**Child/Adolescent Participant Information Sheet**

**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.

Before you decide if you would like to be part of this study you should read this information booklet. You can also talk about this study to your family, friends or anyone else.

1. **‘What is this study about?’**

This study is to look for causes of IBD. IBD may be caused by what you eat and where you live. But what you eat and where you live can change your microbiome. We want to look at your microbiome over time to work out how much your microbiome is causing your IBD.

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

You have been invited to participate in this study because you have IBD.

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

If you join the study you will need to sign the consent form. You will also need to answer some questions about your family, what you eat, where you live and what you do. Your parents, family or friends can help you answer these questions if you wish. You will also need to give some blood, stool (poo), urine (wee) and saliva (spit) for this study. If you are having an endoscope investigation, we will also collect some small pieces of your gut. We will also get information about your IBD from your medical records.

**5****. ‘Is this study dangerous?’**

For blood sample collection you may experience some mild pain and minor bruising or swelling where the blood is collected. There is danger with collection of poo, wee or spit. If you are having a colonoscopy, the doctor will collects small pieces of your gut so they know what is happening with your IBD. We will collect a few more pieces for this study but you will not notice.

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

You will not directly benefit from this study. However, the study may help people with IBD in the future.

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

Nothing will happen if you do not want to join the study. 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. Whatever your decision, your relationship with the staff caring for you will be the same.

**8.**  **Will anyone know I am in the study?**

Other than your parents/guardians and the doctors and nurses who help you manage your IBD, no one will know you are in the study unless you want them to know.

**9.**  **What will happen to my samples?**

Your samples will only be used for IBD research. We will keep your samples because they may be useful for other IBD studies, that our group will do in the future.

**10.**  **Can I leave the study?**

You can leave the study anytime. You do not need a reason to leave the study. If you wish to leave the study you should tell your parents or you doctor you want to leave the study.

**11.**  **Will I get money or gift to participate?**

No you will not get money or gifts to participate in this study. We are doing this study to help people with IBD.

**12. ‘****What should I do if I want to talk more about this study before I decide?’**

When you have read this information, you can talk to the researcher [name] and/or you parents, family or friends. You can ask any questions you like. If you would like to know more information any time you can contact him/her on [phone number xxxx xxxx].

**12.**  **‘Who should I contact if I am worried about what happens in this study?’**

This study has been approved by the South Eastern Sydney Local Health District Human Research Ethics Committee. If you are worried or have a complaint about this study you should contact the Research Support Office. You can contact them on 02 9382 3587, or email SESLHD-RSO@health.nsw.gov.au and say [HREC project number].

This study at the [name of site] has been authorised by the [name of health district]. If you are worried or have a complaint about this study, you can also contact [details of the Research Governance Officer of the health district].

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

**If you wish to take part in it, please sign the consent form on the Parent/Guardian Information sheet.**

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