An Audit of Savi Scout ® Radar localisation for non-palpable breast lesions

PARTICIPANT CONSENT FORM

I,.....*[full name]*

of.....*[address]*

have read and understood the Participant Information Sheet, and hereby agree to participate in the study described and give my consent to the collection of any data that is relevant and required for the purpose of the study from my medical records.

- I have been made aware of why I have been selected, the aims and procedure of the study including how my data would be securely stored, de-identified (De-identified data means that you/your information will not be identifiable) and kept confidential, and, if any, the possible risks of the study. The information sheet has also been explained to me to my satisfaction.

- Before signing this consent form, I have been given the opportunity to ask any questions relating to any possible physical and mental harm I might suffer as a result of my participation, and I have received satisfactory answers.

- I understand that I can withdraw from the study at any time without prejudice to my relationship with the cancer specialists at Chris O'Brien Lifehouse and any other clinicians caring for me.

- I agree that research data gathered from the results of the study may be published, provided that I cannot be identified.

- I understand that if I have any questions relating to my participation in this research, I may contact A/Prof Cindy Mak who will be happy to answer them.

- I also understand that the research study is strictly confidential.

- I would like to receive a lay summary of the results of the findings once they become available. My email address is: _____

- I acknowledge receipt of a copy of this consent form and the participant information sheet.

Complaints may be directed to the Chris O'Brien Lifehouse Research Governance Executive Officer on 02 9515 6766 and quote protocol number X23-0162.

Participant Name:_____

Participant Signature:_____

Date:_____

Name of Person conducting informed consent:_____

Signature of Person conducting informed consent: _____

Date:_____

An Audit of Savi Scout ® Radar localisation for non-palpable breast lesions
Data Custodian: A/Prof Cindy Mak

PARTICIPANT INFORMATION SHEET - DATABASE

Title	*An Audit of Savi Scout ® Radar localization for non-palpable breast lesions*
Short Title	*Savi Scout ® Audit*
Protocol Number	X23-0162
Project Sponsor	Chris O'Brien Lifehouse
Coordinating Principal Investigator/ Principal Investigator	Dr. Farhad Azimi
Associate Investigator(s)	A/Prof Cindy Mak, A/Prof Sanjay Warrier, Dr. Belinda Chan, Dr. Susannah Graham
Location	Chris O'Brien Lifehouse

1. Introduction

You are invited to contribute your health information to a database of patients receiving medical treatment for non-palpable breast tumours at the Chris O'Brien Lifehouse.

It is hoped that researchers will use the information collected in this database to help better understand the feasibility and safety of widespread use of the Savi Scout ® System as a device to locate breast tumours.

The database is being established and overseen within this institution by:
- A/Prof Cindy Mak, Head of Breast Surgery, Chris O'Brien Lifehouse
- Dr. Farhad Azimi, Breast Surgeon, Chris O'Brien Lifehouse
- A/Prof Sanjay Warrier, Breast Surgeon, Chris O'Brien Lifehouse
- Dr. Belinda Chan, Breast Surgeon, Chris O'Brien Lifehouse
- Dr. Susannah Graham, Breast Surgeon, Chris O'Brien Lifehouse

The database is part of a national / international collaboration coordinated by researchers from the United Kingdom as part of the iBRAnet Study Group.

In addition to the researchers named above, RuYu (Ruth) Li (Medical Student) would be conducting the study to contribute to the requirements of Doctor of Medicine (University of Sydney) under the supervision of Dr Farhad Azimi.

You and the study sponsor will not benefit financially or commercially from the results of the data.

2. Participating in this study

If you agree to contribute to this database, you will not be required to do anything other than sign the Patient Consent Form. Relevant information will then be obtained from your medical record and stored in the database. This will include simple demographic, surgical procedure and process data such as your age and BMI (body mass index), pre-surgical imaging details, pre-surgical medical treatment (if any), location of the scout device, type and length of surgery, laboratory analysis results of your tumour and any post-surgical side effects that may arise.

3. Data storage, Confidentiality, Length of Data storage / Data destruction

All data collected from you for the study will be treated confidentially and will be stored on an online secure password protected research database (REDCap) at the University of Manchester. In the database, your health information will be de-identified with a unique alphanumeric study identification code to protect your privacy. De-identified data means that you/your information will not be identifiable. Your name will be recorded in connection with this code on a code sheet which would be kept only at Chris O'Brien Lifehouse and not be shared. Only the de-identified information linked to your ID code are stored in the shared database.

Your data will not be disclosed, transferred, or made available to any third party and only A/Prof Cindy Mak (the database custodian), the researchers named above, and authorised members of the iBRA-net study management team who will be analysing your data at the University of Manchester will have access to your data.

The study results may be presented at a conference or published in a scientific journal in which you would be notified and be acknowledged, in oral, visual or written form, as the source of data set. All data for use in such circumstances would likewise be de-identified.

Your data will be stored in this database for 15 years from the day the study is completed. Once the retention expires, the files will be disposed of securely.

4. Benefits

While we intend this database to be used to further medical knowledge and to improve treatment of breast cancer in the future, it may not be of direct benefit to you.

5. Costs

Contributing to this database will not cost you anything, nor will you be paid.

6. Voluntary Participation

Contributing to this database is entirely voluntary. You do not have to do so. If you do, you can withdraw your health information at any time without having to give a reason. Regardless of your decision, you can be assured that it will not affect your medical treatment or your relationship with the staff who are caring for you.

7. Withdrawal Process

If you decide to withdraw from this research project, you will need to notify a member of the research team (details listed under further information section below) and you will need to complete the withdrawal form. Thereafter, the research team will not collect additional health information about you. However, data collected up until the time you withdraw may be included in the study to ensure that the results of the research project can be measured properly. If you do not want them to do this, you must tell the researchers at the time of your withdrawal.

8. Future use of Data

The data collected in this project will not be shared for future use in other studies.

9. Further Information

When you have read this information, A/Prof Cindy Mak will discuss it with you further and answer any questions you may have. If you would like to know more at any stage, please feel free to contact them on 8514 0255.

If you would like to receive a lay summary of the findings once it becomes available, please provide your email address in the Consent Form.

10. Ethics Approval and Complaints

The establishment of this database has been approved by the Ethics Review Committee (RPAH Zone) of the Sydney Local Health District. Any person with concerns or complaints about it should contact the Executive Officer on 02 9515 6766 and quote protocol number X23-0162.

This information sheet is for you to keep.