

Assent Form for Child Participants Ages 7 to Age of Majority (AOM)

Sponsor / Study Title: Sprout Pharmaceuticals Inc. / “Pregnancy Registry Study to Evaluate Adverse Pregnancy Outcomes and Major Congenital Malformations in Pregnancies Exposed to ADDYI®”

Protocol Number: SPR-22-01

**Principal Investigator:
(Study Doctor)** Amy Miller, RPh, PharmD

Telephone: 1-855-265-6954 (24-Hours)

Address: UBC
933 Canyon Road
Morgantown, WV 26508

Dear Subject,

You are being invited to take part in an observational study because you are pregnant and may or may not have been diagnosed with hypoactive sexual desire disorder (HSDD) and were exposed to ADDYI anytime during your pregnancy. In an observational study you will not be asked to change your medical treatment or care for the study. Your treatment or care, including any prescription of medicines, will be decided by you and your doctor based on standard medical practice and independently of the study.

What it would mean for you to participate:

To be part of this Registry you will not have to make any extra office visits, take any extra tests, or take any additional drugs. Your participation in this study will last until your baby turns 12 months at maximum. If your doctor or your baby’s doctor does not answer our calls, we may also ask you for some of this information directly.

Important things to know:

You do not have to be in this study if you don’t want to. You have the right to stop your participation at any time. Tell your principal investigator or parent/legal guardian if you want to stop being in the study. No one will be mad at you and your medical care will not change.

Statement of Assent:

I have read or someone has read to me this form called assent. My parent(s)/legal guardian(s) and the principal investigator (if applicable) have explained the study to me and have answered my questions. I agree to be in this study. I also agree that my personal information and my medical information can be used in the study.

Printed Name of Person Explaining Assent Form

Signature of Person Explaining Assent Form

Date

You will be mailed a signed and dated copy of this assent form for to keep.