Research Imaging NSW

Level 1, Building 3
Prince of Wales Hospital
Barker Street, Randwick NSW 2031

PARTICIPANT INFORMATION STATEMENT AND CONSENT FORM
Quality control and staff training for Magnetic Resonance Imaging
Professor Claudia Hillenbrand
HC200919

1. What is the project about?

You are invited to participate in a research study looking to develop novel Magnetic Resonance Imaging (MRI) methods and techniques, or in activities related to staff training and quality assurance for an MRI scanner at 'Research Imaging NSW', which is a University of New South Wales (UNSW) facility located at Prince of Wales Hospital (POWH). The scanner is used both for clinical and research purposes.

We hope to develop new methods and protocols so that they may be used by researchers for novel research applications in the future, or for better clinical care. Your participation is also assisting us in training staff in the use of novel MRI methods and imaging protocols. Examples for new developments are:

- Methods that speed up how long it takes to have a scan taken or improve the overall image quality; for example, to make images of moving organs such as the heart less blurry.
- Techniques that allow us to see different biological processes (e.g., signals and chemicals in the brain, blood flow, organ stiffness).
- Integration of different medical devices to be used together with the MRI, such as EEG to simultaneously measure brain waves.

You have been invited because you have no medical conditions that would prevent you from undergoing MRI scanning.

2. Who is conducting this project?

The project is being carried out by:

- Professor Claudia Hillenbrand, Director Research Imaging NSW
- Dr Ralf Loeffler, MR Physicist, Research Imaging NSW
- Professor Daniel Moses, Radiologist, Medical Director Research Imaging NSW & Director, Medical Imaging Department, Prince of Wales Hospital
- Dr Jiyang Jiang, Senior Research Fellow, Research Imaging NSW
- Dr Hannes Almgren, Senior Research Associate, Research Imaging NSW
- Dr Mihee Shin, Research Officer, Research Imaging NSW
- Ms Siuly Liao, Senior Research Radiographer, Research Imaging NSW & Medical Imaging Department, Prince of Wales Hospital
- Mr Simon Pilgrim, Senior Radiographer, Research Imaging NSW & Medical Imaging Department, Prince of Wales Hospital
- Mr Nicholas Tranter, Radiographer, Research Imaging NSW & Medical Imaging Department, Prince of Wales Hospital
- Mr Mathew Lynar, Radiographer, Research Imaging NSW & Medical Imaging Department, Prince of Wales Hospital
- Ms Grainne McGread, Radiographer, Research Imaging NSW & Medical Imaging Department, Prince of Wales Hospital

3. Inclusion/Exclusion Criteria

Before you decide to participate in this project, we need to ensure that it is permissible for you to take part. The project is looking to recruit people who meet the following criteria:

- Adults aged 18-65 (women and men)
- Have no medical conditions or implanted devices (e.g., no pacemaker, metal pins or implants etc.) that would preclude undergoing MRI scanning.
- Fluent in English and capable of providing written-informed consent.

4. Do I have to take part in this project?

Participation in this project is voluntary. If you do not want to take part then you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at any stage.

If you decide you want to take part in the project, you will be asked to:

- Read this information carefully;
- When you meet us at the facility for your scan, ask us any questions if necessary;
- If you would still like to participate, sign the consent form and nominate a medical practitioner who we can contact if we have to;
- Take a copy of this form home with you to keep.

Your decision not to participate or to withdraw from the study will not affect your relationship with UNSW Sydney, Professor Claudia Hillenbrand, the Prince of Wales Hospital or the South East Sydney Local Health District.

5. What does participation in this project require, and are there any risks involved?

An MRI scanner is a machine that uses electromagnetic radiation (radio waves) in a strong magnetic field to take clear pictures of the inside of the body. Electromagnetic radiation is not the same as ionising radiation used, for example, in X-rays. The pictures taken by the machine are called MRI scans. This is a non-invasive, painless procedure, which involves you lying inside the MRI scanner. MRI equipment has been in routine clinical use for over four decades and is approved by the Australian Therapeutic Goods Administration for this purpose.

If you agree to participate in this study, please note the following:

Preparation for your Scan

Please read this Participant Information Statement and Consent Form, but do not sign it until you have spoken with us.

Please read the MRI safety screening form carefully and fill in the information whenever you are able.

For two to three hours before your appointment, avoid drinking coffee and other diuretics that may require you to urinate often.

In rare cases, certain types of eye makeup (especially eye liners) may cause problems with the MR images. You may wish to come without makeup to avoid having to remove it for the scan.

Bring only the minimum number of jewelry items (watches, rings, earrings, etc.), as all of these must be removed prior to scanning.

Logistics and Requirements

Come to Research Imaging NSW (Level 1, Building 3, Prince of Wales Hospital, Barker St, Randwick) for an Magnetic Resonance Imaging (MRI) scan.

At the facility you will be screened using the MRI safety screening for contraindications to scanning, such as the presence of a pacemaker, metal pins or shards (e.g. from shrapnel or association with metal work) or other metal implants. Your suitability for scanning will be independently confirmed by the operators of Research Imaging NSW.

Due to the powerful magnetic field, you must not bring any metal into the scanner room. We will therefore ask you to change into a clean hospital gown that we will provide you with.

We will then ask you to lie down on a motorised bed, which will move you into the open chamber

inside the MR scanner.

Once scanning starts, the machine will record information on one or more of your body regions. These could be your head, neck, arms, legs or torso. You will be advised of the body region when organising your scan. The scan may or may not involve a visual component such as watching a video or presentation on a screen while in the scanner. Also, we may record several of your physiological signals (e.g., your heartbeat, respiratory motion, blood oxygen content).

The visit will take approximately 1-1.5 hours to complete, of which up to one hour will be spent inside the MRI scanner. The duration depends on factors including the selected scanning protocol, specific body region and tissue type, and the number of regions scanned. We will advise you of the likely time before you enter the scanner.

The scans are taken for optimisation, testing and development of MR methods and protocols and are for research purposes only. They are not comparable to clinical examinations. The scans cannot be used to diagnose, treat or manage a particular medical condition. You will not be provided a copy of your scan.

Following your scan, you may be asked if we can contact you again to have an MRI scan at a later time. If you would not want to do so, you will not be contacted again. If you agree to volunteer again, you would not be invited to have more than four (4) MRI scans in any one year and may refuse any or all requests without providing a reason. Because MRI has no radiation or X-Rays, MRI scans could be scheduled on consecutive days.

Discomfort and Potential Risks

It is important that you keep very still during the scanning. We will make sure you are in a comfortable position so that you can keep still.

The width of the chamber is 60 or 70 cm, and some people may experience symptoms of claustrophobia from lying in a confined space. If you do experience discomfort at any time during the scan, you will be able to alert staff by pressing a call button provided to you.

The scanner is very noisy, and we will give you either earplugs or headphones to reduce the noise.

The scan can be stopped at any time for any reason (you will be given a call button to hold for this purpose), and you are free to stop the scan and withdraw from the study at any time with no ill consequence.

There are no proven long-term risks related to 3T MRI scans. The technique of magnetic resonance imaging has been shown to be safe and painless in other studies.

Metal and other conductive material pose danger to MRI, it is therefore very important that you fill out the screening form truthfully and completely (e.g., reporting any surgery, injury. implanted devices, or relevant medical condition) to avoid potential injury or burns.

MRI is most commonly used in diagnosing human diseases and may find an unusual feature or unexpected pathology that is a significant risk to your health. A specialist doctor (radiologist) in the Medical Imaging Department, Prince of Wales Hospital, will review the scans collected from you to check for any unusual features. If there is an unusual feature that may affect your health, the radiologist will report this to your medical practitioner. Your nominated medical practitioner will then be responsible for discussing any unusual findings with you. We cannot guarantee that we will find any/all unusual features as the quality and/or number of images may be not sufficient for diagnosis.

If your nominated medical practitioner cannot be reached or if they are unable to contact you, RINSW will locate an alternative registered and qualified medical practitioner to discuss the finding with you.

It is recommended that you consider any contractual duties that may require you to share your health-related information to a third party (e.g. health insurer, employer).

If you experience discomfort or feelings of distress while participating in the project and you require support, you can stop participating at any time. You can also tell a member of the team and they will provide you with assistance immediately.

If you suffer a medical emergency while in the magnet, team members will remove you immediately from the magnet, transport you to the control area and attend to you. They will decide to call the code blue team depending on severity of the situation.

6. What are the possible benefits to participation?

Your participation is assisting us in training staff in the use of the MRI scanner and in calibrating standard MRI scanning protocols to verify their robustness, reproducibility and reliability as part of quality assurance processes.
There will be no clear benefit to you from your participation.

7. What will happen to information about me?

By signing the consent form you consent to the team collecting and using information about you for this project. Your information will be used to schedule your MRI scan and the scans obtained will be used for quality assurance purposes to ensure the scanner is operating successfully. Your identified information will be used to inform your GP if your images show any potentially significant health findings. We may review your data to see whether it can be used for other research purposes. In this case, your data may be shared with other researchers, but only with all of your identifying information removed.

We will store your information in the Prince of Wales Hospital picture archive and communication system (PACS) in the same way as the hospital would for a patient receiving an MRI scan. That means the information will become part of your medical record with NSW Health. As part of your medical record, it will be stored in an identifiable format and will be kept for a minimum of 7 years. However, it is accessible only to medical professionals involved in your care in the same way as any other part of your medical record. That means medical professionals treating you in the future may be able to access the scans we are collecting, if they are relevant to a condition that they are treating you for. It will also be sent to My Health Record unless you have opted out of that system. Further storage can also be undertaken for deidentified data only through the secure RINSW data archive.

The information you provide is personal information for the purposes of the Privacy and Personal Information Protection Act 1998 (NSW). You have the right of access to personal information held about you by the University, the right to request correction and amendment of it, and the right to make a complaint about a breach of the Information Protection Principles as contained in the PPIP Act. Further information on how the University protects personal information is available in the **UNSW Privacy Management Plan** (https://www.legal.unsw.edu.au/compliance/privacyhome.html).

8. How and when will I find out what the results of the project are?

The team intends to use the results of the project as part of a quality assurance process. The results of the project will likely not be published or made available to you.

9. What if I want to withdraw from the project?

If you do consent to participate, you may withdraw at any time. You can do so by completing the 'Withdrawal of Consent Form' which is provided at the end of this document. Alternatively you can ring the team and tell them you no longer want to participate. Your decision not to participate or to withdraw from the study will not affect your relationship with UNSW Sydney, Prince of Wales Hospital or the South Eastern Sydney Local Health District.

10. What should I do if I have further questions about my involvement in the project?

If you experience distress or have an adverse event after completion of the study, please call 000 immediately and subsequently inform the project team at the number provided below.
If you require further information regarding this project or if you have any problems which may be related to your involvement in the project, you can contact the following member of the team.

Project Team Contact Details

Name	Professor Claudia Hillenbrand
Position	Director, Research Imaging NSW, UNSW
Telephone	+61 2 9065 3788
Email	claudia.hillenbrand@unsw.edu.au

11. Support Services Contact Details

If at any stage during your participation, you become distressed or require additional support from someone not involved in the project please contact:

Name/Organisation	UNSW HREC
Email	humanethics@unsw.edu.au

If you have any complaints or concerns about this study please email:

Name/Organisation	Tamer Kilani, UNSW Sydney
Position	Manager, Complaints Resolution
Email	complaints@unsw.edu.au

For any non-emergency health issues please contact your GP or the below GP hotline or mental health service:

Name/Organisation	Health Direct
Telephone	1800 022 222

Name/Organisation	Lifeline
Telephone	13 11 14

Consent Form – Participant providing own consent

Declaration by the participant

- ☐ I understand I am being asked to provide consent to participate in this project;
- ☐ I have read the Participant Information Sheet or someone has read it to me in a language that I understand;
- ☐ I understand the purposes, project tasks and risks of the project described;
- ☐ 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 project as described and understand that I am free to withdraw at any time during the project and withdrawal will not affect my relationship with any of the named organisations and/or team members;
- ☐ I provide my consent for the information collected about me to be used for the purpose of this project only;
- ☐ I agree to nominate a medical practitioner who can be contacted in case of any incidental findings:

  Name of Nominated Medical Practitioner: _____

  Medical Practitioner's Address: _____

  Medical Practitioner's Phone Number: _____

- ☐ I would be interested in receiving information via email about future potential research studies. I understand that this would involve information only and would not oblige me to take part in these studies. I understand that this information would be limited to two potential studies per year, I have provided my details below and ask that they be used for this purpose *(Provide contact details below)*.

  Name: _____

  Address: _____

  Email Address: _____

- ☐ **Optional:** I provide consent to share my de-idenfied data with 3rd parties for research and development.

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

Participant Signature

Name of Participant (please print)	
Signature of Participant	
Date	

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Declaration by person obtaining consent*

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

Person obtaining consent's signature*

Name (please print)	
Signature	
Date	

***An appropriately qualified member of the team must provide the explanation of, and information concerning the project.**

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

Form for Withdrawal of Participation

I wish to **WITHDRAW** my consent to participate in this project described above and understand that such withdrawal **WILL NOT** affect my relationship with The University of New South Wales, Prince of Wales Hospital, or the South Eastern Sydney Local Health District. In withdrawing my consent. I understand that any information collected about me during my participation that has been de-identified cannot be withdrawn.

Participant Signature

Name of Participant (please print)	
Signature of Participant	
Date	

The section for Withdrawal of Participation should be forwarded to:

CI Name:	Professor Claudia Hillenbrand
Email:	Claudia.hillenbrand@unsw.edu.au
Phone:	+61 2 9065 3788
Postal Address:	Research Imaging NSW Level 1, Building 3, Prince of Wales Hospital, Barker St, Randwick, NSW 2033