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**LOYOLA UNIVERSITY MEDICAL CENTER**

**MAYWOOD, ILLINOIS**

**Department of Urology**

**CHILD'S ASSENT FORM**

Project Title: A Study of the Safety and Effectiveness of the Mentor Soft-Solid Testicular Prosthesis (SSTP)

Patient Information:

**WHAT IS THIS STUDY ABOUT?**

You have only one testicle and this study is to see if a prosthesis (man-made item) can make your scrotum (the part that hangs below your penis) look more normal.

The Soft-Solid Testicular Prosthesis (device) is made by a company called Mentor (The Sponsor). This device is used for a more natural looking scrotum. Mentor is studying how well the device works as well as the safety of the device.

This is a 12-month research study of about 60 males. Your doctor will be paid for his/her involvement. The device to be studied is sold outside the United States, but is only available in the United States through this study. Information on how your body appears after the device is put in and on any problems that may happen because of the prosthesis will be collected and told to the Sponsor. To learn more information about how well the device is working, you will be given Quality of Life Questionnaires (questions that ask about your life) to fill out before surgery and at six months after your surgery.

The Soft-Solid Testicular Prosthesis is a research or experimental device.

**WHAT WILL HAPPEN TO ME IN THIS STUDY?**

The Mentor Soft-Solid Testicular Prosthesis can be used when you have had to have one of your testicles removed and you want your body to look more normal. . The device is the same as the weight, shape and softness of the normal testicle. The prosthesis comes in five sizes - extra-small, small, medium, large and extra-large. The device is made of a molded silicone elastomer shell, filled with silicone elastomer. This will have to be put in by the doctor and you will have to have surgery. One end of the device has a thick patch which your surgeon can use to suture (hold in place) the device.

**WHAT HAPPENS DURING THE OPERATION?**

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Your doctor will explain what happens during the operation, the type of implant that will be used, how and where it will be placed and the type of medicine he/she will use to put you to sleep for the operation. You may have to have this done more than one time. If there are problems with the device, you may have to have some other surgery.

Your surgeon will explain what happens after the surgery while you are getting better.

### **WHAT HAPPENS AFTER THE OPERATION?**

You must be willing to come in to visit your doctor for check-ups at 2 weeks, and 6 and 12 months after your operation. The information gathered from these visits is important for us to study the device. If you move, your doctor will arrange for you to go to another doctor in your new area.

Every time you see your doctor, he/she examines you (measure your testicles and see how the area looks) and asks you some questions so that the Sponsor will know how well the surgery went and how happy you are about it. At the six month exam, you will also be given a Quality of Life questionnaire to fill out during your office visits. Your doctor will not read your answers to the questionnaires. Your answers to the questionnaires will be put together with those answers of other people who have had the same surgery and then the sponsor will figure out the answers to everyone's questions.

### **CAN ANYTHING BAD HAPPEN TO ME IN THIS STUDY?**

You will need to be asleep for this operation. Having surgery is always a little bit dangerous. We may not know all the problems you might have before or after the operation.

Your doctor will talk to you about problems and how your body might be affected by the operation and you need to make sure you understand and ask questions about anything you don't understand. The sponsor depends on your doctor to tell you all of the problems associated with the operations and prosthesis that might happen. This also means that your doctor will tell you about other things that may work besides this operation.

Sometimes the medicine that you take after the operation to have the device put in may cause trouble. Sometimes your body does not like man-made things put into it and this may mean that the device would have to be taken out by another surgery.

### **THINGS THAT PROBABLY WON'T HAPPEN BUT MIGHT:**

The Sponsor knows that problems can happen over a long time and that they cannot make sure that things will still work for a long time. Some things that might happen but usually don't are:

Rupture of the Implant:

Infection

Movement of Implant/Interruption of Wound Healing

Blood in the tissue

Fluid Accumulation

You may not be happy with how it looks

Calcium Deposits

Your doctor will talk to you about any more problems of Soft-Solid testicular implants and your surgery. These implants are not meant to be in your body for life. We don't know how long they should stay in place.

Children's Assent to Consent"

I have been fully informed of the research project and what my part in the project will be as well as any problems that may occur during my participation. I give permission to be part of this study. I know that Dr. Hatch will be available to answer any questions that I may have. I understand that I am free to withdraw this Assent to Consent at any time. I have received a copy of this Children's Assent to Consent.

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(Signature: patient)

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(Signature: Witness to signature)

THE FOLLOWING IS FOR YOUR INFORMATION ONLY:

INFORMED CONSENT REGULATIONS GOVERNING STUDIES INVOLVING CHILDREN

Federal Regulations now require the assent of children for participation in research protocols. Recognizing that the rate of development of many children is different and that their ability to adequately comprehend the implications of participation in research projects vary significantly with age, the Loyola Institutional Review Board has drafted the following statement:

- 1) For children below the age of eight (8), parental consent is all that is required. It is still appropriate that the investigator discuss with the child the mode of therapy in a fashion that may leave the child with some idea of what the plans for his therapy are.
- 2) Between the ages of eight (8) and twelve (12), the investigator must discuss with the child what is involved in the investigational therapy. The types of procedures, medication, side effects and purposes of the investigational protocol should be discussed with the child. While parental consent is still required for children in this age group, formal assent of the child will not be required but is suggested.
- 3) Children above the age of twelve (12) should be treated as adult participants in a research project. Full disclosure must be made to them concerning the risks and benefits of the project as well as procedures, drugs and other factors that may be related to the project.

A witness assent in writing is "required" from a child greater than twelve (12) years of age; parental consent is also required. Witnesses to the children's assent should be impartial observers and neither members of the family nor the investigators team.