Official Title	A Patient-Derived 3D Bioprinted Colorectal Cancer-Stroma-Immune Triad Model Uncovers Microenvironmental Mechanisms of Chemoresistance and Immune Evasion
NCT number	not yet assigned
Center	Peking Union Medical College Hospitol
Informed Consent Form Version No.	1.0
Date	May 23, 2025
Subject Name	
Subject ID	

Dear Subject,

We would like to invite you to participate in a clinical study entitled "Construction of 3D Multicellular Bioprinted Human Colorectal Cancer and Its Liver Metastasis-CAFs Models and Its Clinical Translational Research." Before you decide whether to agree to participate, please read this informed consent form carefully. You may ask the investigators any questions you are concerned about, and you may also consult your family, friends, or others. Once you decide to participate in this study, you will need to sign this informed consent form.

1. Study Background

Colorectal cancer (CRC) is the third most common cancer worldwide. Since the 2000s, combination chemotherapy based mainly on 5-fluorouracil (5-FU) and oxaliplatin, such as leucovorin + 5-FU + oxaliplatin (FOLFOX) and leucovorin + 5-FU plus irinotecan (FOLFIRI), has been the main chemotherapy regimen for patients with advanced CRC, significantly improving the survival of CRC patients. In recent years, targeted drugs such as vascular endothelial growth factor (VEGF) inhibitors and epidermal growth factor receptor (EGFR) inhibitors combined with the above chemotherapy have further improved patients' median survival and quality of life; however, the 5-year survival rate of metastatic CRC, including CRLM, remains less than 15%. The reason is that both CRC and CRLM have high heterogeneity and a complex tumor

microenvironment, and the efficacy of the same drug may differ dramatically among different patients. This study requires a small amount of your tumor tissue. The isolated cells will be subjected to 3D culture, and the tumor cells can be cultured in vitro into a piece of colorectal cancer tissue, allowing in vitro testing of which drugs are more effective for your liver tumor.

We have already achieved significant results in this field. This procedure will not have any impact on your body and will not affect your normal treatment plan. This study has been approved by the Ethics Review Committee of Peking Union Medical College Hospital.

2. What Is the Purpose of This Clinical Study?

The purpose of this study is to use tumor cells isolated during surgery combined with 3D bioprinting technology to construct in vitro 3D culture models, and to propose new approaches to tumor occurrence and development, drug efficacy, and related issues.

3. Study Methods

This is an observational study. The study will not interfere with the subject's clinical diagnosis and treatment.

4. Study Procedures

Before any study-related activity begins, you must first sign this informed consent form. During the screening period, the investigator will ask about and collect your personal information, previous diagnosis and treatment history, previous treatment measures, and relevant auxiliary examinations. During surgery, colorectal cancer or colorectal cancer liver metastasis surgical specimens will be obtained. Cells of interest with relatively high purity will be isolated and cultured in vitro in 3D using a specialized medium.

5. How the Study Will End

If you participate in the specimen collection for this study, a small amount of your tumor tissue will be collected during surgery. You may choose to withdraw from the study at any time, and we will destroy the tumor specimens and will no longer use them.

During the study, the study doctor, study sponsor, regulatory authorities, and the Ethics Committee may terminate the study.

6. Study Benefits

You personally will not receive direct benefit from this study.

Your participation in this study may help doctors develop tumor disease models that can be used for preclinical research, especially tissue models using novel 3D culture methods, in order to address the shortcomings of existing

research platforms. Other patients with the same or similar diseases may benefit from this information in the future.

7. Risks and Inconveniences of the Study

Any study involves known or unknown risks. Some are mild and transient, and some are serious and permanent. Whether risks occur, which risks occur, and their severity vary from person to person. Your study doctor will take all preventive measures and closely monitor your condition. If you experience any discomfort, please be sure to inform your study doctor immediately so that the doctor can take necessary treatment in a timely manner. This study only obtains a very small amount of your cells and will not have any impact on your body.

Collection of other tissues: The tissue collected is derived from surgically resected specimens; there is no associated risk to the patient.

8. New Information During the Study

During the study, if the investigators obtain important new information relevant to the study, we will inform you promptly, and you will decide whether to continue participating in this study.

9. How Will My Samples Be Handled?

A small amount of your tumor tissue will be collected in total in this study.

The samples collected in this study and their use are shown in the table below:

Visit	Sample Type	Sample Amount	Test Item	Laboratory
V1	Tumor tissue	Small amount	3D printing	Our hospital

*Samples sent to our hospital will be destroyed according to routine medical practice after use.

Your biological samples will be used only for the purposes described in the study protocol and this informed consent form.

If you withdraw from the study early, we will not collect new samples, but we will retain samples or data already collected or analyzed.

10. Confidentiality

This study may collect or process your personal information and medical information, including but not limited to your name, sex, date of birth, address, telephone number, diagnosis and treatment, examinations and tests, and medical imaging. Your personal information will be used only for the purposes described in the study protocol and this informed consent form. The medical information obtained from your participation in this study will be kept confidential. Publication of study results in academic journals will not disclose any information that could identify you personally. The investigators will be responsible for storing and using all your personal data in this study. Research

monitors of Peking Union Medical College Hospital, the Ethics Committee, or the Clinical Research Regulatory Department may review your personal data.

11. Funding Source and Possible Conflicts of Interest

The investigators have no conflict of interest with this study.

12. Voluntary Participation

Your participation is completely voluntary. You may choose not to participate or withdraw from this study at any time during the study. This will not affect your relationship with medical staff, and your routine medical care will not be affected in any way.

13. Notes for Subjects

Please truthfully inform the study doctor of your health status and previous treatment measures.

If you experience any discomfort, please inform your study doctor promptly.

14. Contact Information

If you experience any discomfort or have any questions about this study, you may contact the investigator:

Role: Study Doctor

Name: Yilei Mao

Telephone: 13011079603

If you have any questions about your rights as a subject, you may contact the Ethics Committee:

Role: Ethics Secretary

Name: Jiayue Li

Telephone: 010-69156874

Thank you for reading this form and considering whether to participate in this study.

15. Signature Page

Subject:

I confirm the following information:

(1) I have read and understood the above informed consent information and have had sufficient time to consider whether to participate in the study.

(2) All my questions have been answered satisfactorily.

(3) I voluntarily participate in this study and will comply with the study procedures.

(4) I understand that I may withdraw from this study at any time without giving

any reason, and my treatment or rights will not be affected.

(5) I have received a copy of the informed consent information and the signed consent form for my own records.

(6) I agree to the collection and use of my samples as described in this informed consent information.

(7) I permit the collection and use of my personal information in this study.

(8) I understand that I may be contacted in the future to obtain my permission for this study or any related sub-study.

By signing this document, I agree to participate in this study in accordance with the statements in the informed consent information and consent form.

Subject Name (Block Letters): _____

Subject Signature: _____

Date: _____

The following section applies only to subjects without decision-making capacity and requires the guardian's signature.

[Subject Name (Block Letters): _____, Relationship of Guardian to Subject: _____.]

Guardian Name (Block Letters): _____

Telephone: _____

Guardian Signature: _____

Date: _____

The following section applies only to subjects who are unable to read or write and requires the signature of an impartial witness.

Witness Name (Block Letters): _____

Telephone: _____

Witness Signature: _____

Date: _____

Investigator/Authorized Personnel Name (Block Letters): _____

Investigator/Authorized Personnel Signature: _____

Date: _____