SingHealth

PARTICIPANT INFORMATION SHEET AND CONSENT FORM

You are being invited to participate in a research study. Your participation in this study is entirely voluntary. Before you take part in this research study, the study must be explained to you and you must be given the chance to ask questions. Your questions will be answered clearly and to your satisfaction. Please read carefully the information provided here. If you agree to participate, please sign the consent form. You will be given a copy of this document.

If you are a parent or legal guardian giving consent for a child (below 21 years old) to participate in the study, please note that the word "you" refers to your child.

STUDY INFORMATION

Protocol Title:
Predictors of decompensation, acute-on-chronic liver failure and mortality in liver cirrhosis – a multicentre, prospective, observational study from the SingHealth Chronic Liver Disease Registry (SoLiDaRity-DAM)

Principal Investigator:
A/Prof Jason Chang Pik Eu
Senior Consultant, Department of Gastroenterology and Hepatology, Singapore General Hospital

Site Principal Investigator:
Dr Rahul Kumar
Consultant, Department of Gastroenterology and Hepatology, Changi General Hospital

Site Principal Investigator:
Dr Marianne Anastasia De Roza
Consultant, Department of Gastroenterology and Hepatology, Sengkang General Hospital

BACKGROUND OF RESEARCH STUDY

Liver cirrhosis is a progressive liver condition that can lead to decompensation (development of clinical complications such as fluid collection in the abdomen, internal bleeding from swollen veins in the stomach, accumulation of toxins in the brain and yellowing of the eyes), liver failure, liver cancer and death.

In the current era of personalized medicine, it is important for doctors to collect vital clinical information in a systematic manner over the course of the disease. This will allow us to develop a better understanding of the different factors that affect the progression of the disease in a specific individual. Such information is vital to develop new tests and treatments to improve the care of patients with liver cirrhosis.

PURPOSE OF THE RESEARCH STUDY

The purpose of this study is to identify factors that predict the development of decompensation, acute-on-chronic liver failure (ACLF) and death in patients with liver cirrhosis. This information may help doctors to identify patients with cirrhosis who are at risk of deterioration earlier (before they develop complications) and to develop effective treatment strategies to prevent or delay these complications.

You are selected as a potential participant in this study because you have been diagnosed with liver cirrhosis based on your clinical presentation, blood tests and/or scans.
This study aims to enrol and follow-up 2,200 participants from multiple medical institutions (Changi General Hospital, Sengkang General Hospital and Singapore General Hospital) over a period of 5 years to monitor the progression of the condition.

STUDY PROCEDURES & YOUR RESPONSIBILITIES IN THIS STUDY

This study is designed as a prospective, non-interventional, observational study. This means that if you agree to participate in the study, you will not be required to undergo any additional hospital visits, tests, procedures or interventions other than the usual standard-of-care management that your doctor will provide. If you consent to participate in this study, you will be providing the study investigators permission to review and analyse your clinical data from the hospital clinical records. Your data will be collected throughout the course of your disease until liver transplantation or death.

You should continue to follow the advice and directions of your doctor with regards to the visits, tests, medications and interventions that are necessary for the usual management of your clinical condition. These are not part of the study.

WHAT IS NOT STANDARD CARE OR IS EXPERIMENTAL IN THIS STUDY

This is an observational study in which the collection of medical information (data) from participants' medical records is done for research purposes. Study participants will not be subjected to any interventions that are experimental or not part of standard care.

POSSIBLE RISKS, DISCOMFORTS OR INCONVENIENCES

As this is a purely observational study, participants are not expected to be exposure to any additional risks, discomforts or inconveniences as a result of their participation in this study.

Personal privacy and confidentiality:
This study uses health information that may affect your privacy. To protect your confidentiality, only a unique code number will be used to identify data that we collected from you.

As there will be a link between the code and your identifiable information, there is still a possibility of data breach. A data breach is when someone sees or uses data without permission. To prevent this from happening, the link will be kept in a password-protected document and this will be stored in password-protected computers in the offices of

investigators and study team members. Access to data will be tightly restricted to specific identified investigators.

POTENTIAL BENEFITS

If you participate in this study, there are no specific benefits for you, but your participation in this study may add to the medical knowledge and result in better diagnostic tools and strategies in the management of liver cirrhosis.

ALTERNATIVE PROCEDURES IF YOU DO NOT PARTICIPATE IN THE STUDY

There is no alternative to the study procedures (review of medical records). You can choose not to take part in this study, in which case the study procedures will not be carried out.

COSTS & PAYMENTS IF PARTICIPATING IN THIS STUDY

There is no cost to you for participating in this research study. The cost of your usual medical care (procedures, medications and doctor visits) will continue to be billed to you. You will not receive any payments or reimbursements for taking part in this study.

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.

As this is a purely observational study, we do not expect to find any specific incidental findings since the clinical findings would have been performed as part of your regular clinical care and would thus have been noted and addressed by your primary doctor.

PARTICIPANT’S RIGHTS

Your participation in this study is entirely voluntary. You have a right to ask questions, which the study team will do their best to answer clearly and to your satisfaction.

In the event of any new information becoming available that may be relevant to your willingness to continue in this study, you (or your legal representative, if relevant) will be informed in a timely manner by the Principal Investigator or his/her representative and you will be contacted for further consent if required.

In the event of changes to the development of your capacity to make decisions (e.g. when children have reached the age of 21 years old), you will be contacted for further consent.

WITHDRAWAL FROM STUDY

You are free to withdraw your consent and discontinue your participation in the study at any time, without your medical care being affected. If you decide to stop taking part in this study, you should inform the study coordinator or Principal Investigator. However, any of your data that has 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 study.

Your study doctor, the Principal Investigator of this study may stop your participation in the study at any time if the study is cancelled.

RESEARCH RELATED INJURY AND COMPENSATION

If you follow the directions of the Principal Investigator of this research study and you are injured due to the research procedure given under the plan for the research study, our institution will provide you with appropriate medical treatment.

As this is a purely observational study, we do not expect any study participants to experience any injury related to the research.

Payment for management of the normally expected consequences of your treatment (i.e. consequences of your treatment which are not caused by your participation in the research study) will not be provided.

You still have all your legal rights. Nothing said here about treatment or compensation in any way alters your right to recover damages where you can prove negligence.

CONFIDENTIALITY OF STUDY AND MEDICAL RECORDS

Your participation in this study 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. Examples of personal data include name, national registration identity card (NRIC), nationality, passport information, date of birth, and telephone number.

Personal Data collected for this study will be kept confidential. Your study records and medical records, to the extent required by the applicable laws and regulations, will not be made publicly available. Only the study team will have access to the personal data being collected from you. In the event of any publication regarding this study, your identity will remain confidential.

However, the monitor(s), the auditor(s), the Institutional Review Board, and the regulatory authority(ies) will be granted direct access to your original medical records and study records to verify study procedures and data, without making any of your information public.

By signing the Consent Form, you consent to (i) the collection, access to, use and storage of your Personal Data by Singapore General Hospital, Changi General Hospital and Sengkang General Hospital, and (ii) the disclosure of such Personal Data to our authorised service providers and relevant third parties as mentioned above.

Any information containing your Personal Data that is collected for the purposes of research will be stored in Singapore. To protect your identity, your Personal Data will be labelled with a unique code number. The code will be used in place of your name and other information that directly and easily identifies you. The study team will keep a separate file that links your code number to your Personal Data. This will be kept in a safe place with restricted access.

All data collected in this study are the property of Singapore General Hospital, Changi General Hospital and Sengkang General Hospital. The data will be used for the purpose of this research study and future use in other research studies. For this purpose, consent for future research will be sought from you.

By participating in this research study, you are confirming that you have read, understood and consent to the SingHealth Data Protection Policy, the full version of which is available at www.singhealth.com.sg/pdpa.

WHO HAS REVIEWED THE STUDY

This study has been reviewed by the SingHealth Centralised Institutional Review Board for ethics approval.

If you have questions about your rights as a participant, you can call the SingHealth Centralised Institutional Review Board at 8126 3660 during office hours (8:30 am to 5:30pm).

WHO TO CONTACT IF YOU HAVE QUESTIONS REGARDING THE STUDY

If you have questions about this research study or in the case of any injuries during the course of this study, you may contact:

Principal Investigator (Singapore General Hospital)
A/Prof Jason Chang Pik Eu
Head and Senior Consultant, Department of Gastroenterology and Hepatology
Singapore General Hospital
Phone number: +65 6321 4684

Site Principal Investigator (Changi General Hospital):
Dr Rahul Kumar
Consultant, Department of Gastroenterology and Hepatology, Changi General Hospital
Phone number: 6788883

Site Principal Investigator (Sengkang General Hospital):
Dr Marianne Anastasia De Roza
Consultant, Department of Gastroenterology and Hepatology, Sengkang General Hospital
Phone number: 6930500

If you have any feedback about this research study, you may contact the Principal Investigator or the SingHealth Centralised Institutional Review Board.

CONSENT FORM FOR RESEARCH STUDY

Protocol Title:
Predictors of decompensation, acute-on-chronic liver failure and mortality in liver cirrhosis – a multicentre, prospective, observational study from the SingHealth Chronic Liver Disease Registry (SoLiDaRity-DAM)

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Consultant, Department of Gastroenterology and Hepatology, Sengkang General Hospital

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I agree to participate in the research study as described and on the terms set out in the Participant Information Sheet.

The nature, risks and benefits of the study have been explained clearly to me and I fully understand them.

I understand the purpose and procedures of this study. I have been given the Participant Information Sheet and the opportunity to discuss and ask questions about this study and am satisfied with the information provided to me.

I understand that my participation is voluntary and that I am free to withdraw at any time, without giving any reasons and without my medical care being affected.

By participating in this research study, I confirm that I have read, understood and consent to the SingHealth Data Protection Policy.

Name of participant	Signature/Thumbprint (Right / Left)	Date of signing

To be completed by parent / legal guardian / legal representative, where applicable

I hereby give consent for _____ (Name of Participant) to participate in the research study. The nature, risks and benefits of the study have been explained clearly to me and I fully understand them.

I confirm that I have read, understood and consent to the SingHealth Data Protection Policy.

_____	_____	_____
Name of participant's parent/ legal guardian/ legal representative	Signature/Thumbprint (Right / Left)	Date of signing

To be completed by translator, if required

The study has been explained to the participant/ legal representative in

_____ by _____.
Language Name of translator

To be completed by witness, where applicable

I, the undersigned, certify that:

- I am 21 years of age or older.
- To the best of my knowledge, the participant or the participant's legal representative signing this informed consent form had the study fully explained to him/her in a language understood by him/ her and clearly understands the nature, risks and benefits of the participant's participation in the study.
- I have taken reasonable steps to ascertain the identity of the participant or the participant's legal representative giving the consent.
- I have taken reasonable steps to ascertain that the consent has been given voluntarily without any coercion or intimidation.

Witnessed by: _____ _____
Name of witness Date of signing

_____
Signature of witness

1. An impartial witness (who is 21 years of age or older, has mental capacity, who is independent of the research study, and cannot be unfairly influenced by people involved with the research study) should be present during the entire informed consent discussion if a participant or the participant's legal representative is unable to read, and/or sign and date on the consent form (i.e. using the participant's or legal representative's thumbprint). After the written consent form and any written information to be provided to participant is read and explained to the participant or the participant's legal representative, and after the participant or the participant's legal representative has orally consented to the participant's participation in the study and, if capable of doing so, has signed and personally dated the consent form, the witness should sign and personally date the consent form. This is applicable for Clinical Trials regulated by HSA and Human Biomedical Research under the HBRA.

2. For HBRA studies, the witness may be a member of the team carrying out the research only if a participant or the participant's legal representative is able to read, sign and date on the consent form.

Investigator's Statement

I, the undersigned, certify to the best of my knowledge that the participant/ participant's legal representative signing this consent form had the study fully explained to him/her and clearly understands the nature, risks and benefits of the participant's participation in the study.

Name of Investigator/ Person obtaining consent	Signature	Date

INFORMATION & CONSENT FORM FOR FUTURE RESEARCH

This is an optional component that is separate from the research study. You may still participate in the research study if you say "No" to this. Please ask questions if you do not understand why we are asking for your permission.

