PATIENT INFORMATION SHEET – IBD CLINICAL STUDY DATE: August 2009

Preventing Opportunistic Infections in Patients with Inflammatory Bowel Disease (IBD)

You are invited to take part in a patient research study. People with Inflammatory Bowel Disease (Crohn’s Disease and Ulcerative Colitis) often require medications that suppress the immune system, in order to achieve a decrease in symptoms (remission). It is often not obvious at the point of diagnosis which patients will need these medications. You may already be on one or several of these medications or you may need them in the future. These medications certainly help to control the inflammatory bowel disease, and have been shown to decrease the need for surgery and hospitalisation as well as increasing the patient’s quality of life. The problem can be that they may make you more susceptible to certain infections; fortunately, we have vaccinations and screening that can help to avoid many of these infections.

AIM: The aim of this study is to try to ensure that all of your vaccinations and screening are up to date, so that if you need these medications, you will be unlikely to be affected by one of these diseases.

YOUR PARTICIPATION: YOUR PARTICIPATION IS VOLUNTARY. If you agree to be part of this study, you will be asked to fill in a questionnaire regarding your diagnosis, current medications and which vaccinations you have had in the past. If you are not sure exactly what you have or have not had, there are blood tests which we can do to check your immune status. When you see your gastroenterologist today, he/she will go through this form with you and make recommendations on which blood tests, vaccinations and other screening (e.g. Chest X-ray) are required.

No vaccinations will be performed today. The diseases that we are testing for are Hepatitis B, Chicken Pox, Hepatitis C, HIV, Tuberculosis, and Human Papilloma Virus. The possible vaccinations that may be suggested include Hepatitis B, Influenza vaccine (Fluvax), Pneumococcus vaccine (Pneumovax), Chicken pox, Human Papilloma Virus (Gardasil).

Vaccinations can cause some discomfort at the injection site and there is a small chance that you could have a reaction to a vaccination. There are no vaccinations for Hepatitis C or HIV however it is important for your treatment that your doctor knows if these are positive or negative. For females, we are also checking when your last ‘Pap’ smear was performed. Pregnant women should not participate in this study.

YOUR G.P: Recommendations will be explained to you and written down for you to take to your general practitioner. A letter will also be written to your general practitioner outlining these recommendations. No immunisations will be given at today’s clinic, so you will have time to think about the recommendations made.
**FOLLOW-UP:** You will then be contacted within 1 to 3 months to check that the necessary follow up has occurred.

**OUTCOMES:** All data from this study will be owned by Dr Alissa Walsh who is the chief investigator of this study and a gastroenterologist at St Vincent’s Hospital in Sydney. This data will be used at medical presentations and for publication in medical journals. Your personal details e.g. your name, date of birth, and other personal details will all be made anonymous.

**CONSENT:** As part of the procedure for research studies, you will be asked to sign a consent form (see attached forms) that says that you are happy to be involved in this study. You will receive a copy of this consent form to take home with you. All participation is voluntary and you can withdraw consent at any time and it will have no effect on your future treatment. If you have any questions, please do not hesitate to ask your gastroenterologist.

The Principal Researcher at your site is Dr Alissa Walsh. Please do not hesitate to contact Dr Walsh on 8382 1111 if you have any questions.

If there are any concerns or complaints regarding the way that this study is being conducted, please contact the Ethics Officer, Human Research Ethics Committee, Research Services Office, University of Wollongong on 42214457.