PARTICIPANT INFORMATION STATEMENT

INVITATION TO PARTICIPATE IN AN IMPORTANT HEALTH STUDY

Research Title: INTERNATIONAL CONSORTIUM FOR HEALTH OUTCOMES MEASUREMENT (ICHOM): NORTH SHORE PRIVATE HOSPITAL OUTCOMES OF TREATMENT OF LOW BACK PAIN

Investigators:

- Dr Michael Biggs, Neurosurgeon
- Dr Ian Farey, Orthopaedic spine surgeon
- Dr Jeffrey Brennan, Neurosurgeon
- Dr Jonathon Ball, Neurosurgeon
- Dr Nathan Hartin, Orthopaedic spine surgeon
- Dr Roger Laurent, Rheumatologist
- Dr Lewis Holford, Pain management specialist
- Dr Ben Olesnicky, Anaesthetist
- Dr Anthony Delaney, Intensivist
- Dr Jonathon Parkinson, Neurosurgeon
- Dr Rodney Allan, Neurosurgeon
- Dr Brian Hsu, Orthopaedic spine surgeon
- Dr Adam Rehak, Anaesthetist

Study Coordinator: Dr Farnaz (Nazy) Sanaei 8425 3057

Dear Patient,
North Shore Private Hospital is seeking the help of patients presenting with low back pain to take part in an important Study.

Purpose of the Study:
The aim of the Study is to collect patient and practitioner reported outcomes at set intervals and analyse this data in order to determine the best type of treatment and thus improve patient care. This Study will help to guide the medical profession in choosing the best types of treatment for specific low back pain conditions, so that all people presenting with low back pain in the future can benefit. There will also be an opportunity to benchmark results with other units treating low back pain around the world.

This Study will involve patients suffering from low back pain with or without leg pain (sciatica) that may or may not require surgery.

Participation in this research is voluntary. If you do not wish to take part, you do not have to. You will receive the best possible care whether you take part or not.

Through this project we will:

- Measure and evaluate changes in your functional ability, following surgery or medical treatment;
- Identify the best type of surgical procedure for best long-term outcomes;
- Examine changes in your functional ability to find out which prosthetics provide the best long-term outcome, if relevant;
- Enable North Shore Private Hospital to publish de-identified results to inform the wider community; and
- Contribute to an international data set so that all clinicians, globally, can improve their processes with treatment of low back pain.

What do I need to do?
If you consent to participate you will be sent an email with an online survey shortly after your first consultation with your specialist, then a similar online survey at 3 months, 6 months, 1 year, 2 years and 5 years after treatment. The survey asks questions on the degree of pain you are suffering in the back and leg(s) as well as the impact this pain is having on your activities of daily living, and your capacity to work. All of this vital information will map your state of health from onset of symptoms, through your treatment, and your recovery.

You may wish to invite a friend or relative to help you complete the survey. For patients with a legal guardian, we ask that the guardian complete this survey.

How do I do this?
In order for you to access the survey, we will need your email address. Once we have your email address you will automatically receive the surveys at the required timeframes.

If you agree to participate in this Study you will be asked at the end of this Patient Information Statement to complete a consent form to acknowledge your consent to taking part in this Project.

How will my involvement help?
This research will help decision makers to make better choices regarding treatment of low back pain. Once our research is published, your input will help other health professionals to better understand the process of recovery from low back pain, and the best directions to take in healing specific injuries. Your information will also form part of a large international data set that will further help to inform clinicians and improve procedural outcomes globally.

How long will it take?
The survey will take approximately 15 - 30 minutes. Your involvement in the Study will continue from your first consultation for a period of five years. As noted previously, this will involve completion of an online survey around the time of your first consultation and then a similar survey at 3 months, 6 months, 1 year, 2 years and 5 years after treatment.

Will I be identifiable by being involved in this study?
The information you provide will be confidential, allowing you to answer the questions freely. Your Study records may be viewed by your treating doctor for the purpose of

providing the best possible care, and by the Study Coordinator. Your treating doctor may also need to access your medical records at the Hospital(s) at which you are admitted to the extent relevant to this Study.

