

<INSERT
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Mitochondrial DAMPs as mechanistic biomarkers in Crohn's disease and Ulcerative Colitis (MUSIC)

PARTICIPANT CONSENT FORM

Please initial boxes

1	I confirm that I have read and understand the Participant Information and Data Protection Information Sheet (Version __ date: _____ for the above study. I have had the opportunity to consider the information, ask questions and have had these answered satisfactorily.	<input type="checkbox"/>
2	I understand that my participation is voluntary and I am free to withdraw at any time without giving any reason and without my medical care and legal rights being affected.	<input type="checkbox"/>
3	I give permission for my personal information (including name, address, date of birth, community health index (CHI) number, telephone number and consent form) to be passed to the University of Edinburgh for administration of the study.	<input type="checkbox"/>
4	I understand that during the study I may be contacted by telephone, text message, email and letter reminders for any study samples that need to be collected or questionnaires needing completed. I understand that I may be contacted and asked to attend out with my usual medical appointments, only when convenient for both parties.	<input type="checkbox"/>
5	I give the members of the MUSIC research team permission to access and store information about my general physical health and current and past episodes of illness from my medical records. I understand that all information collected about me will be kept strictly confidential by the research team.	<input type="checkbox"/>
6	I understand that relevant sections of my medical notes and data collected during the study may be looked at by individuals from the Sponsor (University of Edinburgh and NHS Lothian), from regulatory authorities or from the NHS organisation where it is relevant to my taking part in this research. I give permission for those individuals to have access to my data and medical records.	<input type="checkbox"/>
7	I agree to undertake further ileo-colonoscopy (camera test examining my lower small and large bowel) and that this test will be video recorded. I understand that results of my ileo-colonoscopy will be made available to my usual NHS consultant, clinical team and GP.	<input type="checkbox"/>
8	I agree that my blood, stool, saliva and gut biopsy samples will be transferred to other study sites and used for DNA analyses, protein and genetic expression studies. The results of these tests cannot be traced back to you, and will only ever be used for research	<input type="checkbox"/>
9	I agree that my anonymised sample(s) may be used by clinical, academic or commercial researchers, and may be used in countries outwith the United Kingdom.	<input type="checkbox"/>

10	I understand that I will not benefit financially if this research leads to the development of a new treatment or medical test.	<input type="checkbox"/>		
11	I agree to my General Practitioner being informed to my participation in the study.	<input type="checkbox"/>		
12	I agree to take part in the above study.	<input type="checkbox"/>		
13	I agree that my clinical samples that I provide (blood, stools, saliva and bowel biopsies and tissue) which are surplus will be anonymised and stored in the South East Scotland Bioresource for future research use when the study is completed. Please clearly circle YES or NO	<table border="1"> <tr> <td>Yes</td> <td>No</td> </tr> </table>	Yes	No
Yes	No			
14	I agree to provide an extra blood sample in the future if necessary, by venepuncture, and an extra stool sample. We will ask you again and you can always decline this in the future if you change your mind. Please clearly circle YES or NO.	<table border="1"> <tr> <td>Yes</td> <td>No</td> </tr> </table>	Yes	No
Yes	No			
15	I agree that during research ileo-colonoscopy, extra biopsy samples can be taken at that time. I understand that there is a small associated risk with extra biopsy samples taken. Please circle clearly YES or NO. You can stay in the study even if you do not provide biopsy samples.	<table border="1"> <tr> <td>Yes</td> <td>No</td> </tr> </table>	Yes	No
Yes	No			

**Name of participant
(please print)**

Signature

Date

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Name of person taking consent

Signature

Date

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Thank you for agreeing to take part in this research

3 Copies:

1 to Participant, 1 (Original) to retained by MUSIC Research Team and stored in Patient File, 1 to be filed in/uploaded to patient's medical records

Study ID label:
