TMU-Joint Institutional Review Board

Subject Consent Form

Project name: Evaluation of the feasibility of developing personalized breast cancer radiotherapy aids with three-dimensional printing
Executive unit: **Department of Radiation Oncology, Taipei Medical University Hospital Tel: 02-27372181#2129** **Project host: CHIU,CHUNG-FENG** **Title: Associate Dean and Section Director** **Contact number: 0970405111** **Co-host: LU,LONG-SHENG** **Title: Assistant Professor / Resident** **Tel: 0970749562** **24- hour emergency contact person: CHIU,CHUNG-FENG** **Mobile phone: 0970405111**
Subject's name: Gender: Date of birth: Age: Medical record number: Mailing address: Phone:
Name of emergency contact person / relationship with subject: mailing address: phone:
1. Test / research background: With the changes in the life style of Taiwanese people, the prevalence of cancer is increasing year by year. Taking female breast cancer as an example, according to the cancer registration data of the Taiwan National Health Administration of the Ministry of Health and Welfare released in 2013, breast cancer accounts for the first place in the incidence of female cancer and the fourth place in mortality. Whole breast radiation therapy can effectively reduce the local recurrence of breast cancer. If the cardiopulmonary radiation exposure can be reduced during full breast radiation, it can further reduce the long-term radiotherapy-related complications of cancer survivors, but related technologies are not popular in Taiwan. In view of this, the research team of Taipei Medical University, Taipei University and Taipei University of Science and Technology will cooperate to study the effect

of PERSBRA, a breast positioning aid tailored by three-dimensional printing technology, on the central lung radiation dose distribution during total breast irradiation. The results will serve as an important reference for the subsequent development of personalized breast cancer radiotherapy aids using three-dimensional printing.

2. Test / research purpose

This study will recruit 50 early breast cancer or carcinoma in situ patients who have decided to receive adjuvant radiotherapy on the affected side after partial mastectomy within two years, using non-imaging computer tomography and commonly clinical radiotherapy planning systems. Try to calculate whether different breast positions will affect the central lung radiation dose distribution in the whole breast irradiation process is an important reference for the subsequent development of the personalized breast cancer radiotherapy aid PERSBRA using three-dimensional printing. It is important reference for the development of a personalized breast cancer radiotherapy aid PERSBRA.

3. Subjects' inclusion and exclusion conditions

Patients with early breast cancer or carcinoma in situ after partial mastectomy have decided to receive adjuvant radiation therapy for the breast on the affected side, and the use of non-contrast computed tomography to obtain localized images is part of the original treatment plan

Exclude conditions:

- Clinical or pathological diagnosis with lymph node metastasis, lymph node micrometastasis, or lymph node tumor cells
- Clinical diagnosis of risk of metastatic cancer, pregnant female, younger than 20 years old
- The subject was unable to read and understand the subject consent form written in Chinese and complete the informed consent procedure

4. Test/research procedures and related inspections

This study was conducted in an open label, self-control design method. After completing the informed consent procedure and the initial condition assessment record, the research team will make a PERSBRA assistive device for each patient who joins the study. The production is in the semi-prone position, the radiologist performs a three-dimensional scan of the chest and abdomen, and then inputs the image to a three-dimensional printer to make wearable aids with plastic materials. In addition to obtaining planned chest CT images in the treatment position according to the standard procedure of breast cancer radiotherapy, patients will also wear the PERSBRA assistive device to obtain chest CT images in the treatment position

before the first treatment and before the sixth treatment. Try to calculate the exposure dose of cardiopulmonary and other critical organs and the reproducibility of PERSBRA placement.

5. Possible side effects, dangers and treatment methods

There are no safety concerns in this study. If the patient feels discomfort wearing the PERSBRA assistive device, record it on the case report form in accordance with the internationally accepted side-effect record standard CTCAE v3.0 or the degree of impact on daily life, and exit the trial process according to the patient's wishes. The patient's discomfort will be immediately evaluated by the radiologist or physician every time the PERSBRA assistive device is worn. During the study, two chest tomographic scans will be performed, and the total radiation exposure will be 0.03% of the routine course of breast cancer radiotherapy, which will not cause additional radiation exposure-related health hazards. The trial host and co-host of this study conducted the research in the hospital attached to Taipei Medical University according to the plan. If it is found that the subjects who signed the informed consent form have adverse events related to trial production and wearing PERSBRA, it will be within 48 hours, report the adverse event notification procedures and forms on the website of the Human Testing Committee of the Taipei Medical University Affiliated Hospital to the Human Testing Committee of the Taipei Medical University Hospital. All adverse events were cared for and tracked by the trial host and co-hosts in accordance with GCP and IRB regulations.

6. The expected effect of the experiment/research

The results of this study are designed according to strict statistical conditions (statistical verification power = 0.8, detection of wearing PERSBRA can cause a 5% difference in cardiopulmonary radiation exposure parameters). It is expected to provide a clear answer to whether the PERSBRA assistive device can change the cardiopulmonary radiation dose distribution of the whole breast.

7. Other possible treatment methods and instructions

This study does not involve the choice of treatment methods for the subjects. The medical care and self-care of the subjects during radiotherapy is the same as the current routine, and they will be properly explained in the radiation oncology clinic.

8. Contraindications or restricted activities during the trial/research

There are no special contraindications or restrictions on activities in this study.

9. Confidentiality

The Taipei Medical University Hospital will treat your information as confidential to the extent regulated by the law. You also understand that the project sponsor (manufacturer), the Ministry of Health and Welfare, and the Taipei Medical

University and Affiliated Hospital Joint Human Research Ethics Committee have all right to view your data and will also observe the ethics of confidentiality.
For the examination results and doctor's diagnosis you get in the research, the researcher will replace your name with a research number to collect data. In addition to the above-mentioned institutions having the right to inspect according to law, we will carefully maintain your privacy. Even if the trial/research results are published, your identity will remain confidential.

10. Withdrawal and suspension of trials/researches, and the processing methods of personal samples and data

Free to decide whether to participate in this trial/research, and can withdraw consent at any time during the trial/research process, and can withdraw from the trial/research without any reason, and it will not cause any unpleasantness or affect the future medical care of your doctor. In addition, have fully understood that the trial/study host may also suspend/terminate the trial/study, if necessary, but your doctor will not affect medical care. The test results are processed and analyzed by the project host and co-hosts.

The images and documents obtained from the research, including case report form, source documentation (containing evidence to study eligibility, history and physical findings, laboratory data, results of consultations, etc.), IRB records or other management documents will be kept in the Radiology Hospital of Taipei Medical University Department of Oncology, for re-examining the original data or reusing it in cancer treatment-related research when new scientific advances in the future occur. The uploaded images and files are preserved by the project leader Dr. CHIU,CHUNG-FENG or the research leader of the Department of Radiation Oncology, Taipei Medical University Affiliated Hospital. The retention period is ten years after the end of the study, and the upper limit is twenty years after the data is obtained. The Taipei Medical University Hospital will treat patient information as confidential to the extent regulated by law and observe the ethics of confidentiality. After the expiration of the retention period, the disposal of the remaining data will be publicly witnessed by a third party for destruction procedures. The relevant documents will be destroyed by a paper shredder. The electronic files will also be witnessed by a third party. The destroyed files cannot be retrieved and read.

11. Test/research damage compensation and insurance

(1) If PERSBRA is used in accordance with the trial/research plan or for reasons related to it, which causes adverse reactions, side effects or injuries, Taipei Medical University affiliated hospital in this plan will be responsible for all damage compensation.

If there are adverse reactions, side effects or injuries caused by the trial/research plan made by this institute, please notify our physician immediately. Taipei Medical University Hospital will provide professional medical care, and do not have to bear the burden of participating in this trial/study due to treatment. The cost of medical care necessary for the adverse reactions, side effects or injuries caused.

(2) No legal rights will be lost by signing this consent form.

(3) This plan does not have insurance. If unwilling to accept such risks, can decide not to participate in this plan or withdraw in the middle of the plan, without any reason, and it will not affect any of rights and interests.

12. Subject's rights and obligations

(1) All costs related to clinical trials/researches will be borne by this project.

(2) During the trial/research process, any major findings related health or disease that may affect willingness to continue the clinical trial/research will be provided too immediately.

(3) In order to carry out research work, must be under the care of the attending physician of the Radiation Oncologist Department. If you have any questions or conditions at present or during the study period, please feel free to contact the attending physician in the Department of Radiation Oncology.

(4) If have questions about the nature of the research work during the research process, have opinions about the rights of the subject or suspect that have been victimized by participating in the trial/research, please feel free to cooperate with Taipei Medical University and Affiliated Hospital on human research ethics Committee contact.

Tel: (02) 66382736 ext. 1728 or Email: tmujirb@gmail.com.