



**INFORMED CONSENT TO
AMNIOCENTESIS AND PRENATAL DIAGNOSIS**

It is very important to Women's Health Center of Lebanon that you understand and consent to the treatment your doctor is rendering and any procedure your doctor may perform. You should be involved in any and all decisions concerning surgical procedures your doctor has recommended. Sign this form only after you understand the procedure, the anticipated benefits, the risks, the alternatives, the risks associated with the alternatives and all of your questions have been answered. Please initial and date directly below this paragraph indicating your understanding of this paragraph.

Patient's Initials or Authorized Representative

Date

I, _____, hereby authorize Dr. _____ and any associates or assistants the doctor deems appropriate, to perform an amniocentesis and prenatal diagnosis.

The doctor has explained the benefits of the procedure(s) to me. However, I understand there is no certainty that I will achieve these benefits and no guarantee has been made to me regarding the outcome of the procedure(s). I also authorize the administration of sedation and/or anesthesia as may be deemed advisable or necessary for my comfort, well being and safety.

Proposed Procedure: An amniocentesis is the insertion of a needle into the uterus through the abdominal wall and the removal of some of the amniotic fluid which surrounds the baby. This is a prenatal test that examines cells shed by the fetus into the surrounding amniotic fluid. It is a reliable indicator of chromosomal abnormalities such as Down's syndrome (a chromosomal disorder that results in mental retardation and physical abnormalities), genetic disorders such as cystic fibrosis, and neural tube defects such as spina bifida.

Your skin is prepared with an antiseptic swab; then an anesthetic to numb the area may be injected, which may cause an initial stinging sensation. An ultrasound is used to determine the position of the fetus and the location of the placenta. Using the ultrasound images for guidance throughout, the doctor then inserts a long, thin needle through the mother's abdomen to extract amniotic fluid from the womb. Once the amniotic fluid is collected, the cells are cultured and stimulated to grow for one to two weeks. After that, the cell chromosomes can be examined. For this reason, test results are not available for up to ten working days after the test is performed.

Risks/Possible Complications: The doctor has explained to me that there are risks and possible undesirable consequences associated with any procedure including, but not limited to, vaginal bleeding, cramping, contractions, fever, leakage of amniotic fluid, miscarriage, and/or premature delivery. I understand that if I need blood or blood products these carry a risk of contracting HIV/AIDS, hepatitis, or other diseases.

The hazard to the mother or the fetus is considered to be extremely small, however, it cannot be guaranteed that the procedure will not cause damage to the mother or fetus or initiate premature labor resulting in miscarriage or premature delivery.

Any particular attempt to obtain amniotic fluid by amniocentesis may be unsuccessful. This may require more than one attempt at a single session or may require attempts at another time. Amniotic fluid which is obtained may not result in growth of fetal cells and therefore, may require an attempt to repeat the amniocentesis. If amniotic fluid cannot be obtained or if the fetal cells fail to grow, some prenatal tests cannot be done. If undiagnosed twins are present or if fluid is obtained from one twin only, the results pertain to only one of the twins.

Although the likelihood of misinterpretation of the genetic tests is considered to be extremely small, a complete and correct diagnosis of the condition of the fetus based on these tests cannot be guaranteed. A normal result from the prenatal test(s) does not eliminate the possibility that the child might have birth defects and/or mental retardation caused by other disorders for which tests are not being done.

In permitting my doctor to perform the procedure(s), I understand that unforeseen conditions may be revealed that may necessitate change or extension of the original procedure(s) or a different procedure(s) than those already explained to me. I therefore authorize and request that the above-named physician, his assistants, or his designees perform such procedure(s) as necessary and desirable in the exercise of his/her professional judgment.

In the unlikely event that one or more of the above inherent complications may occur, my physician(s) will take appropriate and reasonable steps to help manage the clinical situation and be available to me and my family to address our concerns and questions.

Alternative Procedures: The reasonable alternative(s) to the procedure(s) have been explained to me. These alternatives include, but are not limited to: choosing not to have this procedure.

I hereby authorize the doctor to utilize or dispose of removed tissues, parts or organs resulting from the procedure(s) authorized above.

I consent to any photographing or videotaping of the procedure(s) that may be performed, provided my identity is not revealed by the pictures or by descriptive texts accompanying them, so that my physician may follow my therapy progression. I consent to the admittance of students or authorized equipment representatives to the procedure room for purposes of advancing medical education or obtaining important product information.

By signing below, I certify that I have had an opportunity to ask the doctor all my questions concerning anticipated benefits, material risks, alternative therapies, and risks of those alternatives, and all of my questions have been answered to my satisfaction.

_____/_____/_____
Date Time Signature of Patient or Authorized Rep. Relationship of Authorized Rep.

The Patient/Authorized Representative has read this form or had it read to him/her.

The Patient/Authorized Representative states that he/she understands this information

The Patient/Authorized Representative has no further questions.

The Patient/Authorized Representative has read the form in Spanish.

I certify that I have asked the patient/authorized representative the above questions and her responses were noted above.

Date Time Signature of Witness

CERTIFICATION OF PHYSICIAN:

I hereby certify that I have discussed with the individual granting consent, the facts, anticipated benefits, material risks, alternative therapies and the risks associated with the alternatives of the procedure(s).

Date Time Signature of Physician

USE OF INTERPRETER OR SPECIAL ASSISTANCE

An interpreter or special assistance was used to assist patient in completing this form as follows:

_____ Foreign language (specify)

_____ Sign language

_____ Patient is blind, form read to patient

_____ Other (specify) _____

Interpretation provided by _____

(Fill in name of Interpreter and Title or Relationship to Patient)

Signature (Individual Providing Assistance)

Date

Time