




**Research Consent Form  
for Biomedical Research**

Dana-Farber/ Harvard Cancer Center  
BIDMC/BCH/BWH/DFCI/MGH/Partners Network Affiliates

OHRS 04.22.16

**Protocol Title:** THE INTERNATIONAL NUTMIDLINE CARCINOMA REGISTRY

**Protocol Number:** 10-228

**DF/HCC Principal Research Doctor / Institution:**

CHRISTOPHER A. FRENCH, M.D. / BRIGHAM AND WOMEN'S HOSPITAL

**DF/HCC Site-Responsible Research Doctor(s) / Institution(s):**

JIA LUO, M.D. / DANA-FARBER CANCER INSITUTE

**Main Consent**

The International NUT Carcinoma Registry (formerly NUT midline carcinoma registry) (URL: [nc-registry.org](http://nc-registry.org)) is open to individuals of all ages.

If you are a parent or guardian of a child under 18 years old, the word "you" refers to your child. You, the parent, will be asked to read and sign this document to give permission for your child to participate.

**Introduction and key information**

You are being invited to take part in a research study. Research is a way of gaining new knowledge. A person who participates in a research study is called a "participant." This research study collects information about NUT carcinoma (NC) and NUT-related carcinomas (henceforth both referred to as NUT carcinoma). Because it is a rare condition, is expected that about 100 people per year will take part in this research study.

This research consent form explains why this research study is being done, what is involved in participating in the research study, the possible risks and benefits of participation, alternatives to participation, and your rights as a research participant. The decision to participate is yours. If you decide to participate, please sign and date at the end of this form. We will give you a copy so that you can refer to it while you are involved in this research study.

We encourage you to take some time to think this over, to discuss it with other people and your primary doctor, and to ask questions now and at any time in the future.

**1. Why am I being invited to take part in a research study?**

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You are invited to take part in this research study because you have NUT Carcinoma.

### 2. Why is this research being done?

NUT carcinoma (formerly NUT midline carcinoma) is a rare and aggressive form of cancer. Currently there is no standardized or effective way to treat this disease. We are gathering information (creating a Registry) about NUT carcinoma to develop a better understanding of this condition. Because NUT carcinoma is rare and the diagnosis can be missed, very little information is available in the medical literature. The goal of this research will be to better understand NUT carcinoma so that improved ways to diagnose, treat, and cure NUT carcinoma can be developed.

We will gather information about how people with NUT carcinoma are diagnosed, where the tumor grows within the body, its pattern of spread, and how it responds to various treatments. We also will collect specimens of tumor and blood from individuals with NUT midline carcinoma and store them in a central sample bank. These samples will be used for research to discover how this tumor forms, grows, spreads, and resists treatment.

### 3. Who is supporting this research?

The National Cancer Institute (NCI) and Boehringer Ingelheim Pharmaceuticals Inc. are supporting the research study by providing funding for the research study. This study is also funded in part by the Closing the AYA Gap Fund, Alex's Lemonade Stand Foundation, and by the National Institutes of Health (National Cancer Institute) and Boehringer Ingelheim Pharmaceuticals Inc.

### 4. What does this research study involve and how long will it last?

You will be in this research study indefinitely until you, or your next-of-kin posthumously, provide written communication to withdraw from the study.

However, the research investigator may decide to take you off the research study for reasons such as:

- It is considered to be in your best interest
- There is any problem with following study treatments and procedures
- There are any problems with research funding

If you are removed from the research study, the research Investigator will explain to you why you were removed.

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### 5. What are the risks to participating in this study?

There are risks to taking part in any research study. Although many steps will be taken to keep personal information confidential, there is some risk that confidentiality will not be maintained.

If a blood sample is taken from you, there are very few physical risks. Possible side effects from drawing the blood sample include mild pain, bleeding, bruising, and infection at the site of the needle insertion. Fainting or light-headedness can sometimes occur, but usually lasts only a few minutes. Whenever possible, study blood samples will be obtained at the time of routine blood draws. No more than 50 mL of extra blood will be removed for this study in an eight-week period. Researchers may request a blood sample more than once. The blood draws for this study are optional and you can refuse any of these blood draws.

#### Risks of Tissue Collection for Biobanking:

Generally, hospitals will keep some of your tissue. There is a small risk that when this tissue is collected and the sample is submitted to the biobank, your tissue could be used up and unavailable for use in the future.

### 6. Will being in this study benefit me in any way?

There is no immediate or direct benefit to you from being included in this Registry. Indirectly, having medical data and samples in this Registry will help physicians and researchers learn more about NUT carcinoma and its treatment. In the future, the information may be helpful to others in the treatment of NUT carcinoma.

### 7. What are my options?

Taking part in this research study is voluntary. Instead of being in this research study, you have the option to not participate in this research study.

### 8. Do I have to take part in this research?

All research is voluntary. It is your choice whether you take part in this research or not. If you decide to participate, please sign and date at the end of this form. We will give you a copy and you can refer to this consent form at any time.

If you choose not to participate, are not eligible to participate, or 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.

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We encourage you to take some time to think this over, to discuss it with other people and your primary doctor, and to ask questions at any time.

**A. WHAT IS INVOLVED IN THE RESEARCH STUDY?**

**Before the research starts (screening):**

We will need to review a sample to confirm that you have NUT midline carcinoma and thus can be in the research study. If our tests do not confirm that your tumor is NUT midline carcinoma, you will not be able to participate in this study.

**Additional research procedures to be performed at the time of screening but not required to determine eligibility:**

If you participate in this research study, you can choose to share information about your diagnosis, age, sex, and medical records (such as CT scan and CT scan reports, surgical and pathology reports, treatment records, and family medical history) with this Registry.

In addition, you can choose to share pathology specimens of your tumor and a blood sample with this Registry for storage in our sample bank. These specimens would be left over material from biopsies or surgeries that were performed as part of clinical care.

Tumor and blood samples may be subjected to genetic analysis in order to study the genes involved in NUT Midline Carcinoma. These methods study the set of genetic material and molecules of a participant’s cancer cells, referred to as the genome or transcriptome. Due to the in-depth level of analysis, it is possible, but very unlikely, that the results of these tests could contain information that could potentially be used to identify the participant.

Tissue and/or blood in the sample bank will be used for research in a de-identified manner and may be sent to other non-profit academic institutions or for-profit commercial institutions. The material may be subject to DNA genomic analysis. De-identified cancer cells from NUT carcinoma tumors or blood samples containing tumor DNA may be used for research in Dr. French’s laboratory. These may be experiments in collaboration with other academic institutions or in sponsored research studies with for-profit commercial institutions.

Rapid progress in understanding and treating cancer will occur when some of the genetic information derived from your tissues and blood can be shared with

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other researchers. In particular, the National Institutes of Health (NIH) and other organizations have developed special data (information) repositories that analyze data and collect the results of certain types of genetic studies. These central banks will store your genetic information and samples, and provide them to qualified researchers to do more research. Therefore, we are asking your permission to share your results with these public databases. Some of this information may be made available over the internet and will be freely available to anyone who is interested (an open access database). Other, more detailed information may only be accessed by scientists at other research centers who have received special permission to review your de-identified data (a controlled access database).

Your information or samples will be sent only with a code number attached. Your name or other directly identifiable information will not be shared with these repositories or with other investigators. There are many safeguards in place to protect your information and samples while they are stored in these repositories and used for research. There is a slight risk of loss of privacy when sharing this information with these banks, but we have established procedures to encode your samples and information and to protect your data. The repositories also have robust procedures in place to protect the confidentiality of the stored data. We will do everything we can to protect your data, but we cannot absolutely guarantee its privacy or predict how genetic information will be used in the future.

We would like to keep track of your medical condition for the rest of your life. We would like to do this by contacting you or your doctor once a year to see how you are doing. Keeping in touch with you and checking on your condition helps us determine the long-term outcomes of individuals with NUT carcinoma.

**B. WHAT WILL HAPPEN IF I AM REMOVED FROM THE STUDY OR DECIDE TO END MY PARTICIPATION IN THE RESEARCH?**

You have the right to choose not to sign this form. If you decide not to sign this form, you cannot participate in this research study.

You may stop being in the research study at any time. If you choose not to participate, or if you are not eligible for 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.

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**C. WILL I BE PAID TO TAKE PART IN THIS RESEARCH STUDY?**

We may use your samples and information to develop a new product or medical test to be sold. The sponsor and hospital may benefit if this happens. There are no plans to pay you if your samples are used for this purpose.

**D. WHAT ARE THE COSTS?**

Taking part in this research study will not lead to added costs to you or your insurance company.

You or your insurance company will be charged for portions of your care during this research study that are considered standard. You may be responsible for co-payments and deductibles that are typical for your insurance coverage.

If you have questions about your insurance coverage, or the items you might be required to pay for, please call financial services for information. The contact information for financial services:

- Brigham and Women’s Hospital: (617) 732-5524 or (617) 732-7485
- Dana-Farber Cancer Institute: (617) 632-3455
- Boston Children’s Hospital: (617) 355-7188

The National Cancer Institute provides an online resource to help people participating in cancer clinical trials understand which services their insurance company is required by law to pay. This can be found at the website below or can be provided by the study team:

[www.cancer.gov](http://www.cancer.gov) or 1-800-4-CANCER (1-800-422-6237)

**E. WHAT HAPPENS IF I AM INJURED OR BECOME SICK BECAUSE I TOOK PART IN THIS RESEARCH STUDY?**

Due to the nature of this Registry, there is no possibility for injury or becoming sick by participating in this research study.

**F. 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 as listed below:

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Brigham and Women’s Hospital

Christopher A. French, M.D. (Principal Investigator, Pathology): 617-525-4415

Dana-Farber Cancer Institute

Jia Luo, M.D. (Adult Oncology) 617-632-3468

For questions about your rights as a research participant, please contact a representative of the Office for Human Research Studies at DFCI (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.

**G. CONFIDENTIALITY**

We will take measures to protect the privacy and security of all your personal information, but we cannot guarantee complete confidentiality of study data.

Medical information created by this research study may become part of your hospital medical record and may be forwarded to your primary doctor. Information that does not become part of your medical record will be stored in your study file. It may also become part of a DF/HCC research database.

The results of this research study may be published. You will not be identified in publications without your permission. As participation in this study involves providing a specimen of your tissue, please know that if the research doctor leaves the institution, the research and the tissue might remain at the DF/HCC or might be transferred to another institution.

**H. GENETIC RESEARCH**

This research may involve somatic genetic testing. Somatic testing involves testing or sequencing of your tumor and looks for acquired mutations that may have developed due to your cancer. The results are used to plan treatment, including the use of targeted therapy and immunotherapy.

This research may also involve germline testing or genomic sequencing of all or part of your DNA. Sequencing allows researchers to identify your genetic code. Two methods of genetic analysis, **whole exome sequencing and whole genome sequencing**, are increasingly used in healthcare and research to identify genetic variations; both methods rely on new technologies that allow

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rapid sequencing of large amounts of DNA. These approaches are known as next-generation sequencing (or next-gen sequencing).

The Genetic Information Nondiscrimination Act of 2008 (GINA) is a federal law that protects Americans from being treated unfairly because of differences in their DNA that may affect their health, and may prevent discrimination by health insurers and employers based on genetic information. GINA is intended to ease concerns about discrimination that might keep some people from getting genetic tests that could benefit their health, and enable people to take part in research studies such as this without fear that their DNA information might be used against them by health insurers or their workplace. This protection does not extend to disability or life insurance. Additional information can be found at <http://www.genome.gov/10002328>.

### **I. PRIVACY OF PROTECTED HEALTH INFORMATION**

The Health Insurance Portability and Accountability Act (HIPAA) is a federal law that requires Dana-Farber/Harvard Cancer Center (DF/HCC) and its affiliated research doctors, health care providers, and physician network to protect the privacy of information that identifies you and relates to your past, present, and future physical and mental health conditions (“protected health information”). If you enroll in this research study, your “protected health information” will be used and shared with others as explained below.

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

- Existing medical records, including mental health records.
- New health information created from study-related tests, procedures, visits, and/or questionnaires
- Genomic analysis of my tumor or normal tissue obtained from tumor in the tumor bank or from blood. The genomic analysis may include whole genome or transcriptome sequencing that could potentially contain identifying information.

#### **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;

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- 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); and
- To provide the study sponsor with information arising from an adverse event or other event that relates to the safety or toxicity of the drug(s) used in the study and for the purpose of this or other research relating the study drug(s) and their use in cancer;
- To better understand the diseases being studied and to improve the design of future studies; and,
- Other reasons may include for treatment, payment, or health care operations. For example, some medical information produced by this research study may become part of your hospital medical record because the information may be necessary for your medical care. (You will also be given a notice for use and sharing of protected health information.)

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

DF/HCC and its affiliated research doctors and entities participating in the research will use and share your protected health information. In addition, other DF/HCC offices that deal with research oversight, billing or quality assurance will be able to use and share your protected health information.

**4. With whom outside of DF/HCC may my protected 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:

- Outside individuals or entities that have a need to access this information to perform functions relating to the conduct of this research such as analysis by outside laboratories on behalf of DF/HCC and its affiliates (for example, data storage companies, insurers, or legal advisors).
- The sponsor(s) of the study, its subcontractors, and its agent
- Other research doctors and medical centers participating in this research, if applicable
- 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

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necessary for oversight purposes. A qualified representative of the FDA and the National Cancer Institute may review your medical records.

- Hospital accrediting agencies
- A data safety monitoring board organized to oversee this research, if applicable
- Non-profit or for-profit organizations in collaborative efforts to develop new therapeutic strategies. Any information shared with these groups will be de-identified.

Some who may receive your protected 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 research doctors and participating DF/HCC entities 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?"
- You have the right to request access to your protected health information that is used or shared during this research and that is related to your treatment or payment for your treatment, but you may access this information only after the study is completed. To request this information, please contact the researcher listed above in the section: "Whom do I contact if I have questions about the research study?"

**J. CONSENT TO OPTIONAL RESEARCH STUDIES:**

Your participation in these optional research studies is voluntary, and you will not be penalized or lose any benefits if you refuse to participate or decide to stop.

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1. Allow the study staff to retrieve relevant clinical and pathologic information from physicians, nurses, data managers/data clerks and/or Medical Records Department at my previous hospitals and clinics including medical records, consultations, oncology records, treatment records, surgical/operative reports, radiology reports, pathology reports, testing reports, family medical history, and discharge summaries.

YES \_\_\_\_\_ NO \_\_\_\_\_ INITIALS \_\_\_\_\_

2. Allow the collection of samples leftover from tumor specimens removed during biopsies, surgeries, or autopsies to be sent to the research team for inclusion in the sample bank and studied for the purposes of NUT carcinoma research.

YES \_\_\_\_\_ NO \_\_\_\_\_ INITIALS \_\_\_\_\_

3. Allow blood samples to be collected and sent to the research team to be stored in a blood bank or studied for the purposes of NUT carcinoma research.

YES \_\_\_\_\_ NO \_\_\_\_\_ INITIALS \_\_\_\_\_

4. Allow the study staff to contact me, my physician or my next of kin in the future to follow up on my health status and cancer treatment and/or to inform me of future clinical trials that may be appropriate for me.

YES \_\_\_\_\_ NO \_\_\_\_\_ INITIALS \_\_\_\_\_

\_\_\_\_\_  
First and Last name of Physician  
Physician

\_\_\_\_\_  
Contact information of  
Phone number or Email

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Practice location of physician  
Clinic or Hospital

State/ Province, Country

First and Last name of Next of Kin

Contact information of Next of Kin  
Phone number or Email

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**K. DOCUMENTATION OF CONSENT**

My signature below indicates:

- I have had enough time to read the consent and think about participating in this study;
- I have had all of my questions answered to my satisfaction;
- I am willing to participate in this study until either I, or my next-of-kin posthumously provide written communication to withdraw from the study;
- I have been told that my participation is voluntary and I can withdraw any time

\_\_\_\_\_  
Signature of Participant

\_\_\_\_\_  
Date

***Please sign here when a Legally Authorized Representative will sign on behalf of the Participant:***

\_\_\_\_\_  
Signature of Legally Authorized Representative

\_\_\_\_\_  
Date

\_\_\_\_\_  
Relationship of Legally Authorized Representative to Participant

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**AUTHORIZATION FOR RELEASE OF INFORMATION**

**PATIENT NAME:** \_\_\_\_\_  
(Last) (First) (M.I.)

**DATE OF BIRTH:** \_\_\_\_\_ **PHONE NUMBER:** \_\_\_\_\_

**PATIENT ADDRESS:** \_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_  
\_\_\_\_\_

I \_\_\_\_\_ authorize release of my protected health information,  
Patient name (please print)

including but not limited to the requested documents below, sent to the following institution:

**Dana-Farber Cancer Institute/Brigham and Women’s Hospital**  
The International NUT Carcinoma Registry Study  
Christopher French, M.D.  
New Research Building, Rm. 630G  
77 Avenue Louis Pasteur  
Boston, MA 02115  
**Fax: 617-751-7076**

**Requested Documents:**

- Hospital discharge summaries
- Pathologist’s reports on surgical specimens, bone marrow,
- CSF Surgical/operative reports
- Radiology reports (x-ray, CT scan, MRI scan, bone scan etc.)
- Copies of x-ray films, scans, electronic files
- Treatment records (chemotherapy, radiation therapy, including chemo roadmaps)
- Consultations
- Oncology CLINIC records

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Pathology specimens for confirmation of diagnosis and enrollment in  
NC Registry  
Family medical history including family medical history diagram

I understand that the information in my health record may include information relating to sexually transmitted diseases, acquired immunodeficiency syndrome (AIDS), or human immunodeficiency virus (HIV). It may also include information about behavioral or mental health services, child abuse and treatment for alcohol and drug abuse.

This Authorization does not have an expiration date, but I understand that I have a right to revoke this authorization at any time. I understand that to withdraw this authorization, I, or my next-of-kin posthumously, must do so in writing to the International NUT Carcinoma Registry. I understand that stopping this authorization will not apply to information that has already been released or disclosed.

I understand that authorizing the release of this health information is voluntary. I can refuse to sign this authorization. I understand that I may inspect or copy the information to be used or disclosed. I understand that any disclosure of information carries with it the potential for redisclosure and the information may not be protected by federal privacy rules.

\_\_\_\_\_  
Printed Name of Participant or Parent / Legal Guardian

\_\_\_\_\_  
Date Signed

\_\_\_\_\_  
Signature of Participant or Parent / Legal Guardian

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***Please sign here when a Legally Authorized Representative will sign on behalf of the Participant:***

\_\_\_\_\_  
Signature of Legally Authorized  
Representative

\_\_\_\_\_  
Date

\_\_\_\_\_  
Relationship of Legally Authorized Representative to Participant

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**To be completed by person obtaining consent:  
Adult Participant**

The consent discussion was initiated on \_\_\_\_\_ (date).

Signature of individual obtaining consent: \_\_\_\_\_

Printed name of above: \_\_\_\_\_

Date: \_\_\_\_\_

A signed consent form copy will be given to the participant or legally authorized representative.

1) The participant is an adult and provided consent to participate.

1a) Participant or legally authorized representative is a non-English speaker who received and signed the translated Short Form in lieu of English consent document:

*As someone who understands both English and the language used by the participant, I interpreted and/or witnessed, in the participant's language, the researcher's presentation of the English consent form. The participant was given the opportunity to ask questions.*

Signature of Interpreter/Witness: \_\_\_\_\_

Printed Name of Interpreter/Witness: \_\_\_\_\_

Date: \_\_\_\_\_

1b) Participant is unable to sign the consent form because:

The participant is unable to read and write.

The participant has a physical disability.

Other (please describe): \_\_\_\_\_

*The consent form was presented to the participant who was given the opportunity to ask questions and who communicated agreement to participate in the research.*

Signature of Interpreter/Witness: \_\_\_\_\_

Printed Name of Interpreter/Witness: \_\_\_\_\_

Date: \_\_\_\_\_

2) The participant is an adult who lacks capacity to provide consent and his/her legally authorized representative:

2a) gave permission for the adult participant to participate

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<input type="checkbox"/> 2b) did not give permission for the adult participant to participate
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**L. DOCUMENTATION OF AND PARENTAL PERMISSION AND ASSENT  
OF THE CHILD**

**Signature of participant under the age of 18:** The person doing this research study has explained what will happen to me if I take part in this research study. My signature below means that I want to be in this research study until either I or my next-of-kin posthumously gives written communication to withdraw from the study, even after I turn 18. I can decide not to take part in this research study if I do not want to and nothing will happen to me if I decide I do not want to participate.

\_\_\_\_\_  
Signature of Minor Participant

\_\_\_\_\_  
Date

**Permission of Parent/Guardian:**

My signature below indicates:

- I have had enough time to read the consent and think about my child’s participation in this study;
- I have had all of my questions answered to my satisfaction;
- I am willing to have my child participate in this study until either I or my next-of-kin posthumously provide written communication to withdraw from the study;
- I have been told that my child’s participation is voluntary and I can withdraw at any time

\_\_\_\_\_  
Signature of Parent/Legal Guardian

\_\_\_\_\_  
Date

\_\_\_\_\_  
Relationship of Parent/Legal Guardian to Participant

DFCI Protocol Number: 10-228	Approved Date (DFCI IRB Approval): 02/20/2024
Date Posted for Use: 02/20/2024	


**Research Consent Form  
for Biomedical Research**

Dana-Farber/ Harvard Cancer Center  
BIDMC/BCH/BWH/DFCI/MGH/Partners Network Affiliates

**To be completed by person obtaining assent:**

The assent discussion was initiated on \_\_\_\_\_ (date).

The information was presented in age-appropriate terms. The minor:

Agreed to take part in the study

Did not agree to take part in the study

An assent discussion was not initiated with the minor for the following reason(s):

Minor is not able to understand or has a condition that prevents assent discussion

Minor is under 10 years of age

Other \_\_\_\_\_

Signature of Person Obtaining Assent: \_\_\_\_\_

Printed name of above: \_\_\_\_\_

Date: \_\_\_\_\_

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**To be completed by person obtaining permission from the parent:**

The permission from parent discussion was initiated on \_\_\_\_\_ (date).

Signature of individual obtaining permission from parent: \_\_\_\_\_

Printed name of above: \_\_\_\_\_

Date: \_\_\_\_\_

- A copy of this signed consent form will be given to the participant's parent or legal guardian.
- 1) The parent or legal guardian gave permission for the minor to participate.
  - 1a) Parent or legal guardian is a non-English speaker who received and signed the translated Short Form in lieu of English consent document, and was provided a copy:
    - As someone who understands both English and the language used by the participant, I interpreted and/or witnessed, in the participant's language, the researcher's presentation of the English consent form. The participant was given the opportunity to ask questions.*

Signature of Interpreter/Witness: \_\_\_\_\_

Printed Name of Interpreter/Witness: \_\_\_\_\_

Date: \_\_\_\_\_

- 1b) Parent or legal guardian is physically unable to sign the consent form because:
  - The parent or legal guardian is unable to read and write.
  - The parent or legal guardian has a physical disability.
  - Other (please describe): \_\_\_\_\_

*The consent form was presented to the parent or legal guardian who was given the opportunity to ask questions and who communicated agreement for the minor to participate in the research.*

Signature of Interpreter/Witness: \_\_\_\_\_

Printed Name of Interpreter/Witness: \_\_\_\_\_

Date: \_\_\_\_\_

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OHRS 04.22.16

<input type="checkbox"/> 1c) The parent or legally authorized representative did not give permission for the minor to participate
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