**Participant Information Sheet and Consent Form**

**Microbiome Research – IBD**

**Title** Defining the Australian Inflammatory Bowel Disease Microbiome – The AIM Study

**Short Title** The AIM study

**Project Sponsor University of New South Wales**

**Principal Investigator [INSERT]**

**Site [INSERT]**

Protocol Version 1.5, 31st January 2019

Part I – What does my participation in the study involve?

1. **Invitation**

We invite you to participate in this research study on inflammatory bowel disease (IBD). This study is about gut microorganisms in IBD. Gut microorganisms are also call the microbiome.

The study is being coordinated by Prof Georgina Hold and by Prof Rupert Leong. This study is part of a collaboration between many hospitals in New South Wales.

Before you decide whether or not to participate in the study, it is important for you to understand why we are doing the study and what you will need to do. Please take the time to read this information and discuss it with others if you wish.

1. **‘What is the purpose of this study?’**

The purpose of this study is to look for causes of IBD. IBD affects 1 in every 250 Australians (approximately 100,000 people in Australia). There is a lot we don’t know about IBD. But we do know that IBD is more common in developed countries. This may be due to diet and lifestyle. We also know that genes are important for IBD. Diet, lifestyle and genes affect the microbiome. By studying what happens to the microbiome over time, we hope to understand whether changes in the microbiome may cause IBD. This information can help predict who will develop IBD and how the disease will behave. It may also help find new treatments that work by changing the gut microbiome.

1. **‘****Why have I been invited to participate in this study?’**

You have been invited to participate in this study because you do not have IBD. You are what we call a ‘control’. You are important to the study because we will need to compare people with IBD to people like you.

1. **‘What does this study involve?’**

If you join the study we will ask you to:

* + Read this Information sheet and sign the consent form.
	+ Complete the questionnaires about your lifestyle. You will need to complete these questionnaires 3 times (at the start, middle [12 months] and end [24 months] of the study). These questionnaires will take no more than 50 minutes to complete. You will also need to complete shorter questionnaires every 3 months.
	+ Return the questionnaires and signed Consent Form in the Reply-Paid envelope (or in person) to the Study Coordinator. If you are happy to receive questionnaires electronically and complete them on-line, this is possible.
	+ Provide a blood sample (30ml or about 6 teaspoons) 3 times. Blood samples will be collected at the start, middle [12 months] and end [24 months] of the study at pre-arranged study appointments. The blood sample will be collected at the same time as your pre-arranged study visits.
	+ Provide 3 urine samples. These samples will be collected at the start, middle [12 months] and end [24 months] of the study at the pre-arranged study appointment.
	+ Provide 9 stool and oral swab samples. These samples will be self-collected by you every three months during the study and they will be returned to the study processing laboratory in a pre-paid envelope.
	+ If you are having a colonoscopy, we will take additional biopsy samples for this study.
	+ We may also need to contact you by letter, phone or email about this study if we don’t hear from. We may also need to contact you to check something for example, if a response on your questionnaire is unclear.

If you join the study we will:

* + Collect some information from you. This information will include; age, gender, medication history, Body Mass Index, health status and previous hospital visits. This information will be continually updated while you agree to be in the study. If you move from the area we may seek permission to follow you up.
	+ We may also get information about you from centrally held health related databases. These database include the Cancer Registry and the NSW state health database. We will use this information to look for associations between the microbiome and cancer incidence rates.

If you join the study you are consenting to:

* + Your samples and data to be used for this study and any closely related future IBD studies. All future studies will require additional ethics approvals. The purpose of storing your data and samples for future studies is to answer research questions that we don’t know yet but may arise in the future. Therefore, your samples will be kept in the laboratory for a total of 30 years. Your samples will then be destroyed by incineration and your data securely deleted.
	+ Access to any of your previously stored samples which are held within pathology archives. This will allow us to build up a picture of microbiome changes relevant to IBD.

Your blood, stool, urine, oral swab and/or biopsy samples will be transported to a laboratory where they will be stored. These samples will then be analysed. Your samples will be examined for the types of microorganisms present and how they interact with their environment. We will also look at host genes to see how they affect the types of microorganisms present. To do this we will use a combination of microbiology, immunology and molecular techniques. Some of the analysis may be undertaken outside of Australia including China. If this is done, then only samples and not participant identifiable data will be sent overseas.

Your samples will be labelled and stored with a coded ID number. You cannot be identified from your samples. Only the principle investigator at your site and the study coordinator named on this information sheet can link your name with your samples. This information will be kept separately at your local hospital.

Paper copies of information obtained from you and your completed questionnaires will be stored in locked filing cabinets at your local hospital. This information will be transferred to a secure, encrypted study database. The data entered will be de-identified. This means identifiable information (such as names, addressed etc) will not be entered into the database. Therefore, it will not be possible to identify individual participants in the study databases. Participant identity information and ID codes will be kept on a study master file at your local hospital. The study master file will be held by the site Principal Investigator and AIM study co-ordinator. All databases and electronic files will be held on secure password protected computers with an additional level of password protection on the files.

**5****. ‘What are the risks associated with this procedure?’**

For blood sample collection you may experience some mild discomfort and minor bruising or swelling at the site of collection. There is no risk with collection of oral swabs, urine or stool samples. If you are having a colonoscopy, biopsies are often routinely taken. There is a risk of bleeding from taking biopsy samples from the bowel. This bleeding nearly always stops by itself. Very rarely additional measures such as clipping the biopsy site are needed to stop bleeding. There is no additional risk with collecting additional biopsies for this study.

**6. ‘****Will I benefit from this study?’**

The results of this study will not provide you with any direct benefit. However, the study may provide information to improve the management of people with IBD in the future. The results of this study are for research and cannot be directly used to assist your medical treatment.

**7****. What happens if I don’t want to take part in the study?**

Participation in this study is voluntary. It is completely up to you whether or not you participate. If you decide not to participate, it will not affect the treatment you receive now or in the future. Whatever your decision, it will not affect your relationship with the staff caring for you.

**8.** **Will I be given the results of the study?**

No individual results will be available. If you choose, you may view a summary of results when data analysis is finished. Results of this study will be given to HREC for monitoring if it is requested. Grouped results will also be presented in peer-reviewed journals and at conferences or other professional forums. We plan to provide a laymans summary of our findings to participants once data analysis is complete. We will do this using the same form of communication that you are using to provide study data, either email or post.

**9.** **How will my confidentiality be protected?**

All aspects of this study will be kept confidential. Only the people conducting and monitoring the study will have access to your data and results.

We plan to discuss/publish the findings. In any publication, the information will be given in such a way that you cannot be identified.

**10.** **What will happen to my samples after it has been tested?**

Your samples will only be used for IBD research. Your blood and tissue sample/s will be kept at the completion of the study. If new discoveries are made in the future and your samples may help us understand more about IBD, we may use your samples to research these new discoveries. All future research studies, using your samples, will be conducted by our research group and will require ethical approval from an accredited HREC before your samples are used. We will continue to make participants aware of the findings from our research, when data analysis is finished. As indicated in section 8 this will be made available as grouped results not individual results.

**11.** **Will I be able to withdraw my sample if I want to?**

If you wish to withdraw from the study, you should notify the study coordinator at your site. Your samples will be re-identified, removed from storage and destroyed. If you do withdraw your samples, we ask that you allow the results obtained so far to remain in the study database. However, if you wish that all your information, including results from your samples, be removed from the project please tell the AIM Study Coordinator, St George and Sutherland Clinical School, Pitney Building, St George Hospital, Short Street, Kogarah, NSW 2017, [phone number xxxx xxxx].

**12.** **How is this study being paid for?**

The study is being funded through a GESA collaborative grant, the Microbiome Research Centre at UNSW and also through local hospital funds.

**13.** **Will my samples be used for profit in the future?**

There is the possibility that this research may lead to commercially viable technology or treatments. However, you will not be able to claim financial benefit from any discoveries arising from the use of your blood or tissue samples.

**14.** **Will I get any compensation or incentives which to participate?**

There are no incentives or compensation to participate in this study. We are doing this study to help people with IBD. We appreciate that it requires a lot of commitment to participate and provide information and samples over 2 years.

**15. ‘****What should I do if I want to discuss this study further before I decide?’**

When you have read this information, the researcher [name] will discuss it with you and any queries you may have. If you would like to know more at any stage, please do not hesitate to contact him/her on [phone number xxxx xxxx].

