The UNIVERSITY OF CHICAGO
The Division of the Biological Sciences • The University of Chicago Medical Center

CONSENT/AUTHORIZATION BY SUBJECT FOR PARTICIPATION IN A RESEARCH PROTOCOL

Protocol Number: IRB15-0178 Name of Subject: _____

STUDY TITLE: Silymarin Treatment of Trichotillomania in Children and Adults: A Double-Blind, Placebo-Controlled, Cross-Over Study

Doctors Directing Research: Dr. Jon E. Grant

Address: University of Chicago Medical Center
Department of Psychiatry
5841 South Maryland Avenue, MC 3077
Chicago, IL 60637

Telephone Number: 773-834-1325

You are being asked to participate in a research study. A member of the research team will explain what is involved in this study and how it will affect you. This consent form describes the study procedures, the risks and benefits of participation, as well as how your confidentiality will be maintained. Please take your time to ask questions and feel comfortable making a decision whether it is in your interest to participate or not. This process is called informed consent. If you decide you are willing to participate in this study, you will be asked to sign this form.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to evaluate the safety and effectiveness of milk thistle (silymarin) for children and adults with trichotillomania (hair pulling disorder). The hypothesis to be tested is that milk thistle will be more effective and well tolerated in subjects with trichotillomania compared to placebo (inactive drug). The proposed study will provide needed data on the treatment of trichotillomania in children and adults, a population that currently lacks a clearly effective treatment.

Milk thistle is being used as an experimental drug for this study. This means that milk thistle is not approved by the Food and Drug Administration for reducing the symptoms of trichotillomania.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

About 25 people will take part in this study at the University of Chicago.

WHAT IS INVOLVED IN THE STUDY?

In order to determine if you are eligible to participate in the study, the following will take place:

- A review of your medical history, current and past medications, and past treatments for trichotillomania will be completed.
- You will undergo a psychiatric interview and be asked to complete some neurocognitive testing which measures how you act on thoughts (impulsivity) as well as your need to engage in a behavior (compulsivity). This testing involves three different tasks on the computer, measuring attention, impulsivity, and memory.
- You will complete a physical exam with the study doctor; sitting blood pressure, pulse, temperature, weight, and height will be recorded.
- You will be asked to give a urine sample that will be tested for drug use. This test must be negative in order to participate in the study.
- If you are a female capable of having a child, you will complete a urine pregnancy test to ensure that you are not pregnant at the time of study entry. The pregnancy test must be negative in order to participate in the study. If you are sexually active, you also should be using appropriate contraceptives during the course of the study (including abstinence or other acceptable methods such as oral contraceptives (birth control pill), intrauterine device (IUD), injection/shot, male latex condom, vaginal ring, or birth control patch).
- You will be asked about how you are feeling and if you have started taking any new medications or had any changes in medications recently.
- You will be asked to complete questionnaires to assess mood and hair pulling.
- You will receive the study drug or a placebo at the initial study visit to take in-between visits at regular times over the course of the study.
- This visit will take up to 2 hours.

If you are determined to be eligible and provide consent to participate in this study, you will be enrolled in the study. You will be asked to attend seven additional study visits where you will be given the study drug on visits 2, 3, 5, 6, and 7.

For the first six weeks of the study, you will be assigned to receive either milk thistle (600mg) or placebo. You will be randomly assigned (randomization) to receive either the study drug or the placebo. Randomization means you will be assigned by chance to one group or the other, like flipping a coin. No individuals directly related to the study procedures (you or research staff) will know whether you are taking the study drug or the placebo. This is what is meant by "blinding." A placebo does not have any active ingredients but looks the same as the study drug.

Whichever drug (milk thistle or placebo) is not assigned during the first six week phase will be assigned during the second six week phase following a one week wash-out period between phases.

The study doctor will discuss the next study visit scheduling with you during each of the office visits. During visits 2, 3, 6, and 7, the following will occur:

- Your vital signs will be checked
- You will be given the study drug
- You will be asked to complete some questionnaires to assess mood and hair pulling since the last visit
- These visits will take approximately 30 minutes to one hour each.

During visits 4, 5, and 8 you will be asked to complete the following:

- Neurocognitive testing, which will consist of the same computer tasks you were asked to complete at the first visit.
- Completing questionnaires and answering verbal questions about your hair pulling, thoughts about hair pulling, and mood.
- Vital signs, including height, weight, blood pressure, and body temperature.

During this study, Dr. Grant and his research team will collect information about you for the purposes of this research. This information will include the following: your name, preferred contact information (address, email address, and telephone number), basic demographic information (such as date of birth, age, gender, and race), relationship status, sexual orientation, family and other history, medical and medication history, and responses from questionnaires. This information is being collected so that we are able to later evaluate your information and other participants' to find correlations between certain characteristics, trichotillomania, and treatment outcomes.

HOW LONG WILL I BE IN THE STUDY?

We anticipate that you will be in the study for 13 weeks, with a total of eight visits.

Dr. Grant may decide to take you off of the study without your consent if:

- You is unable to meet the requirements of the study;
- Your medical condition changes;
- The study drug is no longer available;
- New information becomes available that indicates that participation in this study is not in your best interest; or
- If the study is stopped.

WHAT ARE THE RISKS OF THE STUDY?

All drugs can cause side effects. Side effects are usually reversible when the drug is stopped but occasionally continue and may cause serious complications. If you experience any side effects, you should contact the study doctor immediately.

While taking the study drug, your condition may remain the same or worsen due to no effect of the study drug.

The most common side effects associated with milk thistle include:

- upset stomach
- diarrhea
- headaches
- bloating

Additionally, if you experience the following you should let the study doctor or staff know right away:

- a skin rash
- skin flushing
- drop in blood pressure
- irregular heart beat
- respiratory distress (i.e., problems breathing or chest tightening)

It is possible that some of the questions on the surveys may cause discomfort or mental stress, such as "do you feel down or sad?" and specific questions that involve your hair pulling habits. If that should happen, study staff members are available to discuss any concerns or problems you may have. Study personnel may remove subjects from this study who have suicidal thoughts. In such a case, the study doctor will provide you with references to obtain additional help and appropriate treatment.

There may be other risks that could arise which are not reasonably foreseeable. If new information becomes available which could influence your willingness to continue your participation, this information will be discussed with both you.

ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?

If you agree to take part in this study, there may or may not be direct medical benefit to you. The study drug may help your hair pulling, but there is no guarantee that the study drug will help you.

We hope the information learned from this study will benefit both you and others with trichotillomania in the future.

WHAT OTHER OPTIONS ARE THERE?

Your participation is voluntary. Instead of being in this study, you may have these options:

- Receiving psychotherapy. While no medication has been approved for the treatment of trichotillomania, treatments without medication are available, including psychotherapy.
- Receiving no treatment

The decision whether or not you wish to participate in this study will not affect your care at the University of Chicago Medical Center.

WHAT ARE THE COSTS?

Clinical services provided during a clinical trial are either research-related or related to usual medical care. Research-related services are done to complete the research and the costs are not the responsibility of you or your insurance.

The costs that are considered research-related for this study include the following: All study drug (milk thistle or placebo) will be provided during the study, physical exams, urine pregnancy tests, urine drug tests, neurocognitive testing and interviews with the study doctor.

Usual medical care costs include any and all services that are considered medically necessary for your disease. The cost of this usual, ongoing medical care will be the responsibility of you or your insurance, and may include deductibles and co-payments. Similarly, this care will be subject to all the same requirements and restrictions of your insurance.

If you suffer an unanticipated injury as a direct result of this research and require emergency medical treatment, the University of Chicago Medical Center will provide such treatment at the University of Chicago Medical Center at no cost to you. You must notify Dr. Grant as promptly as possible after your injury in order to receive this care. An injury is "unanticipated" if it is not one of the known effects of a study drug, medical device or procedure, and is not the result of your disease or condition. The costs of any non-emergency care for such an injury will be billed to you or your insurance in the ordinary manner. If you think that you have suffered a research related injury, you must let Dr. Grant know right away.

WILL I BE PAID FOR MY PARTICIPATION?

For participation in this study you will receive $10 per visit to be paid in the form of cash (US$10.00) at the end of each visit. This gives a total possible compensation of $80.

You will also be compensated for your travel in the form of a parking voucher or bus voucher, which you will receive at the conclusion of each visit.

WHAT ABOUT CONFIDENTIALITY?

Study records that identify you will be kept confidential. All records will be kept a secure office in a locked cabinet of the Psychiatry Department at the University of Chicago. Only study staff will have access to study records. The data collected in this study will be used for the purpose described in the form. By signing this form, you are allowing the research team access to your medical records, which include Protected Health Information. Protected Health Information (PHI) consists of any health information that is collected about you, which could include medical history and new information collected as a result of this study. The research team includes the individuals listed on this consent form and other personnel involved in this study at the University of Chicago.

Your records may be reviewed by federal agencies whose responsibility is to

protect human subjects in research including the Food and Drug Administration (FDA) and Office of Human Research Protections (OHRP). In addition, representatives of the University of Chicago, including the Institutional Review Board, a committee that oversees the research at the University of Chicago, may also view the records of the research. If your research record is reviewed by any of these groups, they may also need to review your entire medical record.

If health information is shared outside the University of Chicago, the same laws that the University of Chicago must obey may not protect your health information.

During your participation in this study, you will have access to your medical record as appropriate. Dr. Jon Grant is not required to release to you research information that is not part of your medical record.

This consent form will be kept by the research team for at least six years. The study results will be kept in your research record and be used by the research team indefinitely. At the time of study completion, either the research information not already in your medical record will be destroyed or information identifying you will be removed from study results. Any research information in your medical record will be kept indefinitely.

Data from this study may be used in academic publications or presentations. Your name and other identifying information will be removed before this data is used. If we wish to use identifying information in publications, we will ask for your approval.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this web site at any time.

WHAT ARE YOUR RIGHTS AS A PARTICIPANT?

Taking part in this study is voluntary. If you choose not to participate in this study or decide to withdraw from the study your care at the University of Chicago/University of Chicago Medical Center will not be affected. You may choose not to participate at any time during the study.

If you choose to no longer be in the study and you do not want any of your future health information to be used, you must inform Dr. Grant in writing at the address on the first page. Dr. Grant may still use your information that was collected prior to your written notice.

You will be given a signed copy of this document. This consent form document does not have an expiration date.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

You have talked to study personnel about this study and you had the opportunity to ask questions concerning any and all aspects of the research. If you have further questions about the study, you may call Dr. Grant at 773-834-1325.

If you have a research related injury, you should immediately contact Dr. Grant (the study doctor) at 773-834-1325.

If you have any questions concerning your rights in this research study you may contact the Institutional Review Board, which is concerned with the protection of subjects in research projects. You may reach the Committee office between 8:30 am and 5:00 pm, Monday through Friday, by calling (773) 702-6505 or by writing: Institutional Review Board, University of Chicago, 5841 S. Maryland Ave., MC7132, I-625, Chicago, Illinois 60637.

CONSENT

SUBJECT

The research project and the procedures associated with it have been explained to me. The experimental procedures have been identified and no guarantee has been given about the possible results. I will receive a signed copy of this consent form for my records.

I agree to participate in this study. My participation is voluntary and 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 CONSENT

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 will give a signed copy of the consent form to the subject.

Signature of Person Obtaining Consent: _____

Date: _____ Time: _____ AM/PM (Circle)

INVESTIGATOR/PHYSICIAN:

Signature of Investigator/Physician _____

Date: _____ Time: _____ AM/PM (Circle)

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CONSENT/AUTHORIZATION BY SUBJECT FOR PARTICIPATION IN A RESEARCH PROTOCOL

Protocol Number: _____ Name of Subject: _____

STUDY TITLE: Silymarin Treatment of Trichotillomania in Children: A Double-Blind, Placebo-Controlled, Cross-Over Study

Doctors Directing Research: Dr. Jon E. Grant
Address: University of Chicago Medical Center
Department of Psychiatry
5841 South Maryland Avenue, MC 3077
Chicago, IL 60637
Telephone Number: 773-834-1325

We are asking you to be in a research study. We do research studies to learn more about how the body works and why people act the way they do. If you decide to be in this study, you will be asked to sign your name at the end of this form.

What we are asking you to do:
In this study, we want to learn whether or not milk thistle helps people stop pulling their hair. We would like to ask you to take an experimental pill over the next few weeks and come in for visits every couple of weeks. We would also like you to fill out a few different questionnaires and play a couple of games on a computer during these visits. During all parts of the visit you can let a member of the study staff know if any question makes you feel uncomfortable.

About 10 kids will take part in this study at the University of Chicago.

We think that you will be in the study for about 13 weeks which will include about 8 clinic visits.

If you are sexually active, you have to be using contraceptives (birth control or condoms).

Will being in this study hurt or help me in any way?
All pills have some chance to cause problems, but these are usually reversible if you don't take the pill anymore. Some problems that the pills in this study might cause are: upset stomach, diarrhea, headaches, or feeling "puffed-up".

If at any time you notice that you have a new rash, your skin feels weirdly hot, you get very light headed suddenly, your heart feels like it is beating weirdly, or you have any problems breathing, let a responsible adult know right away so they can call us, or call us directly at 773-834-3778.

Some of the questions we will ask you might make you feel uncomfortable. If that happens, you can tell us and we will skip those questions. You do not have to answer any questions that you do not want to answer.

We don't know if being in this study will help you. We hope that this study will help us to help other kids like you.

What will you do with information about me?
We will be very careful to keep your information from during the study private. Your doctors will not tell anyone else that you are in this study unless you say it is okay. Before and after the study we will keep all information we collect about you locked-up and password-protected.

Do I have to be in this study?
You do not have to participate in this study. It is entirely up to you. You can say "no" now or you can even change your mind later. No one will be upset with you if you decide not to be in this study, and you will still receive the money for the visits you have completed up until then.

There is no punishment if you do not want to participate, and no one will force you to do anything you do not want to do. If you do not participate, you can let us or a responsible adult in your home know and you will not need to continue.

If you want to stop being in the study, contact Dr. Jon Grant at 773-834-1325 or via email at jgrant4@bsd.uchicago.edu. You can choose not to be in this study at any time. Your doctors will still try to make you feel better even if you don't want to be in this study.

If you have questions about the study, you can ask your mom or dad or contact:
Dr. Jon Grant
Ph: 773-834-1325
Email: jgrant4@bsd.uchicago.edu.

ASSENT:

Please sign your name here if you want to be in this study. My parent/guardian will receive a copy of this form.

Name of Subject (print): _____

Subject's Signature: _____

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 will give a signed copy of the assent form to the subject's parent/legal guardian.

Signature of Person Obtaining Assent: _____

Date: _____ Time: _____ AM/PM (Circle)

INVESTIGATOR/PHYSICIAN:
Signature of Investigator/Physician _____

Date: _____ Time: _____ AM/PM (Circle)

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CONSENT/AUTHORIZATION BY SUBJECT FOR PARTICIPATION IN A RESEARCH PROTOCOL

Protocol Number: _IRB15-0178 Name of Subject: _____

STUDY TITLE: Silymarin Treatment of Trichotillomania in Children: A Double-Blind, Placebo-Controlled, Cross-Over Study

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Telephone Number: 773-834-1325

Your child is being asked to participate in a research study. A member of the research team will explain what is involved in this study and how it will affect you and your child. This consent form describes the study procedures, the risks and benefits of participation, as well as how your child's confidentiality will be maintained. Please take your time to ask questions and feel comfortable making a decision whether it is in your child's interest to participate or not. This process is called informed consent. If you decide you and your child are willing to participate in this study, you will be asked to sign this form, and your child will be asked to give assent in a related form.

WHY IS THIS STUDY BEING DONE?

The purpose of this study is to evaluate the safety and effectiveness of milk thistle (silymarin) for children with trichotillomania (hair pulling disorder). The hypothesis to be tested is that milk thistle will be more effective and well tolerated in subjects with trichotillomania compared to placebo (inactive drug). The proposed study will provide needed data on the treatment of trichotillomania in children, a population that currently lacks a clearly effective treatment.

Milk thistle is being used as an experimental drug for this study. This means that milk thistle is not approved by the Food and Drug Administration for reducing the symptoms of trichotillomania.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

About 25 people will take part in this study at the University of Chicago.

WHAT IS INVOLVED IN THE STUDY?

In order to determine if your child is eligible to participate in the study, the following will take place:

- The study will be discussed with you and you will be asked to sign this consent form.
- The study will be discussed with your child and he/she will be asked to provide assent for participation on a related assent form.
- A review of your child's medical history, current and past medications, and past treatments for trichotillomania will be completed.
- Your child will undergo a psychiatric interview and be asked to complete some neurocognitive testing which measures how he/she acts on thoughts (impulsivity) as well as his/her need to engage in a behavior (compulsivity). This testing involves three different tasks on the computer, measuring attention, impulsivity, and memory.
- He/she will complete a physical exam with the study doctor; sitting blood pressure, pulse, temperature, weight, and height will be recorded.
- He/she will be asked to give a urine sample that will be tested for drug use. This test must be negative in order to participate in the study.
- If your child is a female capable of having a child, she will complete a urine pregnancy test to ensure that she is not pregnant at the time of study entry. The pregnancy test must be negative in order to participate in the study. If your child is sexually active, he/she also must be using appropriate contraceptives during the course of the study (including abstinence or other methods such as oral contraceptives (birth control pill), intrauterine device (IUD), injection/shot, male latex condom, vaginal ring, or birth control patch).
- He/she will be asked about how he/she is feeling and if he/she has started taking any new medications or had any other changes in medications since the last visit.
- He/she will be asked to complete questionnaires to assess mood and hair pulling.
- If he/she qualifies for the study, you will receive the study drug or a placebo at the initial study visit to give your child in-between visits at regular times over the course of the study.
- This visit will take up to 2 hours.

If your child is determined to be eligible and provides assent to participate in this study, he/she will be enrolled in the study. You and your child will be asked to attend seven additional study visits where your child will be given the study drug on visits 2, 3, 5, 6, and 7.

For the first six weeks of the study, your child will be assigned to receive either milk thistle (600mg) or placebo. Your child will be randomly assigned (randomization) to receive either the study drug or the placebo. Randomization means your child will be assigned by chance to one group or the other, like flipping a coin. No individuals directly related to the study procedures (you, your child, or research staff) will know whether your child is taking the study drug or the placebo. This is what is meant by "blinding." A placebo does not have any active ingredients but looks the same as the study drug. Whichever drug (milk thistle or placebo) is not assigned during the first six week phase will be assigned

during the second six week phase following a one week wash-out period between phases.

The study doctor will discuss the next study visit scheduling with you and your child during each of the office visits. During visits 2, 3, 6, and 7, the following will occur:

- His/her vital signs will be checked
- He/she will be given the study drug
- He/she will be asked to complete some questionnaires to assess mood and hair pulling since the last visit
- These visits will take approximately 30 minutes to one hour each.

During visits 4, 5, and 8 your child will be asked to complete the following:

- Neurocognitive testing, which will consist of the same computer tasks he/she was asked to complete at the first visit.
- Completing questionnaires and answering verbal questions about his/her hair pulling, thoughts about hair pulling, and mood.
- Vital signs, including height, weight, blood pressure, and body temperature.

