

**IRB NUMBER: 107592072104**

**LOYOLA UNIVERSITY MEDICAL CENTER**

**MAYWOOD, ILLINOIS**

**Department of Urology**

**INFORMED CONSENT**

**Patient's Name:** \_\_\_\_\_

**Medical Record Number:** \_\_\_\_\_

**Project Title:** A Multi-Center, Open-Label, Active-Controlled, Dose-Titration Study Evaluating the Safety, Efficacy and Pharmacokinetics of Oxybutynin Transdermal Systems in the Treatment of Detrusor Overactivity Associated with a Neurological Condition in Pediatric Patients, Followed by a 12-Week Open-Label Safety Extension Study, protocol 003010

**This project will undergo re-review on or before 07/21/2005.**

Patient Information:

**PRINCIPLES CONCERNING RESEARCH:** You are being asked to allow your child to take part in a research project. It is important that you read and understand the principles that apply to all individuals who agree to participate in the research project described below:

1. Taking part in the research is entirely voluntary.
2. We do not know if your child will benefit from taking part in the research but the knowledge obtained may help others.
3. You may withdraw your child from the study at any time without anyone objecting and without penalty or loss of any benefits to which your child is otherwise entitled.
4. If during your child's participation in the research project, new information becomes available which would affect your child's being in the research project (such as better treatments or the side effects of the treatments), your child's doctor will discuss this new information with you and your child and will help you make a decision about your child's continuing in the research.

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The purpose of the research and how it is to be done and what your part in the research will be is described below. Also described are the risks, inconveniences, discomforts and other important information which you need to make a decision about whether or not your child should participate in the research project. You are urged to discuss any questions you have about this research with the staff members.

**PURPOSE OF STUDY:** Your child is being asked to participate in this research because your child has a condition called “neurogenic bladder”.

Neurogenic bladder is a condition that affects both sexes, and can result from disease, injury or birth defects that affect the brain, spinal cord or nerves leading to the bladder. The most common cause of neurogenic bladder in children is a birth defect of the spinal cord, such as spina bifida.

There are a number of problems that can be associated with neurogenic bladder including incontinence (wetting accidents), urinary retention, frequent bladder infections and increased risk of kidney damage.

This study is being done to see if the oxybutynin patch is as safe and effective as the oral oxybutynin.

In order to be in this study, your child must be taking oxybutynin by mouth (as a liquid, tablet or extended-release tablet) to treat their urinary problems.

Oxybutynin, given as tablets or a liquid, is already approved for use by both children and adults in the United States by the U.S. Food and Drug Administration (FDA). In this study, oxybutynin is contained in a patch that is worn on the stomach, hip or lower back just below the belt line, and the oxybutynin will be absorbed into the blood through the skin.

This study will evaluate the effectiveness of 3 doses of oxybutynin delivered by a patch to children. The 3 patch sizes (that match the 3 different doses) that will be studied are 13 cm<sup>2</sup> (about 1¼ by 1¾ inches), 26 cm<sup>2</sup> (about 1¾ by 2½ inches) and 39 cm<sup>2</sup> (about 2 ¼ by 3 inches).

The 39 cm<sup>2</sup> patch is approved for use, but only for adults over 18 years old.

Because the oxybutynin patch has never been used in children, the patch is considered “investigational.” The word “investigational” means that oxybutynin placed in a patch that is worn on the skin is not yet approved by the FDA for use by children under 18 years old.

If your child is currently taking other medication for neurogenic bladder, that medication must be stopped when instructed to do so by your physician.

This study is sponsored by Watson Laboratories, Inc. Approximately 100 children between the ages of 6 and 15 years old (approximately 50 children between 6 and 10 years old and 50 children between 11 and 15 years old), who have neurogenic bladders associated with a neurological condition, will take part in this study at approximately

10 to 15 centers in the United States.

### **Description of the Study and Study procedures**

The study will consist of a 2- to 3-week screening period to find out if your child qualifies to participate in the study. If he or she qualifies, your child will be assigned by chance (like the flip of a coin) to receive oxybutynin either as a patch that will be worn on the skin, or to take oxybutynin by mouth as a liquid or tablet. In this study, 3 out of every 4 patients will be assigned to the oxybutynin patch.

If your child is assigned to receive the oral form of oxybutynin, your child will be required to make 7 visits to the clinic during the course of the study. Your child's total participation in this study will last up to 19 weeks.

If your child is assigned to receive the patch form of oxybutynin, your child will be required to make up to 11 visits to the clinic during the course of the study. Your child's total participation in this study will last for approximately 29 weeks.

None of the tests performed during this study are investigational.

### **Screening Visits**

The purpose of the screening visits are to determine if your child qualifies for the study and for the study doctor to make sure it is safe for your child to be in the study. There are 3 screening visits that will take place over about 3 weeks. At each visit, your child's blood pressure, heart rate, and temperature will be measured. You will be asked about what medicines (prescription or over-the-counter) your child has been taking. You will be asked questions about your child's general health and if there have been any changes in their health since the last visit. Your child will be instructed not to change their fluid intake level (how much they are drinking each day) while they are in the study. Other activities will take place at each visit, and they are described below.

During the first screening visit, (**Screening Visit 1**), these additional activities will take place:

- a medical and medication history will be collected, and you will be asked for permission for the study doctor to review your child's medical records; your permission may be needed to contact other physicians if necessary to gather all the information needed
- height and weight will be measured;
- a routine physical examination will be performed, checking your child's lungs, abdomen, skin, muscles, bones, arms, legs, head, ears, eyes, nose, throat, lymph nodes, nerves, heart and general appearance;
- blood (approximately one teaspoon) and urine samples will be collected to evaluate your child's general health;
- if your child is a female and is already having her period, she will take a urine pregnancy test;

- you or your child will be asked to complete a questionnaire that will ask 14 questions about common side-effects that your child may have experienced due to their oxybutynin medicine;
- a 2-day urinary diary card along with instructions will be given to you or your child to fill out before the next visit. You and your child will write down in the diary the number of times they were catheterized each day, the number of leaking accidents between catheterizations, and the volume of urine collected each time your child was catheterized.

At **Screening Visit 2**, the following additional activities will take place:

- the previous urinary diary will be collected and reviewed and a new 2-day urinary diary card along with instructions will be given to you or your child to fill out before the next visit;
- any oxybutynin your child is taking will be stopped at this time. Your child will not be allowed to take oxybutynin or any other medication for their urinary problems until after their next clinic visit, that will be a minimum of 3 to 7 days later.

At **Screening Visit 3**, the following additional activities will take place:

- you or your child will be asked to complete a questionnaire that will ask 14 questions about common side-effects that your child may have experienced due to their oxybutynin medicine;
- a recording of heart activity (electrocardiogram or ECG) will be taken;
- a blood sample (approximately 4 mls or a little less than one teaspoon) will be collected to evaluate baseline levels of oxybutynin;
- a test called a urodynamic evaluation will be performed on your child. During this test, a small, flexible tube will be inserted into your child's bladder, and the bladder will be filled with water. This evaluation measures the amount of urine in the bladder, how long it takes to urinate, and the force of the urine stream.

**Study Drug Assignment:** If your child qualifies for the study they will be assigned by chance (like flipping a coin) to either oral oxybutynin or an oxybutynin patch

If your child is assigned to the oxybutynin patch, you will be given a small box containing these patches. The oxybutynin patch size (or dose) your child will be given will be based on how large a dose of oral oxybutynin your child was taking before they started the study. Your child will be instructed to wear one patch on their stomach, hip, or lower back just below their belt line, and to change it every 3 to 4 days. You and your child will also be given further instructions on how to apply and wear the assigned patches, and how to remove and replace them with another.

If your child is assigned to oral medication, you will be given the same form of medication (liquid or tablets) at about the same dose that they were on before starting the study. Your child must take the oxybutynin medication that the clinic gives to you; your

child must not use any of the oxybutynin medication that you may have left over from before they entered the study.

All unused study medication must be returned to the clinic at each study visit, and new study medication will be given for your child to use until the next clinic visit. The study medication should not be taken by anyone other than your enrolled child, and it should be kept out of reach of children or others with a limited capacity to read or understand, and out of reach of pets.

