

## Informed Consent for Intrauterine Transfusion

Name:	Age (in years):	Gender: <input type="checkbox"/> M <input type="checkbox"/> F <input type="checkbox"/> Other
UHID No./Registration No.:		
Interpreter Service: <input type="checkbox"/> Yes <input type="checkbox"/> No	Consultant's Name:	

### Medical Condition

The doctor has explained that I/my child/my .....have the following medical condition:

.....

and I/my child/my.....have been explained and advised to undergo the following treatment/procedure:

.....

I authorise Dr. .... and his/her associates to perform the above treatment/ procedure.

The doctor should document the site and/or side where relevant to the procedure:.....

.....

### Introduction

Foetal anaemia is found by ultrasound doppler changes in the middle cerebral artery. In severe cases, swelling in foetuses' tissues or organs is identified in ultrasound. Foetal anaemia can be due to RH incompatibility between the mother and the foetus. It can also be due to other reasons (genetic / metabolic/ infections/vascular tumours). A baby with foetal anaemia has a low blood count.

An intrauterine blood transfusion can be done to replace the destroyed red blood cells. It is an established form of foetal therapy and is considered as a lifesaving procedure. However, depending on the initial condition of the baby, even after successful transfusion, the foetus may not survive in about 10% of the cases.

The intrauterine transfusion will be done under ultrasound guidance. It normally does not require any sedation for the mother.

It is usually done under local anaesthesia. And it lasts anywhere from 20 to 30 minutes. The doctor will take a blood sample from the baby to examine the blood count and confirm foetal anaemia. If foetal anaemia is confirmed, then the doctor will begin the transfusion. The doctor will decide the amount of donor blood transfused based on the blood count and size of the foetus. More than one procedure may be required during the pregnancy and it depends on the foetal condition and response to the transfusion.

Usually 'O-negative' packed cells appropriately processed for intrauterine transfusion will be given with the objective of temporarily correcting the anaemia. Under ultrasound guidance, the doctor will insert a needle into the foetal umbilical vein in the umbilical cord or a vein in the liver. Sometimes blood may directly be given in the foetal heart or the peritoneal cavity of the foetus. This decision will be taken by the doctor performing the procedure. The discomfort you may feel during the procedure will be equivalent to that of an intramuscular injection. And you might feel slight cramping during the procedure. After the transfusion, the doctor will take another sample to check the baby's blood count.

### Consent for Blood Transfusion

Please see Blood Transfusion Consent Form. This will give you information about the type of the blood products, benefits and risks of blood transfusion. If you have any concern(s), please discuss with your doctor.

### Consent for Anaesthesia

Please see Anaesthesia Consent Form. This will give you information about the type of the anaesthesia, its benefits and general risks. If you have any concern(s), please discuss with your anaesthetist(s).

### Intended Benefits (To be documented by doctor)

### Risks (To be documented by doctor)

- Transient pain due to passage of the needle through the abdominal wall.
- Mild uterine cramping immediately following the procedure.
- Occasional spot bleeding from the vagina after the procedure.
- Procedure related perinatal loss can occur in about 1.8% of the cases.
- Chances of pregnancy loss due to rupture of membrane or intrauterine foetal demise.
- Chances of foetal or maternal infections.
- Emergency caesarean section (c-section) in rare cases.
- Others, if any specify:

### Patient Specific Risks (To be documented by doctor)

- 1)
- 2)
- 3)
- 4)

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**Specific Notes Related to Procedure** (Strike out if not required)

**Precise Action Points Understood by the Patient/Substitute Decision Maker** (To be documented by patient/substitute decision maker in his/her language)

### Patient's Authorisation

- The doctor has explained regarding the condition, treatment, procedure, risks and other associated information. I have fully understood the procedure and the risks, including the risk of miscarriage. The doctor has explained the prognosis, likely outcome of not having the procedure.
- The doctor has also explained relevant treatment options in case of any complications as well as the risks of not having the procedure.
- The doctor has explained my medical condition and the proposed prenatal invasive procedure.
- I have been given the choice to take a second opinion.
- I was able to ask questions and raise concerns with the doctor about my condition, the procedure and its risks.
- All my questions, concerns and doubts have been discussed and answered to my satisfaction.
- I am undergoing the procedure of my own free will and am not being coerced into having it performed.
- The doctor has explained and it has been agreed to me that if immediate life-threatening events occur during the treatment/procedure, they will be treated according to the prevalent medical norms.
- I understand that the treatment/procedure may include blood/blood product transfusion (for which a separate consent shall be obtained).
- The doctor has explained the requirement for anaesthesia for this procedure and I understand the risks associated with anaesthesia, including the risks specific to me (for which a separate consent shall be taken).
- I declare that no guarantee of whatsoever nature has been given by anyone as to the results that may be obtained.
- I am willing to undergo the procedure as required and that I have followed special instructions in respect of the tests/investigations to be performed prior to conduct of such tests.
- I hereby authorise the medical, paramedical staff of the hospital, to provide assessment, evaluation and medical treatment including administration of drugs as may be necessary and/or otherwise as may be deemed necessary.
- I understand that I have the right to refuse treatment or withdraw consent at any time. I agree that any such refusal/withdrawal shall be in writing and acknowledged by the hospital. And I shall be solely responsible for the outcome of such refusal.

- I consent to if any photographing or television of operation(s) or procedure(s) to be performed, including appropriate portions of my body, for medical, scientific or educational purposes. However, suitable precautions shall be taken by the hospital that my identity is not revealed anywhere.  **Yes**    **No**
- For purposes of advancing medical education, I consent to the admittance of observers to the operating room.  **Yes**    **No**

Patient Name:		Signature:		Date and Time:
Substitute Decision Maker Name:	Relationship:	Reason (patient is unable to give consent because):	Signature:	Date and Time:
Witness Name:	Relationship:		Signature:	Date and Time:
Interpreter Name:	Translation given in:		Signature:	Date and Time:

### Declaration by the Doctor

I have explained to the patient / responsible attendants the medical condition, need for the procedure, its alternatives and risks, likely consequences if those risks occur and the significant risks and problems specific to this patient. I have answered all the patient's queries to the best of my knowledge. I believe that the patient has been adequately informed.

Name and Signature of the Doctor with Reg No:

Date and Time: