Informed Consent Form

Evaluation of Fecal Multi-Target Biomarker Testing in Gastrointestinal Cancer Screening: A Multicenter Prospective Observational Cohort Study

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Study Period:	January 1, 2026 – December 31, 2027
Subject ID:	[ ]

Dear Participant,

We sincerely thank you for participating in the project "Evaluation of Fecal Multi-Target Biomarker Testing in Gastrointestinal Cancer Screening" led by the Department of Gastroenterology, Xijing Hospital. This study has been reviewed and approved by the Medical Ethics Committee of Xijing Hospital. This informed consent form provides you with information to help you decide whether to participate in this clinical research. Please read it carefully, and if you have any questions, please raise them with the investigator responsible for this study.

I. BACKGROUND

The disease burden of gastrointestinal cancer in China is substantial. The incidence of upper gastrointestinal cancer remains high, while colorectal cancer continues to rise, posing a serious threat to national health and placing enormous pressure on families and the social healthcare system. Early diagnosis and treatment are key to reducing mortality and improving prognosis, and represent an important public health need for enhancing the health of the entire population.

Fecal immunochemical testing (FIT), due to its non-invasive and convenient advantages, has become an important non-invasive method for colorectal cancer screening. Ultra-sensitive quantitative FIT has a low detection limit and can accurately capture trace amounts of bleeding, achieving "dual management" of cancer and precancerous lesions. Studies suggest that individuals with positive qualitative FIT but negative colonoscopy have a higher incidence of upper gastrointestinal cancer, indicating the potential of ultra-sensitive quantitative FIT for combined screening of upper and lower gastrointestinal cancers. However, relevant systematic studies are scarce, and evidence-based support is lacking.

This study is designed based on this need and gap to validate its combined screening efficacy, optimize screening strategies, and reduce missed diagnoses. It holds significant clinical and public health value, and is ethically justified and necessary. Additionally, we will conduct fecal calprotectin, MG7-Ag, and other novel biomarker testing to explore the clinical application value of multi-target testing.

II. STUDY OBJECTIVES

The primary objective is to evaluate the application value of fecal multi-target biomarker testing in combined screening for upper and lower gastrointestinal tumors, and to establish a precise stratified management strategy for the population, with immediate referral to endoscopic examination for high-risk patients. Furthermore, residual samples after testing will be used for exploration of other gastrointestinal cancer

screening biomarkers.

III. STUDY POPULATION

Population meeting the inclusion and exclusion criteria, with a total planned enrollment of 5,000 participants.

Inclusion Criteria

General Inclusion Criteria:

1) Age greater than 18 years at enrollment;

2) Planned to undergo gastroscopy and colonoscopy;

3) Agree to follow the protocol for a two-year follow-up period;

4) Willing and able to sign the informed consent form.

Exclusion Criteria

General Exclusion Criteria:

1) Received gastrointestinal endoscopic screening within 1 year;

2) History of any type of gastrointestinal malignancy;

3) Comorbid severe diseases that reduce the benefit of screening, such as severe pulmonary disease, kidney disease, liver disease, cardiovascular/cerebrovascular disease, and hematologic disorders;

4) Other situations where the physician assesses that the risk of endoscopic screening is excessive (e.g., hemodynamic instability) or non-beneficial (short life expectancy).

IV. STUDY METHODS

This is a multicenter, observational study. Participants planned for gastrointestinal endoscopic examination will complete epidemiological examination before endoscopy, and provide fecal samples for fecal multi-target biomarker testing, followed by completion of endoscopic examination. After baseline endoscopic screening, all enrolled participants will complete a 2-year follow-up. The primary study endpoint is the sensitivity and specificity of fecal multi-target biomarker testing for gastrointestinal cancer screening.

V. POTENTIAL IMPACTS OF THIS STUDY

Risks and Discomforts:

This study is not a drug or device clinical trial. All research is conducted within routine clinical diagnostic and treatment processes or daily life, and will not bring you additional financial burden or physical harm. The main potential risks of this trial originate from endoscopic screening, with complications including possible bleeding, perforation, infection, cardiovascular/cerebrovascular complications, aspiration, or screening-related death. The research team has extensive clinical experience in subject management and has established a strict adverse event reporting system in this study to maximize risk reduction for participants. During the trial period, the investigator will conduct close follow-up for all enrolled patients, and provide comprehensive management including lifestyle improvement, gastrointestinal cancer warning symptoms, and timely medical consultation through face-to-face and telephone visits to minimize the risks of participating in the clinical trial. At the same time, each participant will be closely monitored for screening-related adverse events.

Study Benefits:

At each follow-up visit, the follow-up staff and physicians of the Department of Gastroenterology, Xijing Hospital of Digestive Diseases will provide you with close medical consultation and certain health guidance

based on your test results. All data information in this study is for scientific research purposes and can provide valuable information for disease research. We will aggregate your data and that of all other participants for further analysis. These real-world data are extremely precious, as they reflect the current status of diagnosis and treatment in China and provide a scientific basis for future development, ultimately promoting the development and improvement of gastrointestinal disease diagnosis and treatment.

Study-Related Costs:

Participants in this study are required to pay for costs including but not limited to: drugs and examinations related to adjuvant chemotherapy (PET/CT, routine blood tests, tumor marker testing, etc.). Specifically: the study will provide fecal testing free of charge, and you do not need to bear any costs for this testing; your routine medical expenses, such as routine examinations and treatments, must be paid according to the hospital's normal fee schedule.

Alternative Treatments:

This study evaluates the application value of fecal multi-target biomarker testing in combined screening for upper and lower gastrointestinal tumors, and establishes a precise stratified management strategy for the population, with immediate referral to endoscopic examination for high-risk patients. It does not involve therapeutic procedures, and therefore there are no alternative treatments.

VI. COMPENSATION AND INDEMNIFICATION

This study does not provide direct financial compensation or remuneration. As this study uses a combination of telephone follow-up and outpatient follow-up during the follow-up process, no specific transportation compensation is provided. If any injury related to participation in this study occurs, please contact the study physician as soon as possible. The hospital will actively provide treatment, and the related expenses will be borne by Xijing Hospital.

VII. CONFIDENTIALITY

If you decide to participate in this study, all information will be kept confidential for you. Your participation in the trial and your personal data during the trial are confidential. Your information will be identified by a study number rather than your name. Information that can identify you will not be disclosed to members outside the research team unless you grant permission. All research members and the study sponsor are required to keep your identity confidential. Your records will be kept in a locked filing cabinet and are only accessible to researchers. To ensure that the study is conducted according to regulations, when necessary, government regulatory authorities or ethics review committee members may access your personal data at the research site according to regulations. When study results are published, your personal information will not be disclosed.

VIII. HOW TO OBTAIN HELP DURING THE STUDY

You may learn about study-related information and research progress at any time. If you have questions about this study, please contact staff member Li Jing [Tel: 13152338671]. If you have questions regarding the protection of participants' rights and interests in this study, you may also call the Xijing Hospital Ethics Committee Office [Tel: 029-84771794].

IX. VOLUNTARY PARTICIPATION

Participation in this study is entirely voluntary. You may choose not to participate in this study, or notify the investigator at any time to request withdrawal from the study. Your data will not be included in the study results, and your normal medical care and personal rights will not be affected.

If you decide to withdraw from this study, please notify the research staff in advance.

INFORMED CONSENT STATEMENT

Consent Statement

1. I have read and understood all the contents of this informed consent form.

2. I have had the opportunity to ask questions, and all questions have been answered.

3. I understand that participation in this activity is entirely voluntary, and I have the right to withdraw unconditionally at any time. My medical services and rights will not be affected.

4. I know that signing the informed consent form does not mean exemption from any fees or obligations.

5. I understand that after signing the informed consent form, if I have any questions, I may consult the National Clinical Research Center for Digestive Diseases, Xijing Hospital.

I voluntarily provide my medical information to the Department of Gastroenterology, Xijing Hospital, for use in this medical teaching and research, to contribute to the early conquest of diseases and treatment of patients.

Participant Signature: _____

Date: _____ Year _____ Month _____ Day

(Note: If the participant has no civil capacity/restricted civil capacity, the legal representative must sign and date.)

Legal Representative (Guardian) Signature: _____ (Relationship to Participant: _____)

Date: _____ Year _____ Month _____ Day

Xijing Hospital Informant Statement

I have accurately explained all the contents of the informed consent form to the participant, answered all questions raised, and provided a copy or photocopy of the signed informed consent form.

Informant: _____

Date: _____ Year _____ Month _____ Day