Official Title:	ADVANCED DIFFUSION IMAGING IN RENAL CANCER PATIENTS: ONCOLOGIC CONTROL AND RENAL FUNCTIONAL RESERVE
NCT Number:	NCT06116253
Study Number:	s21-01230
Document Type:	Informed Consent Form
Date of the Document:	• August 15, 2025

Research Subject Informed Consent Form

Title of Study:	ADVANCED DIFFUSION IMAGING IN RENAL CANCER PATIENTS: ONCOLOGIC CONTROL AND RENAL FUNCTIONAL RESERVE
Principal Investigator:	Eric Sigmund, PhD NYU Langone Health Department Radiology Research 660 1st Avenue, room 202 New York NY 10016
Emergency Contact:	Hersh Chandarana, MD (212) 263-6246

1. About volunteering for this research study

You are being invited to take part in a research study. Your participation is voluntary which means you can choose whether or not you want to take part in this study.

People who agree to take part in research studies are called “subjects” or “research subjects”. These words are used throughout this consent form. Before you can make your decision, you will need to know what the study is about, the possible risks and benefits of being in this study, and what you will have to do in this study. You may also decide to discuss this study and this form with your family, friends, or doctor. If you have any questions about the study or about this form, please ask us. If you decide to take part in this study, you must sign this form. We will give you a copy of this form signed by you for you to keep.

2. What is the purpose of this study?

The objective of this study is to apply new magnetic resonance imaging (MRI) techniques to patients with renal mass. Specifically, these techniques may show the type of the mass and how much risk it poses to the patient, and also predict whether the rest of the kidney tissue that remains will function normally after the mass is removed. Both of these aspects would be helpful in caring for renal mass patients.

We’re asking you to take part in this study because you have been diagnosed with renal mass and are scheduled for surgery.

3. How long will I be in the study? How many other people will be in the study?

This study will involve two visits over a year. About 90 people will take part in this study.

4. What will I be asked to do in the study?

You will be asked to undergo research procedures that last about 4 hours maximum total at the beginning of the study and again at the end of the study, about a year later. These will be done in addition to any scans you will undergo as part of your standard medical care.

The research procedures include a one-hour MRI scan and a three hours Tc-99m DTPA scan. You may

participate in the MRI and DTPA scans or the MRI scan only.

The DTPA scan, which is performed to measure kidney function, consists of a tracer injection, 8-minute imaging, followed by a few blood samples during a several-hour waiting period. If desired, you can complete the MRI scan and DTPA scans on different days no more than a week apart. The MRI scan will take place at one location and the DTPA scan in another nearby facility. The DTPA scan will begin with an injection of an FDA-approved tracer, followed by a gamma camera scan that will visualize this tracer in your kidneys.

Over the course of 3 hours, you will provide 2 samples (each sample will be 9 ml or less than 2 teaspoons). The total blood drawn over both visits of the study is thus 36 ml or about 8 teaspoons at most. In between these samples you will relax in a provided room.

Following your surgery, a pathologist will perform analysis on the renal mass tissue that was removed from your kidney. In this analysis, the tissue will be stained and analyzed in order to estimate the amount of cells and vessels in the tissue. Additionally, further analysis will be performed on this tissue using a technique known as MRI microimaging, which shows aspects of the tissue in fine detail that can help in interpreting MRI results. These results will be correlated with your MRI results. This analysis will not alter your clinical care nor lead to any additional costs for you.

MRI
Complete an MRI safety screening worksheet which will determine your eligibility for this study.

You will then be taken to a changing room and asked to remove all metal from your body and change into a gown. Please note that metal may be present in yoga pants, running apparel, and sports bras which contain anti-bacterial metallic microfibers. Please only wear the clothing provided to you for your scan.

You will be instructed on how to lie on the MRI imaging table and be provided with an emergency squeeze ball, which will allow you to communicate with the MRI technicians. You will be provided with earplugs and headphones to mitigate the noise of the machine. Leads (sticky pads) connected to your chest by a technologist of your same gender in order to monitor and synchronize some aspects of the MRI to your heartbeat. If you have hair on your chest we may ask if we can shave the small areas so the sticky pads capture your heartbeat clearly. You may be asked to hold your breath for 15 seconds two times during the test.

A flexible coil (device that collects signals from your body) will be placed on your abdomen. This coil is FDA-approved.

When the hardware is in place. The MRI table that you are lying on will be moved into the magnet and the technologist will start the study. You will be monitored throughout your MRI visit by a trained MRI technologist.

Tc-99m DTPA
You will receive an injection of a FDA-approved radiotracer (Tc-99m DTPA) and your kidneys will be scanned for 8 minutes using a gamma camera. After 1 hour, a blood sample will be taken (from the arm not used for the injection). One additional blood samples will be taken 2 hours later for a total of 2 blood samples Most of the time for the DTPA scan will thus be relaxing comfortably between sample collection, and not within any scanner.

Optional DTPA Scan

Please indicate your decision to agree or not to agree to the optional DTPA scan by checking the boxes below with your Initials:

☐ Checking this box indicates that I understand and agree to undergo the Tc-99m DTPA procedure as described above.

_____
Subject Initial

☐ Checking this box indicates that I understand and DO NOT agree to undergo the Tc-99m DTPA procedure as described above.

_____
Subject Initial

5. What are the possible risks or discomforts?

Risks of MRI

Magnetic field risk

MRI uses strong magnetic fields and radiowaves to make images of the inside of your body. MRI does NOT involve high-energy radiation (like x-rays). For most people MRI is very safe. However, if you have anything made of metal on your skin or inside your body, MRI may not be safe for you, and you must tell study personnel before your scan. Also, if you have any electronic devices on the outside or inside of your body, you must tell study personnel about those too. Some things, like tattoos, may have metal materials in them even though you might not realize it. For this reason, study personnel will give you a checklist of things that have metal or electronic parts in them. You must read the list carefully before your scan and put a checkmark next to everything that applies to you.

The following paragraphs will describe the possible risks of MRI. To reduce many of these risks, you will be given an emergency squeeze ball to hold in your hand during the scan. If you feel any discomfort you should squeeze the ball. This sets off an alarm that the technologist can hear. The technologist will then talk to you, and will stop the scan if you want. There is a microphone in the scanner so that you can communicate with the technologist. However, the scanner makes a lot of noise when it is running and the technologist may not always hear what you say. If you need to get the technologist's attention, you should squeeze the ball.

Remember, if at any point you feel uncomfortable and want to stop the scan, just squeeze the ball and tell the technologist.

Risks from metal

The strong magnetic field in the scanner will pull on things that contain certain types of metal. If someone takes a metal object into the scan room, it might fly towards the scanner and hurt you. For this reason, everyone (including you) must remove everything metal from their clothes and pockets before going into the scan room. Also, the door to the scan room will be kept closed during the scan to prevent unauthorized people from walking in.

If you have something metal inside your body, the scanner might pull on it and make it move. You must tell study personnel before your scan if you have anything metal inside your body.
Some types of metal might heat up when the scanner is running. If you feel any burning sensation during the scan, you should squeeze the emergency ball and the technologist will stop the scan.

Risks from electronic devices
If you have any electronic devices on the inside or outside of your body, the scanner might make them stop working properly. For this reason, you must tell study personnel before your scan if you have anything electronic on or in your body.

Burns
Metal is not the only thing that can cause burns in MRI. It's possible (although very rare) to get burned by touching the inside walls of the scanner or by making skin-to-skin contact. The technologist will give you a blanket or cushions so that you don't touch the inside walls of the scanner. You should also avoid letting your hands or legs touch each other. Remember, if you feel any burning sensation during the scan, you should squeeze the emergency ball and the technologist will stop the scan.

Tinnitus (ringing in the ears) and hearing loss
The scanner makes very loud sounds while it is running. You will be given earplugs or headphones to wear during the scan. Make sure you roll the earplugs tightly and let them expand in your ears so that they work properly. If the sound of the scanner is still so loud that it causes you discomfort, squeeze the emergency ball and tell the technologist. This is important because very loud sounds can cause ringing in the ears or even hearing loss.

Feeling warm or hot
The radiowaves used in MRI are like those your cellphone uses, but much stronger. Sometimes they are strong enough to make you feel warm (just like standing in bright sunshine makes you feel warm). MRI scanners are designed to try to avoid you getting too hot. However, if you start to feel uncomfortable, squeeze the emergency ball and tell the technologist.

Peripheral nerve stimulation (tingling or twitching)
The magnetic field inside the scanner changes very quickly while the scanner is running. If it changes too quickly, it can give you tingling sensations or make you twitch. MRI scanners are designed to try to avoid this. However, if you experience tingling or twitching, squeeze the emergency ball and tell the technologist.

Claustrophobia (discomfort in enclosed spaces)
Some people get panic attacks inside enclosed spaces. This is known as 'claustrophobia', which means 'fear of confined spaces'. If you know that you are claustrophobic, tell study personnel before your scan. Some people only find out they are claustrophobic when they have an MRI for the first time. If you feel anxious or panicky inside the scanner, squeeze the emergency ball and the technologist will get you out.

