Columbia University Medical Center

Consent Form to Participate in a Research Study and HIPAA Authorization

Protocol Information

Study title: Comprehensive Part of Body **Malignancy Clinical**

Registry Study number: IRB:

Participation duration: Indefinite
Anticipated number of research participants at this site:

Researchers' Contact Information

Principal Investigator: Investigator's Name , MD
Add Location if Applicable

Phone Number: ***(USE A NUMBER THAT HAS AN ONCALL SERVICE)***

What information is on this form?

We are asking you to take part in a research study.

This form explains why we are doing this study and what you will be asked to do if you choose to be in this study. It also describes the way we (researchers) would like to use and share information about you.

Please take the time to read this form. We will talk to you about taking part in this research study. You should ask us any questions you have about this form and about this research study.

You do not have to participate if you don't want to.

Why is this study being done?

We are asking you to take part in this research study because you have or will receive radiation therapy, surgery, hormonal therapy and/or systemic therapy (e.g. chemotherapy, immunotherapy) for Type of Canc cancer. The purpose of this research is to create an organized database of information to record patients' demographics, treatments, sequence of treatment, responses to treatment offered, and other variables that may affect the outcome following radiation, surgery, and chemotherapy for your Type of Cance cancer. Having information about the effects and outcomes of treatment approaches to Type of Ca cancer will be informative to us and will allow us to make appropriate quality improvement decisions, as well as provide data for publication for guiding future practices in oncology for better treatment of Type of Can cancer.

What will I be asked to do if I choose to be in this study?

If you agree to participate in the study, we will collect clinical data from your medical records related to demographics, such as age, sex, weight, height, ethnicity, medical/surgical history, symptoms, diagnosis, pathology, cancer risk factors, treatment modalities/responses, and post-treatment course including side effects of treatments, treatment outcomes such as recurrence and death.

In the future, we may also access your tissue specimens from your biopsy, surgery, blood or urine that are stored in the pathology department. *[APPLICABLE IF YOU ARE ACCESSING ARCHIVED/PREVIOUSLY COLLECTED SPECIMENS- NEEDS PATHOLOGY APPROVAL AND MUST INCLUDE SUBJECT'S CONSENT IN FUTURE USE SECTION]*

If you consent to participate in the Herbert Irving Comprehensive Cancer Center (HICCC) database shared resource (DBSR) and there are available samples from you, these samples may be requested from the DBSR by the study team. *[APPLICABLE IF STUDY IS LINKED TO DBSR- MUST HAVE WRITTEN AGREEMENT FROM DBSR AND MUST BE LINKED IN RASCAL TO DBSR AND VICE VERSA]*

Blood Collection: *APPLICABLE IF COLLECTING BLOOD. TAILOR TO THE AMOUNT BEING COLLECTED*
You may be asked to give up to X mL (X tablespoons) of blood. The blood will be collected for the analysis of the immunological response to your treatment. This is optional and will not affect your care.

Are there any risks?

We do not expect any risks from the collection, analysis and storage of clinic data, except as detailed in the following paragraph.

Blood Draw

Risks of having blood drawn are soreness and/or a black and blue mark at the site from where the blood is drawn. Sometimes, people feel uncomfortable at the time of the blood draw. Occasionally people feel lightheaded or weak. There is also a small risk of infection whenever blood is drawn.

Loss of confidentiality *DO NOT REMOVE*

A risk of taking part in this study is the possibility of a loss of confidentiality or privacy. Loss of privacy means having your personal information shared with someone who is not on the study team and was not supposed to see or know about your information. The study team plans to protect your privacy. Their plans for keeping your information private are described in the "What about my privacy?" section of this consent form.

Are there any benefits?

You will not benefit from taking part in this study, but your participation may help people who have Type of Can cancer in the future.

Are there any alternative procedures?

You may choose not to take part in this research study. This decision will not influence your course of cancer-directed treatment.

What about confidentiality?

Any information collected during this study that can identify you by name will be kept confidential. We will do everything we can to keep your data secure, however, complete confidentiality can never be promised. Despite all of our efforts, unanticipated problems such as a stolen computer may occur, although it is highly unlikely.

Access to your health information is required to be part of this study. If you choose to take part in this study, you are giving us the authorization (i.e. your permission) to use your protected health information and information collected during the research that can identify you. The health information that we may collect and use for this research does NOT include medical history that may be considered sensitive, such as, HIV status, a history of drug or alcohol abuse, or mental health information. *REVIEW AND DETERMINE IF SENSITIVE INFORMATION WILL BE COLLECTED*

Information about you may be obtained from any hospital, doctor, and other health care provider involved in your care that is needed for this research purpose, including information related to your cancer-directed therapy and possible adverse effects.

Your participation in this research study will be documented in your electronic medical record. This record can be viewed by authorized personnel from Columbia University Irving Medical Center, Weill Cornell Medical Center and New York-Presbyterian Hospital and its affiliated institutions, because these institutions share the electronic medical record system. Study monitors and others who provide oversight of the study may also need to access this record.

Any research information that is shared with people outside of Columbia University Irving Medical Center and New York-Presbyterian Hospital will not include your name, address, telephone number or any other direct identifier unless disclosure of the information is required by law or you have authorized the disclosure.

Your personal and health information will be assigned a code number, and will be separated from your name or any other information that could identify you. The research file that links your name to the code number will be kept as an encrypted data file on a password-protected computer and only the investigator and authorized study staff will have access to the file. Identifiers might be removed from the identifiable private information or identifiable biospecimens and that, after such removal, the information or biospecimens could be used for future use without additional consent from you.

The following individuals and/or agencies will be able to look at, copy, use, and share your research information:

- The investigator, Columbia Irving University Medical Center and New York-Presbyterian Hospital study staff and other medical professionals who may be evaluating the study

- Authorities from Columbia Irving University and New York-Presbyterian Hospital, including the Institutional Review Board ('IRB')

- The Office of Human Research Protections ('OHRP')

- Other government regulatory agencies

If there are outside collaborator(s), list here, ensure that a DUA is in place

Your authorization to use and share your health information does not have an expiration (ending) date.

If your health information has been disclosed to a third party (for example, a pharmaceutical company participating in a study), federal privacy laws may no longer protect it from further disclosure.

You may change your mind and revoke (take back) this consent and authorization at any time and for any reason. To revoke this consent and authorization, you must contact the Principal Investigator, Dr. Investigator's Name .

However, if you revoke your consent and authorization, you will not be allowed to continue taking part in the research. Also, even if you revoke this consent and authorization, the researchers may continue to use and disclose the information they have already collected.

Will I get paid or be given anything to take part in this study?

You will not receive any payment or other reward for taking part in this study.

Will I incur costs if I take part in this study?

There will be no costs to you for being in this study.

Do I have to be in this study?

Taking part in this study is your choice. You can decide not to take part in or stop being in the study at any time. Your choice will not affect the treatment you receive from doctors and staff at Columbia University Medical Center and New York-Presbyterian Hospital.

What are my rights if I take part in this study?

Taking part in this study is your choice. You can decide not to take part in or stop being in the study at any time. Your choice will not change the treatment you receive from doctors and staff at Columbia University Irving Medical Center and New York-Presbyterian Hospital.

Who can I call if I have questions?

You may call Dr. Investigator's Name at telephone number if you have any questions or concerns about this research study.

If you have any questions about your rights as a research participant, or if you have a concern about this study, you may contact the Institutional Review Board listed below.

Institutional Review Board
Columbia University Medical Center
154 Haven Avenue, 1st Floor
New York, NY 10032
Telephone: (212) 305-5883
irboffice@columbia.edu

REVIEW- CONTAINS IRB BOILERPLATE LANGUAGE

FUTURE USE OF TISSUE AND DATA

The researchers may want to use the tissue that is stored at Columbia University Irving Medical Center/New York Presbyterian Hospital from a prior biopsy and/or surgery so that additional research studies can be done now or in the future. If you agree to have the investigator or research team to access and use your unused or stored tissue for future research, they may be kept forever. **Your tissue will be labeled with a code and will not include your name or any other identifiable information.** The list that links the code to your name will be stored in an encrypted data file on a password-protected computer separated from the rest of the research data. If this information is shared, your name and other identification will not be included.

We would like to store the data and biological samples that you agreed to provide as part of this study and possibly use them for future research. They will be stored at CUMC either with the researchers on this study or in a central storage facility called a repository.

With your permission, your data and samples will be stored at CUMC indefinitely in a non-identifiable form. Your data and samples will be labeled with a code number that the researchers on this study or the people managing the repository will be able to link to you.

Also with your permission, your data and samples may be used by other Columbia researchers or researchers at other institutions, including commercial companies, for research on your medical condition and/or other diseases. If they are given to researchers who are not researchers on this study, they will only be given in deidentified form. This means that your name and other identifying information have been permanently removed from your data and samples OR that your data and samples are coded and the researchers who will use them will not have the key to the code.

Any future testing or research using your data and samples may lead to the development and use of information, products, tests, and treatments having commercial value. You will not receive any compensation that may result from these tests or treatments.

Please <u>initial</u> below to indicate your choice.

[_____ I agree] [_____ I do not agree] to the storage of my tissue for future use by the investigators who are conducting this study

[_____ I agree] [_____I do not agree] to the use of my data and samples for future research and/or testing, including for commercial purposes, that may or may not be related to this study. I understand that my data and samples will only be given to researchers in deidentified form or coded.

You can change your mind regarding storage and future use of your samples at any time. Please see the Contact section of the consent form for further information. You will need to notify the Principal Investigator, Dr. Investigator's Name , if you change your mind and want your information removed from all CUMC databases so that your samples and/or data will not be included in any future analyses. However, there are limitations on our ability to exclude your information or remove your biological samples after they have been de-linked from identifying information or deposited in scientific databases, and, if you have given your permission to do so, used or shared with other researchers.

GENETIC TESTING

Your tissue may be used for genetic research. No results of the genetic testing will be reported to you as this is a research study.

We are requesting your permission to perform genetic testing on your biological samples in the future to identify variants and consider their relationship to your cancer. Genetic research is evolving rapidly. When performed, we expect that these tests will include whole genome and exosome sequencing but other genetic tests in addition to, or in place of, whole exome sequencing (WES) or whole genome sequencing (WGS) may be performed, including new genetic tests that may be developed in the future.

Information that could directly identify you will never be included. This will allow a large number of researchers to benefit from the research being conducted. Researchers who want to study the information must apply to the database

Re-identified data could potentially be used to discriminate against or stigmatize participants, their families, or groups. In addition, there may be unknown risks due to computational methods, analytic technologies, or techniques (e.g., generation of information that could allow participants' identities to be readily ascertained).

In the event of consent withdrawal, data will be withdrawn from any repository, if possible, but data already distributed for research use will not be retrieved.

There may be researchers who ask to use your samples for future genetic research. If done, this type of research does not change your insurance coverage. Any information from genetic research studies is not considered to provide meaningful genetic information about your health. Therefore, if you are asked if you have had genetic testing, you should say no.

Please initial below to indicate your choice.

[_____ I agree] [_____ I do not agree] to have my tissue used for future genetic testing.

[_____ I agree] [_____ I do not agree] to have my tissue shared with others for future genetic testing.

Statement of consent and signatures

Statement of consent and HIPAA authorization

I have read this consent form and HIPAA authorization. The research study has been explained to me. I agree to be in the research study described above. A copy of this consent form will be provided to me after I sign it. By signing this consent and HIPAA authorization form, I have not given up any of the legal rights that I would have if I were not a participant in the study.

Signatures

_____

Research Participant Date

_____

PRINT Name of Research Participant

_____

Person Obtaining Consent Date

_____

PRINT Name of Person Obtaining Consent

_____

Legally Authorized Representative (IF APPLICABLE) Date

_____

PRINT name of Legally Authorized Representative

_____

Witness (IF APPLICABLE) Date

_____

PRINT name of Witness