Official Title of the study:

A cohort study protocol of nutritional status and clinical outcomes in patients with common malignancies (NCOM study)

NTC number: 06219083

Date: 03/28/2025

Informed Consent Form

Study Title:
A cohort study protocol of nutritional status and clinical outcomes in patients with common malignancies (NCOM study)

Dear Participant,

You are being invited to participate in the research study titled "A cohort study protocol of nutritional status and clinical outcomes in patients with common malignancies (NCOM study)" Before deciding whether to take part, please carefully read the following information regarding the purpose, procedures, potential risks, and benefits of this study. Your participation is entirely voluntary.

1. Study Overview:
The incidence and mortality rates of malignant tumors in China have been steadily rising. According to the Global Cancer Statistics 2020 report by the International Agency for Research on Cancer (IARC) of the World Health Organization (WHO), China now ranks among the countries with the highest cancer burden. In 2020, China recorded 4.57 million new cancer cases (2.48 million men and 2.09 million women) and 3 million cancer-related deaths (1.82 million men and 1.18 million women). The 5-year relative survival rate for malignant tumors in China is approximately 40.5%, significantly lower than that of developed countries. Cancer patients, especially those with gastrointestinal malignancies, are prone to malnutrition. Although cancer patients in China generally hold a positive attitude toward nutritional therapy, their nutritional knowledge and behaviors remain insufficient and in need of improvement. This study aims to address the major national health challenge of malnutrition and unbalanced nutrient intake among cancer patients. By collecting and analyzing large-scale and detailed data on the diet and nutrition of cancer patients in Shaanxi Province, this study will contribute to developing dynamic and evidence-based nutritional solutions and intervention strategies. The findings will be essential for the comprehensive medical nutrition management of cancer patients, clarify the role of nutrition in cancer prevention and treatment, promote precise nutrition management, and help participants develop a healthier Knowledge-Attitude-Practice (KAP) model.

2. Study Procedures:
We will collect and record detailed information related to your clinical treatment, including personal data, disease status, laboratory test results, clinical outcomes, and lifestyle data (such as nutritional status, appetite, sleep quality, and psychological well-being). Throughout the study, professional dietitians will provide you with nutritional counseling and dietary guidance, in close collaboration with clinicians who will monitor your nutritional status, offer psychological and sleep-related support, and conduct regular follow-ups.

3. Potential Benefits:
This is a basic medical research study. Participation may provide you with professional nutritional and lifestyle guidance, which may benefit your health (subject to individual differences). Additionally, your participation will provide valuable data to advance basic medical research.

4. Potential Risks or Inconveniences and Compensation:
This is an observational study. There are no foreseeable risks or adverse effects associated with your participation, and no compensation measures are required.

5. Confidentiality:
All personal information collected in this study will remain strictly confidential and will be used solely for research and scientific analysis purposes. By signing this informed consent form, you authorize the study team and designated personnel to collect and review your personal

6. Your Rights:
Your participation in this study is entirely voluntary. You are free to decide whether to participate without any coercion. If you choose to participate, you will be asked to sign two copies of this informed consent form. By signing, you confirm that you have carefully read and understood the information provided above before engaging in any study-related procedures.

Thank you for your support and for contributing to research on cancer prevention and treatment.

Consent Statement

I have understood the purpose, process, potential benefits, and possible adverse reactions of this study. I voluntarily agree to participate in this study and will do my best to follow the study procedures.

Participant Name:

_____

Date of Birth:

_____

Participant Signature:

_____

Date of Consent Signature:

_____

Participant Contact Number:

_____ (Mobile)

Guardian Signature (if applicable):

_____

Date of Consent Signature:

_____

Guardian Contact Number:

_____