**16.** **‘****Who should I contact if I have concerns about the conduct of this study?’**

This study has been approved by the South Eastern Sydney Local Health District Human Research Ethics Committee. Any person with concerns or complaints about the conduct of this study should contact the Research Support Office which is nominated to receive complaints from research participants. You can contact them on 02 9382 3587, or email SESLHD-RSO@health.nsw.gov.au and quote [HREC project number].

The conduct of this study at the [name of site] has been authorised by the [name of health district]. Any person with concerns or complaints about the conduct of this study may also contact the [details of the Research Governance Officer of the health district]

**17.** **‘****What happens if I get injured or have complications as a result of the study?’**

If you are injured or have complications because of this study you should contact your study doctor as soon as possible. Your doctor will help arrange appropriate medical treatment for you. You may have a right to take legal action to obtain compensation for any injuries or complications resulting from the study. Compensation may be available if your injury or complication is caused by any study procedures, or by the negligence of any of the parties involved in the study. If you receive compensation for medical expenses, you will be required to pay for your medical treatment from those compensation monies.

If you are not eligible for compensation for your injury or complication under the law, but are eligible for Medicare, then you can receive any medical treatment required for your injury or complication free of charge as a public patient in any Australian public hospital.

**Thank you for taking the time to consider this study.**

**If you wish to take part in it, please sign the attached consent form.**

**This information sheet is for you to keep.**

**PARTICIPANT CONSENT FORM**

**Title** Defining the Australian Inflammatory Bowel Disease Microbiome – The AIM Study

**Short Title** The AIM study

**Project Sponsor University of New South Wales**

**Principal Investigator Prof. Georgina Hold**

**Site St George Hospital**

**Protocol**  **Version 1.5 31st January 2019**

1. I,................................................................................................................. of................................................................................................................

agree to participate as a subject in the study described in the participant information statement set out above***.***

2. I acknowledge that I have read the participant information statement, which explains why I have been selected, the aims of the study and the nature and the possible risks of the investigation, and the statement has been explained to me to my satisfaction.

3. Before signing this consent form, I have been given the opportunity of asking 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.

4. I understand that I can withdraw from the study at any time without prejudice to my relationship to the ***University of New South Wales*** and ***St George******Hospital.***

1. I agree that research data gathered from the results of the study may be published, provided that I cannot be identified.
2. I consent to the use of my DNA and /or tissue for the purposes described in the Information Sheet. I understand that my samples may be sent overseas, including China for the purposes of analysis.
3. I consent to being contacted if information I have provided requires clarification.
4. I consent to linkage of my data for the purposes of IBD research to other centrally held databases including the cancer registry and other NSW health databases.
5. I consent to my data and samples being held after the end of the AIM study for use in future research studies, by the research team, on the understanding that additional HREC ethical approval is obtained.
6. I understand that if I have any questions relating to my participation in this research, I may contact Prof Hold on telephone 9113 1855, who will be happy to answer them.
7. I acknowledge receipt of a copy of this Consent Form and the Participant Information Statement.

Complaints may be directed to the Research Support Office, South Eastern Sydney Local Health District, Prince of Wales Hospital, Randwick NSW 2031 Australia (phone 02-9382 3587, fax 02-9382 2813, email SESLHD-RSO@health.nsw.gov.au.

# Signature of participant Please PRINT name Date

# [*or person responsible] (insert or delete as necessary*)

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**Signature of witness Please PRINT name Date**

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# Signature of investigator Please PRINT name Date

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***WITHDRAWAL OF PARTICIPATION***

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**Project Sponsor University of New South Wales**

**Principal Investigator Prof. Georgina Hold**

**Site St George Hospital**

**Protocol**  **Version 1.5 31st January 2019**

## WITHDRAWAL OF CONSENT

I hereby wish to **WITHDRAW** my consent to participate in the study described above and understand that such withdrawal **WILL NOT** jeopardise any treatment or my relationship with the ***University of New South Wales*** and ***St George******Hospital*** *or my medical attendants)*.

Signature Date

Please PRINT Name

The section for Revocation of Consent should be forwarded to The AIM Study Co-ordinator, St George and Sutherland Clinical School, Pitney Building, St George Hospital, Short Street, Kogarah, NSW 2017, [phone number xxxx xxxx].