# Informed Consent

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The informed consent form shall be divided into two sections, and its content shall include:

## Part I: Informed Consent Form – Information Disclosure Page

I. Introduction to the Experiment/Study

The title of this study is "Comparative Study of Rotational Cryobiopsy Needle and Automated Biopsy Needle in Transthoracic Needle Biopsy for the Diagnosis of Peripheral Pulmonary Lesions"; this study was supported by Beijing Chaoyang Hospital, Capital Medical University, with Dr. Li Wan serving as the principal investigator.

This study is an experimental study that has been reviewed and approved by the Medical Ethics Committee of Beijing Chaoyang Hospital. Please read this informed consent form carefully and make a prudent decision regarding whether to participate in this study. Participation in this study is entirely your voluntary choice. As a participant, you must provide written consent prior to joining the clinical trial. When your research physician or investigators discuss the informed consent form with you, you may ask them to explain any sections that you do not understand.

This study is a single-center trial; participants were enrolled starting from the project initiation date until the total number of enrolled subjects reached 308, at which point enrollment was terminated; the study site aims to enroll 308 subjects.

This study will last for 36 months, followed by a 24-month follow-up period to monitor postoperative complications (including pneumothorax, hemorrhage, pleural effusion, fever, etc.) and collect diagnostic information; detailed medical records will be gathered during this period to enable us to better understand your condition. Your treatment plan is determined by your physician, and no investigational drugs will be administered as part of this study.

If you decide not to participate in this clinical trial, there are other alternative treatment options available for your current condition, including bronchoscopy and surgical intervention.

II. Trial/Study Objective

1. Research Objective: The subjects were randomly assigned (1:1) to either the CassiII rotational core biopsy group (experimental group) or the automated biopsy needle group (control group). The study compared diagnostic accuracy, the incidence of procedure-related complications, as well as the size and quality of the obtained tissue specimens.

2. Research Steps

If you agree to participate in this study, please sign this informed consent form.

①A total of 308 patients with unexplained peripheral pulmonary nodules were consecutively enrolled in this study after signing informed consent forms.

②Review the preoperative chest CT scans and other laboratory test results of the patient.

③Based on pre-prepared random envelopes, subjects are randomly assigned to either CassiII rotational core biopsy group (experimental group) or the automated biopsy needle group (control group) （1：1）.

④Optimize preoperative preparation: all patients shall fast for 6 hours and abstain from oral intake for 2 hours prior to surgery. A contrast-enhanced CT scan performed before surgery is used to determine the location, size, and relationship of the nodule with surrounding blood vessels. The surgeon will plan the optimal puncture trajectory, ensuring it avoids major blood vessels and bronchi. During the procedure, local infiltration anesthesia or nerve block anesthesia will be administered.

a) CassiII rotational core biopsy group: Under CT guidance, a coaxial needle is percutaneously inserted; upon reaching the target lesion, a CassiII rotational core needle is advanced along the coaxial needle for biopsy. At the same lesion site, ≥1 biopsy is performed; depending on sample adequacy, the maximum number of biopsies shall not exceed 3, with at least 1 tissue specimen obtained from each procedure. Subsequently, the CassiII rotational core needle and the coaxial needle are withdrawn sequentially. After rest for 5–10 minutes, a repeat CT scan is performed to assess for any complications such as hemorrhage or pneumothorax.

b) Automated biopsy needle group: Under CT guidance, a coaxial needle is percutaneously inserted; upon reaching the target lesion, an automatic biopsy needle is advanced along the coaxial needle and activated. Biopsy is performed at least once at the same lesion site; depending on sample adequacy, the maximum number of biopsies allowed does not exceed 3, with at least one tissue specimen obtained from each procedure. Subsequently, the automatic biopsy needle and the coaxial needle are withdrawn sequentially. After resting for 5–10 minutes, a repeat CT scan is performed to assess for any complications such as hemorrhage or pneumothorax.

c) For specimens obtained from both groups, an Artificial Intelligence-assisted Rapid On-Site

Evaluation was performed; subsequently, the tissue samples were placed in formalin-fixed specimen containers for pathological examination. The pathological diagnosis was independently assessed by two pathologists using a back-to-back review approach: if the results were consistent, the diagnosis was confirmed; if the results differed, a third pathologist conducted a final review, and the definitive diagnosis was established through consensus among all three experts.

⑤ Postoperative management: The patient should remain in a supine position for 4 hours postoperatively, with close monitoring of vital signs, oxygen saturation levels, and for any signs of complications. A chest imaging study should be performed within 24 hours postoperatively to exclude asymptomatic pneumothorax or hemorrhage. If no complications are observed, the patient may be discharged after 24 hours, with follow-up scheduled accordingly.

⑥ Data collection: Clinical data include medical history, physical signs, laboratory results, pulmonary function tests, and imaging studies; record the number and size of biopsy specimens; document surgical-related complications such as hemorrhage, pneumothorax, or infection (occurring within 7 days postoperatively); assess the severity of complications and record the corresponding management approach; report pathological findings; and document follow-up results.

⑦Follow-up: Follow-up visits will be conducted at 1 month, 3 months, 6 months, 12 months, and 24 months postoperatively. For pathologically negative subjects, a repeat chest CT scan will be performed to evaluate their final diagnosis based on changes in pulmonary nodules and results from surgical biopsies.

⑧Organize data and perform statistical analysis.

3. Subject Selection

(1) Inclusion criteria:

Subjects enrolled in this trial must meet all of the following criteria:

① Age: 18－90 years; gender: unrestricted;

② If a chest CT scan reveals pulmonary nodules with an unknown nature, a biopsy is required for definitive diagnosis; if the chest CT shows multiple pulmonary nodules, one of these nodules should be selected as the target lesion;

③ Axial chest CT imaging reveals peripheral pulmonary nodules located in the pulmonary region, with diameters ranging from 8 mm to 30 mm;

④ Voluntarily undergo CT-guided lung puncture biopsy and meet all preoperative requirements;

⑤ Participants demonstrate good compliance, are able to cooperate with the study observations, are fully informed of the study's objectives and methods, acknowledge the potential risks, agree to participate in the study, and sign the informed consent form.

(2) Exclusion criteria

No subject meeting any of the criteria specified below shall be eligible for inclusion in this trial:

① Severe cardiopulmonary dysfunction;

② Irreversible coagulation disorders;

③Suspected vascular lesions or arteriovenous malformations (assessed by contrast-enhanced CT), or presence of bronchial artery invasion at the planned biopsy site, or suspected pulmonary metastasis from renal cell carcinoma, indicating a high risk of hemorrhage;

④ PET-CT findings indicate a malignant pulmonary nodule; surgical evaluation may prioritize surgical intervention for the patient;

⑤ Women who are pregnant or breastfeeding;

⑥ Patients with psychiatric disorders or those unable to cooperate during the puncture procedure;

⑦ Presence of anesthesia contraindications; allergy to anesthetic agents; or a history of multiple severe allergies or a hereditary predisposition to allergies;

⑧ If the participant has participated in other studies within the past three months without withdrawing or completing those studies, this will affect the observation of the present study;

⑨ Refusal to participate in this study, unwillingness to accept the follow-up protocol, or other circumstances in which the investigator deems the participant unsuitable for participation in this study.

4. Grouping and Intervention

Using pre-prepared random envelopes, subjects were randomly assigned to one of two groups—CassiII rotational core biopsy group (experimental group) or the automated biopsy needle group (control group)—in a 1:1 ratio, involving a total of 308 cases.

5. Exit criteria

You may withdraw from the study at any time without losing any benefits you would otherwise have received. However, if you decide to withdraw from the study during its conduct, we strongly encourage you to consult your research physician first. Should you experience a serious adverse event, or if your research physician determines that continuing participation in the study does not align with your best interests, they will decide to allow your withdrawal from the study. The sponsor or regulatory authority may also terminate the study during its conduct. Nevertheless, your withdrawal will not affect your standard medical care or entitlements.

If you withdraw from the study for any reason, you may be asked about your participation in the study.

6. Information and biological specimens collected during the study

In this study, we will collect your relevant training and surgical procedure information and store it in the clinical trial project management system. All information will be anonymized and securely stored to ensure that your data is not disclosed.

This study does not involve the collection of biological samples.

7. Disposal method for remaining samples or other research purposes.

Since this study does not involve the collection of biological samples, it does not address the disposal method for remaining samples or any other research purposes.

III. Risks and Benefits

1. What are the risks associated with participating in this study?

The potential risks associated with participating in this study are as follows. You should discuss these risks with your research physician or, if you prefer, with your regular healthcare provider.

This study is an interventional clinical trial in which both the experimental and control groups undergo needle biopsy using different biopsy needles. This study does not introduce any additional risks beyond those associated with percutaneous biopsy; the risks associated with the

procedures involved in this study are as follows:

The main risks include:

CT-guided percutaneous lung biopsy is a traumatic medical procedure that entails certain medical risks; potential intraoperative or postoperative adverse events and complications may occur during this procedure. These primarily include: (1) pneumothorax, subcutaneous emphysema, and mediastinal emphysema; (2) hemorrhage, major hemorrhage, and hemothorax; (3) pleural effusion and pleuritic reaction; (4) fever, pulmonary infection, thoracic cavity infection, and empyema; (5) hypoxemia and respiratory failure; (6) coughing, expectoration, chest pain, and hemoptysis; (7) air embolism and pulmonary embolism; (8) needle tract seeding metastasis; (9) cardiovascular and cerebrovascular events, such as severe arrhythmia or cardiac arrest; (10) anaphylaxis to anesthetic agents; (11) radiation exposure; (12) other unpredictable adverse events.

This study requires participants to complete a follow-up questionnaire (which may require additional time), but does not introduce any significant risks unrelated to routine clinical care.

Secondary risks include: the risk of data leakage or privacy violation.

This study is a prospective study conducted on the basis of CT-guided percutaneous lung puncture; therefore, participating in this study will not affect the diagnosis or treatment provided by your physician. The procedure you undergo constitutes standard medical care; thus, participation in this study does not entail any additional risks beyond those associated with routine medical care.

If you experience any discomfort during the study period, if your condition undergoes any new changes, or if any unexpected event occurs—regardless of whether it is related to the study—you should promptly notify your physician; they will then make an assessment and provide appropriate medical care.

During your study period, you will need to attend hospital follow-up visits on schedule and undergo certain examinations; this may require some of your time and could potentially cause you inconvenience or disruption.

This study is a research project applied for by investigators, and no participant insurance has been provided. Should this study result in severe irreversible functional impairment or death of any participant, medical compensation shall be determined in accordance with relevant national

laws and regulations.

2. What are the benefits of participating in this study?

Direct benefits: If you agree to participate in this study, our physicians will provide you with standardized diagnostic, therapeutic, and treatment recommendations based on your current medical condition, potentially offering you direct medical benefits. Additionally, your physician will conduct close follow-up care; both you and your physician will gain a deeper understanding of your condition, enabling you to better manage your disease with the support of your physician.

Potential benefits: We will continue to monitor any changes in your condition, which may help slow the progression of your disease. The findings from this study may hold significant importance for selecting diagnostic approaches for future patients with unexplained peripheral pulmonary nodules and for advancing the development of such technologies. We hope that the information obtained from your participation in this study can benefit you or other patients with similar conditions in the future.

IV. The Principles of Voluntariness and Privacy

1. Voluntary Participation Principle: Your decision to participate or not is entirely voluntary. If you choose to participate and are successfully selected for this trial/study, we expect you to commit to completing the trial/study; however, you may withdraw from this trial/study at any time without any obligation or reason. Upon withdrawal, we will conduct a health assessment for you; if any abnormalities are detected, follow-up monitoring will continue until your condition returns to normal or reaches a stable stage. Should you withdraw from the trial/study, we guarantee that your future treatment and care will not be affected in any way.

2. Privacy Principle: Your right to privacy shall be protected. Your personal information will be kept confidential; however, your data may be subject to review by relevant authorities (such as the Ethics Committee or the Food and Drug Administration). The results and data from the clinical trial may be made publicly available, but any private details pertaining to your personal information will not be disclosed to third parties.

V. Handling and Compensation for Damages Related to Trials/Research

Participation in this study will not entitle you to any compensation; should any research-related harm occur during the study, you will receive prompt medical treatment. In cases where research-related harm occurs and is assessed by the Principal Investigator as a puncture biopsy-related

complication or as a potential complication that may arise during clinical diagnosis and treatment, no compensation will be provided. Should severe complications arise during the study, the Principal Investigator shall be responsible for providing the corresponding compensation.

VI. Contact Information for the Research Physician

During your participation in this clinical trial/study, if you have any questions or encounter any emergencies, please contact your study physician at the phone number: 13439802812.

VII. Ethical Issues

1. Informing the subject: The study physician will provide you with detailed information regarding this study to ensure you have a full understanding of the above content, and will give you sufficient time to consider whether to participate in the trial/study and make your decision accordingly.

2. During the trial/research period, if any information is received that may affect the subject's continued participation in the trial/research, the subject or their guardian will be promptly notified; where necessary, a newly signed informed consent form will be obtained from you.

3. This trial/study protocol has been approved by the Medical Ethics Committee of Beijing Chaoyang Hospital. Should any violation of this trial/study protocol occur during the trial/study process, or if your rights are affected, you may file a complaint with the hospital's Medical Ethics Committee.

4. Contact information for the Medical Ethics Office of Beijing Chaoyang Hospital: No.8 Gongti South Road, Beijing Chaoyang Hospital; Postal Code: 100020; Tel.: 010-85231484 (please call during business hours: 8:00 – 11:30 AM and 13:00 – 17:00 PM); Email: cyylunli2019@163.com; Fax: 010-85231484.

**Before you (or your legal guardian) decide to participate in this clinical trial/study, please read this informed consent form carefully. The study physician will assist you in answering any questions regarding the investigational product and this trial/study. If you choose to participate voluntarily, after reviewing these materials, please sign and date the final page of this informed consent form.**

## Part II: Informed Consent Form

1. I have carefully read the contents of the "Subject Information" section in this trial/study's

informed consent form; the research physician has provided me with a detailed explanation and answered all my relevant questions; I fully understand the purpose and procedure of this trial/study, as well as my rights and potential risks. I voluntarily participate in this trial/study, and I agree to cooperate with the research physician in treatment and follow-up procedures in accordance with the terms outlined in this informed consent form, and to do my utmost to complete this trial/study.

Participant Signature:

(Printing style)_____(Handwriting) _____Date_____

Or signature of a neutral witness:

(Printing style)_____(Handwriting) _____Date_____

Or signature of guardian (if required):

(Printing style)_____(Direct relationship with the subject_____

(Handwriting) _____Date_____

2. I or my research team have provided the subject with a thorough explanation of the purpose of this trial/study, its procedure, as well as any potential risks and possible benefits associated with participation in this trial/study, and have satisfactorily addressed all relevant questions raised by the subject.

Researcher or researcher-designated

physician notification signature:

(Printing style)_____(Handwriting) _____Date_____

Both the subjects and the investigators must sign two identical informed consent forms, with each party retaining one copy.