Patient Information

Patient information and consent to Craniotomy and 5ALA-resection of brain tumour in adults

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 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.

- Please call the clinical nurse specialist on telephone number 01223 256246 if you have any questions or concerns about this procedure or your appointment.

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.

Craniotomy and resection of brain tumour/insertion gliadel implants, CF386, V7, August 2019
About craniotomy and resection of brain tumour

During a craniotomy procedure, the neurosurgeon makes an incision in the scalp (skin) before removing a small piece of the skull (bone) to expose the brain. This removal of your bone is referred to as a bone flap.

Sometimes it is not safe for the neurosurgeon to take out the entire tumour (known as complete resection), for example, the tumour might have invaded vital structures. When the tumour is partially removed, this is referred to as a partial resection or debulking procedure.

During resective surgery, the surgeon performs a craniotomy and then removes as much tumour as possible before replacing the skull (bone flap) and closing the wound.

About Fluorescence-guided surgery (5ALA)

In some cases your consultant may feel that a more complete removal of your tumour could be achieved using a substance called Gliolan® (5-ALA). One of the difficulties in removing a brain tumour is knowing where the tumour stops and normal brain tissue starts. There is no sharp edge to the tumour as it merges with normal brain. Being too aggressive with tumour removal runs the risk of causing damage to parts of the brain, and not being aggressive enough runs the risk of leaving tumour behind.

5-ALA is a substance that can help identify the edge of the tumour. The liquid is taken three to five hours before the operation. 5-ALA enters into the tumour cells but not the normal brain. In the tumour 5-ALA is converted to a substance that glows pink when exposed to ultraviolet light. During the operation the surgeon will use a blue light filter on a microscope to identify remaining tumour cells which can then be removed.

Intended benefits

The aims of the craniotomy and resection procedure are:

- To get a diagnosis.
- To remove as much of the tumour as possible.

Who will perform my procedure?

This procedure will only be performed by a consultant neurosurgeon or neurosurgery specialist registrar operating under the supervision of a consultant. These surgeons will have undergone extra training in treating people with 5-ALA.

Before your procedure

Most patients attend a pre-admission clinic, when you will be given the details of your specialist nurse. This is the person to contact if you have any questions or need advice or support.

At this clinic, we will ask for details of your medical history and carry out any necessary clinical examinations and investigations. The investigations will include 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. We are particularly interested in Aspirin, Warfarin or other drugs that affect blood clotting. 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 general or local anaesthesia (sometimes referred to as an awake craniotomy – please see our other leaflet entitled: Undergoing an awake craniotomy). 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.

Most people who have this type of procedure will need to stay in hospital for two to four days after the operation. In most cases you will be discharged home, but should the need arise, we will transfer you to a hospital closer to home.

You will be admitted the day before your operation. Before you leave home, you should telephone the admissions office on 01223 217100 to check that there is a bed available and which ward you need to go to.

You will be asked to not eat or drink from midnight on the day of your operation.

Hair removal before an operation
The healthcare team need to see or reach your skin and 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
You will be taken to neurosurgery theatres on your hospital bed. The surgeon shaves a small amount of hair and then makes an incision in your scalp. The size and shape of the opening will depend on the size and position of the tumour. The incision will be made behind the hairline so the scar is hidden when the hair grows back. The neurosurgeon then takes out a small piece of the bone of your scalp and then as much of the tumour as is safe to remove. The bone is then replaced and the skin closed with stitches or clips (staples) and covered with a dressing. The time this takes depends upon the complexity of the procedure but you will be away from the ward for several hours.

After the procedure
Once your surgery is completed you will usually be transferred to the recovery area 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. You may also have a tube in the wrist called an arterial line, a tube in the neck called a central line and a urinary catheter.

Sometimes the surgeon recommends closer observation and in this case you would be transferred to our Neurosciences Critical Care Unit (NCCU). 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 may eat and drink as soon as you feel able. It is recommended you start with clear fluids and move to light food after a few hours.

