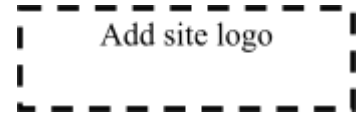




FUSION VERSUS BEST CONSERVATIVE CARE



Participant Information Sheet and Consent Form

Study title:

The clinical and cost-effectiveness of lumbar fusion surgery for patients with persistent, severe low back pain:

FusiOn veRsus bEst conservative Care (FORENSIC-Australia)

Coordinating Principal Investigator:	Sponsor:	Funder:	Site name:	Site Principal Investigator:
Professor Nadine Foster	The University of Queensland	The National Health and Medical Research Council (NHMRC)	[Add Site Name]	[Add PI Name]

We would like you to join our study.

Before you decide, it is important to understand:

- Why this study is happening.
- What it would be like to take part.

Please take time to read this information sheet. Discuss it with family, friends, or your doctor before you decide whether this study is right for you.

Do you have any questions? Would you like a large print version of this information? Contact the local study team at: [Add Phone Number/Email]



Why have I been invited to take part?

You have been invited to take part because you have reported that you have on-going, severe low back pain, you have had some non-surgical treatment for your back problem, and your health care team believes your symptoms may be improved either by an **operation (Lumbar Fusion Surgery)** or by receiving **Personalised Spinal Care** (a form of best conservative care).

Around 270 people will take part in this study, many from public hospitals and private hospitals/clinics around Australia.



What is the purpose of this study?

Lumbar Fusion Surgery and Best Conservative Care are treatments that are currently offered to some patients with on-going, severe low back pain and certain features on spinal scans, but we do not know if one of these treatments is better than the other. We want to find out:

- If Lumbar Fusion Surgery or Best Conservative Care is better in terms of the ability to do everyday activities over 24 months.
- If Lumbar Fusion Surgery or Best Conservative Care are good value for money for the Australian health care system.



Do I have to take part, and can I change my mind?

Taking part is up to you

You can decide whether you take part in this study. You can say yes or no.

Your decision will not affect your relationship with those treating you or your relationship with [Add Site Name].

You do not have to take part in this study to receive treatment at your hospital/clinic. Your health care team will discuss other options with you before you decide whether to take part in this study.

If you take part in this study, you will be in it for 24 months.

You can change your mind at any time

If you do take part, you can withdraw from the study at any time or from certain aspects of the study. If you want to withdraw, please tell a member of the local study team before you withdraw.

We will keep the information we have already collected about you, and encourage you to still complete some key follow-ups, so we can measure the study results properly. Data collected up to the point of full withdrawal is key to keep and include in the analysis. Please only join this study if you are happy with this approach.

The study might stop for other reasons. We might need to stop the study while you are taking part. If this happens, we will explain the reasons to you.

We may also ask you to stop taking part in the study if it is no longer in your best interests. If this happens, we will discuss this with you.



What do I have to do if I take part?

Recruitment Information Study

The FORENSIC-Australia study also includes a **Recruitment Information Study**. This helps us understand how people decide to join studies like the FORENSIC-Australia study.



- You may be asked if we can audio-record the conversations you have with hospital or clinic staff about this study. This will help us find the best way to explain the study to patients in the future.



- You may be asked to take part in an interview with a researcher about your experience of being invited to join the FORENSIC-Australia study and/or about the treatment you received.

You can agree to take part in the FORENSIC-Australia study only, the Recruitment Information Study only, both, or neither. If you decide not to join the FORENSIC-Australia study, we would like to interview you. This will help us understand why you decided not to join. The goal is not to change your mind, but you will help us make sure the study is explained clearly to others in the future.

If you agree to speak with a researcher, the interview can be done using Zoom, Microsoft Teams, or by phone. With your consent, we will audio-record the interview to make sure we understand your answers correctly. The interview will last about 45 minutes. A researcher from the FORENSIC-Australia study at The University of Queensland will contact you to set up a time and date that works for you.