The information collected during the Study will include personal information such as your name, date of birth, address, and hospital unit number. The Study survey will also include health information relating to your low back pain. This information will only be accessible by your treating specialist and the Study Coordinator. De-identified information collected as part of the Study may be used for publication in journal articles, or at conference presentations, or for future international benchmarking to compare our results with other treatment centres around the world. This international benchmarking project is being coordinated by the International Consortium of Health Outcome Measurements (ICHOM), based in Boston, USA. As mentioned, any information we publish, present or use for benchmarking would be non-identifiable, meaning that all of your identifying details (for example your name, date of birth, address, and hospital unit number) would be removed so that you cannot be identified.

How will the information be stored?
All information in the database will be protected using standard hospital procedures and will be managed in accordance with the *Privacy Act* 1988 (and other applicable State laws regarding the collection, use, disclosure and storage of personal information). Confidentiality will be respected and no personal information will be used or disclosed other than as set out in this Patient Information Statement or as required by law. The information that is collected for the Study will be securely stored for 15 years.

Are there any risks or discomforts if I am involved?
It can be an emotional experience to discuss injury or recall details. If this happens and you feel that you need assistance, you need to advise our Study Coordinator (see page 1) and we can provide you with access to our hospital counselling service. This applies whether you are completing this questionnaire online, over the phone or in the doctor's rooms with secretarial staff or our Study Coordinator.

Should you decide you don't want to participate any more, you can withdraw from the Study (as detailed below) and the survey process will be terminated immediately. You will continue to receive the best possible care.

Are there any benefits to participating in this Study?
You may or may not receive any direct benefit from participating in this Study, although as noted above any information you provide will be used to improve health care delivery. New knowledge resulting from this Project will be made available to the medical community through publications. No identifiable information on an individual participant will be released. If tests or therapies are incorporated into medical practice in the future and doctors make use of that new knowledge, it may improve the care of patients. You may experience satisfaction from participating in research that may benefit medical science.

The data collected may also help us to identify those patients who may be eligible to participate in future research projects that involve more than just an analysis of existing data. In the future you may be approached by your doctor to participate in other research projects. In those instances, you will be given detailed information

describing the project and you will have the opportunity to decide at that time whether or not you want to participate in the new project.

Can I withdraw from the Study?
You may choose not to participate in this Study. Participation in this Study is voluntary. You may refuse to participate, or refuse to allow data to go to the research database at any time with no effect on your future care. If you decide to withdraw from the Study, information from your medical records will no longer be collected. Information that has already been transferred to the research database will not be able to be withdrawn as it would compromise the findings of the research that had already been completed. If you wish to stop your participation just let the Study Coordinator know (Nazy Sanaei 0431 772 599) and she will forward to you a consent withdrawal form for your signature.

How do I agree to participate?
To take part in the Study, simply sign the consent at the end of this Patient Information Statement, then login to the survey when it is sent to you via email.

Who will see my information?
Your doctor and the Study Coordinator will have access to your data. Any other individual or body accessing this data will only be able to see non-identifiable information. We will publish journal articles from this research and present at conferences to make sure that this important information is understood by and promoted to other medical professionals. We may also benchmark with other International Units. However, as stated, your personal information will not be identifiable.

Will I be paid for my time?
This research is conducted on a not-for-profit basis, so North Shore Private Hospital cannot pay participants. No investigator on this Project is receiving remuneration from the sponsor of this research.

Is this research project approved?
The North Shore Private Hospital Human Research and Ethics Committee has reviewed this Study. Should you wish to discuss the Study or view a copy of the Complaint Procedure with someone not directly involved, particularly in relation to matters concerning policies, information or complaints about the conduct of the Study or your rights as a participant, you may contact the North Shore Private Hospital Human Research and Ethics Committee on
Ph: (02) 8425 3037 or by email to ethicscommittee.nsp@ramsayhealth.com.au

We appreciate your help with this important Study. Please see over for consent form.