Participant Information Sheet

Study title: CHHIM Study - Therapeutic Hookworm Phenotyping Study

Locality: Wellington, New Zealand **Ethics committee ref:** 19/CEN/81

Lead investigator: Stephen Inns **Contact phone number:** 04 4996914
(Mali Camberis/Brittany Lewer/Sophia Noble)

You are invited to take part in a study which aims to establish a controlled human hookworm model. 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.

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 10 pages long, including the Consent Form. Please make sure you have read and understood all the pages.

WHAT IS THE PURPOSE OF THE STUDY?

It is thought that the loss of gut parasites (i.e. hookworms) from humans may be partially at fault for the increase in inflammatory and atopic autoimmune diseases. People who come from developed; Westernised countries experience less parasitic diseases (i.e. hookworm infection) but have higher rates of inflammatory and autoimmune disease.

Hookworms can alter the immune system of their human host to help them survive. They do this by producing compounds that dampen down the immune system. This allows the hookworm to be tolerated by the human host but leaves the immune system strong enough to be able to protect the human host against other diseases. Because of the effect hookworms have on the immune system it is thought they could be used to treat several

inflammatory and autoimmune diseases such as coeliac disease, asthma, multiple sclerosis and inflammatory bowel disease.
The aim of our research is to establish a controlled human hookworm model to ensure a reliable source of hookworms for future studies. We also plan to investigate the effects human hookworms have on a person's immune system and gut bacteria composition and function.

This study is being funded by the Health Research Council. The principal investigator is Dr Stephen Inns, University of Otago, Wellington (email address: hookworm@malaghan.org.nz). This study has been approved by the Health and Disability Ethics Committee (19/CEN/81).

WHAT WILL MY PARTICIPATION IN THE STUDY INVOLVE?

You have been invited to take part in this study. If you choose to participate in the study, you will be asked to attend ten study visits - see participant schedule on page 5. The visits will be at the Malaghan Institute of Medical Research in Wellington with one visit at the Rutherford Clinic in Lower Hutt.

Visit 1
At the initial study visit your eligibility to participate in the study will be assessed.

The following assessment will be performed:

- Eligibility questionnaire.
- Full physical exam.
- Blood sample taken for testing.

You will also be given instructions on how to:

- Collect a stool/poo sample.
- Record your dietary intake using a three-day diet record.

This initial study visit will take around 60 minutes.

Visit 2 (week 0)
If you are eligible you will be invited to attend the 2nd study visit.

At this study visit:

- The dose of hookworms will be administered via your skin by an experienced researcher.
- You will swallow a vitamin sized "Smart pill" to assess your gut function.
- Have a blood sample taken.
- Collect a stool/poo sample.
- Bring a completed three-day diet record.
- Have a photograph of your forearm taken to check for skin irritation.

This study visit will take around 60 minutes.

Visit 3 (week 4)

At this study visit you will:

- Have a blood sample taken.
- Collect a stool/poo sample.
- Bring a completed three-day diet record.
- Have a photograph of your forearm taken to monitor for skin irritation.
- Complete a symptom questionnaire.

This study visit will take around 30 minutes.

Visit 4 (Week 6)

- Collect a stool/poo sample.
- You will swallow a vitamin sized “Smart pill” to assess your gut function.
- Complete a symptom questionnaire.

This study visit will take around 30 minutes.

Visit 5 (week 8)

This study visit involves the same procedures as **visit 3**

This study visit will take around 30 minutes.

Week 10 (No visit)

- Collect a stool/poo sample.
- Complete a symptom questionnaire.

Visit 6 (week 12)

At this study visit:

- Have a blood sample taken.
- Collect a stool/poo sample.
- You will swallow a vitamin sized “Smart pill” to assess your gut function.
- Bring a completed three-day diet record.
- Complete a symptom questionnaire.
- Have a photograph of your forearm take to monitor for skin irritation

This study visit will take around 30 minutes.

Visit 7 (week 20)

At this study visit you will:

- Be asked to swallow a vitamin sized capsule-encased camera.

This study visit will take place at The Rutherford Clinic.

Week 32 (No visit)

- Complete a symptom questionnaire.

Visits 8 and 9 (week 24 and 36)

At this study visit you will:

- Have a blood sample taken.
- Collect a stool/poo sample.
- Bring a completed three-day diet record.

This study visit will take around 30 minutes.

Visit 10 (week 48)

This study visit involves the same procedures as **visit 6** without having to complete the symptom questionnaire.

This study visit will take around 30 minutes.

All study visits can be arranged at a time that is suitable for you.

You will also need to collect stool/poo samples at home as not all stool/poo collections will coincide with a study visit. For these stool/poo collections you will be provided with instructions and a stool/poo collection kit. Once the stool/poo sample has been collected the sample can be dropped off to the Malaghan Institute of Medical Research. Also, you will need to take photographs of your forearm each week from week 0 to 7 and a Symptom questionnaire from week 1 to 12. On the weeks that you don't have a study visit you will need to email the photographs and Symptom questionnaires to the research team to review.

