*Southern Adelaide Local Health Network*

**Participant Information Sheet/Consent Form**

**Interventional Study** -*Adult providing own consent*

*Flinders Medical Centre*

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| **Title** | *Use of ROTEM guided blood product utilisation in cirrhotic patients undergoing interventional procedures (PROTEM Trial)* |
| **Short Title** | *PROTEM TRIAL* |
| **Protocol Number** | *HREA V1.3.1 (2018)* |
| **Coordinating Principal Investigator/ Principal Investigator** | *A/Professor Alan Wigg* |
| **Associate Investigator(s)**  *(if required by institution)* |  |
| **Location** *(where CPI/PI will recruit)* | *Flinders Medical Centre* |
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**Part 1 What does my participation involve?**

**1 Introduction**

You are invited to take part in this research study because you have been diagnosed with chronic liver disease (CLD) and require a procedure with a moderate to high risk of bleeding. This study aims to test whether using a new blood test called rotational thromboelastometry (ROTEM) will help us better determine the amount of blood product transfusions you may require prior to the procedure. It is hoped that using ROTEM will reduce the use of blood products and the risk of adverse events that can be associated with blood product transfusion.

This Participant Information Sheet/Consent Form tells you about the research project. It explains the treatments involved. Knowing what is involved will help you decide if you want to take part in the research.

Please read this information carefully. Ask questions about anything that you don’t understand or want to know more about. Before deciding whether or not to can take part, you might want to talk about it with a relative, friend or your local doctor.

Participation in this research is voluntary. If you don’t wish to take part, you don’t have to. You will receive the best possible care whether or not you take part in this study.

If you decide you want to take part in the research project, you will be asked to sign the consent section. By signing it you are telling us that you:

• Understand what you have read

• Consent to taking part in the research project

• Consent to having the tests and treatments that are described

• Consent to the use of the your personal and health information as described.

You will be given a copy of this Participant Information and Consent Form to keep.

**2 What is the purpose of this research?**

This study is looking at patients with CLD who require a procedure with a moderate to high risk of bleeding. Due to your CLD, your blood may not be able to clot as well as it normally does. This can be determined by a routine blood test, and if required, we will give you blood products to prevent bleeding problems related to the procedure you are having.

The purpose of this study is to test the effectiveness of a blood test called rotational thromboelastometry (ROTEM) in guiding the amount of blood product transfusions you may require prior to the procedure. It is suggested that ROTEM can predict the risk of clots forming and the risk of bleeding in people with liver disease more accurately than the tests we have readily available at the moment. It is hoped that using ROTEM will reduce the use of blood products and the risks associated with blood product transfusion. We are doing this study in the hope that we can optimise treatment management of patients with liver cirrhosis who require a procedure with a moderate to high risk of bleeding.

This research has been initiated and coordinated by Associate Professor Alan Wigg, Head of the Hepatology and Transplant Medicine Unit in Flinders Medical Centre, South Australia.

**3 What does participation in this research involve?**

You will be participating in a randomized controlled trial. Sometimes we do not know which treatment is best for treating a condition. To find out we need to compare different treatments. We put people into groups and give each group a different treatment. The results are compared to see if one is better. To try to make sure the groups are the same, each participant is put into a group by chance (random). You have a 50/50 chance of being in the group that is allocated to receive the ROTEM blood test. Approximately 8 patients will be assigned to each study group.

If you choose to take part in this study, blood samples will be collected from you on the day of the procedure for ROTEM testing, fibrinogen level, coagulation studies, platelet count, full blood examination and crossmatch.

You will receive a phone call from the study coordinator 48 hrs after your procedure to ask you about the care you received and the problems and benefits of that care. This phone call will take approximately 5-10 minutes.

There are no additional costs associated with participating in this study, nor will you be paid.

**4 Other relevant information about the research project**

A total of 16 people are expected to participate in this study at four hospitals (Flinders Medical Centre, Royal Adelaide Hospital, Lyell McEwin Hospital and Sir Charles Gardiner Hospital).

**5 Do I have to take part in this research project?**

Participation in any research project is voluntary. If you do not wish to take part, you do not have to. Whether you take part or not, your medical care will not be affected in any way. If you do decide to take part, you will be given this Participant Information and Consent Form to sign and you will be given a copy to keep. You are free to withdraw from the study at any time.

**6 What are the alternatives to participation?**

You do not have to take part in this research project to receive treatment at this hospital. If you decide not to participate, your medical care will not be affected in any way.

**7 What are the possible benefits of taking part?**

We cannot guarantee or promise that you will receive any benefits from this research; however, information gained from this study may help us to improve the services provided to other patients who have cirrhosis and require procedures associated with a moderate to high risk of bleeding.

