Study Protocol

Official Title of the study: Evaluation of the Safety and Efficacy of a Wideband Electric Pulse Tumor Ablation System for Malignant Pulmonary Nodules: A First-in-Human (FIM) Trial

Affiliation: Sir Run Run Shaw Hospital, Zhejiang University School of Medicine

Department: Department of Respiratory and Critical Care Medicine

Date of the document: May 01, 2026

Evaluation of the Safety and Efficacy of a Wideband Electric Pulse Tumor Ablation System for Malignant Pulmonary Nodules: A First-in-Human (FIM) Trial

Background:

A pulmonary nodule (PN) refers to a round or irregular lesion within the lung with a diameter ⩽3 cm. Radiologically, it appears as a focus of increased density, which may be solitary or multiple, with well-defined or ill-defined margins. The malignant probability of pulmonary nodules varies according to their density, and based on nodule density, they are classified into three types: solid nodules, part-solid nodules, and ground-glass nodules [1]. Currently, lung cancer is the most common and deadliest cancer worldwide, and is also one of the most prevalent malignant tumors in China. Malignant pulmonary nodules are considered an early manifestation of lung cancer; therefore, early detection, early diagnosis, and early treatment are key to improving patient survival.

Current clinical treatment options for pulmonary nodules include surgical resection and ablation techniques, such as radiofrequency ablation, microwave ablation, and cryoablation [3][4]. However, for pulmonary nodules located in special sites, hot or cold ablation may easily damage the pleura, leading to bronchopleural fistula, and often results in incomplete ablation due to the heat sink effect.

Irreversible electroporation (IRE) employs a mechanism and technical application features completely different from other physical ablation methods. This technique delivers high-voltage electrical pulses via electrode needles to create a high-electric-field ablation zone. Within this zone, numerous irreversible nanoscale pores are formed in the cell membrane, disrupting the intra- and extracellular environment balance and inducing apoptosis, thereby permanently destroying tissue cells. During IRE ablation, only the lipid bilayer of the cell membrane within the ablated area is disrupted, while critical structures such as blood vessels are not severely damaged. Owing to this unique ablation characteristic, IRE offers irreplaceable advantages in the treatment of various diseases, including short treatment time, applicability to more complex conditions, preservation of vital structures within the treatment zone, complete ablation, and well-defined ablation margins.

Study purpose and design:

This clinical trial aims to evaluate the safety and efficacy of the wideband electric pulse tumor ablation system (manufactured by Hangzhou Win-Onco Medical Technology Co., Ltd.) in treating malignant pulmonary nodules, providing reference data for the subsequent formal trial.

Study population

This study is designed as a single-center, prospective, single-arm clinical trial, with a planned enrollment of 5 participants at the Sir Run Run Shaw Hospital, Zhejiang University School of Medicine.

Inclusion and exclusion criteria

Inclusion criteria:

(1) Age ≥ 18 years.

(2) Subjects with malignant pulmonary nodules (confirmed by histopathology) planned for ablation therapy, including:
a. Stage IA primary non- small cell lung cancer; or
b. Intrapulmonary metastatic tumors with the primary lesion well controlled.

(3) Solitary lesion size ≤ 2 cm, and total number of lesions ≤ 3.

(4) ECOG performance status score ≤ 2.

Patients who are ineligible for surgery/radiotherapy, or who refuse surgery/radiotherapy, or who voluntarily participate.

Exclusion criteria:

A patient will be excluded from participation in this clinical trial if any of the following conditions apply:

(1) Severe bleeding tendency, platelet count < 50×10^9/L, or coagulation dysfunction (prothrombin time > 18 s, prothrombin activity < 40%) that cannot be corrected in the short term.

(2) Anticoagulant therapy and/or antiplatelet medications discontinued for less than 1 week prior to ablation.

(3) Infectious or radiation- induced inflammation around the lesion, poorly controlled skin infection at the puncture site, systemic infection, or fever > 38.5° C.

(4) Severe dysfunction of the liver, kidney, heart, lung, or brain; severe anemia, dehydration, or serious nutritional/metabolic disorders that cannot be corrected or improved in the short term.

(5) Poorly controlled malignant pleural effusion.

(6) Distant metastasis of lung cancer.

(7) Concurrent other malignancies with extensive metastasis, and expected survival < 6 months.

(8) Presence of implanted electronic devices near the target area, or an implanted cardiac pacemaker or defibrillator.

(9) The target lesion has received prior local treatments (e.g., radiotherapy, ablation) within 3 months before enrollment.

(10) Participation in any drug and/or medical device clinical trial within 1 month before enrollment.

(11) Pregnancy, lactation, or planned pregnancy within one year.

(12) Any other condition that the investigator considers inappropriate for enrollment.

Interventions

Anesthesia management: Intravenous anesthesia
Surgical procedure:
1. Intraoperative monitoring of blood pressure, electrocardiogram (ECG), and oxygen saturation.
2. Insertion of the ablation catheter/needle into the nodule position.
3. Application of IRE to perform ablation of the pulmonary lesion.
Guidance approach:
1. The subject will first undergo interventional bronchoscopy to reach the target lesion via the bronchial pathway.
2. Intraoperative percutaneous needle placement under CT guidance.

Outcomes

The primary outcome:Success rate of nodule ablation at 1 month after ablation
Definition of ablation success:No obvious enhancement in the ablated area on contrast- enhanced CT, indicating complete ablation. The success rate is assessed per nodule, and each nodule is evaluated independently.

Secondary Efficacy Endpoints:

(1) Technical success rate: Defined as the proportion of ablation procedures in which the investigational device is successfully placed in the target lesion, completes ablation, and is successfully withdrawn after treatment, relative to all ablation procedures performed.

(2) Complete nodule ablation rate at 3 and 6 months post-ablation.

(3) Nodule recurrence rate at 6 months post-ablation.

(4) Progression-free survival rate at 6 months post-ablation.

Complete ablation:
① Lesion disappears;
② Complete cavity formation;
③ Lesion fibrosis (may appear as scar tissue);
④ Solid nodule shrinks, remains unchanged, or enlarges, but with no enhancement on contrast-enhanced CT;
⑤ Atelectasis, with no contrast enhancement of the lesion within the atelectatic area on CT scan.

Incomplete ablation:
① Incomplete cavity formation with a solid component and evidence of enhancement on contrast - enhanced CT;
② Partial fibrosis with contrast enhancement around or at the margin of the fibrotic area on CT;
③ Solid nodule with no change in size or enlargement, accompanied by contrast enhancement on CT scan.

Local progression:
① Lesion enlargement ≥10 mm, with irregular margins or increased internal enhancement on CT;
② New lesion(s) appearing locally, with new evidence of enhancement on CT.

Ethical approval and informed consent statement

The trial was approved by the Ethics Committee of the Sir Run Run Shaw Hospital, Zhejiang University School of Medicine (approval number: 2025-1052-02) (See the attachment "Ethics Approval Document"). For statistical analysis, subject identities were expressed as codes, which did not involve disclosure of subjects'privacy and personal information, and the study did not involve commercial interests, so informed consent was waived by the Ethics Committee (See the attachment”Informed consentfom”).

Study Protocol

Official Title of the study: Evaluation of the Safety and Efficacy of a Wideband Electric Pulse Tumor Ablation System for Malignant Pulmonary Nodules: A First-in-Human (FIM) Trial

Affiliation: Sir Run Run Shaw Hospital, Zhejiang University School of Medicine

Department: Department of Respiratory and Critical Care Medicine

Date of the document: April 22, 2025

Evaluation of the Safety and Efficacy of a Wideband Electric Pulse Tumor Ablation System for Malignant Pulmonary Nodules: A First-in-Human (FIM) Trial

Background:

A pulmonary nodule (PN) refers to a round or irregular lesion within the lung with a diameter ⩽3 cm. Radiologically, it appears as a focus of increased density, which may be solitary or multiple, with well-defined or ill-defined margins. The malignant probability of pulmonary nodules varies according to their density, and based on nodule density, they are classified into three types: solid nodules, part-solid nodules, and ground-glass nodules [1]. Currently, lung cancer is the most common and deadliest cancer worldwide, and is also one of the most prevalent malignant tumors in China. Malignant pulmonary nodules are considered an early manifestation of lung cancer; therefore, early detection, early diagnosis, and early treatment are key to improving patient survival.

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Ethics Committee Approval (Original Chinese version)

Official Title of the study: Evaluation of the Safety and Efficacy of a Wideband Electric Pulse Tumor Ablation System for Malignant Pulmonary Nodules: A First-in-Human (FIM) Trial

Affiliation: Sir Run Run Shaw Hospital, Zhejiang University School of Medicine

Department: Department of Respiratory and Critical Care Medicine

Date of the document: April 22, 2025

浙江大学医学院附属邵逸夫医院伦理审查批件

Ethics Committee Approval Letter of Sir Run Run Shaw Hospital, Zhejiang University School of Medicine

