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www.joincountmein.org

Research Consent Form
(Count Me In)

If you have questions about the study or the consent form at any time, please contact us at 651-403-5315 or info@joincountmein.org.

RESEARCH CONSENT FORM (Count Me In) - KEY POINTS

"Count Me In" is a patient-driven movement that enables cancer patients to directly transform research and discovery. Any individual who has ever been diagnosed with cancer has the opportunity to share information about their experience through completing surveys, sharing biological samples (saliva, blood and/or cancer samples, and in some cases, stool samples), and copies of their medical records with researchers in order to accelerate the pace of discovery. Because we are open to participants across the country regardless of where they are being treated, this study will allow many more cancer patients to contribute to research than has previously been possible.

1. What is the purpose of this study?

We can better understand cancers so that we can develop more effective therapies. By partnering directly with patients, we are able to study many more aspects of cancer than would otherwise be possible.

2. What will I have to do if I agree to participate in this study?

After signing a consent form, you will be asked to complete surveys about your experience with cancer. Additional survey(s) may become available during the course of this research study that you can choose to complete.
We will ask that you send a saliva sample to us in a pre-stamped package that we wil provide.
We will ask you to complete a medical release form so that we are able to request your medical records. If we do so, we will take care of obtaining copies of your records from the hospitals or centers where you receive your medical care. If needed, we may contact you to ask if you would be willing to sign additional authorization forms or documents that certain hospitals or centers may require in order to share copies of your medical records with us.
If you choose to share tissue specimens with us, we may also obtain small amounts of your stored cancer samples from hospitals or centers where you receive your care.
If you choose to share blood with us, we may ask for a sample (or samples) of blood (1 tube, or 2 teaspoons per sample) to be drawn at your physician's office, local clinic, or nearby lab facility – we will provide detailed instructions on how to do this.

3. Do I have to participate in this study?

No. Taking part in this study is voluntary. Even if you decide to participate, you can always change your mind and leave the study.

4. Will it cost me anything to participate in this study?

No.

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5. Will I benefit from participating?

While taking part in this study may not improve your own health, the information we collect will aid in research efforts to provide better cancer treatment and prevention options to future patients. We will provide updates about key research discoveries made possible by your participation.

6. What are the risks of taking part in this research?

If you elect to share blood, there are small risks associated with obtaining a sample of blood. You may experience slight pain and swelling at the site of the blood draw. These complications are rare and should resolve within a few days. If they do not, you should contact your doctor.

There may be a risk that your information (which includes your genetic information and information from your medical records) could be seen by unauthorized individuals. However, we have procedures and security measures in place designed to minimize this risk and protect the confidentiality of your information.

In the unlikely event of an unauthorized disclosure, there is a Federal law, known as the Genetic Information Nondiscrimination Act (GINA), which protects you from genetic discrimination. GINA generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against you based on your genetic information. However, this law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. If you already have or have had cancer, any unauthorized disclosure of genetic results is unlikely to change an insurer's view of your risk.

6.

7. Will it cost me anything to participate in this study?

No.

8. Who will use my samples and see my information?

Your samples and health information will be available to researchers at the Broad Institute of MIT and Harvard, a not-for-profit biomedical research institute. After removing your name and other readily identifiable information, we will share results obtained from your participation with the greater research community as well as central data banks at the National Institutes of Health.

9. Can I stop taking part in this research study?

Yes, you can withdraw from this research study at any time, although any of your information that has already been entered into our system cannot be withdrawn. Your information would be removed from future studies.

10. What if I have questions?

If you have any questions, please send an email to info@joincountmein.org or call 651-403-5315 and ask to speak with a member of the study staff about this study.

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FULL RESEARCH CONSENT FORM

Count Me In

A. Introduction

You are being invited to participate in a research study that will collect and analyze samples and health information of patients with cancers. This study will help doctors and researchers better understand why cancers occur and develop ways to better treat and prevent them.

Cancers occur when the molecules that control normal cell growth (genes and proteins) are altered. Changes in the genes of tumor cells and normal tissues are called "alterations". Several alterations that occur in certain types of cancers have already been identified and have led to the development of new drugs that specifically target those alterations. However, the vast majority of tumors from patients have not been studied, which means there is a tremendous amount of information still left to be discovered. Our goal is to discover more alterations, and to better understand those that have been previously described. We think this could lead to the development of additional therapies and cures.

Genes are composed of DNA "letters," which contain the instructions that tell the cells in our bodies how to grow and work. We would like to use your DNA to look for alterations in cancer cell genes using a technology called "sequencing."

Gene sequencing is a way of reading the DNA to identify alterations in genes that may contribute to the behavior of cells. Some changes in genes occur only in cancer cells. Others occur in normal cells as well, in the genes that may have been passed from parent to child. This research study will examine both kinds of genes.

You are being asked to participate in the study because you have a brain tumor. Other than providing samples of saliva and, if you elect to, blood sample(s) (1 tube or 2 teaspoons per sample), participating in the study involves no additional tests or procedures.

This form explains why this research study is being done, what is involved in participating, the possible risks and benefits of the study, alternatives to participation, and your rights as a participant. The decision to participate is yours. We encourage you to ask questions about the study now or in the future.

B. Why is this research study being done?

We want to understand cancer better so that we can develop more effective therapies. By partnering directly with patients, we will be able to study many more aspects of cancer than has previously been possible. In addition, because we are enrolling participants across the country regardless of where they are being treated, this study will allow many more patients to directly contribute to research than might otherwise be feasible.

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C. What other options are there?

Taking part in this research study is voluntary – you may choose not to participate. Your decision not to participate will not affect your medical care in any way or result in any penalty or loss of benefits.

D. What is involved in the research study?

With your consent, we may obtain copies of your medical records and ask that you collect a sample of saliva at home–we will provide detailed instructions on how to do this. We may contact you to ask if you would be willing to sign an additional release form for your medical records to be shared with us. You may also choose to send your medical records directly to us. If you elect to share tissue samples with us, we may request a portion of your tumor tissues through already stored biopsies or surgical specimens in hospitals or centers where you received your medical care in the past.

If you elect to share blood samples with us as well, we may ask you to have a sample of blood (1 tube or 2 teaspoons) drawn at your physician's office, local clinic, or nearby lab facility. We'll ask you to send any blood and/or saliva sample(s) to us in pre-stamped packages that we will provide. We may ask you to provide blood at multiple different time points. We will contact you before sending the blood kit. If you do not want to participate in the blood draw at that time, please just inform one of the study staff members.

We will analyze the genes in your cancer cells (obtained from your tissue or blood sample) and your normal cells (obtained from the blood sample or from your saliva sample). No additional procedures will be required. The results of this analysis will be used to try to develop better ways to treat and prevent cancers.

We will link the results of the gene tests on your cancer cells and normal cells with medical information that has been generated during the course of your treatment. We are asking your permission to obtain a copy of your medical record from places where you have received care for your cancer.

In some cases, a research doctor may contact you to find out if you would be interested in participating in a different or future research study based on information that may have been found in your samples or medical information.

To allow sharing of information with other researchers, the National Institutes of Health (NIH) and other organizations have developed central data (information) banks that analyze information and collect the results of certain types of genetic studies. These central banks will store your genetic and medical information and provide the information to qualified researchers to do more studies. We will also store your genetic and medical information at the Broad Institute of MIT and Harvard and share your information with other qualified researchers. Therefore, we are asking your permission to share your results with these special banks and other researchers, and have your information used for future research studies, including studies that have not yet been designed, studies involving diseases other than cancer, and/or studies that may be for commercial purposes (such as the development or approval of new drugs). Your

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information will be sent to central banks and other researchers only with a code number ttached. Your name, social security number, and other information that could readily identify you will not be shared with central banks or other researchers. We will never sell your readily identifiable information to anyone under any circumstances.

E. How long will I be in this research study?

You may be asked to give samples of blood, tissue, and/or saliva after you consent to enrolling in this study. You may also be asked to complete additional questionnaires. We will keep your blood, tissue, and saliva samples and medical records indefinitely until this study is finished, unless you inform us that you no longer wish to participate. You may do this at any time. More information about how to stop being in the study is below in paragraph I.

Once the study is finished, any left over blood and saliva samples and your medical records will be destroyed. Any tissue samples that we have will be returned to the pathology department at the hospital or other place where you received treatment.

F. What kind of information could be found in this study and will I be able to see it?

The gene tests in this study are being done to add to our knowledge of how genes and other factors affect cancer. This information will be kept confidential and while you will not receive information about your personal results obtained from studying your blood, saliva, or tissue samples, we will provide general results and major discoveries to all participants. We will do this by regularly updating the website that you used to enroll in this study. Furthermore, we will publish important discoveries found through these studies in the scientific literature so that the entire research community can work together to better understand cancer. Your individual data will not be published in a way in which you could be readily identified. Abstracts, which are plain language summaries of the published reports, will be available to you and the general public.

G. What are the risks or discomforts of the research study?

If you elect to share blood, there are small risks associated with obtaining the tube of blood. You may experience slight pain and swelling at the site of the blood draw. These complications are rare and should resolve within a few days. If they do not, you should contact your doctor.

There is a small risk that by participating in this study, the gene test results, including the identification of genetic changes in you or your cancer, could be seen by unauthorized individuals. We have tried to minimize this risk by carefully limiting access to the computers that would house your information to the staff of this research study.

In the unlikely event of an unauthorized disclosure, there is a Federal law, known as the Genetic Information Nondiscrimination Act (GINA), which protects you from genetic discrimination. GINA generally makes it illegal for health insurance companies, group

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health plans, and most employers to discriminate against you based on your genetic information. However, this law does not protect you against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. If you already have or have had cancer, any unauthorized disclosure of genetic results is unlikely to change an insurer's view of your risk.

There is a small but real risk that if your samples are used for this research study, they might not be available for clinical care in the future. However, we have attempted to minimize this risk in the following way: the pathologists in the department of pathology where your specimens are kept will not release your specimen unless they believe that the material remaining after the research test is performed is sufficient for any future clinical needs.

H. What are the benefits of the research study?

Taking part in this research study may not directly benefit you. By joining this study, you will help us and other researchers understand how to use gene tests to improve the care of patients with cancer in the future. We will provide study participants updates on our project website about key research discoveries made possible by your participation.

I. Can I stop being in the research study and what are my rights?

You can stop being in the research study at any time. We will not be able to withdraw all the information that already has been used for research. If you tell us that you want to stop being in the study, we will return any remaining tumor samples from where we obtained them, and destroy any remaining blood, saliva samples, or DNA samples we have. We will not perform any additional tests on the samples. Additionally, we will not collect any additional medical records and we will destroy the medical records we already have.

However, we will keep the results from the tests we did before you stopped being in the study. We will also keep the information we learned from reviewing your medical records before you stopped being in the study. We will not be able to take back the information that already has been used or shared with other researchers, central data banks, or that has been used to carry out related activities such as oversight, or that is needed to ensure quality of the study.

To withdraw your permission, you must do so in writing by contacting the researcher listed below in the section: "Whom do I contact if I have questions about the research study?" If you choose to not participate, or if you are not eligible to participate, or if you withdraw from this research study, this will not affect your present or future care and will not cause any penalty or loss of benefits to which you are otherwise entitled.

J. Will I be paid to take part in this research study?

There is no financial compensation for participation in this study.

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K. What are the costs?

There are no costs to you to participate in this study.

L. What happens if I am injured or sick because I took part in this research study?

There is little risk that you will become injured or sick by taking part in this study. There are no plans for this project to pay you or give you other compensation for any injury. You do not give up your legal rights by signing this form. If you think you have been injured as a result of taking part in this research study, please tell the person in charge of this research study as soon as possible. The research doctor's contact information is listed in this consent form.

M. What about confidentiality?

We will take rigorous measures to protect the confidentiality and security of all your information, but we are unable to guarantee complete confidentiality. Information shared with the research team through email, or information accessible from a link in an email, is only protected by the security measures in place for your email account. Information from your medical records and genomics tests will be protected in a HIPAA compliant database.

When we receive any of your samples, your name, social security number, and other information that could be used to readily identify you will be removed and replaced by a code. If we send your samples to our collaborators for gene testing, the samples will be identified using only this code. The medical records that we receive will be reviewed by our research team to confirm that you are eligible for the study and to obtain information about your medical condition and treatment.

We will store all of your identifiable information related to the study (including your medical records) in locked file cabinets and in password-protected computer files or secure databases at the Broad Institute and we will limit access to such files. We may share your identifiable information or coded information, as necessary, with regulatory or oversight authorities (such as the Office for Human Research Protections), ethics committees reviewing the conduct of the study, or as otherwise required by law.

When we send the results of the gene tests and your medical information to central data banks or other researchers, they will not contain your name, social security number, or other information that could be used to readily identify you.

The results of this research study or future research studies using the information from this study may be published in research papers or included in presentations that will become part of the scientific literature. You will not be identified in publications or presentations.

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Whom do I contact if I have questions about the research study?

If you have questions about the study, please contact the research doctor or study staff listed below by emailing info@joincountmein.org or calling 651-403-5315:

- Nikhil Wagle, MD
- Corrie Painter, PhD
- Elana Anastasio

For questions about your rights as a patient, please contact a representative of the Office for Human Research Studies at (617)-632-3029. This can include questions about your participation in the study, concerns about the study, a research related injury, or if you feel/felt under pressure to enroll in this research study or to continue to participate in this research study. Please keep a copy of this document in case you want to read it again.

O. Authorization to use your health information for research purposes

Because information about you and your health is personal and private, it generally cannot be used in this research study without your written authorization. Federal law requires that your health care providers and healthcare institutions (hospitals, clinics, doctor's offices) protect the privacy of information that identifies you and relates to your past, present, and future physical and mental health conditions.

If you sign this form, it will provide your health care providers and healthcare institutions the authorization to disclose your protected health information to the Broad Institute for use in this research study. The form is intended to inform you about how your health information will be used or disclosed in the study. Your information will only be used in accordance with this authorization form and the informed consent form and as required or allowed by law. Please read it carefully before signing it.

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

· Health information created from study-related tests and/or questionnaires

· Your medical records

· Your saliva sample

If elected (at the end of this form):

· Your blood sample(s)

· Your tissue samples relevant to this research study and related records

2. Why will protected information about me be used or shared with others?

The main reasons include the following:

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· To conduct and oversee the research described earlier in this form;

· To ensure the research meets legal, institutional, and accreditation requirements;

· To conduct public health activities (including reporting of adverse events or situations where you or others may be at risk of harm);

· To better understand the diseases being studied and to improve the design of future studies

3. Who will use or share protected health information about me?

The Broad Institute and its researchers and affiliated research staff will use and/or share your personal health information in connection with this research study.

4. With whom outside of the Broad Institute may my personal health information be shared?

While all reasonable efforts will be made to protect the confidentiality of your protected health information, it may also be shared with the following entities:

· Federal and state agencies (for example, the Department of Health and Human Services, the Food and Drug Administration, the National Institutes of Health, and/or the Office for Human Research Protections), or other domestic or foreign government bodies if required by law and/or necessary for oversight purposes. A qualified representative of the FDA and the National Cancer Institute may review your medical records.

· Outside individuals or entities that have a need to access this information to perform functions relating to the conduct of this research such as data storage companies.

Some who may receive your personal health information may not have to satisfy the privacy rules and requirements. They, in fact, may share your information with others without your permission.

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

There is no scheduled date at which your protected health information that is being used or shared for this research will be destroyed, because research is an ongoing process.

6. Statement of privacy rights:

· You have the right to withdraw your permission for the doctors and researchers to use or share your protected health information. We will not be able to withdraw all the information that already has been used or shared with others to carry out related activities such as oversight, or that is needed to ensure quality of the study. To

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withdraw your permission, you must do so in writing by contacting the researcher listed above in the section: "Whom do I contact if I have questions about the research study?"

· You have the right to request access to your personal health information that is used or shared during this research and that is related to your treatment or payment for your treatment. To request this information, please contact your doctor who will request this information from the study directors.

P. Participation Information

If you decide to sign this consent form, we may ask you for information about contacting your physicians and the hospitals that you were treated at for your brain tumor. We will not disclose details about the results of your participation in this study with any of the individuals that we contact, but rather ask them to provide us with your medical history and your tissue samples.

Q. Documentation of Consent

This is what I agree to:

· You can work with me to arrange a sample of blood to be drawn at my physician's office, local clinic, or nearby lab facility.

☐ Yes ☐ No

· You can request my stored tissue samples from my physicians and the hospitals and other places where I received my care, perform (or collaborate with others to perform) gene tests on the samples, and store the samples until this research study is complete.

☐ Yes ☐ No

In addition, I agree to all of the following:

· You can request my medical records from my physicians and the hospitals and other places where I received and/or continue to receive my treatment and link results of the gene tests you perform on my saliva and, if I elect on this form, blood and tissue samples with my medical information from my medical records.

· You can analyze a saliva sample that I will send you, link the results to my medical information and other specimens, and store the specimen to use it for future research.

· You can perform (or collaborate with others to perform) gene tests on the blood and saliva samples that I will send you and store the samples until this research study is complete.

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· You can use the results of the gene tests and my medical information for future research studies, including studies that have not yet been designed, studies for diseases other than cancer, and/or studies that may be for commercial purposes.

· You can share the results of the gene tests and my medical information with established public databases (e.g., the NIH, cBioPortal, Tumor Portal, The Exome Aggregation Consortium (ExAC)/Genome Aggregation Database (gnomAD)) and with other qualified researchers in a manner that does not include my name, social security number, or any other information that could be used to readily identify me, to be used by other qualified researchers to perform future research studies, including studies that have not yet been designed, studies for diseases other than cancer, and studies that may be for commercial purposes.

· You can contact me in the future for reasons related to this research study, for example to ask if I would be willing to sign any additional documents that my hospital(s) may require in order to share my medical records.

My full name below indicates:

I have had enough time to read the consent and think about agreeing to participate in this study;

I have had all of my questions answered to my satisfaction;

I am willing to participate in this research study;

I have been told that my participation is voluntary and if I decide not to participate it will have no impact on my medical care;

I have been told that if I decide to participate now, I can decide to stop being in the study at any time.

I acknowledge that a copy of the signed consent form will be sent to my email address.

Your Full Name:

Date of Birth (mm/dd/yyyy):

Date: