Hospital Logo		Patient Identification Label

Informed Consent for Multifetal Pregnancy Reduction

Name:	Age (in years):	Gender: ☐ M ☐ F ☐ Other
UHID No./Registration No.:		
Interpreter Service: ☐ Yes ☐ 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

An ultrasound is performed to evaluate the uterus, placentas and foetuses. If all the foetuses appear normal, the most technically accessible foetus(es) is/are targeted for reduction. The multifetal pregnancy reduction is commonly performed between 10 and 12 weeks of pregnancy. The doctor will inject a local anaesthetic.

Under ultrasound guidance, the doctor will insert a needle through your abdomen into the targeted pregnancy to inject potassium chloride. This will stop foetal heart motion. This procedure will be repeated for each foetus to be reduced and is usually performed through a separate needle insertion.

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)

- Reduced risk for mother: Each added foetus may increase the risk of gestational diabetes, preeclampsia and anaemia. This procedure will reduce these risks for the mother.
- Reduced risk for infants: The procedure may improve your chances of carrying your pregnancy longer and your chances of delivering one or more healthy babies.
- Carrying triplets or more increases the risk of miscarriage, stillbirth, premature birth and disability. The procedure reduces these risks.
- Others, if any specify:

Risks and Complications (To be documented by doctor)	**Risks and Outcome of No Treatment (To be documented by doctor)**	**Patient Specific Risks (To be documented by doctor)**
• Loss of the entire pregnancy prior to 20 weeks gestation in 5-10% cases after the procedure. • 3 – 4% background risk of congenital anomaly (malformation), which cannot be detected at such an early gestational age. • It may be a possibility that a normal (euploid) pregnancy may get reduced / eliminated due to the procedure and the foetus(es) remaining may have some congenital anomaly (malformation). • The procedure-related risk of miscarriage prior to 20 weeks of gestation may be higher. • Women whose pregnancies are reduced to twins remain at risk for premature delivery compared with those who have spontaneous twin pregnancies. • Tear in the amniotic membrane, which usually seals on its own but in rare cases can lead to continuous vaginal leaking. • Inadvertent tear in the uterus or its vasculature. This is extremely rare complication which may need more surgical correction or hospitalisation. • Infection. • Redness, pain and swelling at the site of introduction of the needle.		**1)** **2)** **3)** **4)**

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• Occasionally, it may not be possible to instil / inject the drug (potassium chloride) into the foetal heart which is known as "failed procedure". In such a case, the needle should be reintroduced or the procedure should be performed after a couple of days. • Incidence of failed procedure is higher in obese patients and / or with retroverted uterus. • Very rarely, air may enter into the blood stream during the procedure leading to air embolism. This can cause heart to stop and can be fatal. • There is an extremely rare possibility of foetal tissue injury; tenting of the foetal membranes surrounding the baby / foetus leading to limb hypoplasia or oro-mandibular dysplasia. • Others, if any specify:		

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 explained about 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.
- I understand that the foetal tissue (amniotic fluid) extracted would be retained for the intended test and then disposed of sensitively by the hospital.
- Foetal tissue (genetic material) will not be used for any other purpose or subjected to any other test than what has been advised and consented for.
- The doctor has explained any significant risks and problems specific to me and the likely outcomes if complications occur. The doctor also has explained relevant treatment options as well as the risks of not having the procedure.
- 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 understand that if organs or tissues are removed during the surgery that these may be retained for tests and shall be disposed of sensitively by the hospital as per the regulatory provisions.
- 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 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 investigation 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 further agree to give any separate consent as may be required for any other invasive procedures/surgery/anaesthesia etc.
- 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**

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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: