Children's Hospital of Pittsburgh

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CONSENT FOR A CHILD TO BE A SUBJECT IN MEDICAL RESEARCH ANDAUTHORIZATION TO PERMIT THE USE AND SHARING OF IDENTIFIABLE MEDICAL INFORMATION FOR RESEARCH PURPOSES

TITLE: Risk Factors for Renal Scarring in Children after Urinary Tract Infection

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Evening/Week-end Coverage: 412-999-3277 (999-EARS)

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What is this study about and why is it being done?

You are being asked to allow your child to be a part of a research study because your child has had a urinary tract infection (UTI). Please read this form carefully. As the research study staff discusses this consent form with you, please ask them to explain any words that you may not understand.

This research study will help our medical team to improve the care that they give to children with UTI. Taking part in this research study is your choice. Your child will receive medical care for her/his UTI if your child is in the study or not. Your child may leave this research study at any time.

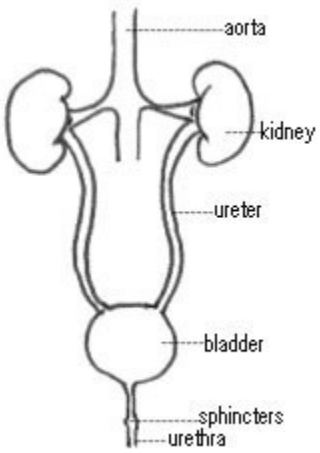
We will explain how the study will be done and what you and your child will be doing. This form describes the importance, the benefits and the risks of the study. We will answer all of your questions.

What is the urinary tract and how does it work?

The Urinary System is made up of two kidneys, the bladder and two ureters. The kidneys remove waste from the body by making urine. The urine flows from the kidneys down through the ureters (tubes) to the bladder (balloon-shaped bag).

What is a UTI?

Your child had a UTI. UTIs are common in children. By 5 years old, about 8% of girls and about 2% of boys have had one. In older children, UTIs may cause obvious symptoms such as burning or pain with urination (peeing). In infants and young children, UTIs may be harder to find because children cannot tell us their symptoms. In fact, fever is sometimes the only symptom.



Most UTIs are caused when bacteria infect the urinary tract. The urinary tract is made up of the kidneys, ureters, bladder, and urethra. Each of these helps to remove liquid waste from the body. The kidneys filter the blood and make urine; the ureters carry the urine from the kidneys to the bladder; and the bladder holds the urine until it is sent out of the body through the urethra.

An infection can happen anywhere along this tract, but the lower part - the urethra and bladder - is most commonly involved. This is a bladder infection. If the infection goes up the ureters to the kidneys, it is a kidney infection. A kidney infection is more serious than a bladder infection.

Bacteria are not normally found in the urine. But, they can easily enter the urinary tract from the skin around the anus. The bacteria *E. coli* is found in the bowel movement and around the anus. This bacteria is the most frequent cause of UTIs.

How is UTI usually treated?

UTIs are treated with antibiotics. The type of antibiotic used will depend on the type of bacteria that is causing the infection. Children with a UTI may be treated with antibiotics taken by mouth.

Sometimes, children are admitted to the hospital, where they will be treated with antibiotics by intravenous or IV (delivered through a vein right into the bloodstream).

Children with UTI do very well when they take antibiotics, but it's important to start the medication early. UTIs that are not treated soon can lead to kidney damage, especially in children younger than 6 years of age.

What is the purpose of this study?

We hope to learn why some children with UTI get kidney scars. To find new information, we will look at many things. We will keep track of the age of the children when they had the UTI. We will look at different blood and urine results among the children. We will study the different kinds of germs that your child and other children had. We will look at another study of children with UTI who also have a problem with the ureters that are not working right. We will save urine and blood samples for future tests on genes that are passed from the parent to child. All of this information will help us understand why some children get kidney scars after UTI.

This study will include children from Children's Hospital of Pittsburgh, The Children's Hospital of Philadelphia and Children's National Medical center in Washington DC. About 360 children, including both girls and boys, ages 2 months to 6 years, will take part in this study. Our goal at The Children's Hospital of Pittsburgh is to enroll 120 children over 2 years. The study is being funded by a grant from the National Institutes of Health.

What are my child and I being asked to do?

We are not testing a medicine or procedure. We will carefully write down information about your child's health and medical care over the next 2 years. Then, we will compare that to the health and medical care of other children to see if we can tell why some children get kidney scars.

Your child will have 5 visits during the study. At each visit your child will have a brief physical exam. We will ask you questions about your child's health. During the first and last visits your child will also have a test called DMSA kidney scan. This gives us a picture of the kidney to see if your child has any kidney damage. We will take some blood and urine samples to measure how well their kidneys are working. We will call you every 2 months to ask how your child is doing. Your child's primary care doctor will be told that he/she is participating in this study. We will send your child's primary care doctor updates about his/her participation in this study.

This is what will happen at each visit. All enrollment visits happen at the CHP Primary Care Center. If it is more convenient for you, follow-up visits may be completed at CCP Armstrong Pediatrics, The Children's Pine Center in Wexford, or the Primary Care Center at UPMC Mercy Health Center.

First Visit (today):

This visit will find out if your child can be in this study. After we have talked about the study and your questions, if you want your child to be in the study, you will be asked to sign this consent form. Your child will have a physical exam. This takes about 5 minutes. We will ask questions about your child's health and any medical problems. You will fill out a short questionnaire. The nurse or doctor will collect from your child a sample of blood (about 1

teaspoon), and a urine sample. This takes 5 – 10 minutes. The physical examination, urine for urinalysis and culture are standard care for children who have had a UTI. The blood and urine tests for microalbumin, creatinine, electrolytes and cystatin C are done for the study. Saving urine or blood for the NIH repository is an optional part of this study.

Follow-up Visits (6, 12, and 18 Month Visits):

Your child will have a physical exam and we will ask you about any medical problems that have happened since the last visit. The nurse, nurse practitioner or doctor will examine your child. This visit will take about 15 minutes.

End of Study Visit (24 Month Visit):

Your child will have a physical exam and we will ask you questions about any medical problems that have happened since the earlier study visits. At this visit, we will also collect from your child a sample of blood (about 1 teaspoon), and a urine sample. The nurse, nurse practitioner or doctor will examine your child. This visit will take about 15 minutes. The DMSA kidney scan done when your child had the UTI will be repeated in the radiology department at Children's Hospital by experienced radiology doctors and technicians. A dimercaptosuccinic acid (DMSA) scan is a test that can look at the shape of the kidneys and evaluate how much scarring is present. A DMSA scan is a common test done after children have a UTI and is part of routine care. Your child will have a small amount technetium-99m DMSA (a radioactive chemical), injected into a vein of the arm or hand. After the injection, you will be able to leave the radiology department and then return in approximately 1.5-2 hours after the injection. This delay will allow the kidneys to absorb the radioactive chemical. When you return, we will ask your child to urinate and then we can start the imaging. The imaging will take about 30-60 minutes. It is important for your child to remain as still as possible. For children who had signs of a kidney infection on the DMSA scan at the time of the UTI, a follow-up DMSA scan is standard of care. For children who did not have signs of a kidney infection on the DMSA scan at the time of the UTI, the follow-up DMSA scan will be part of this study.

Phone calls: We will call you every 2 months during the study to find out how your child is doing. We will ask questions about any medical problems that have happened since we last talked with you.

Special procedures for children with moderate scarring on the first DMSA scan: : If your child's first DMSA scan shows moderate kidney scarring, then your child will have another DMSA scan, if your child has another UTI with fever. We will continue the study visits and phone calls.

Special procedures for children with recurrent UTIs: If your child has a new UTI during the study, we may do another DMSA to check for kidney scarring. We will continue the study visits and phone calls.

Release of additional medical information: We will ask you to sign a Release of Medical Information form so that we can find out about any medical problems, particularly as they may relate to any UTIs, for which your child has received care from doctors other than those at Children's Hospital of Pittsburgh. We will also ask you to allow us to contact a family member

or other individual you've identified if CHP staff is unable to make contact with you during the study. We will ask for permission to release medical information to your child's physician regarding your child's care in the study.

Will my child's primary care doctor be notified about his/her participation in this study?

Your primary care doctor will be told that your child is in this study. We will send your child's primary care doctor reminders that your child is in this study. We are doing this so your child's primary care doctor knows how to treat your child if he/she gets a UTI.

What are the risks of being in this research study?

Potential risks to your child while being in the study are described below. You can discuss these with Dr. Hoberman and our study staff and/or your child's regular doctor.

Blood Drawing: Risks of drawing blood from your child's arm are discomfort (likely about 25 out of 100) and/or bruising (infrequently, 1-10 out of 100). Infection and excess bleeding are possible, but rare (less than 1 out of 100). Lightheadedness and inflammation at the site of injection are rare (less than 1 out of 100). Localized clot formation may occur, but this is rare (less than 1 out of 100). Fainting may occur infrequently (1-10 out of 100), during or shortly after having blood drawn.

DMSA scans: A DMSA kidney scan is used to show areas of kidney infection or kidney damage. A DMSA scan requires inserting an intravenous (IV), injecting a radioactive substance into the blood stream, and taking a pictures of the kidney with a special camera. Commonly (10-25 out of 100), children may have some discomfort with the placement of the IV. IVs can fall out and some fluid can go into the arm outside of the vein, but this is rare (1 out of 100).

The radiation exposure from a DMSA scan is less than half of the natural background radiation during one year. Participation in this research study involves exposure to radiation from the [Tc-99m] DMSA scans. The amount of radiation exposure that your child will receive from this procedure is approximately 0.14 rem (a unit of radiation exposure) or less. There is no known minimum level of radiation exposure that is recognized as being totally free of the risk of causing genetic defects (abnormal cells) or cancer. However, the risk associated with the amount of radiation exposure that your child will receive from this study is considered to be low and comparable to everyday risks.

Storage of Blood and Urine for Research Purposes: Rarely (less than 1 out of 100), there is a risk of loss of confidentiality. To minimize the risk of loss of confidentiality, before your child's sample is sent, the sample will be labeled with the study identification number only. Personal identifying information such as name, address, and date of birth will be removed from the sample. Personal information that could link the sample to your child's identity will be kept in locked cabinets and password-protected computers that are only used by study staff.

Confidentiality: Rarely (less than 1 out of 100), there is a risk of loss of confidentiality. In order to minimize the risk of loss of confidentiality, all records related to study data will be kept in locked cabinets, and access to this information will be restricted. A password system (like an electronic lock) will be used to control access to all information stored on a computer. All reports or articles based on this study will be prepared such that no individual patient can be identified.

What if problems occur during this study?

Your child's health is more important than following the research plan. If any changes are needed to protect your child's health, we will talk with you about them before they are made. The researchers have taken steps to minimize the known or expected risks. However, your child may still have problems or side effects. It is important that you tell our staff about any injuries, side effects, or other problems that your child has during this study. You will have our phone number to call at any time 412-692-3277. This is a 24 hour cell phone to either Dr. Hoberman or the other study staff.

We will inform you of new information from this or other studies that may affect your child's health, welfare, or your willingness to stay in this study.

You can withdraw your child from this study at any time, without penalty. The researchers also have the right to stop your child's participation at any time. This could be because your child has had an unexpected reaction, or you have failed to follow instructions, or because the entire study has been stopped.

If you withdraw your child or are withdrawn from the study early, you may be asked to come in for one more clinic visit. This visit will allow your study doctor to collect final (outcome) data about your child. Your child will have a physical exam. We will ask you questions about your child's health and any medical problems that have happened since the earlier study visits. At this visit, we will also collect from your child a small stool sample from a rectal swab, a sample of mucous from the front and back of the nose, a sample of blood (about a teaspoon) and a urine sample. The DMSA imaging performed at the beginning of the study may be repeated or scheduled at this visit.

What are the possible benefits of my child being in this study?

There is no guarantee that your child will get any direct benefit from being in this study. The information that is collected will be useful scientifically and possibly helpful to others. We hope that this study may benefit society by helping us understand why some children get kidney scars after UTIs.

The testing in this study will provide information about your child's disease that may benefit your child. For example, the DMSA scan could allow early discovery of kidney scars. This would alert the doctors to closely monitor your child so that the risk of new scars might be less. The blood and urine tests may also provide early information about kidney damage.

Will I or my insurance provider be charged for the costs of any procedures performed as part of this research study?

You will not be charged for any of the physical examinations as provided by the study while your child is in this study. You will not be charged for the special urine and blood tests that measure kidney function (microalbumin, creatinine, cystatin c, electrolytes). For children who have a normal DMSA scan initially and do not have a repeat UTI, it may not be considered routine to repeat the DMSA renal scan. For those children, the study grant will pay for the repeat DMSA. Otherwise, other laboratory tests and radiographic imaging are considered routine care (the standard care for your child's illness) and will be billed to you or your insurance company in

the standard manner. All costs not paid by your insurance will be your responsibility. Please ask about any expected added costs or insurance problems.

Will my child or I be paid for taking part in this research study?

To help cover any expenses such as transportation or time off from work, you will be given $50 today at the first visit and $25 at the 6, 12, and 18 month visits. There will be a $25 bonus given at the 24 month visit, if you bring your child to all follow up visits. If you park in our parking lot, you will receive free parking.

May I refuse to give my OK for the use of my child's medical information for the purpose of this research study?

Your OK to use and share your child's medical information for the purpose of this research study is completely up to you. However, if you do not provide your OK, your child will not be allowed to be in this study.

What alternatives are available to my child if I don't give my OK for him/her to participate in this study?

Children with UTI are usually treated with antibiotics. They visit their regular doctor for medical care. Participation in this study is entirely up to you. Choosing not to be in this study will not affect you or your child's present or future relationship with the Children's Hospital of Pittsburgh or any affiliated health care provider of the University of Pittsburgh.

Consent for Storing Blood, Tissue, or Body Fluid for research purposes

Biological Sample: During the blood and urine specimen collection at the first visit and the 24 month visits, we would like to collect another small amount of blood and urine to send to the National Institutes of Diabetes and Digestive and Kidney Diseases (NIDDK), of the National Institutes of Health (NIH) Central Repository. The purpose of this collection is to provide samples for future research of UTI. Collecting samples for a repository is also called specimen banking. Sending samples to the Repository may give scientists valuable research material that can help them to develop new diagnostic tests, new treatments, and new ways to prevent disease. The amount of extra blood will be about 1-2 teaspoons at each visit that the specimens are drawn for the Repository, depending upon your child's age.

The Repository will take measures to protect your privacy, although no guarantee of confidentiality can be absolute. Before your child's sample is sent to the Repository, the sample will be labeled with the study identification number. Personal identifying information such as name, address, and date of birth will be removed. The Repository will have some data about your child such as age, sex, race, and diagnosis. You will not be given any information, nor will any appear in your child's medical record, as to how these samples are used.

You will not get any direct benefit or payment for letting us draw the extra blood, but your child's sample may benefit other children with UTI. It is possible that data from the use of your child's sample may be used in a research publication. If that happens, your child's name and other personal information will not be included.

There is no cost to you or your insurance company for the storage and use of the specimens. Your child's donation does not entitle you or your child to compensation from any commercial

use of the products that may be come from the specimen. You and your child will not be informed about future use or results. Your child's donation is voluntary, and if you choose not to have your child be in this part of the study, your child can still be in the rest of the study. Your child will need to sign a new consent form at age 18 for the continued use of their research specimens.

If you agree to have your child's sample stored in the Repository, you can change your mind up until the end of the study. All that is needed is an instruction from you to the study researchers and they will destroy your child's sample and all information that identifies your child. Once the study is over, the sample will stay in the Repository indefinitely.

Any tissue, blood, cell, or other biologic samples that your child provides as a participant in this research study are donations of these samples to the NIH. You and your child will not have any property rights to the samples, nor will you or your child have any property rights to or be entitled to compensation of any type for any products, data, or other items or information that is developed from the samples. If you would like your sample to be destroyed you can contact Dr. Alejandro Hoberman at 412-692-7382.

Optional Consent for blood specimen saving (Only for children over 20 pounds):

_____ _____ I **give permission** for my child to participate in the
Initials Date blood sample banking part of the study.

_____ _____ I **do not give permission** for my child to participate in the
Initials Date blood sample banking part of the study.

_____ N/A (child weighs less than 20 pounds.)

Optional Consent for urine specimen saving:

_____ _____ I **give permission** for my child to participate in the
Initials Date urine sample banking part of the study.

_____ _____ I **do not give permission** for my child to participate in the
Initials Date urine sample banking part of the study.

Genetic Sample: Also during the first visit, we would like to collect another small amount of blood that will be sent to the NIDDK Genetic Repository at Rutgers University. The amount of extra blood will be about 1-2 teaspoons depending on your child's age. The same standards and guidelines outlined above for the Biological Samples apply to the Genetic Samples. Scientists will look at DNA (heredity material in cells) of the blood to help them develop new diagnostic tests, new treatments, and new ways to understand diseases. The genetic sample will only be used for research on UTIs. Banked samples will be identified by a code number. You will not be informed of the results of future genetic testing of this sample because at this time we don't know how this information would be helpful. The DNA that your child provides as a participant in this research study is a donation to the NIH. You and your child will not have any property rights to the samples, nor will you and your child have any property rights to or be entitled to compensation of any type for any products, data, or other items or information that is developed from the samples. If you would like your child's sample to be destroyed, you can contact Dr. Alejandro Hoberman at 412-692-7382.

Optional Consent for genetic sample saving:

_____ _____ I **give permission** for my child to participate in the
Initials Date genetic sample banking part of the study.

_____ _____ I **do not give permission** for my child to participate in the
Initials Date genetic sample banking part of the study.

What if my child's doctor is one of the investigators for this research study?

If your child's doctor is an investigator in this research study, he/she will be interested both in your child's medical care and in this research. Before putting your child in this study or at any time during the study you may discuss your child's care with another doctor at CHP, a doctor who isn't at CHP or your child's pediatrician or family doctor who is in no way associated with this research project. It is entirely up to you whether to let your child be in any research study offered by your child's doctor.

Do any of the investigators on this study have any other conflicts of interest?

This study is supported by the National Institutes of Health. Investigators in the study do not receive individual compensation from your child's participation in this trial.

What if there is new information while my child is in this study?

If any information is learned that might affect your willingness to have your child continue to be in this study, you will be informed.

How will my child's privacy rights be protected?

Under the Health Insurance Portability and Accountability Act (HIPAA), your child's private health care information cannot be used for the research purposes of this study without your OK. You will be informed of the specific uses and disclosures of your child's medical information for the purpose of this research study and who will have access to your child's health information.

What uses of my child's medical information will this research involve?

This research study will involve the recording of existing medical information as well as medical information that will become available while your child participates in this study from your child's hospital and/or physician records. From this material, case report forms will be prepared so that your child's medical information, such as prior treatments, medical history and diagnosis can be compared to that of other children participating in this research. These forms will be analyzed by the investigators; the information on the form will not contain any information identifying your child. If the results of this study are published, information concerning your child will be in a form such that he/she cannot be identified.

During your child's participation in this clinical study, the study staff will collect your child's age, gender (male or female), medical history and information on the health and ethnic origin of your child. This information will be reported to the NIH, Data Coordinating Center at the University of North Carolina. We will store and process the information about your child using a computer. Your child's personal identity (name, address, and other identifiers) will remain confidential. In the database, your child will only be referred to by a code number and initials.

Only the study staff will be able to link the code number to your child's name. The NIH, the Children's Hospital Institutional Review Board or regulatory authorities may directly access your child's medical records in order to determine the accuracy of the reported data. These representatives will observe professional secrecy and keep your child's identity confidential to the extent permitted by law.

Will participation in this research result in medical information being placed in my child's medical records?

Your child's participation in this study may result in health information being placed in the Children's Hospital of Pittsburgh medical chart, electronic medical record, outpatient chart, or research record, regarding the usual tests that would be useful for your child's doctor to know. Information from the genetic testing will not be placed in your child's medical chart.

Who will have access to my child's medical information related to his/her participation in this research study?

- In general, research records are kept confidential. Paper records are stored in locked cabinets and computerized records are password protected. There are, however, some disclosures of your child's research-related medical information that may occur. In addition to the investigators listed on the first page of this authorization form and their research staff, the following persons may have access to your child's identifiable private health information related to your child's participation in this research study.
- Authorized representatives of the University of Pittsburgh Research Conduct and Compliance Office may review your identifiable research information (which may include your child's identifiable medical information) for the purpose of monitoring the appropriate conduct of this research study. In unusual cases, the investigators may be required to release identifiable information (which may include your child's identifiable medical information) related to your child's participation in this research study in response to an order from a court of law. If the investigators learn that you or someone with whom you are involved is in serious danger or potential harm, they will need to inform, as required by Pennsylvania law, the appropriate agencies.
- Authorized representatives of the NIH, including the Data Coordinating Center team at the University of North Carolina, the Office for Human Research Protections (OHRP) and the Food and Drug Administration (FDA) may review and/or obtain your child's identifiable medical information for the purpose of monitoring the accuracy and completeness of the research data, for performing required scientific analyses of the research data, and reanalysis of the research data at a later date and to be sure that the research is being conducted according to the guidelines of each institution. While these organizations have provided their assurance that they will not release your child's identifiable medical information to anyone else, the Children's Hospital of Pittsburgh cannot guarantee this. In unusual cases, the investigators may be required to release your child's research information in response to a court order.
- Research investigators may be required under Pennsylvania law to report any suspicion of child abuse to child protection services. If the investigators learn that you or someone

with whom you are involved is in serious danger of potential severe harm, they may need to warn those who are in danger and contact other agencies to ensure safety.

May I have access to my child's medical information resulting from participation in this research study?

In accordance with the Children's Hospital of Pittsburgh's Notice of Privacy Practices document which you have been provided, you are allowed to look at information (including information resulting from your child's participation in this research study) contained within your child's medical records unless specifically stated.

Can I stop my child's participation in this study and may I withdraw my OK for the use of my child's medical information for the purpose of this research study?

You have the right to stop your child's participation in this study at any time. Your child's participation in the study may also be discontinued without your consent, by your doctor, the NIH, Office for Human Research Protections or the FDA, if based on their judgment it might improve your child's medical care or if you fail to follow the study schedule. Your child will receive the same quality of care at this hospital whether or not he/she is in the study. Additionally, you may withdraw, at any time, your OK for the use of your child's medical information for the purpose of this research study. Of course, if you withdraw your OK for the use of your child's health information, your child may no longer participate in this research study. To the extent that researchers have already used your child's health information in data analysis and/or scientific publication, this information cannot be withdrawn. Any publication of information will be such that your child's information will not be identifiable. If you decide to withdraw your OK, you should notify your child's study doctor in writing along with the date of your decision. Your decision to withdraw your OK for the use of your child's private health information for this research study will have no effect on your or your child's current or future medical care at Children's Hospital of Pittsburgh, a UPMC Health System Hospital or affiliated health provider or the University of Pittsburgh.

For how long will the investigators be permitted to use my child's identifiable health information?

Dr. Hoberman and his study staff will be permitted to use your child's identifiable health information indefinitely.

Will there be any compensation if my child is injured or becomes ill as a result of participating in this study?

There is the possibility with any medical treatment or research that a patient may suffer some physical illness or injury. In the event of an injury or illness resulting from this research, any immediate emergency treatment that may be necessary will be provided without charge. There is no plan for monetary compensation. You do not, however, waive any legal rights by signing this form. You may contact Dr. Hoberman to obtain information about treatment if needed.

Voluntary Consent and Authorization

All of the above has been explained to me and all of my current questions have been answered. I understand that I am encouraged to ask questions about any aspect of this research study during the course of this study, and that such future questions will be answered by the researchers listed on the first page of this form. Any questions which I have about my child's rights as a research participant will be answered by the Human Subjects Protection Advocate of the IRB Office, University of Pittsburgh (1-866-212-2668). Dr. Hoberman (412-999-3277) will be available for questions about this research, my child's rights, and any possible research-related injury. I will receive a signed copy of this consent form.

_____

Printed Name of Child (Research Subject)

"I understand that, as a minor (age less than 18 years), the above-named child is not permitted to participate in this research study without my consent. Therefore, by signing this form, I give my consent for his/her participation in this research study."

_____ _____

Parent's Name (PRINT) Relationship to Child

_____ _____

Parent's Signature Date

Certification of Informed Consent

I certify that I have explained the nature and purpose of this research study to the above-named individual and I have discussed the potential benefits and possible risks of study participation. Any questions the individual has about the study have been answered and we will always be available to address future questions as they arise. I further certify that no component of this protocol was begun until after this consent form was signed.

_____ _____

Signature of Investigator Date

_____ _____

Printed Name of Investigator Date