VUMC Institutional Review Board
Informed Consent Document for Research

Study Title:	Monitoring Disease Burden and Biology Using Tumor Cell Free DNA in Metastatic Kidney Cancer
Version Date:	03/11/2021
PI:	Scott Haake, MD

Name of participant: _____ Age: _____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a copy of this consent form.

Key Information:
The first section of this document contains some key points that the research team thought you would find important. The study is described in more detail after this section. If you do not understand something, please ask someone.

Key information about this study:
This study seeks to assess whether DNA released by kidney cancer into the blood stream and urine of patients can be used to monitor tumor burden and tumor response to treatment in patients receiving immunotherapy. The results of this study will not directly influence your clinical care. The benefits to science and humankind that might result from this study include learning more about the biology of renal cell cancer and new technologies to monitor tumor response to treatment. One risk of giving samples for this research may be the inadvertent release of your name that could link you to the stored samples and/or the results of the tests run on your samples. To prevent this, these samples will be given a code. Only the study staff will know the code. The name that belongs to the code will be kept in a locked file or in a computer with a password. Only Dr. Scott Haake or the study coordinator will have access to your name. Samples will be obtained during the course of routine clinical care. Therefore, no extra needle sticks or time commitment is required. There will be no costs to you for any of the tests done on your samples. You will not be paid for the use of your samples.

Detailed Information:
The rest of this document includes detailed information about this study (in addition to the information listed above).

You are being asked to take part in this research study because you are receiving an immunotherapy-containing treatment for metastatic kidney cancer. You will be one of up to 180 participants enrolled at Vanderbilt University Medical Center. The purpose of this study is to assess our ability to use DNA released by kidney cancer as a tool to monitor patient response to immunotherapy. We will take tumor

Study Title:	Monitoring Disease Burden and Biology Using Tumor Cell Free DNA in Metastatic Kidney Cancer
Version Date:	03/11/2021
PI:	Scott Haake, MD

DNA we isolate from your blood and urine back to the laboratory, measure changes in the amount of tumor DNA overtime, and correlate these changes with the results of your routine imaging studies. In order to do this analysis, we will collect 20-40 mL of blood in addition to the 20-30 mL that are normally collected for standard of care laboratory evaluation, as well as up to 15 mL of urine.

You do not have to be in this research study. You may choose not to be in this study without changing your healthcare, services, or other rights. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told so that you can decide whether or not you still want to be in this study. Your medical record may contain a note saying you are in a research study and may contain some research information about you. Anyone you authorize to receive your medical record will also get this information.

This study is funded by the Department of Defense (DOD), and the DOD or their representatives will have access to the research records.

Side effects and risks that you can expect if you take part in this study:
There are no expected side effects for taking part in this study because all samples collected for research will be taken when you are having other procedures or tests as part of the regular treatment for your illness. This may take up to an extra 10 minutes of your time for collection. Pain, redness, soreness, bruising, or infection may occur at the needle stick site. Rarely some people faint. The study doctor may put some cream (called EMLA) on your skin to numb the area so you will not feel the needle stick as much. The numbing cream may make your skin or the area have a change in skin color, but this is rare.

Risks that are not known:
A risk to study participation includes loss of confidentiality of private health information. However, all efforts, within reason, will be made to keep your protected health information (PHI) private. PHI is your health information that is, or has been gathered or kept by Vanderbilt as a result of your healthcare. No other expected side effects or unknown risks are expected while taking part in this study because all samples collected for research are being done as standard of care treatment.

Good effects that might result from this study:
The benefits to science and humankind that might result from this study include learning more about the biology of renal cell cancer and new technologies to monitor tumor response to treatment.
The benefits you might get from being in this study are: There is no direct benefit to you from being in this study.

Study Title:	Monitoring Disease Burden and Biology Using Tumor Cell Free DNA in Metastatic Kidney Cancer
Version Date:	03/11/2021
PI:	Scott Haake, MD

Payments for your time spent taking part in this study or expenses:
No payment is being offered to participate in this study.

Costs to you if you take part in this study:
There is no cost to you for taking part in this study.

Who to call for any questions or in case you are injured:
If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact Dr. Scott Haake at (615) 343-3740 (office).

For additional information about giving consent or your rights as a person in this study, to discuss problems, concerns, and questions, or to offer input, please feel free to call the VUMC Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Reasons why the study doctor may take you out of this study:
None

What will happen if you decide to stop being in this study?
If you decide to stop being part of the study, you should tell your study doctor.

Confidentiality:
Patient samples will be labeled by the tissue procurement team at the time of tissue banking. Therefore, laboratory and other personnel will not have access to identifying or clinical information on research samples. Only the primary investigator and study coordinator who are certified HIPAA compliant will have access to linking information between research samples and clinical information. This information will be held on the primary investigator or study coordinator's computer protected by a password.

Vanderbilt may share your information, without identifiers, to others or use it for other research projects not listed in this form. Vanderbilt, Dr. Scott Haake, and his staff will comply with any and all laws regarding the privacy of such information. There are no plans to pay you for the use or transfer of this de-identified information.

Study Title:	Monitoring Disease Burden and Biology Using Tumor Cell Free DNA in Metastatic Kidney Cancer
Version Date:	03/11/2021
PI:	Scott Haake, MD

Disclosures that you consent to in this document are not protected. This includes putting research data in the medical record or sharing research data for this study or future research. Disclosures that you make yourself are also not protected.

Privacy:
Any samples and information about you may be made available to others to use for research. To protect your privacy, we will not release your name. You will not receive any benefit as a result of the tests done on your samples. These tests may help us or other researchers learn more about the causes, risks, treatments, or how to prevent this and other health problems.