**Getting about after the procedure.** After this procedure you are able to get up as soon as you feel well enough. Often, this is within a few hours of returning to the ward. 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.

It is normal for the wound to feel strange but rarely painful. The scar and skin may look bruised and swollen. The scar will fade to a thin pale line in three to six months. Any shaved hair will normally re-grow.

**Leaving hospital.** Most people who have had this type of procedure will be able to leave hospital after two to four days. The actual time that you stay in hospital will depend on your general health, how quickly you recover from the procedure and your doctor’s opinion.

The stitches or clips are removed seven to ten days after surgery. You will be asked to make an appointment with your GP surgery so your practice nurse can remove them.

**Resuming normal activities.**

**Work:** You may return to light domestic work and exercise as soon as you feel able to do so. If you intend to return to work, it is best to discuss this with your neurosurgeon and your occupational health department, if applicable. How quickly you are able to return to work will depend upon the physical skills and demands of the job. You may find it easier to return on a phased return.

**Contact sport:** You are advised to avoid contact sports such as boxing or rugby for at least three months.

**Driving:** This depends on the type of tumour you have been diagnosed with. In most cases, a driving ban of minimum two years following completion of your treatment (this includes any chemotherapy or radiotherapy you may need) is required. Please see our separate leaflet entitled ‘DVLA driving regulations: Brain tumours’ for further information and speak to your doctor or specialist nurse.
Failure to notify the DVLA is an offence and may result in a fine of up to £1,000. 

**Flying**: You are advised to avoid flying for 6 weeks after your surgery.

### Special measures after the procedure:

**Hair washing**: You can gently wash your hair **two days after** your procedure and we recommend all dressings are removed.

**Skin staples / stitches**: Most stitches are self-absorbable (dissolvable) so they will take care of themselves. Dissolvable stitches need to get wet in order to dissolve. It is recommended you use a gentle shampoo for this. We can remove any skin staples in clinic if required or make an appointment with your GP. Its best to avoid hair dyes and perms for one month as this will irritate the scar.

**Wound leaks / infections**: If you experience ANY problems with your wound, including superficial infections treated by your GP, please contact your specialist nurse immediately. The development of any deeper infections will put on hold further treatments (such as chemotherapy / radiotherapy), so our early involvement is imperative.

**Dexamethasone**: You may be taking steroids (dexamethasone). It is usual to increase the dose of this around the time of surgery and then wean the dose down again within a few days of surgery.

### Check-ups and results:

A sample of the tumour will be sent for analysis. The test results take about one week. When the tests are complete, you will be invited to the next available outpatient clinic. At this clinic we will check on your progress, do more blood tests, discuss the test results and will discuss any further treatment that is recommended. If you wish, please do bring family and/or friends to clinic.

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

There are risks of surgery in general and risks associated specifically with craniotomy and resection surgery. The risks of surgery in general include urinary infections, problems with breathing, such as chest infection and blood clots, for example in the legs and, less frequently, the lungs.

- Infection in the brain (some reports suggest higher risk with Gliadel): two in 100 people.
- Leakage of brain fluid (CSF): five in 100 people.
- Bleeding (haemorrhage) into the brain: four in 100 people.
- Superficial wound infection: two in 100 people.
- Delayed wound healing: 15 in 100 people.
- Brain swelling: nine in 100 people.
- Permanent ‘neurological deficit’ such as speech, visual, arm or leg weakness if the tumour is away from a critical area of the brain: five in 100 people.
- Permanent ‘neurological deficit’ such as speech, visual, arm or leg weakness if the tumour is in or close to a critical area of the brain: 15 in 100 people.
- Death: two in 100 people.
The risks of your surgery depend very much upon the location of your brain tumour. Your surgeon will discuss your particular risks with you. If you do wake up with a new neurological deficit then remember that most patients with a new neurological deficit following this procedure will improve over a few days. Some resolve completely.

**Side-effects of 5-ALA**

The use of 5-ALA can result in side effects, though they are rare.

