INFORMED CONSENT/REFUSAL FOR GENETIC TESTING

1. The purpose of amniocentesis is to detect certain birth defects, including most fetal chromosome disorders and neural tube defects. My reason for having amniocentesis is _________________________________________________.

2. Before the amniocentesis I will have an ultrasound to help locate the placenta and fetus. Ultrasound may also detect twins, incorrect dating of the pregnancy, and some, but not all, physical defects in the fetus.

3. Amniocentesis involves inserting a needle through the women’s abdomen into the fluid in her uterus. A small amount of fluid (less than 1 ounce) is taken out. There may be some discomfort when the needle is inserted.

4. There are serious complications in less than 1% of amniocentesis procedures. The most serious is miscarriage. Other possible, but rare serious complications include cramping, vaginal spotting and slight leakage of amniotic fluid, and soreness where the needle was inserted. Early amniocentesis (12-15 weeks gestation) may have a slightly higher risk than standard amniocentesis (after 15 weeks gestation) for pregnancy loss, amniotic fluid leakage, and culture failure.

5. Fewer than 1 in 100 amniocentesis need to be repeated because not enough fluid is obtained the first time. Occasionally, even though fluid is obtained, a diagnosis cannot be made and the amniocentesis needs to be repeated.

6. The standard testing performed on an amniotic fluid sample is chromosome analysis, which can identify over 99% of chromosome disorders, and AFP (alpha-fetoprotein) analysis, which can identify over 90% of open neural tube defects. Testing for other conditions will not be performed unless indicated in (1) above.

7. 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 can contaminate the sample. In addition, 3.5% of all pregnancies have birth defects which cannot be detected by testing amniotic fluid or by ultrasound examination.

Additional Items of consent/refusal applicable to any of the above screening/testing

1. In case of twins or multiple fetuses, the results may pertain to only one of the fetuses.

2. In case of abnormal diagnostic results, the decision to continue or to terminate the pregnancy is entirely mine.

3. The decision to consent to, or to refuse any of the above procedures/testing is entirely mine.

4. No test(s) will be performed and reported on my sample other than those authorized by my doctor, and any unused portion of my original sample will be destroyed within 2 months of receipt of the sample by the laboratory.

5. My signature below indicates that I have read, or had read to me the above information and I understand it. I have had the opportunity to discuss it, including the purpose and the information I want, and all my questions have been answered.

YES: I REQUEST that Dr. Nawar Hatoum performed amniocentesis and/or the genetic screening or testing marked above I understand and accept the consequences of this decision.

_______________________________________   ______________                       ___________________________________
Patient Signature                                      Date     Witnessed By

NO: I DECLINED to have amniocentesis and/or genetics screening/testing offered to me. I understand and accept the consequences of this decision.

_______________________________________  _______________                       ___________________________________
P a t i e n t  S i g n a t u r e      D a t e      W i t n e s s e d  B y