CONSENT FORM

Access to Medical Records and Remaining Blood Samples for Future Research

Doctor In Charge: Chief, Department of Gastroenterology & Hepatology
National University Hospital
5 Lower Kent Ridge Road
Singapore 119074
Contact No. 67795555

Research is the great opportunity to contribute to understanding disease and develop new treatments. We ask you to agree to be our partners in advancing medical knowledge and making breakthroughs. All you have to do is to allow us to use your medical records anonymously for research and permit your remaining blood samples for routine tests to be used for research.

Your participation is voluntary.

No extra effort, extra visit, extra procedure or extra blood samples are needed!

Your records will be anonymous and kept confidential and will not be made available publically. Your identity will not be revealed without your consent.

All our research studies will be reviewed by NHG Domain Specific Review Board (the central ethics committee) to protect your interests, consequently, if you wish to have an independent opinion of your rights as a research subject you may contact the NHG Domain Specific Review Board Secretariat at 6471-3266.

- □ **I allow / do not allow*** my **medical records** to be accessed by the Department of Gastroenterology and Hepatology for the purpose of future research with the aim of improving treatment and care.

- □ **I allow / do not allow*** my **remaining blood sample** from the laboratory to be accessed by the Department of Gastroenterology and Hepatology for the purpose of future research with the aim of improving treatment and care.

* Please delete where appropriate

Name of Patient: _____

NRIC of Patient: _____

Signature of Patient: _____

Date: _____

ACCESS MEDICAL INFORMATION/DATA AND LEFTOVER BIOLOGICAL SPECIMEN

1. Contact Details

Contact Person: Prof Lim Seng Gee
Address: 5 Lower Kent Ridge Rd, Singapore 119074
Phone: (65) 6779 5555
Email: NUH_Enquiries@nuhs.edu.sg

2. Purpose

The Program will seek the consent from all patients of the *Department of Gastroenterology and Hepatology*, NUH. You are invited to give consent to this research program because you are a patient of the *Department of Gastroenterology and Hepatology*, NUH.

It is important to us that you first take time to read through and understand the information provided in this form. Before you give consent, the Program will be explained to you and you will be given the chance to ask questions. After that, if you agree to give your consent, you can proceed to sign this informed consent form. You will be given a copy of this consent form.

NUH is committed to improving clinical care, by obtaining a better understanding of diseases and developing new treatments, through research. In order to facilitate this, our researchers will need your consent to access your past and future medical information/data, and your leftover biological specimens. Your medical information/data and leftover biological specimens will provide the basic materials for our researchers to study *gastrointestinal and liver related diseases*.

3. What procedures will be followed in this Program

If you agree to consent to the Program, your medical information/data and leftover biological specimens will be donated and used for future research. You are not required to make any additional clinic visits or undergo any additional tests. Only future research studies which obtain the approval of an Institutional Review Board (IRB) will be able to use your medical information/data and leftover biological specimens. Medical information/data and left over biological specimens will be released in the de-identified/coded form for the future research.

(i) Your medical information/data will include the clinical notes taken by your physician, laboratory test results, diagnostic scans and any other forms of documentation taken during the course of your clinical care.

(ii) If you are in NUH for a diagnostic or treatment procedure, as explained by your physician, some tissues may be taken from your body to help in the diagnosis and treatment of your condition. This biological specimen may be, but not limited to, solid (e.g. tumour, liver biopsies), semi-solid (e.g. stool) or fluid (e.g. blood or liver perfusate). If there are leftover biological specimens available after the procedure, it will be collected and stored indefinitely. Otherwise, it will normally be discarded or destroyed. No additional specimen/samples will be taken as part of the program.

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

"Incidental findings" are findings that have potential health or reproductive importance to research participants like you and are discovered in the course of conducting the study, but are unrelated to the purposes, objectives or variables of the study. These findings may affect your current or future life and/or health insurance coverage. You will be asked to indicate whether you wish to be re-identified and notified in the case of a clinically significant incidental finding that is related to you.

If you agree to be re-identified and notified, your study doctor/a qualified healthcare professional will explain the incidental finding to you/your child and discuss and advise you on the next steps to follow. For this purpose, please inform the Principal Investigator or any of the study contact persons listed in this document whenever there are changes in your contact details. You may wish to do more tests and seek advice to confirm this incidental finding.