Very common side effects (likely to occur in more than 1 of 10 patients):
- Mild alterations of blood cell counts.
- Transient (temporary) alterations in blood tests of liver function.

Common side effects (likely to occur in more than 1 of 100 patients but less than 1 of 10 patients):
- Nausea (unsettled stomach) or vomiting (sickness).
- Neurological disorders including weakness of one side of the body, speech problems, seizures or some loss of vision. These problems do not result from receiving 5-ALA, but occur because the amount of tumour removed is greater.
- Blood clots in the leg or more uncommonly the lung. Again, these are unlikely to be directly related to receiving 5-ALA, but rather a greater extent of tumour resection.

Uncommon side effects (likely to occur in more than 1 of 1,000 patients but less than 1 of 100 patients):
- Decrease of blood pressure.
- Skin reactions (for example rash, looking like sunburn).

Very rare side effects (likely to occur in less than 1 of 10,000 patients), including isolated reports:
- Decrease of your sense of touch.
- Diarrhoea.

**Warnings**

After administration of this medicine, you should avoid strong light for 24 hours, for example, direct sunlight or brightly focused indoor light.

**Do not take 5-ALA**
- If you are allergic to 5-aminolevulinic acid hydrochloride (5-ALA) or porphyrins.
- If you have or are suspected to have acute or chronic types of porphyria.
- If you are or might be pregnant.
5-ALA should be used with caution if:

**If you have a heart disease or had heart disease in the past**
You should tell your doctor. In this case, this medicine should be used with caution because the blood pressure may be decreased.

**Women who are breastfeeding**
It is not known whether this medicine enters breast milk. Breast-feeding mothers should not breastfeed for 24 hours after treatment with this medicine.

**If you are taking other medicines**
Please tell your doctor or pharmacist if you are taking or have recently taken any other medicines, particularly medicines that may cause skin problems when the skin comes under strong light (for example some types of antibiotics), but also medicines obtained without prescription (for example hypericin or Saint John’s wort extracts). You should not take any such products up to two weeks after you have taken 5-ALA.

**Alternative procedures that are available**
There are generally two other treatment options for brain tumours:

- Brain tumour biopsy. During this procedure a small amount of the tumour is removed and sent for analysis. Once a diagnosis is known, further treatment options can be discussed. This is the safest and least intrusive surgical procedure but it probably offers less benefit too.
- You may decide not to have surgery at all. This may also prevent you from having other types of treatment such as radiotherapy or chemotherapy as these depend upon having a tissue diagnosis. The full implications of deciding not to have surgery will be discussed with you.

**Information and support**
- If you have any questions or anxieties, please feel free to ask your specialist nurse or any other member of staff at any time even after discharge. The specialist nurses can be contacted directly on 01223 256246 or via switchboard (01223 245151) on bleeps 154-506 or 152-090
- The Brain Tumour Charity – for regular meetings, phone pals, information and advice telephone: 0808 800 0004, website: [www.thebraintumourcharity.org](http://www.thebraintumourcharity.org)
- Brainstrust Charity – to find out more about brainstrust call 01983 292 405; email: hello@brainstrust.org.uk or visit [www.brainstrust.org.uk](http://www.brainstrust.org.uk)
- Macmillan Cancer Support – for online information, advice and support visit: [www.macmillan.org.uk](http://www.macmillan.org.uk) or phone 0808 808 0000.

**References:**
EMEA – European Medicines Agency ‘European public assessment report (EPAR) on Gliolan’.

Craniotomy and resection of brain tumour/insertion gliadel implants, CF386, V7, August 2019
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 ‘pre-med’ 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 pre-med 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. 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 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
- Equipment failure

Deaths caused by anaesthesia are very rare. There are probably about five deaths for every million anaesthetics in the 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 256998, or email: interpreting@addenbrookes.nhs.uk For Large Print information please contact the patient information team: patient.information@addenbrookes.nhs.uk.

