**Consent Form**

Auckland Bioengineering Institute

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Lead researcher: Dr Gonzalo Maso Talou

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Ethics committee ref: **XXX**

The Hemodynamic Encephalopathy Risk Study (The “HER” Study)

Using Advanced MRI Biomarkers to Stratify Cerebrovascular Sex Differences Associated with Brain Damage and Dementia.

University of Auckland Bioengineering Institute and Faculty of Medical and Health Sciences,
Mātai Medical Research Institute, Gisborne



THIS CONSENT FORM WILL BE HELD FOR A PERIOD OF TEN YEARS

**Principal Investigators:** Senior Research Fellow Dr Gonzalo Maso Talou

**Associate Investigators:** Mr Sergio Dempsey, Dr Kelly Burrowes, Dr James Fisher

I have read or had it explained to me in a way I can understand the Participant Information Sheet, understood the nature of the research and my role as a participant. I have had the opportunity to discuss my concerns (if any) with the study investigators or a Māori representative and have had them answered to my satisfaction.

* I have been given sufficient time to consider this study and I know whom to contact if I have any questions or concerns (More contact information on participant information sheet).
* I understand that taking part in this study is voluntary (my choice), that I am free to withdraw from the study at any time without giving a reason, and that I may request a copy of my data and results at the study conclusion.
* I understand that I will visit the imaging research institute twice to complete a familiarisation visit for 45minutes, and a second scanning and collection visit for ~2.5hrs.
* I understand that during the second visit, I will be donating blood for analysis, and that any remaining blood can be returned to me if I request it.
* I understand that no karakia will be performed during the destruction of my blood after it has been processed if I do not request it be returned.
* I understand that it is possible that the scan and or gas inhalation could make me feel anxious. Investigators will be available to discuss any concerns and I will practice the scan beforehand with a researcher. The investigators cannot, however, provide me with in-depth professional counselling.
* I understand I will need to bring my general practitioner (GP) details and NHI number (if known) to the MRI scan – for incidental finding communication.
* I understand that the data will be kept for a period of ten years after which it will be purged by Gonzalo Maso Talou (or delegate) or converted to completely anonymous data for secondary research beyond 10 years if I consent.
* I understand that I can withdraw my data at any time but any publication of my results prior to my withdrawal will not be amended.
* 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 or presentations on this study. I understand my name will appear only on this form and only used for incidental findings or communication I approve.
* I understand the data used in this research is de-identified, coded by number, and only available to the study investigators who are mentioned above for the study purposes stated in the Participant Information Sheet.
* I understand that data acquired will be used in publications, such as PhD theses, journal papers, and conference presentations.
* I understand that I can speak to a Māori representative at any stage during the study (Contact information in participant information sheet).
* I understand that I will be eligible for petrol reimbursement ($25 voucher per visit) for travel. Otherwise, I understand that I will have a taxi service provided free of charge if other transport cannot be arranged.
* I understand that I will be eligible for reimbursement ($100 voucher) for my participation in this study.

*Please circle:*

* I **wish / do not wish** to receive an electronic copy of my MRI and ultrasound scan.
* I **wish / do not wish** to receive any potentially significant, but non-actionable incidental findings or study results.
* I **wish / do not wish** to receive a copy of the overall study results/communication when they become available.
* **I wish / do not wish** to receive communication if a follow up study is done in the future that would benefit from my participation.

I can be emailed at this address: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

* **I can / cannot be** called instead of emailed, at the phone number provided in the declaration for any communication purposes.

Secondary research:

* I understand that my anonymised data can benefit secondary research (by the researchers on this study, or by different researchers). If I am happy for my anonymised data to be used in secondary research or by different researchers, then I have ticked the box below.

□ I **DO** give permission for my anonymised data to be used for secondary research by different researchers.

*Please circle:*

* I **wish / do not wish** to receive communication of any secondary research talks or publications using my anonymised data.

**Declaration by participant:**

I hereby consent to take part in this study.

Participant’s name:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Participant’s phone number:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Participants GP and Medical Practice:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Signature: \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ \_ Date:\_\_\_\_\_\_\_\_\_\_\_\_\_\_

Participant Number (Researcher use only): \_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_

**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:\_\_\_\_\_\_\_\_\_\_\_\_ \_\_\_\_\_\_\_\_\_\_\_