Informed Consent Form

STUDY TITLE:	**PC-PEP Phase 4: Predictors of Mental Health for Men with Prostate Cancer undergoing a Patient Empowerment Program (PC-PEP)**
CLINICAL STUDY REGISTRATION NUMBER:	NCT04895839
PRINCIPAL INVESTIGATOR:	Gabriela Ilie, Ph.D. Endowed Soillse Research Scientist in Prostate Cancer Quality of Life Research Assistant Professor, Dalhousie University Department of Community Health and Epidemiology Department of Urology Room 401, Centre for Clinical Research 5790 University Ave Halifax, NS, B3H 1V7 Office: (902) 494-4527
SUB-INVESTIGATOR (CLINICAL LEAD)	Dr. Rob Rutledge, MD, FRCPC Radiation Oncologist, Nova Scotia Cancer Centre Associate Professor, Dalhousie University Room 2025, Dickson Building 5820 University Ave Halifax, NS, B3H 1V7 Office: (902) 473-6185 Cell: (902) 489-6423
FUNDERS:	Dalhousie Medical Research Foundation Department of Urology, Dalhousie University Department of Radiation Oncology, Dalhousie University Research Nova Scotia Corporation

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1. Introduction

You have been invited to take part in a research study. A research study is a way of gathering information on a treatment, procedure or medical device or to answer a question about something that is not well understood. Taking part in this study is voluntary. It is up to you to decide whether to be in the study or not. Before you decide, you need to understand what the study is for, what risks you might take and what benefits you might receive. This consent form explains the study. You may take as much time as you wish to decide whether or not to participate. Feel free to discuss it with your friends and family, or your family doctor.

Please ask a member of the research team or the Principal Investigator to clarify anything you do not understand or would like to know more about. Make sure all your questions are answered to your satisfaction before deciding whether to participate in this research study.

The researchers will:

- Discuss the study with you;
- Answer your questions;
- Be available during the study to deal with problems and answer questions.

You are being asked to consider participating in this study because you are a man greater than 18 years of age with a history of a prostate cancer diagnosis including:

- Men who are scheduled for curative prostate cancer treatment (surgery, radiotherapy with and without hormone therapy)
- Men choosing active surveillance or on observation
- Men recovering from curative treatment
- Men being followed for prostate cancer
- Men with recurrence of the cancer on life-long hormone therapy (injections that lower the male hormone)
- Men with advanced prostate cancer (including those with cancer spread to the bone) undergoing hormone treated and/or targeted therapy (special pills that block cancer cell growth).

If you decide not to take part or if you leave the study early, your cancer treatment and/or your usual health care will not be affected.

2. Why is there a need for this study?

More than 20,000 men are told they have prostate cancer each year in Canada. Most men with prostate cancer will need some kind of treatment. About half of these men pick prostate surgery and the other half will choose radiotherapy. Both of these treatments have potential side effects including urinary problems, loss of erections, fatigue, problems with sleep, and many more. Men also may get started on hormone treatments (are part of a curative treatment) or hormone treatment and/or targeted therapies (if their cancer is not curable). These treatments can cause problems like fatigue, hot flushes, and loss of sex drive. All these side effects can negatively affect quality of life and decrease mental health and well-being.

The goal of this study is to test a patient empowerment program (Prostate Cancer – Patient Empowerment Program, or PC-PEP) that can be started before or after surgery, radiation or hormone treatment, or at any time during the prostate cancer journey. This program aims to improve the mental and physical health in men with a prostate cancer diagnosis by 1) providing helpful life skills that may help reduce the side effects related with surgery, radiotherapy, hormone treatment or targeted therapy; 2) decreasing urinary problems by improving pelvic floor function (‘Kegels’); 3) increasing healthy behaviors for better overall health including exercise, healthy diet, stress reduction/relaxation techniques, connection advice and social support opportunities.

3. What is being tested?

This study tests a six-month empowerment program (PC-PEP) which includes physical exercise, meditation/relaxation techniques, healthy lifestyle advice, relationship training and social support in addition to the treatment you will receive from the medical system.

The goals of this study are:

(1) To see if this 6-month program improves physical and mental health at 6, 12 and 24 months after the program starts
(2) To see if it is safe for men to exercise and do strength training at home
(3) To see which men (with which characteristics) benefit most and least from the program.

4. How long will I be in the study?

You will be involved with this study for two years.

For the first six months, you will be enrolled in the patient empowerment program where you will be asked to follow a fitness program, read daily instructional emails, and watch short videos. These activities will take approximately 60 minutes per day and can be fit into your schedule in a way that works for you. You will then be asked to fill out an online survey at the end of the six months and at the one- and two-year points.

5. How many people will take part in this study?

It is anticipated that about 400 men from Nova Scotia with prostate cancer will participate in this study. In addition, men who live outside of Nova Scotia who hear about the program through word of mouth and who qualify for the study may also be able to participate.

6. How is the study being done?

All participants in this study will follow the program for the first 6 months after being enrolled. You will be asked to complete a questionnaire at the start of the program, at the end of the program (6 months), and then one year and two years after being enrolled in the program. You will also be asked to complete a weekly questionnaire during the first 6 months, asking you how compliant you were with each component of the program (e.g. number of minutes doing strength exercise each day).

7. What will happen if I take part in this study?

If you are interested in taking part in the study, please visit www.PCPEP.org to learn more.

Screening and Consent

Before you can start the program, you will need to complete the following screening steps:

1 – Make sure it's safe to do aerobic exercise which includes walking at a moderate rate, and many other activities which raises your heart rate and gets you to breathe harder. You must pass one of the following tests to prove it is safe for you to exercise:

a. Pass an online survey by being able to answer 'no' to all of the following questions:
    1. Heart condition or high blood pressure?
    2. Pain in your chest?
    3. Lose balance due to dizziness or lost consciousness recently?
    4. Diagnosed with another chronic medical condition?
    5. Currently prescribed medications for a chronic medical condition?
    6. Do you have a bone, joint, or soft tissue problem that could be made worse through exercise?
    7. Has your doctor told you that you can only exercise while being medically supervised?
b. Or talk to your family doctor, urologist, or oncologist, and have them deem you safe to exercise
c. Or talk to the Study Physician or a Clinical Exercise Physiologist and have them to deem you safe to exercise

2 – Make sure it's safe to do strength training. You must pass one of the following to prove it is safe for you to exercise.

a. Watch a video of all the strength training exercises used on the patient empowerment program. Ensure you have no problems with your joints, muscles, ligaments or bones, and you feel you can do each of the exercises for 15 seconds without hurting yourself.
b. Meet with a personal trainer with expertise working with people with cancer or the study clinical exercise who can help you do the exercises correctly, modify the program and/or offer advice. They would need to deem you safe to do the strength training program.

Once you have completed the steps above you will need to speak with the Research Coordinator who will see if you are right for the study by asking you a few more questions.

These questions will be about whether or not you:

(1) have prostate cancer;
(2) have an email account, internet connection, computer/smartphone/tablet capable of hosting a videoconference, and are willing to read your email and watch YouTube videos daily;
(3) speak and understand English

The Research Coordinator will also ask if you have ever been told your prostate cancer has spread to your bones or that you have advanced prostate cancer. If one of these is true, the Research Coordinator will connect you with the Study Physician who will ask you questions about your health to determine if it's safe for you to join the program. If it appears you are safe to exercise and for you to be in the study, the Study Physician will talk to the study's Exercise Trainer about your medical history in order to make sure that the exercises prescribed are safe for you. If you have advanced prostate cancer and the Study Physician thinks that this study is not appropriate for you, he will let you know why and discuss his decision with you.

You can contact the Research Coordinator by email at PEP@nshealth.ca or telephone at 902-237-6277 to inform them of any changes to your prostate cancer diagnosis that may affect your safety to exercise at any time.

If you are right for the study you will be given more information about the study by the Research Coordinator. If you agree to participate in the study, the Research Coordinator will provide you with a link to an electronic version of the informed consent form hosted on secure NSHA servers. The team member will discuss this consent form with you via telephone and give you the opportunity to ask any questions before you sign and consent to participate.

Baseline

After consenting to participate, you will be asked to complete an online survey that takes about 30 minutes and asks questions about diagnosis, treatment, and various aspects of quality of life (such as mental health, urinary, bowel and sexual function). You do not have to answer questions from the survey that make you uncomfortable if you do not want to answer them and you can withdraw your participation from the study at any time.

Program

Each week of the six-month program (PC-PEP) you will be asked to:

1. Do strength training at home twice per week
2. Do aerobic physical activity on the days of the week when you don't do strength training
3. Practice pelvic floor exercises three times a day for 5-10 minutes each time,
4. Practice a relaxation technique for 10 minutes every day
5. (Optionally) Contact two other men in the study once per week (if you consent to have two "buddies" in the PC-PEP Program)
6. (Optionally) Join a confidential videoconference (or voice only) call with other men on the program and the investigators once per month
7. Read an email and watch a short video (3-5 minutes) each day with instructions and healthy lifestyle advice from the lead investigators of PC-PEP (Drs. Ilie and Rutledge).
8. Complete a short online questionnaire regarding what you did that week

If you have surgery during the six months you will be asked to stop your exercise program just before the surgery and restart it after you have been given the 'go ahead' from your surgeon (usually six weeks after the surgery).

You will be able to email or call the Study Exercise Trainer if you have questions throughout the six months of the program. If you have advanced prostate cancer, the Exercise Trainer will arrange for you to join a videoconference to make sure it's safe for you to continue to exercise or not, and to answer your questions. You can also call or email the Study's Physician, Research Coordinator and/or the Principal Investigator at any time during your participation in the study if you have any questions or concerns related to your participation in the study.

1. *Informational Videos*

At the beginning of the program, you will watch three videos explaining the science behind each part of PC-PEP, including:

1. Healthy Lifestyle (exercise, diet, sleep, etc.)
2. Pelvic Floor Exercises
3. Connection / Relationship training

You will have access to all the videos above including others which you can follow along with (strength, pelvic floor, and relaxation) at any time during the active part of the program.

2. *Daily PC-PEP emails*

For six months of the PC-PEP program you will receive a daily email explaining what you need to do the next day and offering healthy lifestyle advice. In the email, there will be a link to a 3-5 minute YouTube video which you will be recommended to watch. On Mondays and Thursdays, you will be reminded to do your strength training that day. Every other day you will be asked to do any type of aerobic exercise of your choice (recommendations will be provided). The emails will remind you to practice your prescribed strength, aerobic, pelvic floor and relaxation exercises, and connect with someone in your life every day.

3. *Pelvic Floor (Kegels) Training*

All participants will be encouraged to follow pelvic floor training and speak with a Pelvic Floor Specialist assigned to them from the medical system.

Each day during the 6-month intervention, you will receive an email with a link to an 8-10 minute video outlining the pelvic floor exercise for that day. Every week the video changes, slowly increasing in intensity of the exercises, and teaching you different techniques. You are expected to follow the video instructions three times a day. Almost every week the program provides an additional educational video explaining the modifications for that week.

If you have a smart phone which can receive texts, we will ask you if you'd like to receive text reminders or automated phone calls three times a day to do your Kegel exercises.

4. *Surveys during the program*

Every Sunday during the six months you will be sent an email with a link to a survey. You will be asked to report on how much of each activity of the program you did the previous week. Once per month during the six months the weekly survey will also ask you whether you had any problems with the strength training program or any unexpected events such as injuries.

5. *Stress-reduction, Meditation and Heart-Rate Biofeedback Sensor*

You will have the option to receive a heart rate biofeedback sensor that measures your heart rate variability (HRV), the difference in time between each heartbeat and an indicator of stress, to use at home throughout the 6-month program. This will allow you to have consistent biofeedback and further help you learn how to relax (increase your HRV). You can choose either a Bluetooth

compatible unit which can synch to your smartphone or tablet if you have one, or a handheld version that can connect via USB to a desktop or laptop computer. You will learn meditation techniques by watching videos produced by the HeartMath Institute and meditation sequences and relaxation exercises provided by daily emails. The start of each pelvic floor exercise video also starts with two minutes of simple relaxation/meditation instruction.

6. *Strength and Aerobic Exercise*

You will be prescribed a strength exercise routine developed by a Certified Exercise Physiologist specifically for men with prostate cancer. You will be instructed to follow the routine at least twice per week (Mondays and Thursdays) for the duration of the 6-months. You can have an optional consultation via videoconference with the Exercise Trainer if you require additional on the exercises. You will also be encouraged to do aerobic exercises and be given tips, ideas, and encouragement to incorporate more aerobic exercises into your daily life.

Optional Activities:

Weekly 'Buddy' Call

You will begiven the option to consent to being assigned two "buddies" (other participants in the program at the same time as you) who we ask you to call or email once per week. The groups of participants will be chosen to be similar in age, treatment and geography. Previous feedback of men who participated in the buddy system suggests this is a much valued and appreciated aspect of our program, and past participants strongly recommend this system to other men entering the program. Prior to starting this component, the Research Coordinator will have a discussion with you to give instruction on how to respect other participants privacy, confidentiality, boundaries, and dealing with any grief you may experience, etc. A list of suggested "check-in" questions that you can ask your "buddies" during your phone conversations will also be provided. Each participant has the right to share as little, or as much, as they wish with their "buddies". You are encouraged to: look at issues from more than one point of view; share honest points of view in a respectful way; be reflective of diverse populations and perspectives in our community; and be respectful, kind, supportive and compassionate. The research team will be available to help in the rare event that a situation of inappropriate "buddy" behavior arises (e.g. excessive calling, not respecting boundaries, etc.). We can contact the "buddy" and address any issues anonymously, or help you end your connection with that buddy. If you consent to this component, only your name and phone number will be provided to the other participants. By consenting to participate in this component, you also agree keep all contact information of the other participants confidential. You do not have to provide your contact information and participate in the "Buddy Call" if you do not want to, and you can still participate in the rest of the study. You can withdraw your participation in this component of the program at any time and for any reason, and we can help you exit this component (e.g. instruct you how to block the participants number).

Monthly Videoconference or Telephone Conference Call

During the six months of the PC-PEP program, you can join an hour-long videoconference meeting hosted once every month by the research team and a group of highly selected men (mentors) who have already gone through prostate cancer treatment. These selected men will act as volunteer patient mentors and will have signed a pledge of confidentiality with Nova Scotia

Health to keep any information obtained during their involvement with this study confidential. During the meeting you can choose to join the conversation or simply listen

Focus groups and/or face-to-face interviews

You may also be invited to join an optional group discussion (focus group) with approximately 5 men that will be audio taped and/or participate in a face-to-face, one on one interview with the study's Principal Investigator. All information collected during the focus-groups and/or face-to-face interview will be for research will be kept confidential. You will be asked about your experience with the program.

Summary

All men in the study will be asked to join a six-month comprehensive home-based Patient Empowerment Program for patients with Prostate Cancer (PC-PEP) aimed at educating and teaching the men life skills/habits in order to improve their mental health issues, fitness levels and overall quality of life, and to decrease treatment related side effects. The program also aims to improve the overall health of the participants in the long term. All men will go through their usual medical care appointments throughout the duration of the study.

Schedule of Participant Activities for the Prostate Cancer Patient Empowerment Program (PC-PEP)

Participant Activities	**Before Starting the Study**	**At Home Program For first 6 months**			**6-24 month**
		Weekly	**Daily**	**Monthly**	
Phone call with Research Coordinator	√				
Phone call with Study Physician if you have advanced prostate cancer	√				
Informed consent form	√				
Online questionnaires	√				At Month 0, 6, 12, 24
Watch Educational videos	√				
Zoom meet with Research Coordinator to set up the biofeedback monitor	√				
Watch video/read email			√		
Aerobic exercise		4-5/week	30 minutes		
Strength training		2 / week	30 minutes		
Kegels exercises		7 / week	30 minutes		
Relaxation Technique with biofeedback		7 / week	10 minutes		
Contacting 2 other study participants (optional)		1 time			
Weekly adherence surveys		1 time			
Fun or social activity		1 time			
Monthly strength training survey				1 time	
Monthly videoconference/teleconference (optional)				1 time	
Focus group					Optional

8. Are there risks to the study?

There are risks with this, or any study. To give you the most complete information available, we have listed many *possible* risks, which may appear alarming. We do not want to upset you, but we do want to make sure that if you decide to participate in the study that you have had a chance to carefully think about the risks. Please also be aware that there may be risks in participating in this study that we do not know about yet.

Many studies on exercise have reported some common side-effects that might be related to increasing your activity level. These side-effects may include mild tiredness, shortness of breath, increased body temperature, and sore or stiff muscles. These symptoms will depend on your fitness before starting the study. For example, someone who has not exercised in a long time, will most likely have more muscle stiffness at the beginning of the program than at the end. We encourage you to listen to your body and not push it too hard, especially when starting a new exercise program. If you experience any problems or have questions about soreness or injury, we will encourage you to call your doctor or our research team. Contact information for our team members are listed below.

If you have been told that you are at "high risk" of experiencing medical problems (e.g., heart attack) as a result of your cancer treatment or any other health condition, you may be asked to do more medical tests (e.g., stress test to assess your heart health). If you have been told that you are a "high risk" participant, you will need approval from a Cardiologist or Family Physician to take part in the study. In this situation, booking an appointment with a Cardiologist or Family Physician (or any extra test they may require) in order for them to determine your suitability to participate in this study will be your responsibility.

You will be asked to complete four surveys (just before you start, and months 6, 12 and 24) and possibly be a part of a group discussion (at the end of the six-month active part of the study). These surveys will ask you questions about your lifestyle habits, symptoms related to cancer, and quality of life. The focus group will ask you about your opinion and experiences about the six-month program. This group discussion will be recorded on audio tape. If you are uncomfortable in answering any of these questions you can leave them blank, refuse to answer, or you are free to withdraw from the study at any time without penalty.

You may feel some of the questions on the questionnaires may put you at psychological and/or emotional risks such as anxiety, distress, embarrassment, or feelings of sadness that may arise from questionnaires and interviews about sensitive issues. You may find the interviews and questionnaires you receive during the course of the study upsetting or distressing. You may not like all of the questions that you will be asked. You do not have to answer those questions you find too distressing.

It is possible for you to maintain full identification confidentiality from other study participants if you choose to not participate in the "buddy" program and if you choose not to participate in the focus groups or face-to-face interviews. If you choose to participate in any or all of these aspects of the program you could maintain partial confidentiality from other study participants by identifying yourself with your research participant number, instead of your own name.

During this study we will be sending you daily reminders to perform the Kegel exercises via text using an NSHA mobile phone. No personal health information will be sent to you via text messaging. During the study we will also send information regarding the next day's program schedule. No personal health information will be sent to you via email messaging. The subject of the email will be PC-PEP Day _x_ (x= day 1 to day 180 of the program) and will come from the PI's, Clinical Lead (Dr. Rob Rutledge's) or the Research Coordinator's NSHA email address.

Email communication sent from an nshealth.ca email account to another nshealth.ca email account is secure as it travels within the internal nshealth.ca firewall.

You must be aware that Texting contains the added risk of confusion or misinterpretation as it is an informal, short-hand form of communication. Certain E-Messaging mediums such as email and text, carry the risk of a breach of privacy, as confidentiality and security cannot be assured. Unauthorized individuals may be able to access, read, and possibly modify messages that are sent to or from NSHA. In addition, there are risks associated with possible delays in the receipt of the information sent.

The emails you will receive during this study contain the following disclaimer: "This email message may contain confidential information and is intended only for the individual named. If you are not the named addressee you should not disseminate, distribute or copy this email. Please notify the sender immediately by email if you have received this email by mistake and delete this email from your system. Email transmissions cannot be guaranteed to be secure or error free as information could be intercepted, corrupted, lost, destroyed, arrive late or incomplete, or contain viruses. The sender therefore does not accept any liability for errors or omissions in the contents of this message that arise as a result of email transmissions. If verification is required, please request a hard copy version." Your email address will be listed "BCC" (blind carbon copy) and will not be accessible to other participants in the study.

You are encouraged to contact the Research team via email or telephone if you experience any unexpected adverse effects. These may include, but are not limited to, exercise induced mental stress or disease progression.

If you experience unanticipated health events beyond the symptoms previously described, we ask that you contact the study investigators and notify us of these changes immediately. Examples of an unanticipated health events may be, but are not limited to, a heart attack or a broken bone.

9. Are there benefits of participating in this study?

You may or may not benefit directly from participating in this study. However, possible benefits include improved fitness levels, energy, sleep quality, urinary continence, quality of life and overall well-being. Your participation may or may not help other people with cancer in the future.

10. What happens at the end of the study?

If you would like a summary of the results, please notify the research team and a summary will be emailed to you upon completion of the study. Should you be interested in continuing with an

exercise or activity program please speak to a member of the study team that will tell you about opportunities to continue with a maintenance program or other programming in your area.

11. Are There Other Choices?

If you decide not to participate in this study, other choices may be available. Contact your physician or health care provider to inquire about similar programs in your community. You may seek help for incontinence issues through a physiotherapist trained to provide pelvic floor training. You may seek fitness advice through a gym in the community that you live in. You may seek meditation or mindfulness, and/or dietary training/advice in your community through services provided by private providers. You may seek connection and intimacy advice and council through a private councilor in your community. You are free to seek other opinions or choices in other hospitals or cities if you wish.

12. What are my responsibilities?

As a study participant you will be expected to:

- Answer the questions about safety to exercise / do strength training honestly
- Follow the directions of the research team in a way that feels comfortable to you;
- Report any changes in your health or treatment to the research team;
- Report any problems that you experience that you think might be related to participating in the study.

13. Can my participation in this study end early?

The Nova Scotia Health Authority (NSHA) Research Ethics Board (REB) and the principal investigators have the right to stop patient recruitment or cancel the study at any time.

The principal investigators may decide to remove you from this study without your consent for any of the following reasons:

- You do not closely enough follow the directions of the research team;
- You are experiencing side-effects that are harmful to your health or well-being; and/or
- There is new information that shows that being in this study is not in your best interests.

If you are withdrawn from this study, a member of the research team will discuss the reasons with you.

You can also choose to end your participation at any time. If you choose to withdraw from this study by informing the research team, your decision will have no effect on your current or future medical treatment and healthcare.

If you withdraw your consent, the information about you that was collected before you left the study will still be used. No new information about you will be collected without your permission.

14. What about new information?

It is possible that new information may become available while you are in the study about side-effects or a new treatment for your condition. You will be told about any other new information that might affect your health, welfare, or willingness to stay in the study and will be asked whether you wish to continue taking part in the study or not.

15. Will it cost me anything?

Compensation

You will not be compensated for participating in this study.

Research Related Injury

If you become ill or injured as a direct result of participating in this study, necessary medical treatment will be available at no additional cost to you. Your signature on this form only indicates that you have understood to your satisfaction the information regarding your participation in the study and agree to participate in the study. In no way does this waive your legal rights nor release the principal investigators, the research team, or involved institutions from their legal and professional responsibilities.

16. What about my privacy and confidentiality?

Protecting your privacy is an important part of this study and every effort to protect your privacy will be made. However, complete privacy cannot be guaranteed. For example, the principal investigators may be required by law to allow access to your research records.

If the results of this study are presented to the public, nobody will be able to tell that you were in the study.

If you decide to participate in this study, the research team will collect *personal health information* from you and your health record. The research team will collect and use only the information they need for this study and to judge the safety and usefulness of the exercise intervention.

"Personal health information" is health information about you that could identify you because it includes information such as your;

- Name;
- Telephone number;
- Age or month/year of birth (MM/YY);
- Provincial Health Card Number;
- Information from the study interviews and questionnaires;
- New and existing medical records; and/or
- The types, dates and results of various tests and procedures.

If you decide to take part in this study, you will be asked to participate in activities that involve a group of people (buddy system, focus group and/or face-to-face interviews). These activities are

optional, and you may choose not to participate in them. For example, you will be asked to call two other men who are also taking part in the study and check in on how they are doing with their exercises (buddy system is optional). You will also be asked to take part in a group discussion at the end of the study (focus group and/or face-to-face interviews are optional). Participants in the study will be given guidelines and tips on how to form social connections and how to protect confidentiality during these activities. Participants will be asked to keep any information or stories shared during these activities private/confidential/to themselves (not to share with others).

Access to Records

Other people may need to look at your personal health information to check that the information collected for the study is correct and to make sure the study followed the required laws and guidelines. These people might include:

- The NSHA REB and people working for or with the NSHA REB because they oversee the ethical conduct of research studies within the NSHA;

These people will view your study records at this institution and will not take identifying information away with them.

Use of Your Study Information

No study data about you will be sent outside of the NSHA.

The research team and the other people listed above will keep the information they see or receive about you confidential, to the extent permitted by applicable laws. Even though the risk of identifying you from the study data is very small, it can never be completely eliminated.

The research team will keep any personal health information about you in a secure and confidential location for 7 years and then destroy it according to NSHA policy. Your personal health information will not be shared with others without your permission.

After your part in the study ends, we may continue to review your health records for safety and data accuracy until the study is finished or you withdraw your consent.

The REB and people working for or with the REB may also contact you personally for quality assurance purposes.

Your Access to Records

You have the right to access, review, and request changes to your study data at any time.

A description of this clinical trial will be available on *http://www.ClinicalTrials.gov*. This website will not include information that can identify you. At most, the website will include a summary of the results. You can search this website at any time.

17. Declaration of financial interest

This study is funded by the following:

- Research Nova Scotia Corporation
- Dalhousie Medical Research Foundation
- Department of Radiation Oncology, Dalhousie University
- Department of Urology, Dalhousie University

The principal investigator has no vested financial interest in conducting this study.

18. What about questions or problems?

For further information about the study you may call the principal investigator who is the person in charge of this study and/or any other research team member listed below.

Gabriella Ilie *Principal Investigator*	Telephone: 902 494-4527	Email: Gabriella.Ilie@dal.ca
Rob Rutledge *Clinical Lead / Sub-Investigator*	Telephone: 902-473-6185	Email: Rob.Rutledge@nshealth.ca
Cody MacDonald *Research Coordinator*	Telephone: 902-473-7727	Email: Cody.MacDonald@nshealth.ca
Jeff Zahavich *Certified Exercise Physiologist*	Telephone: 902-473-2035	Email: Zahavich@dal.ca

If you experience any symptoms or possible side-effects or other medical problems, please let the principal investigator (Dr. Gabriela Ilie), the Clinical Lead (Dr. Rob Rutledge) or the study's Research Coordinator know as soon as possible.

In the event of a medical emergency, please contact Emergency Health Services (911). Please call the principal investigator (Dr. Gabriela Ilie), or the Clinical Lead (Dr. Rob Rutledge) or the study's Research Coordinator the next business day to tell them about the possible side-effects or other medical problems you experienced.

19. What are my rights?

You have the right to all information that could help you make a decision about participating in this study. You also have the right to ask questions about this study and your rights as a research participant, and to have them answered to your satisfaction before you make any decision. You also have the right to ask questions and to receive answers throughout this study. You have the right to withdraw your consent at any time.

If you have questions about your rights as a research participant, and/or concerns or complaints about this research study, you can contact the Nova Scotia Health Authority Research Ethics Board manager at 902-473-8426 or Patient Relations at (902) 473-2133 or 1-855-799-0990 or healthcareexperience@nshealth.ca.

20. Consent Form Signature Page

I have reviewed all of the information in this consent form related to the study called:

PC-PEP Phase 4: Predictors of Mental Health for Men with Prostate Cancer undergoing a Patient Empowerment Program (PC-PEP)

I have been given the opportunity to discuss this study and all of my questions have been answered to my satisfaction. I authorize access to my personal health information, and research study data as explained in this form.
By checking the checkbox on this consent form, I agree to take part in this study. I understand that I am free to withdraw at any time without affecting my future medical care.

You do NOT have to agree to have your contact information shared with other participants to still participate in the other components of this study.

☐ I **AGREE** to have my contact information shared with other participants in this study and I agree to keep the contact information of other participants that I receive confidential, as described in this consent form.

☐ I **DO NOT AGREE** to have my contact information shared with other participants as described in this consent form.

☐ I **AGREE** to audio recordings as described in this consent form.

☐ I **DO NOT AGREE** to audio recordings as described in this consent form.

☐ I **AGREE** with participating in this study and the conditions as outlined here in this consent.

☐ I **DO NOT AGREE** with participating in this study and the conditions as outlined here in this consent.

E-messaging (email and texting) can be used by a member or members of the research team to communicate with you while you are in this study. All communication done with you will be done only through a NSHA Webmail account, or text by a phone issued to a research member through NSHA. All efforts are made to keep information sent or received private, but it is possible other people may be able to see, read, and change messages sent to or from NSHA.

☐ I give my permission to be contacted by a member or members of the research team from an NSHA Webmail account or an NSHA cell phone by research staff to communicate during this study. _____ (initials and date).

Email	yes ☐	no ☐
Text message	yes ☐	no ☐

☐ I do not wish to be contacted by email or text message, unless I otherwise give permission at another time during this study _____ (initial and date).

☐ Not applicable.

_____	_____	____ / ____ / ____
Signature of Participant	Name (Printed)	Year Month Day*
_____	_____	____ / ____ / ____
Signature of Person Conducting Consent Discussion	Name (Printed)	Year Month Day*
_____	_____	____ / ____ / ____
Signature of Principal Investigator	Name (Printed)	Year Month Day*

**Note: Please fill in the dates personally*

An electronic copy of this consent form will be sent to your email from an NSHA email account with the subject line: PC-PEP Informed Consent Form. Please review the risks associated with email communication in the Section 8, above.

Thank you for your time and patience!