**Parent/Guardian 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 participation in the study involve?

1. **Invitation**

We invite you and your child 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 and your child decide whether or not to participate in the study, it is important for you and your child 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 your child and 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 has my child been invited to participate in this study?’**

You and your child have been invited to participate in this study because your child has IBD.

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

If your child joins the study we will ask you to:

* + Read this Information sheet and sign the consent form.
	+ Complete the questionnaires about your lifestyle and your child’s IBD. These questionnaires 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. A shorter questionnaires will need to be completed 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.
	+ Your child will need to 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. The blood sample will be collected at the same time as your child’s clinic visit bloods.
	+ Your child will need to provide 3 urine samples. These samples will be collected at the start, middle [12 months] and end [24 months] of the study at the same time as your child’s clinic visit bloods.
	+ Your child will need to provide 9 stool and oral swab samples. These samples will be collected every three months during the study and they will be returned to the study processing laboratory in a pre-paid envelope.
	+ If your child is having a colonoscopy, we will take additional biopsy samples for this study.
	+ Your child will need to provide an additional stool sample if they experience a flare during the 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 a questionnaire is unclear.

If your child joins the study we will:

* + Collect information about your child’s IBD from their medical records. This information will include; age, gender, blood test results, medication history, Body Mass Index, health status and previous hospital visits. This information will be continually collected while you and your child agree to be in the study. If you move from the clinic we may seek permission to follow up your child.
	+ We may also get information about your child 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 your child joins the study you and your child are consenting to:

* + Your child’s 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 child’s 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 child’s samples will be kept in the laboratory for a total of 30 years. Your child’s samples will then be destroyed by incineration and your child’s data securely deleted.
	+ Access to any of your child’s 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 child’s 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 for factors associated with IBD. Your child’s 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 child’s samples will be labelled and stored with a coded ID number. Your child cannot be identified from their samples. Only the principle investigator at your child’s site and the study coordinator named on this information sheet can link your child’s name with their samples. This information will be kept separately at your child’s local hospital.

Paper copies of clinical information obtained from your child’s medical records and the completed questionnaires will be stored in locked filing cabinets at your local hospital. This information will be transferred to a secure, encrypted database. The data entered will be de-identified. This means identifiable information (such as names, addressed etc) will not be entered into these databases. 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 child’s 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 your child 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 your child is 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 my child benefit from this study?’**

The results of this study will not provide your child 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 child’s medical treatment.

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

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

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

No individual results will be available. If you and your child 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 your child’s study data, either email or post.

**9.** **How will my child’s 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 your child cannot be identified.

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

Your child’s samples will only be used for IBD research. Your child’s blood and tissue sample/s will be kept at the completion of the study. If new discoveries are made in the future and your child’s samples may help us understand more about IBD, we may use your child’s samples to research these new discoveries. All future research studies, using your child’s 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 we be able to withdraw my child’s sample if we want to?**

If you or your child wish to withdraw from the study, you should notify the study coordinator at your child’s site. Your child’s samples will be re-identified, removed from storage and destroyed. If you do withdraw your child’s samples, we ask that you allow the results obtained so far to remain in the study database. However, if you wish that all your child’s information, including results from their 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 child’s 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 or your child will not be able to claim financial benefit from any discoveries arising from the use of your child’s blood or tissue samples.

**14.** **Will we 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 we do if we want to discuss this study further before we decide?’**

When you have read this information, the researcher [name] will discuss it with you and your child 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 we contact if we 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 18/173].

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 my child gets injured or have complications as a result of the study?’**

If your child is injured or has complications because of this study you should contact your study doctor as soon as possible. Your doctor will help arrange appropriate medical treatment for your child. 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 child’s 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 your child’s medical expenses, you will be required to pay for your child’s medical treatment from those compensation monies.

If your child is not eligible for compensation for their injury or complication under the law, but are eligible for Medicare, then they can receive any medical treatment required for their 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 for your child to take part in it, please sign the attached consent form.**

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

**PARENT/GUARDIAN 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 for my child………………………………………………………………

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 parent/guardian information statement, which explains why my child has 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 my child might suffer as a result of my participation and I have received satisfactory answers.

4. I understand that my child 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 my child cannot be identified.
2. I consent to the use of my child’s DNA and /or tissue for the purposes described in the Information Sheet. I understand that my child’s samples may be sent overseas, including China for the purposes of analysis.
3. I consent to being contacted if information I or my child has provided requires clarification.
4. I consent to linkage of my child’s 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 child’s 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 or my child have any questions relating to my participation in this research, we 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 parent/guardian Please PRINT name Date

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

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**Signature of participant Please PRINT name Date**

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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**

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## WITHDRAWAL OF CONSENT

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

Parent/Guardian Signature Date

Parent/Guardian Name

Participant 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].