CHORION VILLUS SAMPLING (CVS) CONSENT

I, the undersigned, request that an attempt be made to perform prenatal diagnosis of certain detectable birth defects for which my unborn child is possibly at risk by performing a procedure called chorionic villus sampling (CVS).

I understand that the first step in this procedure is an examination of my abdomen by sonography (ultrasound). This involves the use of high frequency sound waves to locate the fetus and placenta, detect multiple pregnancies, determine the gestational age of the pregnancy, and look for possible structural abnormalities of the fetus. It will also be used to determine the specific approach for the sampling procedure (transabdominal vs transcervical).

I understand that following the ultrasound examination any significant findings will be discussed with me and I shall have an opportunity to decide whether to proceed with further studies.

I understand that the sample required for the prenatal diagnosis studies is a very small biopsy of the placenta to harvest tissue called chorionic villi. This involves either the insertion of a needle through my abdominal wall and into my uterus, or by passing a slender flexible catheter through the cervix into the uterus. The tissue obtained will be grown in tissue culture and a study of their chromosomes (the structures that carry the genetic material and determine the sex of the fetus) will be performed.

I understand that since alpha-fetoprotein is not sampled by CVS, that CVS cannot be used to rule out spina bifida and certain other fetal anomalies.

I understand that these are the only prenatal studies that will be performed and that no other studies will be done unless specifically indicated.

I understand the following important points regarding the procedure:

a. Although CVS is an established technique that has been used extensively and the risk to me or the fetus is considered to be small (approximately .5%), there is no positive assurance that the procedure will not cause damage to me or my fetus, initiate premature labor, or result in a miscarriage.

b. I understand that the attempt to obtain chorionic villi may be unsuccessful, the fetal cells may not grow in the laboratory, or ambiguous results may be found. These situations may require amniocentesis or parental blood tests to obtain or clarify results.

c. The chromosomes and/or biochemical analysis may not be successful due to potential laboratory complications.

d. Although the likelihood of a misinterpretation of the chromosomal and/or biochemical analysis is considered to be small, a complete and accurate diagnosis of the condition of the fetus based on the tests cannot be assured or guaranteed.

e. The finding of a normal chromosomal constitution and/or biochemical status does not eliminate the possibility that the fetus may have birth defects, abnormalities and/or mental retardation that are not detectable by these methods of prenatal diagnosis. Thus, the tests provide no guarantee of a normal baby.
This CVS is being performed on me for the following reasons:

I full recognition of the possible medical risks and with full understanding of the techniques and interpretations involved in the prenatal diagnosis of my unborn child, I agree and consent to have the analysis attempted.

I have had the opportunity to ask questions regarding CVS, and all of my questions have been answered fully.

I have read and fully understand the foregoing information and consent.

Signed ____________________________________________________________

Patient Signature ________________________________ Spouse or Responsible Party

Date ________________________________ Witness ____________________