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T 651-403-5315
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Research Consent Form
(Count Me In)

Please read through the consent form text below and click “Next” when you are done to move on to the next section. 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 cancer 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 want to 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 different cancers 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 will 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

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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 now, you can always change your mind and leave the study at any time.

4. Will it cost me anything to participate in this study?
No.

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 choose to share blood, you may experience slight pain and swelling where the blood was drawn. 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 or surveys you've completed) could be seen by individuals who do not have permission to view it. However, we have procedures and security measures in place designed to reduce this risk and protect the confidentiality of your information. There is also 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

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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.

7. Who will use my samples and see my information?
Your samples and health information will be available to study staff and researchers at Count Me In and the Broad Institute of MIT and Harvard, which are both not-for-profit research organizations. After removing your name and other readily identifiable information, we will share results obtained from your participation with the greater research community via established public scientific databases (for example, the National Institute of Health/National Cancer Institute data portals such as the Genomic Data Commons and dbGaP, and the cBioPortal for Cancer Genomics). Some of these databases are publicly viewable by anyone with internet access, and some are restricted to qualified researchers.

8. Can I stop taking part in this research study?
Yes, you can withdraw from this research study at any time, although any information that has already been shared with researchers cannot be retrieved, and will not be deleted from our databases. Your information would be removed from future studies.

9. 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 this research study because you have been diagnosed with cancer. This study will collect and analyze samples and health information of many patients with cancer, in order to 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 cell growth (such as genes or proteins) become changed or altered. Changes in genes are called “alterations” and can occur in cancer cells or normal tissues. Some alterations that occur in certain types of cancers have already been identified, which has led to the development of drugs that specifically target those alterations. However, the vast majority of cancer patients have not yet been studied, which means there is a tremendous amount of information still left to be discovered. A key goal of this research study is to discover more alterations, and to better understand those that have been previously described. We think this could lead to the future development of new or improved ways to treat and prevent cancer.

We may perform different tests or analyses to determine if cells in the samples provided through this study contain any alterations. As an example, we would like to use your DNA to look for alterations in cells using a technology called “sequencing.” Sequencing can be used to read the “letters” of DNA in samples and look for these alterations. Genes are composed of DNA “letters,” which contain the instructions that tell the cells in our bodies how to grow and work. Using gene sequencing as a way to read DNA is one way to identify alterations that may contribute to the behavior of cancer. Some alterations or changes occur only in cancer cells. Other alterations may occur in normal cells as well, including in the genes that may have been passed from parent to child. This research study will examine both normal and cancer samples to look for alterations.

Other than providing a saliva sample and, if you choose to, blood sample(s) (1 tube or 2 teaspoons per sample), participating in the study involves no new or additional tests or procedures. Cancer samples used for this study will come from stored samples

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obtained from previous clinical procedures. Study staff will not request samples unless they believe that the material remaining is sufficient for any future clinical needs.

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.

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?
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 also ask you to collect a sample of saliva at home--we will provide a kit and detailed instructions on how to do this.

As part of this research study, we may obtain copies of your medical records. We may contact you to ask if you would be willing to sign any additional forms or documents that some hospitals or centers may require in order to share your medical records with us. You may also choose to send your medical records directly to us. We may link the information that comes from processing your samples with the information from your medical records.

If you choose to share blood samples with us, 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

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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 a study staff member.

If you choose to share cancer samples with us, we may request a portion of your cancer sample through already stored biopsies or surgical specimens in hospitals or centers where you have received your medical care.

We may study the cells from your samples (such as your saliva, cancer samples, and/or blood samples), including the genes found in the cells. No additional procedures will be required. The results will be used to try to develop better ways to treat and prevent cancers.

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, collect, and share the information and results of certain types of genetic studies. Some (controlled-access) central data banks may store your genetic and medical information and provide the information to qualified researchers to use for further research. Other (open-access) data banks are publicly viewable by anyone with internet access. 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 data 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 information will be sent to central banks and other researchers only with a code number attached. Your name 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.

In some cases, a researcher or study team member 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.

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

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We will keep your saliva, blood, and cancer 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 can be found below in section K: “Can I stop being in the research study and what are my rights?”

Once the study is finished, any left over saliva and blood samples and copies of your medical records will be destroyed. Any cancer 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?

While you will not receive information about your personal results obtained from studying your saliva, blood, or cancer samples, we will provide general results and major discoveries to all participants. We will do this by regularly updating participants through email newsletters, posts on social media, the Count Me In app, and/or the website that you used to enroll in this study. We will also 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 summaries of the published reports, will be available to you and the general public.

G. 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 about key research discoveries made possible by your participation.

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

If you choose to share blood, you may experience slight pain and swelling where the blood is drawn. These complications are rare and should get better within a few days. If they do not, you should contact your doctor.

There is a risk that your information (which may include information from your survey responses, medical records, and/or sample testing and analysis) could be seen by people who do not have permission. However, we have procedures and security measures in place designed to minimize this risk and protect the confidentiality of your information. We have tried to minimize this risk by only providing trained study staff

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members access to where your information is stored. 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.

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 where your specimens are kept will not release your specimen unless they believe that there is enough material remaining for your future medical care.

I. Will I be paid to take part in this research study?
You will not be paid to take part in this study.

J. What are the costs to take part in this research study?
There are no costs to you to take part in this study.

K. 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 cancer samples from where we obtained them, and destroy any remaining 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 copies of 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 section N: "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

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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.

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. How will this study protect patient 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 genomic, histologic, and/or molecular tests will be protected in a HIPAA compliant database. HIPAA is a federal law that established national standards to protect sensitive health information from being disclosed without a patient's consent or knowledge.

Your name and other information that could be used to readily identify you will be removed from your samples, and replaced by a randomized code. If we send your samples to other researchers for testing, the samples will be identified using only this code.

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 federal Office for Human Research Protections), ethics committees reviewing the conduct of the study, or as otherwise required by law. When we send information to central data banks or other researchers, it will not contain your name or other information that could be used to readily identify you.

The results of this research 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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N. 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 surveys
· Your medical records
· Your saliva sample
If elected (at the end of this form):
· Your blood sample(s)
· Your cancer samples relevant to this research study and related records

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2. Why will protected information about me be used or shared with others? The main reasons include the following:
· 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.
· 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.

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 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?”

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· 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

We may ask you for information about contacting your physicians and the hospitals that you were treated at for your cancer. 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 (if you have agreed) your tissue samples.

Q. Documentation of Consent

This is what I agree to:

Please Check “Yes” or “No” for each point below:

· You can work with me to arrange blood sample(s) to be drawn at my physician’s office, local clinic, or nearby lab facility. You can perform (or work with others to perform) genomic and/or molecular tests on blood sample(s), and store the sample(s) until this research study is complete. [ ] Yes [ ] No

· You can request my stored cancer samples (e.g. tumor biopsies, surgical specimens, bone marrow samples, etc) from my physicians and the hospitals and other places where I received my care, perform (or work with others to perform) genomic, histological, and/or molecular 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 perform (or work with others to perform) genomic and/or molecular tests on the saliva sample(s) that I will send you and store the sample(s) until this research study is complete.
· 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 any tests you perform on my saliva and blood and cancer samples (if I have chosen to share them with you) with my medical record information.

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· You can store the answers that I provide in study surveys until this research study is complete. You can contact me to notify me as additional survey(s) become available during the course of this research study that I can choose to complete.
· You can study and share the results of the genomic, histologic, and/or molecular tests, survey responses, and my medical information with established public databases (e.g., NIH/NCI data portals, cBioPortal for Cancer Genomics, Tumor Portal, The Exome Aggregation Consortium/Genome Aggregation Database) and with other qualified researchers in a manner that does not include my name, 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 use the results of studying my biological samples 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 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

_____

Your Contact Information:
First Name

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Last Name

Country/Territory

Street

Apt/Floor #

City

State/Province

Zip/Postal Code

Phone Number (optional)

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Research Consent Form - Parent or Guardian (Count Me In)

Please read through the consent form text below and click “Next” when you are done to move on to the next section. 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 and their families to directly transform cancer 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 want to better understand cancers so that we can develop more effective therapies. By partnering directly with patients and their families, we are able to study many more aspects of different cancers than would otherwise be possible.

2. What will I/my child have to do if we agree to participate in this study?
After signing a consent form, you will be asked to complete surveys about your child’s 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 sample of your child’s saliva to us in a pre-stamped package that we will provide.

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We will ask you to complete a medical release form so that we are able to request your child's medical records. If we do so, we will take care of obtaining copies of your child's records from the hospitals or centers where your child receives their 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 child's medical records with us.

If you choose to share tissue specimens with us, we may also obtain small amounts of your child's stored cancer samples from hospitals or centers where your child receives their care.

If you choose to share your child's blood with us, we may ask for a sample (or samples) of your child's blood (1 tube, or 2 teaspoons per sample) to be drawn at your child's physician's office, local clinic, or nearby lab facility – we will provide detailed instructions on how to do this.

3. Does my child have to participate in this study?
No. Taking part in this study is voluntary. Even if you decide to have your child participate now, you can always change your mind and leave the study at any time.

4. Will it cost me/my child anything to participate in this study?
No.

5. Will my child benefit from participating?
While taking part in this study may not improve your child's 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 child's participation.

6. What are the risks of taking part in this research?
If you choose to share sample(s) of your child's blood, they may experience slight pain and swelling where the blood was drawn. These complications are rare and should resolve within a few days. If they do not, you should contact your child's doctor.

There may be a risk that your child's information (which includes your child's genetic information and information from your child's medical records or surveys you've completed) could be seen by individuals who do not have permission to view it.

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

7. Who will use my child's samples and see my child's information?
Your child's samples and health information will be available to study staff and researchers at Count Me In and the Broad Institute of MIT and Harvard, which are both not-for-profit research organizations. After removing your child's name and other readily identifiable information, we will share results obtained from your child's participation with the greater research community via established public scientific databases (for example, the National Institute of Health/National Cancer Institute data portals such as the Genomic Data Commons and dbGaP, and the cBioPortal for Cancer Genomics). Some of these databases are publicly viewable by anyone with internet access, and some are restricted to qualified researchers.

8. Can my child stop taking part in this research study?
Yes, you can withdraw your child from this research study at any time, although any of your child's information that has already been shared with researchers cannot be retrieved, and will not be deleted from our databases. Your child's information would be removed from future studies.

9. What if my child or 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 enroll your child in this research study because your child has been diagnosed with cancer. This study will collect and analyze samples and health information of many patients with cancer, in order to 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 cell growth (such as genes or proteins) become changed or altered. Changes in genes are called “alterations” and can occur in cancer cells or normal tissues. Some alterations that occur in certain types of cancers have already been identified, which has led to the development of drugs that specifically target those alterations. However, the vast majority of cancer patients have not yet been studied, which means there is a tremendous amount of information still left to be discovered. A key goal of this research study is to discover more alterations, and to better understand those that have been previously described. We think this could lead to the future development of new or improved ways to treat and prevent cancer.

We may perform different tests or analyses to determine if cells in the samples provided through this study contain any alterations. As an example, we would like to use your child’s DNA to look for alterations in cells using a technology called “sequencing.” Sequencing can be used to read the “letters” of DNA in samples and look for these alterations. Genes are composed of DNA “letters,” which contain the instructions that tell the cells in our bodies how to grow and work. Using gene sequencing as a way to read DNA is one way to identify alterations that may contribute to the behavior of cancer. Some alterations or changes occur only in cancer cells. Other alterations may occur in normal cells as well, including in the genes that may have been passed from parent to child. This research study will examine both normal and cancer samples to look for alterations.

Other than providing your child’s saliva sample and, if you choose to, your child’s blood sample(s) (1 tube or 2 teaspoons per sample), participating in the study involves no new or additional tests or procedures. Cancer samples used for this study will come from

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stored samples obtained from previous clinical procedures. Study staff will not request samples unless they believe that the material remaining is sufficient for any future clinical needs.

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 child's rights as a participant. The decision 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.

C. What other options are there?
Taking part in this research study is voluntary – you may choose to not have your child participate. Your decision to not have your child participate will not affect your child's medical care in any way or result in any penalty or loss of benefits.

D. What is involved in the research study?
After signing a consent form, you will be asked to complete surveys about your child's experience with cancer. Additional survey(s) may become available during the course of this research study that you can choose to complete.

We will also ask you to collect a sample of your child's saliva at home--we will provide a kit and detailed instructions on how to do this.

As part of this research study, we may obtain copies of your child's medical records. We may contact you to ask if you would be willing to sign any additional forms or documents that some hospitals or centers may require in order to share your child's medical records with us. You may also choose to send your child's medical records directly to us. We may link the information that comes from processing your child's samples with the information from your child's medical records.

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If you choose to share your child's blood samples with us, we may ask you to have a sample of your child's blood (1 tube or 2 teaspoons) drawn at your child's 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 your child to participate in the blood draw at that time, please just inform a study staff member.

If you choose to share your child's cancer samples with us, we may request a portion of your child's cancer sample through already stored biopsies or surgical specimens in hospitals or centers where your child has received their medical care.

We may study the cells from your child's samples (such as your child's saliva, cancer samples, and/or blood samples), including the genes found in the cells. No additional procedures will be required. The results will be used to try to develop better ways to treat and prevent cancers.

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, collect, and share the information and results of certain types of genetic studies. Some (controlled-access) central data banks may store your child's genetic and medical information and provide the information to qualified researchers to use for further research. Other (open-access) data banks are publicly viewable by anyone with internet access. We will also store your child's genetic and medical information at the Broad Institute of MIT and Harvard and share your child's information with other qualified researchers. Therefore, we are asking your permission to share your child's results with these special data banks and other researchers, and have your child's 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 child's information will be sent to central banks and other researchers only with a code number attached. Your child's name and other information that could readily identify your child will not be shared with central banks or other researchers. We will never sell your child's readily identifiable information to anyone under any circumstances.

In some cases, a researcher or study team member may contact you to find out if you would be interested in having your child participate in a different or future research

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study based on information that may have been found in your child's samples or medical information.

E. How long will my child be in this research study?
We will keep your child's saliva, blood, and cancer samples and medical records indefinitely until this study is finished, unless you inform us that you no longer wish to have your child participate. You may do this at any time. More information about how to stop being in the study can be found below in section K: "Can my child stop being in the research study and what are my child's rights?"

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

F. What kind of information could be found in this study and will I be able to see it?
While you will not receive information about your child's results obtained from studying your child's saliva, blood, or cancer samples, we will provide general results and major discoveries to all participants. We will do this by regularly updating participants through email newsletters, posts on social media, the Count Me In app, and/or the website that you used to enroll in this study. We will also 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 child's individual data will not be published in a way in which your child could be readily identified. Abstracts, which are summaries of the published reports, will be available to you and the general public.

G. What are the benefits of the research study?
Taking part in this research study may not directly benefit your child. 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 about key research discoveries made possible by your child's participation.

H. What are the risks or discomforts of the research study?
If you choose to share your child's blood, they may experience slight pain and swelling where the blood is drawn. These complications are rare and should get better within a few days. If they do not, you should contact your child's doctor.

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There is a risk that your child's information (which may include information from survey responses, medical records, and/or sample testing and analysis) could be seen by people who do not have permission. However, we have procedures and security measures in place designed to minimize this risk and protect the confidentiality of your child's information. We have tried to minimize this risk by only providing trained study staff members access to where your child's information is stored. There is a Federal law, known as the Genetic Information Nondiscrimination Act (GINA), which protects your child from genetic discrimination. GINA generally makes it illegal for health insurance companies, group health plans, and most employers to discriminate against your child based on your child's genetic information. However, this law does not protect your child against genetic discrimination by companies that sell life insurance, disability insurance, or long-term care insurance. If your child already has or has had cancer, any unauthorized disclosure of genetic results is unlikely to change an insurer's view of your child's risk.

There is a small but real risk that if your child's 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 where your child's specimens are kept will not release the specimens unless they believe that there is enough material remaining for your child's future medical care.

I. Will my child or I be paid to take part in this research study?
You and your child will not be paid to take part in this study.

J. What are the costs to take part in this research study?
There are no costs to you or your child to take part in this study.

K. Can my child stop being in the research study and what are my child's rights?
Your child 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/your child want to stop being in the study, we will return any remaining cancer samples from where we obtained them, and destroy any remaining 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 copies of the medical records we already have. However, we will keep the results from the tests we did before your child stopped being in the study. We will also keep the information we learned from reviewing

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your child's medical records before your child 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 section N: "Whom do I contact if my child or I have questions about the research study?" If you/your child choose to not participate, or if your child is not eligible to participate, or if you withdraw your child from this research study, this will not affect your child's present or future care and will not cause any penalty or loss of benefits to which your child is otherwise entitled.

L. What happens if my child is injured or sick because they took part in this research study?

There is little risk that your child will become injured or sick by taking part in this study. There are no plans for this project to pay you/your child or give you/your child other compensation for any injury. You and your child do not give up your legal rights by signing this form. If you/your child 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. How will this study protect patient confidentiality?

We will take rigorous measures to protect the confidentiality and security of all your child's 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 you/your child's email account. Information from your child's medical records and genomic, histologic, and/or molecular tests will be protected in a HIPAA compliant database. HIPAA is a federal law that established national standards to protect sensitive health information from being disclosed without a patient's consent or knowledge.

Your child's name and other information that could be used to readily identify them will be removed from their samples, and replaced by a randomized code. If we send their samples to other researchers for testing, the samples will be identified using only this code.

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We will store all of your child's identifiable information related to the study (including your child's 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 child's identifiable information or coded information, as necessary, with regulatory or oversight authorities (such as the federal Office for Human Research Protections), ethics committees reviewing the conduct of the study, or as otherwise required by law. When we send information to central data banks or other researchers, it will not contain your child's name or other information that could be used to readily identify your child.

The results of this research study may be published in research papers or included in presentations that will become part of the scientific literature. Your child will not be identified in publications or presentations.

N. Whom do I contact if my child or I have questions about the research study?
If you or your child 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 child's 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 child's participation in the study, concerns about the study, a research related injury, or if your child feels/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 child's health information for research purposes
Because information about your child and your child's health is personal and private, it generally cannot be used in this research study without your written authorization. Federal law requires that your child's health care providers and healthcare institutions (hospitals, clinics, doctor's offices) protect the privacy of information that identifies your child and relates to your child's past, present, and future physical and mental health conditions.

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If you sign this form, it will provide your health care providers and healthcare institutions the authorization to disclose your child's protected health information to the Broad Institute for use in this research study. The form is intended to inform you about how your child's health information will be used or disclosed in the study. Your child's 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 my child will be used or shared with others during this research?

· Health information created from study-related surveys
· Your child's medical records
· Your child's saliva sample

If elected (at the end of this form):

· Your child's blood sample(s)
· Your child's cancer samples relevant to this research study and related records

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

The main reasons include the following:

· 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 your child 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 child's 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 child's 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

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Office for Human Research Protections), or other domestic or foreign government bodies if required by law and/or necessary for oversight purposes.
· 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.

5. For how long will protected health information about me be used or shared with others?
There is no scheduled date at which your child's 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 child's 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 withdraw your permission, you must do so in writing by contacting the researcher listed above in the section: "Whom do I contact if my child or I have questions about the research study?"
· You have the right to request access to your child's personal health information that is used or shared during this research and that is related to your child's treatment or payment for your child's treatment. To request this information, please contact your child's doctor who will request this information from the study directors.

P. Participation Information
We may ask you for information about contacting your child's physicians and the hospitals that your child was treated at for their cancer. We will not disclose details about the results of your child's participation in this study with any of the individuals that we contact, but rather ask them to provide us with your child's medical history and (if you have agreed) your child's tissue samples.

Q. Documentation of Consent
This is what I agree to:

Please Check "Yes" or "No" for each point below:

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· You can work with me to arrange my child's blood sample(s) to be drawn at my child's physician's office, local clinic, or nearby lab facility. You can perform (or work with others to perform) genomic and/or molecular tests on blood sample(s), and store the sample(s) until this research study is complete. [ ] Yes [ ] No

· You can request my child's stored cancer samples (e.g. tumor biopsies, surgical specimens, bone marrow samples, etc) from my child's physicians and the hospitals and other places where my child received care, perform (or work with others to perform) genomic, histological, and/or molecular 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 perform (or work with others to perform) genomic and/or molecular tests on the saliva sample(s) from my child that I will send you and store the sample(s) until this research study is complete.
· You can request my child's medical records from my child's physicians and the hospitals and other places where my child received and/or continue to receive their treatment and link results of any tests you perform on my child's saliva and blood and cancer samples (if I have chosen to share them with you) with my child's medical record information.
· You can store the answers that I/my child provide in study surveys until this research study is complete. You can contact me to notify me as additional survey(s) become available during the course of this research study that I/my child can choose to complete.
· You can study and share the results of the genomic, histologic, and/or molecular tests, survey responses, and my child's medical information with established public databases (e.g., NIH/NCI data portals, cBioPortal for Cancer Genomics, Tumor Portal, The Exome Aggregation Consortium/Genome Aggregation Database) and with other qualified researchers in a manner that does not include my child's name, or any other information that could be used to readily identify my child, 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 use the results of studying my child's biological samples and my child's medical information for future research studies, including studies that have not yet been

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designed, studies for diseases other than cancer, and/or 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 child's hospital(s) may require in order to share my child's medical records, or to ask for my child's contact information when they are approaching the age of consenting for themselves.
· You can collect my child's medical information until my child is able to consent for themselves (age of majority; between 18 and 21 years old depending on location). The data collection and generation may occur after my child reaches age of majority, but will only be done with information generated from when my child was a minor.
· If my child remains in the study when they reach the age that they must consent for themselves, you may contact them about reconsenting to the study. You may contact me to get my child's contact information. If my child reconsents, the project team will continue to request medical records and cancer samples from any point in my child's cancer treatment.

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 our questions answered to my satisfaction;
I am willing to have my child participate in this research study;
I have been told that my child's participation is voluntary and if I decide not to have my child participate it will have no impact on my child's medical care;
I have been told that if I decide to have my child participate now, I can decide to withdraw my child from the study at any time. I acknowledge that a copy of the signed consent form will be sent to my email address

Your Child's Full Name:

_____
Your Child's Date of Birth (mm/dd/yyyy)

_____
Your Full Name:

_____

Date

_____

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Relationship to Child (Parent/Guardian)

_____

Your Contact Information:
First Name

Last Name

Your Child's Mailing Address
Country/Territory

Street

Apt/Floor #

City

State/Province

Zip/Postal Code

Phone Number (optional)

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Research Assent Form (Count Me In)

The form below will tell you more about the research study and how to be part of Count Me In. When you are done, click “Next” to move on to the next section that your parent will complete. If you have questions about the study or the consent form at any time, please have your parent contact us at 651-403-5315 or info@joincountmein.org.

RESEARCH ASSENT FORM (Count Me In)

We want to tell you about a research study we are doing. A research study is a way to learn more about something. We would like to find out more about cancers by having patients with cancers share their medical records, saliva and/or cancer or blood samples with researchers. You are being asked to join the study because you had or have cancer.

If you agree to join this study, your parent will be asked to share information about where you were treated and you will be asked to provide a saliva sample with a kit sent by the project team. You can also choose to share blood sample(s), if you want. After that, the project team will take care of the rest. They will request medical records and get cancer samples and process the blood and saliva kits. All of this information will help researchers better understand cancers.

If you choose to share blood samples(s), there are small risks from getting a sample of blood. You may have pain and swelling at the site of the blood draw.

Joining this research study may not improve your health, but we may learn something that will help others with cancers one day.

You do not have to join this study. It is up to you. You can say okay now and change your mind later. All you have to do is tell your parent that you want to stop. No one will be mad at you if you don’t want to be in the study or if you join the study and change your mind later and stop.

If you have any questions about this study, please have your parent contact the project team at 651-403-5315 or info@joincountmein.org

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If you sign your name below, it means that you agree to take part in this research study.

Child/Adolescent Assent

_____ _____ DATE