PARTICIPANT INFORMATION SHEET AND CONSENT FORM

**Title: Early Nurse Initiated Fascia Iliaca Regional Nerve Blocks for Fractured Neck of Femur in Elderly Emergency Department Patients: an Implementation and Generalisability Study**

***Principal Investigator:***

*Dr Mark J Gillett* Director of Research & Senior Staff Specialist, Emergency Department, RNSH

***Associate Investigators:***

*Dr Chris Trethewy* Director of Emergency Medicine Research,

Gosford Hospital

*Professor Marg Fry* Director of Research and Practice Development, Nursing and Midwifery Executive

*Dr Sarah Wilks* Research Associate, Emergency Department,

Royal North Shore Hospital

*Ms Lesley Fitzpatrick* Clinical Nurse Educator, Emergency Department, Royal North Shore Hospital

*Dr John Vassiliadis* Director, Sydney Medical Simulation Centre

***Location:*** Emergency Department, Royal North Shore Hospital, Sydney

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1. **Introduction**

You are invited to participate in a research study called *“Early Nurse Initiated Fascia Iliaca Regional Nerve Blocks for Fractured Neck of Femur in Elderly Emergency Department Patients: an Implementation and Generalisability Study.”* This study will examine the provision of nurse-administered nerve blocks to relieve pain for hip fracture patients. We want to find out how patients fare after their hospitalisation, when they return home.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the research involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don’t understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or local doctor. Participation in this research is voluntary. If you don’t wish to take part, you don’t have to. You will receive the best possible care whether or not you take part.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

• Understand what you have read

• Consent to take part in the research project

• Consent to providing the information described

• Consent to the use of your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

1. **What is the purpose of this research?**

The purpose is to find out about the longer-term outcomes for hip fracture patients with respect to pain levels and return to everyday activities after their hospitalisation. The study is funded by NSW Health under the Translational Research Grants Scheme.

1. **What does participation in this research involve?**

This study is an observational study: we will not be testing any new treatment on you. We wish to track your progress after you’ve gone home and compare your after-recovery pain levels and degree of activity with your pre-fracture levels.

At admission, a member of staff in the Emergency Department will ask you questions about your usual daily activities. This is called an Activities of Daily Living (ADL) assessment. You will also be asked about your pain levels. All patients are asked these questions are part of their normal care.

If you consent to take part in this study, your participation will involve a telephone interview approximately 3 months after your return home. This interview will take no more than half an hour. During the interview you will be asked questions about any pain you may still have, and how you are managing everyday activities such as walking, shopping, leisure, housework etc. You will also be consenting to us recording your responses to the questions about your Activities of Daily Living that you were asked in hospital for research purposes so that we can compare this information with your after-recovery activity and pain levels. In addition, the researchers would like to have access to your medical records to obtain information relevant to the study.

1. **What do I have to do?**

As a participant in this project you will be asked to undertake a 30 minute follow-up phone interview approximately 3 months after you have left hospital and returned to your home. You will be asked questions about your recovery and any pain you are experiencing.

1. **Other relevant information**

This study is part of a larger initiative which aims to improve the way hip fracture patients are treated in Emergency Departments. The changes mean that patients should receive effective pain relief much sooner after their arrival at hospital than has been the case in the past. We will then be aiming to have this change in practice implemented in all Emergency Departments across NSW. We will be following up patients from Royal North Shore Hospital, and later, from Gosford Hospital, to track their longer-term outcomes. Approximately 500 patients will be enrolled in this study.

1. **Do I have to take part in this research project?**

Participation in this study is entirely voluntary. It is completely up to you whether or not you participate. If you do decide to participate, you will be given this participant Information and Consent Form to sign and you will be given a copy to keep.

If you decide not to participate, or you did decide to take part and then withdraw, it will not affect the treatment you receive now or in the future. Whatever your decision, it will not affect your relationship with the staff caring for you or your relationship with (your treating) Hospital. If you wish to withdraw from the study at any stage, you can do so at any time without having to give a reason.

1. **What are the alternatives to participation?**

You can simply say ‘no.’ You do not have to take part in this research project to receive treatment at this hospital. If you decide not to participate in this study, you will still receive the standard treatment available for your condition. If you decide not to participate, it will not affect the treatment you receive now or in the future. Whatever your decision, it will not affect your relationship with the staff caring for you.

1. **What are the possible benefits of taking part?**

There are no direct benefits to you as a participant: however, it is possible that the results of this study may benefit others with a similar diagnosis in the future. Participation in this study will not cost you anything nor will you be paid.

1. **What are the possible risks and disadvantages of taking part?**

There are no risks to you if you participate in the study as the treatment you receive will be unaffected and any information you disclose to us will be kept strictly confidential.

1. **What if I withdraw from this research project?**

If you wish to withdraw from the study at any stage, you can do so at any time without having to give a reason. If you do withdraw your consent during the research project, the study doctor and relevant study staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law.

**Part 2 How is the research project being conducted?**

1. **What will happen to information about me?**

By signing the consent form you consent to the study doctor and relevant research staff collecting and using personal information about you for the research project. Information about you may be obtained from your health records held at this and other health services for the purpose of this research. By signing the consent form you agree to the research team accessing health records that are relevant to your participation in this research project.

It is anticipated that the results of this research project will be published and/or presented in a variety of forums. In any publication and/or presentation, we will be combining the results from all participants and the information relating to any single participant (eg yourself) will not be identifiable.

Any information obtained for the purpose of this research project that could identify you will be treated as confidential and securely stored. The information will be heldsecurely at Royal North Shore Hospital Emergency Department under suitable security and only the researchers working on this project (and the Northern Sydney Local Health District and the Human Research Ethics Committee (HREC) for monitoring purposes) will have access to it. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law. All information and data collected during this project will be stored securely for 7 years and be destroyed at that time point. Any electronic copies (on a secure server) will be deleted and any paper copies will be shredded.

In accordance with relevant Australian and/or New South Wales privacy and other relevant laws, you have the right to request access to the information collected and stored by the research team about you. You also have the right to request that any information with which you disagree be corrected. Please contact the research team member named at the end of this document if you would like to access your information.

1. **Complaints**

In the event that you feel the need to register a complaint, in the first instance you should contact the Principal Investigator, Dr Mark Gillett: mgillett@med.usyd.edu.au Mobile: 0457829396. If you would rather not contact him for any reason, or if you are still dissatisfied after contacting him, you should contact the Research Office on 02 9926 4590 and quote (insert ethics clearance number here).

1. **Who is organising and funding this research?**

This research project is being conducted by Dr Mark Gillett, Director of Research and Staff Specialist in the Emergency Department of Royal North Shore Hospital and the Associate Investigators listed on the front page of this document.

This research project is being funded by NSW Health under the Translational Research Grants Scheme.

No member of the research team will receive a personal financial benefit from your involvement in this research project (other than their ordinary wages).

1. **Who has reviewed the research project?**

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of Northern Sydney Local Health District.

This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)*. This statement has been developed to protect the interests of people who agree to participate in human research studies.

1. **Further information and who to contact**

**For further information contact**:

* the Principal Investigator, Dr Mark Gillett: mgillett@med.usyd.edu.au mobile: 0457829396, or
* (insert local contacts here
* and here )

**Clinical Contact person**: (insert details for Dr Gillett or Dr Trethewy here)

**Complaints Contact**: Any person with concerns or complaints about the conduct of this study should contact either Dr Mark Gillett (details above) or the Research Officer who is nominated to receive complaints from research participants. You should contact them on 02 9926 4590 and quote HREC reference number “HREC/16/HAWKE/203”.

**Thank you for taking the time to consider this study.**

**If you wish to take part in it, please sign the attached consent form.**

**This information sheet is for you to keep.**

**Consent Form -** *Adult providing own consent*

**Title** Early Nurse Initiated Fascia Iliaca Regional Nerve Blocks for Fractured Neck of Femur in Elderly Emergency Department Patients: an Implementation and Generalisability Study

**Principal Investigator:**Dr Mark J Gillett

**Associate Investigators:**Dr Chris Trethewy, Professor Marg Fry, Dr Sarah Wilks, Ms Lesley Fitzpatrick, Dr John Vassiliadis

**Location:** Emergency Department, (insert name of Hospital here)

**Declaration by Participant**

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my future health care.

I understand that I will be given a signed copy of this document to keep.

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|  | Name of Participant (please print) |  |  |  |  |
|  |
|  | Signature |  |  Date |  |  |
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**Declaration by Study Doctor/Senior Researcher†**

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

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|  |
|  | Name of Study Doctor/Senior Researcher† (please print) |  |  |
|  |  |
|  | Signature |  |  Date |  |  |
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† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

**Form for Withdrawal of Participation -** *Adult providing own consent*

**Title** Early Nurse Initiated Fascia Iliaca Regional Nerve Blocks for Fractured Neck of Femur in Elderly Emergency Department Patients: an Implementation and Generalisability Study

**Principal Investigator:**Dr Mark J Gillett

**Associate Investigators:**Dr Chris Trethewy, Professor Marg Fry, Dr Sarah Wilks, Ms Lesley Fitzpatrick, Dr John Vassiliadis

**Location:** Emergency Department, (insert name of Hospital here).

**Declaration by Participant**

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with Royal North Shore Hospital.

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|  | Name of Participant (please print) |  |  |  |  |
|  |
|  | Signature |  |  Date |  |  |
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*In the event that the participant’s decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to provide a description of the circumstances below.*

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**Declaration by Study Doctor/Senior Researcher†**

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

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|  |
|  | Name of Study Doctor/Senior Researcher† (please print) |  |  |
|  |  |
|  | Signature |  |  Date |  |  |
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† A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.