Hospital Logo		Patient Identification Label

Informed Consent for Chorionic Villus Sampling

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

Prenatal invasive procedure or chorionic villus sampling (CVS) is a prenatal test procedure. CVS is usually done after 10^{th} – 11^{th} week of pregnancy. The doctor will insert a needle and withdraw the chorionic tissue and subject it to appropriate testing as prescribed.

Reasons for undergoing the procedure:

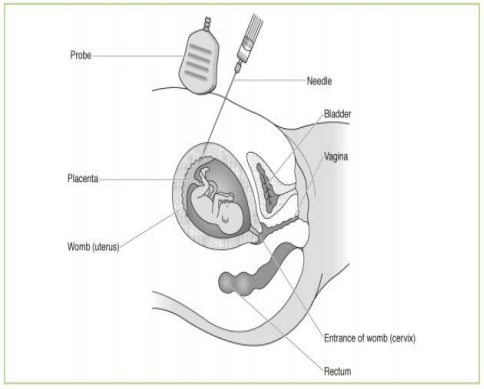
- Women who are 35 or older at the time of delivery.
- Those with a previous pregnancy with a chromosomal abnormality.
- Foetuses is at a risk for an inherited disorder potentially diagnosable by DNA analysis (For example: Cystic fibrosis and sickle cell disease).
- Abnormal aneuploidy screening results.
- A patient requesting procedure after counselling.

A woman who is RH negative and ICT negative will be administered an injection of Anti-D injection after the procedure.

Types of CVS

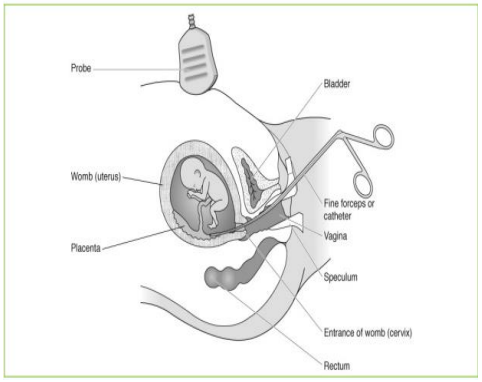
Transabdominal CVS

- A transabdominal CVS may be performed from 13 weeks onwards.
- For this, you might be given some local anaesthetic to numb the area.
- The doctor will clean the skin in the area where the needle will be inserted.
- Using an ultrasound probe to guide the direction, the doctor will push the needle through the abdomen and the wall of the womb into the placenta.
- A small amount of placental tissue will be sucked up into a syringe by moving the needle in and out of your abdomen.
- After the procedure, the doctor will take out the needle and check the baby on ultrasound.



Transcervical CVS

- Transcervical CVS is usually performed between 11 and 13 weeks.
- The doctor will clean your vagina and cervix.
- And insert a speculum into your vagina.
- Using ultrasound guidance, the doctor will pass a fine forceps or a small tube through the cervix to the placenta.
- The doctor will remove a small amount of placental tissue, using either forceps or a fine suction catheter.
- After the procedure, the doctor will check the baby on ultrasound.



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).

Hospital Logo		Patient Identification Label

Informed Consent for Chorionic Villus Sampling

Intended Benefits (To be documented by doctor):
It provides accurate results very early in pregnancy in contrast with the traditional amniocentesis.
Others, if any specify:

Risks and Complications (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. • Occurrence of miscarriage or foetal loss. • There might be an insufficient specimen or a culture failure or technical challenges in the testing laboratory. In such instances, you should seek appropriate counselling. • The results of the test from the laboratory may be conclusive or inconclusive. If it is inconclusive, further plan of action should be decided after due consultation with the treating team. • In rare instances, based on the results of the genetic tests from the CVS sample, a further testing may be necessary to come to a conclusion. This is because rarely, the placental and foetal genetic structures may be different or there may be contamination of mother's cells in the sample. • 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)**

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.
- 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 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 and I agree 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 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 televising of the 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**

Hospital Logo		Patient Identification Label

Informed Consent for Chorionic Villus Sampling

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: