Principal Investigator:	**Saketh Guntupalli, MD**
COMIRB No:	**16-1096**
Version Date:	**26-Mar-2017**
Study Title:	**Reducing Urinary Tract Infection Rates using a Controlled Aseptic Protocol for Catheter Insertion**
	NCT03101371

You are being asked to be in a research study. This form provides you with information about the study. A member of the research team will describe this study to you and answer all of your questions. Please read the information below and ask questions about anything you don't understand before deciding whether or not to take part.

Why is this study being done?
This study plans to learn more about urinary tract infections (UTI) after surgery and how we can prevent them.

You are being asked to be in this research study because you are undergoing surgery at the University of Colorado Hospital that requires a urinary catheter, and is expected to last more than 1 hour.

Other people in this study
Up to 250 people from your area will participate in the study.

What happens if I join this study?
If you join the study, you will participate in the following study visits over 2 weeks.

- Visit 1**:** You will have a physical exam completed and we will ask you questions about your health history, clinical diagnosis, and current medications. A urine sample will be collected.
- Visit 2**:** You will be randomized (like flipping a coin) to either receive the standard catheter insertion protocol or your catheter will be dipped in Povidone Iodine prior to insertion and a plastic cover will be used.
- Visit 3**:** You will be assessed at 24 hours after your operation for signs of a UTI and will be asked to complete a survey about your satisfaction with the procedure. A urine sample will be collected.
- Visit 4**:** At your routine care visit 2 weeks after your operation, you will be assessed for signs of a UTI and will be asked to complete a survey about your satisfaction with the procedure. A urine sample will be collected. You will also have a physical exam and we will collect information from your medical record about your hospital stay.

'If you develop a UTI or abnormal urinalysis results during the study, you will be treated with the current standard of care treatment options. Upon completion of Visit 4, your participation in the study will end.

What are the possible discomforts or risks?
Risks or Discomforts which you may experience while in this study include the following:

- Breach of Confidentiality: There is a risk that your privacy may not be protected. We will do all that we can to keep your information secure.
- The placement of catheter: There may be risks associated with this procedure, however, these are risks that you would encounter even if you were not in this study. You will be told of these risks as part of your routine pre-operation care.
- Use of Povidone Iodine: You may experience skin irritation (burning, redness, or general irritation). It is

possible you could have an allergic reaction to the iodine which could result in a rash, hives, itching, difficulty breathing, tightness of your chest, swelling of your face, lips, or tongue. This is unlikely and rare.

- Use of Plastic Sleeve: You may experience increased irritation due to the protective plastic cover.

There is a risk that people outside of the research team will see your research information. We will do all that we can to protect your information, but it can not be guaranteed.

The study may include risks that are unknown at this time.

What are the possible benefits of the study?
This study is designed for the researcher to learn more about urinary tract infections (UTI) after surgery and how we can prevent them.

There is no guarantee that you will not develop a UTI if you join this study. Also, there could be risks to being in this study. These are described in the section above.

Will I be paid for being in the study?
You will not be paid for participation in this study.

Will I have to pay for anything?
It will not cost you anything to be in the study. However, all costs associated with routine standard of care procedures for catheter insertions and diagnosing and treatment of a UTI will be the responsibility of you or your insurance provider.

Is my participation voluntary?
Taking part in this study is voluntary. You have the right to choose not to take part in this study. If you choose to take part, you have the right to stop at any time. If you refuse or decide to withdraw later, you will not lose any benefits or rights to which you are entitled.

If you leave this study, you will still receive your normal medical care. The only medical care that you will lose is the medical care you are getting as part of this study. You might be able to get that same kind of medical care outside of the study. Ask your study doctor.

If there are any new findings during the study that may affect whether you want to continue to take part, you will be told about them.

Can I be removed from this study?
The study doctor may decide to stop your participation without your permission if the study doctor thinks that being in the study may cause you harm, or for any other reason.

What happens if I am injured or hurt during the study?
If you have an injury while you are in this study, you should call Dr. Guntupalli immediately. His phone number is 303-266-4172.

We will arrange to get you medical care if you have an injury that is caused by this research. However, you or your insurance company will have to pay for that care.

Who do I call if I have questions?
The researcher carrying out this study is Dr. Saketh Guntupalli. You may ask any questions you have now. If you have questions, concerns, or complaints later, you may call Dr. Guntupalli at (303)266-4172. You will be given a copy of this form to keep.

You may have questions about your rights as someone in this study. You can call Dr. Guntupalli with questions. You can also call the responsible Institutional Review Board (COMIRB). You can call them at 303-724-1055.

Who will see my research information?
The University of Colorado Denver (UCD) and its affiliated hospital(s) have rules to protect information about you. Federal and state laws including the Health Insurance Portability and Accountability Act (HIPAA) also protect your privacy. This part of the consent form tells you what information about you may be collected in this study and who might see or use it.

The institutions involved in this study include the University of Colorado Denver and the University of Colorado Hospital.

We cannot do this study without your permission to see, use and give out your information. You do not have to give us this permission. If you do not, then you may not join this study.

We will see, use and disclose your information only as described in this form and in our Notice of Privacy Practices; however, people outside the UCD and its affiliate hospitals may not be covered by this obligation.

We will do everything we can to maintain the confidentiality of your personal information but confidentiality cannot be guaranteed.

The use and disclosure of your information has no time limit. You can cancel your permission to use and disclose your information at any time by writing to the study's Principal Investigator (PI), at the name and address listed below. If you do cancel your permission to use and disclose your information, your part in this study will end and no further information about you will be collected. Your cancellation would not affect information already collected in this study.

Dr. Saketh Guntupalli
12631 E. 17th Street, MS B198-4
Aurora, CO 80045

Both the research records that identify you and the consent form signed by you may be looked at by others who have a legal right to see that information, such as:

- Federal offices such as the Food and Drug Administration (FDA) and the Office of Human Research Protections (OHRP) that protect research subjects like you.
- People at the Colorado Multiple Institutional Review Board (COMIRB)
- The study doctor and the rest of the study team.
- Officials at the institution where the research is conducted and officials at other institutions involved in this study who are in charge of making sure that we follow all of the rules for research

We might talk about this research study at meetings. We might also print the results of this research study in relevant journals. But we will always keep the names of the research subjects, like you, private.

You have the right to request access to your personal health information from the Investigator.

Information about you that will be seen, collected, used and disclosed in this study:

- Name and Demographic Information (age, sex, ethnicity, address, phone number, etc.)
- Portions of your previous and current Medical Records that are relevant to this study, including but not limited to Diagnosis(es), History and Physical, laboratory or tissue studies, radiology studies, procedure results
- Research Visit and Research Test records

What happens to Data and Specimens that are collected in this study?

Scientists at the University of Colorado Denver and the hospitals involved in this study work to find the causes and cures of disease. The data and specimens collected from you during this study are important to this study and to future research. If you join this study:

- The data and specimens given by you to the investigators for this research no longer belong to you.
- Both the investigators and any sponsor of this research may study the data and specimens collected from you.
- If data and specimens are in a form that identifies you, UCD or the hospitals involved in this study may use them for future research only with your consent or Institutional Review Board (IRB) approval.
- Any product or idea created by the researchers working on this study will not belong to you.
- There is no plan for you to receive any financial benefit from the creation, use or sale of such a product or idea.

Agreement to be in this study and use my data

I have read this paper about the study or it was read to me. I understand the possible risks and benefits of this study. I understand and authorize the access, use and disclosure of my information as stated in this form. I know that being in this study is voluntary. I choose to be in this study: I will get a signed and dated copy of this consent form.

Signature:_____Date:_____

Print Name:_____

Consent form explained by:_____Date:_____

Print Name: _____

For subjects unable to read:

Witness Signature: _____ Date: _____

Witness Print Name: _____

Witness of Signature □

Witness of consent process □