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FOR IRB USE ONLY

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RELEASED DATE: 03/08/17
EXPIRATION DATE: 03/06/18

INFORMED CONSENT DOCUMENT

Project Title: Analysis of Histological, Genomic, Molecular, and Clinical Factors in CNS Cancer: The Neuro-Oncology Group

Principal Investigator: Jian Campian, M.D.

Research Team Contact: Jian Campian, M.D. – (314) 747-7509

This consent form describes the research study and helps you decide if you want to participate. It provides important information about what you will be asked to do during the study, about the risks and benefits of the study, and about your rights as a research participant. By signing this form you are agreeing to participate in this study.

- If you have any questions about anything in this form, you should ask the research team for more information.
- You may also wish to talk to your family or friends about your participation in this study.
- Do not agree to participate in this study unless the research team has answered your questions and you decide that you want to be part of this study.

WHAT IS THE PURPOSE OF THIS STUDY?

This is a research study. We invite you to participate in this research study because you have had or are scheduled to tissue surgically removed that is or is suspected to be brain cancer or metastases to your brain from cancer in another part of your body.

The purpose of this research study is to discover genetic changes associated with cancer by documenting the DNA changes that occur in brain cancer cells. This may lead to better ways of preventing, detecting, and treating cancer and perhaps other diseases as well.

WHAT WILL HAPPEN DURING THIS STUDY?

Body tissues are made up of cells. Cells contain DNA, which is unique genetic material that carries the instructions for your body's development and function. DNA can be sequenced so that your exact genetic code can be identified; using this technique, we can detect changes to your DNA sequence changes that are specifically related to cancer. Cancer can result from changes in a person's DNA 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.

In this study, we will compare the genetic material from cancerous tissue to the genetic material from normal tissue to find the differences that exist. By studying many different kinds of cancer in this way, we expect to identify most of the genetic changes associated with different kinds of cancer. We also will combine your genetic information with information about your health. We will study the relationship between this information in order to learn more about how to personalize cancer treatment in the future.

Tissue and Blood Collection

Your participation will involve donation of a piece of the tumor that was or will be collected at any or all of the following time points:

- when your cancer was diagnosed;
- during a prior surgery or biopsy;
- during an upcoming surgery or biopsy;
- during a future surgery or biopsy.

If your doctors need to use the tissue taken during any of these biopsies or surgeries for further tests related to your routine care, we will allow them to use it. Also, if any of your previous surgeries or biopsies were done at an institution other than Washington University / Siteman Cancer Center, we would like your permission to get some of that tissue from that institution, if possible.

In addition to tissue, you will be asked to donate a blood sample when your cancer is diagnosed, at the time of any surgeries or biopsies (if possible), or, if your cancer recurs, at the time of recurrence. Between 4 and 10 teaspoons of blood will be drawn from a vein in your arm.

Also, if you have other cancerous tissue not in your brain, we may request research biopsies either during routine surgery or as a separate biopsy procedure.

Your samples will be transported to the Siteman Cancer Center Tissue Procurement Facility (Tissue Bank), where any information that could identify you will be removed and replaced with a unique patient number (UPN) and sample number. The samples will then be frozen and stored for future testing, including genetic sequencing (described in more detail below). Some of the tissue collected may be imaged before it is stored in the tissue bank (these tissue samples will be de-identified). To maintain your confidentiality, any specimens that are removed from the Tissue Bank for future testing will only be identified by the UPN, not by any identifiable information.

I agree to allow the study team to collect tumor tissue that was previously collected at a site other than Washington University or Siteman Cancer Center.

__X__ yes ____ no

Collection of Health Information

In addition to the tissue and blood samples, we will also collect health information from your medical record. This information includes your medical history, findings from recent physical exams, and results of laboratory testing. If you have not recently been seen by a physician, we may contact you to determine your current health status. Review of your records and any personal contact with you will only be made by members of the study team.

Storage and Release of Samples and Medical Information for Future Research

Your coded blood and tumor samples will be processed at the Tissue Bank, and portions of your samples will then be sent to different types of laboratories as part of this project. One type of laboratory will sequence your DNA, which means that your complete DNA sequence (or genome sequence) will be

generated during this analysis. In addition, recent technology allows for the determination of the number and order of changes occurring in the tumor DNA compared to normal tissue samples, so the changes associated with your tumor may be mapped out and analyzed as well.

Your samples and data may be studied by other laboratories in other ways besides genome sequencing. The remaining portions of your samples will be stored for an unlimited period of time for future use in research related to cancer or in other research projects. Coded samples and data may be shared with other researchers both within Washington University as well as outside of Washington University for future research as well.

Part of the analysis of your samples involves the storage of genetic information in online databases. Some of these databases are what is known as controlled-access, which means that only people who have been authorized may view the information kept in the database. Other databases are open-access, which means that information there may be browsed online or downloaded without prior permission or authorization. Information being stored in open-access databases will not be information that can identify you, but will be general information about this study (or other studies conducted using your samples) and the information collected. The purpose of making this information available through these databases is so that it can be used by other researchers to study cancer and other diseases.

Results of Genetic Sequencing

Your tissue samples may be used to determine the sequence of some or all of your genes (DNA). This DNA sequence information could indicate that you may have gene mutations that could affect not only your future health, but also the health of your children. If the researcher, together with a panel of other medical center experts, feel that this information may be very important for you or your children to know about, then you or a person designated by you (in the event of your death or incapacitation) would be contacted by a member of the study team and given the opportunity to talk with a genetic counselor. The purpose of this would be to help explain the significance of the findings and advise you of any steps to be taken to further minimize the health risk to you or your offspring. If you choose to be notified about these results, this will occur only once, around the time that the sequencing takes place; the research team will not be continuously checking samples as time passes to see if more relevant results are found.

If we discover genetic changes that may be important for the care of your illness or that may be relevant for your health or the health of close family members (for example, your parents, siblings, or children), would you like us to notify you about these results? [X] yes [ ] no

We may also find genetic changes that you have inherited. These changes could also be present in one or both of your parents, your siblings, or your children. These inherited changes may affect your risk or a family member's risk of getting cancer or other medical conditions. For this reason, we may recommend that you speak to a genetic counselor who will describe the results and what they mean. The genetic counselor will also ask you questions about conditions that run in your family. This will not happen immediately, but will happen around the time that the sequencing takes place. AT that time, you and/or your next-of-kin will be given the option to decide whether you want to receive these results. Some of these findings could be important for your healthcare or for the healthcare of closely related family members, and you will be able to share these results with them if you so choose.

In the event of your death or incapacitation, may we contact your next-of-kin to discuss results of genetic testing performed on your donated tissue that could affect the health of your offspring or other family members? [X] yes [ ] no

If yes, please provide name of contact: [redacted]

Will you save my samples or research data to use in future research studies?

As part of this study, we are obtaining data, tumor tissue, and blood samples from you. We would like to use your data, tumor tissue, and blood samples for studies going on right now as well as studies that are conducted in the future, including future genetic research or the creation of cell lines, which are distinct families of cells grown in a lab that are all the same and can be used for research. These studies may provide additional information that will be helpful in understanding brain cancers, or other diseases or conditions, including research to develop investigational tests, treatments, drugs or devices that are not yet approved by the U.S. Food and Drug Administration. It is unlikely that what we learn from these studies will have a direct benefit to you. There are no plans to provide financial compensation to you should this occur. By allowing us to use your data, tissue, and blood, you give up any property rights you may have in the data, tissue, and blood.

We will share your data, tissue, and blood with other researchers. They may be doing research in areas similar to this research or in other unrelated areas. These investigators may be at Washington University, at other research centers and institutions, or industry sponsors of research. We may also share your research data with large data repositories (a repository is a database of information) for broad sharing with the research community. If your individual research data is placed in one of these repositories only qualified researchers, who have received prior approval from individuals that monitor the use of the data, will be able to look at your information.

If you change your mind and do not want us to store and use your tumor tissue, blood samples, and data for future research you should contact the research team member identified at the top of this document. The tumor tissue, blood samples, and data will no longer be used for research purposes. However, if some research with your tumor tissue, blood samples, and data has already been completed, the information from that research may still be used. Also, if the data has been shared with other researchers it might not be possible withdraw it to the extent it has been shared.

Please note that, in general, we will not give you any individual results from the analysis of your tumor tissue or blood. This is because it will probably take a long time for this study to produce information that we will know how to interpret accurately. However, we will tell you if we find that you have a communicable disease that we are required by law to report, although we don't at this time anticipate running any tests that may result in such findings.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 1000 people will take part in this study conducted by investigators at Washington University

HOW LONG WILL I BE IN THIS STUDY?

Data about your health status will be collected for the ten years that follow your enrollment on the study unless you choose to withdraw from this research or there's no way for the research team to contact you or your physician. This means that a member of the study team may contact you in the future to document your health status, or that this information may be obtained by reviewing your office visit notes. You will be contacted at least once a year and no more than every three months dependent upon routine care for your diagnosis. If you have more biopsies or surgeries in the future, we would like to obtain samples of that tissue as well. However, you may withdraw your consent to participate at any time; if you do so, your samples will be destroyed and no further data will be collected. Please be aware, though, any data that has already been collected will continue to be used and analyzed by researchers at Washington University and other facilities. Data that has been shared in online databases can also not be withdrawn. Data will be stored indefinitely.

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

Some risks described in this consent document, if severe, may cause death.

Risks Associated with Loss of Privacy and Confidentiality

Your privacy is very important to us and we will use many safety measures to protect your privacy. However, despite all of the safety measures that we have put in place, it is impossible to guarantee that links between you and the genetic information and health information we have obtained will never become known.

Although your genetic information is unique to you, you do share some genetic information with your children, parents, siblings, and other relatives. It may be possible that genetic information from them could be used to try to identify your sample. Similarly, it may be possible that genetic information from you could be used to help identify them.

Even though the online databases developed for this project will NOT contain information that is traditionally used to identify you, people may develop ways in the future that would allow someone to link the genetic or medical information in these databases back to you. For example, someone could compare information in one of these databases with information from you (or a relative) in another database and be able to identify you (or your relative). It is also possible that there could be violations in the security of the computer system used to store the codes linking your genetic and medical information to you.

Since some genetic variations can help to predict future health problems you and/or your relatives may have, there could be a risk that this information might be of interest to employers, health providers, insurance companies, and others. Genetic information also can be used by law enforcement agencies to identify a person or his/her relatives. Therefore, your genetic information potentially could be used in ways that could cause you or your family distress, such as by revealing that you (or a relative) carry a genetic disease. We emphasize that we will do everything we can to protect your private information.

Furthermore, a new federal law called the Genetic Information Nondiscrimination Act (GINA) generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information, meaning that:

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

Be aware that this new Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

In addition to the risks described above, there may also be other privacy risks that we have not foreseen.

Blood Drawing
Likely: discomfort, swelling, bruising, and/or bleeding at the site of the needle insertion.

Less likely: dizziness or feeling faint.

Rare: infection (symptoms may include fever, shaking, chills, fatigue, confusion, joint aches, or rapid pulse).

Biopsy
Your doctor will inform you in detail about the risks associated with biopsy. The level of risk will depend on where the tumor is located. In general, having a biopsy can cause pain, swelling, bleeding, and/or infection at the site where the biopsy needle penetrates through the skin. Depending on the area of the biopsy, a local anesthetic (to numb the area) may be injected into the skin, or a sedative medication (medicine that makes you feel sleepy) may be given orally or intravenously. The risks of the anesthetic are minimal and include bleeding, bruising, infection, and allergic reaction. The risks associated with use of a sedative are similar, but also include feeling sleepy, slurred speech, staggering gait (not being able to walk normally), poor judgment, and slowed reflexes.

You may experience all or some of the risks listed above. There may also be unknown risks. The investigator is willing to discuss any questions you might have about these risks and discomforts.

WHAT ARE THE BENEFITS OF THIS STUDY?

You will not benefit from being in this study. However, we hope that, in the future, other people might benefit from this study because it may help research and health professionals around the world to better understand the causes of cancer and other diseases so that they can find better ways to prevent, detect, treat, and cure such illnesses.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?
You will not have any additional costs for being in this research study. However, this study will not pay for the cost of any genetic counseling that you elect to have. Genetic counseling is not mandatory but is recommended if you choose to have certain types of genetic results returned to you. Some insurance companies do pay for genetic counseling; however, any costs associated with genetic counseling not covered by insurance will be your responsibility.

WILL I BE PAID FOR PARTICIPATING?
You will not be paid for being in this research study.

WHO IS FUNDING THIS STUDY?
The University and the research team are not receiving payment from other agencies, organizations, or companies to conduct this research study.

WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?
Washington University investigators and staff will try to reduce, control, and treat any complications from this research. If you feel you are injured because of the study, please contact the investigator at (314) 362-5677 and/or the Human Research Protection Office at 1-(800)-438-0445.

Decisions about payment for medical treatment for injuries relating to your participation in research will be made by Washington University. If you need to seek medical care for a research-related injury, please notify the investigator as soon as possible.

HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?
We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- Government representatives, (including the Office for Human Research Protections) to complete federal or state responsibilities
- The U.S. Food and Drug Administration
- Your primary care physician if a medical condition that needs urgent attention is discovered
- Public health agencies to complete public health reporting requirements
- Hospital or University representatives, to complete Hospital or University responsibilities
- Washington University's Institutional Review Board (a committee that reviews and approves research studies)
- Other researchers in other laboratories, to conduct research on cancer or other projects; these may be individual researchers at other institutions, or they may be other researchers as part of a cooperative group
- The NIH data repository, called the Database of Genotypes and Phenotypes (dbGaP); this is one of the open- and controlled-access online databases described above

The Siteman Cancer Center at Washington University School of Medicine and Barnes-Jewish Hospital is supported by funding from the National Cancer Institute (NCI). To meet NCI requirements, your PHI relating to your participation in this study (including your social security number) will be stored in a

secure database at the Siteman Cancer Center. This database and also your treatment records may be reviewed by Siteman Cancer Center personnel. All information will be securely and confidentially maintained.

To help protect your confidentiality, no identifying information such as your name, birth date, or social security number will be made available to researchers who receive your health information. Furthermore, the study team will keep the master code list that links your UPN with your name and other identifying information in locked storage in a locked office (for paper copies) or on a secured network on a password-protected computer (for electronic copies). Access to either paper or electronic copies will be limited to the Principal Investigator (Dr. Campian), members of the study team, and members of the Tissue Bank.

We stress that we will make every attempt to protect your confidentiality and to make sure that your personal identity does not become known. The only copy of this signed consent form will be stored at Washington University in a secure location only accessible to a few authorized people involved in the project. If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified.

This consent form or similar documentation that you are participating in a research study will be included in your clinical medical record. Anyone with access to your medical record, including your health insurance company will be able to see that you are participating in a research study.

Are there additional protections for my health information?

Protected Health Information (PHI) is health information that identifies you. PHI is protected by federal law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this research, you must give the research team permission to use and disclose (share) your PHI for the study as explained in this consent form. The research team will follow state and federal laws and may share your health information with the agencies and people listed under the previous section titled, "How will you keep my information confidential?".

Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.

The research team will only use and share your information as talked about in this form. When possible, the research team will make sure information cannot be linked to you (de-identified). Once information is de-identified, it may be used and shared for other purposes not discussed in this consent form. If you have questions or concerns about your privacy and the use of your PHI, please contact the University's Privacy Officer at 866-747-4975.

Although you will not be allowed to see the study information, you may be given access to your health care records by contacting your health care provider.

If you decide not to sign this form, it will not affect

- your treatment or the care given by your health provider.
- your insurance payment or enrollment in any health plans.

- any benefits to which you are entitled.

However, it will not be possible for you to take part in the study.

If you sign this form:

- You authorize the use of your PHI for this research
- Your signature and this form will not expire as long as you wish to participate.
- You may later change your mind and not let the research team use or share your information (you may revoke your authorization).
  - To revoke your authorization, complete the withdrawal letter, found in the Participant section of the Human Research Protection Office website at http://hrpo.wustl.edu/participants//withdrawing-from-a-study/ or you may request that the investigator send you a copy of the letter. .
    - **If you revoke your authorization:**
      - The research team may only use and share information already collected for the study.
      - Your information may still be used and shared if necessary for safety reasons.
      - You will not be allowed to continue to participate in the study.

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Dr. Jian Campian at (314) 747-7509.

If you have questions, concerns, or complaints about your rights as a research participant, please contact the Human Research Protection Office, 660 South Euclid Avenue, Campus Box 8089, St. Louis, MO 63110, 1-(800)-438-0445, or email hrpo@wustl.edu. General information about being a research participant can be found by clicking "Participants" on the Human Research Protection Office web site, http://hrpo.wustl.edu. To offer input about your experiences as a research subject or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by agreeing to participate in this study. As a participant you have rights and responsibilities as described in this document and including:

- To be given enough time before signing below to weigh the risks and potential benefits and decide if you want to participate without any pressure from the research team or others.
- To understand all of the information included in the document, have your questions answered, and receive an explanation of anything you do not understand.

- To follow the procedures described in this document and the instructions of the research team to the best of your ability unless you choose to stop your participation in the research study.
- To give the research team accurate and complete information.
- To tell the research team promptly about any problems you have related to your participation, or if you are unable to continue and wish to stop participating in the research study.

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a signed and dated copy of this form.

Do not sign this form if today's date is after EXPIRATION DATE: 03/06/18.

[redacted] 5-8-2017

(Signature of Participant) (Date)

[redacted]

(Participant's name – printed)

Statement of Person Who Obtained Consent

I have discussed the information in this document with the participant or, where appropriate, with the participant's legally authorized representative. It is my opinion that the participant understands the risks, benefits, and procedures involved with participation in this research study.

[signature] 5/8/17

(Signature of Person who Obtained Consent) (Date)

PUSPANJALI BHATTA

(Name of Person who Obtained Consent - printed)

[redacted]

BRK

[redacted]

INFORMED CONSENT DOCUMENT

Project Title: Analysis of Histological, Genomic, Molecular, and Clinical Factors in CNS Cancer: The Neuro-Oncology Group

Principal Investigator: Jian Campian, M.D.

Research Team Contact: Jian Campian, M.D. – (314) 747-7509

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The purpose of this research study is to discover genetic changes associated with cancer by documenting the DNA changes that occur in brain cancer cells. This may lead to better ways of preventing, detecting, and treating cancer and perhaps other diseases as well.

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I agree to allow the study team to collect tumor tissue that was previously collected at a site other than Washington University or Siteman Cancer Center.

_X_ yes ____ no

Collection of Health Information

In addition to the tissue and blood samples, we will also collect health information from your medical record. This information includes your medical history, findings from recent physical exams, and results of laboratory testing. If you have not recently been seen by a physician, we may contact you to determine your current health status. Review of your records and any personal contact with you will only be made by members of the study team.

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number and order of changes occurring in the tumor DNA compared to normal tissue samples, so the changes associated with your tumor may be mapped out and analyzed as well.

Your samples and data may be studied by other laboratories in other ways besides genome sequencing. The remaining portions of your samples will be stored for an unlimited period of time for future use in research related to cancer or in other research projects. Coded samples and data may be shared with other researchers both within Washington University as well as outside of Washington University for future research as well.

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Your tissue samples may be used to determine the sequence of some or all of your genes (DNA). This DNA sequence information could indicate that you may have gene mutations that could affect not only your future health, but also the health of your children. If the researcher, together with a panel of other medical center experts, feel that this information may be very important for you or your children to know about, then you or a person designated by you (in the event of your death or incapacitation) would be contacted by a member of the study team and given the opportunity to talk with a genetic counselor. The purpose of this would be to help explain the significance of the findings and advise you of any steps to be taken to further minimize the health risk to you or your offspring. If you choose to be notified about these results, this will occur only once, around the time that the sequencing takes place; the research team will not be continuously checking samples as time passes to see if more relevant results are found.

If we discover genetic changes that may be important for the care of your illness or that may be relevant for your health or the health of close family members (for example, your parents, siblings, or children), would you like us to notify you about these results? [X] yes [ ] no

We may also find genetic changes that you have inherited. These changes could also be present in one or both of your parents, your siblings, or your children. These inherited changes may affect your risk or a family member's risk of getting cancer or other medical conditions. For this reason, we may recommend that you speak to a genetic counselor who will describe the results and what they mean. The genetic counselor will also ask you questions about conditions that run in your family. This will not happen immediately, but will happen around the time that the sequencing takes place. AT that time, you and/or your next-of-kin will be given the option to decide whether you want to receive these results. Some of these findings could be important for your healthcare or for the healthcare of closely related family members, and you will be able to share these results with them if you so choose.

In the event of your death or incapacitation, may we contact your next-of-kin to discuss results of genetic testing performed on your donated tissue that could affect the health of your offspring or other family members? [X] yes [ ] no

If yes, please provide name of contact: [redacted]

Will you save my samples or research data to use in future research studies?

As part of this study, we are obtaining data, tumor tissue, and blood samples from you. We would like to use your data, tumor tissue, and blood samples for studies going on right now as well as studies that are conducted in the future, including future genetic research or the creation of cell lines, which are distinct families of cells grown in a lab that are all the same and can be used for research. These studies may provide additional information that will be helpful in understanding brain cancers, or other diseases or conditions, including research to develop investigational tests, treatments, drugs or devices that are not yet approved by the U.S. Food and Drug Administration. It is unlikely that what we learn from these studies will have a direct benefit to you. There are no plans to provide financial compensation to you should this occur. By allowing us to use your data, tissue, and blood, you give up any property rights you may have in the data, tissue, and blood.

We will share your data, tissue, and blood with other researchers. They may be doing research in areas similar to this research or in other unrelated areas. These investigators may be at Washington University, at other research centers and institutions, or industry sponsors of research. We may also share your research data with large data repositories (a repository is a database of information) for broad sharing with the research community. If your individual research data is placed in one of these repositories only qualified researchers, who have received prior approval from individuals that monitor the use of the data, will be able to look at your information.

If you change your mind and do not want us to store and use your tumor tissue, blood samples, and data for future research you should contact the research team member identified at the top of this document. The tumor tissue, blood samples, and data will no longer be used for research purposes. However, if some research with your tumor tissue, blood samples, and data has already been completed, the information from that research may still be used. Also, if the data has been shared with other researchers it might not be possible withdraw it to the extent it has been shared.

Please note that, in general, we will not give you any individual results from the analysis of your tumor tissue or blood. This is because it will probably take a long time for this study to produce information that we will know how to interpret accurately. However, we will tell you if we find that you have a communicable disease that we are required by law to report, although we don't at this time anticipate running any tests that may result in such findings.

HOW MANY PEOPLE WILL PARTICIPATE?

Approximately 500 people will take part in this study conducted by investigators at Washington University

HOW LONG WILL I BE IN THIS STUDY?

Data about your health status will be collected for the ten years that follow your enrollment on the study

unless you choose to withdraw from this research or there's no way for the research team to contact you or your physician. This means that a member of the study team may contact you in the future to document your health status, or that this information may be obtained by reviewing your office visit notes. You will be contacted at least once a year and no more than every three months dependent upon routine care for your diagnosis. If you have more biopsies or surgeries in the future, we would like to obtain samples of that tissue as well. However, you may withdraw your consent to participate at any time; if you do so, your samples will be destroyed and no further data will be collected. Please be aware, though, any data that has already been collected will continue to be used and analyzed by researchers at Washington University and other facilities. Data that has been shared in online databases can also not be withdrawn. Data will be stored indefinitely.

WHAT ARE THE RISKS OF THIS STUDY?

You may experience one or more of the risks indicated below from being in this study. In addition to these, there may be other unknown risks, or risks that we did not anticipate, associated with being in this study.

Some risks described in this consent document, if severe, may cause death.

Risks Associated with Loss of Privacy and Confidentiality

Your privacy is very important to us and we will use many safety measures to protect your privacy. However, despite all of the safety measures that we have put in place, it is impossible to guarantee that links between you and the genetic information and health information we have obtained will never become known.

Although your genetic information is unique to you, you do share some genetic information with your children, parents, siblings, and other relatives. It may be possible that genetic information from them could be used to try to identify your sample. Similarly, it may be possible that genetic information from you could be used to help identify them.

Even though the online databases developed for this project will NOT contain information that is traditionally used to identify you, people may develop ways in the future that would allow someone to link the genetic or medical information in these databases back to you. For example, someone could compare information in one of these databases with information from you (or a relative) in another database and be able to identify you (or your relative). It is also possible that there could be violations in the security of the computer system used to store the codes linking your genetic and medical information to you.

Since some genetic variations can help to predict future health problems you and/or your relatives may have, there could be a risk that this information might be of interest to employers, health providers, insurance companies, and others. Genetic information also can be used by law enforcement agencies to identify a person or his/her relatives. Therefore, your genetic information potentially could be used in ways that could cause you or your family distress, such as by revealing that you (or a relative) carry a genetic disease. We emphasize that we will do everything we can to protect your private information.

Furthermore, a new federal law called the Genetic Information Nondiscrimination Act (GINA) generally

makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information, meaning that:

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

Be aware that this new Federal law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance.

In addition to the risks described above, there may also be other privacy risks that we have not foreseen.

Blood Drawing
Likely: discomfort, swelling, bruising, and/or bleeding at the site of the needle insertion.

Less likely: dizziness or feeling faint.

Rare: infection (symptoms may include fever, shaking, chills, fatigue, confusion, joint aches, or rapid pulse).

Biopsy
Your doctor will inform you in detail about the risks associated with biopsy. The level of risk will depend on where the tumor is located. In general, having a biopsy can cause pain, swelling, bleeding, and/or infection at the site where the biopsy needle penetrates through the skin. Depending on the area of the biopsy, a local anesthetic (to numb the area) may be injected into the skin, or a sedative medication (medicine that makes you feel sleepy) may be given orally or intravenously. The risks of the anesthetic are minimal and include bleeding, bruising, infection, and allergic reaction. The risks associated with use of a sedative are similar, but also include feeling sleepy, slurred speech, staggering gait (not being able to walk normally), poor judgment, and slowed reflexes.

You may experience all or some of the risks listed above. There may also be unknown risks. The investigator is willing to discuss any questions you might have about these risks and discomforts.

WHAT ARE THE BENEFITS OF THIS STUDY?

You will not benefit from being in this study. However, we hope that, in the future, other people might benefit from this study because it may help research and health professionals around the world to better understand the causes of cancer and other diseases so that they can find better ways to prevent, detect, treat, and cure such illnesses.

WILL IT COST ME ANYTHING TO BE IN THIS STUDY?

You will not have any additional costs for being in this research study. However, this study will not pay

for the cost of any genetic counseling that you elect to have. Genetic counseling is not mandatory but is recommended if you choose to have certain types of genetic results returned to you. Some insurance companies do pay for genetic counseling; however, any costs associated with genetic counseling not covered by insurance will be your responsibility.

WILL I BE PAID FOR PARTICIPATING?
You will not be paid for being in this research study.

WHO IS FUNDING THIS STUDY?
The University and the research team are not receiving payment from other agencies, organizations, or companies to conduct this research study.

WHAT IF I AM INJURED AS A RESULT OF THIS STUDY?
Washington University investigators and staff will try to reduce, control, and treat any complications from this research. If you feel you are injured because of the study, please contact the investigator at (314) 362-5677 and/or the Human Research Protection Office at 1-(800)-438-0445.

Decisions about payment for medical treatment for injuries relating to your participation in research will be made by Washington University. If you need to seek medical care for a research-related injury, please notify the investigator as soon as possible.

HOW WILL YOU KEEP MY INFORMATION CONFIDENTIAL?
We will keep your participation in this research study confidential to the extent permitted by law. However, it is possible that other people such as those indicated below may become aware of your participation in this study and may inspect and copy records pertaining to this research. Some of these records could contain information that personally identifies you.

- Government representatives, (including the Office for Human Research Protections) to complete federal or state responsibilities
- The U.S. Food and Drug Administration
- Your primary care physician if a medical condition that needs urgent attention is discovered
- Public health agencies to complete public health reporting requirements
- Hospital or University representatives, to complete Hospital or University responsibilities
- Washington University's Institutional Review Board (a committee that reviews and approves research studies)
- Other researchers in other laboratories, to conduct research on cancer or other projects; these may be individual researchers at other institutions, or they may be other researchers as part of a cooperative group
- The NIH data repository, called the Database of Genotypes and Phenotypes (dbGaP); this is one of the open- and controlled-access online databases described above

The Siteman Cancer Center at Washington University School of Medicine and Barnes-Jewish Hospital is supported by funding from the National Cancer Institute (NCI). To meet NCI requirements, your PHI relating to your participation in this study (including your social security number) will be stored in a secure database at the Siteman Cancer Center. This database and also your treatment records may be reviewed by Siteman Cancer Center personnel. All information will be securely and confidentially

maintained.

To help protect your confidentiality, no identifying information such as your name, birth date, or social security number will be made available to researchers who receive your health information. Furthermore, the study team will keep the master code list that links your UPN with your name and other identifying information in locked storage in a locked office (for paper copies) or on a secured network on a password-protected computer (for electronic copies). Access to either paper or electronic copies will be limited to the Principal Investigator (Dr. Campian), members of the study team, and members of the Tissue Bank.

We stress that we will make every attempt to protect your confidentiality and to make sure that your personal identity does not become known. The only copy of this signed consent form will be stored at Washington University in a secure location only accessible to a few authorized people involved in the project. If we write a report or article about this study or share the study data set with others, we will do so in such a way that you cannot be directly identified.

This consent form or similar documentation that you are participating in a research study will be included in your clinical medical record. Anyone with access to your medical record, including your health insurance company will be able to see that you are participating in a research study.

Are there additional protections for my health information?

Protected Health Information (PHI) is health information that identifies you. PHI is protected by federal law under HIPAA (the Health Insurance Portability and Accountability Act). To take part in this research, you must give the research team permission to use and disclose (share) your PHI for the study as explained in this consent form. The research team will follow state and federal laws and may share your health information with the agencies and people listed under the previous section titled, "How will you keep my information confidential?".

Once your health information is shared with someone outside of the research team, it may no longer be protected by HIPAA.

The research team will only use and share your information as talked about in this form. When possible, the research team will make sure information cannot be linked to you (de-identified). Once information is de-identified, it may be used and shared for other purposes not discussed in this consent form. If you have questions or concerns about your privacy and the use of your PHI, please contact the University's Privacy Officer at 866-747-4975.

Although you will not be allowed to see the study information, you may be given access to your health care records by contacting your health care provider.

If you decide not to sign this form, it will not affect

- your treatment or the care given by your health provider.
- your insurance payment or enrollment in any health plans.
- any benefits to which you are entitled.

However, it will not be possible for you to take part in the study.

If you sign this form:

- You authorize the use of your PHI for this research
- Your signature and this form will not expire as long as you wish to participate.
- You may later change your mind and not let the research team use or share your information (you may revoke your authorization).
  - To revoke your authorization, complete the withdrawal letter, found in the Participant section of the Human Research Protection Office website at http://hrpo.wustl.edu/participants//withdrawing-from-a-study/ or you may request that the investigator send you a copy of the letter. .
    - **If you revoke your authorization:**
      - The research team may only use and share information already collected for the study.
      - Your information may still be used and shared if necessary for safety reasons.
      - You will not be allowed to continue to participate in the study.

IS BEING IN THIS STUDY VOLUNTARY?

Taking part in this research study is completely voluntary. You may choose not to take part at all. If you decide to be in this study, you may stop participating at any time. If you decide not to be in this study, or if you stop participating at any time, you won't be penalized or lose any benefits for which you otherwise qualify.

WHAT IF I HAVE QUESTIONS?

We encourage you to ask questions. If you have any questions about the research study itself, please contact: Dr. Jian Campian at (314) 747-7509.

If you have questions, concerns, or complaints about your rights as a research participant, please contact the Human Research Protection Office, 660 South Euclid Avenue, Campus Box 8089, St. Louis, MO 63110, 1-(800)-438-0445, or email hrpo@wusm.wustl.edu. General information about being a research participant can be found by clicking "Participants" on the Human Research Protection Office web site, http://hrpo.wustl.edu. To offer input about your experiences as a research subject or to speak to someone other than the research staff, call the Human Research Protection Office at the number above.

This consent form is not a contract. It is a written explanation of what will happen during the study if you decide to participate. You are not waiving any legal rights by agreeing to participate in this study. As a participant you have rights and responsibilities as described in this document and including:

- To be given enough time before signing below to weigh the risks and potential benefits and decide if you want to participate without any pressure from the research team or others.
- To understand all of the information included in the document, have your questions answered, and receive an explanation of anything you do not understand.
- To follow the procedures described in this document and the instructions of the research team to the best of your ability unless you choose to stop your participation in the research study.
- To give the research team accurate and complete information.

- To tell the research team promptly about any problems you have related to your participation, or if you are unable to continue and wish to stop participating in the research study.

Your signature indicates that this research study has been explained to you, that your questions have been answered, and that you agree to take part in this study. You will receive a signed and dated copy of this form.

Do not sign this form if today's date is after EXPIRATION DATE: 05/11/16.

[redacted] 6-22-2015

(Signature of Participant) (Date)

[redacted]

(Participant's name – printed)

Statement of Person Who Obtained Consent

I have discussed the information in this document with the participant or, where appropriate, with the participant's legally authorized representative. It is my opinion that the participant understands the risks, benefits, and procedures involved with participation in this research study.

Ann Woodside 6/22/2015

(Signature of Person who Obtained Consent) (Date)

Ann Woodside

(Name of Person who Obtained Consent - printed)