Ethics Submission

[Hide]

Study Details | **Attachments** | **Endorsement** | **History** | **DSRB Attachments** | **Form Version**

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Main Page

Please select the appropriate form for submission to the DSRB. Please refer to the explanatory notes below if you need more information.*

- (•) DSRB Application Form 1 - Non Exempt Category
- ( ) DSRB Application Form 2 - Exempt Category

Research activities in which the only involvement of human subjects will be in one or more of the following categories may be able to qualify for the Exempt category.

*Please click on the **DSRB Application Form 2 - Exempt Category** option above to view the categories.*

Don't know which to choose? **Click here**

Section A - Study Title & Study Administrators

A1 Please enter the full title for this study.*

The clinical profile and outcome of acute-on-chronic liver failure in Singapore.

A2 Study Administrators are persons who are responsible for administrative matters related to the Study. They can be the Study Coordinators, Research Nurses or Clinical Research Associates, and need not be part of the Study Team.

While the Principal Investigator remains the primary contact person, the DSRB may contact the Study Administrators for clarification of administrative matters related to the Study.

Study Administrators may also assist the PI in drafting the various online forms and reports, however, only the PI may 'submit' these online forms and reports to the DSRB.

This section is optional but PI's are encouraged to nominate at least one Study Administrator. You may assign Study Administrators for this study below.

Name	Institution	Department	Role	Email
Phyo Wah Wah	National University Hospital	General Medicine	Study Administrator	wah_wah_phyo@nuhs.edu.sg

Section B - Study Team & Submission Domain

B1 Study Sites & Study Team Members

All investigators who have a responsibility for the consent process and/or direct data collection for this study should be listed below. Study Team Members from NHG and DSRB's partner institutions should be added through their registered user accounts so that they will be notified of their participation in this study when the Application is submitted.

For a Multi-centre studies, within NHG institutions and/or institutions under the oversight of NHG DSRB, each institution must have a Site Principal Investigator who is responsible for the conduct of the study in his /her institution.
One of the Site PIs should be designated as Overall Principal Investigator. The Principal Investigator will be the Site PI for his/her own Institution, and will also be the primary contact person for the DSRB.
Note: All Principal Investigators and Co-Investigators from NHG institutions or institutions under the oversight of NHG DSRB have to complete the mandatory minimum training requirement, i.e. CITI Training Program/SGGCP. Please provide a copy of the certification if the minimum training status is reflected as "Not Completed".

(i) 'Overall Principal Investigator': GUAN HUEI LEE

(ii) Study Sites under the oversight of NHG DSRB Click here for help

Add Team Member Delete Site

Main Site	Study Site	Name	Study Role	Institution	Department	Min Training
◉	National University Hospital	Dr GUAN HUEI LEE	PI	National University Hospital	Gastroenterology & Hepatology	Completed
		A/Prof Seng Gee Lim	Co-Investigator	National University Hospital	Gastroenterology & Hepatology	Completed
		Dr Yin Mei Lee	Co-Investigator	National University Hospital	Gastroenterology & Hepatology	Completed
		Dr HOW CHENG LOW	Co-Investigator	National University Hospital	Gastroenterology & Hepatology	Completed
		Dr Boon Leng Kieron Lim	Co-Investigator	National University Hospital	Gastroenterology & Hepatology	Completed
		Dr Thwin Maung Aye	Co-Investigator	National University Hospital	Gastroenterology & Hepatology	Completed
		Dr TAN POH SENG	Co-Investigator	National University Hospital	Gastroenterology & Hepatology	Completed
		Dr Yock Young Dan	Co-Investigator	National University Hospital	Gastroenterology & Hepatology	Completed

(iii) Other external Study Sites under the supervision of the 'Overall Principal Investigator' (eg. Nursing Home, Community Hospitals, Community Centres etc)

Study Site	Institution Authorisation	IRB Approval	Contact Person

B2 External Study Site (for Institutions NOT under the oversight of NHG DSRB)

(i) Are there any other independent study sites by another PI which are conducting the same study?*
○ Yes
◉ No

B3 Research Specialty

Please select the Primary Specialty, and then choose the relevant Sub specialty that has been matched according to the Primary Specialty selected. If the Primary Specialty and/or Sub specialty cannot be found from the list, please choose 'Others' and specify.

No.	Primary Specialty		Primary Sub Specialty	
1	Gastroenterology		Gastroenterology & Hepatology	

Please indicate/add Secondary Specialties.

No.	Secondary Specialty	Secondary Sub Specialty
1	-Please Select-	-Please Select-

B4

i. Which Domain Specific Review Board (DSRB) is this application being submitted to?*

DSRB Domain E

ii. Has the study been submitted to another IRB?*

- (•) No
- ( ) Yes

iii. Has the application been previously rejected by any IRB? (Including NHG-DSRB)*

- (•) No
- ( ) Yes

Section C - Conflict of Interest Declaration

With effect from 1 January 2015, all study team members involved in the design, conduct or reporting of the research are required to complete and endorse a Conflict of Interest Declaration Form during initial submission. This declaration includes any conflicts of interest of their immediate family members (includes parents, siblings, spouse and each dependent child).

The Conflict of Interest Declaration Forms must be attached with this DSRB Application Form under "Attachments" tab (see top of this page), Section/Question to select as "Others", to be submitted to DSRB for review. The Conflict of Interest Declaration Form can be downloaded from https://www.research.nhg.com.sg/wps/wcm/connect/romp/nhgromp/hspp/financial+conflict+of+interest/fcoi+policy

An updated Conflict of Interest Declaration Form must be submitted to the DSRB via study amendments as soon as possible but no later than 30 days if any of the circumstances relevant described herein change during the conduct of the research.

C1 Does the Principal Investigator or any study team members have any potential conflict of interest? The Declaration is also for the immediate family members of the person(s) listed below. *

Dr GUAN HUEI LEE (Principal Investigator):*

- (•) No
- ( ) Yes

A/Prof Seng Gee Lim (Co-Investigator):*

- (•) No
- ( ) Yes

Dr Yock Young Dan (Co-Investigator):*

- (•) No
- ( ) Yes

Dr Yin Mei Lee (Co-Investigator):*

- (•) No
- ( ) Yes

Dr HOW CHENG LOW (Co-Investigator):*

- (•) No
- ( ) Yes

Dr Boon Leng Kieron Lim (Co-Investigator):*

- (•) No
- ( ) Yes

Dr Thwin Maung Aye (Co-Investigator):*

- (•) No
- ( ) Yes

Dr TAN POH SENG (Co-Investigator):*

- (•) No
- ( ) Yes

Please be reminded to attach the completed Conflict of Interest Declaration Form for all study team members involved in the design, conduct or reporting of the research. They may include study coordinators, biostatisticians etc. who may not be listed in Section B and C of the DSRB Application Form.

Section D - Nature of Research

This is a smart form. The choice you make here will determine which sections of the application form will appear.

Clinical Trials

Choose this if your research involves:

(1) Administering a drug, device, or biologic as part of the research intervention, or

(2) Performing surgical procedures as part of research intervention

Questionnaire/ Survey/ Interviews

Choose this if your research involves:

(1) Administering questionnaires/surveys/interviews. This type of research may also include a medical records review component.

Medical Records Review

Choose this if your research involves:

(1) Collection of data for a specific research project by review of medical records including results of routine diagnostic tests performed for standard clinical purposes

(2) Prospective and/or retrospective data collection

Clinical Research

Choose this if your research involves:

(1) Collection of blood by venepuncture, finger stick, etc or

(2) Prospective collection of biological specimen by invasive or non invasive means including biopsies, FNAC's, fundoscopy etc or

(3) Collection of data through research procedures such as X rays, MRI, ultrasound, ECG, EEG, etc or

(4) Any other research categories that are not listed in the options above.

D1 Please select one category that best describes your research activities.*

- ( ) Clinical Trials (which includes Drug, Device and Surgical-Procedure Trials)
- ( ) Questionnaire/ Survey/ Interviews
- (•) Medical Records Review
- ( ) Clinical Research

Note: Clinical Trial Certificate from Health Sciences Authority might be required if you are testing the safety and efficacy of the medicinal product. You should check with HSA if you are unsure.

D2 Is this a US FDA IND/IDE study or data is intended to be reported to FDA in support of a IND/IDE application?*

- ( ) Yes
- (•) No

Note: US FDA-regulated (IND) research activities cannot qualify for Exemption from DSRB Review and Waiver of Informed Consent. The application must be submitted using the DSRB Application Form 1 - Non Exempt Category.

D3 Is this study subjected to any of the following regulations:

- (•) No
- ( ) Yes

- [ ] US Code of Federal Regulations 45 CFR 46
- [ ] US Code of Federal Regulations 21 CFR 50
- [ ] US Code of Federal Regulations 21 CFR 56
- [ ] US Code of Federal Regulations 21 CFR 312
- [ ] US Code of Federal Regulations 21 CFR 812
- [ ] Others

Section E - Study Funding Information

E1 Who will be responsible for the payment and compensation of injury or illness arising from participation of subjects in the study?

The PI should ensure that insurance coverage is available to provide payment and compensation to research subjects

for injury or illness arising from their participation in the study.

(Note: For investigator-initiated studies - Contact your OBR/CRU for more information on available NHG Clinical Trial Compensation Insurance Scheme.

For Sponsored Studies - Sponsors should be primarily responsible for ensuring that subjects receive payment and compensation in the event of injury or illness as a result of their participation in a research study.)*

There is no risk of injury or illness arising from participation of this study. The study will be carried out through data collection and analysis.

E2 Please give information regarding the study's Funding source or Sponsor information.*

- (•) No funding is required for this study to be carried out
- ( ) Pharmaceutical / Industry Sponsored
- ( ) Grant

E3 Who will be responsible for research-related costs? For sponsored studies, please list the costs that will be borne by the sponsor. You may wish to attach the Financial Agreement / Clinical Trial Assurance if it is available. * Click here for help

The study will be carried out by existing manpower.

Dr_Lee_YM.pdf

Section F - Research Methodology

F1 Please provide an abstract of your proposed research (Up to 300 words).

Your abstract must contain: *

Aims
Methodology
Importance of proposed research to science or medicine
Potential benefits & risks

Acute-on-chronic liver failure (ACLF) is a distinct disease entity encompassing an acute deterioration of liver function in patients with chronic liver disease. It is a life-threatening condition with a high short term mortality of 50-90%[2].
Aim:1 To clearly understand the clinical profile of the patients with ACLF in NUHS. From this, the precipitating risk factors towards ACLF could be treated and/or prevented.
2.To study the prognostic indicators of ACLF thereby discussing ways to improve the outcome.
Methodology:It is a retrospective study. Patients who present with acute decompensation of a chronic liver disease will be identified and screened by the involved clinicians to meet the inclusion criteria for ACLF of either APASL or EASL guidelines. Selected patients' data, without the personal identifiers, will be sent to one of the responsible coordinators and then be managed and statistically analyzed. and statistically analyzed.
Importance:No research has been done currently on the chronic liver disease associated with ACLF. The increase in concern for ACLF is due to its high short-term mortality and lack of clear understanding in the natural history and clinical profile of the patients comprising the condition.
Potential benefits amp; risks:As this is a retrospective study, there is no significant risk associated with the participating subjects with regards to their management and safety. This research will provide preliminary data about the clinical profile and outcome of this condition. Also, the relevance and applicability of the current two guidelines for ACLF diagnosis and prognosis can also be compared to see which is more suitable for Singapore context. In addition, this study can be extended to provide physicians with a better knowledge about this disease entity and allow for better prediction of outcome resulting in better management.

