Participant's Name_____ Medical Record # _____

Consent of an Adult to Be in a Research Study

In this form "you" means a person 18 years of age or older who is being asked to volunteer to participate in this study.

Principal Investigator:	Dr. Christopher Moskaluk, University of Virginia Health System, PO Box 800214, Charlottesville, VA, 22908, Phone: 434-982-4408
Sponsor:	University of Virginia Health System M2Gen

What is the purpose of this form?

This form will provide you with information about this research study. You do not have to be in the study if you do not want to. You should have all your questions answered before you agree to be in this study.

Please read this form carefully. If you want to be in the study, you will need to sign this form. You will be given a signed copy of this form.

Who is funding this study?

This study is being funded by the UVA Health System, with additional funding described on pages 8 and 9 of this form.

Why is this research being done?

A key mission at the University of Virginia is research about diseases. This study will expand the specimen bank (repository) at UVa that has been established in order to provide researchers with tissue and fluid samples for research to increase our understanding of various diseases and to improve diagnosis and treatment of these diseases. If you agree to participate, we will also obtain information from medical records and clinical records to help us find better ways to diagnose and treat cancer and other diseases. We also will make these samples and information available to other researchers outside of UVA.

We are asking you to participate in this study to help us answer many important questions that have not been answered before. There are more than 200 types of cancer, and we hope this study will help doctors learn more about the different types of cancer, risks for cancer, and the best treatment for each cancer. The study is also designed to help find ways to prevent cancer in the future.

Body tissues are made up of cells. Cells contain DNA, which is the genetic material that carries the instructions for your body's development and function. Cancer can result from changes in

a person's genetic material that causes cells to divide in an uncontrolled way and, sometimes, to travel to other organs. Currently, researchers and doctors know some of the genetic changes that can cause cancer, but they do not know all of them. By combining genetic information with clinical data, such as the responses of different kinds of cancers to different treatments, this study could lead to more knowledge about why certain cancers respond differently to treatments. With such knowledge, future treatments potentially could become customized to a patient's unique genetic make-up.

Therefore, in addition to collecting your health information and your tissue for research, we would like to study the genetic material from your blood and tissue as part of this study. This includes tests for changes in genes that you may have been born with or that may have occurred in your body during your lifetime that possibly increase cancer risks, cause cancer, or could be targeted in the future for treatment. By combining this type of information with clinical data, it may be possible to identify the genetic changes that are associated with an individual's particular type of cancer.

How many people will take part in this study?

We anticipate that up to 30,000 people at the University of Virginia will take part in this study. We expect that hundreds of thousands of people will be enrolled at all places.

How long will I be in the study?

When you agree to take part in this study, we will collect your samples and information about you for as long as the study remains in progress, which we hope will be for the rest of your life.

What will happen if I take part in this study?

When you take part in this study, you will let us:

- **Review your medical records:** This includes your health information as well as your answers to any medical and health questionnaires you complete as part of your standard medical care visit. We will review your medical records in the future to study your medical treatment, even if your medical care is transferred to another doctor.

- **Store excess tissue removed if you have surgery:** If you have surgery to remove a tumor as part of your standard care, usually a small amount of tissue is leftover. We may study this leftover tissue that the lab usually throws away. In addition, if you elect to have an autopsy and sign the autopsy consent form, extra tissue may be collected for research. The tissue you donate to the University of Virginia for the purpose of this research study may be used immediately after surgery for research or may be stored indefinitely for future cancer research purposes. Your standard surgery will not be different if you agree to take part in this study.

- **Take samples of blood:** As part of your standard treatment, your doctor will collect blood from you for clinical tests at regular intervals; sometimes weekly, monthly, or yearly. We may collect some additional blood (about 4 teaspoons per blood draw) for future cancer research purposes at any of these scheduled blood draws or during

another research blood draw. These additional samples would not exceed 12 teaspoons over an 8-week period and may be collected on an ongoing basis as needed as long as you wish to participate. At some blood draws, 12 teaspoons of blood may be drawn instead of 4 teaspoons. We would still only draw 12 teaspoons total in an 8-week period. This means that it may occur in one blood draw instead of several over an 8-week period. All research blood samples will be considered a donation to the University of Virginia and may be used immediately for research or may be stored indefinitely for future cancer research purposes.

- **Additional bone marrow samples** may be collected when possible after collecting the amount needed for clinical care by your physician during any clinically indicated procedure. Research samples may be collected on subsequent, clinically indicated bone marrow procedures. The maximum amount of bone marrow aspirate collected for research purposes would not exceed 2 teaspoons over a 4-week period.

