low voltage electrical currents to the spinal cord to interfere with or block the sensation of pain. This interference provides an alternative pleasant tingling sensation over the painful area. Recently developed systems may not even need to produce a tingling sensation, yet they seem to be able to block the pain signalling anyway. The exact mechanisms of how SCS works are still not completely understood. It is thought to be an electrophysiological equivalent to ‘rubbing it better’, like when we bang an elbow. The brain may also be responding to the electrical stimulation by activating natural pain suppressing mechanisms and release of natural painkillers. In many well selected patients SCS will significantly reduce pain as well as enable patients to become more active and energetic, enjoy better sleep and reduce their pain medication.
Picture1. A diagram of a spinal cord and a SCS electrode placed on it. The electrical field is recruiting large nerve fibres and producing a tingling sensation carried into the brain and thus shutting the gate for pain signal transmission.

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SCS is minimally invasive and reversible. A typical SCS system has **four** components:

- **An electrode(s)** placed in the epidural space near the spinal cord.
- **A neurostimulator** (special battery) that generates an electrical pulse.
- **A lead that connects the electrode(s)** to the neurostimulator.
- **A remote controller** that is used to turn the neurostimulator on or off and to adjust the level of stimulation up or down.

There are two different types of electrodes currently used:

- **Percutaneous electrodes** which are cylindrical electrodes placed through the skin via a special needle into the epidural space (the space between the spine bone and the outermost layer of the spinal cord)
- **Surgical electrodes** sometimes also called “paddle electrodes”, which are flat electrodes placed via surgical incision and a tiny hole in the lamina (spinal bone) and sutured to the dura (the outermost layer surrounding the spinal cord).

The choice of the electrodes used depends on factors such as a patient’s pain history, diagnosis, anatomy, general health and anaesthetic considerations.

Neurostimulators are implantable pulse generators (IPG’s) which use either a non-rechargeable or a rechargeable internal battery. Neurostimulators are not specific to types of pain conditions, however, they will have different longevities dependant on a person’s pain patterns, stimulation power required and area of the body involved. Therefore the choice of neurostimulator will also depend on these factors.

Patient’s selected for SCS normally have a stimulation trial to determine suitability for permanent implantation of a neurostimulator. The SCS trial involves implanting the electrode(s) and leads with a temporary external device which is used to mimic the effects of an implanted neurostimulator. The SCS trial will assess the degree to which your area of chronic neuropathic pain is covered, the level of pain relief likely to be achieved with full implantation and whether you feel the mild tingling stimulation sensation will be tolerable to live within the longer term (patients may continue to use SCS for the rest of their life as a method of managing their pain). We will discuss with you in detail how long the SCS trial will be planned for, appointments for review during the trial; likely dates for neurostimulator implant and follow up clinic appointments as appropriate.

**Intended benefits**

SCS aims to reduce a patient’s chronic pain in the affected area and improve function, sleep and quality of life. It also aims to help the patient reduce the amount of pain medications they take and increase their independence, which may include going back to work, not needing to see their doctor as often, etc.

**Who will perform my procedure?**

We have a team of Pain Management Consultants and Consultant Neurosurgeons specialising in SCS.
It will be a member of this team who will perform the procedure for you depending on the type of SCS electrodes and neurostimulator chosen. A SCS nurse will also be present during your procedure.

**Before your procedure**

You will have met with the SCS nurses for education and information to help you to consider if this is a therapy you want to trial. You will also have had an assessment with one of the pain service psychologists. In addition most patients will attend a pre-admission clinic, when we will ask you to confirm details of your medical history, any allergies you may have and carry out any necessary clinical examinations and investigations. This may involve blood tests and skin swabs. 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.

SCS procedures may involve the use of local anaesthesia (LA), intravenous sedation (IVS) and/or general anaesthesia (GA). The trial phase is most often carried out under local anaesthesia as it is essential for the success of the procedure that you are clearly able to report back the stimulation sensations felt. The second stage of the procedure involving the battery placement and tunnelling to internalise the SCS system can be done either under LA with IVS or GA. Further explanation about the different types of anaesthesia or sedation we may use can be found at the end of this leaflet. Should you need a general anaesthetic; you will be seen by an anaesthetist before your procedure.

Most people who have SCS will need to stay in hospital for six to eight hours after the procedure, however there is also a possibility you may stay in overnight. Your doctor will discuss the length of stay with you.

**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 for SCS Trial:**

Just before going into the operating theatre you will have an intravenous cannula (a small plastic pipe) placed into the back of one of your hands and be given some antibiotics through it.

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You will then be brought into the theatre and assisted onto the operating table so that you are laying on your front. Pillows and special medical padding will be used underneath you so that you are comfortable and to straighten your spine, which aids the doctor with the placement of the SCS electrode(s).

You will stay in this position throughout the procedure so it is important we make you as comfortable as possible; please let us know if you need any extra padding.

The healthcare team in operating theatre will be wearing special hats and face masks as the procedure is performed under sterile (free from germ) conditions.

To create a sterile field around you, special drapes will be used; these will be attached to poles to the left and right of your shoulders and form a tented area around your head and arms. You will have someone sitting with you who you can talk face to face with throughout the procedure.

Monitoring equipment for your heart rate, blood pressure and oxygen content will be attached to you. Your back will be cleaned with an antiseptic solution that can briefly feel wet and very cold. Your back will then be covered with the sterile drapes. An x-ray machine, covered in sterile drapes, will also be in the theatre and used during the procedure.

Your doctor will administer local anaesthetic to the appropriate area on your back, this can feel a little uncomfortable initially and it may also make your heart beat a little faster. After your skin and deeper layers have been numbed by the local anaesthetic a special needle will be inserted into your epidural space, through this the electrode lead will be passed until the electrode tip reaches the target area. You may feel an occasional twinge or even some pain whilst the electrode lead is being placed into position but patients generally do manage and tolerate this temporary discomfort quite well.
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**Picture 2.** *An electrode is passed into the epidural space through an epidural needle.*

**Picture 3.** *The epidural needles have been inserted into the epidural space and the spinal cord stimulation (SCS) electrodes are passed through the needles.*

Once the electrode has reached the target area, it will be attached to an external stimulation device called a neurostimulator. A brief test will check all connections are working, you may or may not feel a slight tingle sensation at this time and then the trial stimulation will commence. This will be undertaken by the SCS nurse using a special hand-held device. It is essential that you are able to concentrate on the sensations in your body at this time so that you can report when and where you are feeling the tingling stimulation sensation. The aim is to achieve a pleasant mild tingling sensation in the area where you normally experience your chronic pain. The trial of stimulation, including making any necessary adjustments may take up to 15 minutes to complete.

Sometimes, a stimulation system will be used that does not require you to experience and report any tingling or other sensations. This will be discussed with you before a procedure.

Once you are experiencing the pleasant tingling sensation in the area of your chronic pain the doctor will secure the electrode lead in place. To do this they will make a small incision in your back under local anaesthetic and stitch the lead, anchoring it to the fascia (casing) of your deep back muscle. An extension wire will then be connected and tunneled under your skin so that it exits your body as far away from the original injection site as is practical. The exiting end of the extension wire will then be attached to a lead which plugs into an external neurostimulator. The wounds will be sutured (stitched) closed and dressed appropriately.

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After your procedure

The SCS nurse will see you on the ward prior to your discharge and you will be shown how to work through the trial programs. You will need to be seen twice in clinic during the trial phase for wound checks and to assess how effective the SCS therapy is. This is when a decision on whether to proceed to full implant is made.

During the procedure for SCS Full Implant:

If you are having a neurostimulator implanted the pain management consultant and consultant neurosurgeon will discuss with you the appropriate site options for the implant, e.g. buttock area or a lower abdominal area. Once the site for the implant has been agreed the consultant will use a special pen to mark the site on your skin.

In theatre you will be asked to lie on your side if the site is your lower abdominal area or on your front if the site is in your buttock area.

This stage is normally done under general anaesthesia.

Your doctor will administer local anaesthetic to appropriate areas on your back; this can feel a little uncomfortable initially and it may also make your heart beat a little faster. Once your skin and deeper layers have been numbed by the local anaesthetic small incisions will be made to enable your doctor to remove the trial extension lead from the electrode(s). If required a new extension lead will then be attached and tunelled under the skin to where your neurostimulator will be implanted.