### **Treatment Period Visits**

During the Treatment Period, your child will return to the clinic for 4 or 5 visits over about 14 to 16 weeks, as described below. At each visit during the Treatment Period, your child's blood pressure, heart rate, and temperature will be measured. You will be asked about what medicines (prescription or over-the-counter) your child has been taking since the last visit. You will be asked questions about your child's general health and if there have been any changes in their health since the last visit. Your child will be instructed not to change their fluid intake level (how much they are drinking each day) while they are in the study.

*If your child is assigned to the oxybutynin patch, they should be wearing a patch when they come to the clinic for each visit.*

At each treatment visit, you will be given a new 2-day urinary diary to complete. There are two other diaries that you and your child may also be asked to complete between study visits. One diary will be used to record any health-related events that your child experiences that are not normal for them. The second diary will only be given to children applying the oxybutynin patch and will be used to record how well the patch stays on. All of these diaries must be brought back to the clinic at each visit.

Other activities will take place at each visit, and they are described below:

At the **Treatment Week 2 Visit**, the study doctor will review the diaries to see how your child's urinary symptoms are being controlled on the study medication, and to evaluate any side effects your child might be having. At this visit, your study doctor may adjust the dose of study medication, if it is needed. Children who were given the smallest patches (1.3 cm<sup>2</sup>) at Screening Visit 3 and have their dose increased to a bigger patch (2.6 cm<sup>2</sup>) will be asked to come back in 2 weeks for an additional visit so that the study doctor can continue to evaluate your child's urinary symptoms.

At the **Treatment Week 8 Visit**, your child will have another recording of their heart activity (electrocardiogram or ECG).

At the **Treatment Week 14 Visit**, the following additional activities will take place:

- a blood sample (a little less than two teaspoons) will be collected to see how much study medication is in their blood and to evaluate your child's general health;
- a urine sample will also be collected to evaluate your child's general health;
- if your child is a female and is already having her period, she will take a urine pregnancy test;

- a urodynamic evaluation will be performed on your child, just like the one performed at Screening Visit 3.

Your child will return to the clinic in 1 to 2 days (24 to 48 hours after this visit) for a Treatment Period Follow-up Visit. Your child should not take any medication for their unstable bladder condition until after the next visit, or until after instructed to do so by your study doctor.

At the **Treatment Period Follow-Up Visit** (1 to 2 days after the Week 14 Visit) a blood sample (a little less than one teaspoon) will be collected to see how much study medication is in their blood.

If your child was assigned to receive oral oxybutynin during this study, your child's participation in this study has been completed. The study doctor will restart your child on their oral medication similar to what they were taking before starting this study.

If your child was assigned to receive the patch form of oxybutynin during this study, your child will be able to continue to receive oxybutynin patches for 12 more weeks by entering the Safety Extension Period of the study. The purpose of this Safety Extension Period is to collect more data on the safety of the patches. You will be given more oxybutynin patches and instructed to return to the clinic in 6 weeks.

Your child should be wearing the patch when they come to the clinic for their next visit.

#### **Safety Extension Period Visits:**

During the **Safety Extension Period**, your child will return to the clinic for 3 visits over about 12 weeks. During this period, you will be given two diaries to complete between each visit. One diary will be used to record any health-related events that your child experiences that are not normal for them. The second diary will be used to record how well the patch stays on. Both diaries must be brought back to the clinic at each visit. Other activities that will take place at each visit are described below:

At the **Safety Extension Week 20 Visit**, your child's blood pressure, heart rate, and temperature will be measured. You will be asked about what medicines (prescription or over-the-counter) your child has been taking since the last visit. You will be asked questions about your child's general health and if there have been any changes in their health since the last visit. Your child will be instructed not to change their fluid intake level (how much they are drinking each day) while they are in the study.

At the **Safety Extension Week 26 Visit**, all of the procedures described at the Week 20 visit will be performed. In addition, the following activities will take place:

- you or your child will be asked to complete a questionnaire that will ask 14 questions about common side-effects that your child may have experienced due to their oxybutynin medicine;
- a routine physical examination will be performed, checking your child's lungs, abdomen, skin, muscles, bones, arms, legs, head, ears, eyes, nose, throat, lymph nodes, nerves, heart and general appearance;
- a recording of heart activity (electrocardiogram or ECG) will be taken;

- blood (one teaspoon) and urine samples will be collected to evaluate your child's general health;
- if your child is a female and is already having her period, she will take a urine pregnancy test;

Your child will return to the clinic in 1 to 2 days (from 24 to 48 hours after this visit) for a Safety Extension Period Follow-up Visit. Your child should not take any medication for their unstable bladder condition until after the next visit or until after instructed to by your study doctor.

At the **Safety Extension Follow-Up Visit** (1 to 2 days after the Week 26 Visit) the following procedures will be performed:

- any medications your child is currently taking or has taken since your child's last visit will be reviewed;
- your child will be asked questions about how they feel.

At this time, your child's participation in this study has been completed and the study doctor will restart your child on their oral medication similar to what they were taking prior to starting this study.

**RISKS/DISCOMFORTS:** The drug may not be effective in treating your child's condition.

The treatment your child may be assigned to receive may be less effective or may be associated with more problems than the other treatments that they did not receive in this research.

Participation in this project may require that your child stop some of his/her medications. Your child's condition may worsen.

Your child is currently taking oxybutynin. Because he or she is participating in this project, your child will have more tests and procedures done than would be the case if your child just continued taking the oxybutynin.

It is possible for any drug to cause side effects. You and your child need to know about side effects that can occur in the study before you agree to be a study participant. In addition to the risks listed below, there may be risks that are currently unknown. If further risks are identified during the study, you will be told about them. There may be increased risks caused by taking these drugs in combination with other medications. It is important that you tell the study staff about any side effects you have during the study. Your child may experience side effects that are not yet known or have not yet been reported. The study drug used in this study may cause all, some or none of the side effects discussed below.

If your child is currently taking oxybutynin as a tablet or liquid for neurogenic bladder, they must stop using that medication for a minimum of 3 to 7 days before getting study medication; therefore, your child can expect to see an increase in his or her neurogenic

bladder symptoms such as wetting accidents and increased number of catheterizations while they are not taking oxybutynin and for the first week after they start study medication. The study medication may not work as well for them as the medication they are currently taking and they may continue to have neurogenic bladder symptoms throughout the study.

As with any medication, undesirable side effects may sometimes happen. The most frequently reported side effects of the oxybutynin patch when studied in adults were skin irritation like redness, swelling, itching or a rash at the place where the patch was applied. These reactions are not expected to be a health hazard and are expected to go away within a few days. Other common side effects reported by adults who wore the oxybutynin patches were dry mouth, constipation, diarrhea, blurred vision, and painful urination.

Your child is currently taking oxybutynin by mouth, so you may already know the kinds of side effects your child may get from the drug. In adults, the most frequently reported side effects of oral oxybutynin were dry mouth, constipation, drowsiness, headache, blurred vision, dry eyes and dizziness.

Oxybutynin, either taken by mouth or as a patch, can make your child sweat less. This means that your child may be more likely to get a fever or heat exhaustion if they are in a hot place, like playing out in the sun or sitting in a hot tub. You should be careful that your child does not overheat during the study.

Caution should be used to avoid transfer of the medication from the oxybutynin patch, liquid or tablet to the eyes. You and your child should wash your hands immediately after handling the any study drug.

Possible side effects of blood drawing include faintness, inflammation of the vein, pain, bruising, or bleeding at the puncture site. There is also a slight possibility of infection.

After the urodynamic studies, your child may feel discomfort the first few times he or she urinates. Sitting in a tub of warm water may help. There is a slight possibility that your child may experience continued discomfort while urinating, cloudy urine, fever higher than 100°F, or his or her urine smells bad. If any of these happen, you should call your study doctor right away.

**REPRODUCTIVE AND SEXUAL ACTIVITY INFORMATION:** Because of possible dangers to an unborn child, if your child is of childbearing age (meaning that she had already started menstruating), she will be admitted to the study only if she is not breast-feeding or pregnant (a pre-study urine test for pregnancy will be provided at no cost). To prevent pregnancy during the study period, she **must agree** to either abstain from sexual intercourse, or use a method of birth control (for example: oral contraceptives, barrier methods, Norplant, or Depo Provera) for the duration of the study. If she does become pregnant while on this study, you must agree to inform the study doctor immediately, so that she can be withdrawn from the study.

**POTENTIAL BENEFITS:** We do not know if your child will benefit from being in this research project. The information we learn may help others.

