SUPPLEMENTAL CONSENT AND INFORMATION: LUMBAR (LOW BACK) SPINAL SURGERY

AFFIX PATIENT LABEL

Plans have been made for you to undergo **lumbar (low back) spinal surgery** as detailed below:

Procedure .....

.....

Other Procedure .....***Bone Graft*** .....

Reason for Surgery.....

Surgeon's signature .....***Date*** .....

It is important for you to understand the nature of your operative procedure, what to expect from your surgery and the risks which may occur with this operation and also rare, but significant, other complications which have been known to occur. These complications have been listed below, however, this is not an exhaustive and exclusive list and other unforeseen complications may occur. Please sign each of the sections below together with the formal Hospital Consent Form.

1. I understand the operation that my spinal surgeon is performing and I have been given the chance to ask any questions about the operation. I understand that the operation is not a "cure" and it is the nature of spinal surgery to expect a good percentage improvement and / or prevent progression of the underlying condition. I understand that improvements may not be immediate but may be gained over time. I understand there is the possibility that the surgery may not help and that my symptoms may worsen. I am aware of the likely outcome if I do not have surgery.

   Signature: ..... Date: .....

2. I understand that complications which may occur with this type of procedure include: bleeding; infection; nerve injury; scar (fibrous) tissue formation around the nerves; spinal cord injury (weakness, numbness, bladder and bowel problems); durotomy / spinal fluid leak; skin and nerve pressure problems; stiffness / reduced movement; failure to improve symptoms; recurrence of my problem; inadequate correction of any deformity; implant related problems including incorrect position, loss of position, loosening, breakage and non union (failure of the bones to fuse together); problems above and / or below the operated part of the spine; organ injury; sexual dysfunction; problems removing wound drains (if required). In addition, the complications of anterior spinal surgery include blood vessel injury, thigh numbness, warm leg and hernia. General anaesthetic and medical problems may include deep venous thrombosis / pulmonary embolism (blood clots), chest infections, urinary infections, acute confusional state, emotional distress and others. I understand that I may require a urinary catheter (tube in the bladder). A blood transfusion may be required. I understand that I will be exposed to radiation in the form of X-Ray or CT during the procedure.

   Signature: ..... Date: .....

3. Finally, I understand that there are also very rare but serious complications which have been recorded from this type of surgery which, in extreme circumstances, might include: death, paralysis, cauda equina syndrome, severe bleeding, organ injury, ureteric injury, eye complications including blindness, stroke, allergic reactions and other serious anaesthetic and medical problems. Very rarely wrong level and wrong side surgery can occur.

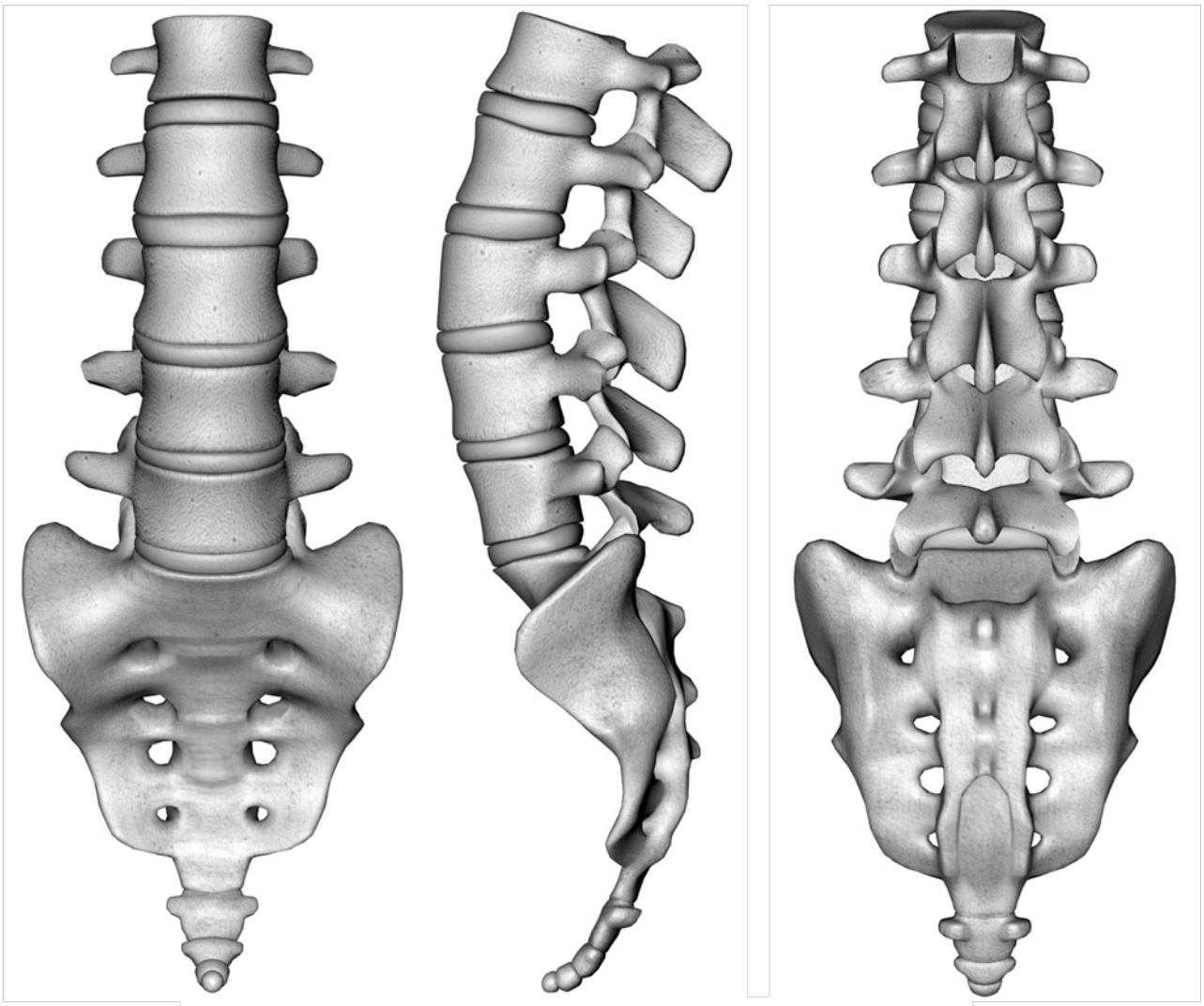
   Signature: ..... Date: .....

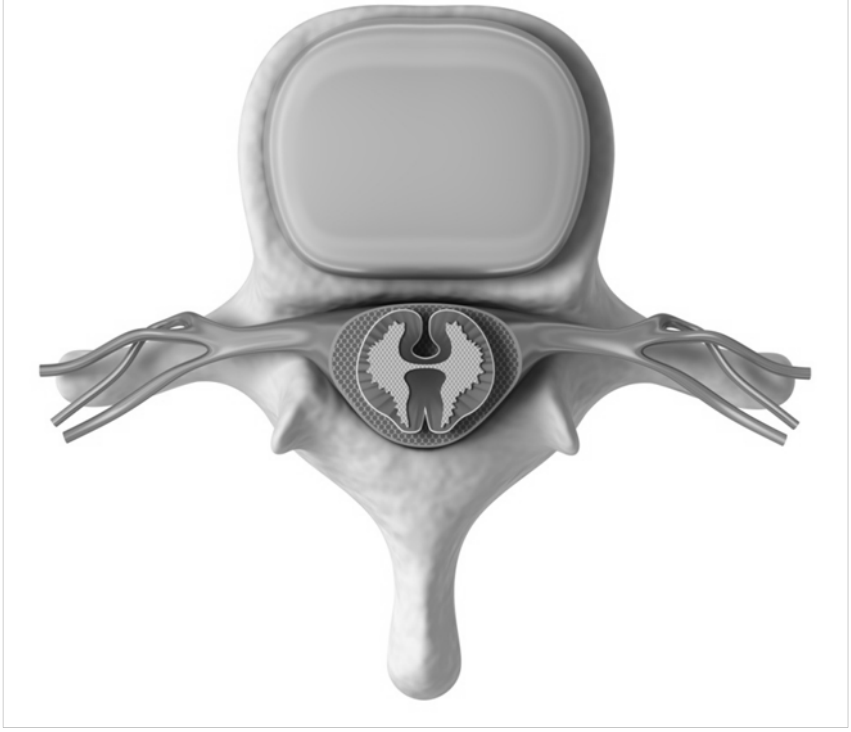
4. I consent to blood virology testing in the event of a staff needle stick injury Yes / No
   I consent to medical photography for educational and teaching purposes and Yes / No
   my anonymized medical data to be used for educational and teaching purposes Yes / No
   I consent to being entered on the British Spinal Registry Yes / No
   I understand that I will be required to complete outcome questionnaires Yes / No

   Signature: ..... Date: .....

5. I understand that there are risks regarding COVID19 (and other pandemic infections) and I will follow the current guidelines and advice given to me by the hospital including social distancing, isolation and COVID19 testing.

   Signature: ..... Date: .....





PUT PHOTO OF CONSENT FORM HERE

British Spine Registry Consent Form

Helping to improve patient care through knowledge

Please tick to confirm that you have been given / read the 'BSR patient information leaflet' ☐

Surname: _____

First Name: _____

Date of Birth: _____/_____/_____

Postcode: _____

Email address (if you are happy for us to send you email links to questionnaires):

_____

I CONSENT to:

- Personal details being recorded in the British Spine Registry.
- I understand information in the Registry will be used to look at the outcomes of treatment and may be used for research purposes and results will be published.
- I understand that data identifying me will not be released to anyone unless required by law or where there is a clear public need to do so.
- Your data may be accessed by other spinal medical professionals in the future who are involved in your medical care.
- I understand that I may ask for my details to be removed at any time and may request access to my personal data.
- I understand that my health data may be linked to other national health databases.

Patient / Parent agreement to data collection for Registry and Research:

Signature: _____ **Date:** _____/_____/_____

To be completed by the person accepting patient consent

Name: _____ **Position:** _____

Signature: _____ **Date**: _____/_____/_____

This form should be retained.

Bwrdd Iechyd Prifysgol Caerdydd a'r Fro
Cardiff and Vale University Health Board

Thromboprophylaxis Recommendations

Specialty specific advice

Acute spinal injury (T&O): Patients should receive mechanical prophylaxis. Please discuss with the consultant spinal surgeon if enoxaparin should be prescribed as they may require surgical intervention.

Elective spinal surgery (T&O): Prescribe mechanical prophylaxis (stockings, plus foot impulse devices). Do not prescribe enoxaparin pre-operatively. Discuss with consultant spinal surgeon before starting enoxaparin post-operatively. Patients with ruptured cranial/spinal vascular malformations or acute traumatic/non traumatic haemorrhage must not be offered enoxaparin prophylaxis until the lesion is secured or the patient's condition stabilised

Cardiac surgery: 'Patients should be prescribed enoxaparin pre-operatively *unless contraindicated*, but enoxaparin should be omitted for at least 24 hours prior to surgery. Patients should be prescribed mechanical prophylaxis. Prescribe prophylactic enoxaparin post-operatively until discharge, unless patient is receiving therapeutic anticoagulation (either IV heparin or therapeutic enoxaparin) or acquires a contraindication.

Head and Neck surgery: Prophylaxis is not routinely used for this patient group

Ophthalmology: Day case / SSSU patients do not require VTE prophylaxis if (1) LA (2) GA less than 90mins. Patients with GA > 90mins should receive AES prophylaxis. This does not apply to paediatric cases.

Trauma: There is an increased **initial** risk of haemorrhage in patients following poly-trauma, multi part or unstable pelvic fractures and potentially unstable spinal pathology pending MRI scan. Discuss with consultant
.

Nephrology and transplant: For this patient group refer to **appropriate** risk assessment form

Patient details (affix addressograph)	Cardiff and Vale University Health Board Bwrdd Iechyd Prifysgol Caerdydd a'r Fro	**Weight: ……kgs** Date recorded:……
		COMPLETE AND FILE IN PATIENT'S NOTES

THROMBOPROPHYLAXIS FOR ELECTIVE ADULT ORTHOPAEDIC SURGERY (exc hip/ knee replacement)

UNLESS CONTRAINDICATED: Prescribe both pharmacological and mechanical thromboprophylaxis for all patients:

- **undergoing surgery** who have ≥ 1 risk factor for venous thromboembolism
- **undergoing surgery** where duration of anaesthesia & surgery to the lower limb/pelvis ≥ 60 minutes

DOES THE PATIENT HAVE RISK FACTORS FOR VENOUS THROMBOEMBOLISM? (VTE) (✓)

Age ≥ 60 years		Obesity (BMI > 30kg/m^2)	
Active cancer or cancer treatment		Personal or first degree relative with history of VTE	
Chronic inflammatory conditions		Pregnancy or ≤ 6weeks post partum	
Critical care admission (planned or unplanned)		Use of hormone replacement therapy	
Dehydration		Use of oestrogen-containing contraceptive therapy	
Duration of anaesthesia & lower limb/pelvic surgery ≥ 60 minutes		Varicose veins with active phlebitis	
Known thrombophilia			

Risk identified?	Y/N	Thromboprophylaxis indicated?	Y/N	Sign	Name	Date

PATIENT AGE: ____ **If patient ≥ 70 years old request an eGFR since they may have undiagnosed renal impairment**

DOES THE PATIENT HAVE A CONTRAINDICATION TO:

pharmacological thromboprophylaxis?	✓		**mechanical methods?**	✓	
Assessment	**1**	**2**	Assessment	**1**	**2**
Currently receiving therapeutic anticoagulation			Arterial insufficiency (suspected or proven): - absent or weak foot pulses - intermittent claudication - slow capillary filling (pinched nailbed/toepad that takes >3 seconds to return to normal colour)		
Uncontrolled systolic hypertension > 180mmHg					
Thrombocytopenia: platelet count < 70 x 10^9/l					
New-onset stroke, intra-cerebral haemorrhage or untreated sub-arachnoid haemorrhage					
Severe liver disease			Peripheral neuropathy		
Known bleeding disorder *			Severe peripheral oedema/pulmonary oedema		
Renal impairment with eGFR < 30ml/min *			Known allergy to material of manufacture		
Active bleeding or at risk of bleeding			Currently receiving noradrenaline *		
Known heparin allergy *			Skin: - pressure ulcer - 'tissue paper' skin - recent skin graft - skin infections - leg or foot ulceration		
Previous heparin induced thrombocytopenia *					
Lumbar puncture/epidural/spinal anaesthesia within past 4 hours or expected in next 12 hours / **SPINAL SURGERY**					
Contraindication present? (✓/ x)			**Contraindication present? (✓/ x)**		

*** seek further advice from coagulation registrar/patient's consultant**

PRESCRIBE THROMBOPROPHYLAXIS, ACCORDING TO RISK ASSESSMENT, ON DRUG CHART

N.B. Reassess risk of bleeding and venous thromboembolism within 24 hours and if clinical situation changes

Pre-op / first 24 hours post-op **Consultant:**

Enoxaparin (Clexane) sub-cutaneously Weight (Kg)	**Dose**	✓	**Select one mechanical method**	✓
< 50	Seek advice *		Calf length anti-embolism stockings	
50 - 100	40mg od		Foot impulse devices	
101- 150	40mg bd		Intermittent pneumatic compression devices	
> 150	60mg bd			
Contraindication present			Contraindication present	

If using bd dose omit a.m. dose on day of surgery

If no contraindications exist and thromboprophylaxis is not prescribed state reason:

Sign	Name	Date

Reassessment at 24 hours post-op **Consultant:**

Enoxaparin (Clexane) sub-cutaneously Weight (Kg)	**Dose**	✓	**Select one mechanical method**	✓
< 50	Seek advice *		Calf length anti-embolism stockings	
50 - 100	40mg od		Foot impulse devices	
101- 150	40mg bd		Intermittent pneumatic compression devices	
> 150	60mg bd			
Contraindication present			Contraindication present	

If using bd dose omit a.m. dose on day of surgery

Sign	Name	Date

PRESCRIBING ADVICE

TIMING of enoxaparin administration:

- **if given day before surgery**: administer **no later** than 18:00hrs
- **day of surgery**: administer at 18:00hrs OR 6 hours post-op for afternoon cases (d/w consultant surgeon/anaesthetist)
  subsequent post-op days: prescribe at 18:00hrs

Following surgery under spinal/epidural anaesthesia: Wait at least 4 hours before giving enoxaparin

Patients with epidural analgesia post-op: Do not remove epidural catheter within 12 hours of enoxaparin
Following removal of epidural catheter wait 4 hours before giving next dose of enoxaparin

Heparin induced thrombocytopenia (HIT): Check platelet count before commencing and following 5-7 days of treatment

Reassess need for ongoing thromboprophylaxis prior to discharge/transfer

Approximate Recovery Times in Weeks for Spinal Operations

The following is a guide for recovery times following spinal surgery. It is important to note that recovery times will vary between patients and that this is only a guide.

	Lumbar Microdiscectomy / Decompression	Multilevel Lumbar Decompression	Lumbar Decompression and Fusion	Thoracolumbar Fusions: PLF / TLIF / XLIF / ALIF and #s*
Wound Healing	2 to 4	2 to 4	2 to 4	2 to 4
Office / Desk Job	4 to 6+	6+	6+	6+
Manual Job	6+	6 to 12	12+	12+
Driving	Approximately 4 to 6 weeks when you are comfortable getting into and out of a car, can turn your body to look out of the back window and can safely perform an emergency stop.			
Walking	As soon as able. This is an excellent form of gentle exercise to aid your recovery. It is important to slowly pace yourself and build up distances gradually.			
Showering	Initially the wound should be covered by a waterproof dressing whilst taking brief showers. Once it has healed fully longer showers and bathing are permitted.			
Housework	When comfortable. Avoid bending at the back and use your knees. Avoid twisting when hoovering and when ironing make sure the board is set at an appropriate level or you can sit down to iron. Avoid over stretching.			
Lifting	Lifting light objects and shopping can be performed when comfort allows. Avoid bending at the back and use your knees. Use both arms to carry shopping and avoid carrying for long periods.			
Swimming	Your wound must have healed fully before you can swim. If you have been fused please wait until you have had a follow up X-Ray. In line strokes are best following lumbar spine surgery (front crawl and back stoke).			
Gardening	6+	6+	12+	12+
Cycling	6+	6+	6+	6 to 12+
Racquet sports, golf, cricket, jogging	6+	12+	12-24+**	12-24+**
Yoga, Pilates, tai chi, aerobics, gentle aerobic gym activity	6+	6+	12+**	12+**
Weight lifting, contact sports, gymnastics (including football and rugby)	12+	12+	26-52 (if at all)**	26-52 (if at all)**

* PLF = Posterolateral Fusion, TLIF = Transforaminal Lumbar Interbody Fusion, XLIF = Extreme Lateral Interbody Fusion, ALIF = Anterior Lumbar Interbody Fusion, #s = Fractures

** After discussion with your surgeon

MJHM 2019

Anticipated Times and Information for Spinal Operations

	Anaesthetic	Operative	Recovery	Length of Hospital Stay	Urinary Catheter
Cervical Surgery					
ACDF IVDR 1-2 Levels	<30 mins	1-2 hours	30-45 mins	1 day	No
ACDF IVDR ≥ 3 Levels	<30 mins	2-3 hours	30-45 mins	2 days	No
Anterior Cervical Corpectomy	30-45 mins	2 hours	60 mins	2-3 days	No
Posterior Cervical Decompression +/- Fusion / Laminoplasty	30-45 mins	2-3 hours	60 mins	3 days	No
Lumbar Surgery					
Microdiscectomy / microdecompression	<30 mins	1-2 hours	30 mins	1 day	No
Decompression 1-2 Levels	<30 mins	1-2 hours	30-45 mins	1-2 days	No
Decompression ≥ 3 Levels	<30 mins	2-3 hours	45-60 mins	2-3 days	Not Routinely
Decompression and Instrumented Fusion 1-2 Levels	<30 mins	2-3 hours	45-60 mins	3-4 days	Not Routinely
Decompression and Instrumented Fusion ≥ 3 Levels	<30 mins	3 hours	60-90 mins	4-5 days	Likely
PLIF / TLIF 1-2 Levels	30-45 mins	3-4 hours	60-90 mins	3-5 days	Likely
XLIF 1-2 Levels	30-45 mins	1-2hours	60-90 mins	1-2 days	Possible
XLIF 1-2 Levels plus Posterior Surgery	30-45 mins	3-4 hours	60-90 mins	3-4 days	Possible
ALIF 1-2 Levels	30-45 mins	2-3 hours	60-90 mins	3-4 days	Yes
ALIF 1-2 Levels plus Posterior Surgery	30-45 mins	4 hours	60-90 mins	3-5 days	Yes
Deformity Surgery / Other					
Paediatric Posterior Scoliosis Correction	45-60 mins	3-4+ hours	60-90 mins	5 days	Yes
Adult Posterior Spinal Deformity Correction with osteotomy / cages	45-60 mins	5+ hours	60-90 mins	1+ week	Yes
Posterior Thoracolumbar Fracture / Tumour / Infection Fixation	45-60 mins	2-3+ hours	60-90 mins	1+ week	Yes (Possible for Fracture)
Anterior Thoracolumbar Fracture / Tumour / Infection Fixation	45-60 mins	3+ hours	60-90 mins	1+ week	Yes