Your samples may be used to make new products or tests. These may have value and may be developed and owned by the study staff, Vanderbilt University, Vanderbilt University Medical Center, and/or others. If this happens, there are no plans to provide money to you. The research may include whole genome sequencing.

Study Results:
Information learned from future research with your samples will not be shared with you because the link connecting your limited medical information with the sample will have been broken.

Authorization to Use/Disclose Protected Health Information
What information is being collected, used, or shared?
To do this research, we will need to collect, use, and share your private health information. By signing this document, you agree that your health care providers (including both Vanderbilt University Medical Center and others) may release your private health information to us, and that we may use any and all of your information that the study team believes it needs to conduct the study. Your private information may include things learned from the procedures described in this consent form, as well as information from your medical record (which may include information such as HIV status, drug, alcohol or STD treatment, genetic test results, or mental health treatment).

Who will see, use or share the information?
The people who may request, receive or use your private health information include the researchers and their staff. Additionally, we may share your information with other people at Vanderbilt, for example if needed for your clinical care or study oversight. By signing this form, you give permission to the research team to share your information with others outside of Vanderbilt University Medical Center. This may include the sponsor of the study and its agents or contractors, outside providers, study safety monitors, government agencies, other sites in the study, data managers and other agents and

contractors used by the study team. We try to make sure that everyone who sees your information keeps it confidential, but we cannot guarantee that your information will not be shared with others. If your information is disclosed by your health care providers or the research team to others, federal and state confidentiality laws may no longer protect it.

Do you have to sign this Authorization?
You do not have to sign this Authorization, but if you do not, you may not join the study.

How long will your information be used or shared?
Your Authorization for the collection, use, and sharing of your information does not expire. Additionally, you agree that your information may be used for similar or related future research studies.

What if you change your mind?
You may change your mind and cancel this Authorization at any time. If you cancel, you must contact the Principal Investigator in writing to let them know by using the contact information provided in this consent form. Your cancellation will not affect information already collected in the study, or information that has already been shared with others before you cancelled your authorization.

Study Title:	Monitoring Disease Burden and Biology Using Tumor Cell Free DNA in Metastatic Kidney Cancer
Version Date:	03/11/2021
PI:	Scott Haake, MD

If you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

_____ _____
Date Signature of patient/volunteer

Consent obtained by:

_____ _____
Date Signature

_____
Printed Name and Title

Time: _____

Study Title: Monitoring Disease Burden and Biology Using Tumor Cell Free DNA in Metastatic Kidney Cancer
Version Date: 03/11/2021
PI: Scott Haake, MD

Consent for Genetic Research

The purpose of this study is to look at genes (DNA) and how they affect health and disease. Genes are the instruction manual for your body. The genes you get from your parents decide what you look like and how your body behaves. They can also tell us a person's risk for certain diseases and how they will respond to treatment.

You are being asked to give a blood sample for genetic research. What we learn about you from this sample will not be put in your health record. Your test results will not be shared with you or your doctor. No one else (like a relative, boss, or insurance company) will be given your test results.

A blood sample of 2-3 tablespoons will be drawn from a vein in your arm using a needle. This will take about 5 minutes of your time.

Blood samples – You may feel bothered or pained from the needle stick. You may have a bruise or the site may get infected. It is rare, but some people faint. This blood sample will be drawn at the same time as standard of care laboratory testing associated with your treatment.

One risk of giving samples for this research may be the release of your name that could link you to the stored samples and/or the results of the tests run on your samples. This may cause problems with insurance or getting a job.

To prevent this, these samples will be given a code. Only the study staff will know the code. The name that belongs to the code will be kept in a locked file or in a computer with a password. Only Dr. Scott Haake and his study team will have access to your name.

Health insurance companies and group health plans may not use your genetic information when making decisions regarding your eligibility or premiums. Employers with 15 or more employees may not use your genetic information that comes from this research when making a decision to hire, promote, or fire you or when setting the terms of your employment.

Your sample will be used to make DNA that will be kept for an unknown length of time (maybe years) for future research. The sample will be destroyed when it is no longer needed.

Your samples may be used to make new products, tests or findings. These may have value and may be developed and owned by the study staff, Vanderbilt University, Vanderbilt University Medical Center, and/or others. If this happens, there are no plans to provide money to you.

Your samples and information about you may be shared with others to use for research. To protect your privacy, we will not release your name.

You will not receive any benefit as a result of the tests done on your samples. These tests may help us learn more about the causes, risks, treatments, or how to prevent this and other health problems.

Study Title:	Monitoring Disease Burden and Biology Using Tumor Cell Free DNA in Metastatic Kidney Cancer
Version Date:	03/11/2021
PI:	Scott Haake, MD

At any time, you may ask to have your sample destroyed. You should contact Dr. Scott Haake and his study team [office phone: (615) 343-3740; address: 2220 Pierce Ave, 777 PRB, Nashville, TN 37232] to have your sample destroyed and no longer used for research. We will not be able to destroy research data that has already been gathered using your sample. Also, if your identity was removed from the samples, we will not be able to locate and destroy them.

There will be no costs to you for any of the tests done on your samples. You will not be paid for the use of your samples.

Please check Yes or No to the questions below:

My blood/tissue sample may be used for gene research in this study.

☐ Yes ☐ No

My blood/tissue sample may be stored/shared for future cancer gene research.

☐ Yes ☐ No

My blood/tissue sample may be stored/shared for future gene research for other health problems (such as cancer, heart disease, etc).

☐ Yes ☐ No

Signature: _____ Date: _____