F2 What are the Specific Aims of this study?*

1.To clearly understand the clinical profile of the patients with ACLF in NUHS. From this, the precipitating risk factors towards ACLF could be treated and/or prevented.

2.To study the prognostic indicators of ACLF thereby discussing ways to improve the outcome.

F3 What is the Hypothesis of this study?*

The clinical profile of patients with ACLF in Singapore would represent a mixture of both Asian and Western characteristics owing to the diverse ethnic, liver disease aetiologies and lifestyle factors unique to the population.
From studying the relevant prognostic indicators, it will allow the clinicians to better predict the outcome and to provide prompt effective intervention, thereby improving the outcome of the ACLF patients.

F4 Please briefly describe the background to the current study proposal. Critically evaluate the existing knowledge and specifically identify the gaps that the proposed study is intended to fill.*

Acute-on-chronic liver failure is a distinct disease entity encompassing an acute deterioration of liver function in patients with chronic liver disease[1]. It is a life-threatening condition with varied etiology and manifestations with a short term mortality of 50-90%[2]. This is a significantly higher short term mortality than expected with decompensated liver cirrhosis. It is usually associated with a precipitating event (acute decompensation), having a reversible component to the acute deterioration, although the underlying cirrhosis is irreversible[3].
Although there are no widely accepted diagnostic criteria for ACLF, the Asia-Pacific Association for the study of the liver (APASL) and the American Association for the Study of Liver Disease and the European Association for the Study of the Liver (EASL) consensus definitions are commonly used. Although these definitions describe the same disease entity, they are based on fundamentally different features[4]. Furthermore, these two definitions are based on populations with different disease patterns. In addition, it is to be noted that there are currently no studies that have been done regarding ACLF in Singapore.

F5 Please provide a list of relevant references.*

1. Sarin SK, Kumar A, Almeida JA, Chawla YK, Fan ST, et al (2008). Acute-on-chronic liver failure: consensus recommendations of the Asian Pacific Association for the study of the liver (APASL).Hepatol Int. 2009 Mar;3(1):269-82.
2. Moreau R, Jalan R, Gines P, Pavesi M, Angeli P, Cordoba J, et al (2013). Acute-on-chronic liver failure is a distinct syndrome that develops in patients with acute decompensation of cirrhosis.Gastroenterology. 2013 Jun;144(7):1426-37, 1437.e1-9.
3. Kim TY, Kim DJ (2013). Acute-on-chronic liver failure. Clin Mol Hepatol. 2013 Dec;19(4):349-59.
4. Wlodzimirow KA1, Eslami S, Abu-Hanna A, Nieuwoudt M, Chamuleau RA (2013). A systematic review on prognostic indicators of acute on chronic liver failure and their predictive value for mortality. Liver Int. 2013 Jan;33(1):40-52.
5. Garg H, Kumar A, Garg V, Sharma P, Sharma BC, Sarin SK (2012). Clinical profile and predictors of mortality in patients of acute-on-chronic liver failure. Dig Liver Dis. 2012 Feb;44(2):166-71.
6. Katoonizadeh A1, Decaestecker J, Wilmer A, Aerts R, Verslype C, Vansteenbergen W, Yap P, Fevery J, Roskams T, Pirenne J, Nevens F (2007). MELD score to predict outcome in adult patients with non-acetaminophen-induced acute liver failure. Liver Int. 2007 Apr;27(3):329-34.
7. López-Velázquez JA, Chávez-Tapia NC, Ponciano-Rodríguez G, Sánchez-Valle V, Caldwell SH, Uribe M, Méndez-Sánchez N (2014). Bilirubin alone as a biomarker for short-term mortality in acute-on-chronic liver failure: an important prognostic indicator. Ann Hepatol. 2013 Jan-2014 Feb;13(1):98-104.
8. Moreau R, Arroyo V (2014). Acute on Chronic Liver Failure: A New Clinical Entity. Clin Gastroenterol Hepatol. 2014 Feb 28. pii: S1542-3565(14)00312-7.

