Participant Information Sheet

Study title:	***Sentimag use for sentinel node biopsy***		
Locality:	**Department of General Surgery** **Auckland City Hospital**	Ethics committee ref.:	**16/NTB/97**
Investigators:	**Dr A. Anna Morrow** **Mr Isaac Cranshaw** **Dr Alex Jacobson**	Contact email: Contact phone:	**AlexJ@adhb.govt.nz** **(09) 307 4949 ext. 22787**

You are invited to take part in a study looking at a new technique for sentinel node biopsy. Whether or not you take part is your choice. If you don't want to take part, you don't have to give a reason, and it won't affect the care you receive. If you do want to take part now, but change your mind later, you can pull out of the study at any time without having to give a reason, with no impact on your care.

This Participant Information Sheet will help you decide if you'd like to take part. It sets out why we are doing the study, what your participation would involve, what the benefits and risks to you might be, and what would happen after the study ends. We will go through this information with you and answer any questions you may have. You do not have to decide today whether or not you will participate in this study. Before you decide you may want to talk about the study with other people, such as family, whānau, friends, or healthcare providers. Feel free to do this.

If you agree to take part in this study, you will be asked to sign the Consent Form on the last page of this document. You will be given a copy of both the Participant Information Sheet and the Consent Form to keep.

This document is 5 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

WHAT IS THE PURPOSE OF THE STUDY?

Your breast cancer treatment includes a procedure called sentinel node biopsy. This involves checking the first few lymph nodes in your armpit that your cancer drains to ("sentinel lymph nodes") for cancer cells. The current technique involves a special injection of radioisotope the day before your operation as well as using a blue dye that we inject on the day of your operation. This study will be looking at a new technique using an injection of magnetic tracer solution (Sienna). This study is being run by the Breast Surgery team at Auckland City Hospital. The lead investigators are Drs Anna Morrow and Alex Jacobson, surgical registrars, and Mr Isaac Cranshaw, Consultant Breast Surgeon. They can be contacted anytime with questions or concerns – their details are at the top of this page. This study has received ethical approval from the Northern B Health and Disability Ethics Committee.

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

You have been chosen to participate because you meet the inclusion criteria for the study: you are over 18 years of age and are undergoing breast cancer surgery with sentinel node biopsy. You would **not** be able to participate if you have the following: an allergy to iron or dextran compounds, iron overload disease, a pacemaker or ferrous metal-containing device in the chest wall, are pregnant or breastfeeding.

You yourself will not be doing anything different from what you would normally have to do. On the day before your operation, when you come to the Nuclear Medicine Department for your radioisotope injection. On the day of your operation once you are asleep under general anaesthetic, you will receive an injection of the magnetic tracer as well as the blue dye. We will firstly use the magnetic probe to find the sentinel nodes, then we will use the standard methods (i.e. radioisotope and blue dye) to see if there are any further sentinel nodes which the magnetic probe did not find. This will allow us to calculate the detection rates for both methods. We will send these all sentinel nodes found by both techniques off to the lab to be tested in the usual manner. Your follow up after the operation will be the same.

WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?

The injection of magnetic tracer solution may stain your skin a brownish colour. There is also a chance of allergic reaction to the magnetic tracer solution but none has specifically been documented with the use of the magnetic tracer solution in the overseas studies so far.

If this new technique has similar results to the current technique – which it has in the overseas studies so far – this would improve our management of patients with breast cancer as it would mean patients do not have to go to the Nuclear Medicine Department for radioisotope injection. This can be a particularly significant issue for patients who do not live close to a big hospital with a Nuclear Medicine Department and need to travel to another city to undergo this procedure. Furthermore patients would not be exposed to patent blue dye, which stains the skin blue and is associated with a 1:500 risk of significant allergic reaction.

WHO PAYS FOR THE STUDY?

There will be no cost to you to participate in the study. The magnetic probe machine will be on loan from the company that produces it. We have applied for funding from the Breast Cancer Foundation and the Breast Cancer Research Trust for the magnetic tracer solution; this solution is already widely available and in use in the hospital for MRI contrast studies.

