What will my participation involve if I decide to enroll in the study?

After you are enrolled in the study, a study representative will contact you at select time points to collect pregnancy-related health information. You will be contacted once during each trimester and around the time of your estimated delivery date or when you give birth.

A study representative will also contact your healthcare provider at two time points during the study: approximately 6 to 7 months for prenatal follow-up and around the time of your estimated delivery date, or when you give birth.

In addition, a study representative will contact your infant's paediatrician at three time points during the study: when your baby is born, at 6 months of age and 1 year of age.

The ADDYI Pregnancy Registry Study

To speak to a study representative, contact the ADDYI Pregnancy Registry Study toll-free at:

855-265-6954

Hours of Operation:
M-F 9:00am-5:00pm, EST

For more information visit:
www.AddyiPregnancy.com

The ADDYI Pregnancy Registry Study

Patient Information Brochure

What is the ADDYI Pregnancy Registry Study?

Sprout Pharmaceuticals, Inc., the manufacturer of ADDYI® (flibanserin), is conducting this observational study to collect health information from women who have taken at least 1 dose of ADDYI at any time during their pregnancy, compared to women who have not taken ADDYI during their pregnancy. If you decide to participate in this study, you will be asked to provide health information about your pregnancy and your infant's growth and development up to their first birthday.

During the development of pharmaceutical products, women who are pregnant are typically excluded from clinical trials, and therefore, limited information is available on the use of ADDYI during pregnancy.

The information collected in this study will be provided to the Food and Drug Administration so that other women who become pregnant while being treated with ADDYI can better understand the effects of ADDYI on their pregnancy and their infants.

Participation in this study will not impact your or your infant's treatment or care, and you and your infant will continue to receive standard care as decided by your healthcare provider(s).

Why should I participate in this Study?

By participating in this study, you and your infant will provide important information that will help Sprout Pharmaceuticals, Inc. evaluate health outcomes of women who took at least 1 dose of ADDYI while pregnant and their infants growth and development up to their first birthday.

Your decision to participate in this study is entirely voluntary. While enrolled in the study, your personal and medical information will be kept strictly confidential.

Am I eligible to participate in the study?

If you have taken at least 1 dose of ADDYI at any time during your pregnancy you may be eligible to participate in this study. In addition, women who either stopped taking ADDYI within a month of becoming pregnant or have never taken ADDYI may also be eligible to participate.

How do I participate in this Study?

To learn more about the ADDYI Pregnancy Registry Study and to find out if you are eligible to participate, please contact a study representative at 855-265-6954. You may also ask your healthcare provider to refer you.

If you are eligible to participate and decide you would like to enroll in the study, a study representative will describe the study in more detail, answer any of your questions and ask for your verbal or electronic consent along with a written release of medical records. Your consent acknowledges your understanding of the study and allows you and your infant's healthcare information to be collected. After receiving your consent, a study representative will contact your healthcare provider to confirm your personal health information.

Will my privacy be protected?

All personal and medical information will be kept strictly confidential. Information about your health while you are enrolled in the ADDYI Pregnancy Registry Study will be kept anonymous and any identifying information will not be used.