In this Consent Form for Future Research, we seek your permission to keep your data for future research. The data will be kept in Singapore General Hospital, Changi General Hospital and Sengkang General Hospital. Except if you withdraw your consent or there are limits imposed by law, there is no limit on the length of time we will store your data. Researchers will use your data for research long into the future.

This is what will be done with your stored data:

- We may use the data to answer additional research questions in other research studies. This is outside the scope of the research study but still related to liver diseases.
- We may share the data with other researchers at SingHealth and other academic institutions in Singapore, as well as with researchers outside of Singapore The stored data will be labelled with a code instead of information that directly identifies you (e.g. your name, NRIC, date of birth, etc.). We will keep a separate file (key) that links your code to your identifiable information.
- When we share your data with other researchers, it will be in coded manner. They will not be able to identify you from the coded data.
- You will be asked to indicate whether you wish to be re-identified and notified in the event of an important incidental finding that is related to you.
- If you decide at a later time that you do not want your data to be used for future research, you can contact the Principal Investigator or study team at any time. All your stored data that have not been used or shared with other researchers will be removed from the database discontinued from further use, unless this information is already included in analyses or used in publications.

The use of your data in future research may result in intellectual property rights and commercial profits. If this should occur, you will not be compensated and will not receive any financial benefits or proprietary interest.

CONSENT FORM FOR FUTURE RESEARCH

This component is optional. You do not have to agree to it in order to participate in the research study.

Please indicate your choice using the relevant checkbox.

☐ I do not agree to have my data stored for future use in other research studies.

☐ I agree to have my data stored for future use in other research studies.

I understand the purpose and nature of this optional component (storage of data for future use in other research studies). I have been given the Information & Consent Form for Future Research and the opportunity to discuss and ask questions about this optional component and am satisfied with the information provided to me.

I confirm that I have read, understood and consent to the SingHealth Data Protection Policy.

Name of participant	Signature/Thumbprint (Right / Left)	Date of signing

Name of participant's parent/ legal guardian/ legal representative	Signature/Thumbprint (Right / Left)	Date of signing

To be completed by translator, if required

The optional component (storage of data for future use in other research studies) has been explained to the participant/ participant's legal representative in

_____ by _____.
Language Name of translator

To be completed by witness, where applicable

I, the undersigned, certify that:

- I am 21 years of age or older.
- To the best of my knowledge, the participant or the participant's legal representative signing this Information & Consent Form for Future Research had the optional component fully explained to him/her in a language understood by him/ her and clearly understands the purpose and the nature of this optional component.
- I have taken reasonable steps to ascertain the identity of the participant or the participant's legal representative signing this Information & Consent Form for Future Research.
- I have taken reasonable steps to ascertain that the participant or the participant's legal representative has not been coerced into giving consent.

Witnessed by: _____ _____
Name of witness Date of signing

_____
Signature of witness

1. An impartial witness (who is 21 years of age or older, has mental capacity, who is independent of the research study, and cannot be unfairly influenced by people involved with the research study) should be present during the entire informed consent discussion if a participant or the participant's legal representative is unable to read, and/or sign and date on the consent form (i.e. using the participant's or legal representative's thumbprint). After the written consent form and any written information to be provided to participant, is read and explained to the participant or the participant's legal representative, and after the participant or the participant's legal representative has orally consented to the participant's participation in the study and, if capable of doing so, has signed and personally dated the consent form, the witness should sign and personally date the consent form. This is applicable for Clinical Trials regulated by HSA and Human Biomedical Research under the HBRA.

2. For HBRA studies, the witness may be a member of the team carrying out the research only if a participant or the participant's legal representative is able to read, sign and date on the consent form.

Investigator's Statement

I, the undersigned, certify to the best of my knowledge that the participant/ participant's legal representative signing this Information & Consent Form for Future Research had the optional component (storage of data for future use in other research studies) fully explained to him/her and clearly understands the purpose and the nature of this optional component.

Name of Investigator/ Person obtaining consent	Signature	Date