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## Informed Consent and Release - Chorionic Villus Sampling (CVS)

To whom it may concern:

I hereby authorize Dr. \_\_\_\_\_ at UT Medical Group, Inc. and the University of Tennessee, Memphis to perform genetic studies on my fetus. I understand that the cells required for such an analysis are obtained by one of three approaches: (1) Transabdominal CVS involves penetration of the mothers abdominal and uterine walls by a hypodermic needle and aspiration of chorionic villi from the developing placenta. (2) Transcervical CVS involves passage of a flexible catheter through the vagina and cervix into the developing placenta with aspiration of chorionic villi. (3) Transvaginal CVS involves penetration of the vagina and uterine wall by a hypodermic needle and aspiration of chorionic villi from developing placenta.

The following points have been explained to me an I understand and accept them:

- Chorionic villus sampling is a proven technique and has been used extensively. The major risk is considered to be pregnancy loss, estimated as an increase of 1/200 or higher over the baseline loss rate by some studies. Hazard to the mother or fetus is considered to be extremely small; however, it cannot be guaranteed that the procedure will not cause injury to the mother (e.g., infection, vaginal bleeding), injury to the fetus (e.g., fetal limb defects, spontaneous abortion), or result in pregnancy complications like premature labor or premature rupture of the membranes.
- A given attempt to obtain chorionic villus may be unsuccessful.
- Chromosome analysis of chorionic villus may be unsuccessful or the chromosome preparation may be of such poor quality as to be uninterpretable.
- The likelihood of a misinterpretation of the chromosome studies is considered to be small. However, analysis based on study of non-embryonic tissue (e.g., maternal cells) may not always reflect the status of the embryo, per se. Accordingly, a complete and correct diagnosis of the condition of the fetus based on the chromosome analysis cannot be guaranteed.
- Testing will ordinarily detect only chromosome abnormalities, such as Down syndrome.
- Tests to detect other genetic disorders are available, but will not be attempted unless specified. Other tests will be specifically delineated:
- I understand that neither the results of the chorionic villus sampling nor the ultrasound examination can guarantee the delivery of a normal, healthy baby.
- The fluid and tissue that was not used for diagnostic purposes may be stored and used for future scientific investigations.
- I understand that information regarding this test, the outcome of my pregnancy, and the condition and development of my child may be used in coded form for research purposes and may be obtained from my obstetrician and pediatrician.

Aware of the possible hazards and limitations of chorionic villus sampling, I elect to undergo chorionic villus sampling.

\_\_\_\_\_  
 Signature

\_\_\_\_\_  
 Printed name

\_\_\_\_\_  
 Date

\_\_\_\_\_  
 Witness Signature

\_\_\_\_\_  
 Witness Printed name