Information and Consent for Blood/Tissue/DNA (Genetic) Collection, Storage and Testing for Research

AN INVESTIGATION INTO THE NATURAL HISTORY AND GENETICS OF INFLAMMATORY BOWEL DISEASE

REQUIREMENTS OF STUDY:

In general, the South Metropolitan Area Health Service Human Research Ethics Committee requires that the collection, use and storage of blood/tissue/DNA samples be conducted in accordance with the NHMRC *National Statement on Ethical Conduct in Research Involving Humans* (1999) and the *Guidelines for Genetic Registers and Associated Genetic Material* (2000).

Accordingly, in this study patients' samples will be used in the following ways (these are to be explained to the patient by the study nurse or doctor):

A. SPECIFICITY OF RESEARCH

1. Samples will be used only for the purposes specified for this study: Yes X No ☐

2. Samples will be used for other unspecified research purposes: Yes ☐ No X

B. STORAGE OF SAMPLES

1. Place of storage:

   Inflammatory Bowel Disease Research Group at Fremantle Hospital Department of Medicine and Pharmacology, University of Western Australia

2. Body responsible for storage procedures:

   Inflammatory Bowel Disease Research Group, Department of Medicine and Pharmacology, University of Western Australia

3. Contact details for patient use to arrange for retrieval or destruction of samples, or to obtain information about results:

   Dr Ian Lawrance MB BS (Hons) PhD FRACP
   Senior Lecturer
   School of Medicine and Pharmacology
   University of Western Australia
   Fremantle Hospital
   T Block, Alma Street
   FREMANTLE WA 6160
   AUSTRALIA

   ph 618 9431 3333
   Fax 618 9431 3160

4. Duration of storage:

The information will be stored for 30 years. This will be sufficient time to allow for reference, as It is likely that the data will generate interest and discussion for up to this length of time following publication. All information/ samples will be destroyed by incineration. Furthermore, Information/ Samples will be destroyed at any stage upon patient request.

- current storage for specific use: Yes X No ☐
- long-term storage for specific use: Yes X No ☐
- long-term storage for unspecified use: Yes ☐ No X

5. Can stored samples and information be traced back (directly or indirectly) to the patient? Yes X No ☐

Samples will initially be labelled with the patients' name and date of birth, but this will be replaced by a unique identification number as soon as the samples reach the laboratory, and all other identifiers will be removed. Only the Principal Investigator, Dr Ian Lawrance and the Fremantle IBD Research Co-ordinator, will have access to the paper based records of participants from Fremantle Hospital, in so far as they are involved in the administrative phases (recruitment, consent, data collection and data entry) of the study. Once processed, hard copies will be stored in a locked cabinet, and will only be accessible to the Principal Investigator and the Fremantle IBD Research Co-ordinator.

(*If the answer to 5 is "No" then all answers to "C" must be "No")*

C. ACCESS TO SAMPLES AND RESEARCH RESULTS

1. Will the patient be able to receive results of their testing? Yes ☐ No X
2. Will the patient be able to retrieve/destroy samples if they withdraw from the study or wish to at a later date? Yes X No ☐
3. Could future testing of the sample reveal paternity/maternity? Yes X No ☐

If an instance arises where non-paternity, non-maternity and non-relationship to siblings is discovered, the indicated person will be removed from our family studies. This information will, under no circumstances, be reported to the participant or their family members in order to maintain their privacy, confidentiality and welfare

4. Will the test results be available to family members?
   - Upon the patient's request Yes ☐ No X
   - Upon the family's request Yes ☐ No X
   - Under any other circumstances (specify) Yes ☐ No X

Results from the study are only generated from aggregate data and reported in summary form. Participants' responses and names remain completely confidential and will never be identified in any report. This study is not considered as genetic testing, as there is currently no test that can identify whether a person will get IBD. The work, however, will examine your DNA for markers that may in the future allow for genetic testing to be undertaken to diagnose or identify a person's risk in developing inflammatory bowel disease. Therefore, your samples will not be individually tested for specific genes.

CONSENT

I, _____ of _____

_____

have read and understand the nature of this study as stated in the above details. The Information and any questions I have asked have been answered to my satisfaction.

.....	.....	.....
Name of Patient	Signature of Patient	Date
.....	.....	.....
Name of Witness to Patient Signature	Witness to Signature	Date
.....	.....	.....
Name of Investigator	Signature of Investigator	Date

* The NHMRC advises the Australian community and Commonwealth and State Governments on standards of individual and public health, and supports research to improve those standards.

The South Metropolitan Area Health Service Human Research Ethics Committee has given ethics approval for the conduct of this project. If you have any ethical concerns you can contact the Chairman of the Human Research Ethics Committee on (08) 9431 2929. All study participants will be provided with a copy of the Information Sheet and Consent Form for their personal records.

SOUTH METROPOLITAN AREA HEALTH SERVICE

Providing Comprehensive Health Services to Fremantle, Peel & Rockingham/Kwinana, Armadale and Bentley regions

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REVOCATION OF CONSENT FORM

If at any time you wish to withdraw from the study, please complete this form and send it to the address below.

IBD Research
Level 5 T Block
School of Medicine and Pharmacology
University of Western Australia
Fremantle Hospital
Fremantle 6159, WA

All data collected up until the time you withdraw will be deidentified, so that the researchers will not be able to identify any information as coming from you. Please also indicate if you would like us to destroy the biological samples (blood/tissue) that you have previously donated to the study or if you are happy for us to keep these for research purposes, on the understanding that you will not be identified or contacted about this study again.

I hereby wish to **WITHDRAW** my consent to any further participation in the study named above and understand that such withdrawal **WILL NOT** make any difference to my medical care.

I wish you to destroy the biological sample that I had previously donated to the study:

- ☐ YES, please destroy my biological sample/s
- ☐ NO, I am happy for you to keep the sample/s

Full Name: (please print clearly) _____
If your name has changed, please include your previous name

Date of Birth _____

Signature _____ Date _____

Please post to: