INFORMED CONSENT FORM

1. Study Information

A multi-centre Asian Paediatric Inflammatory Bowel Disease Registry

Principal Investigator & Contact Details:

Dr James Huang
Department of Paediatrics,
NUHS Tower Block, Level 12,
1E Kent Ridge Road,
Singapore 119228
Contact No: +65-67724420
24-hour hotline: +65-97860421

2. Purpose of Database

You are invited to participate in a research database because we would like to collect data on your child's medical condition and well-being. Data will be used for future research into paediatric inflammatory bowel disease in Asia. It is important to us that you first take time to read through and understand the information provided in this sheet. Nevertheless, before you take part in this research database, the database will be explained to you and you will be given the chance to ask questions. After you are properly satisfied that you understand this database, and that you wish to take part in the database, you must sign this informed consent form. You will be given a copy of this consent form to take home with you.

You (and your child) have been asked because your child has inflammatory bowel disease (IBD) that requires medical follow-up. Children with IBD require regular medical appointments, procedures (blood tests, scans, endoscopy) and they may need to take medications for a long-time. Some patients may require surgery and/or hospitalizations. Psychological and social well-being of the child and family can be affected. Data collected about your child's diagnosis and quality of life will facilitate future research to achieve the best long-term medical and social outcomes for patients like your child.

This research database will recruit 100 existing IBD subjects from National University Hospital and all subsequent newly diagnosed paediatric IBD cases.

3. What procedures will be followed in this database

If you agree for your child to participate, you are consenting for data from your child's medical records to be collected. These include information on your child's demographics, gastrointestinal disease, laboratory / investigation results, outpatient and hospitalization details, as well as (gastrointestinal) biopsies and surgeries (if these are done). The medical data may be collected from NUH and other healthcare institutions, and will include previous data (going back to your pregnancy, if available), and up to ten years after your child is no longer with our paediatric service.

At periodic times over the years of follow-up, when you/ your child comes to the clinic or hospital, you will be asked to answer questions on things like the quality of life, psychological and emotional well-being, and how you and your family are coping. These questionnaires will be administered on paper, electronically such as an iPad, or through face-to-face interviews. The questions take about 5-20 minutes to complete. After you (your child) leaves the paediatric service, you may be surveyed annually for the first 5 years, and then every two years for the next 6 years. This may be done through a phone interview, a questionnaire

during clinic appointments, or email, and expected to take 5-10 minutes.

NUH staff will do the medical data collection; there is nothing for you to do except answer the survey questions.

Your/your child's participation in the database will last throughout the course of clinical care in National University Hospital. There will be no need for additional hospital visits just for this research database. All activities that take place will be done during clinic visits (or when you child is in hospital) that are part of standard clinical care, or the care that your child requires.

If you/your child agree to take part in this database, the following will happen to you/your child:

i. Individually identifiable information about you/your child's disease characteristics and disease risk factors, laboratory tests, endoscopic findings, quality of life questionnaire information and therapeutic information will be collected at the point of diagnosis of IBD

ii. Individually identifiable information about you/your child's disease characteristics and disease risk factors, laboratory tests, endoscopic findings, quality of life questionnaire information and therapeutic information will be collected at yearly intervals from the date of diagnosis of IBD

iii. Individually identifiable information about you/your child's disease characteristics and disease risk factors, laboratory tests and endoscopic findings will be collected at each time of disease flare activity

All individually identifiable information will be coded to protect the subjects' privacy and confidentiality and would be stored at a password protected central disease data registry hosted by Singapore Clinical Research Institute. Any individually identifiable information obtained during the course of this database will be analysed for the purposes of this database and stored for a period of 20 years for future related research studies.

There is a possibility that we might unintentionally come to know of new information about your/your child's health condition from tests that is/are conducted as part of future research studies. These are called "incidental findings".

"Incidental findings" are findings that have potential health or reproductive importance to research participants like you/your child and are discovered in the course of conducting the database, but are unrelated to the purposes, objectives or variables of the database. These findings may affect your/your child's current or future life and/or health insurance coverage. There will not be any incidental findings from storing your health information in this database.

4. Your Responsibilities in This Database

If you (and your child) agree to participate in this database, you should follow the advice given to you by the database team and follow the procedures as listed above.

5. What Is Not Standard Care or is Experimental in This Database

There will be no experimental procedures or analyses involved in this database.