FORENSIC-Australia Study



Screening – *audio-recording for the Recruitment Information Study may occur here.*

Staff at your hospital/clinic looking after you will ask you some questions about your back problem to make sure this study is suitable for you. This study may be suitable for you if:

- You are aged 18 – 65 and have on-going, severe low back pain for more than 6 months.
- You have previously tried recommended non-surgical treatments for your low back pain.
- Your recent imaging scan (Magnetic resonance imaging (MRI) and/or single photon emission computed tomography-computerised tomography (SPECT-CT)) of your lower back, show specific features. (If you do not have recent imaging, the local study team may arrange a scan to be done.)

Consent – *audio-recording for the Recruitment Information Study may occur here* 

You will be given time to read the study information, talk to the study team, and ask questions. If you are suitable for this study and you decide to take part, you will be asked to sign the consent form at the end of this information sheet or an electronic consent form that will be sent to your email address.

By signing the consent form, you allow the local study team to pass on your contact details to the central trial team based at The University of Queensland. This will help them get in touch with you about your study follow-up activities over 24 months.

We will also ask you to consent to long-term follow-up at five years if we get extra money to do this additional follow-up.

With your consent, we will inform your General Practitioner (GP) that you are taking part in this study.

Baseline (first) questionnaire

After you have signed the consent form, you will be given a baseline questionnaire to complete. This questionnaire will ask you about your back pain and general health.

If you prefer to do this online, we will send you a link to your email address. If you prefer a paper questionnaire, we will give this to you with a Reply-Paid envelope to return this questionnaire to us.

Please turn over

Receiving Treatment

To decide which treatment you are offered, you will be randomised. This means that you are put into a group by chance, like flipping a coin. We do this so we can compare the treatments fairly to see which one is better. You will have an equal chance (50:50) of being offered Lumbar Fusion Surgery or Personalised Spinal Care (not involving surgery). You will not be able to choose the treatment and neither can we. This is the only way to ensure the groups are as similar as possible before any treatment starts. This allows us to make a fair comparison between how people in each treatment group do.

To join the study, you must be comfortable accepting either Lumbar Fusion Surgery or Personalised Spinal Care. If you have a strong preference for one treatment or another, you may not be suitable for this study and should discuss this with us.


We ask that you give the treatment you are offered the best chance of helping your back problem by staying in your allocated group for the 24-month study period.

Follow-up

You will be contacted at **6-, 12-, and 24-months** to fill in a **questionnaire**. This can be done either electronically, over the phone, or by completing a paper version and posting it back to us in the Reply-Paid envelope provided. We will send you a text message or email to remind you that a questionnaire is due. If you need help completing any questionnaire, a study team member can contact you by phone to help you.

You will also be sent a **text message or email once a month for 24 months** asking you to tell us how severe your low back pain is.

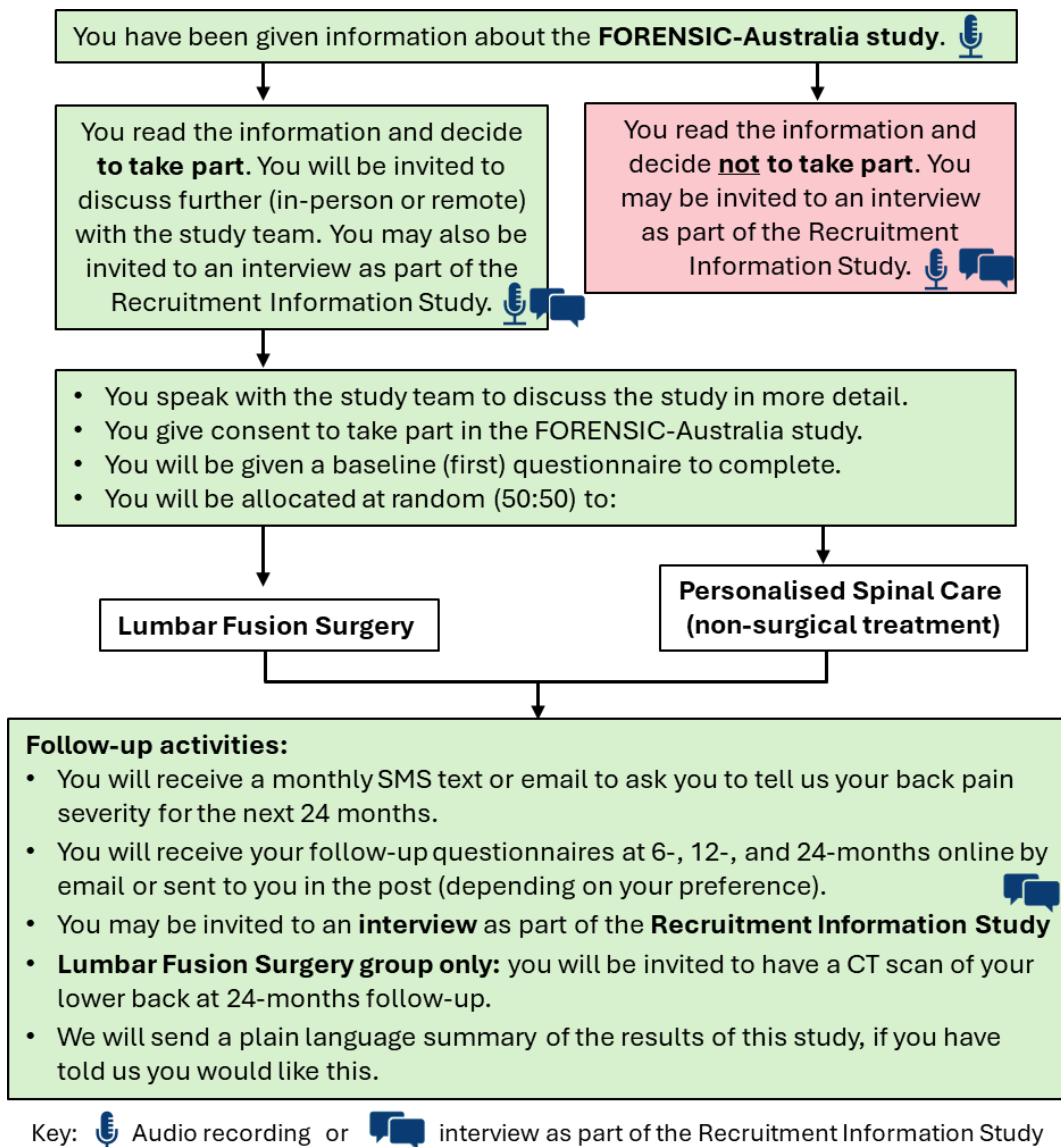
Example: *“Over the last 2 weeks, on average, how severe was your lower back pain?”*
[Responses from 0 = no pain to 10 = worst pain ever].

As part of the Recruitment Information Study, you may be asked if you would like to take part in  interview to ask about your experiences of being invited to take part in the study or the treatment you received. This is optional.

If you have Lumbar Fusion Surgery, you will also be invited to have a CT scan at 24-months of your lower back.

We will also seek your consent to contact you for longer-term follow-up in five years (we will only do that longer-term follow-up if we secure additional funding).

The diagram below summarises what taking part involves:



Please turn over



Information about the treatments

Lumbar Fusion Surgery



If you are allocated to be offered Lumbar Fusion Surgery, your surgeon will add you to their surgical list. Your clinical care will include before and after surgery consultations as is usual at your hospital/ clinic. Your surgeon will describe the type of fusion surgery they will perform as this is specific to each patient and surgeon. They will also give you information on the possible risks and benefits, and how to prepare for surgery.

During lumbar fusion surgery

Your surgeon will perform lumbar fusion while you are sedated. There are several ways to do lumbar fusion surgery, depending on where the bones to be fused are in the spine.

After the surgery

A hospital stay of two to three days is usually required following lumbar fusion surgery. Depending on the location and extent of your surgery, you may experience some pain and discomfort, but the pain can usually be controlled well with medications.

After you go home, contact your surgeon if you have signs of infection, such as redness, tenderness, or swelling, shaking chills and or fever (temperature higher than 38°C).

It may take several months for the affected bones in your spine to heal and fuse together. You will be offered usual post-operative care following the usual service pathways at your hospital/clinic. This may involve seeing a physiotherapist who can provide advice and exercise to help your recovery and allow you to get back to your normal activities. This is part of the usual clinical care after surgery.

We will invite you to have a CT scan of your spine in 24-months as part of this study.

Your surgeon will be able to provide you with further details of your surgery.

Personalised Spinal Care



If you are allocated to be offered Personalised Spinal Care, you will be assessed by a clinician with experience in back pain. They will ask about you and your back problems, perform a detailed assessment, and review previous treatments you have had and how effective you thought they were.

Following your assessment, your clinician will work with you to create a personalised spinal care treatment plan. This will consist of treatment that is recommended in guidelines and locally available to you for the management of your back pain, however the care will be personalised to you. Personalised care is different from the standard care available in several ways: it recognises that each person is different, and treatment is tailored accordingly, it considers all the factors that are affecting your health now and decisions are made about treatment together with you based upon your experiences and goals. The following recommended treatments are available as part of the FORENSIC-Australia Personalised Spinal Care at your hospital/clinic/or the community:

[Site to remove bullet point(s) from this list below as applicable]:

- Support for active self-management, this may include advice and education.
- Structured and supervised exercise therapy with or without manual therapy, with a healthcare professional, which may include an individualised exercise programme.
- Structured and supervised combined physical and psychological programme with a healthcare professional to help you get through pain, become fitter, and return to activities.
- Structured and supervised psychological programme with a healthcare professional.
- Structured and supervised programme of treatment led by a pain service which may include support to become more active, managing flare ups successfully and becoming more confident in managing your pain.
- Radiofrequency denervation for pain management. This is a procedure to stop the nerves in your lower back sending pain signals to your brain.
- Signposting to other health materials, online resources, or referral to other healthcare professionals.

The length of your treatment will be based on your individual needs and what is available to you. The treatment sessions may be face-to-face, over the phone, via video/telehealth, or a mix of these, in line with the usual approaches at your hospital/clinic/or the community.

Your FORENSIC-Australia clinician will give you with further details of your treatments.

Your time and expenses

You will not have extra out-of-pocket costs beyond your usual standard of care costs by taking part in this study. In recognition of your time taking part:

- We will provide gift vouchers to help cover some of your travel costs. You can get up to \$40 for each visit related to the study (like appointments or scans).
- If you need to travel long distances, we can also help cover some of your study-related travel costs and overnight accommodation costs. We will discuss this with you on a case-to-case basis. Please discuss this with the study team.
- When you finish the last questionnaire, we will send you a \$50 gift voucher as a thank you.
- If you prefer to complete paper questionnaires, we will give you a Reply-Paid envelope so you can send these back to us free of charge.

If you have any out-of-pocket costs associated with getting MRI or SPECT-CT scans of your lower back that are required, we will fund up to \$100 for the MRI scan and up to \$120 for the SPECT-CT scan.

If you have been allocated to the Lumbar Fusion Surgery group, your CT scan at 24-months after randomisation will be at no cost to you, as this is a research cost. We will pay for the cost of the CT scan directly to the radiology centre.

Some of the scans and/or treatments used in this study are part of standard care used and to maintain your health even if you did not take part in the study. You will be responsible for meeting the cost of this standard care in the usual way through Medicare, private health insurance, and your personal contribution depending on your circumstances, or workers compensation if appropriate.

If you are treated in the **public system** via Medicare:

- Treatment will be free, but there may be longer waiting times for your treatment.
- Outpatient services may be limited.

If you are treated in the **private system** and have private health insurance:

- Your private health insurance will cover some of your hospital and surgical costs, but you may still have out-of-pocket costs.
- Depending on your Extras cover, you may have reduced out-of-pocket costs for extras services, such as physiotherapy and psychology.
- Please check the cost of the treatment with your treating clinician and with your private health insurer to find out the amount of cover you are eligible for.

If you are claiming treatment costs related to a **workers' compensation claim**, please check with your insurer.”



What are the possible benefits and risks of taking part?

By taking part, you will help us understand the best treatment for people with on-going, severe low back pain. This knowledge may help people in the future.

You will be offered either Lumbar Fusion Surgery or Personalised Spinal Care to help treat your back problem. We hope that your treatment will help your back problem, but we cannot guarantee that.

If you agree to take part in the Recruitment Information Study, you will also be helping us find out how to improve how this type of research is best discussed with patients and how patients find taking part in research.

The table on the next page shows the possible benefits and risks of taking part in this study.

	Lumbar Fusion Surgery	Personalised Spinal Care
What are the possible benefits ?	<ul style="list-style-type: none"> Your pain and physical ability may improve. You may no longer require on-going treatment or pain relief. 	<ul style="list-style-type: none"> Your pain and physical ability may improve. You may no longer require on-going treatment or pain relief.
What are the possible risks ?	<ul style="list-style-type: none"> Your pain and physical ability may not improve, or they may get worse. Risks associated with any operation include bleeding from wound site, bone fracture, vascular injury, needing further surgery. Risks with any general anaesthetic of nausea, dizziness, tiredness, headache, sore throat. Risks of side-effects of medication. Risk with radiation exposure during the 24-month CT scan. ** MRI scan to check your suitability for this study: no known side-effects of MRI provided you do not have any implants or objects that must not go into the scanner. **Exposure to radiation due to the SPECT-CT scan to check your suitability for this study. 	<ul style="list-style-type: none"> Your pain and physical ability may not improve, or they may get worse. Risk of increased pain associated with a new exercise or manual therapy. Risk of bruising around the site of needle insertion and temporary numbness and/or weakness in the legs due to local anaesthetic spread from radiofrequency denervation. Risks of side-effects of medication. ** MRI scan to check your suitability for this study: no known side-effects of MRI provided you do not have any implants or objects that must not go into the scanner. **Exposure to radiation due to the SPECT-CT scan to check your suitability for this study.

****MRI and SPECT-CT scans are part of your usual standard of care to check your suitability for Lumbar Fusion Surgery. This request for imaging scan will only take place if you have not had recent imaging of your lower back (i.e., within the last 12months).**

Although there are potential risks to you from taking part in this study, the treatments offered in this study are currently available in Australian hospitals/clinics or the community. Therefore, taking part in the study means that there are no extra risks over and above what your clinician or surgeon would normally tell you about.

There are some risks with **Personalised Spinal Care**. Some people may have some muscle soreness for a few days after exercise or manual therapy, there may be side effects from prescribed medications, or bruising around the site of needle insertion and temporary numbness and/or weakness in the legs due to local anaesthetic spread from radiofrequency ablation/denervation.

There are also some risks with Lumbar Fusion Surgery. There are risks with surgery, including blood clots, bleeding, infection, stiffness, poor wound healing, injury to blood vessels or nerves in and around the spine, and pain at the bone graft site, but these are the same risks for people that have this surgery but do not take part in the study.

The risks of the treatment will be discussed with you in more detail by your clinician, as part of your treatment.

Risks from exposure to radiation

In this study, if you have the Lumbar Fusion Surgery, you will be invited to have a non-contrast computerised tomography (CT) scan of your spine after 24-months.

A CT scan combines a series of X-ray images taken from different angles around your lower back. CT scan images provide more detailed information than X-rays. During a CT scan, you will be briefly exposed to ionising radiation.

[Site to delete the following radiation exposure wording that is not relevant]

QUEENSLAND RBWH DMI Wording:

This research study involves exposure to an amount of radiation. As part of everyday living, everyone is exposed to naturally occurring background radiation and receives a dose of about 2 millisieverts (mSv) each year. The effective dose from this study is about 22mSv. The benefits from the study should be weighed against the possible detrimental effects of the additional radiation exposures, including an increased risk of cancer induction. In this study, the risk is moderate, and the estimated risk of such harm is up to about 1 in 300.

QUEENSLAND LUMUS IMAGING Wording:

This research study involves exposure to a small amount of radiation. As part of everyday living, everyone is exposed to naturally occurring background radiation and receives a dose of about 2 millisievert (mSv) each year. The effective dose from this study is about 4-9mSv. At this dose level, no harmful effects of radiation have been demonstrated as any effect is too small to measure.

WESTERN AUSTRALIA SKG RADIOLOGY Wording:

This research study involves exposure to a small amount of radiation. As part of everyday living, everyone is exposed to naturally occurring background radiation and receives a dose of about 2 millisieverts (mSv) each year. The effective dose from this study is about 8mSv. At this dose level, although harmful effects cannot be proven, there is evidence to indicate that such a dose may give a very small risk of developing cancer. The risk is approximately 1 in 2200, which is equivalent to approximately 0.75 times the estimated risk of dying on Western Australian roads in the next 10 years.

The CT scan of your lower back at 24-months is for research purposes. It is not intended to be used like scans taken for a full clinical examination. The scan will not be used to help diagnose, treat or manage a particular condition. A specialist will look at your CT scan for features relevant to the study. On rare occasions, the specialist may find an unusual feature that could have a significant risk to your health. If this happens, we will contact you to talk about the findings. We cannot guarantee that we will find any/all unusual features.

Recruitment Information Study

Taking part in an interview may involve discussion of sensitive issues; however, the research team and interviewer will be fully trained and will support you during this discussion. As we expect the interview will last about 45 minutes, the interview will also take up some of your time. In recognition of your time taking part, we will send you a \$50 gift voucher.



How will my information be collected, used, and stored for this study?

This section tells you how this study will collect, store, and use your information. If you do not want us to collect this information, you cannot take part in this study.

Collecting your information

We will collect information for the study directly from you and from your health records (including study-related imaging scans of your lower back) held at the [Add Site Name] for purposes of this research. By signing the consent form you agree to the study team accessing health records if they are relevant to your participation in this study.

We will also collect information on the health services you have used related to your back problem during your time in this study through your responses in the follow-up questionnaires at 6-, 12-, and 24-months.

If you are allocated to the Lumbar Fusion Surgery group and your surgeon is

participating in the Australian Spine Registry (ASR), we will seek your consent to information collected about you from the ASR to help assessing long-term outcomes.

Where will we collect your information from	What kind of information we will collect
Australian Spine Registry	General health questionnaire responses, surgery details, surgery outcome questionnaire responses.

Keeping your information and study-related imaging scans safe

To keep your information safe, we will:

- Follow all relevant privacy requirements
- Store information and imaging scans securely at your hospital/clinic, and on an electronic database called REDCap, and electronically on a secure server at The University of Queensland
- Take steps to prevent anyone from accessing information that identifies you unless they are authorised to do so
- Give your information and imaging scans a study participant ID number and keep them separate from your name and contact information

Confidentiality and privacy:

- The information that the study team collect, and use are your contact details, information from your health records, imaging scans related to taking part in this study, questionnaire and back pain severity responses.
- If you also agree to take part in the Recruitment Information Study, the information that the study team collect and use also include the audio-recording of your conversation with staff about this study, and audio-recording of interview(s) about this study. Some audio-recordings of your conversation with staff and interviews will be transcribed by Digital & Audio Transcription Services (DAATS) or the Microsoft Word Transcribe function. If transcription is done by DAATS, audio files and transcripts are stored on their Australian-based servers and are deleted permanently after 30 days. All transcripts downloaded from DAATS will be de-identified and stored securely at on The University of Queensland servers. If transcription is done using Microsoft Word Transcribe, audio files and transcripts are stored on The University of Queensland servers. Although your voice in the audio-recording could lead to your identification, this file will not be used during analysis. Instead, pseudo-anonymised transcriptions (the text file copy of your interview but hiding your identity) will be used for analysis.
- By signing the consent form you consent to the local study team, the central trial

team, and relevant research staff collecting and using your personal information for this study. Any information collected about you relating to this study that can identify you will remain confidential (private). We will use a study participant ID number (code) to label your study documents, audio-recordings, transcripts and information collected by study staff, including answers you provide when completing study questionnaires.

Storage and access:

- Information collected about/from you will be stored securely at your local hospital/clinic where this study is taking place, and at The University of Queensland in the secure and password-protected Research Data Management, REDCap database systems, and on private Microsoft Teams/SharePoint.

Please turn over

- Access to your identifiable information is limited to approved members of the study team for the purposes of contacting you and providing you information about the study and providing treatment to you.
- If you consent to be contacted for future research, the central trial team will store your contact details (name, address, phone number, email) on the secure University of Queensland Research Data Management system, only accessible to the central team, and may contact you about future research studies. By agreeing to be contacted, does not mean you have to take part in future studies.
- When this study ends, the information collected about/from you will be securely stored at The University of Queensland for a minimum of 15 years.
- If you take part in the Recruitment Information Study, audio-recordings will be uploaded to a secure University of Queensland server and stored within a private Microsoft Teams/SharePoint, with access only provided to the researchers involved in this study and to DAATS for transcription purposes. Pseudo-anonymised transcriptions of the audio-recorded discussions or interviews will be securely stored at The University of Queensland for a minimum of 15 years.
- If you take part in this study, your health records, and any information obtained during the research study are subject to inspection (for the purpose of verifying the procedures and the data) by the relevant authorities and authorised representatives of the Sponsor (The University of Queensland), the institution relevant to this Participant Information Sheet ([Add Name of Institution]), or as required by law. By signing the Consent Form, you authorise release of, or access

to, this confidential information to the relevant study personnel and regulatory authorities as noted above.



How will my information be shared?

With you:

After the study is finished, if requested, we can provide you with the summary study results.

With your GP:

If you agree, we will tell your doctor/GP that you are taking part in this study. They may add this information to your health records. If we find out information relevant to your on-going care, we will share this information with your doctor/GP, so you can receive the care you need.

With our 'sibling' study, FORENSIC-UK:

After this study is finished, we will share **de-identified data** (data that has your identification removed) with the research group at The University of Oxford, United Kingdom, who are leading the 'sibling' study called FORENSIC-UK. We will follow The University of Queensland's data sharing policy.

Publishing study information:

We will share certain de-identified information and restricted access data repositories from this study so that others can use it and understand the study findings. This study information will not identify you individually. We will make this study information available through journal articles, presentations, and a short video/infographic. By being in this study, you agree to us sharing study information for these purposes.

Other research studies:

We intend that the de-identified FORENSIC-Australia study dataset be made available for sharing to help future research. We will also ask for your consent to consider sharing your de-identified information for ethically approved future research closely related to this study. However, in the future, as the open science initiative progresses, ethical approval may not be required to analyse de-identified data for secondary research purposes. The researchers may be in Australia or overseas. They may work for a commercial organisation like a pharmaceutical company or medical device company.

When we share your de-identified data, we will take steps to make it difficult for anyone to link this data back to you. This includes removing information that could easily identify you, like your name. There is still a small chance that someone could identify you again.

If you agree to share your de-identified data, you will not be told about the future research studies or any results from these studies. If you change your mind, you have the option to ask us to stop sharing your de-identified data. However, if your de-identified data have already been shared, it may not be possible to retrieve or destroy them.



Who is doing and funding for this study?

This study is being done by [Add Site Name].

This study is being organised by The University of Queensland (Sponsor)

This study has been funded by The National Health and Medical Research Council (NHMRC).



What if something goes wrong?

In an emergency, you should call 000 or go to the emergency department at your nearest hospital. If your injury is not urgent, you should contact the local study team who can help you organise appropriate care.

If you are harmed because of taking part in this study, contact the local study team (contact details below). If you are eligible for Medicare, you can receive the treatment you need to treat the harm free of charge as a public patient in any Australian public hospital.

You do not give up any legal rights to compensation by taking part in this study.

Local study team	[Add Name]	[Add Phone Number/Email]
-------------------------	------------	--------------------------



Who has reviewed this research?

The Metro North Health Human Research Ethics Committee (HREC) has approved this study. This is an independent committee that makes sure that this study meets Australian ethical standards for research that involves people.

This document has been reviewed by the FORENSIC-Australia Consumer and Community Involvement (CCI) group. Our CCI group consists of members of the public who live with low back pain or are carers of those who have low back pain. Our CCI

group will continue to be involved in reviewing participant-facing documents until the end of the study.

Comments or complaints about how this study is being run

If you have any comments or complaints about this study, please contact:

Human Research Ethics contact	Metro North Health HREC	Telephone: 07 3646 5280 Email: MetroNorthResearch-Ethics@health.qld.gov.au
Complaints contact (local Research Governance contact)	[Add Name]	[Add Phone Number/Email]



Where can I find more information?

Thank you for taking the time to read this information about our study. If you any questions, please contact our FORENSIC-Australia central trial team at The University of Queensland.

Trial Manager	[Add Name]	Email: forensic@uq.edu.au Mobile: 0461 378 578
----------------------	------------	---

Please turn over for the Participant Consent Form

Participant Consent Form

Participant study ID:	
Title:	The clinical and cost-effectiveness of lumbar fusion surgery for patients with persistent, severe low back pain: FusiOn veRsus bEst conservative Care
Short Title:	FusiOn veRsus bEst conservative Care (FORENSIC-Australia)
Study Sponsor:	The University of Queensland
Coordinating Principal Investigator:	Professor Nadine Foster
Site Principal Investigator:	[Add Site PI Name]
Site name:	[Add Site Name]

If you wish to take part in the FORENSIC-Australia study, please read carefully, sign and date this form.

Declaration by Participant

1. I have read and understand the Participant Information Sheet, or someone has read it to me in a language that I understand. I have had the opportunity to ask any questions which have been answered to my satisfaction.

2. I understand the purposes, procedures and risks of the research described in the study.

3. I give permission for my doctors, other health professionals, hospitals or health services outside this hospital/clinic to release information to [Add Site Name] concerning my back problem and treatment for the purposes of this study. I understand that such information will remain confidential.

4. I give permission for the relevant sections of my health records, data, and spine imaging scans and reports to be accessed for the purposes of this study.

5. I agree for my data including my spine scans and scan results to be collected and stored for the purposes of this study.

Please turn over

6. I understand that if I am placed in the Lumbar Fusion Surgery group of this study, I will have a CT scan at 24-months, and that this CT scan will be for the research study. If my imaging shows something concerning, I will only be informed if a Doctor thinks it is medically important such that the finding has clear implications for my current or future health.
7. I understand that if I am placed in the Personalised Spinal Care group of this study, I will be offered care that is likely to involve a course of treatment, and that this will require me to be able to engage in these treatment sessions over several weeks or months.
8. I understand that taking part in the study means that I will be asked to give the treatment I am offered the best chance of helping my back problem, over the follow-up period of 24 months.
9. I agree to my contact details being shared with the central trial team at The University of Queensland, so they can contact me about the follow-up questionnaires, monthly SMS text message or email about my back pain severity, and the Recruitment Information Study and/or interview.
10. I understand that I can stop taking part in the study or some parts of the study, at any time without affecting my health care.
11. I understand that, if I decide to stop taking part in the study, a member of the study team may request my permission to obtain access to the relevant sections of my health records for collection of follow-up information for the purposes of research and analysis. I understand I can refuse this at that time.
12. I understand my de-identified data (data that has my identification removed) may be shared with the “sibling” study (FORENSIC-UK) at The University of Oxford, United Kingdom, to enable future additional data analyses.
13. I understand that records relating to me will be kept confidential. No information will be released or printed that would identify me without my permission unless required by law.

(mark one box)

14. I freely agree to take part in this study as described above. Yes No

Please turn over

Optional Consent: Answering 'Yes' or 'No' will not affect your participation in the study:

15. I agree to provide my General Practitioner (GP)'s contact details to the study team and I agree to my GP being informed of my participation in the study and being advised of any significant information relating to my health and safety that arises during my participation.

Yes / No (please circle appropriate)

16. **Recruitment Information Study:** I agree to being interviewed about my experience regarding the FORENSIC-Australia study and I am happy to be contacted by the study team about this.

Yes / No (please circle appropriate)

17. I agree to being contacted in future to ask about taking part in a longer-term follow-up for this study. I understand that I can change my mind about this at a later date.

Yes / No (please circle appropriate)

18. I agree for my de-identified data (i.e., data where I am not identifiable) including imaging scans being collected, stored, and shared for ethically approved future research that is closely related to this one. I understand that in the future, ethical approval may not be required to analyse my de-identified data for secondary research purposes.

Yes / No (please circle appropriate)

19. I agree to be contacted about ethically approved research studies for which I may be suitable. I understand that agreeing to be contacted does not oblige me to take part in any further studies.

Yes / No (please circle appropriate)

20. I would like a copy of the study results.

Yes / No (please circle appropriate)

21. **Australian Spine Registry (ASR):** If I am allocated to the Lumbar Fusion Surgery arm and my surgeon is participating in the ASR, I agree for my ASR data to be collected, analysed, and stored for the purposes of this study.

Yes / No (please circle appropriate)

Print name	Signature
------------	-----------

Name of participant (<i>please print</i>)	Date DD/MM/YYYY	Signature of participant
Print name		Signature
Name of person receiving consent (<i>please print</i>)	Date DD/MM/YYYY	Signature of person receiving consent