<Insert Site Logo>

(Affix patient identification label here)

URN:

Family Name:

Given Names:

Address:

Date of Birth: Sex: ☐ M ☐ F ☐ I

Clinical Research Consent

Parent/Guardian Information and Consent Form

Fibrinogen Concentrate vs. Cryoprecipitate in Traumatic Haemorrhage in Children: A Pilot Randomised Controlled Trial

Coordinating Principal Investigators		
Name	Position	Contact
<insert local PI>	<insert local PI>	

You are being asked to consider consenting for your child to participate in the Fibrinogen Concentrate vs. Cryoprecipitate in Traumatic Haemorrhage in Children: A Pilot Randomised Controlled Trial. It's ok to say no if you do not want to be a part of this study. If you choose not to participate it will not affect your child's care during this hospital stay and your child will be provided the usual treatments and care offered by this hospital.

Your child has been admitted to this hospital with injuries resulting in severe bleeding. The purpose of this study is to determine if replacement of a clotting factor (called fibrinogen) early in the treatment of bleeding helps to stop the bleeding sooner and helps to improve outcomes.

Why are we doing this study?

Severe bleeding after an injury can be difficult to control, this is because the clotting factors in the blood get used up and need to be replaced using stored blood products in the hospital.

There are two different ways to replace one of the most important clotting factors (known as fibrinogen). The first is from a frozen blood product called cryoprecipitate, this is stored in the freezer of the blood blank and takes time to thaw, be sent to the emergency department or intensive care unit and then be given to a patient. The second is from a concentrated product called fibrinogen concentrate which can be stored on the shelf in the emergency department of intensive care unit and given very quickly when needed.

This study is looking at whether fibrinogen concentrate is actually quicker to give and if this quicker replacement of blood clotting factors stops the bleeding sooner.

How are we doing this study?

Your child will be randomly assigned to receive either Fibrinogen Concentrate or Cryoprecipitate. They will have a 50% chance (like flipping a coin) of receiving one or the

other. Patients will remain in their allocated groups and will continue to receive either Fibrinogen Concentrate or cryoprecipitate, if required, for the duration of their hospital stay.

Blood samples will be collected as part of your child's usual care, wherever possible these blood samples will be taken from an intravenous or arterial line already in place to ensure that there is no discomfort to your child. The amount of blood that is required per day will be adjusted according to the previous clotting results, blood clotting factors given and whether the patient is showing clinical signs of ongoing bleeding. There is an additional blood test required which is equal to between 1 and 4ml of blood. This amount of blood required will not cause any risk to your child.

Basic information (e.g. age, gender) and information about your child's health status will be collected from their hospital record for duration of the study (7 days). This will include their medical history, the amount of bleeding, blood results and other information recorded in the medical chart by the doctors and nurses looking after your child.

Following discharge from hospital we will contact you by telephone at 30 and 90 days after being entered into the study. A standard set of questions about your child's health and normal activities will be asked, which will take about 10 minutes.

/* Storage of samples is optional for sites, delete if not appropriate for this site */

Use and storage of leftover blood samples for future research

[*Specify name of facility*] will store left over blood from the samples which will be frozen and analysed at a later date for coagulation function. We ask that you consider giving your permission for storage of a sample of your blood at [*specify name of facility*] for possible use in future research. Not all potentially beneficial future research can be known at any one time, as the need for future research is determined by ongoing developments in trauma research.

/* Storage of samples is optional for sites, delete if not appropriate for this site */

What will happen your child's blood samples?

The frozen samples will be kept in a locked area in a -80 degrees freezer for a maximum of 5 years. After this time they will be destroyed. The sample may be sent outside of Australia for further analysis. Any sample sent outside of Australia will be labelled with a unique identifier code and date of collection. De-identified data collected may be sent with the sample.

/* Storage of samples is optional for sites, delete if not appropriate for this site */

How will you know if your child's samples are being used in the future?

If you agree to your child's blood samples being stored for future research, they may be used for research projects in the future with approval of a Human Research Ethics Committee. The Human Research Ethics Committee will determine whether or not your consent should be obtained at that time for a particular research project. However, notifying you and obtaining your consent for specific research may not be possible if the stored sample is not linked to your identifying information. It may not be possible to provide you with feedback about the findings of potential future research.

/* Storage of samples is optional for sites, delete if not appropriate for this site */

Will the blood sample be identifiable as my child's after it is stored?

The stored blood sample will not be identifiable as your child's. It will be labelled with a unique study number to maintain your confidentiality.

/* Storage of samples is optional for sites, delete if not appropriate for this site */

Who will have access to my child's blood sample once it has been stored?

The Coordinating Principal Investigator and Principle Investigators are charged with ensuring appropriate standards are met regarding the access, storage and management of blood samples. Researchers involved in research approved by a Human Research Ethics Committee may also have access to your sample.

Consent

This study has been approved by the Children's Health Queensland Human Research Ethics Committee. We are approaching you to ask for your permission to enter your child in this study prior treating them with further blood products to control the bleeding. This is entirely voluntary and is your decision; it is ok to say no. Your decision either way will not affect the level of care, which your child will receive.

Are there any risks or discomforts?

We do not believe there to be any risks or discomforts to taking part in this study. If the blood tests cannot be obtained from an existing intravenous or arterial line, there may be pain, bruising, swelling, redness, tenderness, or infection at the site of the blood draw. This will be avoided wherever possible and blood collections with performed with other blood tests required for the routine hospital care to minimise any discomfort to your child.

The replacement clotting factors can have unknown side effects but as the patient will be being assessed daily all known and unknown will be closely monitored and documented by research staff.

<u>Known adverse events of Fibrinogen Concentrate.</u>

- *Allergic reactions - rare*
- *Blood clots including Deep Vein Thrombosis (DVT) or pulmonary embolism (PE) – very rare*
- *Increase in body temperature - rare*
- *Headache – rare*

<u>Known adverse events of Cryoprecipitate.</u>

- Allergic reactions - rare
- Breathing difficulties (known as transfusion related lung injury) – very rare
- Increase in body temperature - rare
- Breakdown of red blood cells (known as haemolytic transfusion reactions) – very rare
- Fluid overload - rare
- Infection – very rare

There may be side effects that the researchers do not expect or do not know about and that may be serious. Tell your study doctor immediately about any new or unusual symptoms that the participant gets.

What are the potential benefits?

This study may not have any direct benefits for your child; however, it will help us find out if the use of fibrinogen concentrate is an effective alternative method of fibrinogen replacement. This will then this will help us develop guidelines for its future use in children with severe traumatic bleeding.

Who will have access to the research records?

Only nursing and medical staff in the emergency department and paediatric intensive care who are directly involved with this study will have access to the information collected. Your child's privacy will be maintained at all times. Your child's name will not be used in any presentations or publications of the study results.

Will there be any costs for taking part in the study?

There will be no additional costs for participants in this study.

Does my child have to take part in this study?

Your child's participation in the study is entirely voluntary. If you decide now, or at a later stage, that you do not wish your child to participate in this research project, that is entirely your right and will not in any way affect any present or future treatment, it is ok to say no. If you do withdraw your consent during the study, the information already collected will remain available for inclusion in the study, but no further data will be collection and your child will revert to the standard treatment of the hospital.

Who do I speak to if any problems arise?

If you are concerned for your child then you must tell the nurse or doctor caring for them. If you have any concerns about the way in which the research has been carried you, please do not hesitate to contact the Principal Investigator or research co-ordinator, which is outlined on page 1 of this consent.

This study has been approved by the Children's Health Queensland Hospital and Health Service, Human Research Ethics Committee (HREC) and you may contact the Children's Health Queensland Hospital and Health Service, Human Research Secretariat on +61 (07) 3069 7002, should you have any complaints about the conduct of the research, or wish to raise any concerns.

Thank you for your time and consideration of participation in this study.

<insert site logo>

(Affix patient identification label here)

URN:

Family Name:

Given Names:

Address:

Date of Birth: Sex: ☐ M ☐ F ☐ I

Consent Form for Parents or Guardians

Project Title: Fibrinogen Concentrate vs. Cryoprecipitate in Traumatic Haemorrhage in Children: A Pilot Randomised Controlled Trial

Investigators: <insert local PI>

- I understand that I have been asked to allow my child to participate in a study investigating the use of fibrinogen concentrate in the treatment of severe traumatic bleeding
- I have read and understood the information sheet.
- The details of the study have been explained to me and my questions have been answered satisfactorily.
- The possible risks and benefits of my child participating have been explained to me.
- I understand that the project is for the purpose of research and not for treatment, so may not directly benefit me or my child.
- I have been informed that the confidentiality of the information will be maintained and safeguarded and give permission for access to my child's medical records for the purpose of research.
- I give permission for medical practitioners, other health professionals, and hospitals outside this hospital, to release information concerning my child's disease and treatment which is needed for this trial and understand that such information will remain confidential.
- I understand that I may withdraw my child form the study at any time without affecting the care he/she receives.

CONSENT

I/We _____, being the parent(s)/guardians of

_____ give permission for my/our child to take part in this study.

/* Storage of samples is optional for sites, delete if not appropriate for this site */

Possible future use of stored blood, please pick one of the choices below:

☐ The blood samples may be stored and used in future research to learn about, prevent or treat trauma related coagulation or other health problems e.g. trauma coagulation disorders.

☐ The blood samples may not be used in future research. I do not want researchers to contact me about future studies.

I/We would like to be informed of the study results NO ☐ YES ☐

if yes please provide email contact: _____

Parent name	Parent signature	Date
Consenting Clinician name	Consenting Clinician signature	Date

(Affix patient identification label here)

URN:

Family Name:

Given Names:

Address:

Date of Birth: Sex: ☐ M ☐ F ☐ I

<insert site logo>

Revocation of Consent Form for Parents or Guardians

Project Title: Fibrinogen Concentrate vs. Cryoprecipitate in Traumatic Haemorrhage in Children: A Pilot Randomised Controlled Trial

Investigators: Dr Shane George, Dr James Winearls, <insert local PI>

I hereby wish to WITHDRAW my intent for my child to participate further in the above research project and understand that such withdrawal will not jeopardise my child's future health care.

Child's name: _____

Parent/Guardian Name: _____

Signature: _____

Date: _____

If a verbal withdrawal:
In the event the parent / guardian decided to withdraw verbally, please give a description of the circumstances. Principal Investigator to provide further information here:

Principal Investigator's Name: _____

Signature: _____

Date: _____

Coordinating Investigator to sign the withdrawal of consent form on behalf of the parent / guardian if verbal withdrawal has been given