KAISER PERMANENTE®

STATE OF CALIFORNIA - HEALTH AND HUMAN SERVICES AGENCY
Department of Public Health
Genetic Disease Screening Program

MR #: _____

Name: _____

STATEMENT OF INFORMED CONSENT/DECLINE TO HAVE TRANSCERVICAL (TC CVS) OR TRANSABDOMINAL (TA CVS) CHORIONIC VILLUS SAMPLING PERFORMED AT OR AFTER 10 WEEKS OF PREGNANCY

IMPRINT AREA

1. The purpose of Chorionic Villus Sampling is to detect fetal chromosomal disorders and other specific disorders of the fetus.
2. Before the CVS is performed, I will have ultrasound guidance to help locate the placenta and fetus. Ultrasound may also detect twins, incorrect dating of the pregnancy, and some other conditions.
3. The transcervical (TC) CVS procedure consists of inserting a catheter (sterile plastic tube) under ultrasound guidance through the woman's cervix to obtain placental tissue (chorionic villi). I have been informed that the transabdominal (TA) CVS procedure consists of inserting a needle under ultrasound guidance through the woman's abdomen to the placenta to obtain placental tissue.
4. The procedure-related pregnancy loss rate for CVS appears to be similar to the rate for amniocentesis: there is a minimal increased risk for miscarriage following CVS of about 1 in 450 procedures. Other rare complications may include major bleeding, early rupture of the membranes, or infections. Minor complications include cramping, vaginal spotting, or slight leakage of amniotic fluid for up to 2 weeks.
5. Occasionally CVS procedures need to be repeated because not enough tissue is obtained the first time.
6. If twins or triplets are present, attempts to obtain chorionic villi from each fetus may not be successful, or the wrong placenta may be sampled. Rarely, this could result in an incorrect diagnosis.
7. Not all birth defects can be detected by CVS and the accompanying ultrasound guidance, but CVS can identify over 99 in 100 cases of all chromosomal disorders. However, a complete and correct diagnosis of the fetus cannot be guaranteed.
8. There is a small chance that the chorionic villi obtained during the procedure may not represent the genetic make-up of the fetus, either due to chromosomal mosaicism (2 or more cell types) or maternal cell contamination.
9. An amniocentesis or fetal blood sampling may be recommended in the second trimester to clarify the results of CVS.
10. All abnormal findings will be explained to me. The decision to continue or to have the pregnancy terminated is entirely mine.
11. My participation in this procedure is entirely voluntary. If I decline this procedure, I will still be eligible for any services supported by State funding.
12. CVS procedures do not detect neural tube defects. Therefore, a blood test or ultrasound exam which can screen for neural tube defects will be offered to me between 15 and 20 weeks of pregnancy.
13. There is another method of obtaining diagnostic information about the chromosomal or biochemical status of the fetus. This procedure, called amniocentesis, is usually done in the second trimester at 15 to 20 weeks of pregnancy. It involves placing a needle, under ultrasound guidance, through the abdominal wall into the uterus to sample fluid that surrounds the fetus. I have been informed that based on currently available information* there is a minimal increased risk for a miscarriage following amniocentesis of about 1 in 900 procedures. The risks and benefits of amniocentesis compared to CVS have been explained to me in detail.
14. My signature below indicates that:
    I have read, or had read to me, the above information and I understand it. I have had an opportunity to discuss it, including the purpose and possible risk of chorionic villus sampling, with my doctor or the doctor performing the procedure. I have received all of the information I want. All my questions have been answered.

Yes	I REQUEST that Dr. _____ and/or associates perform CVS. I understand and accept the consequences of this decision. Signed _____ Date _____ Witnessed by _____ Date _____
No	I DO NOT WANT to have CVS. I understand and accept the consequences of this decision. Signed _____ Date _____ Witnessed by _____ Date _____

The California Information Practices Act of 1977 (Civil Code 1798 et seq.) requires that the following information be provided. The California State Department of Public Health, Genetic Disease Screening Program, will receive a confidential report of all abnormal tests performed by state-approved Prenatal Diagnosis Centers. This information is collected under the authority of California Code of Regulations Sections 6531 and 6532. This information will be used to ensure that all approved Prenatal Diagnosis Centers meet state standards for services and to improve the detection, prevention, and treatment of birth defects.

If you have any questions, requests, or complaints about the use of your personal health information or desire a copy of the Notice of Information and Privacy Practices as required by the Health Insurance Portability and Accountability Act of 1996 (HIPAA), please contact the Chief of the Genetic Disease Screening Program, 850 Marina Bay Parkway; Richmond, CA 94804, 510-412-1502.

CDPH 4457 English (08-17) CVS

*ACOG Practice Bulletin, Prenatal Diagnostic Testing for Genetic Disorders, No. 162, May 2016