INFORMED CONSENT FORM

NCT Number: [To be provided] Document Date: September 17, 2025 Version: 1.0

Research on Early Diagnosis and Risk Stratification Biomarkers of Anti-Tumor Drug-Associated Interstitial Pneumonia Driven by Multi-Omics Integration

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Research on Early Diagnosis and Risk Stratification Biomarkers of Anti-Tumor Drug-Associated Interstitial Pneumonia Driven by Multi-Omics Integration

Research Institution: Fujian Provincial Hospital, Fujian University Principal Investigator: [To be completed] Informed Consent Version: 1.0, August 29, 2025

Patient Name: _____ Patient Name Abbreviation: _____

Dear Participant,

You are being invited to participate in a research study titled "Multi-omics Integration-Driven Biomarker Research for Early Diagnosis and Risk Stratification of Antitumor Drug-Related Interstitial Pneumonitis." Before you participate in this study, please carefully read this informed consent form and make a thoughtful decision about whether to participate. You may ask your research doctor/research staff about anything you do not understand and have them explain it until you fully understand. Before making your decision to participate in this study, you may discuss it thoroughly with your family and friends. If you are currently participating in another study, please inform your research doctor or research staff. The main content of this study is as follows:

I. RESEARCH BACKGROUND

1.Nature of the Study: This research is a project by Fujian Provincial Hospital titled "Multi-omics Integration-Driven Early Diagnosis and Risk Stratification of Antitumor Drug-Related Interstitial Pneumonitis," led by the Department of Respiratory and Critical Care Medicine, jointly organized with 2 domestic institutions. The principal investigator is Xie Baosong, and the study period is from September 2025 to September 2026.

2.Research Purpose: To improve early and accurate diagnosis of antitumor drug-related interstitial pneumonitis and guide individualized treatment, we will conduct blood testing-related research. For this purpose, we need to use your remaining samples after routine clinical examinations, including bronchoalveolar lavage fluid and blood (serum/plasma), all from remaining samples without additional sampling required.

3.Ethics Approval: This study has been approved by the Ethics Committee of Fujian Provincial Hospital. The Ethics Committee is an organization that protects the rights and interests of research participants/patients.

II. STUDY DESIGN AND PROCESS

1.Study Population: This study will include patients with lung cancer, breast cancer, and gastrointestinal tumors along with controls, with a sample size of approximately 200 cases. Designed as a single-center prospective cohort: baseline collection of bronchoalveolar lavage fluid and blood, follow-up blood collection only at 2-4 weeks and 8-12 weeks post-treatment, with longitudinal evaluation of biomarkers.

2.Participation Process: If you voluntarily participate in this study, we will collect your remaining blood and bronchoalveolar lavage fluid samples from routine clinical examinations and treatments. The use of these specimens will not affect your normal diagnosis and treatment. You will also authorize Fujian Provincial Hospital to access your medical records and test results in this study for scientific research purposes.

3.Sample Management: After collecting these samples, we will establish dedicated tissue and serum/plasma sample databases. Database content includes "sample number" and "participant name abbreviation." Sample numbers will be marked on sample tubes to ensure "double insurance" of participant information and sample numbers, ensuring information accuracy during data analysis. These samples will be sent to our center laboratory for multi-omics testing and routine biochemical and inflammatory marker testing. Remaining biological samples will be returned to Fujian Provincial Hospital for storage.

4.Privacy Protection Measures: Samples will be processed with personal identity de-identification during collection to protect participant privacy. After enrollment, you will use a unified project number. Personal data and case information will be entered and stored by dedicated sample management personnel. Users will only see individual numbers without access to participant names and other information. Your sample data will be stored electronically on a dedicated computer with password protection, accessible only to sample management personnel (1 person). Sample storage freezers are dedicated biological sample preservation freezers with keys kept by dedicated sample management personnel.

III. POSSIBLE RISKS AND BENEFITS

1.Possible Risks: This is a non-interventional study that will not affect or interfere with your routine medical diagnosis and treatment, therefore will not add extra risks. If you encounter any questions during the study, you may consult with research doctors or the ethics committee.

2.Possible Benefits: Since this is a non-interventional study, results may not directly apply to your diagnosis and treatment. However, testing your samples or analyzing your medical data will help future clear diagnosis or effective treatment of antitumor drug-related interstitial lung disease and improve cure rates. We thank you for participating in scientific research and contributing to medical development!

IV. VOLUNTARY PARTICIPATION

Your participation in this study is completely voluntary. You may withdraw from the study at any time without reason, which will absolutely not affect your relationship with medical staff or future diagnosis and treatment.

V. STUDY COSTS

Specimen testing costs will be borne by researchers. Participating in this study will not increase your expenses.

VI. COMPENSATION

If any damage related to this study occurs or serious adverse events happen, the sponsor will bear treatment costs and provide appropriate compensation according to Chinese legal regulations.

VII. CONTACT INFORMATION

If you have any questions about this study, you may directly contact Fujian Provincial Hospital researchers at: (0591-88217531). If you have any questions related to participant rights, or want to report difficulties, dissatisfaction, and concerns encountered during participation in this study, or want to provide opinions and suggestions related to this study, please contact the Ethics Committee of Fujian Provincial Hospital at: 0591-88216023.

INFORMED CONSENT SIGNATURE PAGE

- I have read this informed consent form.
- I had the opportunity to ask questions and all questions have been answered.
- I understand that participation in this study is voluntary.
- I may choose not to participate in this study, or withdraw at any time by notifying researchers without discrimination or retaliation, and my medical treatment and rights will not be affected.
- If I need other treatments, or I do not comply with the study plan, or study-related injury occurs, or for any other reasons, the research physician may terminate my continued participation in this study.
- I will receive a signed copy of this "informed consent form."

Participant Name (Print): _____ Participant Signature: _____
Contact Information: _____

Date: _____ Year _____Month _____Day

Guardian Name (Print): _____ Guardian Signature: _____
Relationship to Participant: _____

Contact Information: _____

Date: _____ Year _____Month _____Day

Witness Name (Print): _____ Witness Signature: _____
Contact Information: _____

Date: _____ Year _____Month _____Day

Researcher Name (Print): _____Researcher Signature: _____

Contact Information: _____

Date: _____ Year _____Month _____Day

END OF INFORMED CONSENT FORM