

# PATIENT INFORMATION SHEET (COHORT)

(Pt Info Cohort V13 10Oct2011.doc)

You have been admitted to hospital because you have bowel problems. This might be a new problem and you will have tests to find out what is causing this or it may be a flare-up of a disease that you already know about.

This information leaflet is about an important study that is doing research into inflammatory bowel diseases called ulcerative colitis and Crohn's disease. Specifically, it is looking into the long term effects ulcerative colitis has on people's quality of life. About 150,000 people in the UK have ulcerative colitis and it is one of the most important diseases seen by gastroenterologists.

We would like to invite you to take part in this research study. This leaflet gives you information about the study - please take time to read it carefully to decide whether or not you wish to take part. Your consultant or specialist nurse will talk to you about the study. Please talk to others, such as your family about it if you wish. Please ask if there is anything that is not clear or if you would like more information.

## **What is the purpose of the study?**

We want to find out more about the progress of these conditions and the outcomes following treatment for the diseases. By taking part in this study, you will be helping us to learn more about ulcerative colitis and Crohn's disease and their treatment.

## **Why have I been invited?**

We are inviting all patients admitted to hospital who might have ulcerative colitis or Crohn's disease, to take part.

## **Do I have to take part?**

No. Your participation in this study is entirely voluntary. It is up to you to decide whether to take part or not. Even if you do decide to take part, you are free to leave the study at any time and without giving a reason. This will not affect your future medical care in any way. If you do decide to participate you will be given this information sheet to keep and be asked to sign a consent form.

## **What will happen to me if I take part?**

If you agree to take part, we will first ask you to:

- Sign the consent form which is your indication that you understand the study and agree to take part.
- Complete a questionnaire that will include questions about your health, feelings and quality of life and use of health services. The questionnaires take around 30 minutes to complete.
- If you are found to have inflammatory bowel disease you will stay in the study. If not, then you are not able to take part.
- In addition, we will follow your progress over 10 years, using hospital information about any investigations, treatment or surgery you may have.

If you are found to have ulcerative colitis rather than Crohn's disease, you will be treated over the next few days with drugs known as steroids (although both illnesses may be treated with steroids). Steroids work in the majority of cases of ulcerative colitis but not in all. If they do not make you better, surgery may be needed. There are also two powerful drug treatments that some hospitals use to try to treat the attack and avoid the need for surgery. We are comparing these two treatments in a clinical trial to see which is best. If steroids are not sufficiently effective in treating you, we will tell you more about this clinical trial to see if it would be suitable for you. Taking part in the first section of the study would not oblige you to take part in the treatment trial.

## **What will I have to do?**

At the moment all we are asking you to do is to be part of the group of patients who will complete one questionnaire and whose progress will be followed over the next ten years.

**Will my taking part in this study be kept confidential?**

Yes. All information which is collected about you during the course of the research will be kept strictly confidential in accordance with ethical and legal practice and the Data Protection Act.

You will be given a unique study number and any data will be collected and stored with this number. Any personal identification will be stored separately from the data. The clinical team looking after you and the research team are the only people who will know specific personally identifiable information that would allow someone to identify you and contact you. Your personal information (name, date of birth, home postcode and NHS number) will not be revealed in any audit, study report or publication, at any time.

If you agree to take part your GP will be informed.

**What will happen to the results of the research study?**

The results of the study will be used to help doctors understand the progress and outcomes following treatment of inflammatory bowel disease.

**Who is organising and funding research?**

The study is being run by the College of Medicine at Swansea University in collaboration with the University of Glamorgan and Bangor University. The study is funded by the National Institute for Health Research Health Technology Assessment Programme.

**Who has reviewed the study?**

All research in the NHS is looked at by an independent group of people, called a Research Ethics Committee to protect your safety, rights, wellbeing and dignity. This study has been reviewed and approved by Wales Research Ethics Committee.

**What happens when the research study stops?**

As a patient with ulcerative colitis or Crohn's disease you will continue to be reviewed in the gastroenterology clinic so your follow up will be as normal.

**What will happen if I don't want to carry on with the study?**

You may withdraw your consent and discontinue your participation in this study at any time without the need to give us a reason. This would not in any way affect the normal standard of care you receive.

**What if there is a problem?**

If you have a concern about any aspect of this study, you should ask to speak to the Trial Manager, Anne Seagrove, XXXX or the Trial Administrator, Emma Riordan, XXXX, who will do their best to answer your questions.

For information regarding your treatment, you should speak to [\[PI details\]](#).