PARTICIPANT INFORMATION SHEET

The Austin Hospital

VERSION 1: DATED: 15.11.2014

PROTOCOL NO.:

FULL PROJECT TITLE:

STUDY 1: A cross-sectional investigation into the utilisation and acceptance of a tablet-based application to briefly assess mental health and physiological well-being in an inflammatory bowel disease (IBD) outpatient service

NAME/S OF INVESTIGATORS

Dr Simon Knowles (Swinburne University, Austin Hospital?), Dr Lindy Jackson & Dr Peter De Cruz (Austin Hospital)

**1. Introduction**

You are invited to take part in this research project to help us evaluate a brief psychological and physiological assessment tool designed to be used in the inflammatory bowel disease (IBD) outpatient service or online. Our aim is to develop a range of computer programs that may be used online or in the outpatient service to help us better support patients attending the Austin IBD outpatient service.

This Participant Information and Consent Form tells you about the research project. It explains the procedures involved. Knowing what is involved will help you decide if you want to take part in the research. This information sheet is four pages long.

Please read this information carefully. Ask questions about anything that you don’t understand or want to know more about. Before deciding whether or not to take part, you might want to talk about it with a relative, friend or healthcare worker.

Participation in this research is voluntary. If you don’t wish to take part, you don’t have to. You will receive the best possible care whether you take part or not.

If you decide you want to take part in the research project, you will be asked to complete a questionnaire and return it to your gastroenterologist. The return of the questionnaire will be signalling that you are telling us that you:

• understand what you have read;

• consent to take part in the research project;

• consent to participate in the research processes that are described;

* consent to the use of your personal and health information you provide as described

 2. What is the purpose of this research project?

We are aware that having Inflammatory Bowel Disease can have a significant impact on your health, both physiologically (e.g., fatigue, pain) and well as psychologically (e.g., stress, anxiety). It is well recognized that anxiety, stress and even depression, can be common problems in individuals undergoing treatment for a medical condition, however these issues are often not directly assessed.

The purpose of this study is to explore your views on the use and acceptance of a brief psychological and physiological assessment tool designed to be used in the inflammatory bowel disease (IBD) outpatient service and online. We aim to recruit a total of 150 participants from each hospital outpatient clinic.

Based on the information collected we will be able to better identify and target patient psychological concerns and in turn enhance health and treatment outcomes, and quality of life.

3. What does participation in this research project involve?

If you join the study you will be asked to complete a 10-minute assessment program using a tablet PC. The program will ask about your perceived IBD status, pain levels, sleep quality and quantity and questions relating to anxiety, stress and depression. Based on the information you provided you will be given feedback about your mental health and then asked to provide advice about the feedback and attitudes towards using a program similar to this online to help us better track your IBD symptoms, medications and well-being. After completing the program you will be asked to write down several of the findings so that you can talk over them with your Gastroenterologist or IBD nurse.

This research involves the collaboration between the Austin Hospital and Swinburne University of Technology.

**4. What are the possible risks?**

There are no foreseeable risks from participating in this study. If you become upset or distressed as a result of your participation in the research, the researcher is able to arrange for counselling or other appropriate support. Any counselling or support will be provided by staff who are not members of the research team.

**5. Do I have to take part in this research project?**

Participation in this research project is voluntary. If you do not wish to take part, you do not have to. If you decide to take part and later change your mind, you are free to withdraw from the project at a later stage. If you do decide to leave this project, the researchers would like to keep the personal and health information about you that has been collected. This is to help them make sure that the results of the research can be measured properly. If you do not want them to do this, you must tell them before you withdraw from the study.

6. How will I be informed of the results of this research project?

The research group conducting the study plan to write a report, which will be made available to anyone who is interested, in the form of a newsletter and placed around the hospital IBD outpatient area. Findings from the study will also be made into brief reports to be published in the Australian Crohn’s and colitis association magazine. The results will also be written for publication in a scientific medical journal.

7. What will happen to information about me?

Any information obtained in connection with this project and that can identify you will remain confidential. It will only be disclosed with your permission, except as required by law. No information used in future presentations or written publications like articles or books will identify any participant. This is done through coding all participants using numbers and keeping all documents involved with individuals in a locked cabinet, accessible only to people involved in the project. All information will be kept in a secured PC in a password protected file for a period of 7 years and subsequently shredded. Information about you may be obtained from your health records held at this health service for the purposes of this research.

8. Can I access research information kept about me?

In accordance with relevant Australian and /or Victorian privacy and other relevant laws, you have the right to access the information collected and stored by the researches about you. You also have the right to request that any information, with which you disagree, be corrected. Please contact one of the researchers named at the end of this document if you would like to access your information.

9. Is this research project approved?

The ethical aspects of this research project have been approved by the Austin Hospital Human Ethics Committee. This project will be carried out according to the *National Statement on Ethical Conduct in Human Research (2007)* produced by the National Health and Medical Research Council of Australia. This statement has been developed to protect the interests of people who agree to participate in human research studies.

**11. Who can I contact?**

If you want further information concerning this project or if you have any problems which may be related to your involvement in the project, you can contact the Principal Researcher, Dr Peter De Cruz, on 03 92148206 or sknowles@swin.edu.au.

**12. Complaints**

If you have any complaints about any aspect of the study or the way in which it is being conducted you may contact the Patient Liaison Officer at the Austin Hospital (Phone: 9496 5000). You will need to tell the Patient Liaison Officer the name of the person who is noted above as principal investigator.If you have any complaints about any aspect of the study or the way in which it is being conducted you may contact the Patient Representative at the Austin Hospital. You will need to tell the Patient Representative the name of the person who is noted above as principal investigator.

**13. Research Participant Rights**

If you have any questions about your rights as a research participant, then you may contact the Executive Officer Research at the Austin Hospital (Phone: 9496 2901).