**Document history**
Authors: Ingela Oberg, Bridget Featherstone
Department: Cambridge University Hospitals NHS Foundation Trust, Hills Road, Cambridge, CB2 0QQ www.cuh.org.uk
Contact number: 01223 245151 extension 56246
Publish/Review date: August 2019/August 2022
File name: CF386_craniotomy_resection_gliadel.doc
Version number/Ref: 7/CF386/Document ID 8280
Consent Form

Patient agreement to investigation or treatment for neurosurgery, spinal surgery or vitreoretinal surgery

Please use 'Procedure completed' stamp below on completion:

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

Patient safety – at the heart of all we do

Addenbrooke’s Hospital | Rosie Hospital
Craniotomy and resection of brain tumour/insertion gliadel implants, CF386, v7, August 2019

Urinary infections; problems with breathing; blood clots, for example in the legs and, less frequently, the lungs; infection in the brain; leakage of brain fluid (CSF); bleeding into the brain; superficial wound infection; delayed wound healing; brain swelling; permanent 'neurological deficit' such as speech, visual, arm or leg weakness if the tumour is in, close to or away from a critical area of the brain; death.

Craniotomy and 5ALA-resection of brain tumour

To get a diagnosis, to remove as much of the tumour as possible and insert chemotherapy to further reduce the number of tumour cells

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 get a diagnosis, to remove as much of the tumour as possible and insert chemotherapy to further reduce the number of tumour cells

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

Urinary infections; problems with breathing; blood clots, for example in the legs and, less frequently, the lungs; infection in the brain; leakage of brain fluid (CSF); bleeding into the brain; superficial wound infection; delayed wound healing; brain swelling; permanent 'neurological deficit' such as speech, visual, arm or leg weakness if the tumour is in, close to or away from a critical area of the brain; death.

c) what the procedure or treatment is likely to involve, the benefits and risks of any available alternative treatments (including no treatment) and any particular concerns of this patient:

d) any extra procedures that might become necessary during the procedure such as:
   □ Blood transfusion □ Other procedure (please state)

e) Was the patient born after 1 January 1997? □ Yes □ No

The following information leaflet has been provided:

Version reference and date: CF386 v7 August 2019

or □ I have offered the patient information about the procedure but this has been declined.

This procedure will involve:

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

Signed (Health professional): ____________________________ Date: DD/MM/YYYY

Name (PRINT): ____________________________ Time (24hr): HH:MM

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 on ‘Consent’ and then put a tick in the relevant boxes for the following questions:

1  Creutzfeldt Jakob disease (CJD)
   a) 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

   b) Have you had a history of CJD or other prion disease in your family? □ Yes □ No

   c) Have you ever received growth hormone or gonadotrophin treatment? If yes, please give details below:
      Please specify:
      (i) whether the hormone was derived from human pituitary glands □ Yes □ No

      (ii) the year of treatment

      (iii) whether the treatment was received in the UK or another country □ UK □ Other

   d) Have you ever had surgery on your brain, eye or spinal cord? □ Yes □ No
      If yes, please give details below:

   e) Since 1980, have you had any transfusions of blood or blood components (red cells, plasma, cryoprecipitate or platelets)? □ Yes □ No
      If yes, please answer questions below:

      Have you either:
      (i) received more than 50 units of blood or blood components, □ Yes □ No
      or
      (ii) received blood or blood components on more than 20 occasions □ Yes □ No

      Where possible, please provide the names of all the hospitals where you received blood or blood components:

In the case of a positive reply to any CJD question, staff should immediately inform Infection Control on ext 3497 (bleep numbers 152-198 or 151-803) and the theatre co-ordinator (24 hour bleep number 152-585); out of hours contact the on call medical microbiologist via the hospital contact centre.

2  Photography, Audio or Visual Recording
   a) I agree to the use of any of the above type of recordings for the purpose of diagnosis and treatment. □ Yes □ No

   b) I agree to unidentified versions of any of the above recordings being used for audit and medical teaching in a healthcare setting. □ Yes □ No

3  Medical Training
   I agree to the involvement of medical and other students as part of their formal training. □ Yes □ No
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 entitled Consent 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: ____________________________________________

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 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: __________________________