F6 Please submit a copy of at least two relevant papers. *

12072_2008_Article_9106.pdf
cmh-19-349.pdf

F7 Please state concisely the importance of the research described in this application by relating the specific aims to the long term objectives.*

No research has been done currently on the chronic liver disease associated with ACLF in Singapore. The increase in concern for ACLF is due to its high short-term mortality and lack of clear understanding in the natural history and clinical profile of the patients comprising the condition. Achieving the aims of this study, it will provide preliminary data about the clinical profile and outcome of this condition. Also, the relevance and applicability of the current two guidelines for ACLF diagnosis and prognosis can also be compared to see which is more suitable for Singapore context. In addition, this study can be extended to provide physicians with a better knowledge about this disease entity and allow for better prediction of outcome resulting in better management.

F8 Discuss in detail the experimental design and procedures to be used to accomplish the specific aims of the study. (If this study involves a retrospective medical record review, please specify the period of data collection.)

Note: W.e.f. 1 July 2014, all research studies submitted from National University Hospital (NUH), involving the use of radioactive materials and/or radiation-emitting equipment will need to obtain approval from the NUH Radiation Safety Committee (RSC) prior to the commencement of the study. For more information and to receive a copy of the 'Guidelines to undertake Research which involves the use of Ionizing and/or Non-Ionizing Radiation', please contact the NUH Radiation Safety Officer (michael_tong@nuhs.edu.sg) or the NUHS Research Office (clinical_research@nuhs.edu.sg).

This is a retrospective study done on the existing data of patients admitted to the National University Hospital in Singapore. The pool of patients to be screened for ACLF will be drawn from the list of patients admitted to the hepatology team by all the involved physicians, from January 2009 to November 2014. All relevant data had been recorded in the hospital electronic medical records, ICU monitoring system and the patients' case files. In this study, the diagnosis of ACLF is made by using either APASL or EASL definitions.

Data Collection: All the relevant data will be collected by the involved clinicians through their individual inpatient patient list and transferred the data to the study administrator in an anonymised manner. Data collection includes age, gender, body mass index, information about existing chronic liver disease, information about acute decompensation, other relevant laboratory values of the patient during admission (white cell count, creatinine, bilirubin, international normalized ratio, C-reactive protein, etc.), treatments and outcome. We estimate that more than 90% of the eligible patients would have passed away due to their advanced disease status. The very high mortality rates of the patients with ACLF make it impossible to obtain prospective consent from the vast majority of them. Therefore, since this study does not directly involve the patient or alter their management in any way, the safety of patients will be ensured with standard routine care. Confidentiality of the patients will also be preserved by anonymising the data collected. The subject data will be assigned code numbers which do not reflect personal identifiers.

Waiver of consent: The reason for waiver of consent is the high mortality of the patients with disease of interest and thus it is impossible to prospectively obtain informed consent from subjects. For the rest of the patients (20-25% estimated) who are still alive, the consent form for the the Department of Gastroenterology Generic Protocol (DSRB Reference: 2010/00538), was already taken from the patients earlier before the specimen collection, and do not need to be re-taken.

These anonymised data will be shared and analysed together with the Asia-Pacific Study of Liver Disease (APASL) ACLF Research Consortium as part of the large Asia-Pacific database for the refinement of the APASL ACLF criteria and prognostic factor analysis.

F9 Please provide details on sample size and power calculation and the means by which data will be analyzed and interpreted (If applicable). * Click here for help

Statistical Analysis: The data will be enter into a spreadsheet format and analysed using the SPSS software version 20, including Chi Square, Student's t-test, multivariate analysis for various risk factors for positive and negative outcomes. P value less than 0.05 will be regarded as statistical significance.

F10 List all activities that are carried out as part of research in this study. Please state/list all procedures involved in this research study and attach the data collection form (if any) which will be used for DSRB review. The data collection form should be attached under "Attachments" tab, Section "Others". * Click here for help

1. Identification of patient fulfilling ACLF criteria by individual physicians from their own hospital admission lists.
2. Collection of data from hospital inpatient record for subjects fulfilling the inclusion/exclusion criteria. De-identification of subject data. Data collection form as attached.
3. Data analysis.
4. Submission for publication.

F11 List all activities that are performed for routine diagnostic or standard medical treatment as part of the subject's standard care. All research-related activities should not be stated in this section.*

Routine clinical diagnosis, investigations and treatment would be continued with respect to the need of individual patient. The patients will continue to be follow-up at the outpatient liver clinics until their demise.

F12 Please describe the subject's visits (frequency and procedures involved). For studies with multiple visits, please attach study schedule. (If applicable)*

Not applicable. This study merely has no effect on the subjects' routine visits and standard of care.

ACLF Data Collection Form v1_DSRB 15-Oct-2014.xlsx

F13 Discuss the potential difficulties and limitations of the proposed procedures and alternative approaches to achieve the aims.*

Patients may have been admitted to other hospitals in Singapore for previous episodes of acute decompensation and therefore the full clinical progress of the patient cannot be analyzed. Certain laboratory investigations that are required for data analysis in the study may not have been done for the patient and certain subjective data may not have been documented in the records resulting in incomplete data.

F14 What are the Potential Risks to Subjects?*

There is no risk to patients' management and safety as well as confidentiality. Only the patients' own physicians have access to the identity of their own patients.

F15 What are the Potential Benefits (direct as well as indirect) to subjects? Indirect benefit may refer to the medical knowledge gained in the future, from the research.*

This research will provide preliminary data about the clinical profile and outcome of this condition. Also, the relevance and applicability of the current two guidelines for ACLF diagnosis and prognosis can also be compared to see which is more suitable for Singapore context. In addition, this study can be extended to provide physicians with a better knowledge about this disease entity and allow for better prediction of outcome resulting in better management.

F16 Preliminary Studies / Progress Reports. Please provide an account of the Principal Investigator's preliminary studies (if any) pertinent to this application.*

NA

F17 What is the estimated timeline for this study? Click here for help

Estimated Start Date: * 01-Apr-2015

Estimated End Date: * 31-Mar-2017

Estimated duration for this study: **2**year(s) **0**month(s)

F18 Does this study have a Study Protocol? Note: For Clinical Trials, investigators are required to submit a Study Protocol for review.*

- ( ) Yes
- (•) No

F19 The PI is responsible for ensuring that all Study Subjects give informed consent before enrolling into the study.

Please select all the applicable consent scenarios.*

- ( ) Informed Consent will be taken for all study subjects.
- (•) Waiver of Informed Consent is requested for all study subjects.
- ( ) A combination of both Informed Consent and Waiver of Consent is required for different study populations.

Section H - Recruitment Details

H1 How will potential subjects be identified? (Please tick all the applicable boxes)*

- [ ] Referral by attending healthcare professional
- [x] Patients of study team
- [ ] Databases
- [ ] Other methods of subject identification

H2 Who will make the first contact with subject (Enter NA if not applicable)? * Click here for help

NA

H3 How will the subject be contacted (Enter NA if not applicable)? * Click here for help

NA

H4 Will any advertising / recruitment materials be used to recruit research subjects? * Click here for help

- ( ) Yes
- (•) No

H5 Will any other recruitment strategies be used? (Eg. Talks in public places, societies etc.)*

- ( ) Yes
- (•) No

H6 What is the Recruitment Period (if applicable)? Please provide us with the approximate recruitment period. Click here for help

Start Date: 01-Jan-2009

End Date: 30-Nov-2014

Period of study recruitment period: **5**year(s) **11**month(s)

H7 Please indicate the length of time of the subject's direct involvement in the study. E.g. For clinical visits, examinations etc. (If applicable)

NA

Section I - Study Sites & Recruitment Targets

I1 Please state the target number of research subjects to be recruited for each study site in Singapore. If the exact numbers are not available, please give an approximate number range in the Recruitment Target Minimum and Maximum columns.*

Please note that recruiting subjects beyond the Max. No. without DSRB's approval would constitute a Non-Compliance. If you intend to recruit beyond the Max. No., please submit a study amendment to increase the recruitment target.

For the distribution of Males, Females and Children to be recruited into the study, please use the Recruitment Target Max. No. to provide an approximate distribution ratio.

(Go back to Section B1 to add additional study site)

No.	Study Site	Recruitment Target Min *	Recruitment Target Max *	Males *	Females *	Children *
1	National University Hospital	60	100	50	50	0

I2 Is this study part of an international study?*

(•) Yes

Please state the total number of worldwide research subjects targeted for enrollment into this study. If exact numbers are not available, please give an approximate number. *

1500

( ) No

Section Q - Consent Process - Waiver of Consent

Q NO. Informed consent will not be obtained from Research Participants before enrollment into the study.

The DSRB may waive the requirement to obtain informed consent if the DSRB finds that the study meets the following criteria:

Q1 The study poses no more than minimal risk to research subjects.

Please elaborate and justify why your study meets this criterion. * Click here for help

There is minimal risk to research subjects since the study team will only be collecting existing data of patients and analyse them.

Q2 Waiver of informed consent will not adversely affect the rights and welfare of research subjects?

Please elaborate and justify why your study meets this criterion. * Click here for help

All the data collected from electronic medical records, ICU physiological data records and patients' case files from NUH by the involved physicians will be anonymised and coded before sending to the responsible administrator. This means that the study does not involve the patients or alter their management in any way and and thus, the safety and confidentiality of patients will be ensured.

Q3 The study cannot be practically conducted without the waiver of informed consent. (eg. the subjects are no longer on follow-up, lost to follow-up or deceased).

Please elaborate and justify why your study meets this criterion. * Click here for help

The very high mortality nature of the condition makes it unfeasible to obtain informed consent from deceased subjects. However, generic consent (Department of Gastroenterology Generic Protocol (DSRB Reference: 2010/00538)) will be obtained from the subjects who survived. PDPA review form is attached in "Others" for DSRB reference.

Q4 Whenever appropriate, will the research subjects be provided with additional pertinent information after participation? * Click here for help

(•) No

( ) Yes

Please elaborate.*

Not applicable.

Q5 Do you have any additional comments supporting the waiver of informed consent? * If Yes. Please describe.*

( ) No

(•) Yes

Please elaborate.*

The reason for waiver of consent is the high mortality of the patients with disease of interest and thus it is impossible to

prospectively obtain informed consent from subjects. For the rest of the patients (20-25% estimated) who are still alive, the consent form for the the Department of Gastroenterology Generic Protocol (DSRB Reference: 2010/00538), was already taken from the patients earlier before the specimen collection, and do not need to be re-taken.

Section R - Research Data Confidentiality

R In general, to protect the Study Subject's confidentiality, research data should be coded, and the links between the Subject's identifiers and the codes should be stored separately from the research data.

R1 Will coded / anonymous research data be sent to the study sponsor (e.g. pharmaceutical-sponsored studies)?*

(•) No, the study team would store all research data within the institution

i. Please state where the research data (soft copy and/or hardcopy) will be stored and indicate if the location storage is secured (i.e Password Protected PC or Laptop, data stored in physical location with lock and key access.)*

All the data will be password protected. The subjects will be anonymized after complete data collection.
The data file containing subjects' particulars will be stored in password protected laptop, locked inside the cabinet of PI's office.
The key to the cabinet will be kept with PI. There will be a back-up data just in case the laptop is lost.

ii. Who will have access to the research data, and how will access to the research data be controlled and monitored? (Please state the personnel who will have access to the study data eg. PI, Co-investigator, study coordinator.) * Click here for help

PI and co-investigators are the only personnel who will have access to the study data. PI is the one who will provide and monitor the access of the data. One research assistant will be assisting in the analysis of the data and so she will be adequately trained before she is allowed to get access to the study data.

iii. Are there any other measures in place to protect the confidentiality of the research data? * Click here for help

In addition to the measures from R1 (i), the records will be kept in password-protected computers in the locked office. The computers used are not connected to a network.

iv. Are there any research data sharing agreements with individuals or entities outside the Institution, to release and share research data collected? * Click here for help

( ) No
(•) Yes

Please describe the agreement. Submit a copy of the agreement if available.*

Only the anonymized data will be shared and analysed together with the Asia-Pacific Study of Liver Disease (APASL) ACLF Research Consortium as part of the large Asia-Pacific database for the refinement of the APASL ACLF criteria and prognostic factor analysis.

v. Describe what will happen to the research data when the study is completed. * Click here for help

The study data will be kept for 6 years. After that, all the records will be destroyed.

( ) Yes, the study team would send research data to the study sponsor

R2 Will any part of the study procedures be recorded on audiotape, film/video, or other electronic medium?*

(•) No
( ) Yes

Section U - Principal Investigator's Curriculum Vitae

This section shows the Principal Investigator's as well as Study Team Members' Curriculum Vitae. Please ensure that the information shown here is accurate and up to date.

If the PI or Study Team Member Currivulum Viate does not appear on the list, the team member needs to upload or update his/her CV, it could be done through his/her ROAM profile.

The DSRB will use the information contained here to assess the qualifications of the Principal Investigator and Study team members to carry out the Study as described in this Application.

Study Site	Name	Study Role	CV
National University Hospital	Dr GUAN HUEI LEE	PI	Circulum Vitae v11_5 Mar 2012.doc 18-May-2012
	A/Prof Seng Gee Lim	Co-Investigator	LimSengGeeCV2011.doc 03-Jul-2011
	Dr Yin Mei Lee	Co-Investigator	cv 2014.doc 13-Apr-2015
	Dr HOW CHENG LOW	Co-Investigator	CV_Low How Cheng 2015_1 Research CV.doc 08-Apr-2015
	Dr Boon Leng Kieron Lim	Co-Investigator	Curriculum Vitae_KLBL_July2011.doc 24-Jul-2011
	Dr Thwin Maung Aye	Co-Investigator	ThwinMaungAye_CV_Jan_2015.pdf 02-Feb-2015
	Dr TAN POH SENG	Co-Investigator	CVTanPohSeng.doc 19-Aug-2011
	Dr Yock Young Dan	Co-Investigator	Dan_YY_CV_11.doc 11-Aug-2011

Section V - Declaration of Principal Investigator

Your DSRB Application is now complete and ready for submission.

Principal Investigator's Declaration

I will not initiate this study until I have received approval notification from the DSRB and all applicable regulatory authorities.

I will not initiate any change in the study protocol without prior written approval from the DSRB, except when it is necessary to reduce or eliminate any immediate risks to the Research Participants. Thereafter, I will submit the proposed amendment to the DSRB and all applicable regulatory authorities for approval.

I will promptly report any unexpected or serious adverse events, unanticipated problems or incidents that may occur in the course of this study.

I will maintain all relevant documents and recognise that the DSRB staff and applicable regulatory authorities may inspect these records.

I understand that failure to comply with all applicable regulations, institutional and DSRB policies and requirements may result in the suspension or termination of this study.

I declare that there are no existing or potential conflicts of interest for any of the investigators participating in this study and their immediate family members. If there are, I have declared them in the relevant section of this application form.

By checking the "I agree" box, you confirm that you have read, understood and accept the Principal Investigator's Declaration

☑ **I have read and agree to the above declaration.**

Principal Investigator: GUAN HUEI LEE

Close