CONSENT FORM AND AUTHORIZATION FOR DISCLOSURE OF PROTECTED HEALTH INFORMATION

STUDY TITLE: A RANDOMIZED TRIAL OF BETADINE BLADDER IRRIGATIONS VS. STANDARD OF CARE PRIOR TO INDWELLING CATHETER REMOVAL TO REDUCE BACTERIURIA AND CATHETER-ASSOCIATED URINARY TRACT INFECTIONS

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INTRODUCTION

Why is this study being done?

You are being asked to participate in a research study. The purpose of research is to look at the nature of disease and try to develop improved methods to diagnose and treat disease. The doctor or clinician in charge of the study believes you meet the initial requirements to take part in the study. Before agreeing to participate, it is important for you to read and understand the following explanation of the research procedures. This Consent and Authorization form describes the purpose, procedures, benefits, risks and discomforts of the study. It also describes the alternatives available to you, and your right to withdraw (quit) from the study at any time.

Please read this information carefully and ask as many questions as you like before deciding whether or not you would like to take part in this research study.

The goal of this study is to evaluate whether instilling (filling with a liquid) 2% povidone-iodine (Betadine) into the bladder before removing an indwelling catheter (one that remains in place for a period of time) reduces the rate of urinary tract infections. Povidone-iodine is a commonly used solution that reduces the risk of infection on the surface of the skin or in the eye. Povidone-iodine is an FDA approved antiseptic, but its use in the bladder is not approved.

Up to 120 patients will be enrolled in the study at Beaumont Hospital, Royal Oak.

How long will I be in the study?

If you decide to take part in this study, your participation is expected to last approximately 1 month. You may not take part in this study if you are currently enrolled in another related research study which could alter or influence the study results.

DESCRIPTION OF THE STUDY

What will happen if I take part in the research study?

You are being asked to take part in this research study because you have had an indwelling catheter in your bladder for at least five days. Indwelling bladder catheters increase the likelihood of developing bacteriuria (bacteria in the urine) by about 5% each day, as well as the risk of actual urinary tract infection.

If you agree to take part in this study you will be randomly assigned to one of two treatment groups. Randomization is like "the flip of a coin".
The treatment groups are:

A. Study drug: approximately 60 mL of 2% povidone-iodine solution will be instilled into the bladder through the indwelling catheter and allowed to remain for 10 minutes, at which point the bladder will be drained and the catheter will be removed
B. Standard of care for your condition: immediate removal of the indwelling catheter without povidone-iodine instillation.

Below is a table describing what will occur at each study visit:

	Screening/Treatment	**Visit 2** ***In Hospital or Clinic***	**Visit 3** ***Phone Call***	**Visit 4** ***Phone Call***
Visit Window		**48-72 hours**	**7 ± 3 days**	**28 ± 3 days**
Informed consent	X			
Review inclusion and exclusion criteria	X			
Review medications	X	X	X	X
Urine collection[a]	X	X		
Urinary symptom questionnaire		X[b]	X[b]	X[b]
Indwelling catheter removal	X			
2% Povidone-Iodine Bladder Instillation	X[c]			
Assess for side effects	X	X	X	X

[a]All urine test results will be for research purposes only and not part of your clinical chart/electronic medical record

[b]The Urinary symptom questionnaire may be completed in person, over the phone, or at home and returned by US mail, fax, or email[c]2% Povidone-Iodine bladder instillation will only be performed if you are randomized to receive it

FDA Clinical Trial Information
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 website at any time.

RISKS, SIDE EFFECTS AND DISCOMFORTS
Ask your doctor what the standard of care risks are as well as the study risks.
What side effects or risks can I expect from being in the study?

Risks, side effects, and/or discomforts from the study medication and procedures are described below:
Risks of Urinary Catheterization:
Less Frequent (occurring from 1% to 10% of the time):
- Temporary inability to urinate
- Bleeding
- Mild cramping
- Urinary tract infection

Risks of 2% Povidone Iodine:
Less Frequent (occurring from 1% to 10% of the time):
- Local irritation of the bladder

Rare (occurring less than 1% of the time):
- Allergic reaction

Unknown Risk:
- Brown discoloration of urine

Risks of Bladder Instillation Procedure:
Less Frequent (occurring from 1% to 10% of the time):
- Discomfort while the indwelling urinary catheter is clamped

There is a rare risk of breach of confidentiality (release of information which personally identifies you).

Not all possible effects are known. With any drug, unusual, unexpected or previously unreported side effects may occur. You will be informed of any significant new findings, which develop during the course of this research study which may change your decision to continue participating in this study.

BENEFITS
What are the benefits of taking part in this study?
Receiving Povidone-iodine bladder instillation may reduce the chances of getting a urinary tract infection, improve quality of life, and delay or eliminate the need for additional treatment. However, there may be no direct benefit to you from taking part in this study. Information gained from the results of this study may be of benefit to others in the future, with a similar medical condition. Your condition may improve, but this cannot be guaranteed.

ALTERNATIVE OPTIONS

What are my choices other than taking part in this study?

You do not have to take part in this study to receive treatment for your condition. The current standard of care is to remove the indwelling catheter without any additional treatment.

ECONOMIC CONSIDERATIONS

What are the costs of taking part in this study?

The study medication will be provided to you at no cost. There will be no cost to you for the study procedures described in this consent (e.g. 2 urine sample collections, 3 questionnaires, and 1 possible bladder instillation treatment). Routine procedures you would have had done even if you were not taking part in this study will be billed to your health insurance company and/or group health plans as usual. If these routine care costs are not covered by your health insurance/group health plan, the cost will be your responsibility.

You will be reimbursed for your time and travel during the course of the study, as outlined in the table below. You will receive a stipend check (sent via US mail) in the amount listed below after each completed visit which is eligible to receive a stipend. If you are unable to complete all study visits, you will be paid only for the visits you were able to complete.

Visit	**Stipend Per Visit**
Screening and Treatment Visit	$25.00
Study Visit 2	$25.00
Study Visit 3	$0.00
Study Visit 4	$0.00
Maximum Total (if all visits are included)	$50.00

COMPENSATION

What happens if I am injured because I took part in this study?

Your involvement in this study is voluntary. The possible risks and side effects which might occur during the course of the research study have been described in this Consent and Authorization form.

A research injury is any physical injury or illness caused by the medications, devices, or procedures required by the study which are administered, used, or performed appropriately. These medications, devices, or procedures are different from the medical treatment you would have received if you had not taken part in the study.

Should you experience a research injury, there are no designated funds provided for subsequent medical care or compensation by either the study doctor/clinician or Beaumont Health.

What are my rights if I take part in this study?
You are not giving up any of your legal rights by signing this form.

CONFIDENTIALITY, DISCLOSURE AND USE OF YOUR INFORMATION
Will my medical information be kept private?
We will keep your personal health information as confidential as possible. It is not likely your information will be given to others without your permission. In order for this research study to take place, you must also authorize the researchers to access and use some of your protected health information (PHI). PHI is information which could identify you as an individual such as name, address, date of birth, etc. By signing this Consent and Authorization Form, you give Beaumont permission to use and/or disclose (release) your health information related to this research. Your medical and billing records collected for the purpose of the study will remain confidential, but may be disclosed (released) or used by the following and/or their representatives:

- The investigators (study doctor/clinician, research staff)
- Beaumont and its' parent, Beaumont Health and affiliated hospitals
- The Food and Drug Administration
- Other governmental regulatory agencies (domestic and/or foreign)
- Your health insurance company and/or group health plans and their intermediaries (companies contracted to process claims) may also have access to your medical and billing records of the study.
- Primary Care Physician

The purpose for this disclosure (release) or use is, for example, to assure compliance with the study protocol, to evaluate the effectiveness of the study, and/or to provide protection to you as a research study participant. The disclosure and use of your information will continue after your involvement in the study has ended. There is no expiration date for the use of your medical and billing records from the study. Any information about you disclosed to the parties identified above may be re-disclosed by them; however, such re-disclosure is not under the protections of this Consent and Authorization.

You will not be identified in any publication or other release of study results, data, and other information (such as in professional writings, at professional meetings, and/or in advertising or other promotional materials).

If you decide to withdraw your authorization for the researchers to access and use your protected health information before the end of the study, you will be withdrawn from the research study. However, where the study relied on your Consent and Authorization for the time you participated in the study, your Consent and Authorization cannot be withdrawn and the information already collected may still be used and disclosed as you previously authorized.

STOPPING STUDY PARTICIPATION

What if I decide to stop taking part in the study?

Taking part in this research study is completely voluntary. You may choose not to take part or to stop being in the study (withdraw) at any time without penalty or loss of benefits to which you are otherwise entitled, or without jeopardizing your medical care by your doctor at Beaumont. However, if you do not agree to sign this Consent and Authorization form, you will not be able to take part in this study.

If you decide to withdraw from the study you will need to notify the study doctor/clinician of your decision to stop taking part in the study. Written notification is preferred. This notice may be sent to Jay Hollander, MD at William Beaumont Hospital, 3535 W. 13 Mile Road, Suite 438, Royal Oak, MI 48073.

Your participation in this study may be stopped by the study doctor/clinician, without your consent, for any reason, which will be explained to you. Examples include:

- The study medication or procedures appear to be medically harmful to you.
- You fail to follow directions for participating in the study.
- It is discovered you do not meet the study requirements.
- The study is canceled.
- It is determined to be in your best interest (for example, your disease has progressed despite treatment).

CONTACTS

Who can answer my questions about the study?

You may talk to the study doctor/clinicians about any questions or concerns regarding your study participation, or you think you may have suffered a research-related injury. The doctor/clinician in charge of the study, Jay Hollander, MD, may be reached at: (248) 551-9238 to answer your questions.

Your study contact is Danielle Tenney, MA. You may contact her at (248) 551-3565.

If you have questions regarding your rights as a research participant, or have problems, concerns, complaints, want information or would like to offer input, you may contact the Institutional Review Board Chairperson at (248) 551-0662. The Institutional Review Board is charged with the oversight of all human participant research conducted at Beaumont facilities.

STATEMENT OF VOLUNTARY PARTICIPATION

I have read the above, have asked questions and have received answers about this study to my satisfaction. I understand what I have read and willingly give my consent to participate in **A RANDOMIZED TRIAL OF BETADINE BLADDER IRRIGATIONS VS. STANDARD OF CARE PRIOR TO INDEWELLING CATHETER REMOVAL TO REDUCE BACTERIURIA AND CATHETER-ASSOCIATED URINARY TRACT INFECTIONS**. I understand I will receive a signed copy of this document and will be promptly informed of any new findings regarding this study. I further authorize the use or disclosure of my health and personal information contained in records as described above.

_____
RESEARCH PARTICIPANT NAME (PLEASE PRINT)

_____ _____ _____
RESEARCH PARTICIPANT SIGNATURE DATE TIME

ALTERNATIVE SIGNATURE (for use only when participant is a minor, cognitively impaired or critically ill**)**
AS THE PERSONAL/LEGAL REPRESENTATIVE OF THE STUDY PARTICIPANT, PLEASE PRINT PARTICIPANTS NAME ON THIS LINE_____, AND CHECK ONE OF THE BOXES BELOW AS THE BASIS FOR YOUR AUTHORITY TO SIGN THIS CONSENT AND AUTHORIZATION:

☐ COURT-APPOINTED GUARDIAN
*COURT LETTER IS REQUIRED

☐ DURABLE POWER OF ATTORNEY
*ATTORNEY LETTER MUST BE PRESENT & VERIFIED BY 2 PHYSICIANS

☐ NEXT OF KIN

_____ _____
NAME (PLEASE PRINT) RELATIONSHIP TO PARTICIPANT

_____ _____ _____
SIGNATURE DATE TIME

☐ WITNESS TO SIGNATURE ON CONSENT ☐ WITNESS TO CONSENT PROCESS AND SIGNATURE

_____
WITNESS NAME (PLEASE PRINT)

_____ _____ _____
WITNESS SIGNATURE DATE TIME

AUTHORIZED CONSENT PROVIDER STATEMENT:

I have explained this study and have offered the study participant an opportunity for any further discussion or clarification.

_____ _____ _____
NAME (PLEASE PRINT) CREDENTIALS PHONE NUMBER

_____ _____ _____
SIGNATURE DATE TIME