Columbia University Medical Center

Consent Form to Participate in a Research Study and HIPAA Authorization

Title of research study and general information

Study title: Comprehensive Type of Cancer **Radiotherapy Clinical**

Database Study number: IRB: AAAXNNNN

Participation duration: indefinite
Anticipated number of research participants at this site: NNNN

Researchers' contact information

Principal Investigator: Investigator's Name, MD
Phone Number: Phone Numbe ***(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?

You have been asked to take part in research study because you have or will receive chemotherapy, radiotherapy and/or surgery in the Body Part . The purpose of this research is to create an organized database of information about the Body Part as a resource for researchers studying the effects of chemotherapy, radiotherapy and/or surgery on the Body Part *The collection and analysis of the data will allow us to see treatment outcomes at our own institution and identify factors associated with response to treatment. This will enable quality improvement, as well as provide data for publication.AS APPLICABLE*

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 related to your diagnosis, symptoms, treatment, and post-treatment course. Your radiotherapy, surgery, chemotherapy, laboratory, radiology, and pathology clinical information will be collected and entered into the database record by the staff within the Department of Radiation Oncology. This information will be obtained from available standard clinical sources, including paper and electronic medical records.

Are there any risks?

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

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 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 radiotherapy, chemotherapy and surgery of the Body Part in the future.

What about my privacy?

Every effort will be made to keep your personal information confidential. However, we cannot guarantee total privacy.

The data collected will be given a code number, and 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 in a password protected database. Only the Principal Investigator and the study staff will be able to see this file.

If information from this study is published or presented at scientific meetings, your name and other personal information about you will not be used.

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 the 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 will include medical history. Information that is considered sensitive will not be collected. *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.

The research information that is shared with people outside of Columbia University 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.

The following people and/or agencies will be able to look at, copy, use and share your research information:
- The investigator, Columbia University Medical Center and New York Presbyterian Hospital study staff, and other professionals who may be evaluating the study;

- Authorities from Columbia University, including the Institutional Review Board ('IRB'). An IRB is a committee organized to protect the rights and welfare of people involved in research.
- The Federal Office of Human Research Protections ('OHRP');
If there are outside collaborators, 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.

Once 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, at Phone Number .

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 and the Sponsor (if applicable) 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.

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 Medical Center.

Who can I call if I have questions?

You may call Dr. Investigator's Name at telephone number Phone 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

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