The area for your neurostimulator will also be injected with local anaesthetic, this can feel a little uncomfortable initially and it may also make your heart beat a little faster. Once your skin and deeper layers have been numbed, by the local anaesthetics, an incision will be made to enable the neurostimulator to be implanted (usually between 1 and 4 cm below the surface of the skin). The lead from the electrode(s) will then be connected to the neurostimulator; a brief test by the SCS nurse using a special hand held device will check all connections are working; you may or may not feel a slight tingle sensation at this time.

Once it has been confirmed that the SCS system is working correctly your doctor will suture (stitch) all wounds closed and dress them appropriately.

After the procedure:

The SCS nurse will visit you on the ward prior to discharge and answer any questions you may have regarding the procedure. The SCS therapy is not switched on at this point in order to let the IPG wound site to heal. You will be seen in clinic at one week after full implant where your wounds will be checked and your SCS therapy is switched on. This time, you will be shown how to use the equipment and work through the therapy programs to find the one that is most effective for you.
Once you are transferred to the ward you will continue to remain on bed rest for about six hours. If you need the toilet during this time a nurse will assist you to transfer on to a commode. The nursing staff will also continue to monitor your heart rate, blood pressure and oxygen levels. After the procedure you must not bend, flex or twist the spine, lift your arms above your head or lift anything above 2.5kgs (5lbs); so the nursing staff will help you if necessary with mobilising and activities such as getting washed and dressed.

The SCS nurse will visit you on the ward before you are discharged to check if the settings of your stimulator need adjusting and will do so as necessary. They will also check that you understand how to use your hand held device. The SCS nurse will give you information about your discharge care and your appointments for review and follow up in pain clinic. The pain management consultant and consultant neurosurgeon will also visit you on the ward to assess and discuss with you when you can be discharged home.

**Eating and drinking.** You can have sips of water in recovery and on the ward after this procedure, however you will not be able to sit fully upright to properly eat and drink until about six hours after the procedure.

**Getting about after the procedure.** You will be on bed rest for about six hours after the procedure and it is very important that you do not bend, flex or twist the spine, lift your arms above your head or lift anything above 2.5kgs (5lbs). We will help you to become mobile as soon as is possible as 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.** Generally most people who have had this operation will be able to leave hospital after about eight hours, however if you are to stay overnight it is likely you will leave as soon as the SCS team are happy for you to leave and you have all your necessary medications. The actual time that you stay in hospital will depend on your general health, how quickly you are recovering from the procedure and your doctor's opinion.

**Resuming normal activities including work.** Usually patients are signed off work for the duration of their SCS trial and the initial healing period after the SCS system is implanted. You will need to continue to avoid bending, flexing or twisting your spine, raising your arms above your head or lifting anything above 2.5kgs (5lbs) throughout the SCS trial period (usually 7 to 10 days) and also for the first few weeks (usually four to six weeks) following the SCS full implant. You will not be able to drive during the SCS trial or for four weeks after the full SCS implant. You may need to adapt how you resume normal activities or have someone who can help you. Your SCS nurse will advise you on how quickly you can resume normal and more vigorous activity.
Special measures after the procedure: You will need to continue to use the Octenisan wash during the SCS trial and you must not let the dressings get wet. After the SCS full implant you will need to continue to use the Octenisan wash for three days. We will give you further verbal and written information about special measures you need to take after the procedure and also give you information about things to watch out for that might be early signs of problems (eg. infection).

Check-ups and results: Before you leave hospital we will give you an appointment to return to pain clinic to see one of the SCS nurses to check your wounds and assess the effect of your SCS trial / check all is going well with your newly implanted SCS system. At this appointment if necessary we may arrange for you to have clinical investigations such as blood tests and we will discuss with you any further surgery or treatment if any is required.

Significant, unavoidable or frequently occurring risks of this procedure

Risks associated with this procedure: Risks associated with this procedure can be categorized into two groups: related to the actual placement of electrode(s) and /or insertion of the IPG, and those related to having the SCS implant in your body and of the SCS therapy long term.