WHAT IF SOMETHING GOES WRONG?

If you were injured in this study you would be eligible for compensation from ACC just as you would be if you were injured in an accident at work or at home. You will have to lodge a claim with ACC, which may take some time to assess. If your claim is accepted, you will receive funding to assist in your recovery.

If you have private health or life insurance, you may wish to check with your insurer that taking part in this study won't affect your cover.

WHAT ARE MY RIGHTS?

Your participation is **entirely voluntary**. You do not have to take part in this study and if you choose not to take part, this will not affect any subsequent clinical care you may require. You may withdraw from the study at any stage, **without giving a reason** and this will in no way affect your continuing health care.

During the study we will be monitoring the data being collected. You will be told of any new information about adverse or beneficial effects related to the study that becomes available during the study that may have an impact on your health. Again, you may withdraw from the study **at any stage**.

Your participation in this study is confidential and no material which could identify you will be used in any reports and/or publications on this study. Any information and data collected will be kept confidential and stored in a secure place within the Department of General Surgery, Auckland City Hospital, accessible only by those involved in the study.

You have the right to access information about them collected as part of the study. At the conclusion of the study the results can be discussed with you and we can also provide you with a written summary of the study at your request. The results of the study will also be published in a medical journal. At no time would there be any information about you as an individual be released.

WHAT HAPPENS AFTER THE STUDY OR IF I CHANGE MY MIND?

If you change your mind you may withdraw from the study at any stage, without giving a reason and this will in no way affect your continuing health care.

After the study, the results can be discussed with you and we can also provide you with a written summary of the study at your request.

WHO DO I CONTACT FOR MORE INFORMATION OR IF I HAVE CONCERNS?

If you have any questions, concerns/complaints about the study at any stage, you can contact:

Name: Dr Alex Jacobson, Surgical Registrar
Email: AlexJ@adhb.govt.nz
Phone: 09 307 4949 ext. 22787

If you want to talk to someone who isn't involved with the study, you can contact an independent health and disability advocate on:

Phone: 0800 555 050
Fax: 0800 2 SUPPORT (0800 2787 7678)
Email: advocacy@hdc.org.nz

You can also contact the health and disability ethics committee (HDEC) that approved this study on:

Phone: 0800 4 ETHICS
Email: hdecs@moh.govt.nz

Consent Form

If you need an INTERPRETER, please tell us.
If you are unable to provide interpreters for the study, please clearly state this in the Participant Information Sheet

I have read, or have had read to me in my first language, and I understand the Participant Information Sheet.
I have been given sufficient time to consider whether or not to participate in this study.
I have had the opportunity to use a legal representative, whanau/ family support or a friend to help me ask questions and understand the study.
I am satisfied with the answers I have been given regarding the study and I have a copy of this consent form and information sheet.
I understand that taking part in this study is voluntary (my choice) and that I may withdraw from the study at any time without this affecting my medical care.
I consent to the research staff collecting and processing my information, including information about my health.
If I decide to withdraw from the study, I agree that the information collected about me up to the point when I withdraw may continue to be processed.
I consent to my GP or current provider being informed about my participation in the study and of any significant abnormal results obtained during the study.
I agree to an approved auditor appointed by the New Zealand Health and Disability Ethic Committees, or any relevant regulatory authority or their approved representative reviewing my relevant medical records for the sole purpose of checking the accuracy of the information recorded for the study.
I understand that my participation in this study is confidential and that no material, which could identify me personally, will be used in any reports on this study.
I understand the compensation provisions in case of injury during the study.

I know who to contact if I have any questions about the study in general.
I understand my responsibilities as a study participant.
I wish to receive a summary of the results from the study. (Please circle) **Yes** **No**

Declaration by participant:

I hereby consent to take part in this study.

Participant's name: _____

Signature: _____ Date: _____

Declaration by member of research team:

I have given a verbal explanation of the research project to the participant, and have answered the participant's questions about it.

I believe that the participant understands the study and has given informed consent to participate.

Researcher's name: _____

Signature: _____ Date: _____