

STANFORD UNIVERSITY – Child’s Assent Form (Age 7-17)

Protocol Title: Optimizing the Dose of Depot Leuprolide for Treatment of Precocious Puberty

Protocol Director: E. Kirk Neely, M.D.

Meeting date February 9, 2010

What will happen to me in this study?

Your doctors have explained the reasons for the visits in this study. They have told you that you are going to be given a medicine to slow puberty (changes in the body that make you grow up) because you have started puberty too early. You will be given the medicine for puberty by injection (shot) either every 3 months or every 4 months. To make sure that the medicine is working properly, you will have a blood test done in the clinic every 3 or 4 months. This blood test will be done to monitor hormone levels.

Can anything bad happen to me?

If you want you will be given a special cream to apply to your skin before injections and blood tests. This cream will keep it from hurting. Sometimes the medicine slows down growth more than we want, and you can stop the medicine.

Can anything good happen to me?

The medicine will stop your puberty until you are at a more normal age.

Do I have other choices?

You do not need to participate in the study. If you don’t want to be in the study, you can still go on the monthly shot, or not start any medicine at all and continue through puberty.

Will anyone know I am in the study?

Your being in the study will be kept secret, but information without your name attached could be given to the drug company or a government office under special circumstances.

What happens if I get hurt?

Your parents will read and sign a different form explaining the study and what to do if you are unhappy about it or are hurt. You can always contact Doctor Neely or the other doctors at 650 723-5791.

Who can I talk to about the study?

If you are not happy about this study or if you have any questions, please contact the Stanford Institutional Review Board (IRB) to speak to someone other than your doctor at (650)-723-5244 or toll free at 1-866-680-2906 or write the Stanford

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IRB, Administrative Panels Office, Stanford University, Stanford, CA 94305-5401.

What if I do not want to do this?

You do not need to participate in the study. If you start the study, you can withdraw at any time.

SIGNATURE CLAUSE

Do you understand this study and are you willing to participate?

YES

NO

Signature of Child

Date