THE UNIVERSITY OF TEXAS
MD Anderson Cancer Center

Informed Consent

INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH

CONTEMPORARY CHARACTERISTICS OF PENILE CARCINOMA: AT M.D. ANDERSON CANCER CENTER, HARRIS HEALTH SYSTEM AND AT THE M.D. ANDERSON HOUSTON AREA LOCATIONS IN KATY, SUGAR LAND, THE WOODLANDS AND BAY AREA PCR04-0148

Subtitle: MD Anderson, Harris Health System and MD Anderson Houston Area Locations in Katy, Sugarland, The Woodlands and Bay Area - Management of Penile Carcinoma

Study Chair: Curtis A. Pettaway

MD Anderson and Harris Health System Informed Consent

Protocol Number:
Approval Date:
Expiration Date:
(Harris Health System)

Researcher at the Harris Health System: **Steven Canfield, MD**

Researcher at MD Anderson Houston Area Locations: **John Papadapoulos, MD**

Researcher at MD Anderson: **Curtis A. Pettaway**

_____ _____
Participant's Name Medical Record Number

This is an informed consent and authorization form for a research study. It includes a summary about the study. A more detailed description of procedures and risks is provided after the summary.

This research has been reviewed and approved by an Institutional Review Board (IRB - a committee that reviews research studies).

STUDY SUMMARY

The goal of this informational research study is to collect new and ongoing data on the symptoms, features, management, and outcome of patients with penile carcinoma at MD Anderson, Harris Health System and at the MD Anderson Houston Area Locations in Katy, Sugar Land, The Woodlands, and Bay Area.

This study is investigational.

Future patients may benefit from what is learned. There may be no benefits for you in this study.

Your participation is completely voluntary. Before choosing to take part in this study, you should discuss with the study team any concerns you may have, including potential expenses and time commitment. If you take part in this study, you may be uncomfortable due to the sensitive nature of the data being collected, as well as the possible loss of privacy.

You can read a list of potential risks below in the Possible Risks section of this consent.

You will still be able to receive treatment for your penile carcinoma without taking part in this database study.

These procedures will be performed at no cost to you.

You may choose not to take part in this study. You will still be able to receive treatment for your penile carcinoma without taking part in this database study. The study doctor can talk to you about the risks and benefits of standard of care treatment and participating in this research study.

1. STUDY DETAILS

While carcinoma of the penis accounts for less than 1% of cancers among American males, occurring in only 1 out of every 100,000 males each year, it continues to be a serious health problem in underdeveloped countries around the world. In some areas of Africa and South America, it may make up as much as 20% of all cancers in men and up to 40% of all tumors of the genitals and/or urinary system, for patients in this group. Because of the rarity of this disease in the United States, there is little published information or experience that doctors can use as a basis for treatment.

Extra research is needed to critically look at our experience with the treatment of penile carcinoma. Ongoing study of patients, with careful collection of data, will help researchers create a detailed analysis of features related to the first diagnosis of the

disease that can help to predict how it should be treated. Also, researchers will continue to learn how useful the information already known about predicting treatment response is.

You will be asked to complete 2 questionnaires (the American Urological Association [AUA] BPH Symptom Score Index and the Index of Erectile Function [IIEF-5]), which include questions about urinary and erectile function. You will fill out these questionnaires one time, at the beginning of the study. They will take about 5-10 minutes to complete.

Researchers will collect data from your medical records every 6 months for 15 years to review your treatment and response history. This data will be compiled to gather information about disease treatment and response. Your records will be maintained in a confidential database. Your data will be given a code number. Only the study chair and his immediate staff will have access to your records. No identifying information will be directly linked to your data. Only the researcher in charge of the database will have access to the code numbers and be able to link the data to you. This is to allow medical information related to your data to be updated as needed. Other researchers using your data will not be able to link this data to you.

Up to 1,000 patients will take part in this study. Up to 800 will be enrolled at MD Anderson and the MD Anderson Houston area locations. Up to 200 will be enrolled at the Harris Health System.

2. POSSIBLE RISKS

While on this study, you are at risk for side effects. You should discuss these with the study doctor. The known side effects are listed in this form, but they will vary from person to person.

Some questions in the **questionnaires** may be sensitive in nature. You may refuse to answer any question that makes you feel uncomfortable. If you have concerns after completing the questionnaires, you are encouraged to contact your doctor or the study chair.

MD Anderson and others can learn about cancer and other diseases from your **banked data**. MD Anderson will not be able to give you, your family, or your doctor the reports about the research done with your data, and these reports will not be put in your health records. If this information were released to you, your family, or third parties, it could be misused. Such misuse could be distressing, and it could cause you or your family members to have difficulty obtaining insurance coverage and/or a job. In the future, people who may do research with your data may need to know more information about your health. This information may be collected from your medical record. MD Anderson will make reasonable efforts to preserve your privacy, but cannot ensure complete privacy. Sometimes your data may be used for genetic research about diseases that are passed on in families. If your data were used for this kind of research, the results would not be put in your health records.

If you withdraw your consent to the storage of your data in the research database, then the leftover data will no longer be collected for storage. Any of your data that remains in the research database will no longer be used for research and will be deleted from the research database.

However, if any of your de-identified data was already released for research purposes before you withdrew consent, MD Anderson will not be able to delete it.

Although every effort will be made to keep study data safe, there is a chance that your personal health information could be lost or stolen, which may result in a **loss of confidentiality**. All study data will be stored in password-protected computers and/or locked file cabinets during the study and will continue to be stored securely after the study. Only authorized people who are working on this study will have access to study data.

This study may involve unpredictable risks to the participants.

3. COSTS AND COMPENSATION

Payment for Injury for Harris Health System participants: In the event of injury resulting from this research, MD Anderson and/or the Harris Health System are not able to offer financial compensation nor to absorb the costs of medical treatment. However, necessary facilities, emergency treatment, and professional services will be available to you, just as they are to the general community. You should report any injury to Dr. Steven Canfield, MD at 713-500-7337 and to the MD Anderson IRB at 713-792-6477. You may also contact the Chair of MD Anderson's IRB at 713-792-2933 with questions about study-related injuries. By signing this consent form, you are not giving up any of your legal rights.

Payment for Injury for MD Anderson participants
If you suffer injury as a direct result of taking part in this study, MD Anderson health providers will provide medical care. However, this medical care will be billed to your insurance provider or you in the ordinary manner. You will not be reimbursed for expenses or compensated financially by MD Anderson for this injury. You may also contact the Chair of MD Anderson's IRB at 713-792-6477 with questions about study-related injuries. By signing this consent form, you are not giving up any of your legal rights

There are no plans to compensate you for any patents or discoveries that may result from your participation in this research.

You will receive no compensation for taking part in this study.

Additional Information

4. You may ask the researchers (Dr. Steven Canfield, MD, at 713-500-7337, or Dr. Curtis A. Pettaway, at 713-792-3250) any questions you have about this study. You may also contact the Chair of MD Anderson's Institutional Review Board (IRB - a committee that reviews research studies) at 713-792-6477 with any questions that have to do with this study or your rights as a study participant.

5. You may choose not to take part in this study without any penalty or loss of benefits to which you are otherwise entitled. If you decide you want to stop taking part in the study, it is recommended for your safety that you first talk to your doctor. If you withdraw from this study, you can still choose to be treated at MD Anderson and the Harris Health System. If you withdraw from the study, the study staff may ask if they can continue collecting the results of routine care from your medical record.

6. This study or your participation in it may be changed or stopped at any time by the researcher or the IRB of MD Anderson.

7. MD Anderson and the Harris Health System may benefit from your participation and/or what is learned in this study.

Future Research

Your personal information is being collected as part of this study. This information, or data, may be used by researchers at MD Anderson or shared with other researchers and/or institutions for use in future research. **Allowing research to be stored for future research is a required part of this study.**

Before being shared for future research, every effort will be made to remove your identifying information from any data. If all identifying information is removed, you will not be asked for additional permission before future research is performed.

In some cases, all of your identifying information may not be removed before your data are used for future research. If this research is performed at MD Anderson, the researchers must get approval from the Institutional Review Board (IRB) of MD Anderson before your data can be used. At that time, the IRB will decide whether or not further permission from you is required. The IRB is a committee of doctors, researchers, and community members that is responsible for protecting study participants and making sure all research is safe and ethical.

If this research is not performed at MD Anderson, MD Anderson will not have oversight of any data.

Authorization for Use and Disclosure of Protected Health Information (PHI):

A. During the course of this study, MD Anderson and the Harris Health System may be collecting and using PHI, including identifying information, information from your

medical record, and study results. For legal, ethical, research, and safety related reasons, your doctor and the research team may share your PHI with:

- Federal agencies that require reporting of clinical study data (such as the FDA, National Cancer Institute [NCI], and OHRP)
- The IRB and officials of MD Anderson
- Officials at the Harris Health System and the Harris Health System Research and Sponsored Programs Department
- Study monitors and auditors who verify the accuracy of the information
- Individuals who put all the study information together in report form

Study sponsors and/or supporters receive limited amounts of PHI. They may also view additional PHI in study records during the monitoring process. MD Anderson's contracts require sponsors/supporters to protect this information and limit how they may use it.

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

B. Signing this consent and authorization form is optional but you cannot take part in this study if you do not agree and sign.

C. MD Anderson and the Harris Health System will keep your PHI confidential when possible (according to state and federal law). However, in some situations, the FDA could be required to reveal the names of participants.

Once disclosed outside of MD Anderson and the Harris Health System, federal privacy laws may no longer protect your PHI.

D. The permission to use your PHI will continue indefinitely unless you withdraw your authorization by sending or faxing your request. For MD Anderson participants, instructions on how to do this can be found in the MD Anderson Notice of Privacy Practices (NPP). You may contact the Chief Privacy Officer of MD Anderson at 713-745-6636 with questions about how to find the NPP. For Harris Health participants, send or fax your request in writing to:

Steven Canfield, MD
Department: Urology
5656 Kelley Street
Houston, Texas 77026
Phone: 713) 500-7337
Fax: (713) 500-7319

If you withdraw your authorization, you will be removed from the study and the data collected about you up to that point can be used and included in data analysis. However, no further information about you will be collected.

CONSENT/AUTHORIZATION

I understand the information in this consent form. I have had a chance to read the consent form for this study, or have had it read to me. I have had a chance to think about it, ask questions, and talk about it with others as needed. I give the study chair permission to enroll me on this study. By signing this consent form, I am not giving up any of my legal rights. I will be given a signed copy of this consent document.

_____ _____
SIGNATURE OF PARTICIPANT DATE

_____
PRINTED NAME OF PARTICIPANT

LEGALLY AUTHORIZED REPRESENTATIVE (LAR)

The following signature line should only be filled out when the participant does not have the capacity to legally consent to take part in the study and/or sign this document on his or her own behalf.

_____ _____
SIGNATURE OF LAR DATE

_____
PRINTED NAME and RELATIONSHIP TO PARTICIPANT

WITNESS TO CONSENT

I was present during the explanation of the research to be performed under this protocol.

_____ _____
SIGNATURE OF WITNESS TO THE VERBAL CONSENT PRESENTATION (OTHER THAN PHYSICIAN OR STUDY CHAIR) DATE

A witness signature is only required for non-English speakers utilizing the short form consent process (VTPS) and patients who are illiterate.

_____
PRINTED NAME OF WITNESS TO THE VERBAL CONSENT

PERSON OBTAINING CONSENT

I have discussed this research study with the participant and/or his or her authorized representative, using language that is understandable and appropriate. I believe that I have fully informed this participant of the nature of this study and its possible benefits and risks and that the participant understood this explanation.

_____ _____
PERSON OBTAINING CONSENT DATE

_____
PRINTED NAME OF PERSON OBTAINING CONSENT

TRANSLATOR

I have translated the above informed consent as written (without additions or subtractions) into_____and assisted the people
(Name of Language)
obtaining and providing consent by translating all questions and responses during the consent process for this participant.

_____ _____ _____
NAME OF TRANSLATOR SIGNATURE OF TRANSLATOR DATE

☐ Please check here if the translator was a member of the research team. (If checked, a witness, other than the translator, must sign the witness line.)