CONSENT FOR CANCER RESEARCH

Project Title: Integrated 3D X-Ray and Ultrasound Guided Radiation Therapy of Soft Tissue Targets
Principal Investigator: Ping Xia, Ph.D; (216) 444-1938
Sponsor: National Institute of Health

Cancer research studies are coordinated by physicians and scientists from Cleveland Clinic, University Hospitals and Case Western Reserve University (CWRU) through the NIH National Cancer Institute (NCI) designated Case Comprehensive Cancer Center (Case CCC). The goal of this collaboration is to enhance cancer treatment and research in Northeast Ohio. This study is being offered at Cleveland Clinic (CC).

Introduction
We are asking you to participate in a research study. The purpose of this document is to summarize your discussion with the research team and provide you with written information to help you decide whether you want to participate in research. Your decision is completely voluntary.

Your treating doctor may also be an investigator on this research study. If so, your doctor will have an interest in both your welfare and in the research study. You are not required to take part in this research study offered by your doctor. You may ask for a second opinion from another doctor who is not linked to this study. If you choose not to be in this study, the quality of your regular medical care will not be affected.

Please ask any questions you may have about the study or this consent form before signing it. Please take your time to make your decision. You will be given a copy of this form to keep.

Conflict of Interest Disclosure:
One or more of the Investigators conducting this study serve as paid speakers, consultants or advisory committee members for the company that is paying for this research or a company that makes products used in this study. These financial interests are within permissible limits established by the Cleveland Clinic Conflict of Interest Policy. If you have any questions regarding conflicts of interest, please ask your study doctor or call the Institutional Review Board at 216-444-2924.

Purpose
You are being asked to participate in a research study of Integrated 3D x-ray and ultrasound Guided Radiation Therapy of Soft Tissue Targets, led by, Dr. Ping Xia at the Department of Radiation Oncology at Cleveland Clinic Main campus. The purpose of the study is to investigate whether a combined ultrasound images (Clarity, Elekta) and CAT scan can improve radiation treatment precision to localize the treatment target prior to and during radiation. Ultrasound imaging alone has been clinically used in our department for localizing the tumor prior to radiation treatment. Likewise, the CAT scan has been clinically used in our department to ensure the correct patient positioning. Because of tumor motion due to breathing or other physiological reasons during treatment, we will study whether a commercial holding device, FISSIO Holding arm (Baitella), can hold the ultrasound detector during radiation to monitor the tumor motion. The second purpose of this research is to use a mock/simulation study to

determine whether the presence of the holding device may block the entries of the radiation beam using a computer simulation. If we identify that the holding device blocks the radiation beam during the mock study, we will proceed with your treatment as follows: (1) only use the ultrasound imaging (Clarity system) without the FISSIO holding arm to localize the tumor prior to treatment; and (2) not use the ultrasound imaging (Clarity) to monitor the tumor motion during the treatment.

About 30 people will take part in this research study.

Study Procedures
As a participant in this study, you will go through many routine clinical procedures of radiotherapy, including initial consultation, simulation, treatment verification, and a course of daily treatment, which may last one week to seven weeks, depending on your specific treatment prescription.

As a participant in this study, during simulation procedure, you will be asked to acquire additional ultrasound study to identify the location of tumor in addition to the routine CAT scan. The cost of this research ultrasound study will not be charged to you or your insurance. During your daily treatment, in addition to your routine CAT for position verification, additional ultrasound study will be performed to localize the tumor prior to each treatment. If the ultrasound probe is identified not to block your radiation beams during simulation study, the ultrasound probe will be attached to your body held by the FISSIO holding arm during treatment to further monitor the tumor motion.

There are no additional visits involved to participate in this study. During your routine simulation, the added ultrasound study may prolong your simulation for 10 minutes. During routine pre-treatment imaging verification, the added ultrasound study may prolong your setup for 5 minutes.

Centralized data collection or registries.
Data will be stored electronically on a secure server in a password protected file. Access to data will be restricted with only principal and co-investigators as well as study coordinators and appointed regulatory reviewers having access to the file's contents.

Risks
We do not anticipate any discomfort or medical risks to you if you decide to participate in this research. There is a possibility, however, of a loss of confidentiality. We will take steps to protect your personal information by the following methods: (a) only the research members will have access to your file and all members of our research team will be bound by rules of confidentiality not to reveal your identity to others; (b) we will keep our research results in a locked office and stored in a password protected computer; (c) we will publish or report our results without the identities of individuals.

Benefits
This study may have potential benefits to you as a participant in this study. If we see substantial target motion during treatment, we may use our routine imaging verification method to reposition you to improve accuracy of radiation delivery.

Alternatives to Participation
You do have a choice not to participate in this study and receive standard routine radiotherapy.

Costs and Compensation
There is no cost to you or your insurance for participation in this protocol. You will not be paid for your participation in this study either.

Research-Related Injury
If you experience physical injury or illness as a result of participating in this research study, medical care is available at the Cleveland Clinic or elsewhere; however, the Cleveland has no plans to provide free care for lost wages.

Further information about research-related injuries is available by contacting the Cleveland Clinic Institutional Review Board at (216) 444-2924.

Privacy and Confidentiality

Authorization to Use or Disclose (Release) Health Information that Identifies You for a Research Study

If you volunteer to participate in this research, your protected health information (PHI) that identifies you will be used or disclosed to ***Dr. Ping Xia*** and their research staff at Cleveland Clinic for the purposes of this research and to Case Western Reserve University for administration.

The PHI that we may use or disclose (release) for this research may include your name, address, phone number, date of birth, Social Security number, information from your medical record, lab tests, or certain information relating to your health or condition.

Some of the tests and procedures done solely for this research study may also be placed in your medical record so other doctors know you are in this study. Upon completion of the study, you may have access to the research information that is contained in your medical record.

In addition to the investigators and research staff listed above, your PHI may be looked at by other groups involved with the study such as the Cleveland Clinic Institutional Review Board and the Case Comprehensive Cancer Center Protocol Review and Monitoring Committee. Your PHI may also be used by and/or disclosed (released) to:

- The National Cancer Institute (NCI);
- The Food and Drug Administration;
- The Department of Health and Human Services;
- Other Institutional Review Boards;
- Data Safety and Monitoring Boards;

Once your personal health information is released it may be re-disclosed and no longer protected by privacy laws.

Your research information may be used and disclosed indefinitely, but you may stop these uses and disclosures at any time by writing to:

Ping Xia, Ph.D.
Cleveland Clinic
Radiation Oncology CA-50
9500 Euclid Avenue
Cleveland, OH 44195

Your participation in the research will stop, but any information previously recorded about you cannot be removed from the records and will continue to be used as part of this research. Also, information already disclosed outside the Cleveland Clinic cannot be retrieved. This will not affect your rights to treatment or benefits outside the research study.

The Cleveland Clinic will not use your information collected in this study for another research purpose without your written permission; unless the Cleveland Clinic Institutional Review Board (IRB) assures your privacy and confidentiality is protected. The IRB is a committee whose job it is to protect the safety and welfare of research subjects.

By signing this informed consent form, you are authorizing such access to your research and medical record information. If you choose not to sign this consent form, you will not be able to participate in this research study. This Authorization does not have an expiration date.

Voluntary Participation
Your participation in this research study is voluntary. Choosing not to participate will not alter your usual health care or involve any penalty or loss of benefits to which you are otherwise entitled. If you decide to join the study, you may withdraw at any time and for any reason without penalty or loss of benefits. If information generated from this study is published or presented, your identity will not be revealed.

In the event new information becomes available that may affect the risks or benefits associated with this study or your willingness to participate in it, you will be notified so that you can decide whether or not to continue participating.

Termination of Participation
Your participation in this study may be discontinued by the sponsor (NIH) or investigator without your consent if we find that your tumor cannot be localized by the ultrasound images.

Questions About the Research
If you have any questions, you can ask the Principal Investigator and/or research staff.
Ping Xia, PhD at (216) 444-1938.

Emergency and After-hours Contact Information
If you are a Cleveland patient, and you need to contact study staff outside of normal business hours, you should contact the page operator at (216) 444-2200 or toll free at (800) 223-2273, and ask for the oncologist (cancer doctor) that is on call.

If you have questions about your rights as a research subject, you may contact the Institutional Review Board (IRB) at Cleveland Clinic IRB 216-444-2924.

Where Can I Get More Information?

You may call the National Cancer Institute's Cancer Information Services at:
1-800-4-CANCER (1-800-422-6237)

You may also visit the NCI website at http://cancer.gov

- For NCI's clinical trials information, go to: http://cancer.gov/clinicaltrials
- For NCI's general information about cancer, go to http://cancer.gov/cancerinfo

You will get a copy of this form. If you want more information about this study, ask your study doctor.

Signature

Signing below indicates that you have been informed about the research study in which you voluntarily agree to participate; that you have asked any questions about the study that you may have; and that the information given to you has permitted you to make a fully informed and free decision about your participation in the study. By signing this consent form, you do not waive any legal rights, and the investigator(s) or sponsor(s) are not relieved of any liability they may have. A copy of this consent form will be provided to you.

_____	_____	_____
Signature of Participant	***Date***	***Printed Name of Participant***

I have discussed the information contained in this document with the participant and it is my opinion that the participant understands the risks, benefits, alternatives and procedures involved with this research study.

_____	_____
Signature of Person Obtaining Consent	***Date***

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Printed Name of Person Obtaining Consent