TMU-Joint Institutional Review Board

Informed Consent Form

Protocol name：Evaluate the therapeutic response by using in vitro circulating tumor cell expansion system

Trial Institution：

Taipei Medical University Hospital, Department of Radiation Oncology
Taipei Medical University Hospital, Division of Hematology and Oncology
Taipei Medical University Hospital, Department of Pediatrics
Taipei Medical University Hospital, Translational laboratory
Wan Fang Hospital, Department of Oral and Maxillofacial Surgery

Principal Investigator： Lai-Lei Ting **Title**：Attending physician **Phone No.**：0970405391
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24-hour emergency contact person：Lai-Lei Ting **Phone No.**：0970405391

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：

Circulating tumor cell enumeration is an emerging cancer biomarker. Circulating tumor cell detection could be considered "liquid biopsy" and many large-scale studies have confirmed that CTC count has been proven as a prognosis predictor. Through the expansion of circulating tumor cells, it will help to analyze relevant molecular characteristics and establish a drug screening platform. This study will develop a high efficiency circulating tumor cell expansion system and establish a personalized drug screening platform based on circulating tumor cells. The novel strategy to analyze and characterize the circulating tumor cells and establish a personalized circulating tumor cell drug screening platform will enhance the theoretical basis and clinical application of circulating tumor cells. Please fully understand the content of this informed consent form before agreeing to participate in this research project. The content of this informed consent form includes the purpose of the test, test methods and procedures, possible benefits, possible dangers, discomforts and precautions. The informed consent form also mentions other treatment methods and your right to withdraw from this trial at any time. If you agree to participate in this study, you will receive a copy of this informed consent form.

2.Test/research purpose

To establish a rapid circulating tumor cell expansion model. The expanded circulating tumor cells can be used for molecular analysis and test cell sensitivity to drugs.

3. Main inclusion and exclusion criteria of the trial:

Inclusion Criteria：Patients with malignant tumors

Exclusion Criteria：Unsuitable for recruitment by clinical judgement or non-compliance with regular follow-up.

4. Test/research procedures and related inspections

The physicians will evaluate and decide whether to accept the subject and collect its clinical information and medication records after obtaining informed consent. Obtain blood samples from cancer patients. 10 ml of venous blood will be collected from the peripheral vein according to the routine blood sampling procedure. The type is venous blood. The quantity is one piece. The collection site is the elbow vein. For circulating tumor cell expansion, isolated circulating tumor cells are aliquots placed in the self-assembling culture plate, which consisted of different nanostructures for CTC incubation. The expanded CTCs will perform molecular analysis and drug sensitivity assay. For drug sensitivity assay, the amplified CTCs are seeded into the self-assembling plate, and different anti-cancer drugs, including the drugs recommended in the treatment guidelines, and the sensitivity of cancer cells to the drugs is analyzed and observed the correlation of the above test results with clinical treatment response and molecular test results. In addition, we will ask your attending physician to provide your clinical medical records for result analysis, including height, weight, test values (hematology and biochemical serum test), test results (physiological and imaging tests), medication records, pathology reports, etc.

5.Possible side effects, dangers, and treatment methods

Intravenous blood sampling is a routine clinical procedure with minimal side effects, including a slight tingling sensation. A few people may experience dizziness and pain at the blood sampling site. It is often self-limiting and can be recovered without medical treatment. Relevant information will be followed the human research standards of Taipei Medical University and domestic regulations for clinical research. To participate in this study, you do not need to receive new medical treatment. Based on the above factors, the side effects and risks related to this study are minimal.

6.Anticipated results and potential commercial benefit(s) derived from the trial:

This study is expected to establish a novel circulating tumor cell expansion system to evaluate drug response. In addition to scientific value, such methods will also be used as the basis for follow-up prospective clinical research to develop a novel therapeutic strategy

7. Other possible treatment methods and instructions

You do not need to participate in this trial for treatment; the attending physician will discuss the risks and benefits of your treatment plan.

8. Contraindications or restricted activities during the trial/research

No exceptional food restriction or fasting before the blood draw

9. Confidentiality/handling methods of collecting data and samples after the termination of the trial:

The Taipei Medical University Hospital will abide by the law to keep the confidentiality of any record containing your information. You also understand that the Ministry of Health and Welfare and Taipei Medical University Joint Institutional Review Board have the right to review your information and observe confidentiality ethics.

For the examination results and physician's diagnosis in the research, the research staff will assign your name with a research code to collect data. Except for the institutions mentioned above having the right to inspect according to law, we will carefully protect 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 sample and the data.

After collecting the blood samples, circulating tumor cells will be isolated and cultured on a self-organized culture plate. The expanded CTC cells can be used for molecular analysis and drug sensitivity test. After the specimens obtained in this study are disconnected, your samples collected by us will be frozen or refrigerated and stored in Taipei Medical University Hospital translation laboratory for up to a maximum of ten years, calculated from the end of the main study. After the study is completed, the disposal of the remaining specimens or data will be publicly witnessed by a third person for destruction procedures, and the remaining specimens and related data will be destroyed following the procedures. After the study is completed, the blood sample will be destroyed by bleaching and autoclaving. A paper shredder will destroy the relevant documents, the electronic file will be deleted, and third-party witnesses confirm that the destroyed file cannot be recovered and read.

You are free to decide whether to take part in this trial. During the trial, you can withdraw your consent and leave the trial at any time, without giving any reason, and no unpleasantness will be caused, nor will your medical care from your physician be affected. In addition, you have fully understood that Principal Investigator or the Trial Sponsor will terminate the clinical trial or your participation in the trial whenever necessary but will not affect your medical care from your

physician.

The deidentifying residual samples obtained in this study (the residual samples after the operation of this study) will be frozen or refrigerated and stored in Taipei Medical University Hospital translation laboratory for up to a maximum of 10 years, calculated from the end of the main study. Without the subjects' permission, the remaining specimens collected will be destroyed ten years after the end of the project.

Regarding the residual samples (the residual samples after the operation of this study), if you decide to withdraw from this trial/research or if the Principal Investigator decides to terminate your participation in this trial, the samples collected before your withdrawal will be processed according to your choice. However, the data you have obtained before your withdrawal will be retained and analyzed. If it exceeds the original scope of use, need to obtain your informed consent again, and another consent should be reviewed and approved by the Taipei Medical University Joint Institutional Review Board.

For the samples:

□ I give my consent to authorize the trial to continue using the samples for research related to the trial. Another consent should be reviewed and approved by the Taipei Medical University Joint Institutional Review Board if the scope of use exceeds this original informed written consent.

□ I do not give my consent to authorize the trial to continue using the samples. Please destroy my trial-related samples on the day of my withdrawal. (Including self withdraws and Principal Investigator decides to terminate your participation in this trial)

11. Test/research compensation and insurance

(1) If used under the trial/research plan or for reasons related to it, which causes adverse reactions, side effects or injuries, the Taipei Medical University hospital in this plan shall be responsible for all damage compensation. If there are adverse reactions, side effects, or injuries caused by this institute's trial/research plan, please notify our physician immediately. The Taipei Medical University Hospital will provide professional medical care and consultations for adverse events or damages resulting from following the protocol designed for this clinical trial. You will not be responsible for the necessary medical expenses with respect to the treatment for the adverse events or damages.

(2) You will not lose any legal rights pursuant to your signing of this Informed 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. Subjects' rights and obligations

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

(2) Trials/research

☐Provide ☐ Transportation fee

☐ Nutrition fee

☐ Gift

Provided according to your participation progress/proportion, and no need to pay back if you withdraw

■ Does not provide any subsidies or gifts, please help free of charge

(3) 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.

(4) To carry out research work, must be under the care of Dr. Lai-Lei Ting from the Radiation Oncology Department of the Taipei Medical University Hospital. If you have any questions or conditions at present or during the study period, please feel free to contact Dr. Lai-Lei Ting at the Radiation Oncology Department of the Taipei Medical University Hospital.

(5) 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 Joint Institutional Review Board. Tel: (02) 66382736 ext. 1728 or Email: tmujirb@gmail.com. ◦

(6) In addition to the above circumstances, the subject or his legal representative, guardian, assistant, or person with the right to consent has any ignorance or familiarity with current, future or past research, and would like to discuss and answer questions Please feel free to contact the Taipei Medical University Joint Institutional Review Board. We will provide a person who is not related to the research to provide information. If necessary, please contact the Joint Human Research Ethics Committee of Taipei Medical University and Affiliated Hospital Contact (Tel: (02)66382736 ext. 1728 or Email: tmujirb@gmail.com).

13. Signature:

Statement by the subject

I fully understand the research method mentioned above and the possible risks and benefits after the explanation, and my questions about the clinical trial have been answered in full detail. I agree to participate in this research voluntarily and will hold a duplicate of the Informed Consent Form. If I have any questions in the future, I can contact Dr. Lai-Lei Ting from the Department of Radiation Oncology, Taipei Medical University Hospital.

Print name of subject: _____

Date of birth: _____

Signature: _____

Date: _____

Print name of legal representative/ guardian/ assistant: _____

Signature: _____

Relationship with the Subject: _____

Date: _____

If you are not the subject or legal representative, but due to facts, the subject or his legal representative is temporarily unable to sign this consent form and must be signed by you as a person with the right to give consent. Please write your name in printed letters and indicate your relationship with the subject

Name (print name): _____

Relationship with the Subject: _____

(Those who have the right to consent, please inquire according to the regulations of the trial/research)

National ID number: _____

Telephone No: _____

Correspondence address: _____

Signature: _____

Date: _____

Statement by the researcher

I confirm that a member of my research team (representative who has been authorized to carry out this step) or I have explained this trial/study to the potential participant, including the purpose, procedure, and participation of this trial/study. Research on possible related risks and benefits, as well as currently possible alternative treatments. All questions raised by the subjects have been answered.

Print name of principal investigator/sub-investigator: _____

Signature: _____

Date: _____

Print name of staff participating in the explanation: _____

Signature: _____

Date: _____

Oral Consent Script

(If the subject cannot read the above content, a witness shall be present during oral explanation.)
This is to certify that the project leader and research staff have fully explained the contents of this experiment/research to the subjects.

Print name of witness: _____ (The trial staff shall not be a witness)

National ID number: _____

Telephone No: _____

Correspondence address: _____

Signature: _____

Date: _____

In the event that none of the subject, legal representative or the person who has right to give consent can read, a witness shall be present during every discussion of subject's consent. The witness shall confirm that the consent given by the subject, legal representative or person who has right to give consent is of voluntary nature before signing and dating the Informed Consent Form.

The trial staff shall not be a witness.