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PARTICIPANT INFORMATION SHEET & INFORMED CONSENT FORM

Randomised Double Blind Clinical Trial in Acute Severe Colitis: IASO Trial Sub-Study

You are being invited to take part in an optional research sub-study. Before deciding whether to take part, you need to understand why this research is being done and what it involves. Please take time to read the following information carefully and talk to others about the trial if you wish. Please ask us if anything is not clear or if you would like more information. Please take time to decide whether or not you wish to take part.

Section 1 tells you the purpose of the IASO sub-study and what will happen to you if you take part.
Section 2 gives you more detailed information about the conduct of the sub-study.

1 What is the purpose of doing a sub-study?

The main IASO study will tell us whether the drug anakinra can be used to help treat your severe flare of ulcerative colitis. To help us understand more about how and why this treatment may work, we would like to collect additional information from some of the patients taking part in the main trial. This additional information will help us to continue to improve treatment options for colitis patients.

2 What is involved in the sub-study?

This sub-study will involve an additional procedure on approximately day 3 after you start the study medication as part of the main IASO trial. The additional procedure, called a flexible sigmoidoscopy, involves insertion through the anus of a videocamera on a flexible tube. This camera is used to examine the last part of the large bowel.

Biopsies (samples of tissue about the size of half a grain of rice) will be collected from the bowel using a special device passed through the camera tube. This is a painless procedure and is routinely performed in clinical practice in patients with your condition. We would also collect photographs of the bowel lining to help assess the extent of your disease, which would form part of your study record and be used for analysis purposes.

This sub-study, like the main research trial, is completely voluntary. You do not need to participate in this sub-study in order to participate in the main study.

3 What are the possible benefits of taking part?

The clinical findings from the procedure will be shared with you and your doctors and may help guide your standard care treatment decisions.

4 What are the possible disadvantages and risks of taking part?

The flexible sigmoidoscopy procedure can be uncomfortable. Your clinical team will discuss options for painkillers and sedation with you, although these are not always necessary. Occasionally the procedure can cause damage to the lining of the bowel, resulting in bleeding or tearing of the bowel wall (perforation). Such tears occur in fewer than 1 in 1000 procedures, but can be serious and may require surgery to repair.

5 What if I decide I no longer wish to participate in the sub-study?

You are free to withdraw from this sub-study at any time without giving a reason and without affecting your future care or medical treatment.

6 What will happen to my samples?

Biopsies and photographs taken during the procedure will be labelled with your study identification number but no other personal details. Biopsies will be stored locally prior to shipment to the central study laboratories at the University of Cambridge. They will be analysed in Cambridge and in collaborating UK institutions for markers that may

help us understand the impact of the disease and any treatments you have been receiving. Anonymous data and materials derived from your biopsy samples may be stored indefinitely. However, these data or materials will be stored in such a way to have no connection to your name or other personal identifiers. No genetic testing will be performed on the samples. Any unused materials from the biopsies will be stored to allow for future further analysis, either in Cambridge or in collaborating UK institutions in future approved research.

If you wished to withdraw from the sub-study at any point, you can request destruction of all samples which have not been analysed. This would in no way affect your current or future medical care.

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INFORMED CONSENT FORM FOR SUB-STUDY

Trial Title: IASO Optional Sub-study

Principal Investigator: **Participant Number:** _____

If you agree with each sentence below, please initial the box		**INITIALS**
1	I confirm that I have read and understood the optional sub-study information sheet version 1.0, dated 03 August 2017 for the above trial and have had the opportunity to ask questions.	
2	I understand that my participation is voluntary and I am free to withdraw at any time, without giving reason.	
3	I understand that this is an optional sub-study and that I do not need to participate in this in order to participate in the main trial.	
4	I agree for a flexible sigmoidoscopy with pinch biopsy collection to be performed approximately 3 days after I start the study medication as part of the main IASO trial. I understand that anonymised materials and data prepared from these samples may be stored indefinitely with no connection to my name or other personal identifiers.	

I agree to participate in this optional sub-study:

_____	_____	_____
Name of patient	Signature	Date
_____	_____	_____
Name of person taking consent	Signature	Date

Time of Consent (24hr clock) _____:_____

1 copy for the patient, 1 copy for the trial team, 1 copy to be retained in the hospital notes.