

**ASSENT TO PARTICIPATE IN RESEARCH (PROTOCOL #13472A)  
Gonadotropin Releasing Hormone Agonist Test in Disorders of Puberty  
Healthy Volunteers**

1. My name is \_\_\_\_\_(Staff obtaining assent)
2. We are asking you to take part in a research study because we are trying to learn more about how well a medication called leuprolide can help us find out if children like you are growing and developing normally.
3. If you agree to be in this study, you will come and stay on a special floor in the hospital for two nights. When you first arrive, we will put a tube in your arm to take blood through (IV) in order to see how many hormones (the chemicals your body makes to help you grow) you are making at different times of the day and night. We will have to use a needle to put the tube into your arm and it may hurt for a short time while we do that. You will have the tube in your arm the whole time you are here and we will draw blood at all different times during the days and nights you are here. On the second day you are here, we will give you a shot of Leuprolide, a medication that may cause your body to make more hormones, under your skin. We will keep drawing blood through the IV at different times to see how many hormones your body makes after the shot.
4. There is a risk that people will find out you participated in this study and the results of your tests. It is possible that you may have bruising, swelling, redness, infection or pain which can sometimes happen in the place on your arm where the IV tube is placed. It is also possible that you may develop swelling or rash from the Leuprolide we give you. We will do all we can to prevent these from happening.
5. You may not benefit from this study. This study will help us to understand if Leuprolide can help us find out what parts of growth and development are normal so we can take care of children who need help with these problems. If your hormones turn out to unexpectedly be too low or too high, we will share the results with you, your parents, and, if you wish, your personal physician. We will pay you with a check made out in your name, \$50 for finishing the sleep test, \$50 for finishing the leuprolide test, or \$150 for finishing both.
6. Please talk this over with your parents before you decide whether or not to participate. We will also ask your parents to give their permission for you to take part in this study. But even if your parents say “yes” you can still decide not to do this.
7. If you don’t want to be in this study, you don’t have to participate. Remember, being in this study is up to you, and no one will be upset if you don’t want to participate or even if you change your mind later and want to stop.

8. You can ask any questions that you have about the study. If you have a question later that you didn't think of now, you or your parents can call Dr. Rosenfield at (773)702-6432.
9. Signing your name at the bottom means that you agree to be in this study. You or your parents will be given a copy of this form after you have signed it.

## **SUBJECT**

The research project and the procedures have been explained to me. I have received a signed copy of this assent form for my records.

I agree to participate in this study. I am aware that my participation is voluntary and that I do not have to sign this form if I do not want to be part of this research study.

Signature of Subject: \_\_\_\_\_  
Date: \_\_\_\_\_ Time: \_\_\_\_\_ AM/PM (Circle)

## **PERSON OBTAINING ASSENT**

I have explained to \_\_\_\_\_ the nature and purpose of the study and the risks involved. I have answered and will answer all questions to the best of my ability. I have given a signed copy of the assent form to the subject and his or her family.

Signature of Person Obtaining Assent: \_\_\_\_\_  
Date: \_\_\_\_\_ Time: \_\_\_\_\_ AM/PM (Circle)

## **INVESTIGATOR**

Signature of Investigator: \_\_\_\_\_  
Date: \_\_\_\_\_ Time: \_\_\_\_\_ AM/PM (Circle)