6. Possible Risks and Side Effects

Participation in any research database may risk a breach in patient confidentiality, However, to mitigate these risks, all individually identifiable data will be coded and treated in strictest confidentiality and secured by strong encryption technology. Access is available only to the doctors/ investigators. Because long-term follow-up is required, this data cannot be anonymous when collected but only coded information will be stored on a central password-protected registry at Singapore Clinical Research Institute. However, if any of this information is to be published, the data will be anonymized and only reported in aggregate.

7. Possible Benefits from Participating in the Database

There is no known benefit from participation in this database. However, your participation in this research database may add to the medical knowledge about paediatric inflammatory bowel disease and would contribute to enhanced understanding of disease behaviour and an improved overall standard of IBD care in Singapore.

8. Alternatives to Participation

Participation in this research database does not influence standards of IBD care you (and your child) will receive. Regardless of your participation status, you will receive standard care for your condition.

9. Costs & Payments if Participating in the Database

If you/your child take part in this database, the consultation charges, costs of blood taking and endoscopy will be borne by you/your child as part of standard care for the diagnosis and treatment of his/her condition. No payments will be paid to the participants for participating in this database.

If you/your child take part in this database, the following will be performed at no charge to you: **Individually identifiable disease data collection and storage of coded information on a central password-protected disease registry at Singapore Clinical Research Institute** . These costs will be borne by research grant funding.

10. Voluntary Participation

Your participation in this research database is voluntary. You may stop participating in this database at any time. Your decision not to take part in this database or to stop your participation will not affect your medical care or any benefits to which you are entitled. If you decide to stop taking part in this database, you should tell the Principal Investigator.

In the event of any new information becoming available that may be relevant to your willingness to continue in this research database, you (or your legally acceptable representative, if relevant) will be informed in a timely manner by the Principal Investigator or his/her representative.

If you withdraw from the database, you will be required to tell the custodian, Dr James Huang at 65-67724420.
However, the data that have been collected until the time of your withdrawal will be kept and analysed. The reason is to enable a complete and comprehensive evaluation of the research database that is already using your/your child's data for research

11. Compensation for Injury

Injuries are not expected since this database only involves data collection from medical records. By signing this consent form, you will not waive any of your legal rights or release the parties involved in this study from liability for negligence

12. Confidentiality of Database and Medical Records

Your participation in this database will involve the collection of "Personal Data". "Personal Data" means data about you which makes you identifiable (i) from such data or (ii) from that data and other information which an organisation has or likely to have access. This includes medical conditions, medications, investigations and treatment history.

Information and "Personal Data" collected for this database will be kept confidential. Your records, to the extent of the applicable laws and regulations, will not be made publicly available.

However, NUH, Regulatory Agencies *(HSA, FDA, if relevant)* and NHG Domain Specific Review Board and Ministry of Health will be granted direct access to your original medical records to check database procedures and data, without making any of your information public. By signing the Informed Consent Form attached, you (*or your legally acceptable representative, if relevant*) are authorising (i) the collection, access to, use and storage of your "Personal Data", and (ii) the disclosure to authorised service providers and relevant third parties.

Data collected and entered into the Case Report Forms are the property of *NUH*. In the event of any publication regarding this database, your identity will remain confidential.

Research arising in the future, based on your "Personal Data", will be subject to review by the relevant institutional review board.

Information containing your "Personal Data" that is collected for the purposes described in this Informed Consent Form will be stored in Singapore. Only anonymised data will be transferred out of Singapore to local or overseas collaborators.
By participating in this research database, you are confirming that you have read, understood and consent to the Personal Data Protection Notification available at :
http://www.nuhs.edu.sg/personal-data-protection/nuhsnuh-data-protection-policy.html
Hardcopies may be made available on request.

13. Who To Contact if You Have Questions

If you have questions about this research database, you may contact the Principal Investigator:

Dr James Huang
Department of Paediatrics,
NUHS Tower Block, Level 12,
1E Kent Ridge Road,
Singapore 11922
Contact No: +65-67724420
24-hour hotline: +65-97860421

The database has been reviewed by the NHG Domain Specific Review Board (the central ethics committee) for ethics approval.

If you want an independent opinion to discuss problems and questions, obtain information and offer inputs on your rights as a research subject, you may contact the NHG Domain Specific Review Board Secretariat at 6471-3266. You can also find more information about

participating in clinical research, the NHG Domain Specific Review Board and its review processes at www.research.nhg.com.sg.

If you have any complaints or feedback about this research database, you may contact the Principal Investigator or the NHG Domain Specific Review Board Secretariat.

14. Consent to be Contacted for Future Research (Optional)

You are being asked for permission to be contacted in the future for participation in research studies that you may be suitable for. If you agree to be contacted, your information and contact details will be entered and stored in a secured database in NUHS. Your information and contact details will not be released to any parties outside NUHS without your permission. When investigators from NUHS identify you to be suitable for a particular research study, the investigators or authorised personnel from NUHS will contact you to inform you about the research study. Your decision to be contacted for future research studies is completely voluntary and separate from your decision to participate in this study. Your decision will not affect your medical care or any benefits to which you are entitled. You may change your mind at any time by contacting Dr James Huang at 67724420/97860421.

CONSENT FORM

Protocol Title:

A multi-centre Asian Paediatric Inflammatory Bowel Disease Registry

Principal Investigator & Contact Details:

Dr James Huang
Department of Paediatrics,
NUHS Tower Block, Level 12,
1E Kent Ridge Road,
Singapore 11922
Contact No: +65-67724420
24-hour hotline: +65-97860421

I voluntarily consent to take part in this research database. I have fully discussed and understood the purpose and procedures of this database. This database has been explained to me in a language that I understand. I have been given enough time to ask any questions that I have about the database, and all my questions have been answered to my satisfaction. I have also been informed and understood the alternative treatments or procedures available and their possible benefits and risks.

By participating in this research database, I confirm that I have read, understood and consent to the NUH Personal Data Protection Notification.

Consent for the Use of Data for Future Research

☐ Yes, I agree to donate my data for future research as long as the research is related to paediatric inflammatory bowel disease.

Please also check one of these boxes:

☐ There are no restrictions on the kind of research that may be done with my data.

☐ The Investigator may use my data for future research as long as the research is related to IBD and IBD-associated conditions.

☐ No, I do not agree to donate my data for future research.

Consent to be Contacted for Future Research

☐ Yes, I agree to be for contacted for future research that I may be eligible for.
I agree to be contacted via:

☐ Phone _____

☐ Mail _____

_____

☐ Email _____

☐ Others _____

☐ No, I do not agree to be contacted for future research.

For parent:

I agree to let my child / children participate in this database by the National University Hospital to study disease behaviour and long-term complications associated with IBD. I understand that this involves clinical data collection as well as the use of questionnaires.

This database has been explained to me in a language _____ (State language used) that I understand.

Parent's or Guardian's Name: _____

Relationship: _____

Signature: _____

Date: _____

For child (6-12 years of age):
The child will have to sign a separate assent form which is to be attached with the parent consent form.

For child (if more than 12 years of age):

I agree to let my child / children participate in this database by the National University Hospital to study disease behaviour and long-term complications associated with IBD. I understand that this involves clinical data collection as well as the use of questionnaires.

Subject's Name: _____

Signature: _____

Date: _____

Translator Information
The study has been explained to the participant / legally acceptable representative in

_____ _____by _____

Witness Statement
I, the undersigned, certify that:

• I am 21 years of age or older
• I have taken reasonable steps to ascertain the identity of the participant/ the participant's legally acceptable representative giving the consent.

• I have taken steps to ascertain that the consent has been given voluntarily without any coercion or intimidation.

Name of Witness	Signature	Date

1. In accordance with Section 6(d) of the Human Biomedical Research Act and Regulation 25 of the Human Biomedical Research Regulations 2017, appropriate consent must be obtained in the presence of a prescribed witness who is 21 years of age or older, and has mental capacity. The witness must be present during the entire informed consent discussion, and must not be the same person taking the appropriate consent. The witness may be a member of the team carrying out the research.

2. However, if the participant/ the participant's legally acceptable representative is unable to read, and/ or sign and date on the consent form, an impartial witness should be present instead. The impartial witness should not be a member of the database team.

Investigator Statement

I, the undersigned, certify that I explained the database to the participant and to the best of my knowledge the participant signing this informed consent form clearly understands the nature, risks and benefits of his / her participation in the database.

Name of Investigator / Person administering consent	Signature	Date