UREC Reference Number: UREC/21.1.6.8

STUDY TITLE: PRESTO: Development of a new patient reported outcome measure (PROM) to assess psychosocial response to stoma in people with IBD

We would like to invite you to take part in this original study being carried out by a team of researchers led by Professor Lesley Dibley, Centre for Chronic Illness and Ageing, Institute for Lifecourse Development at The University of Greenwich, London. Lesley is a chronic illness researcher and has researched patient experiences of IBD since 2008. The research team includes IBD & rehabilitation researchers, a health psychologist and a biomedical ethicist. This study aims to develop a new questionnaire informed by the experiences of those living with IBD, so that they can report outcomes relevant to the issues that matter to them.

You should only take part if you want to; choosing not to take part will not disadvantage you in any way. Before you decide if you want to take part, it is important that you understand why the research is being carried out and what you would be asked to do. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear, or if you would like more information. You can contact us using the details on the final page.

What is this study about? We aim to produce a new questionnaire, designed with input from people with IBD who have had stoma surgery. This kind of questionnaire is called a patient-reported outcome measure (PROM). We have done the first phase of the study and have collected lots of data about peoples' experiences of life with a stoma. We now need to turn this into the new PROM, and then check that it works as we intend.

Why do you need my help? You are being asked to participate as you might be able to help with either an interview or in completing the new questionnaire. We are looking for people who have been diagnosed with IBD, are at least 18 years old and either have or are waiting for a stoma. We would like to ask for your help with ONE of the following: a) a cognitive interview; or b) validation.

What will happen if I do decide to take part? We will check that you are eligible for the study, and ask you to confirm your gender, age at diagnosis, age now, whether you have had surgery, that we have seen proof of diagnosis (record or letter), highest level of education, current employment status, and county of residence within the UK. This information enables us to describe the people who took part, without identifying anyone. We need to do this when the study is published, so that we can show that we had the right people taking part.

We will also ask you how you would like to help us by choosing ONE of these two options:

A) Cognitive interviews: you will be asked to take part in a one-to-one online interview in which we ask you to complete the draft PROM. The focus is on how easy it is to understand the questions, to check for any misinterpretation or language issues, or any other difficulties associated with filling the draft PROM in. This will take about 30 minutes of your time. We will

then make design changes to the draft PROM, based on your comments. We will ask for your contact details and your availability and use this information to arrange the interview with you.

B) Validation: you will be asked to complete the finalised new PROM twice, about two weeks apart. You will also be asked to complete several other quality of life measures so that we can see how the new PROM compares to those. This will take about 40 minutes of your time, on two occasions.

Before you take part, we will remind you about the study and give you the chance to ask questions. We want to be certain you are fully informed and that you wish to take part. You will be asked to sign a consent form confirming your involvement in the study, which we will countersign and send back to you as a PDF that cannot be altered.

How will the research be done? The interviews and the validation will take place online. You will be sent an electronic link to access the online forms in a programme called Qualtrics, and given a unique Study ID number to use. You will not be able to be identified. The cognitive interviews will take place online via MS Teams These will be carried out by Prof Lesley Dibley and other members of the research team, at a time to suit you.

Who can take part? We are looking for people from all four member countries of the UK, representing both genders, and a range of ages, who:

- Are at least 18 years old
- have a confirmed diagnosis of IBD that can be confirmed
- and have ***EITHER***:
  - had stoma surgery
  - or are awaiting stoma surgery

We are sorry, but people who had stoma surgery because of a condition other than IBD cannot take part.

You will need to have access to a computer with internet connection for the interviews and validation, for the cognitive interview we will be using Microsoft Teams®. You do not need to have Teams installed on your device, as you can join via the web.

Even if you offer to take part in any way, you may not be invited to do so if more people offer to take part in the study than are needed. We will let you know one way or the other.

How will you record the cognitive interviews? We will use a digital audio voice recorder with a telephone earpiece. It can be used with a telephone (for phone interviews) and with a headset (headphones and microphone) for video-link interviews. This means we can record the data securely, and not via any of the technology we use to link with you.

Are there any risks to me in taking part? There may be a small risk of you becoming a little distressed when you talk about your experiences. The team members who will do the interviews are all skilled

researchers with extensive experience of caring for people with health conditions in clinical settings and during research projects. They will make sure that you feel emotionally safe before they leave you when your interview or focus group is over. If you do continue to feel distressed after the researchers have left you, you can seek support via your GP or please call Crohn's and Colitis UK helpline on 0300 222 5700 or helpline@crohnsandcolitis.org.uk

What about confidentiality and anonymity? Your personal details (name, contact details) will remain confidential to Prof Lesley Dibley, Dr Ryan Essex & Dr Ann Hanrahan (the research fellows on the study) and will not be shared with anyone else. We will only use these details to contact you about this study. Personal data will be stored in line with the General Data Protection Regulations (GDPR) and deleted as soon as the study is completed. Other data we collect from you such as treatment type, and employment status will be reported anonymously. You will not be able to be identified.

Your identity will be known by the team member who interviews you and the person who transcribes your interview. The digital audio file of your interview will be stored securely in a password protected study folder on the University's OneDrive. Audio files will be transcribed in-house by the research team. The audio file will be deleted once the transcription has been checked for accuracy by the person who interviewed you, and all identifying features have been removed. The digital transcripts will be kept securely on the University's central server for 5 years. Paper transcripts will be stored in a locked filing cabinet in our research office at the University of Greenwich for 5 years.

If you take part in an interview or the validation phase, your identity will not be linked to your data – participation will be anonymous. In any reports or publications, anything which identifies you will be removed, such as names, the hospital you attended, the name of your surgeon. We will use a study number or pseudonym to represent you instead.

What are the possible benefits? You may benefit from being able to talk freely about your concerns and experiences. What you tell us will enable us to evidence the long-term impacts of IBD and stoma surgery and help us develop the new PROM. It will help us continue our research endeavours to provide information which informs government policy (such as that related to definitions of disability), employment rights (including enabling practices to facilitate employment in people facing challenges) and health care (including understanding that the consequences of IBD do not end when clinical treatment is concluded). We will send you a summary of the findings of this part of the study, unless you tell us you do not want to receive this.

What will you do with the results of the study? The new PROM will enable people who are diagnosed with IBD and have a stoma to accurately report the impact of their diagnosis and treatment on all areas of their life. We will also publish at least two academic paper arising from the whole study and present our findings at a range of medical and nursing conferences. All data used in academic papers, conference presentations and reports will be anonymous. You will not be able to be identified.

Who is funding the study? This study is not receiving external funding but is being hosted by the University of Greenwich.

Do I have to take part? It is up to you to decide whether to take part in this study or not. Even if you decide to take part, you are still free to withdraw from the study at any time up to 30th June 2023 (for cognitive interview participants) and 30th Sept 2023 (for validation participants) without consequence. After then, the data you provide will have been analysed and combined with all other data. You do not have to give a reason for withdrawing.

What happens now? You should spend at least 24 hours deciding if you want to take part or not. If you ***do not*** wish to take part, you do not have to do anything else. If you ***do*** want to take part, please contact us using the details below:

Professor Lesley Dibley Professor of Qualitative Nursing Research
University of Greenwich | Institute for Lifecourse Development | Centre for Chronic Illness and Ageing
Email: L.B.Dibley@Greenwich.ac.uk
I am currently working from home: please contact me by email

Dr Ryan Essex, Research Fellow
University of Greenwich | Institute for Lifecourse Development | Centre for Chronic Illness and Ageing
Email: R.W.Essex@Greenwich.ac.uk | Mobile: +447591 065535
I am currently working from home: please contact me by email, or via the study mobile number provided

What if I need to know more, before I can decide? For information and independent guidance about taking part in medical research, please visit: http://www.nihr.ac.uk/get-involved/take-part-in-research.htm

What if there is a problem? If you have a concern about any aspect of this study, or need more information, please contact Professor Lesley Dibley using the details above. Lesley will do her best to answer your questions. If you have a complaint, you should talk to a member of the research team who will try to answer your questions.

This study is sponsored by the University of Greenwich. The sponsor will, at all times, maintain adequate insurance in relation to the study, in respect of any claims brought by or on behalf of a study participant.

Thank you very much for taking the time to read this information leaflet