Participant Consent Form
A randomised trial of krill oil for osteoarthritis of the knee

1. I acknowledge that I have received, read and understood the Information Sheet provided that explains this study to me and what is required of me if I choose to participate in this study.
2. The details of the procedure proposed have been explained to me, including how long it will take, how often procedures will be performed, and an indication of any discomfort which may be expected. I understand that my involvement means:
   - An Xray at screening;
   - An MRI scan at screening and 6 months;
   - Collection of a small amount of blood (approximately 9 ml) at screening and after 3 and 6 months, to be taken by a qualified venepuncturist. This is to assess lipids (fats) and markers of inflammation. Some of this will be analysed straight away and the rest of the sample will be stored for analysis of inflammatory markers;
   - Taking ~~a~~ krill oil or placebo tablets each day for 6 months;
   - Answering questions about knee pain and function, quality of life, health and wellbeing, medication use and side effects, and use of health services. Some of these questions will be asked only once, and others monthly;
   - Measurement of height, weight and physical measures (eg leg strength);
   - Researchers accessing health information from the following databases or sources for the period 01 Jan 2016 to 31 December 2020:
     Medicare and Pharmaceutical Benefits Scheme (PBS) datasets, the National Death Index, the National Joint Replacement Registry, and state-based hospital emergency databases and hospital inpatient databases, and other health datasets.
3. I understand that there are the following risks or possible discomfort:
   - Having blood taken causes minimal risk, but there may be a chance of discomfort and bruising;
   - Xrays involve a small amount of ionising radiation;
   - I understand that MRI scans may be claustrophobic, but are otherwise considered safe.
   - Krill oil is considered a very safe treatment. Krill oil may reduce insulin sensitivity, but whether this is by a large enough amount to worsen glucose control in people with impaired glucose tolerance / diabetes is not yet clear.

Sometimes, changes in blood lipids and inflammatory markers occur, but we expect these to improve rather than become worse.

4. I have been informed that if my MRI scan shows effusion or synovitis (fluid in the knee or swelling of the synovial membrane), I will be asked to continue in the study. If my MRI scan does not show this I will not be asked to continue with the study.

By signing this form, I acknowledge that:

- I have received, read and understood the Information Sheet provided that explains this study to me and what is required of me if I choose to participate in this study.

- I understand that the purpose of this research project is to improve the quality of medical care, and that my involvement may not be of any benefit to me.

- I have been given the opportunity to have a member of my family or friend present while the project was explained to me.

- I understand that no identifying information regarding any medical history will be divulged and the results of any tests involving me will not be published so as to reveal my identity.

- I understand that my involvement in the project will not affect my relationship with my medical advisers in their management of my health.

- I also understand that I am free to withdraw from the project at any stage and any of my data/specimens that have been collected. My withdrawal will not affect my legal rights, my medical care or my relationship with the hospital or my doctors.

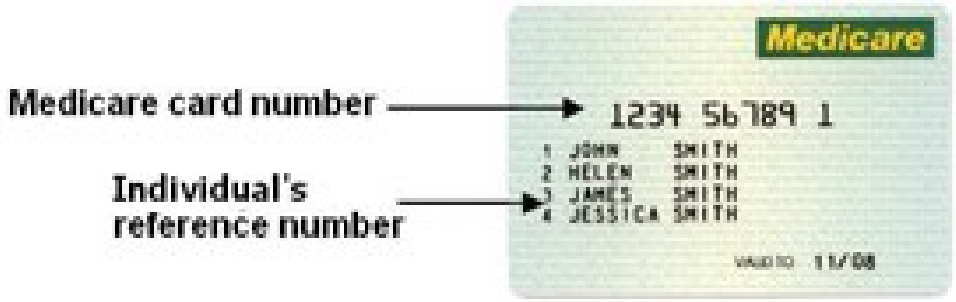
- I will be given a signed copy of this patient information sheet and consent form. I am not giving up my legal rights by signing this consent form.

- I understand that the trial will be conducted in accordance with the latest versions of the *National Statement on Ethical Conduct in Human Research 2007* and applicable privacy laws.

To consent to participate in the krill oil study, please sign at the bottom of the page, and fill in your Medicare number below:

☐☐☐☐ ☐☐☐☐☐ ☐

Your reference number (see picture below): ☐



CONSENT

Name of participant _____

Signature of participant _____ Date _____

The following section regarding the witness is not essential but may be appropriate for patients where the research teams feel that the participant should have a witness to the consent procedure or where the protocol insists upon witnesses.

Name of witness (if appropriate) _____

Signature of witness _____ Date _____

I have explained this project and the implications of participation in it to this volunteer and I believe that the consent is informed and that he/she understands the implications of participation.

Name of investigator _____

Signature of investigator _____ Date _____

The following is provided by the Department of Human Services and gives an example of what is collected by Medicare and the PBS.

This is for your information only.

APP 5 - DEPARTMENT OF HUMAN SERVICES PRIVACY NOTICE

Your personal information is protected by law, including the Privacy Act 1988, and is collected by the Australian Government Department of Human Services. The collection of your personal information by the department is necessary for administering requests for statistical and other data.

Your information may be used by the department or given to other parties for the purposes of research, investigation or where you have agreed or it is required or authorised by law.

You can get more information about the way in which the Department of Human Services will manage your personal information, including our privacy policy at humanservices.gov.au/privacy or by requesting a copy from the department.

A sample of the information that may be included in your Medicare claims history:

Date of service	Item number	Item description	Provider charge	Schedule Fee	Benefit paid	Patient out of pocket	Bill type
20/04/09	00023	Level B consultation	$38.30	$34.30	$34.30	$4.00	Cash
22/06/09	11700	ECG	$29.50	$29.50	$29.50		Bulk Bill

Scrambled ordering Provider number*	Scrambled rendering Provider number*	Date of referral	Rendering Provider postcode	Ordering Provider postcode	Hospital indicator	Item category
	999999A		2300		N	1
999999A	999999A	20/04/09	2300	2302	N	2

Scrambled Provider number refers to a unique scrambled provider number identifying the doctor who provided/referred the service. Generally, each individual provider number will be scrambled and the identity of that provider will not be disclosed.

A sample of the information that may be included in your PBS claims history:

Date of supply	Date prescribed	PBS item code	Item description	Patient category	Patient contribution (this includes under copayment amounts**)	Net Benefit (this includes under copayment amounts**)	Scrambled Prescriber number*	Pharmacy postcode
06/03/09	01/03/09	03133X	Oxazepam Tablet 30 mg	Concessional Ordinary	$5.30	$25.55	9999999	2560
04/07/09	28/05/09	03161J	Diazepam Tablet 2 mg	General Ordinary	$30.85		9999999	2530

Form Category	*ATC Code*	*ATC Name*
Original	*N05 B A 04*	*Oxazepam*
Repeat	*N05 B A 01*	*Diazepam*

* Scrambled Prescriber number refers to a unique scrambled prescriber number identifying the doctor who prescribed the prescription. Generally, each individual prescriber number will be scrambled and the identity of that prescriber will not be disclosed.

** Under co-payments can now be provided for data after 1 June 2012.