The costs for any care that will be needed to diagnose or treat an incidental finding would not be paid for by this research study. These costs would be your responsibility."

4. What Is Not Standard Medical Care in the Program

The only part of the Program that is not part of standard medical care is the access of your medical information/data and the donation of your leftover biological specimens. Your leftover specimens will not be

used for future research that is prohibited and restricted by the Third and Fourth Schedules of the Human Biomedical Research Act. Biological samples will not be used for restricted human biomedical research involving human-animal combinations.

5. Possible Risks and Side Effects

There is no additional risk to you by donating your leftover biological specimens. As medical information/data will be accessed, there may be a possible minimal risk of breach of confidentiality. However, the institution has security measures in place to protect your data, such as restricting access to only authorised personnel.

6. Possible Benefits from Participating in the Program

Whilst there may be little or no medical or personal benefit to you, the results from the research may be beneficial to future patients. As the research results are for research and education purposes only, they will not be shared with you.

7. Alternatives to Participation Whether or not you consent to the Program, you will continue to receive the standard medical care for your condition. If you choose not to participate in this Program, we will not collect and store the leftover biological specimens available after your procedure, or review your medical information/data for future research.

8. Costs & Payments if Consenting to the Program There are no costs or payments involved in the Program.

9. Voluntary Participation

Your consent in the Program is voluntary. You may withdraw your consent from the Program at any time. Your decision not to give consent to the Program or to withdraw your consent will not affect your medical care or any benefits to which you are entitled. If you decide to withdraw your consent from this Program, you should inform *Prof Lim Seng Gee*. 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 future research study.

The leftover biological specimens collected for the Program will be deemed to be gifted to NUH and will not be returned to you. You will also not have any right or claim to any share in the commercial gain derived from the research (if any). However, you retain your right to ask NUH to discard or destroy any remaining samples if they have not been anonymised.

11. Compensation for Personal Injury It will not be possible for you to sustain any personal injury as only your medical information/data and donated leftover biological specimen will be used for future research. However, if you follow the directions of the doctors in charge of this study and you are physically injured due to the procedure given under the plan for this study, NUH will pay the medical expenses for the treatment of that injury.

Payment for management of the normally expected consequences of your treatment will not be provided by NUH.

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 Medical Information/Data

Information collected for the Program will be kept confidential. Except as stated below or as required by the applicable laws and regulations, your medical information/data, will not be disclosed to any third party. In particular, the Government Regulatory Agencies and National Healthcare Group (NHG) Domain Specific Review Board (DSRB) and Ministry of Health (MOH) may require access to your medical information/data to check research procedures and data. Authorised service providers collaborators may also require access to your medical information/data strictly for the purposes of the research. By signing the Informed Consent Form attached, you

are authorising the disclosure, collection, access to, transfer, use and storage of your medical information/data and Personal Data as set out herein.

"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 is likely to have access to. This includes medical conditions, medications, investigations and treatment history.

All research arising in the future must first be approved by the relevant Institutional Review Board (IRB) to make sure they are ethical and scientifically sound. Data collected and entered into the Case Report Forms are the property of NUH. In the event of any publication regarding any future research studies using your medical information/data and/or leftover tissues/biological specimens, your Personal Data will not be disclosed and your identity will remain confidential.
Any leftover biological specimens and/or information containing your Personal Data that is collected for the purposes described in this Informed Consent Form will be stored in Singapore. Only anonymised leftover biological specimens and/or anonymised data will be transferred out of Singapore to overseas research collaborators.
By participating in the Program, you are confirming that you have also read, understood and consent to the Personal Data Protection Notification available at www.nuhs.edu.sg/personal-data-protection/nuhsnuh-data-protection-policy.html

13. Who to Contact if You Have Questions

The Program has been reviewed by the NHG DSRB for ethics approval. If you want an independent opinion to discuss problems and questions and offer inputs on your rights as a research subject, you may contact the NHG DSRB Secretariat at 6471-3266. You can also find more information about participating in clinical research, the NHG DSRB and its review processes at www.research.nhg.com.sg. If you have any complaints or feedback about the Program, you may contact *Prof Lim Seng Gee*, or the NHG DSRB Secretariat.