CANCER IRB CONSENT FOR INVESTIGATIONAL STUDIES
FOR USE BY ALL COMPREHENSIVE CANCER CENTER MEMBERS

Project Title: CASE 14807 Improving Urinary Continence and Quality of Life in Prostate Cancer Patients

University Hospitals Principal Investigator: Amy Y. Zhang, Ph.D.
Cleveland Clinic Co-Investigator: Eric Klein, M.D.

INTRODUCTION

This is a research study of urinary incontinence in men diagnosed with prostate cancer. You are invited to participate in this research study because your ability to maintain urinary continence may have been affected by your disease and medical treatment. This consent form provides information about study procedures. You may want to talk with family and friend before making a decision about participation. Your participation in this research study is voluntary. Refusing to participate will not alter you usual health care or involve any penalty or loss of benefits to which you are entitled.

PURPOSE OF THE STUDY

The purpose of this research study is to evaluate the effect of an intervention on urinary continence of prostate cancer patients. Prostate cancer and its medical treatment (surgery, chemotherapy or radiation) may result in incontinent symptoms such as dripping, leaking and frequent urge for urination due to weakened sphincter muscles. Pelvic Floor Muscle Exercises (PFME), or so called "Kegel exercises," is a technique of muscle contraction and can strengthen sphincter muscles to reduce urinary urgency and leakage. Learning PFME through biofeedback training can improve identification and contraction of correct muscles, hence enhancing the exercise outcome. Incontinence symptoms (e.g., urge or leakage) are also contingent upon routine activities such as the type and amount of daily fluid intake or toileting habits. Learning problem solving skills will help patients manage these activities to minimize incontinent symptoms. The intervention tested in this study combines biofeedback-trained PFME and "Problem Solving Therapy" to improve outcomes of PFME and symptom self-management in prostate cancer patients. The study will evaluate long-term urinary continence and quality of life following the intervention.

STUDY PROCEDURES

312 prostate cancer patients will participate in this study at Cleveland Clinic and the University Hospitals Case Medical Center. The study investigators will randomly assign (like throwing a die) the participants to one of the three study groups: a support group, a telephone group and a control group. One of every three patients will be assigned to either group. The support and telephone groups will undergo the intervention that consists of PFME biofeedback training and six support group or telephone sessions. The control group will be observed and will not receive the intervention. The duration of this study is seven months including a month of screening and baseline assessment, a three-month study intervention, and a three-month follow-up. Participants in all groups will be assessed in Month 1 (baseline), Month 4 and 7.

The current standard care for incontinent prostate cancer patients includes medication and surgery. This research study provides a behavioral treatment that combines biofeedback training in PFME and follow-up care to be delivered through support group or telephone sessions by health professionals. This behavioral treatment is available only through participation in this research study. The participation in this study will involve two visits to the University Hospital Case

Medical Center for biofeedback sessions if you are assigned to an intervention group and three home visits by research nurses/staff. Specific study procedures are explained below.

Screening
A research nurse/staff will contact you by telephone and ask you some questions to determine your eligibility for the study. To be eligible for this study, you need to have a diagnosis of prostate cancer in early stage (I-III), have completed all treatments six months prior, and be experiencing incontinent symptoms such as frequent urgency for urination and urinary leakage. If you have urinary track infection, you will be referred to treatment and will be recruited only after your infection has been cured. This screening process takes 15 to 20 minutes to complete.

Baseline (T_1)
If you are eligible and agree to participate in this research study, a research nurse/staff will schedule a baseline assessment at your preferred time and place. This assessment takes 90 minutes to complete and can take place at your home, hospital or other private places. The following activities will be conducted at this assessment.

1. **1-hour pad test**. This is a standard test for urinary leakage. The test will start without your voiding. During the first 15 minutes, you will drink two bottles (500 mL) of water. Between 15 and 60 minutes, you will do some moderate exercises such as walking or climbing stairs. You will be asked to wear a thin pad before the test starts. The pad will be weighed before and after the test to assess an amount of urine leakage that you may have.

2. **Questionnaires**. You will receive a package of questionnaires via mail prior to the assessment. You are encouraged to complete the questionnaires prior to the assessment. Completion of the questionnaires may take 60 to 75 minutes. The research nurses/staff will go over the questionnaires with you to answer any questions that you may have.

3. **Urinary diaries**. You will receive the urinary diary in mail prior to the assessment. You will be asked to keep a diary of your fluid intake and voiding activities for 3 days. At the baseline assessment, the research nurse/staff will explain to you how to complete the urinary diary and provide you with a urinal for this measure. You can return the completed urinary diary using a provided, self-addressed and stamped envelope.

Randomization
If you participate in this study, you will be assigned to a study group by chance using a process similar to the flip of a coin. You have a 2 in 3 chance of receiving the study intervention (biofeedback plus support group or telephone). This process is called randomization. Neither you nor study staff will select the group to which you will be assigned. The research nurse/staff that conducts study assessments will be blind to, that is "do not know", the study group that you belong to. The study coordinator (project manager) will phone you to inform your group assignment.

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Study Intervention
Subjects in the control group will receive no investigational treatment but will be monitored by research nurse/staff. If you are assigned to the control group, you will only need to complete the three assessments in Month 1 (baseline), Month 4 (post-treatment) and Month 7 (follow-up). You may receive educational readings in mail periodically during the first four months. Under your request, a one-time free consultation about urinary incontinence and treatment will be provided to you after you complete the study.

The study intervention includes two arms: (1) biofeedback plus support groups and (2) biofeedback plus telephone sessions. If you are assigned to either intervention arm, you will need to attend two biofeedback sessions in Month 1 (baseline) and Month 4 (post-treatment), respectively. You also need to complete the three assessments in Month 1 (baseline), Month 4 (post-treatment) and Month 7 (follow-up). In addition, you will be asked to wear a wristwatch to record daily PFME practice during a period of three months. The study procedures for the two intervention groups are explained below.

(1) Biofeedback
The biofeedback training session will take place at the University Hospital Case Medical Center. You will learn PFME individually from a biofeedback technician who is experienced in teaching PFME and trained by the manufacturer in performing the biofeedback procedure. During this 60-minute session, you will be asked to insert a sensor into your rectum area in a private room. The sensor will be connected to a computer. The therapist will teach you PFME while you are viewing a computer monitor to learn how to contract your muscles correctly. The therapist will also provide instruction on how to practice PFME at home. At the end of this session, the therapist will present you a wristwatch and teach you how to use it to monitor and record your daily PFME practice. You will be asked to use it to record daily PFME practice for three month. The wristwatch will be replaced monthly via mail.

(2) Support group
Following the completion of biofeedback session, participants of the support groups will be asked to attend a group meeting every other week for a total of six times at the Louis Stokes Cleveland Department of Veterans Affairs Medical Center (LSVAMC) - Wade Park. The meeting lasts $1^1/_2$ to 2 hours each time and consists of four to six participants. Each meeting will be moderated by a health care professional (a health psychologist or nurse specialist). At these meetings, you will learn more about PFME and problem-solving skills for self-management. Theses skills are taught to help you train your bladder and control or reduce incontinent symptoms. You will also have an opportunity to socialize with other prostate cancer patients.

(3) Telephone group
If you are assigned to the telephone group, a health care professional (a health psychologist or nurse specialist) will talk with you over the phone every other week for a total of six times. The

phone conversation normally lasts 45 to 60 minutes. You will have an opportunity to learn more about PFME and problem-solving skills for self-management. You will also have an opportunity to talk about your personal concerns and receive recommendation for managing your incontinent symptoms. The telephone sessions may be audiotaped for the purpose of quality control. You can ask to turn off the recorder if you do not feel comfortable with the audiotaping.

POST-TREATMENT ASSESSMENT (T_2)
At the end of the study intervention in Month 4, all study participants will undergo the second assessment that entails the following activities. This assessment takes 90 minutes to complete and may take place at your home, hospital or other private places that you prefer.

1. **1-hour pad test**. This test will be repeated to assess an amount of urinary leakage.

2. **Questionnaires**. The same package of questionnaires will be mailed to you prior to this assessment. Completion of the questionnaires may take 60 to 75 minutes. The research nurses/staff will go over the questionnaires with you to answer any questions that you may have.

3. **Urinary diaries**. You will receive the urinary diary in mail prior to the assessment. You will be asked to keep a diary of your fluid intake and voiding activities for 3 days prior to the assessment.

4. **Wristwatch**. If you are assigned to one of the study intervention groups, you will be asked to record the time of daily PFME practice for past three months. The wristwatch will be collected during this assessment.

5. **Biofeedback**. If you are assigned to one of the study intervention groups, you will be scheduled for another biofeedback session at the University Hospital Case Medical Center. This biofeedback session will last 30 minutes and reassess your muscle conditions. The study coordinator (project manager) will phone you to set up this appointment.

FOLLOW-UP ASSESSMENT (T_3)
A follow-up assessment will be conducted at the end of the study in Month 7. At this assessment, you will be asked to complete the measures 1-3 as described above, including the 1-hour pad test, completion of questionnaires and urinary diaries. In addition, the research nurse/staff will conduct a 30-minute interview to discuss your study experience. This in-person interview will be audiotaped for the purpose of data analysis. You can ask to review the audiotape and request portions of the recording not to be used for research purpose.

If you withdraw from the study prior to its completion, you will be asked to inform the research nurse/staff about your decision immediately and return study materials such as the wristwatch.

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You will also be asked to complete questionnaires, pad test and urinary diaries at your convenience.

RISKS

Your participation in this study does not involve any physical risk to you. Biofeedback is a safe procedure. However, you may experience brief discomfort while inserting a sensor into your rectum. You may dislike doing it. If you have problems with rectum area and consider sensor insertion harmful, an external sensor may be used in this special circumstance. The therapist will discuss the options with you during the biofeedback session.

The risk associated with practicing PFME is minimal. Although incorrect muscle exercises can result in muscle fatigue, this condition usually resolves itself. Incorrect exercises primarily reduce PFME efficacy but is unlikely to cause any prolonged or permanent muscular damage.

You may be asked to discuss issues that you consider private or which could be upsetting in light of your own personal experiences. You may not feel comfortable discussing these issues with people that you do not know well. However, you may escape any question and talk as much or as little as you like.

Reproductive Health/Sexual Activity

Biofeedback and PFME practice do not have any known adverse effect on reproductive and sexual activities. Strengthening pelvic floor muscles is not expected to solve an impotence problem. However, PFME may increase blood flow in genital area that is beneficial to erectile functioning.

BENEFITS

You may or may not directly benefit from participating in this study. Your participation may help researchers discover better ways to reduce urinary incontinence in prostate cancer patients. You may also enjoy exchanging thoughts and ideas or sharing your experience with an interviewer, a health care professional or other prostate cancer patients. You may experience improved urinary continence following the study intervention.

ALTERNATIVES TO PARTICIPATION

You have the alternative to not participate. Other alternatives include surgery, implants and medication. You need to discuss these treatment options with your urologist.

COSTS AND COMPENSATION

There is no cost to you or your insurance for participation in this research study. The study will pay for the procedures and materials that are directly associated with this research study. They include biofeedback training sessions, wristwatch and other study materials. However, procedures or drugs that are considered standard of care will be the responsibility of you or your insurance

company. This includes surgery or medication for the treatment of urinary incontinence or urinary track infection that you decide to take outside of the study.

Participants in all three groups will be paid an honorarium of $400 for completing all three assessments, with $100 at each assessment in Month 1 (baseline), Month 4 (post-treatment) and Month 7 (follow-up) and $25 in Month 2, 3, 5 and 6. The payment will be made in the form of a check at the completion of each assessment or the end of each month whichever it is applicable.

Additionally, participants will be reimbursed for parking, transportation expense and time incurred for biofeedback session with $25 per attendance at a total of $50, and for support group or telephone sessions with $20 per session at a total of $120. The total amount of payment is no greater than $570. If you withdraw from the study, the payment will be prorated and you will be paid for the portions that you have completed.

If you agree to participate in the urodynamic testing through a separate consent, you may receive an additional $60. For a research study that involves a reimbursement amount of $600 or greater in a year, this reimbursement may be considered taxable and may be reported to the Internal Revenue Service.

RESEARCH-RELATED INJURY

If you experience physical injury or illness as a result of participating in this research study, medical care is available at the Cleveland Clinic Foundation and/or University Hospitals Case Medical Center or elsewhere; however, the Cleveland Clinic Foundation and/or University Hospitals Case Medical Center will not provide free care or compensation for lost wages. Further information about research-related injuries is available by contacting the Case Cancer Institutional Review Board at (216) 368-3771.

CONFIDENTIALITY

The information collected from you will be kept in a locked cabinet at the School of Nursing, Case Western Reserve University. Only the researchers will have access to the data. All the collected data including audiotapes will be destroyed in four years after the study is completed.

TERMINATION OF PARTICIPATION

If you decide to take surgery, medication or other medical treatment to treat urinary incontinence while you are participating in this research study, your continence condition may change as a result of this intervention. In this case, you may become ineligible to the study. Please inform the research nurse/staff or any research team member as soon as possible about any step that you have taken medically to treat incontinence. The sponsor (National Cancer Institute) or investigator may discontinue your participation in this study without your consent if your eligibility status has changed, you become ill with urinary track infections, your health condition deteriorates and harms your participation, or you cannot comply with the study requirements.

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HIPAA AUTHORIZATION SECTION
Authorization To Use Or Disclose (Release) Health Information That Identifies You For A Research Study

If you sign this document, you give permission to Dr. Zhang, her research team and their research staff at Case Western Reserve University, the Cleveland Clinic Foundation, and University Hospitals Case Medical Center to use or disclose (release) your protected health information, or PHI, that identifies you for the purposes of the research study described below:

This is a research study of urinary incontinence in men diagnosed with prostate cancer. The purpose of this research study is to evaluate the effect of an intervention on urinary continence of prostate cancer patients. The PHI that we may use or disclose (release) for this research includes information on your cancer diagnosis and treatment, laboratory test results, medical conditions that may affect your treatment, general health, personal information such as address and phone number, social security number for filing your payment, and a copy of your hospital bills during the study period that allow researchers to analyze the cost effectiveness of the study intervention.

In addition to the investigators and research staff listed above, your PHI may be looked at by other groups involved with the study such as the Case Cancer Institutional Review Board, and the Case Comprehensive Cancer Center Protocol Review and Monitoring Committee. Your PHI may also be used by and/or disclosed (released) to:

- National Cancer Institute, the sponsor of the Research Study;
- The Food and Drug Administration;
- The Cleveland Clinic Foundation and/or University Hospitals Case Medical Center.

Case Western Reserve University is required by law to protect your health information. By signing this document, you authorize Case Western Reserve University, the Cleveland Clinic Foundation, and/or University Hospitals Case Medical Center to use and/or disclose (release) your health information for this research. Those persons who receive your health information may not be required by Federal privacy laws (such as the Privacy Rule) to protect it and may share your information with others without your permission, if permitted by laws governing them.

Please note that you do not have to sign this Authorization, but if you do not, you may not be able to participate in this research study. This will not affect your right as a Cleveland Clinic Foundation and/or University Hospitals Case Medical Center patient to treatment or benefits outside the research study.

You may change your mind and revoke (take back) this Authorization at any time. Even if you revoke this Authorization, the Principal Investigator and the research staff may still use or disclose

health information they already have obtained about you as necessary to maintain the integrity or reliability of the current research. If you revoke this Authorization, you will not be able to continue to participate in the study. To revoke this Authorization, you must write to:

Dr. Amy Zhang
Frances Payne Bolton School of Nursing
Case Western Reserve University
10900 Euclid Avenue
Cleveland, OH 44106

This Authorization does not have an expiration date.

If you have any questions, you can ask the Principal Investigator and/or research staff, or if you have questions later, you can contact the Case Western Reserve University Research Administration Officer, the Associate Dean for Research Administration who is the Privacy Officer's designee at (216) 368-1158, or the Privacy Officer at (216) 368-4389. You will be given a signed copy of this authorization form for your records. By signing this informed consent form, you authorize the use of your identifiable information as described in this form.

SUMMARY OF YOUR RIGHTS AS A PARTICIPANT IN A RESEARCH STUDY

Your participation in this research study is voluntary. Refusing to participate will not alter your usual health care or involve any penalty or loss of benefits to which you are otherwise entitled. If you decide to join the study, you may withdraw at any time and for any reason without penalty or loss of benefits. If information generated from this study is published or presented, your identity will not be revealed. In the event new information becomes available that may affect the risks or benefits associated with this study or your willingness to participate in it, you will be notified so that you can decide whether or not to continue participating. If you experience physical injury or illness as a result of participating in this research study, medical care is available at Cleveland Clinic Foundation and/or University Hospitals Case Medical Center or elsewhere; however, the Cleveland Clinic Foundation and/or University Hospitals Case Medical Center has no plans to provide free care or compensation for lost wages.

DISCLOSURE OF YOUR STUDY RECORDS

Efforts will be made to keep the personal information in your research record private and confidential, but absolute confidentiality cannot be guaranteed. The Case Cancer Institutional Review Board may review your study records. If this is a treatment study, the records must be available to the Food and Drug Administration, the study sponsor, and possibly foreign regulatory agencies. If your records are reviewed, your identity could become known.

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CONTACT INFORMATION

_____ has described to you what is going to be done, the risks, hazards, and benefits involved, and can be contacted at _____ _____. During the non-business hours, you can call the research team at 216-368-6342. For medical emergency, please contact your treating physician's office or dial 911. Further information with respect to illness or injury resulting from a research procedure as well as a research subjects' rights is available from the Case Cancer Institutional Review Office at (216) 368-3771.

SIGNATURE

Signing below indicates that you have been informed about the research study in which you voluntarily agree to participate; that you have asked any questions about the study that you may have; and that the information given to you has permitted you to make a fully informed and free decision about your participation in the study. By signing this consent form, you do not waive any legal rights, and the investigator(s) or sponsor(s) are not relieved of any liability they may have. A copy of this consent form will be provided to you.

Signature of Participant	**Date**	**Printed Name of Participant**

Signature of Person Obtaining Consent	**Date**

Printed Name of Person Obtaining Consent

Signature of Principal Investigator	**Date**