INFORMED CONSENT

Genetic Amniocentesis

By signing below, I,_____, request that genetic amniocentesis be performed by Dr. H.Sakamoto for the purpose of prenatal diagnosis of certain birth defects.

It has been explained to me by my doctor or by someone my doctor has designated and I understand that:

1. Amniocentesis is the withdrawal of a small sample (less than 1 oz) of the fluid surrounding the fetus. This fluid is obtained by inserting a needle through the abdominal wall into the uterus (womb). Ultrasound is usually performed to help locate the placenta and the fetus. Ultrasound may also detect twins, may be used to date the pregnancy, and may detect some, but not all, physical defects in the fetus.

2. Amniocentesis involves a small risk to both the mother and the fetus. The most common serious complication is miscarriage. In general, the risk of miscarriage from amniocentesis performed after 15 weeks of pregnancy is less than 1 in 200. Other possible, but rare, serious complications include hemorrhage, infection or injury to the fetus. Minor complications, which occur in approximately 1 in 100 women having amniocentesis, include cramping, vaginal spotting, or slight leakage of amniotic fluid.

3. Any particular attempt to obtain amniotic fluid may be unsuccessful. Occasionally, even if sufficient fluid is obtained, laboratory testing may not be possible or may not yield results. In these cases, the amniocentesis may need to be repeated.

4. The standard laboratory testing performed on the amniotic fluid sample consists of chromosome analysis, which can usually detect a high percentage of all chromosomal disorders, and amniotic fluid AFP (alphafetoprotein), which can usually detect a high percentage of all open neural tube defects.

5. Testing for other kinds of birth defects will not be performed unless indicated below.

6. Normal test results do not guarantee the birth of a normal child. As in any laboratory test, there is a small possibility of error, and maternal cells may contaminate the sample. In addition, approximately 2-3% of all pregnancies have birth defects which cannot be detected by testing amniotic fluid or by ultrasound examination.

7. Any part of this amniotic fluid sample not used for diagnostic testing may be stored and used for medical research or education as log as my name and any other identifying information have been removed.

8. The reason for my having amniocentesis is _____
   My risk for abnormal results is _____

_____ _____

Signature of patient *Date*

_____ _____

Witness *Date*

INFORMED CONSENT

InSight™

By signing below, I,_____, authorize my doctor send a portion of my amniotic fluid sample for *InSight™* testing.

It has been explained to me by my doctor or by someone my doctor has designated and I understand that:

9. *InSight™* is a rapid test designed to detect the most common chromosome abnormalities, including Down syndrome, in samples of amniotic fluid. The test gives numeric information about chromosomes 13, 18, 21, X and Y. The test result are usually available 5 working days after the amniocentesis procedure.

10. Other chromosome abnormalities, which occur more rarely, cannot be detected by *InSight™* These are usually found by routine chromosome analysis. This is required for all *InSight™* samples and usually take 14 days for results.

11. In 1-2% of cases, uninformative analysis of *InSight™* results are obtained. In some cases, this is because the maternal blood is in the amniotic fluid. In other cases the sample is a mosaic cell pattern for normal cell and abnormal cell.

12. In approximately 10% of cases, no *InSight™* results are obtained. In some cases this is because the amount of amniotic fluid in the sample is too small. In other cases, the test is attempted but does not give any results.

13. The accuracy of *InSight™* for detecting abnormalities involving these five chromosomes is usually high. There is a small possibility that the *InSight™* results are incorrect, and that the routine chromosome results are different from *InSight™*.

14. *InSight™* is considered investigational by the American College of Medical Genetics. The results are preliminary; therefore, no irreversible decision about a pregnancy should be made on the basis of *InSight™* results alone.

15. Any part of this amniotic fluid sample not used for diagnostic testing may be stored and used for medical research of education as long as my name and any other identifying information have been removed.

_____ _____

Signature of patient *Date*

_____ _____

Witness *Date*

✳Please answer the questions below.

Is your blood type Rhesus Negative? ☐ Yes ☐ No

How about your husband's? ☐ Yes ☐ No