Quench
In very rare circumstances, the scanner can lose its magnetic field. This happens very suddenly and is known as a 'quench'. The helium that helps keep the magnetic field strong will then escape from the scanner. The scanner is connected to a vent so that the helium will go outside the building. However, if for

some reason the vent doesn't work properly, helium might fill the scan room, making it difficult to breathe. In the very unlikely event of a quench, the technologists will get you out of the scanner immediately.

Risks of Tc-99m DTPA scan:

Your participation in this study may involve exposure to radiation from Tc-99m Pentetate also known as Tc-99m DTPA. This exposure is not necessary for your medical care, is for research purposes only and is necessary to obtain the desired medical information. The effective radiation dose you will receive from these research scans is approximately 1.8 mSv which is less than your yearly dose from natural environmental radiation in the US (3.1 mSv) and the limits set by the FDA for individuals participating in basic research studies, which is 50mSV. According to the International Commission on Radiological Protection (ICRP), the increased risk of health effects, such as cancer, from radiation doses of this amount is either too small to be observed or nonexistent.

After the radioactive scan, to help protect the other members of your household, you cannot be near children or pregnant women in the timeframe within 24 hours after the radioactive scan.

The NYULH Radiation Safety Committee has reviewed and approved the use of diagnostic radiation in this research study. Please inform your researcher if you have been exposed to radiation as a result of any other research studies or part of your clinical care. If you participate in future studies that involve the use of radiation, you should discuss it with the researchers performing those studies.

Blood Draws:

The DTPA scan involves blood draws. You may experience pain, bruising, bleeding, dizziness, fainting, or rarely infection.

Other Risks:

There is a small risk that people not connected with this study will learn your identity or personal information. We will follow all institutional guidelines to keep your information confidential.

6. Can I be in the study if I am pregnant or breastfeeding?

You cannot be in this study if you are pregnant or breastfeeding. Pregnant women cannot be exposed to radiation. Women of child bearing potential must have a negative pregnancy test before they can have a Tc-99m DTPA scan. It is important to understand that a negative pregnancy test may occur even if you are pregnant depending on the timing of the test relative to ovulation.

If you become or you think you have become pregnant during the study, you must tell the principal investigator right away and must tell your obstetrician or other health care provider caring for you during your pregnancy that you took part in this study. If you become pregnant, you will have to stop taking part in the study for safety reasons.

7. What if new information becomes available?

During the course of this study we may find more information that could be important to you. This includes information that might cause you to change your mind about being in the study. We will notify you as soon as possible if such information becomes available.

8. What are the possible benefits of the study?

There is no direct benefit to you for participating in this research study. However, the evaluated MRI techniques are important for future MRI studies and management of renal mass patients. The imaging knowledge gained will be of benefit to others with renal mass in the future.

9. What other choices do I have if I do not participate?

The alternative is to not participate in this study. This will in no way affect your present or future care at NYU Langone Health.

10. Will I be paid for being in this study?

You will be paid $50 for each one-hour MRI scan and $50 for each three-hour Tc-99m DTPA scan, for a maximum of $200 for both visits. You will receive this payment once you sign this consent form.

As is required by the laws that apply to NYU Langone, in order for you to receive a payment (cash or electronic reimbursement), you need to give the study staff either your Social Security number or your Alien Registration number and will be asked to complete an IRS W9. If you do not have either of these numbers or are not willing to complete the IRS W9, you may be in the study but will not receive any payment.

You must let us know immediately if/when the total research payments presently equal or are likely to exceed $600.00 total (not including travel reimbursements) for this calendar year. If your total payments (for one or more studies) reach $600.00, please tell the PI on page 1. However, you are required to report to the IRS all payments made to you by NYU Langone for your participation in any research for this calendar year, even payments under $600.00.

In order to receive payments for your participation in research, you may need to provide your Social Security number. This is because NYU Langone is required to report to the Internal Revenue Service (IRS) any amounts that are paid to research participants that are equal to or greater than $600.00. If you will receive payments in any amount by a check, you will need to provide your Social Security number or Alien Registration number and will be asked to complete an IRS W9. If you do not have either of these numbers or are not willing to complete the IRS W9, you may be in the study but will not receive any payment.

11. Will I have to pay for anything?

There is no cost to you or your health insurance plan for the research scan.

You and/or your health insurance may be billed for the costs of medical care during this study if these expenses would have happened even if you were not in the study, or if your insurance agrees in advance to pay. If you have health insurance, the cost of these services will be billed to your insurance company. If your insurance does not cover these costs or you do not have insurance, these costs will be your responsibility.

12. What happens if I am injured from being in the study?

For medical emergencies contact 911. If you think you have been injured as a result of taking part in this research study, tell the Emergency Contact as soon as possible. The Emergency Contact’s name and phone number are listed at the top of page 1 of this consent form.

We will offer you the care needed to treat injuries directly resulting from taking part in this research. We may bill your insurance company or other third parties, if appropriate, for the costs of the care you get for the injury, but you may also be responsible for some of them.

There are no plans for the NYU Grossman School of Medicine or NYU Langone Health to pay you or give you other compensation for the injury. You do not give up your legal rights by signing this form.

13. When is the study over? Can I leave the Study before it ends?

This study is expected to end after all participants have completed all visits, and all information has been collected. This study may also be stopped or your participation ended at any time by the principal investigator without your consent because:

- The principal investigator feels it is necessary for your health or safety. Such an action would not require your consent, but you will be informed if such a decision is made and the reason for this decision.
- You have not followed study instructions.
- The principal investigator or other body responsible for monitoring the safety of the study has decided to stop the study.

If you decide to participate, you are free to leave the study at any time. Leaving the study will not interfere with your future care, payment for your health care or your eligibility for health care benefits.

14. How will you protect my confidentiality?

Your medical information is protected health information, or “PHI”, and is protected by federal and state laws, such as the Health Insurance Portability and Accountability Act, or HIPAA. This includes information in your research record as well as information in your medical record at NYU Langone Health. In compliance with NYU Langone Health policies and procedures and with HIPAA, only those individuals with a job purpose can access this information.

Medical information created by this research study may become part of your medical record. We may include your research information in your medical record for several reasons, including for the billing of services provided in connection with the study, to securely document any medical services you receive, and so that other members of the NYU Langone Health community who may treat you have access to important information about your health.

You have a right to access information in your medical record. In some cases, when necessary to protect the integrity of the research, you will not be allowed to see or copy certain information relating to the study while the study is in progress, but you will have the right to see and copy the information once the study is over in accordance with NYU Langone Health policies and applicable law.

Certificate of Confidentiality

To help us further protect your confidentiality, this research is covered by a Certificate of Confidentiality from the National Institutes of Health (NIH). The NIH has issued a Certificate of Confidentiality for this research. This adds special protection for the research information (data, documents, or biospecimens) that may identify you.

Research information protected by this Certificate of Confidentiality cannot be disclosed to anyone else who is not connected with the research, without your consent. With this Certificate of Confidentiality, the researchers may not disclose or use research information that may identify you in any federal, state, or local civil, criminal, administrative, legislative, or other action, suit, or proceeding, or be used as evidence, for example, if there is a court subpoena, without your consent. However, disclosure, without your consent, is still necessary if there is a federal, state, or local law that requires disclosure (such as to report child abuse or communicable diseases).

The Certificate of Confidentiality cannot be used to refuse a request for information from appropriate government agencies responsible for project oversight.

The Certificate of Confidentiality does not prevent you from releasing information about yourself and your involvement in this research, including for your medical treatment. Federal regulations may also allow for the use or sharing of information for other scientific research.

15. HIPAA Authorization

As noted in the Confidentiality section above, federal law requires us, and our affiliated researchers, health care providers, and physician network to protect the privacy of information that identifies you and relates to your past, present, and future physical and mental health conditions. We are asking for your permission (authorization) to use and share your health information with others in connection with this study, in other words, for purposes of this research, including conducting and overseeing the study.

Your treatment outside of this study, payment for your health care, and your health care benefits will not be affected even if you do not authorize the use and disclosure of your information for this study.

What information may be used or shared with others in connection with this study?
All information in your research record for this study may be used and shared with those individuals listed in this section. Additionally, information in your medical record that the research team believes may be important to the study may be accessed by those listed here. This includes, for example, results from your physical examinations, laboratory tests, procedures, questionnaires, and diaries.

Who may use and share information in connection with this study?
The following individuals may use, share, or receive your information for this research study:

- The research team, including the Principal Investigator, study coordinators, and personnel responsible for the support or oversight of the study
- Study sponsor: National Cancer Institute
- Governmental agencies responsible for research oversight (e.g., the Food and Drug Administration or FDA).
- Health care providers, including your doctors and others who provide services to you in connection with this study, and laboratories or other individuals who analyze your health information in connection with this study.
- Other study sites involved in the research

Your information may be re-disclosed or used for other purposes if the person who receives your information is not required by law to protect the privacy of the information.