Watson Laboratories may benefit from your child's participation in this project if, based on the results of research, the Food and Drug Administration allows them to sell oxybutynin patches for the treatment of children.

**ALTERNATIVES:** You do not have to participate in this project for your child to receive care and treatment at Loyola University Medical Center. If you do not want your child to be in this study, or your child does not want to be in this study, your child can continue to use their current oxybutynin tablets or liquid. There may be other medications that your child can receive. Your child's doctor has discussed other treatment with you along with their risks and benefits.

**FINANCIAL INFORMATION:** You will not be charged for the cost of the study drug or any study procedures that is part of the protocol. Some of the procedures done for the study are standard procedures and your insurance or other third party coverage may be charged to pay for your child's normal medical care.

You or your child will not be paid to participate in this study.

**RESEARCH RELATED INJURY:** All forms of medical diagnoses and treatment, whether routine or investigational, involve some risk of injury. In spite of all precautions, your child might develop medical complications from participating in the study. If such complications arise, the study doctor will assist you in obtaining appropriate medical treatment for your child. If your child is injured due to his or her participation in the study and you and your child have followed the directions of the study personnel, the study sponsor (Watson Laboratories, Inc) will provide reimbursement for the medical expenses necessary to treat the injury. The study sponsor does not routinely provide other compensation. You do not waive any liability rights for personal injury by signing this form.

**INFORMATION COLLECTED AND WHAT WILL HAPPEN TO IT:** In order to meet the goals of the research study (see Purpose of Research section of this consent), we will collect information on you, your test results and how you do. The information will be collected by David Hatch, M.D., the study physician(s), the research nurses, data administrators and secretaries. Information about you will be provided to Loyola University of Chicago, Watson Laboratories, Inc., the research sponsor, its data collection and study verification agencies and/or government regulatory agencies such as the Food and Drug Administration. In this way we will learn about the effectiveness (how well the drug works) and the safety of oxybutynin for treating a condition known as neurogenic bladder in pediatric patients.

The information we will collect and send includes:

- DEMOGRAPHIC INFORMATION (E.G., INITIALS, DATE OF BIRTH, GENDER, RACE)
- BILLING AND PAYMENT INFORMATION
- MEDICAL RECORD (INCLUDING BUT NOT LIMITED TO HISTORY AND PHYSICAL EXAM NOTES, PROGRESS NOTES, CONSULTATION REPORTS, LABORATORY TEST RESULTS, OPERATIVE REPORTS, INFORMATION FROM OTHER PHYSICIANS)
- INFORMATION RELATING TO ACQUIRED IMMUNODEFICIENCY SYNDROME (AIDS) OR HUMAN IMMUNODEFICIENCY VIRUS (HIV) INFECTION
- INFORMATION RELATING TO TREATMENT FOR DRUG OR ALCOHOL ABUSE
- INFORMATION RELATING TO MENTAL OR BEHAVIORAL HEALTH OR PSYCHIATRIC CARE EXCLUDING PSYCHOTHERAPY NOTES.
- PHOTOGRAPHS, VIDEOTAPES, OR DIGITAL OR OTHER RADIOGRAPHIC IMAGES
- TISSUE SAMPLES
- BLOOD SAMPLES

We will collect and provide this information about you for as long as you are in the study. You have the right to see and copy your records in the study doctor's possession. However, by signing this consent you agree that you might not be able to review some of your records related to the study until after the study is done. At that time your right to access will be restored. You always have access to your medical records.

It is possible that the sponsor, Watson Laboratories, Inc., research nurses, its data collection and/or study verification agencies, data administrators, or the Food and Drug Administration will come to Loyola University Medical Center ("LUMC") and view the medical record (which contains personal medical information about you) and the research records. They may take notes or copy pages of the medical record. This is done to verify the accuracy of the information LUMC is sending to them.

The results of this research study may be published in a journal for the purpose of advancing medical knowledge. Your child will not be identified by name or by any other identifying information in any publication or report about this research.

Consent for LUMC to use and disclose your child's medical information is required in order for your child to participate in the study.

**Withdrawal of Consent:** Your consent to use and disclose your child's medical information for the purpose of this research study is completely voluntary. You can withdraw your consent for LUMC to use and disclose your child's information and your child's consent to participate in this study at any time without affecting your ability to receive care and treatment at LUMC unrelated to the research study. Withdrawal means that all study procedures and follow-up will stop and we will not send any more information about your child to the sponsor of this research or its designees. However,

information already used and disclosed to the research sponsor prior to the time of your withdrawal from this study may continue to be used and disclosed by LUMC and the sponsor.

If you withdraw your child from the study, you will need to contact his/her physician(s) to discuss what other options may be available.

If you withdraw your child from the study we will ask that you sign the form attached to this consent and send it to Dr. David Hatch, or give it to the study staff. Your withdrawal from the study will not have any affect on any actions by LUMC taken before the attached form is received by LUMC.

Your study doctor, the Institutional Review Board (IRB), the regulatory authorities, or Watson Laboratories, Inc., may terminate the study at any time with or without your consent. Your study doctor may choose to take you out of the study because of unexpected or serious side effects or treatment non-compliance.

## CONSENT

I have fully explained to \_\_\_\_\_ the nature and purpose of the above described procedure and the risks that are involved in its performance. I have answered and will answer all questions to the best of my ability. I may be reached at 708-216-5099.

\_\_\_\_\_  
(Signature)

\_\_\_\_\_  
Date

Dr. David Hatch, who is the principal investigators for this study, or [his/her] associates will be available to answer any questions you may have. He can be reached at: 708-216-8525.

If you ever feel that you have been injured by participating in this study or if you have any questions concerning your rights as a research participant, you may contact Dr. Kenneth Micetich, Chairman, Institutional Review Board for the Protection of Human Subjects-Medical Center (708-216-4608).

You will receive a signed copy of this informed consent document.

You have been fully informed of the above-described research program with its possible benefits and risks. Your signature below indicates that you are willing to participate in this research study and agree to the use and disclosure of information about you as described above. You do not give up any of your legal rights by signing this consent document.

\_\_\_\_\_  
(Signature: Parent) Date: \_\_\_\_\_

\_\_\_\_\_  
(Signature: Parent) Date: \_\_\_\_\_

\_\_\_\_\_  
(Signature: Witness to signature) Date: \_\_\_\_\_

**Children's Assent to Consent**

The doctors have talked to me about the research project. They have told me what my part in the project will be and any problems that might happen. I give permission to be part of this study. I know that Dr. David Hatch and/or his associates will be available to answer any questions that I may have. I can stop my being in the research project at any time. I have received a copy of this Children's Assent to Consent.

\_\_\_\_\_ Date: \_\_\_\_\_  
(Signature: Patient)

\_\_\_\_\_ Date: \_\_\_\_\_  
(Signature: Witness to signature)

\_\_\_\_\_ Date: \_\_\_\_\_  
(Signature: Person administering the informed consent)

LU 107592: A Multi-Center, Open-Label, Active-Controlled, Dose-Titration Study Evaluating the Safety, Efficacy and Pharmacokinetics of Oxybutynin Transdermal Systems in the Treatment of Detrusor Overactivity Associated with a Neurological Condition in Pediatric Patients, Followed by a 12-Week Open-Label Safety Extension Study, protocol 003010

## REVOCATION OF AUTHORIZATION TO RELEASE

### PROTECTED HEALTH INFORMATION (PHI)

I, \_\_\_\_\_, hereby revoke my consent to participate in the A Multi-Center, Open-Label, Active-Controlled, Dose-Titration Study Evaluating the Safety, Efficacy and Pharmacokinetics of Oxybutynin Transdermal Systems in the Treatment of Detrusor Overactivity Associated with a Neurological Condition in Pediatric Patients, protocol 003010 at Loyola University Medical Center (“LUMC”). I also revoke my consent to release information I provided to LUMC that allowed LUMC to use and disclose my medical information to Watson Laboratories, Inc as outlined on the consent form, which I signed on \_\_\_\_\_. I understand that this revocation does not apply to any action LUMC has taken in reliance on the consent I signed earlier.

\_\_\_\_\_  
Patient Name or Personal Representative

\_\_\_\_\_  
Date

Please return this form to:

Dr. David Hatch  
Dept of Urology, Build 54, Rm 237  
Loyola University Medical Center  
2160 South First Avenue  
Maywood, Illinois 60153

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**THIS IS FOR THE INFORMATION OF THE STAFF:**

*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 investigator's team.*