Useful Links:

American Academy of Orthopaedic Surgeons
http://www.orthoinfo.org/menus/spine.cfm

Backcare
https://backcare.org.uk

British Association of Spine Surgeons
http://www.spinesurgeons.ac.uk

British Pain Society
http://www.britishpainsociety.org

Education Programs for Patients in Wales
http://www.eppwales.org

Eurospine Patient Information
https://www.eurospine.org/patient-line-spine-diseases.htm

Getting It Right First Time
https://gettingitrightfirsttime.co.uk

National Institute of Clinical Excellence
http://www.nice.org.uk

NHS Wales
http://www.wales.nhs.uk

North American Spine Society Patient Information Leaflets
http://www.knowyourback.org/Pages/Brochures/Default.aspx

Patient.info
http://www.patient.info

Scoliosis Association UK
http://www.sauk.org.uk

Scoliosis Research Society
http://www.srs.org/patient_and_family

Spine Dragon:
http://www.spinedragon.com

Spine Health:
https://www.spine-health.com

Spine Universe:
http://www.spineuniverse.com

Understand Spine Surgery
http://understandspinesurgery.com

WebMD:
https://www.webmd.com

British Spine Registry – Patient Information

Helping to improve patient care through knowledge

What is the British Spine Registry (BSR)?

It aims to collect information about spinal surgery across the UK. This will help us to find out which spinal operations are the most effective and in which patients they work best. This should improve patient care in the future.

The Registry will allow patient outcomes to be assessed using questionnaires. These will allow surgeons to see how much improvement there has been from treatment.

This has worked for hip and knee joint replacements through the National Joint Registry. We need your help to improve spinal surgery in the UK.

What data is collected?

Your personal details allow the BSR to link you to the surgery you have had. They also allow us to link together all the questionnaires you complete. If you need any further spinal surgery in the future, details of previous operations will be available to your surgeon.

Personal details needed by the BSR are: Name, Gender, Date of birth, Address, Email, NHS number

Your personal details are treated as confidential at all times and will be kept secure. This data is controlled by the British Association of Spine Surgeons (BASS) and held outside the NHS. Personal details will be removed before any data analysis is performed retaining only age and gender. Your personal data and e-mail address will not be available to anyone outside BASS and its secure IT provider. Anonymised data may be released to approved organisations for approved purposes but a signed agreement will restrict what they can do with the data so patient confidentiality is protected.

Your personal data is very important as this will allow us to link details of your diagnosis and surgery with any problems or complications after surgery. You may also be asked to complete questionnaires before and after surgery to work out how successful the surgery has been. These will only be possible if we can connect you to the questionnaires through your personal details.

Do I have to give consent?

No, your participation in the BSR is voluntary and whether you consent or not, your medical care will be the same. Your personal details cannot be kept without your consent. This will be obtained either by getting you to physically sign a consent form or electronically sign one through an email link to a questionnaire or at questionnaire kiosk in the outpatient clinic.

You can withdraw your consent at any time or request access to your data by contacting your Consultant.

Research

Your consent will allow the BSR to examine details of your diagnosis, surgical procedure, any complications, your outcome after surgery and your questionnaires. These are known as 'service evaluations' or 'audits'.

Operation and patient information including questionnaires in the BSR may be used for medical research. The purpose of this research is to improve our understanding and treatment of spinal problems. The majority of our research uses only anonymised information that means it is impossible to identify individuals. From time to time researchers may wish to gather additional information. In these cases, we would seek your approval before disclosing your contact details. You do not have to take part in any research study you are invited to take part in and saying no does not affect the care you receive.

All studies using data from the Registry will be recorded on the BSR website: www.britishspineregistry.com

Children

Parents are asked to consent for data to be collected from their child. Looking at the outcome of spinal surgical procedures is just as vital in children as it is in adults.

Can I find out more information?

The BSR website (www.britishspineregistry.com) contains more information including details of any studies and any information obtained through the Registry data.

If you want to see what data is stored on you, please write us at the BSR Centre (see below).

Contact Details:

Visit our website at:

www.britishspineregistry.com

Send an email to:

Customer.support@amplitude-clinical.com