NYU Winthrop Hospital

INFORMED CONSENT/AUTHORIZATION FORM

Research Study Title: A pilot study of prostate cancer-specific anxiety in active surveillance
Name of Principal Investigator: Aaron Pinkhasov, MD
Name of Sub-Investigator(s): Carole Filangieri, PhD; Aaron Katz, MD; Deepan Singh, MD; Glenn Werneburg, PhD.
Name of Biostatistician: Melissa Fazzari, PhD
Name of Research Coordinator: Kaitlin Kosinski, MS; Amanda LeSueur, PhD
Name of Research Analyst: Daniel Halpern

Introduction:
You are being asked to participate in a research study. A research study is designed to answer specific questions. This consent/authorization form gives you detailed information about this research study. This information will help you decide if you would like to participate. It is important that you read about and understand the study and the procedures it involves. The investigator will explain the project to you in detail.

Before agreeing to participate in this research study, it is important that you read this consent/authorization form. It describes the purpose, procedures and the possible benefits and risks of the study. It also describes your right to withdraw from the study at any time. Please take your time to make your decision. You may want to discuss your decision with your family and friends. If you decide to participate, you will receive a signed and dated copy of this form to keep for your records.

This research study is sponsored by the Department of Behavioral Health and Department of Urology at Winthrop University Hospital.

Background and Purpose of this Study
The purpose of this study is to determine if treating disease-related anxiety improves quality of life and delays radical elective treatment of prostate cancer. We will also be monitoring symptom progression and remission during and after treatment. Approximately 48 patients from Winthrop University Hospital are expected to take part in this study.

Duration of Study
The active portion of this research study is expected to take approximately 12 weeks. You will be followed for up to two years.

Study Procedures
If you decide to take part in this study you will be asked to complete three validated questionnaires which will ask you questions about your anxiety surrounding your diagnosis of prostate cancer, your feelings of anxiety in general and your ability to function in your day to day activities. The questionnaires should take approximately 5-10 minutes to complete. After you complete these questionnaires, the investigator will determine if you are eligible to participate in this study. If you are eligible to participate, you will be randomly assigned to either attend 12 once-weekly 1 hour group therapy sessions with a licensed

psychologist, or not. Whether you are assigned or not assigned to weekly group sessions, you will follow up with your Urologist as directed.

Possible Risks or Discomforts Involved
Your participation in this study may involve risks. The potential risks of this study are discomfort with answering some of the questions in the questionnaires regarding your feelings of anxiety or your urinary symptoms. You do not have to answer all of the questions if you are not comfortable, but it may impact your eligibility to participate in the study. There is the potential for accidental disclosure of your personal health information, but this risk is very low, as all information is stored in a locked computer with restricted access.

If you are having thoughts about harming yourself or others at any time, please call and notify your doctor or call 911 immediately.

Benefits
It is unknown whether you will receive any benefits from participating in this study. It is our aim to reduce any anxiety related to your prostate cancer diagnosis, and if you are assigned to the group therapy, you may receive some benefit in reducing your feelings of anxiety or worry.

Alternatives
You may choose to not participate in this research study. If you wish to seek treatment for any feelings of anxiety related to your prostate cancer diagnosis, you should speak with your Urologist, or one of the other study doctors, and they may provide a referral for you to speak with a mental health care professional separate from this study.

Confidentiality
This section of the consent form describes how your information in this research study will be used, shared and safeguarded in relation to this study. Your information will only be used in accordance with this authorization/informed consent form and as required or allowed by law. Please read it carefully before signing it.

Authorization to Use Your Health Information for Research Purposes

The federal privacy regulations, Health Insurance Portability and Accountability Act (HIPAA) requires that we get your permission to use personal identifiable health information about you that is either created by or used in connection with this research study. This permission is called an Authorization. The personal identifiable health information (PHI) we will use includes the entire research record and supporting information from your medical records, results of laboratory tests, and both clinical and research observations made during your participation in the research.

What Personal Information Will Be Used or Disclosed?

Your identity will be kept as confidential as possible as required by law. Except as required by law, you will not be identified by name, social security number, address, telephone number, or any other direct identifier.

Who May Use or Disclose the Information?

Your research records may be disclosed outside of Winthrop University Hospital, but in this case, you will be identified only by a unique code number. Information about the code will be kept in a secure location and access limited to only research study personnel. However, the Department of Behavioral Health or Department

of Urology may further release information resulting from this study. Please be aware that once your protected health information is disclosed to a person or organization that is not covered by the federal medical Privacy Rule (HIPPA), the information is no longer protected by the Privacy Rule and may be subject to re-disclosure.

The results of this research study may be presented at scientific or medical meetings or published in scientific journals. However, your identity will not be disclosed**.**

Who May Receive or Use the Information?

Organizations that may request to inspect and/or copy your research and medical records for quality assurance and data analysis include groups such as: The Food and Drug Administration (FDA), the Department of Health and Human Services (HHS), regulatory agencies in other countries, and to Winthrop University Hospital.

If information about your participation in this study is stored in a computer, we will take the following precautions to protect it from unauthorized disclosure, tampering, or damage: all study information is stored on a password protected computer which is connected to a protected network. Access to the folder where study information is stored is restricted to research personnel only.

Will access to my medical record be limited during the study?

While the study is ongoing, the Investigator or Winthrop University Hospital may refuse to permit you to access your personal identifiable health information obtained in the course of the study. However, you will have access to this health information following the completion of this study.

If I sign, can I revoke it or withdraw from the research later?

If you decide to participate in this study, your Authorization allowing us to use and disclose your identifiable health information will expire at the end of the research study, unless you withdraw your authorization sooner. You always have the right to withdraw your Authorization by putting your request in writing to Dr. Aaron Pinkhasov as stated below in the ***"Voluntary Participation and Withdrawal from Study"*** section of this form. If you withdraw your Authorization, you will also be removed from the study, but you will continue to receive any standard medical care and any other benefits to which you would normally receive as a patient at Winthrop University Hospital. However, if you do not send us this request in writing we may continue to use your personal identifiable health information that was collected up until your withdrawal from the research study to maintain the integrity of the study.

Significant New Findings
Any new findings discovered during this research study that may affect your decision to continue to take part in this study will be shared with you by your study doctor as such information becomes available. At times, you may even be asked to sign another informed consent document.

Research-Related Injury

If as a result of your participation you experience physical injury from known or unknown risks of the research procedures as described, immediate medical care and treatment, including hospitalization, if necessary, will be available. No funds have been set aside for compensation; therefore you will be responsible for the costs of such medical treatment, either, directly or through your medical insurance and/or other forms of medical coverage.

Additional Costs and/or Payments

There will be no cost to you for participating in this study, whether you attend the group therapy sessions or not, other than the personal time it takes to attend the group sessions. All medical costs related to your treatment of prostate cancer are your responsibility, and will be paid for by yourself or your medical insurance.

Voluntary Participation and Withdrawal from Study

Your participation in this study is voluntary. You may refuse to participate or you may withdraw from the study at any time during the duration of the study without penalty or loss of any care and without affecting your future medical care at Winthrop University Hospital.

You have the right to refuse to sign this Authorization/Consent form and refuse to take part in this research study. If you choose not to authorize the use and disclosure of your personal identifiable health information (PHI) or to take part in this research study, any standard medical care and any other benefits which you would normally receive as a patient at Winthrop University Hospital will not be affected.

If you withdraw from participating in this study, you may also want to withdraw your authorization for us to use your personal identifiable health information. If you do decide to withdraw, we ask that you contact **Dr. Aaron Pinkhasov** in writing and let him know that you are withdrawing your authorization for the use and disclosure of your identifiable health information. Dr.Pinkhasov's mailing address is

Department of Behavioral Health

Winthrop University Hospital

222 Station Plaza North, Suite 350A

Mineola, NY 11501

However, even after you have requested that we no longer use your personal identifiable health information, we may have to continue to use the information that has been collected prior to your withdrawal in order to ensure the research study can be completed as necessary. We are unable to take back anything we have already done or any information we have already shared with your permission.

We may continue using and sharing the information obtained prior to your withdrawal if it is necessary for the soundness of the overall research.

Should it be decided that it is not in the best interest of the study or your health to continue in this study or if you have been unable to follow the study doctor's instructions, your participation in this study may be terminated by the sponsor or the study doctor. At that time we may ask your permission to continue using any identifiable health information that has already been collected as part of the study prior to your withdrawal. However, as stated earlier, we may continue to use the information that has been collected prior to your withdrawal in order to ensure the research study can be completed as necessary.

The following reason may be given as reasons to end your participation in this study:

- If you develop a side effect or medical condition that may place you at risk of further complications by continuing your participation or if you need a medicine not allowed on this study;

Patient Initials:_____

- If you are unable to perform required procedures as instructed;
- If you are unable to keep your scheduled appointments;
- If the study is cancelled by the sponsor or by the FDA;
- For other administrative reasons

It is important that you remember to send your request to withdraw your authorization for us to use your individually identifiable health information in writing to **Dr. Aaron Pinkhasov**. If you do not send us this request in writing we may continue to use your identifiable health information that was collected up until your withdrawal from the research study.

Contact Information
If you have any questions or concerns about this study or experience any medical problems, you may contact **Dr. Pinkhasov** or one of his associates at 516-663-2691. If you need assistance outside of normal office hours you can call (516) 663-0333 and ask the operator to contact the Behavioral Health Physician on call.

If you have any concerns, complaints or questions about your rights as a research participant, or any other matter related to your participation in this project, you may call Winthrop University Hospital's administrative office of the Institutional Review Board Committee (IRB) at (516) 663-2552. The IRB is a committee required by federal regulations and New York State law. It is an independent committee comprised of Winthrop University Hospital's physicians and staff, as well as lay members of the community not affiliated with the institution. The IRB reviews all proposed research involving human subjects before any study may begin at Winthrop University Hospital.

If you have any questions or concerns that you feel you would like to discuss with someone who is not on the research team, you may also call the Director of Patient Relations at Winthrop University Hospital (516) 663-2058.

Consent to Participate
You have read this page and the preceding ***5*** pages of this consent form. In addition, the study doctor has explained to you the procedures in this study and the potential risks and side effects. You have been given the opportunity to ask questions about this study. You are aware that if you decide not to participate or to withdraw your consent, this will not affect any further treatment at this study site or any treatment by the study doctor. You voluntarily consent to participate in this study. You will receive a copy of this signed and dated consent form. You have not waived any of your legal rights by signing this consent form.

A description of this clinical trial will be available on **www.clinicaltrials.gov**, as required by US Law. 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.

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Participant's Signature	Printed Name	Date
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Printed Name of Investigator Conducting Consent Discussion		Date
_____		_____
Signature of Investigator Conducting Consent Discussion		Date
_____		_____
Printed Name of Person who obtained consent signature (If different from above)		Date
_____		_____
Signature of Person who obtained consent signature (If different from above)		Date