Hospital Logo		Patient Identification Label

Informed Consent for Amniocentesis

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:

……

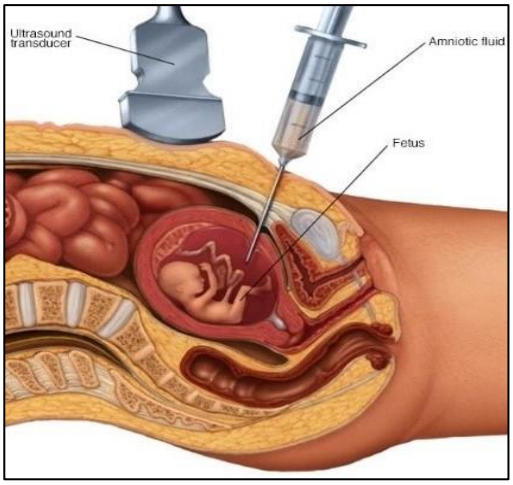
I authorise Dr. …… and his/her associates to perform the above treatment/ procedure.

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

……

Introduction

Amniocentesis is the withdrawal of a small sample of the fluid surrounding the foetus. The doctor will perform an ultrasound to help locate the placenta and the foetus. And obtain the amniotic fluid by inserting a 20 or 22-gauge needle through the abdominal wall into the uterus (womb).



The procedure will be carried out after 15 weeks of gestation, as confirmed by ultrasound. It normally doesn't require any sedation or anaesthesia. 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.

The collected amniotic fluid sample will be subjected to molecular or chromosomal analysis or other appropriate test as deemed necessary.

Amniocentesis will be carried out to:

- Diagnose chromosomal abnormality in the foetus in case of any congenital anomaly / malformation (birth defect).
- Abnormal aneuploidy screening results.
- Test/ store DNA for diagnosis of genetic disorders.
- Test for intrauterine infections or other biochemical parameters in the amniotic fluid.

A woman who is Rh negative and ICT negative will be administered an anti D injection after the procedure.

Intended Benefits (To be documented by doctor)

The procedure intends to provide you with information regarding the karyotype (chromosomal make-up) of your foetus(es). Less commonly, it is carried out with the intention of obtaining biochemical, metabolic or genetic information.

Others, if any specify:

Risks (To be documented by doctor)	**Patient Specific 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. • Miscarriage or foetal loss can occur in about 1 in 300 women. • Rupture of or leakage from fluid within the amniotic sac, which can lead to miscarriage or preterm labour. • In case of an insufficient specimen or a culture failure or technical challenges in the testing laboratory, a second procedure may be offered. • Occasional spot bleeding from the vagina after the procedure. • Bleeding is more common if you have been taking blood thinning drugs (For example: Warfarin, aspirin.) • Others, if any specify:	**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 to me regarding the condition, 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.
- 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 institution where it is tested.
- I understand that in some cases the sample need to be stored and this will be done after consent is obtained.
- 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.
- If the sample is used for research purposes, due consent will be taken from me.
- The doctor has explained and it has been agreed by me that if immediate life-threatening events occur during the treatment/procedure, they will be treated according to the prevalent medical norms as per the protocol of the treating hospital
- 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 understand that I have the right to refuse to undergo the procedure or withdraw consent prior to the procedure. 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: