



Chicago Maternal-Fetal Medicine, S.C. 2507 North Halsted Street, Chicago, IL 60614

PATIENT CONSENT FOR PRENATAL DIAGNOSIS OF GENETIC DISEASE BY CHORIONIC VILLI SAMPLING

I, _____, voluntarily consent to chorionic villi sampling (CVS) as a method of prenatal diagnosis of genetic disease in my developing fetus or fetuses (I understand that, unless specifically modified otherwise, the term "fetus" shall be used to mean the withdrawing of a tiny sample of placental tissue from within my uterus. I desire CVS because I want to know whether the fetus, which I carry, has a chromosomal and/or other genetic abnormality.

PROCEDURES:

I hereby authorize Dr. Nawar Hatoum to perform one or more of the following three procedures on me, which in his judgment, is (are) the best procedure(s) for performing CVS in my clinical circumstances:

- **Transcervical - Introduction of a small catheter (tube) into the uterus through the cervix and attempting withdrawal of sample of chorionic villi under ultrasound guidance.**
- **Transabdominal – Introduction of a needle into the uterus through the abdominal wall and attempting withdrawal of sample of chorionic villi under ultrasound guidance. In some cases, this also requires going through the bladder.**
- **Transvaginal - Introduction of a needle into the uterus through the vaginal wall and attempting withdrawal of a sample of chorionic villi by ultrasound guidance.**

I understand that each of these CVS procedures are usually accompanied by some discomfort or pain and that each procedure usually takes 15-20 minutes to complete.

I understand that up to three (3) individual sampling for chorionic villi may be attempted for each individual fetus, but that there is no guarantee that chorionic villi will be obtained from any of the samplings. I understand that there are obstetrical considerations such as uterine anatomy or placental position, which may preclude me from one, two or all three of these CVS techniques, I also understand that the genetic analysis may not be successful and that the laboratory may need additional samples at a later date.

RISK AND BENEFITS:

I understand and acknowledge that CVS has the following risks:

INFECTION:

There is a small risk of infection following CVS, which may result in spontaneous abortion (miscarriage) of the fetus and may be associated with maternal sepsis (fever, flu-like symptoms, vaginal discharge.) Rarely, (less than 1%), Oligohydramnios Syndrome (diminished fluid surrounding the fetus) may develop in the early second tri-master which may lead to miscarriage or compromise the health of the fetus.

MISCARRIAGE:

There is a risk of miscarriage following CVS due to infection, fetal bleeding, perforation of the bag of waters, or for unknown reasons. CVS-related miscarriage rate is less

MATERNAL BLEEDING:

There may be some bleeding or spotting for up to two weeks following the procedure. I understand that if I have heavy bleeding, or am concerned about the amount of bleeding I should call Dr. Hatoum or my own physician.

BIRTH DEFECTS:

I understand that there is a very small chance that injury to the developing fetus may occur as a result of the CVS.

A significant increase in the incidence of limb reduction defects (missing or undeveloped fingers or toes) has been reported in some centers performing CVS. However, most centers performing CVS, have found no such increase in the risk of limb reduction defects in their patient population when CVS is performed at both the 10th week of gestation or later.

UTERINE PERFORATION:

I understand there is a very small chance that the CVS procedure may result in perforation of the uterus, which can cause bleeding, and in rare circumstances, can require an operation which may result in a hysterectomy.

BENEFITS:

The benefit of CVS is that genetic evaluation can be completed in the first trimester (9-12 weeks) of pregnancy. Therefore, if, as a result of the evaluation, I elect termination of pregnancy, I may experience fewer physical and emotional side effects. Morbidity risks to the patient (complications, health and future fertility risks) are approximately four times less when a pregnancy termination is performed in the 1st trimester than in the late 2nd trimester. Additionally, the risk of death after abortion (which is generally very low-approximately 2 per million) is approximately 10 times lower in the first trimester than in the late second trimester. If I desire additional information about the risk of pregnancy termination in the 1st trimester vs. the 2nd trimester, I should ask Chicago Maternal-Fetal Medicine.

ALTERNATIVE PROCEDURES:

I understand that amniocentesis is an alternative means perinatal diagnosis of genetic diseases in my fetus. This procedure involves the insertion of a needle into the bag of waters in the 2nd trimester of pregnancy (approximately 16 through 18 gestations) and subsequent analysis of the amniotic fluid cells. This procedure has its own set of risk and benefits. As discussed above, if, following amniocentesis, termination of the pregnancy is desired; termination in the 2nd trimester is more difficult, both emotionally and physically. I acknowledge that I have considered the benefits and risk of amniocentesis as an alternative to CVS, that I have had an opportunity to discuss the comparable risks and benefits of CVS and amniocentesis with Chicago Maternal-Fetal Medicine and have had all my questions answered.

ADDITIONAL INFORMATION CONCERNING CVS:

- Most of the genetic abnormalities that may be diagnosed by means of CVS are not curable. If test results indicate that such abnormalities are present, it will be my decision whether or not to terminate the pregnancy.
- I understand that if chorionic villi are not obtained, I may be offered the opportunity to repeat sampling in subsequent weeks or I may be referred directly for amniocentesis in the 2nd trimester.
- I understand that normal CVS results DO NOT guarantee that I will give birth to a normal or healthy infant. There is still a small possibility that my infant will have a birth defect or defects and/or mental retardation due to the other disorder or known causes which can not be detected through CVS.
- I understand that due to slow growth of culture or other technical reasons, the result of the genetic analysis may not be completed by 12 weeks of pregnancy and that I may not be able to have a first trimester termination of pregnancy in the event of abnormal results.
- I understand there is a small chance that the chorionic villi obtained do not represent the genetic make-up of the fetus, due to reasons, which include but are not limited to chromosomal mosaicism (2 or more cell types) or maternal cell contamination.
- I understand that if I have a multiple pregnancy there is a chance that will not be possible to obtain a sampling from each fetus if this occurs Chicago Maternal-Fetal Medicine will notify me.
- I understand that if I'm Rh Negative and not previously sensitized, I will receive Rhogam (standard treatment for Rh Negative women), after CVS.

By signing below, I acknowledge that I have read and understood the information in this consent form, that I have had an opportunity to discuss the information with Chicago Maternal-Fetal Medicine and that all my questions have been answered. I understand that I am free to withdraw my consent and not go forward with the CVS procedure at any time prior to its performance I am consenting to this procedure freely and voluntarily after full consideration after all the risks and benefits.

Patient Signature

Date

Witnessed By