**8 What are the possible risks and disadvantages of taking part?**

The risks associated with this study are related to the procedure you are having and the blood products you may receive prior to the procedure. Patients often receive blood products prior to procedures as part of current standard of care provided at your hospital and are associated with minimal risks, including:

* Fever (0.1% to 1%)
* Chills
* Urticaria (hives) (1-3% of transfusions)

More serious complications are uncommon but include:

* Transfusion transmitted bacterial infection (TTBI) (approximately 1 in 250 000)
* Acute and delayed haemolytic transfusion reactions (1 in 76 000 for acute and 1 in 2500 to 1 in 11 000 for delayed haemolytic transfusion reactions)
* Anaphylaxis (1 in 20 000 to 1 in 50 000)
* Transfusion-related acute lung injury (TRALI) (1 in 1200 to 1 in 190 000)

These problems may require urgent treatment such as treatment of anaphylaxis. If symptoms persist, you should be reported to a doctor immediately, or return to the emergency department.

The risks related to the procedure you are having will be explained to you by your treating doctor during the consent process.

**9 What if new information arises during this research project?**

Sometimes during the course of a research project, new information becomes available about the treatment that is being studied. If this happens, your study doctor will tell you about it and discuss with you whether you want to continue in the research project. If you decide to withdraw, your study doctor will make arrangements for your regular health care to continue. If you decide to continue in the research project you will be asked to sign an updated consent form.

Also, on receiving new information, your study doctor might consider it to be in your best interests to withdraw you from the research project. If this happens, he/ she will explain the reasons and arrange for your regular health care to continue.

**10 Can I have other treatments during this research project?**

While you are participating in this research project, you will receive advice about the medications or treatments you have been taking for your condition or for other reasons. It is important to tell your study doctor and the study staff about any treatments or medications you may be taking, including over-the-counter medications, vitamins or herbal remedies, acupuncture or other alternative treatments. You should also tell your study doctor about any changes to these during your participation in the research project.

**11 What if I withdraw from this research project?**

If you decide to withdraw from the project, please notify a member of the research team before you withdraw. A member of the research team will inform you if there are any special requirements linked to withdrawing.

If you do withdraw during the research project, the study doctor and relevant study staff will not collect additional personal information from you, although personal information already collected will be retained to ensure that the results of the research project can be measured properly and to comply with law.

**12 Could this research project be stopped unexpectedly?**

The likelihood of this research project stopping unexpectedly is very low; however, if it is stopped, you will be notified.

**13 What happens when the research project ends?**

Your treating team will be provided with a summary of the collective results once the data we collect have been analysed.

Results of the study may not be available until about six months after the study finishes. Results of the study will be provided to you if you wish.

No matter what group you are in, at the end of the study you will continue to be followed up in the Liver/Gastroenterology Unit as per usual care.

**Part 2 How is the research project being conducted?**

**14 What will happen to information about me?**

By signing the consent form you consent to the study doctor and relevant research staff collecting and using personal information about you for the research project. Any information obtained in connection with this research project that can identify you will remain confidential. Any information about you that is sent out of the hospital will have a code and will not show your name or address, or any information that directly identifies you. Your information will only be used for the purpose of this research project and it will only be disclosed with your permission, except as required by law.

Information about you may be obtained from their health records held at this and other health services for the purpose of this research. By signing the consent form you agree to the study team accessing these health records if they are relevant to participation in this research project.

It is anticipated that the results of this research project will be published and or presented in a variety of forums. In any publication and/or presentation, information will be provided in such a way that you cannot be identified, except with your permission. This information will be anonymous. This means that the information will not include any details about you and your identity will not be made available.

Information about participation in this research project may be recorded in your health records.

In accordance with relevant Australian and/or *[Name of state/territory]* privacy and other relevant laws, you have the right to request access to your information collected and stored by the study team. You also have the right to request that any information with which you disagree be corrected. Please contact the study team member named at the end of this document if you would like to access your information.

Any information obtained for the purpose of this research project that can identify you will be treated as confidential and securely stored. It will be disclosed only with your permission, or as required by law.

**15 Complaints and compensation**

If you suffer any injuries or complications as a result of this research project, you should contact the study team as soon as possible and you will be assisted with arranging appropriate medical treatment for the participant. If you are eligible for Medicare, they can receive any medical treatment required to treat the injury or complication, free of charge, as a public patient in any Australian public hospital. You also have the right to seek compensation through the legal system.

**16 Who is organising and funding the research?**

This research project is being conducted by a consortium of partners – leaders in the field of Hepatology (liver disease) at various hospitals in South Australia and Western Australia coordinated by Associate Professor Alan Wigg. All clinical information connected with this study will be owned by these sites. No member of the research team will receive a personal financial benefit from the participant’s involvement in this research project (other than their ordinary wages).

**17 Who has reviewed the research project?**

All research in Australia involving humans is reviewed by an independent group of people called a Human Research Ethics Committee (HREC). The ethical aspects of this research project have been approved by the HREC of the Southern Adelaide Local Health Network in South Australia. This project will be carried out according to the *National Statement on Ethical Conduct in* Human Research (2007). This statement has been developed to protect the interests of people who agree to participate in human research studies.