Risks related to the placement of electrode(s) and/or insertion of IPG:

- Superficial skin infection – less than 1 patient in 20
- Localized bleeding – less than 1 patient in 20
- Spinal wound scar haematoma – less than 1 patient in 20
- IPG pocket haematoma – less than 1 patient in 20
- Tunnel site haematoma – less than 1 patient in 20
- IPG pocket seroma (collection of non-infectious body) – less than 1 patient in 100
- Soft tissue infection - less than 1 patient in 100
- Dural puncture and related headache – less than 1 patient in 200
- Wound dehiscence (non-healing of the wound or opening of the wound scar which had already healed) – less than 1 patient in 1000
- High or total spinal anaesthesia – less than 1 patient in 1000
- Hygroma (collection of a spinal fluid in the wound) – less than 1 patient in 1000

Rare and very rare risks:

- Infection around the spinal cord and brain
- Meningo-encephalitis – less than 1 patient in 10000
- Myelitis or epidural abscess – less than 1 patient in 10000
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- Direct or indirect injury to the spinal nerves
- Injury to a nerve/nerve root – less than 1 patient in 10000
Spinal cord injury/paralysis – less than 1 patient in 100000

Risks related to having an SCS implant and SCS therapy:
- Inadequate pain relief - less than 1 patient in 20
- Inability to cover painful area – less than 1 patient in 20
- Lead migration – less than 1 patient in 20
- Undesirable change in stimulation– less than 1 patient in 100
- IPG site pain (uncomfortable IPG position) – less than 1 patient in 100
- Risk of reoperation (excluding replacing depleted battery)– less than 1 patient in 100
- Lead fracture – less than 1 patient in 100
- Unexpected side effects related to stimulation (sexual/bladder/bowel dysfunction) –less than 1 patient in 1000

Risks associated with all major operations and from being hospitalised:
General risks include chest infection, blood clot in the leg (deep vein thrombosis) and nausea/vomiting. The team treating you will ensure these risks are minimized.

Alternative procedures that are available
An alternative to this surgery is a decision not to have surgery and we are happy to discuss with you the implications of deciding not to have surgery. For patients in chronic pain with no clear medical solutions a Pain Management Program led by pain Psychologists may offer an alternative to Spinal Cord Stimulation.

Information and support
If you have any questions or concerns about the SCS trial or full implant procedure please contact the pain clinic (01223 216993) and ask to speak with one of the SCS nurses. In addition we can also recommend information found on the British Pain Society and NICE website:

http://www.nice.org.uk/guidance/TA159

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
- If you or anyone in your family has had problems with anaesthetics
- Any medicines or drugs you use
- If you smoke
- If you have had any abnormal reactions to any drugs or have any other allergies
- About your teeth; if you wear dentures or have caps or crowns.

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

Pre-medication
You may be prescribed a ‘premed’ prior to your operation. This is a drug or combination of drugs that may be used to make you sleepy and relaxed before your procedure, provide pain relief and reduce the risk of sickness or may have effects specific for the procedure 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.

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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 the insertion of electrodes) 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
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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.

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  CreutzfeldtJakob 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, large print or audio, please ask the department where you are being treated, to contact the patient information team: 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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Spinal Cord Stimulation Trial
Spinal Cord Stimulation Full Implant

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)

- Pain reduction
- Covering painful area with a pleasant tingling (when appropriate)
- Improving function
- Improving quality of life
- Improving sleep
- Reduction in Pain Medication use

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

Please refer to information – risks include failure to improve pain, function, and sleep, inadequate coverage of a pain area; reduction of initial benefit over time; superficial or deep infection; spinal infection; dural puncture and associated headache; nerve injury; spinal cord injury and/or paralysis; wound dehiscence, hygroma, seroma; lead migration; lead fracture; sexual/bladder/bowel dysfunction; discomfort around the battery; hardware malfunction; reoperation.

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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1. Any extra procedures that might become necessary during the procedure such as:
   - Blood transfusion
   - Other procedure (please state)

2. The following information leaflet has been provided:
   Spinal Cord Stimulation Trial
   Spinal Cord Stimulation Full Implant
   Version, reference and date: V3, CF482, October 2017
   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
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

Patient safety – at the heart of all we do
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: D.D./M.M./Y.Y.Y.Y.
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: D.D./M.M./Y.Y.Y.Y.
Relationship to patient:

If the patient is unable to sign but has indicated his/her consent, a witness should sign below.

Signed (Witness): .............................................................. Date: D.D./M.M./Y.Y.Y.Y.
Name of witness (PRINT): ..............................................................
Address: ..........................................................................................
Consent Form

Spinal Cord Stimulation Trial
Spinal Cord Stimulation Full Implant

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: ........................
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: ........................
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: ........................

Signed (Health professional): ........................................... Date: ........................
Name (PRINT): ................................................................. Job title: ........................