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IBD BioResource, part of the NIHR BioResource

Version 7, 21/07/23

PATIENT CONSENT FORM

If you agree to take part in the IBD BioResource please:

- initial boxes 1, 2, 3 & 4
- initial your choices for reporting of genetic results feedback and the National Genomic Research Library
- print, date and sign your name at the end of this form

1. TAKING PART

I confirm that I have read and understood the information sheet version [_] dated [__/__/__] for the IBD BioResource, and had the opportunity to ask questions.

I understand the following:

- **The IBD BioResource Cohort is part of the NIHR BioResource**
  By joining the IBD BioResource I am also joining the NIHR BioResource

- **I can decide to join the IBD BioResource or not.**
  My routine healthcare will not be affected in any way if I don't take part.

- **If I join, I can withdraw at any time**
  If I withdraw, I understand that some research may have already taken place using my data, and this can't be undone

I agree to the following:

- I agree to join the IBD BioResource
- I can be contacted by the BioResource to:
  - complete a health & lifestyle questionnaire, future annual update questionnaires (e.g., regarding my medication)
  - invite me to other studies (which may be IBD or non-IBD related), including donating further samples. I am free to decide whether or not to participate in these at the time
  - send me communications (e.g., newsletters, invitations to events)

Box 1

Initial here to show you agree	

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2. SAMPLES

I agree to:

- give samples for research
  - blood or saliva at enrolment into the IBD BioResource study
  - an additional blood sample and up to two stool samples if recently diagnosed or changing treatment or in stable remission
  - up to 6 extra biopsies from 2 sites (12 biopsies) to be taken for research at future colonoscopies done as part of my clinical care
- the use of surplus material already collected or collected in the future as part of my medical care or participation in previous research studies (e.g., archived tissue from previous biopsies or surgeries)
- my samples being tested as outlined in the patient information sheet
- long-term storage and access to my de-personalised samples for use in future research studies in Cambridge or other research institutions without my further permission, with storage to continue in the event of my incapacity or death

I understand:

- that these samples are a gift to the IBD BioResource and NIHR BioResource
- that these samples may be transferred between research institutions

Box 2

Initial here to show you agree	

3. DATA

I agree that:

- my personal details and contact details can be stored on secure databases by the BioResource. These details can be used for communications with me by the BioResource, including invitations to participate in further health-related research studies.
- the BioResource may access my existing and future hospital medical records, GP records and centrally held health records including but not limited to:
  - NHS Digital databases
  - Public Health England databases
  - Prescribing databases
  - National cancer registries
  - IBD Registry
  - Office for National Statistics database
- the BioResource may analyse and store this information long-term, even in the event of my incapacity or death
- the BioResource team may send my personal identifiers (for example NHS number and date of birth) to the above central health data sources so that data they hold about me can be extracted and linked to my other records and results for research purposes

- information gathered about me can be stored for use in future research studies
- data produced by studying my samples may be included in publications and/or placed in electronic archives (with no connection to my name or other personal identifiers)

I understand that:

- I may be invited to participate in other studies based on data held or accessed about me, and/or analysis (including of DNA markers) of samples I have donated.
- this research may include work conducted by commercial companies, and that I will not benefit financially if it leads to new medical tests, treatments or inventions
- I will be provided with full information about these studies, when and if I am contacted. I understand that I am free to decide whether or not to take part in these studies

Box 3

Initial here to show you agree	

4. RESULTS

- The BioResource will not <u>routinely</u> feedback my personal genetic or biochemical results to me
- Joining the IBD BioResource gives the option for feedback in the event that I am found to have an increased risk of specific rare treatable genetic diseases, which might be relevant for my future health (see results feedback options below)
- I understand that consultants will be surveyed to find out whether genetic findings obtained during research might prove useful to inform decisions regarding choice of drug treatment

Box 4

Initial here to show you understand	

Important:
If you are worried that you are at risk of a genetic disease, please talk to your clinical care team. The genetic results from this research study will take some time to be analysed and asking for feedback on the results should not be used in place of genetic testing needed as part of your healthcare

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INCREASED RISK OF GENETIC DISEASE - RESULTS FEEDBACK OPTION

Please put your INITIALS in ONE box only

I would like to be informed if I am at increased risk of rare genetic disease and **do want** this information fed back through my consultant	

OR

I **do not** want information on genetic disease risk to be fed back through my consultant and I only want my sample to be used for research.	

THE NATIONAL GENOMIC RESEARCH LIBRARY

Please put your INITIALS in ONE box only

I understand that my data will be held by the National Genomic Research Library and I give my permission for researchers to access my data for approved research. I understand I can withdraw from the National Genomic Research Library at any time. I agree for my data to be held by the National Genomic Research Library.	

OR

I DO NOT want my data to be held by the National Genomic Research Library.	

Details of participant	
First name and surname (BLOCK CAPITALS)	
Date of consent	
Date of birth	
Signature	
Details of person receiving consent	
Name (BLOCK CAPITALS)	
Date	
Signature	