During this study, Dr. Grant and his research team will collect information about your child for the purposes of this research. This information will include the following: his/her name, preferred contact information (address, email address, and telephone number), basic demographic information (such as date of birth, age, gender, and race), relationship status, sexual orientation, family and other history, medical and medication history, and responses from questionnaires. This information is being collected so that we are able to later evaluate his/her information and other participants to find correlations between certain characteristics, trichotillomania, and treatment outcomes.

HOW LONG WILL I BE IN THE STUDY?

We anticipate that your child will be in the study for 13 weeks, with a total of eight visits.

Dr. Grant may decide to take your child off of the study without your consent if:

- He/she is unable to meet the requirements of the study;
- His/her medical condition changes;
- The study drug is no longer available;
- New information becomes available that indicates that participation in this study is not in your child's best interest; or
- If the study is stopped.

WHAT ARE THE RISKS OF THE STUDY?

All drugs can cause side effects. Side effects are usually reversible when the drug is stopped but occasionally continue and may cause serious complications. If your

child experiences any side effects, you should contact the study doctor immediately.

While taking the study drug, your child's condition may remain the same or worsen due to no effect of the study drug.

The most common side effects associated with milk thistle include:

- upset stomach
- diarrhea
- headaches
- bloating

Additionally, if your child experiences the following you should let the study doctor or staff know right away:

- a skin rash
- skin flushing
- drop in blood pressure
- irregular heart beat
- respiratory distress (i.e., problems breathing or chest tightening)

It is possible that some of the questions on the surveys may cause discomfort or mental stress, such as "do you feel down or sad?" and specific questions that involve your child's hair pulling habits. If that should happen, study staff members are available to discuss any concerns or problems you or your child may have. Study personnel may remove subjects from this study who have suicidal thoughts. In such a case, the study doctor will provide you with references to obtain additional help and appropriate treatment.

There may be other risks that could arise which are not reasonably foreseeable. If new information becomes available which could influence your willingness to continue your child's participation, this information will be discussed with both you and your child.

ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?

If you agree to allow your child to take part in this study, there may or may not be direct medical benefit to your child. The study drug may help your child's hair pulling, but there is no guarantee that the study drug will help your child.

We hope the information learned from this study will benefit both your child and others with trichotillomania in the future.

WHAT OTHER OPTIONS ARE THERE?

Your child's participation is voluntary. Instead of being in this study, your child may have these options:

- Receiving psychotherapy. While no medication has been approved for the treatment of trichotillomania, treatments without medication are available, including psychotherapy.
- Receiving no treatment

The decision whether or not you wish to have your child participate in this study will not affect your care or your child's care at the University of Chicago Medical Center.

WHAT ARE THE COSTS?

Clinical services provided during a clinical trial are either research-related or related to usual medical care. Research-related services are done to complete the research and the costs are not the responsibility of you or your insurance.

The costs that are considered research-related for this study include the following: All study drug (milk thistle or placebo) will be provided during the study, physical exams, urine pregnancy tests, urine drug tests, neurocognitive testing and interviews with the study doctor.

Usual medical care costs include any and all services that are considered medically necessary for your child's disease. The cost of this usual, ongoing medical care will be the responsibility of you or your insurance, and may include deductibles and co-payments. Similarly, this care will be subject to all the same requirements and restrictions of your insurance.

If your child suffers an unanticipated injury as a direct result of this research and require emergency medical treatment, the University of Chicago Medical Center will provide such treatment at the University of Chicago Medical Center at no cost to you. You must notify Dr. Grant as promptly as possible after your child's injury in order to receive this care. An injury is "unanticipated" if it is not one of the known effects of a study drug, medical device or procedure, and is not the result of your child's disease or condition. The costs of any non-emergency care for such an injury will be billed to you or your insurance in the ordinary manner. If you think that your child has suffered a research related injury, you must let Dr. Grant know right away.

WILL I BE PAID FOR MY PARTICIPATION?

For participation in this study you/your child will receive $10 per visit to be paid in the form of cash (US$10.00) at the end of each visit. This gives a total possible compensation of $80.

You will also be compensated for your travel in the form of a parking voucher or bus voucher, which you will receive at the conclusion of each visit.

WHAT ABOUT CONFIDENTIALITY?

Study records that identify your child will be kept confidential. All records will

be kept a secure office in a locked cabinet of the Psychiatry Department at the University of Chicago. Only study staff will have access to study records. The data collected in this study will be used for the purpose described in the form. By signing this form, you are allowing the research team access to your child's medical records, which include Protected Health Information. Protected Health Information (PHI) consists of any health information that is collected about your child, which could include medical history and new information collected as a result of this study. The research team includes the individuals listed on this consent form and other personnel involved in this study at the University of Chicago.

Your child's records may be reviewed by federal agencies whose responsibility is to protect human subjects in research including the Food and Drug Administration (FDA) and Office of Human Research Protections (OHRP). In addition, representatives of the University of Chicago, including the Institutional Review Board, a committee that oversees the research at the University of Chicago, may also view the records of the research. If your child's research record is reviewed by any of these groups, they may also need to review your child's entire medical record.

If health information is shared outside the University of Chicago, the same laws that the University of Chicago must obey may not protect your health information.

During your participation in this study, you will have access to your child's medical record as appropriate. Dr. Jon Grant is not required to release to you research information that is not part of your child's medical record.

This consent form will be kept by the research team for at least six years. The study results will be kept in your child's research record and be used by the research team indefinitely. At the time of study completion, either the research information not already in your child's medical record will be destroyed or information identifying your child will be removed from study results. Any research information in your child's medical record will be kept indefinitely.

Data from this study may be used in academic publications or presentations. Your child's name and other identifying information will be removed before this data is used. If we wish to use identifying information in publications, we will ask for your approval and your child's assent at that time.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify your child. At most, the Web site will include a summary of the results. You can search this web site at any time.

WHAT ARE YOUR CHILD'S RIGHTS AS A PARTICIPANT?

Taking part in this study is voluntary. If your child chooses not to participate in this study, decides to withdraw from the study, or you decide to terminate his/her participation, your child's care at the University of Chicago/University of Chicago Medical Center will not be affected. Your child may choose not to participate at any time during the study.

If your child chooses to no longer be in the study and you do not want any of his/her future health information to be used, you must inform Dr. Grant in writing at the address on the first page. Dr. Grant may still use your child's information that was collected prior to your written notice.

You will be given a signed copy of this document. This consent form document does not have an expiration date.

WHOM DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

You have talked to study personnel about this study and you had the opportunity to ask questions concerning any and all aspects of the research. If you have further questions about the study, you may call Dr. Grant at 773-834-1325.

If your child has a research related injury, you should immediately contact Dr. Grant (the study doctor) at 773-834-1325.

If you have any questions concerning your child's rights in this research study you may contact the Institutional Review Board, which is concerned with the protection of subjects in research projects. You may reach the Committee office between 8:30 am and 5:00 pm, Monday through Friday, by calling (773) 702-6505 or by writing: Institutional Review Board, University of Chicago, 5841 S. Maryland Ave., MC7132, I-625, Chicago, Illinois 60637.

CONSENT

PARENT/GUARDIAN/ OR LEGALLY AUTHORIZED REPRESENTATIVE:

The research project and the procedures associated with it have been explained to me. The experimental procedures have been identified and no guarantee has been given about the possible results. I will receive a signed copy of this consent form for my records.

My child's participation is voluntary and I do not have to sign this form if I do not want them to be part of this research study.

I give my permission for my child/relative/the person I represent to participate in the above described research project.

Name of Subject (print): _____

Parent/Legal Guardian Signature:_____

Date: _____ Time: _____ AM/PM (Circle)

PERSON OBTAINING CONSENT
I have explained to _____,
the parent/legal guardian of _____,
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 will give a signed copy of the consent form to the subject's parent/legal guardian.

Signature of Person Obtaining Consent: _____

Date: _____ Time: _____ AM/PM (Circle)

INVESTIGATOR/PHYSICIAN:
Signature of Investigator/Physician _____

Date: _____ Time: _____ AM/PM (Circle)