**18 Further information and who to contact**

The person you may need to contact will depend on the nature of your query.

If you want any further information concerning this project or if you have any medical problems which may be related to your involvement in the project (for example, any side effects), you can contact the principal study doctor on *[phone number]* or any of the following people:

**Clinical contact person**

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| --- | --- |
| Name | *[Name]* |
| Position | *[Position]* |
| Telephone | *[Phone number]* |
| Email | *[Email address]* |

For matters relating to research at the site at which you are participating, the details of the local site complaints person are:

**Complaints contact person**

|  |  |
| --- | --- |
| Name | *[Name]* |
| Position | *[Position]* |
| Telephone | *[Phone number]* |
| Email | *[Email address]* |

If you have any complaints about any aspect of the project, the way it is being conducted or any questions about being a research participant in general, then you may contact:

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| --- | --- |
| Reviewing HREC name | Southern Adelaide Clinical HREC |
| Position | Executive Officer |
| Telephone | (08) 8204 6453 |
| Email | Health.SALHNOfficeforResearch@sa.gov.au |

**Reviewing HREC approving this research** **and HREC Executive Officer details**

**Consent Form -** *Adult providing own consent*

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| --- | --- |
| **Title** | Use of ROTEM guided blood product utilisation in cirrhotic patients undergoing interventional procedures |
| **Short Title** | *PROTEM Trial* |
| **Project Sponsor** | Flinders Medical Centre SA |
| **Coordinating Principal Investigator/**  **Principal Investigator** | Assoc Professor Alan Wigg/ *Principal Investigator]* |
| **Location** | *[Location where the research will be conducted]* |
| **Title** | Use of ROTEM guided blood product utilisation in cirrhotic patients undergoing interventional procedures |
| **Short Title** | *PROTEM Trial* |

**Declaration by Participant**

I have read the Participant Information Sheet or someone has read it to me in a language that I understand.

I understand the purposes, procedures and risks of the research described in the project.

I have had an opportunity to ask questions and I am satisfied with the answers I have received.

I freely agree to participate in this research project as described and understand that I am free to withdraw at any time during the project without affecting my future health care.

I understand that I will be given a signed copy of this document to keep.

I give permission for my doctors, other health professionals, hospitals or laboratories outside this hospital to release information to Flinders Medical Centreconcerning my condition and treatment for the purposes of this project. I understand that such information will remain confidential.

I understand that, if I decide to discontinue the research project treatment, I may be asked to attend follow-up visits to allow collection of information regarding my health status. Alternatively, a member of the research team may request my permission to obtain access to my medical records for collection of follow-up information for the purposes of research and analysis.

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|  | | | | | | |
|  | Name of Participant (please print) | |  |  |  |  |
|  | | | | | | |
|  | Signature |  | | Date |  |  |
|  | | | | | | |

**Declaration by Study Doctor/Senior Researcher†**

I have given a verbal explanation of the research project, its procedures and risks and I believe that the participant has understood that explanation.

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|  | Name of Study Doctor/  Senior Researcher† (please print) | |  | | |  |
|  | | | | | |  |
|  | Signature |  | | Date |  |  |
|  | | | | | | |

† A senior member of the research team must provide the explanation of, and information concerning, the research project.

Note: All parties signing the consent section must date their own signature.

**Form for Withdrawal of Participation -** *Adult providing own consent*

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| --- | --- |
| **Title** | Use of ROTEM guided blood product utilisation in cirrhotic patients undergoing interventional procedures |
| **Short Title** | *PROTEM Trial* |
| **Project Sponsor** | Flinders Medical Centre SA |
| **Coordinating Principal Investigator/**  **Principal Investigator** | Assoc Professor Alan Wigg/ *Principal Investigator]* |
| **Location** | *[Location where the research will be conducted]* |
| **Title** | Use of ROTEM guided blood product utilisation in cirrhotic patients undergoing interventional procedures |
| **Short Title** | *PROTEM Trial* |

**Declaration by Participant**

I wish to withdraw from participation in the above research project and understand that such withdrawal will not affect my routine treatment, my relationship with those treating me or my relationship with *[Institution]*.

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|  | | | | | | |
|  | Name of Participant (please print) | |  |  |  |  |
|  | | | | | | |
|  | Signature |  | | Date |  |  |
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*In the event that the participant’s decision to withdraw is communicated verbally, the Study Doctor/Senior Researcher will need to provide a description of the circumstances below.*

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**Declaration by Study Doctor/Senior Researcher†**

I have given a verbal explanation of the implications of withdrawal from the research project and I believe that the participant has understood that explanation.

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|  | | | | | | |
|  | Name of Study Doctor/  Senior Researcher† (please print) | |  | | |  |
|  | | | | | |  |
|  | Signature |  | | Date |  |  |
|  | | | | | | |

† A senior member of the research team must provide the explanation of and information concerning withdrawal from the research project.

Note: All parties signing the consent section must date their own signature.