VA RESEARCH CONSENT FORM

Subject Name: _____ **Date:** _____

Title of Study: **The Utility of Urinalysis Prior to In-office Procedures: A Randomized Clinical Trial**

Principal Investigator: **Dr. Kyle Richards** **VAMC:** Madison, WI

STUDY SPONSOR:
University of Wisconsin School of Medicine and Public Health: Department of Urology

INVITATION/SUMMARY
We would like to invite you to participate in a research study conducted by Dr. Kyle A. Richards, Chief of Urology at the William S. Middleton Memorial Veteran's Hospital. As someone scheduled to undergo a urological procedure such as a prostate biopsy, a cystoscopy (a procedure in which a camera is inserted into the bladder for observation), or a BCG treatment installment you are eligible for the study. This study will enroll 664 subjects in total with 564 subjects enrolled at the VA.

Participation in the study is completely voluntary. Choosing not to participate in the study will not affect the health care you are provided by the William S. Middleton Memorial Veterans Hospital. Please carefully read the information bellow and ask any question regarding anything you don't understand before deciding whether or not to participate.

WHAT IS THE PURPOSE OF THIS STUDY?
The purpose of this study is to determine if administering urinalysis is useful to individuals prior to urological in-office procedures. Enrollment in the study is voluntary and has no effect on the treatment you will receive.

WHAT WILL MY PARTICIPATION INVOLVE?
If you choose to volunteer for the study you will:

Be randomized into one of the two groups described below. Randomized means that the group you are assigned to will be made by chance, like by the flip of a coin. Subjects in both groups will be asked to provide a urine sample as they normally would before their procedure. The main difference between the groups is when results may be reported.

If you are assigned to the standard of care group, known as the control group, your urine sample will be processed according to current standard of care at the VA. The urinalysis will be completed before your biopsy, cystoscopy, or BCG treatment. The results of the urinalysis will be reported to the doctor performing your procedure, who may run a urine culture on the sample depending of the specific results of the analysis. This process may require you to go on antibiotics and/or have your procedure delayed until the results of the urine culture are received. Any decisions on needed care will be made by the doctor performing your procedure.

If you are assigned to the experimental group, the results your urinalysis will not be available to the doctor before performing your procedure. Your results will be monitored by the research team instead. If your lab results are positive for infection, the research team will inform you and may arrange for treatment. In case of emergency, you may need to be seen in an Emergency Department (ED) for an assessment of your condition and to obtain treatment

For both groups, you will complete an interview before your procedure and by phone at 7 and 30 days post procedure. This will consist of answering questions about your health and medications you are taking, and completing a lower urinary tract symptoms (LUTS) questionnaire. For example, you will be asked questions such as “Have you ever had a urinary tract infection?” and “Do you have any visible blood in your urine?” These interviews will take 10-15 minutes.

For both groups, your medical records will be reviewed while you are on this study. We will collect information on your history of urological procedure and urinary tract infections. We will also collect information on certain other health issues you may have, such as congestive heart failure or diabetes mellitus, to determine how healthy you are. The research team will review your medical records as far back as we are able to collect information on your history of urological procedures, urinary tract infections, and certain other health issues.

For both groups, a note will be placed in your medical record that shows you are currently participating in a research study. This means that other health care providers at the VA can see that you are participating in this study.

The level of care you receive for your procedure will not change because of your participation in this study. However, your standard of care may be altered by having your doctor not review your urinalysis before your procedure. While the research team will monitor your lab results for infections, you might be at higher risk for a UTI if you choose to participate in this study.

ARE THERE ANY RISKS?

The main risk of this study is the onset of a urinary tract infection (UTI) accompanied by fever or chills. Additionally, there is a risk for bacteremia (high bacteria in the urine) and pyelonephritis (post-procedure kidney inflammation caused by bacteria). However, the research team will monitor your lab results, and will evaluate you for urological problems. If you have a positive lab and symptoms, you will be treated to avoid any complications. Additionally, individuals at high risk of infection have been excluded from the study.

Another potential risk is the breach of confidentiality regarding your medical information. It is our protocol to only give access to such records to research personnel that need to use it for the purpose of the study; therefore, the risk of a confidentiality breach is minimal.

ARE THERE ANY BENEFITS?

The benefits of this study are for the general public and you will not benefit directly. We hope to eliminate unnecessary procedures and use those funds for the improvement of patient care for everyone. In addition, we hope this study will lead to less unnecessary use of antibiotics, helping to lower the growing rate of antibiotic resistance.

ARE THERE ANY COSTS?

Veteran-subjects, or non-Veteran subjects participating in this VA study, will not be required to pay for care received as a subject in a VA research project. Some veterans are required to pay co-payments for medical care and services provided at the VA. These co-payments requirements will continue to apply to medical care and services provided by the VA that are not part of this study. Since you would receive a urinalysis and in-office procedure regardless of study participation, these are not considered medical care or services that are part of the study. However, you would not be billed for scheduling research only visits, such as setting up a time to complete the study questionnaires, or for any time spent discussing the research study and your participation with research staff.

ARE THERE ANY ALTERNATIVES?

If you decide not to participate in this study you will receive the same care you would normally receive before your scheduled urological procedure.

WILL I BE PAID FOR MY PARTICIPATING IN THE STUDY?

There will be no financial compensations for participating in the study.

WILL THERE BE COMPENSATION FOR INJURY?

In the event you sustain injury as a result of participation in this investigation, all necessary and appropriate care will be provided. However, the VA may not pay for the costs of treatment for injuries that result from your non-compliance with study procedures.

IF I DECIDE TO START THE STUDY, CAN I CHANGE MY MIND?

Participation in this study is a choice. You can change your mind at any time and withdraw without any penalties or consequences.

HOW WILL MY CONFIDENTIALITY BE PROTECTED?

Your information used for this study will be kept confidential as required by law. The results of your participation in this study may be used for publication or for scientific purposes, but the results will not include any information that could identify you. Current VA regulations require us to keep study records for 7 years beyond the completion of the study. Your urine sample results will be shared with researchers at the University of Wisconsin-Madison who are working on this study with us. By signing this consent form and the HIPAA authorization form you are giving us permission to share your results with these researchers. Your identity will not be disclosed unless you give specific consent or if required by law. There are times when we may have to show your records to other people. For example, representatives from offices and agencies that oversee research may review your records, such as UW and Madison VA research oversight offices or other federal agencies that oversee research such as the FDA, the Office for Human Subjects Protections, the VA Office of Research Oversight, or the VA Office of the Inspector General.

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 IF I HAVE QUESTIONS?

If you have questions or concerns about this research, please contact the VA study investigator, Dr. Kyle A. Richards at (608) 262-0759. For information on the rights of research subjects, please contact the VA hospital patient relations representative at (608) 280-7182. If you want to confirm this is a valid VA study, please call the VA Research Office at (608) 280-7007.

If you have medical problems or questions, call Dr. Kyle Richards at (608-262-0759) during the day and call (608-262-2122) after hours to page Dr. Richards.

AUTHORIZATION SECTION

I have read the information in this consent form, reviewed any questions, and I voluntarily agree to participate in this study. I have received a copy of this consent form.

_____ _____

Subject's Signature Date

_____

Last 4 digits of Subject's Social Security Number

_____ _____

Signature of Person Obtaining Consent Date