What if I do not want to give permission to use and share my information for this study?
Signing this form is voluntary. You do not have to give us permission to use and share your information, but if you do not, you will not be able to participate in this study.

Can I change my mind and withdraw permission to use or share my information?
Yes, you may withdraw or take back your permission to use and share your health information at any time for this research study. If you withdraw your permission, we will not be able to take back information that has already been used or shared with others. To withdraw your permission, send a written notice to the

principal investigator for the study noted at the top of page 1 of this form. If you withdraw your permission, you will not be able to stay in this study.

How long may my information be used or shared?
Your permission to use or share your personal health information for this study will never expire unless you withdraw it.

1. Electronic Medical Record and Release of Study-Related Information

What is an Electronic Medical Record?
An Electronic Medical Record (EMR) is an electronic version of your medical chart within NYU Langone Health. An EMR is simply a computer version of a paper medical record.

If you are or have been a patient at NYU Langone Health in the past, you have an EMR at NYU Langone Health. Information from your research participation will be added to this EMR.

If you have never been a patient at NYU Langone Health, you may not have an EMR at NYU Langone Health. In connection with your participation in this study, an EMR will be created for you. The purpose of your EMR at NYU Langone Health will be to facilitate this research study and allow the researchers to maintain information arising from your participation in this research study. The creation of this EMR is a requirement of your participation in this study. In order to create your EMR, the study team will need to obtain basic information about you that would be similar to the information you would provide the first time you visit a hospital or medical facility, for example, your name, the name of your primary doctor, the type of insurance you have, your date of birth and other health-related information.

What may be placed in the EMR?
Information related to your participation in the research (e.g., laboratory tests, research-related notes, imaging studies, and clinical procedures, etc.) will be placed in your EMR maintained by NYU Langone Health.
This information will be accessible to other members of the NYU Langone workforce that are not part of the research team. Information within your EMR may also be shared with others who NYU Langone Health has determined may appropriately have access to your EMR (e.g. Health Insurance Company, disability provider, etc.).

Will I have access to research-related information within the Electronic Medical Record?
The 21st Century Cures Act allows patients increased access to their EMR. However, the law allows for exceptions to your immediate access to certain research information when needed for the research study.

As a research participant in this study, some research-related information will be placed in your EMR and will be available to you immediately and some research-related information will not be available to you until the end of the study.

The research-related information that will be available to you immediately are as follows:

- ***Results in the medical record that will be immediately accessible: Estimated glomerular filtration rate (eGFR) from blood test, Proteinuria measurement from urine sample***

For these results, you will have access to the research-related information placed in your EMR before the researchers have had the opportunity to review the information.

In this study, some research-related information in your EMR will not be available to you. This is because the advanced MRI methods and mGFR measurement are either in development or not standard of care and will not impact your care.

16. The Institutional Review Board (IRB) and how it protects you

The IRB reviews all human research studies – including this study. The IRB follows Federal Government rules and guidelines designed to protect the rights and welfare of the people taking part in the research studies. The IRB also reviews research to make sure the risks for all studies are as small as possible. The NYU IRB Office number is (212) 263-4110. The NYU Grossman School of Medicine's IRB is made up of doctors, nurses, scientists, and people from the community.

17. Who can I call with questions, or if I'm concerned about my rights as a research subject?

If you have questions, concerns or complaints regarding your participation in this research study or if you have any questions about your rights as a research subject, you should speak with the Principal Investigator listed on top of the page 1 of this consent form. If a member of the research team cannot be reached or you want to talk to someone other than those working on the study, you may contact the Institutional Review Board (IRB) at (212) 263-4110.

When you sign this form, you are agreeing to take part in this research study as described to you. This means that you have read the consent form, your questions have been answered, and you have decided to volunteer.

Name of Subject (Print)	Signature of Subject	Date

Name of Person Obtaining Consent (Print)	Signature of Person Obtaining Consent	Date

Witness to Consent of Non-English Speaking Subjects Using the "Short Form" in Subject's Spoken Language

Statement of Witness
As someone who understands both English and the language spoken by the subject, I represent that the English version of the consent form was presented orally to the subject in the subject's own language, and that the subject was given the opportunity to ask questions.

Name of Witness (Print)	Signature of Witness	Date

Witness to Consent of a Subject Who Cannot Read or Write

Statement of Witness
I represent that the consent form was presented orally to the subject in the subject's own language, that the subject was given the opportunity to ask questions, and that the subject has indicated his/her consent and authorization for participation by (check box that applies).

- ☐ Subject making his/her own "X" above in the subject signature line
- ☐ Subject showed approval for participation in another way; describe:

Name of Witness (Print)	Signature of Witness	Date