Participant Informed Consent for Clinical Research

Study title for participants: Study of a New Technique for Imaging Pancreatic Cancer

Official study title for internet search on http://www.ClinicalTrials.gov: 89Zr-DFO-HuMab-5B1 (MVT-2163) Imaging in Pancreatic Cancer or Other CA19-9 Positive Malignancies

Subtitle: Pre-surgical Cohort

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If you are the parent or legal guardian of the person who is being asked to participate in this research study, you may give consent on his or her behalf. The word "you" in this document refers to a person with a cognitive impairment for whom you are the Legally Authorized Representative (LAR).

Overview and Key Information

Why is this study being done?

We are asking you to take part in a clinical research study. We do research studies to try to answer questions about how to prevent, diagnose, and treat diseases like cancer.

You are being asked to take part in this research study because you have pancreatic cancer, or a recent imaging scan suggests that you may have pancreatic cancer, and as part of the usual care for your disease you are scheduled to have a biopsy or surgical procedure. In addition, a sample of your blood or tumor tissue has tested positive for the presence of a protein called CA19-9. CA19-9 can be found in normal cells, but a high level of this protein is a sign (tumor marker) of pancreatic cancer; the higher the level of CA19-9, the more widespread the pancreatic cancer is expected to be.

We are doing this study to find out how well the experimental imaging agent ^{89}Zr-DFO-HuMab-5B1 attaches to pancreatic tumors, and to see whether PET/CT scans done with this imaging agent produce better images of your cancer. ^{89}Zr-DFO-HuMab-5B1 contains a radioactive metal, ZR-89, that gives off a small amount of radiation and is attached to a protein called the MVT-2163 antibody. MVT-2163 is designed to attach to CA19-9 on the surface of pancreatic tumor cells. MVT-5873 is also an antibody that attaches to CA19-9, but it is not radioactive. During scanning, MVT-5873 is given first to "filter out" or mask the CA19-9 in normal cells so that MVT-2167 can make better images of the cancer cells. The study researchers want to find out whether imaging scans done with ^{89}Zr-DFO-HuMab-5B1 may be better than the usual imaging technique at detecting pancreatic cancer.

The US Food and Drug Administration (FDA) has not approved ^{89}Zr-DFO-HuMab-5B1 to be used in imaging studies of your cancer or any other disease, but researchers are permitted to test it in studies like this one. The use of ^{89}Zr-DFO-HuMab-5B1 in this study is considered investigational.

Please note that no medical treatment for your cancer will be provided in this study.

Taking part in this study is your choice.

You can choose to take part or not to take part in this study, and you can change your mind at any time. Whatever choice you make, you will not lose access to your medical care or give up any legal rights or benefits.

This document presents important information to help you make your choice. Please take time to read it carefully. Talk with your doctor, family, or friends about the risks and benefits of taking part in this study. It's important that you have as much information as you need, and that all your questions are answered.

What is the usual approach to my pancreatic cancer or CA19-9 positive tumor?

People with pancreatic cancer who are not in a research study are usually diagnosed or have their disease monitored with CT (computed tomography) or MRI (magnetic resonance imaging) scans. Both CT and MRI scans make high-quality images of the body that show where the disease has spread, but neither CT nor MRI scans can tell the difference between pancreatic cancer and benign (non-cancerous) pancreatic diseases, such as chronic pancreatitis.

What are my other choices if I decide not to take part in this study?

- You may choose to have the usual approach described above
- You may choose to take part in a different research study, if one is available
- You may choose not to have any additional imaging studies of your cancer

What will happen if I decide to take part in this study?

If you decide to take part in this study, you will receive MVT- 2163 and MVT-5873 as intravenous (IV) infusions into a vein in your arm. A few days after the infusions, you will have an ^{89}Zr-DFO-HuMab-5B1 PET/CT scan. Within the next 2 days you will have a biopsy or surgical procedure, as part of the standard care for your disease. You will come for a follow-up visit about 3 weeks after your procedure.

Your participation in this study will last for about 28 days.

What are the risks and benefits of taking part in this study?

There are both risks and benefits to taking part in this study. It is important to think carefully about these as you make your decision.

Risks

We want to make sure that you know about a few key risks right now. We will also give you more information in the *What risks can I expect from taking part in this study?* section of this consent form.

If you choose to take part in this study, there is a risk that you could have side effects from the ^{89}Zr-DFO-HuMab-5B1. These side effects may be worse, and they may be different than you would have with the usual approach.

Some of the most common side effects that the study doctors know about are:

- Fever
- Chills
- Headache
- Skin rashes, including hives

- Tiredness
- Gastrointestinal problems, such as nausea or vomiting
- Difficulty breathing

There may be some risks that the study doctors do not yet know about.

Benefits

^{89}Zr-DFO-HuMab-5B1 has been used to image your type of cancer in a limited number of people. However, it may not work in everyone with your cancer. What we learn from this study may help other people in the future.

If I decide to take part in this study, can I stop later?

Yes, you can decide to stop participating in the study at any time.

The study doctor will tell you about new information or changes in the study that may affect your health or your willingness to continue in the study.

If you decide to stop, let the study doctor know as soon as possible. It's important that you stop safely.

If you stop, you can decide whether to let the study doctor or a member of the study team continue to contact you to ask questions about your health. We will not be able to withdraw information about you that has been used or shared with others before you informed us of your decision to stop.

Are there other reasons why I might stop being in the study?

Yes. The study doctor may take you off the study if:

- Your health changes, and the study is no longer in your best interest
- New information becomes available, and the study is no longer in your best interest
- You do not follow the study rules
- For women who are able to have children: You become pregnant while you are in the study
- The study is stopped by the National Cancer Institute (NCI), Institutional Review Board (IRB), the US Food and Drug Administration (FDA), or the study sponsor, Memorial Sloan Kettering Cancer Center (MSK). The study sponsor is the organization that oversees the study.

It is important that you understand the information in this informed consent document before you make a decision about participating in this clinical trial. Please read, or have someone read to you, the rest of this document. If there is anything that you don't understand, ask the study doctor or nurse for more information.

What is the purpose of this study?

The purpose of this study is to see how well the experimental imaging agent 89Zr-DFO-HuMab-5B1 attaches to pancreatic tumors, and to find out whether PET/CT scans done with this imaging agent produce better images of your cancer.

A PET (positron emission tomography) scan is an imaging test that can be used with CT or MRI scans to show how tissues and organs are functioning. PET/CT scans use a radioactive agent (a radiotracer) that provides just enough radioactivity to take pictures, usually without having any good or bad effect on

the body. FDG (fluorodeoxyglucose) is a commonly used radiotracer that measures the amount of sugar (glucose) used up by the organs, which shows the level of activity in the organs and can help distinguish healthy tissue from diseased tissue.

PET/CT scans with FDG have proven to be useful in detecting several disease conditions, including some cancers. However, FDG PET/CT scans have limited use in detecting and staging pancreatic cancer because they cannot tell the difference between cancer and pancreatitis. These scans may also fail to detect some pancreatic tumors, so a tumor may be present but not be seen on the scan.

^{89}Zr-DFO-HuMab-5B1 combines Zr-89, a radioactive metal, with a protein called the MVT-2163 antibody, which is designed to attach to the CA19-9 protein found on the surface of pancreatic cancer cells. MVT-5873 is also an antibody that attaches to CA19-9, but it is not radioactive. The two antibodies are given together during scanning to help distinguish cancer cells from normal cells. The MVT-5873 masks normal cells on the PET/CT images, while the radioactive MVT-2163 gives off a small amount of radiation that can be seen on the scans. This approach may help to show the location of CA19-9-positive tumors like pancreatic tumors. The study researchers think that PET/CT scans done with this investigational tracer may produce more accurate images of pancreatic cancers, which may lead to earlier diagnosis of the cancer and spread of the disease.

The non-radioactive part of the MVT-2163 antibody used in this study will be provided by BioNTech SE.

About 15 people will take part in this study at Memorial Sloan Kettering Cancer Center (MSK).

What are the study groups?

This study has three parts: dose escalation, dose expansion, and a pre-surgery cohort. The dose escalation part of the study has been completed, and the dose expansion part has not begun yet. You are being asked to participate in the pre-surgery part of the study.

During dose escalation, different groups of study participants received different doses of ^{89}Zr-DFO-HuMab-5B1. The first few participants who joined the study received the lowest dose. ^{89}Zr-DFO-HuMab-5B1 did not cause serious side effects in this group, and the next group received a higher dose. The doses continued to increase for every new group until side effects occurred that required the dose to be lower. When this dose was found, the dose escalation part of the study was stopped.

In the dose expansion part of this study, the dose of ^{89}Zr-DFO-HuMab-5B1 that was found during dose escalation part is given to 10 more study participants. This dosing plan helps the study doctors learn more about the side effects that may happen with this tracer.

In the pre-surgical part of this study, a new group of study participants will receive the same dose of ^{89}Zr-DFO-HuMab-5B1 and MVT-5873 that was given during dose expansion, and these participants will have a PET/CT scan before the biopsy or surgical procedure that is part of the usual care for their disease.

What extra tests and procedures will I have if I take part in this study?

Before you begin the main part of the study:

The study doctor will review your medical records and the results of your exams, tests, and procedures to see if it is safe for you to take part in the study. This first part of the study is called screening. Most of

the screening exams, tests, and procedures are part of the usual care that you would have if you were not in a study.

The tests and procedures that will be done only for research purposes, or that may be done more often because you are participating in this study, are listed below.

- Pregnancy test, in women who can have children
- Collection of blood samples for laboratory tests to see how well your kidneys function (uric acid test; 1 teaspoon) and how well your blood clots (coagulation test; ½ teaspoon)
- Collection of blood samples (1 teaspoon) for laboratory tests to measure the tumor markers commonly found in people with cancer, including CA19-9, CA15-3, and CA125. The CA19-9 test is considered part of your usual care, but it is being done more often because you are participating in this study.
- Collection of a blood sample for anti-drug antibodies (ADA) testing to see if your immune system develops proteins that react to MVT-5873, which might affect the way it works. About ½ teaspoon of blood will be collected 1 week before you receive the study tracers.
- FDG PET/CT scan to check the status of your tumor; we will compare this image with the image produced by the investigational scan that you will have during the study

During the study:

On Day 1, you will receive an intravenous (IV) infusion of MVT-5873, followed by an IV infusion of MVT-2163 (^{89}Zr-DFO-HuMab-5B1).

The infusion of MVT-5873 takes about 1 hour to complete, and the MVT-2163 infusion takes about 15 minutes. About 4 to 7 days after these infusions, you will have the investigational PET/CT scan and we will also collect blood samples for tests that show how the scan results relate to your condition. Within the next 2 days, you will have a biopsy or surgical procedure as part of your routine care. The tissue collected during the biopsy or surgical procedure will be used for research tests, as described below in *Exams, Tests and/or Procedures*.

Exams, Tests and/or Procedures

You will have tests and procedures during the main study. The procedures that will be done only for research purposes, or that may be done more often because you are participating in this study, are listed below.

- Pregnancy test in women who can become pregnant, on Day 1
- Collection of blood samples for laboratory tests (about 1 teaspoon for each test) to measure CA19-9, CA15-3, and CA125 between Days 4-7, and on Day 28. The CA19-9 test is considered part of your usual care, but it is being done more often because you are participating in this study.
- Collection of blood samples for anti-drug antibodies (ADA) testing (about ½ teaspoon each time), on Day 1 and Day 28. Additional samples may be collected if you develop a side effect that may be related to an immune reaction to MVT-5873.
- ECG (electrocardiogram) to measure the electrical activity of your heart, on the day you have the investigational PET/CT scan (between Days 4-7)
  - ^{89}Zr-DFO-HuMab-5B1 PET/CT scan, between Days 4-7
  - A sample of your tumor tissue will be collected during the biopsy or surgical procedure being done as part of your usual care. We will test your tissue sample to see how the study tracer

spreads in your tumor, and compare the information from your tissue sample with the images from your ^{89}Zr-DFO-HuMab-5B1 PET/CT scan.

Follow-up visit:
About 3 weeks after your biopsy or surgical procedure (around Day 28), you will come to the clinic for a follow-up visit so that the study doctor can check for any side effects of the study tracer. We will try to schedule this visit on the same day as your routine surgical follow-up visit.

A Study Calendar that shows how often you will have these exams, tests, and procedures is provided at the end of this consent form. The calendar also includes exams, tests, and procedures that are part of your usual care.

Will I receive the results of my research tests?
You will not receive the results of any tests done for research purposes during this study.

What risks can I expect from taking part in this study?
If you choose to take part in this study, there is a risk that:
- You may lose time at work, school, or at home, and you may spend more time than usual in the hospital or doctor's office.
- You may be asked sensitive or private questions that you do not usually discuss.

There is a risk that you could have side effects from the study.

Important information about side effects:
- The study doctors do not know who will or will not have side effects.
- Some side effects may go away soon, some may last a long time, and some may never go away.
- Some side effects may make it difficult for you to have children.
- Some side effects may be mild. Others may be very serious.

Important information about how you and the study doctor can make side effects less of a problem for you:
- If you notice or feel anything different, tell the study doctor. He or she can check to see if you are having a side effect.
- The study doctor may be able to treat some side effects.

The tables below show the most common and the most serious side effects that researchers know about. There may be other side effects that the doctors do not yet know about. If important new side effects are found during this study, the study doctor will discuss them with you.

Possible side effects of ^{89}Zr-DFO-HuMab-5B1:

Occasional, some may be serious In 100 people receiving ^{89}Zr-DFO-HuMab-5B1, between 4 and 20 may have:
• Fever • Chills • Headache • Skin rashes, including hives • Tiredness

Occasional, some may be serious In 100 people receiving ^{89}Zr-DFO-HuMab-5B1, between 4 and 20 may have:
• Difficulty breathing • Gastrointestinal problems, such as nausea, or vomiting

Rare, and serious In 100 people receiving ^{89}Zr-DFO-HuMab-5B1, 3 or fewer may have:
• Swelling of the face, mouth, lips, gums, tongue, or neck • Skin rash • Wheezing • Chest tightness • Anaphylaxis (a serious, potentially life-threatening reaction) or other allergic reaction, causing a rash, difficulty breathing, wheezing, sudden low blood pressure with lightheadedness, swelling around the mouth, throat, or eyes, a racing heartbeat and/or sweating. • Intestinal bleeding, which may cause black or tarry stool, abdominal cramps, dizziness, fatigue, or weakness • Inflammation of the pancreas, which may cause pain in the abdomen, fever, rapid heart rate, nausea, or vomiting • Allergic reaction

Possible risks of radiation-based diagnostic imaging: You will be exposed to low amounts of radiation from the imaging procedures performed during this study. PET/CT scans provide detailed pictures of the inside of the body, like an MRI (magnetic resonance imaging) scan, but using radiation, like an X-ray. Every day, people are exposed to low levels of radiation that comes from the sun and the environment. Scientists think that exposure to too much radiation can be harmful.

The amounts of radiation associated with the scan(s) included in this study are comparable to those from standard-of-care imaging procedures. Each year, many thousands of patients routinely undergo similar diagnostic procedures and receive comparable radiation doses with no short- or long-term adverse effects.

Possible risks of contrast materials: Iodine-based contrast materials, also called contrast agents or contrast media, are injected into a vein in the arm to improve the pictures produced by PET/CT scans and MRI scans. Contrast materials are generally very safe, but adverse reactions ranging from mild to severe may occur. Serious allergic reactions or other reactions are rare. A small percentage of patients may develop a delayed allergic reaction, with a rash that can occur hours to days after the injection of the contrast agent. Most of these rashes are mild, but severe rashes may require medication; please discuss any reactions the study doctor.

Reproductive risks: You should not get pregnant, breastfeed, father a baby, or donate sperm while you are in this study. The ^{89}Zr-DFO-HuMab-5B1 used in this study could be very damaging to an unborn baby. Check with the study doctor about what types of birth control or pregnancy prevention to use while you are in this study. You must continue to use these methods for 1 week after completing the study scan.

Let the study doctor know about any questions you may have about possible side effects. You can ask the study doctor questions about side effects at any time.

What are my responsibilities in this study?

If you choose to take part in this study, you will need to:

- Keep your study appointments
- Tell the study doctor about:
  - All medications and any supplements you are taking
  - Any side effects from these medications or supplements
  - Any doctor visits or hospital stays outside of this study
  - Whether you have been or are currently in another research study

Is there a conflict of interest for this study?

This study is sponsored by Memorial Sloan Kettering Cancer Center with funding from the National Institutes of Health (NIH) and BioNTech. Researchers at MSK discovered MVT-2163, the study drug evaluated in this research. There is a patent for this intellectual property that is owned by MSK. MSK has licensed this intellectual property to BioNTech, and as a result, MSK has financial interests that might be affected by the results of this study. This means that MSK could gain or lose money depending on the results of this study.

If you would like to know more about the steps MSK has taken to protect your best interests while you are in this study, please contact the MSK Patient Representative Department at 212-639-7202.

What are the costs of taking part in this study?

You will not have to pay for the ^{89}Zr-DFO-HuMab-5B1, or for tests and procedures done only for research purposes. The descriptions and schedules for these tests and procedures are provided above in *What extra tests and procedures will I have if I take part in this study?*, and they include:

- ^{89}Zr-DFO-HuMab-5B1 PET/CT scan
- ECG on the day of the investigational PET/CT scan
- Collection of blood samples for laboratory tests that are not part of your routine care (CA19-9, CA15-3, and CA125)
- Collection of blood samples for research ADA tests
- Collection of tumor samples for research tests

It is possible that ^{89}Zr-DFO-HuMab-5B1 may not continue to be supplied while you are in the study. This possibility is unlikely, but if it occurs, your study doctor will talk with you about your options.

You and/or your health plan/insurance company will have to pay for all the other costs of treating and imaging for your cancer while you are in this study. These charges include the costs of insurance co-pays and deductibles, as well as tests, procedures, or drugs that you get during the study to monitor your safety, and to prevent or manage any side effects.

Talk to your insurance provider and make sure that you understand what your insurance pays for and what it does not pay for if you take part in this clinical trial. Also find out if you need approval from your health plan before you can take part in this study.

The study doctor or nurse can help you find the right person to talk to if you are not sure which costs will be billed to you or your insurance provider.

Will I receive payment for taking part in this study?

You will not be paid for taking part in this study.

Your biospecimens (blood, tissue) may be used in the development of new tests, drugs, or other products for sale. If they are, you will not receive any payment from the sale of these products.

You may receive a total of $200 per study visit, to help you pay for some of your travel expenses while you are participating in this study. Participants from out of state may also receive up to $900 for 2 nights hotel stay.

Please submit original itemized receipts when you request reimbursement of your expenses, and please note that only your expenses (not those of your family members) will be reimbursed.

It takes about 10-12 weeks to receive your reimbursement check. Please let someone from the research team know if you would like to have the check sent somewhere other than the home addressed that you provided for other MSK-related mail.

Feel free to contact MSK with any questions or concerns about your reimbursement request.

The study team will provide a separate form with information about reimbursement of travel and lodging expenses.

What happens if I am injured or hurt because I took part in this study?

You will get medical treatment if you are injured as a result of taking part in this study.

If you think that you have been injured as a result of taking part in this research study, tell the study doctor or the person in charge of the study as soon as possible. The name and telephone number of the person in charge of this research are listed on the first page of this consent form.

We will offer you treatment for research injuries that happen as a result of your taking part in this study. You and/or your health plan will be charged for this treatment. Medical services will be offered at the usual charge. You will be responsible for any costs not covered by your health plan/insurance company.

If you think that your injury was a result of medical error, you keep all your legal rights to receive payment for treating the injury, even though you are in a study.

Who will see my medical information?

Your privacy is very important to us, and the researchers will make every effort to protect it. Trained staff at Memorial Hospital may review your records, if necessary.

Access to your protected health information will be limited to those listed in the Research Authorization form, which is a part of the informed consent process.

Your information may be given out, if required by law. For example, some states require doctors to make a report to the state health board if they find that a participant in a research study has a contagious disease like tuberculosis. However, the researchers will do their best to make sure that any information about you that may be released will not identify you.

The study doctors have a Certificate of Confidentiality from the National Institutes of Health for this study. This gives MSK an additional way to protect sensitive information that identifies you in your records if it is requested as part of a legal proceeding. However, MSK may still be required to share some of your medical information if required by law.

In the future, your information (data) and biospecimens may be de-identified, which means that your data and/or biospecimens will be assigned a unique code, and the list that links the code to your name will be stored separately from your biospecimens and data. Your de-identified information and biospecimens may be used for research that has not been described in this consent form, and they may be shared with another investigator for future research. You will not be asked if you agree to take part in future research studies.

If your information from this study is used in any reports or publications, your name and anything else that could identify you will not be used. It is possible that your de-identified information from this study will be shared with other researchers outside of MSK, and may be stored in public databases related to research. All requests for data sharing will be reviewed by the study sponsor, and if individual results are included in the data, they will not contain any identifiable information about you, such as your name, address, telephone number, or Social Security number. Your privacy is very important to us and we use many safety procedures to protect your privacy. However, we cannot guarantee that no one will ever be able to use your information to identify you.

Where can I get more information?

You may visit the NCI web site at http://cancer.gov/ for more information about research studies, or for general information about cancer. You may also call the NCI Cancer Information Service to get the same information at 1-800-4-CANCER (1-800-422-6237).

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

You can talk to the study doctor about any questions or concerns that you may have about this study, or to report side effects or injuries. You may also contact the lead researcher listed on the first page of this consent.

For questions about your rights while you are participating in this study, call the MSK Institutional Review Board (IRB) at 212-639-7592. If you have concerns, complaints, or input on research, or if you would like more information about the informed consent process, please contact the MSK Patient Representative Department at 212-639-7202.

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

Study of a New Technique for Imaging Pancreatic Cancer:
Pre-Surgical Cohort

Federal law requires Memorial Sloan Kettering Cancer Center (MSK) to protect the privacy of information that identifies you and relates to your past, present, and future medical conditions (protected health information; PHI). We are committed to protecting the privacy of your information.

If you enroll in this research study, your protected health information will be used and shared with others, as explained below. MSK must obtain your permission before using or sharing your protected health information for research purposes. This form helps to make sure that you are informed of the ways in which your information will be used or shared in the future.

Carefully read the information below before you sign this form. By signing this form, you agree to the use and disclosure of your information for this research study.

1. What protected health information about me will be used or shared with others during this research?

- Your medical records
- Your research records, including new health information created from study-related tests, procedures, visits, and/or questionnaires
- Any health information or clinical data associated with your biospecimens, if the information or data could be reasonably used to identify you. This information or data will be shared only if you have agreed to it by signing this informed consent document.
- HIV-related information, including any information indicating that you have had an HIV-related test; or that you have HIV infection, HIV-related illness, or AIDS; or any information that could indicate that you may have been exposed to HIV. (New York State requires us to obtain your consent to use or share this information.)

2. Who will use or share my protected health information?

MSK will use and share your protected health information. People and offices that deal with research oversight, quality assurance, and/or billing will be able to use and share your protected health information, including:

- The study's Principal Investigator and Co-Principal Investigators: Neeta Pandit-Taskar, MD; Michael D'Angelica, MD; Jason Lewis, PhD; Eileen O'Reilly, MD
- Your research team at MSK, including the participating investigators, research staff, research nurses, fellows/residents, and clerical support staff
- Any healthcare personnel who provide services to you in connection with this study
- Members and staff of MSK's Institutional Review Board (IRB) and Privacy Board (PB)
- Staff of MSK's Clinical Research Administration, which oversees clinical studies, and Clinical Research Information Technology Group, which manages research databases

- Members of MSK's Data Safety Monitoring Board/Committee and the Quality Assurance Committee

3. With whom outside of MSK may my protected health information be shared?

Although all reasonable efforts will be made to maintain the confidentiality of your protected health information, it may be shared with and used by the following:

- MSK's research collaborators, business partners, subcontractors and agent(s), in the United States or in other countries, working to conduct the study, to monitor the study, or to analyze the study information for this study or for other research about the study drug
- Other research doctors and medical centers participating in this research.
- Federal and state agencies, and other domestic or foreign government bodies, if required by law and/or necessary for oversight purposes, including:
    - Office for Human Research Protections (OHRP) of the US Department of Health and Human Services (HHS)
    - US Food and Drug Administration (FDA) and other regulatory agencies responsible for oversight of research
    - National Cancer Institute (NCI)/National Institutes of Health (NIH)
- Other qualified researchers, approved by MSK, who may receive individual research results that do not identify you.
- Others: BioNTech SE, the company providing the non-radioactive part of the MVT-2163 antibody

Some of the organizations that may receive your protected health information may not have to satisfy the privacy rules and requirements; they may share your information with others without your permission.

4. Why will my protected health information be used by or shared by MSK or others?

The main reasons for the use or sharing of your information include the following:

- To conduct the study, to monitor your health status, to measure the effects of the drug(s)/device(s)/procedure(s) being studied, and to determine the research results
- To ensure that the research meets legal and institutional requirements
- To develop new tests, procedures, and commercial products
- To enhance research databases, so that scientists can design better research studies to develop new therapies for patients and to gain a better understanding of disease
- To assist with MSK medical treatment, billing, or healthcare operations. For example, medical information produced by this research study will become part of your hospital medical record.

5. For how long will my protected health information be used or shared with others?

There is no set date at which your protected health information that is being used or shared for this research study will be destroyed or no longer used. The information used and created during the study may be analyzed for many years, and it is not possible to know when this analysis will be completed.

6. Statement of privacy rights:

- It is your right to refuse to sign this authorization form. If you do not sign this form, you will not be able to participate in this research study. However, if you do not sign, it will not affect your ongoing medical treatment or healthcare coverage.

- You have the right to withdraw your permission for MSK to use or share your protected health information. Please note that we will not be able to withdraw all the information about you that already has been used or shared with others to carry out research-related activities such as oversight, or information that is needed to ensure the quality of the study. To withdraw your permission, write to the study doctor listed on the first page of this consent form at: Memorial Sloan Kettering Cancer Center, 1275 York Avenue, New York, NY 10065. If you withdraw permission for us to use or share your protected health information, you will not be able to continue to participate in this research study.

- You have the right to request access to your protected health information that is being used or shared during this research and that is related to the research or to payment for the research. However, you may access this information only after the study is completed. You may have access to the parts of your medical record that are unrelated to this study at any time. To request this information, please contact the study doctor whose name and telephone number are listed on the first page of this consent form. You may also ask the study doctor to correct any study-related information about you that is wrong.

Notice concerning HIV-related information

Individuals/organizations are prohibited from sharing any HIV-related information about you without your approval, unless they are permitted to do so under federal or state law. You have a right to request the list of people who may receive or use your HIV-related information without your authorization.

If you experience discrimination because of the release or disclosure of your HIV-related information, you may contact the New York State Division of Human Rights at 888-392-3644 or the New York City Commission on Human Rights at 212-306-7500. These agencies are responsible for protecting your rights.

Participant Informed Consent/Research Authorization for Clinical Research

Statement of professional obtaining consent

I have fully explained this clinical research study to the participant or to his/her Legally Authorized Representative (LAR). In my judgment, and in that of the participant or his/her LAR, sufficient information, including risks and benefits, was provided for the participant or his/her LAR to make an informed decision. The consent discussion will be documented in the participant's EMR.

Consenting professional must personally sign and date		
Consenting professional's signature		**Date:**
Consenting professional's name (Print)		

Participant's (or Legally Authorized Representative's [LAR's)]) statement

I have read this form that describes the clinical research study. I have also talked it over to my satisfaction with the consenting professional. By signing below, I agree to the following: (1) to voluntarily participate in this clinical research study; (2) to authorize the use and disclosure of my/the participant's protected health information (data about myself/the participant); and (3) to state that I have received a signed and dated copy of this consent form.

Participant/LAR must personally sign and date		
Participant signature		**Date:**
Participant name (Print)		
LAR relationship to participant		

Witness signature (if required)

- ❑ Witness for non-English speaking participant: I declare that I am fluent in both English and in the participant's (or LAR's) language, and I confirm that the consent discussion was appropriately interpreted for the participant (or LAR).
- ❑ Other: I confirm that the consent discussion occurred, and that the participant agreed to participate in this study by signing this form, making his/her mark, or verbally agreeing.

Name of witness: _____

Signature of witness: _____ **Date:** _____

(The name of the witness must be documented in the EMR.)

Interpreter (if required)

Name of interpreter (if present): _____

ID number (if phone interpreter): _____

(The interpreter's name or ID number must be documented in the EMR.)

The participant/ Legally Authorized Representative must be provided with a **signed copy** of this form.

Memorial Sloan Kettering Cancer Center
IRB Number: 20-342 A(4)
Approval date: 29-Mar-2022

Study Calendar:

This calendar shows the exams, tests, and procedures that will be done as part of this research study, as well as the tests and procedures that are part of your usual care.

Assessment	Screening	Dose of study agent and imaging		Surgery or biopsy	Follow-up visit
	Days -28 to 1	Day 1	Days 4 to 7	Days 7 -9	Day 28
Medical history and physical examination	X				X
Vital signs	X	X	X		X
ECG	X		X		
Routine blood tests	X		X		X
Routine urine tests	X				X
Pregnancy test	X (within 2 weeks of D1)	X			
Standard of care CT/MRI/FDG PET scans	X				
CA19-9 blood test	X	If not done within the last 7 days			X
CA15-3 and CA125 blood tests	X	If not done within the last 7 days			X
ADA blood test	X	X	X		X
Review of side effects			X		
^{89}Zr-DFO-HuMab-5B1 and MVT 5873 administration		X			
^{89}Zr-DFO-HuMab-5B1 PET/CT scan			X		
Tumor biopsy or surgery, according to usual care			For biopsy: As soon as possible following the investigational scan	X	