Participant schedule	Week																						
	Pre	0	1	2	3	4	5	6	7	8	9	10	11	12	16	20	24	28	32	36	40	44	48	52
Eligibility Visit	X																							
Study visit		X				X		X		X				X		X	X			X			X	
Informed consent	X																							
Eligibility questionnaire	X																							
Demographic data	X																							
Medical history	X																							
Full-physical examination	X																							
Hookworm administration		X																						
Stool/poo sample (for egg count)		X						X		X		X		X										
"Smartpill"		X						X						X									X	
Capsule-encased camera																X								
Blood sample	X	X				X				X				X			X			X			X	
Skin photograph		X	X	X	X	X	X	X	X	X														
Stool/poo sample (microbiota)		X				X				X				X			X			X			X	
Stool/poo sample (hookworm collection)														X	X	X	X	X	X	X	X	X	X	X
Symptom questionnaire			X	X	X	X	X	X	X	X	X	X	X	X					X					X
Three-day diet record		X				X				X				X			X			X			X	

5

WHAT ARE THE POSSIBLE BENEFITS AND RISKS OF THIS STUDY?

Benefits

Your involvement in this study will help establish a reliable source of human hookworms for future studies. Participating in this study will also provide crucial information on the immune system and gut bacteria after hookworm infection. You will also be able to ask for information on your gut bacteria, immune function and nutrient intake at the end of the study. You are unlikely to directly benefit from hookworm infection. Your participation in the study will help us better understand the interaction between the human host and hookworm. This new knowledge may lead to hookworms being used to treat people with inflammatory and autoimmune diseases in the future.

Risks

Hookworm infection may lead to mild skin irritation and/or gut symptoms such as bloating. These symptoms will be monitored closely using skin photographs and symptom questionnaires. You will be encouraged to contact the research team immediately if symptoms develop. Medications will be offered to help with any skin irritation. Severe symptoms are unlikely but if they do develop you will be offered treatment to stop the infection.

You may experience some discomfort with having blood samples taken. There is a low risk of bruising. To help prevent bruising the blood sample will be taken by a trained person.

WHO PAYS FOR THE STUDY?

There will not be any extra costs related with participating in this study. You will be reimbursed ($75 per visit) for your time and inconvenience.

If you need treatment for mild or severe symptoms of hookworm infection the costs will be covered by the research team.

WHAT IF SOMETHING GOES WRONG?

If you were injured in this study, you would be eligible **to apply** for compensation from ACC just as you would be if you were injured in an accident at work or at home. This does not mean that your claim will automatically be accepted. 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?

You are under no obligation to accept this invitation – your participation in this study is voluntary. If you decide to participate, you have the right to:

- Withdraw from the study at any time without experiencing any disadvantages.
- Ask any questions about the study at any time during participation.
- Access information about yourself which has been collected as part of the study.
- Provide information and samples on the understanding that these will be de-identified (i.e. your name won't be identifiable) for privacy and confidentiality reasons.
- Be informed of any new information about adverse or beneficial effects relating to the study.

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

During the study, we will keep your data on a secure server, with access restricted to the research team. The primary investigator, Stephen Inns, will be responsible for storing and destroying the data. His contact details are below. Once the study is completed, we will de-identify the data, so it won't be possible to link it to you. We will store the de-identified data securely for 10 years after we publish the results. We will keep your completed consent form for 10 years after the study and destroy it after that time.

If you change your mind and would like to withdraw from the study, you can do this at any time before the study is completed. We will ask you when you withdraw whether you would like to withdraw the data you have provided up until that point. Once the tests on your blood and stool/poo samples are complete, we will destroy them in line with laboratory protocols unless you have separately agreed that we may retain them for future use.

We invite you to show on the consent form if you would like to receive a summary of the results of this study, when they became available.

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

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

Dr. Stephen Inns, Principal Investigator
University of Otago, Wellington
Phone: (04) 918 6848
Email: hookworm@malaghan.org.nz

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@advocacy.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

Please tick to indicate you consent to the following

I have read, or have had read to me in my first language, and I understand the Participant Information Sheet.	Yes ☐	No ☐
I have been given sufficient time to consider whether or not to participate in this study.	Yes ☐	No ☐
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.	Yes ☐	No ☐
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.	Yes ☐	No ☐
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.	Yes ☐	No ☐
I consent to the research staff collecting and processing my information, including information about my health.	Yes ☐	No ☐
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.	Yes ☐	No ☐
I consent to my GP or current provider being informed about any significant abnormal results obtained during the study.	Yes ☐	No ☐
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.	Yes ☐	No ☐

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.	Yes ☐	No ☐
I understand the compensation provisions in case of injury during the study.	Yes ☐	No ☐
I know who to contact if I have any questions about the study in general.	Yes ☐	No ☐
I understand my responsibilities as a study participant.	Yes ☐	No ☐
I wish to receive a summary of the results from the study.	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: _____