- **Collect tissue samples from previous procedure:** If you have undergone a surgical procedure in the past at the University of Virginia or another facility and tissue was collected, you give permission for us to receive that tissue and you donate it to the University of Virginia for use in this study. By signing this consent document you agree to allow us to contact your healthcare providers outside of UVA to obtain tissue and data. Your donated tissue may be used immediately for research or may be stored indefinitely for future cancer research purposes. Having a sample of your tissue from a past procedure could yield important information about cancer for the future.

- **Optional** additional lymph node biopsy samples: As part of your routine clinical care, if your doctor determines that you need to have a biopsy of a lymph node, we would like to collect extra pieces of tissue from the procedure when possible. This procedure would be done for your clinical care and not just for this study. The extra samples would occur with every clinically indicated lymph node biopsy as long as you wish to participate in the study. You may opt out of extra lymph node samples and remain on the study for collection of other samples. You can change your mind about donating the additional lymph node biopsy samples at any time and still stay on this study.

  Please initial one of the options below:
  _____ I do want to give additional lymph node biopsy samples.
  _____ I do NOT want to give additional lymph node biopsy samples.

- **Collect cheek cell sample**: We may ask you to scrape the inside of your cheek using a provided swab. It is possible that we may have you spit about half of a teaspoon of saliva into the container provided or rinse your mouth with sterile water or a commercially available mouthwash and spit into the container provided instead of scraping your cheek. This collection would not exceed more than two times per year as needed for research purposes.

- **Permission to re-contact you in the future:** By participating in this study, you are giving us and others working with us, such as your doctor, permission to re-contact you in the future if we find additional studies that might be suited to you, and to discuss other matters associated with these potential studies.
- **If you are selected, you may be asked to fill out some questionnaires**. These questionnaires ask about:
    - how you are feeling
    - your lifestyle habits
    - medicine use
    - diet
    - daily activities
    - family history
    - how you feel about taking part in this study

You are being asked to give permission for the collection and storage of tissue and blood specimens in the UVA specimen bank. The UVA Biorepository and Tissue Research Facility could give these specimens to researchers within the UVA community, and throughout the United States, including the National Cancer Institute (NCI) Cooperative Human Tissue Network, and internationally, as they search for cures for diseases.

Those who would receive your specimens and your health information would include researchers and the others listed under the "Who will see your information?" section of this consent document.

We may perform **whole genome analysis** on your DNA sample. This is a special type of genetic research. Usually researchers study just a few areas of your genetic code that are linked to a disease or condition. In whole genome studies, all or most of your genes are analyzed and used by researchers to study links to cancer or many other diseases or conditions.

- In order to allow researchers to share test results, the National Institutes of Health (NIH) and other central repositories have developed special data (information) banks that collect the results of whole genome studies. The NIH or other data banks will store your genetic information and give it to other researchers to do more studies. We do not think that there will be further risks to your privacy and confidentiality by sharing your whole genome analysis with these databanks; however, we cannot predict how genetic information will be used in the future.
- The genetic information will be sent to the NIH and other central repositories, and to M2Gen, the for-profit organization assisting with the coordination of this study, and to pharmaceutical companies and other commercial companies. It may also be sent to the NIH if the research is funded by the NIH. The genetic information that goes to the NIH will be sent with only a code number attached. There is a small chance that your genetic information could be shared with others by mistake. It is possible that you could be identified from the sample if someone has another sample from you. Research using

your whole genome information is important for the study of virtually all diseases and conditions. Therefore, the ORIEN databank will provide study data for researchers working on any disease, which could include conditions such as HIV/AIDS, cancer, mental illness, and others.

How Will Your Sample(s) Be Labeled?

Your tissue and blood sample(s) will not be labeled with your name or other information that would identify you directly. Instead, they will have a unique code that allows for them to be linked to your health information listed below. This link means that your samples can be identified with the key to the code, but this key will be kept at UVA and will not be provided to M2Gen, the for-profit organization assisting with the coordination of this study. The key may be provided to UVA researchers who are given portions of your samples and the health information listed below if those UVA investigators have the appropriate IRB approval for their studies at UVA. The key will not be shared with investigators outside of UVA. We can find out if we need to know which sample is yours in the event you wish to end your participation in this study. If you decide to end your participation in this study, we will remove your samples from the UVA repository. However, if any portion of your samples has already been taken from the UVA repository and distributed to a researcher, we will not be able to retrieve it.

Dr. Christopher Moskaluk and the staff of the UVA repository will be responsible for storing your sample and for protecting your privacy while it is stored at UVA.

The information collected from you might be published in a medical journal. This would be done in a way that protects your privacy. No one will be able to find out from the article that you were the person who donated the sample or provided the information.

Which researchers can use your samples and what information about you can they have?

Your sample may be shared with researchers at the University of Virginia and at other institutions or commercial groups. Along with specimens, researchers will receive some health information about you from your medical record. Combining information from the specimen with information from your health records may be useful for research.

Investigators at UVA may receive your protected health information including your name and medical record number if they have the appropriate IRB approval for their research. Investigators outside of UVA would not receive your name or medical record number but may receive other information that would not directly identify you.

The following types of information may be provided:

- Age, ethnicity, gender
- City, state and zip code of home address
- Diagnoses, stage and treatment including dates

- Family history and medical history
- Medications
- Laboratory results
- Risk factors such as whether you have smoked, been exposed to chemicals, or have had cancer before.

What Are The Risks of This Study?

Risks to Privacy from Genetic Research and/or Specimen Banking:

The main risk of allowing us to store and use your samples and health information for research is a potential loss of privacy. One of the risks to you is the release of information from your health records. The University of Virginia will do its best to protect your information so that facts about you and your health will be kept private. The chance that information identifying you will be seen by someone not authorized to receive it is very small. However, both the University of Virginia and M2Gen, which will be given protected health information that does not directly identify you by the University, cannot *guarantee* it will be safe. To further safeguard your privacy, information obtained from future research will not be placed in your medical record.

There are certain risks of having health information given to other people by mistake. In the unlikely event that this happens, it could cause discrimination or mental harm to you or your family members if others were to see this information. It could also hurt family relationships. You should know that the Genetic Information Nondiscrimination Act of 2008, along with other Federal Laws, generally prohibits health insurers or health plan administrators from requesting or requiring genetic information of an individual or the individual's family members, or using it for decisions regarding coverage, rates, or preexisting conditions. The law also prohibits most employers from using genetic information for hiring, firing, or promotion decisions, and for any decisions regarding terms of employment. However, this law does not protect your ability to get or keep other kinds of insurance such as life insurance or long term care insurance.

Your doctor will explain the risks of the routine medical procedure you are having. In some cases, your doctor will ask you to sign a separate clinical consent form that explains the risks of the procedure. Allowing your samples to be saved for future research will not change the risks of the medical procedure itself.

Risk of obtaining tissue from a previous procedure: Because these tissue samples were collected from a previous procedure, there are no additional risks to you for this part of the study**.**

Risks of having your blood drawn:

Having blood drawn may cause:

- ✓ pain (common),
- ✓ a bruise (sometimes),
- ✓ fainting or passing out (not very often), and

- ✓ infection (rare).

If the people doing the study are exposed to your blood or body fluids in a way that could give them a disease, your blood may be tested. The tests might check for:

- ✓ hepatitis,
- ✓ HIV (Human Immunodeficiency Virus), or
- ✓ other infections.

You and the person exposed would be told the test results. However, your name would be kept private. If your test is positive for hepatitis or HIV, we will tell you the results and help you understand what the results mean for you.

Risks of collecting additional bone marrow samples

Having bone marrow aspirate collected may cause:

- √ increased duration of discomfort (sometimes)
- √ increased bleeding risk (not very often)
- √ increased risk of infection (rare)

Risks of collecting additional samples during a lymph node biopsy

Having a lymph node biopsy procedure may cause:

- √ increased duration of discomfort (sometimes)
- √ increased bleeding risk (not very often)
- √ increased risk of infection (rare)

The additional research tissues taken at a biopsy can cause:

1) A mildly increased chance of experiencing these risks if it is a FNA (fine needle aspirate) biopsy, or
2) A moderately increased chance of experiencing these risks if it is a core biopsy (using a larger needle)

The additional research tissues taken at a biopsy can cause a moderately increased chance of experiencing these risks if it is a core biopsy (using a larger needle).

Risks from Completing Questionnaires: Some of the questions asked may be upsetting, or you may feel uncomfortable answering them. If you do not wish to answer a question, you may skip it and move on to the next question.

Risks associated with loss of privacy: Your personal health information will be used and disclosed as provided in this form. The risks associated with this part of the study are low. The risk relates to the chance that your personal information could be given to someone who is not permitted to see it. Many steps are in place, however, to prevent this. The cancer registry database, clinical trial database, health information and tissue tracking data bases used in this

study by UVa and M2Gen will be password protected and encrypted, and can only be accessed by authorized people to perform their job duties.

Will You Find Out the Results of the Research on Your Sample(s) for Genetic Research and/or Specimen Banking?

Neither you, your health care provider**,** nor anyone in your family, will receive the results of any research done on your sample(s). The results will not be put in your health records. Therefore, results from any research done on your sample(s) will not affect your medical care. This helps protect you and other members of your family from harm that might be caused by this information.

Could you be helped by being in this study?

You likely will not benefit from being in this study. However the information researchers get from this study may help others in the future. By studying clinical data, blood, and tissue from thousands of cancer patients, we hope that we might learn more about cancer and how to find it earlier and/or treat it better.

We also hope to find out if new drugs will help future cancer treatments and shorten the time for clinical studies to be completed to make new drugs available faster. With your consent, it will be easier for us and others working with us to contact you about future research studies that may involve new study drugs or medications and to discuss other matters associated with this study.

What are your other choices if you do not join this study?

You do not have to participate in this study to be treated for your illness or condition. You will get the usual treatment, according to what you and your doctor decide, even if you choose not to participate.

If you are an employee of UVa, your job will not be affected if you decide not to participate in this study.

If you are a student at UVa, your grades will not be affected if you decide not to participate in this study.

Will you be paid for being in this study?

You will not get any money for being in this study.

Your blood, tissue, and clinical information may be studied by commercial companies and other organizations - some of whom may be providing funding or other payments related to this study. We hope this study will help researchers find ways to make new drugs and develop new treatments that could treat patients better in the future.

If you agree to participate, your samples will be considered a gift to the University of Virginia. The University of Virginia may share your sample and personal information with others, such as private companies, government agencies, or other universities.

- Your samples and personal information may be used to make new products or technologies. You will not be paid even if these new products or technologies are sold or make money.
- You cannot choose how your samples and personal information will be used. If you do not want to let others decide how your samples and information will be used, then you should not participate in this study.

By agreeing to be in this study, you are donating your blood and tissue samples for research, and giving up any property rights you may have in them. The results of this research using your donated materials may have commercial value. However, you will not receive any payments.

The University may receive payments for the use of your information and samples. Also, M2Gen may be paid fees by commercial companies for coordinating release of your health information to them for research. If M2Gen is paid fees by commercial companies, a portion of those fees will be paid by M2Gen to the University of Virginia as royalties.

Will being in this study cost you any money?

All of the procedures for the study (collection of your tissue and blood samples and health information) will be provided at no cost to you or your health insurance. You will continue to be responsible for your medical care, the cost of travel to come to any clinic visit and for any parking costs.

How will your personal information be shared?

The UVa researchers are asking for your permission to gather, use and share information about you for this study. If you decide not to give your permission, you cannot be in this study, but you can continue to receive regular medical care at UVA.

We understand that information about you and your health is personal, and we are committed to protecting the privacy of that information. Because of this commitment and because of federal law, we must obtain your written authorization before we use or disclose your information for this study.

By signing this form, you are permitting us to disclose your protected health information that does not directly identify you to M2Gen, a for-profit organization assisting with the coordination of the study. You are also permitting M2Gen to disclose your protected health information that does not directly identify you to organizations that participate in this study. Those who would see the information would include researchers and the others listed under “Who will see your information?” section of this consent document.

Some of the people outside of UVA who will receive your information may not have to follow the privacy laws that we follow. They may release your information to others, and it may no longer be protected by those laws.

Certificate of Confidentiality: Your information, collected for this study, will be protected by a Certificate of Confidentiality from the federal government. If UVA receives a subpoena or court order demanding information from the study records that would identify you, we will use the Certificate to resist the demand. However, UVa will not use it in the following cases.

- You have agreed in writing to allow UVa to share the information with your employer, your insurance company for billing purposes, or someone else
- Reports to authorities where there is a danger that you may harm yourself or others, or if there is evidence of probable child or elder abuse or neglect.

In addition, the Certificate does not prevent government authorities who oversee research from reviewing this study. This Certificate does not mean that the government either approves or disapproves of this study. It just helps protect your privacy.

If you sign this form, we may disclose any or all of the following information about you:

- To UVA investigators: Identifiable information only to UVA investigators that have the appropriate IRB approval for their research
- To Investigators outside of UVA including M2Gen: protected health information that does not directly identify you
    - Your personal information: your home city, state, and zip code, your age, ethnicity, gender, and the dates of your diagnosis and treatment and other dates
    - Your health information, including information from your medical records and test results, from before, during and after you sign this consent, and from any of your doctors or health care providers. This may include mental health care records, substance abuse records, and/or HIV/AIDS records.
    - Your tissue, bodily fluids, and blood samples and genome analysis of your DNA derived from your tissue, bodily fluids and blood samples.

Who will see your information?

- The UVA researchers managing Partners in Discovery for Total Cancer Care at UVA protocol to make sure they can conduct the study the right way.
- Investigators at UVA that have appropriate IRB approval for access to your identifiable protected health information for their own research.
- The sponsor(s) of this study, and the people or groups it hires to help perform or review this research. This includes M2Gen, a for-profit organization assisting with the coordination of this study. M2Gen will receive protected health information that does not directly identify

you and health information described above, and may use or disclose it to other organizations.

- Organizations, including academic investigators outside of UVA, pharmaceutical companies and other commercial companies, that M2Gen and UVA provide your protected health information that does not directly identify you and samples for use in their research studies.
- People or groups that oversee the study to make sure it is done correctly, and government agencies that provide oversight such as the Food and Drug Administration (FDA).
- The controlled-access public research data repositories required for broad data sharing, including NIH-designated data repositories, and the pharmaceutical companies and other commercial companies that will receive the genome analysis of your DNA

What if you sign the form but then decide you don't want your information shared?

You can change your mind at any time. Your permission does not end unless you cancel it. To cancel it, please send a letter to the researchers listed on this form. Then you will no longer be in the study. We will then destroy any of your samples that remain in the UVA repository. However, if your sample has been distributed prior to you withdrawing consent, it cannot be retrieved. The information about you that has been collected will continue to be used for research, but we will stop collecting and disclosing new information about you. The information that we have learned will remain as part of the study even if you withdraw. Unless you withdraw from the study, permission for researchers to use your samples and to use and share your private health information will never end.

Please contact the researchers listed below to:

- Obtain more information about the study
- Ask a question about the study procedures
- Report an illness, injury, or other problem (you may also need to tell your regular doctors)
- Leave the study before it is finished
- Express a concern about the study

Dr. Christopher Moskaluk, University of Virginia Health System,
PO Box 800214, Charlottesville, VA, 22908, Phone: 434-982-4408

What if you have a concern about this study?

You may also report a concern about this study or ask questions about your rights as a research subject by contacting the Institutional Review Board listed below.

University of Virginia Institutional Review Board for Health Sciences Research
PO Box 800483
Charlottesville, Virginia 22908

Telephone: 434-924-9634

When you call or write about a concern, please give as much information as you can. Include the name of the study leader, the IRB-HSR Number (at the top of this form), and details about the problem. This will help officials look into your concern. When reporting a concern, you do not have to give your name.

Signatures

What does your signature mean?

Before you sign this form, please ask questions about any part of this study that is not clear to you. Your signature below means that you have received this information and all your questions have been answered. If you sign the form it means that you agree to join the study. You will receive a copy of this signed document.

Consent From Adult

_____	_____	_____
PARTICIPANT (SIGNATURE)	PARTICIPANT (PRINT)	DATE

If an interpreter is involved in the consent process because the potential subject does not speak English well or at all, the participant should NOT sign on the line above – leave this line blank. Instead, the participant should sign the Short Form or full consent written in the language they can understand.

Person Obtaining Consent

By signing below you confirm that you have fully explained this study to the potential subject, allowed them time to read the consent or have the consent read to them, and have answered all their questions.

_____	_____	_____
PERSON OBTAINING CONSENT (SIGNATURE)	PERSON OBTAINING CONSENT (PRINT)	DATE

Interpreter

By signing below you confirm that the study has been fully explained to the potential subject in a language they understand and have answered all their questions.

_____	_____	_____
INTERPRETER (SIGNATURE)	INTERPRETER (PRINT)	DATE

If an interpreter was used to explain this study to a potential subject, the interpreter must sign and date the line above.

Consent from Impartial Witness

If this consent form is read to the subject because the subject is blind or illiterate, an impartial witness not affiliated with the research or study doctor must be present for the consenting process and sign the following statement. The subject may place an X on the Participant Signature line above.

I agree the information in this informed consent form was presented orally in my presence to the subject and the subject had the opportunity to ask any questions he/she had about the study. I also agree that the subject freely gave their informed consent to participate in this trial.

_____	_____	_____
IMPARTIAL WITNESS (SIGNATURE)	IMPARTIAL WITNESS (PRINT)	DATE