批件号 Approval NO.：邵逸夫医院伦审 2025 械第 0602 号

项目名称 Study Title	评估微纳秒协同电脉冲肿瘤消融系统治疗恶性肺结节安全性、有效性的 FIM 试验		
申办方 Sponsor	杭州维纳安可医疗科技有限责任公司		
受理号 Acceptance Number	2025-1051-02		
主要研究者 Principal Investigator	陈恩国	承担科室 Responsible Department	呼吸内科
审查类别 Category of Review	初始审查（复审）	审查方式 Type of Review	快速审查
审查日期 Date of Review	2025 年 10 月 20 日	审查地点 Location of Review	/
审查文件清单 Items Reviewed	见附件		
审评意见 Evaluation	本伦理委员会认为递交的审查材料符合伦理规范，同意开展临床研究。		
审查决定 Decision	委员会对该项目的审查决定为：同意		
主任/副主任委员签字 Chair Signature			
签发日期 Date of issue	2025.10.20		
伦理审查委员会 Stamp of EC	伦理审查委员会盖章		
批件有效期 Period of Validity	自本伦理审查委员会初始审查批准之日起一年内，本临床研究应在本院启动。逾期未启动的，本批件自行废止。		
年度/定期跟踪审查 Continue Review	审查频率为该研究批准之日起每 12 月一次，首次，请于到期前 1 个月递交研究进展报告。 伦理审查委员会有根据实际进展情况改变跟踪审查频率的权利。		
声明 Statement	本伦理审查委员会的职责、人员组成、操作程序及记录遵循《涉及人的生物医学研究伦理审查办法》、《涉及人的生命科学和医学研究伦理审查办法》、《涉及人的健康相关研究国际伦理准则》、《赫尔辛基宣言》、GCP 和 ICH-GCP 等国际伦理指南和国内相关法律法规。		
注意事项：			

1. 请遵循我国相关法律、法规和规章中的伦理原则。
2. 请遵循经本伦理审查委员会批准的临床研究方案、知情同意书、招募材料等开展本研究，保护受试者的健康与权利。对研究方案、知情同意书和招募材料等的任何修改，均须得到本伦理审查委员会审查同意后方可实施。
3. 在本院发生的 SAE/SUSAR 以及研发期间安全性更新报告须按照 NMPA/GCP 最新要求及时递交本伦理审查委员会，国内外其它中心发生的 SAE/SUSAR 需定期汇总、评估后递交本伦理审查委员会。
4. 根据报告情况，本伦理审查委员会有权对其评估做出新的决定。
5. 自今日起，无论研究开始与否，请在跟踪审查日到期前 1 个月提交研究进展报告。
6. 申办方应当向组长单位伦理审查委员会提交中心研究进展报告汇总；当出现任何可能显著影响研究进行或增加受试者危险的情况时，请申请人及时向本伦理审查委员会提交书面报告。
7. 研究纳入了不符合纳入标准或符合排除标准的受试者，符合中止研究规定而未让受试者退出研究，给予错误治疗或剂量，给予方案禁止的合并用药等没有遵从方案开展研究的情况；或可能对受试者的权益或健康以及研究的科学性造成不良影响等违背 GCP 原则的情况，请申办方、监查员或研究者提交违背方案报告。
8. 申请人暂停或提前终止临床研究，请及时提交暂停或终止研究报告。
9. 完成临床研究，请申请人提交结题报告。
10. 采集、保藏、利用、对外提供我国人类遗传资源，应当遵守中华人民共和国人类遗传资源管理条例。
11. 凡经本伦理审查委员会批准的研究项目在实施前，申请人应按相关规定在国家卫健委、药审中心等的临床研究登记备案信息系统平台登记研究项目相关信息。

附件（审查文件清单）：

1.复审申请表

2.知情同意书（V1.1；2025.10.10）

Ethics Committee Approval (English version)

Official Title of the study: Evaluation of the Safety and Efficacy of a Wideband Electric Pulse Tumor Ablation System for Malignant Pulmonary Nodules: A First-in-Human (FIM) Trial

Affiliation: Sir Run Run Shaw Hospital, Zhejiang University School of Medicine

Department: Department of Respiratory and Critical Care Medicine

Date of the document: April 22, 2025

Ethics Committee Approval Letter of Sir Run Run Shaw Hospital, Zhejiang University School of Medicine

Approval No: Sir Run Run Shaw Hospital Ethical Review 2025 Study No. 0602 (Abbreviation: 2025- 0602)

Study Title	Evaluation of the Safety and Efficacy of a Wideband Electric Pulse Tumor Ablation System for Malignant Pulmonary Nodules: A First-in-Human (FIM) Trial		
Sponsor	Hangzhou Win-Onco Medical Technology Co., Ltd.		
Acceptance Number	2025-1052-02		
Principal Investigator	Enguo Chen	**Responsible Department**	Department of Respiratory Medicine
Category of Review	Initial review（re-review）	**Type of Review**	Quick review
Date of Review	2025.10.20	**Location of Review**	/
Items Reviewed	See the attachment		
Evaluation	This ethics committee believes that the submitted review materials comply with ethical norms and agrees to conduct clinical research.		
Decision	The committee's review resolution on the project is: Consent		
Chair signature			
Date of issue			
Stamp of EC	Stamped by the Ethics Review committee.		
Period of Validity	This clinical study shall be initiated in our hospital within one year from the date of the initial review and approval by this ethics review committee.		
Continue Review	The review frequency is once every 12 months from the date of approval of this research. The first time is on June 5, 2025. Please submit the research progress report		

	one month before the expiration of the approval document. The Ethics Review committee has the right to change the frequency of follow-up reviews according to the actual progress.
Statement	The responsibilities, composition of personnel, operating procedures and records of this ethics review committee comply with the "Ethical Review Measures for Biomedical Research Involving Humans", the "International Ethical Guidelines for Research Related to Human Health", the "Declaration of Helsinki", international ethical guidelines such as GCP and ICH-GCP, and relevant domestic laws and regulations.

Precautions

l. Please follow the ethical principles in the relevant laws, regulations and rules of China. 2. Please conduct the study in accordance with the clinical research protocol, informed consent form and recruitment materials approved by the Ethics Review Committee to protect the health and rights of the subjects. Any modification of the study protocol, informed consent form, recruitment materials, etc. must be reviewed and approved by the Ethics Review Committee before implementation. 3. SAE/SUSARs occurring in this institution and safety update reports during the research and development period shall be submitted to the Ethics Review Committee in a timely manner in accordance with the latest requirements of NMPNGCP, and SAE/SUSARs occurring in other centers in China and abroad shall be summarized and evaluated periodically and then submitted to the Ethics Review Committee. 4. The Ethics Review Committee has the right to make a new decision on the evaluation based on the reports. 5. Regardless of whether the study is started or not, please submit the study progress report 1 month before the due date of the follow-up review. 6. The sponsor should submit a summary of the center's research progress report to the Ethics Review Committee of the group leader. The applicant is requested to submit a written report to this Ethics Review Committee in a timely manner when any situation arises that may significantly affect the conduct of the study or increase the risk to the subjects. 7. When the study enrolls subjects who do not meet the inclusion criteria or meet the exclusion criteria, withdraws subjects from the study in accordance with the rules for discontinuation of the study, administers incorrect treatments or dosages, or administers combinations of

medications prohibited by the protocol, etc., and conducts the study without complying with the protocol, or violates the principles of GCP by potentially adversely affecting the rights and interests of subjects or their health as well as the scientific validity of the study, the applicant, the Supervisory Reviewer, or the investigator shall submit a report on the violation of the protocol. investigator to submit a report on the violation of the protocol. 8. If the applicant suspends or prematurely terminates the clinical study, the applicant is requested to submit a report on the suspension or termination of the study in a timely manner. 9. Upon completion of the clinical study, the applicant is requested to submit a completion report. 10. All research projects involving the collection of specimens and data from Chinese human genetic resources must be approved by the China Human Genetic Resources Management Office before the research can be carried out in the Center. 11. 11. Before the implementation of any research project approved by the Ethics Review Committee, the applicant shall register the relevant information of the research project on the clinical research registration information system platform of the National Health and Keystone Commission and the Center for Drug Control and Prevention in accordance with relevant regulations.

Attachments:

1. Re- review Application Form
2. Informed consent form (V1.1; 2025.10.10)

Protocol ID：WNAK-PN-A1-2025-1

Protocol Version and Date：V1.1/2025 /10/10

Evaluation of the Safety and Efficacy of a Wideband Electric Pulse Tumor Ablation System for Malignant Pulmonary Nodules: A First-in-Human (FIM) Trial

Informed Consent Form

Sponsor：Hangzhou Win-Once Medical Technology Co., Ltd.

Affiliation:Sir Run Run Shaw Hospital, Zhejiang University School of Medicine

Principal Investigator (PI)：Enguo Chen

Dear Sir/Madam,

You are invited to participate in a clinical trial. Before you decide whether to take part in this study, please read the following information carefully to help you understand the purpose of the study, why it is being conducted, and the potential benefits, risks, and discomforts it may bring to you. If you have any questions or concerns, please feel free to discuss them with the research staff. You may also consult with your family or friends before making a decision.

This study has been reviewed and approved by the Ethics Committee of Sir Run Run Shaw Hospital, Zhejiang University School of Medicine, and complies with relevant Chinese regulations and the ethical principles of the Declaration of Helsinki for the protection of the rights and welfare of research subjects.

1. Background

A pulmonary nodule (PN) refers to a round or irregular lesion within the lung with a diameter ≤3 cm. Radiologically, it appears as a focus of increased density, which may be solitary or multiple, with well-defined or ill-defined margins. The malignant probability of pulmonary nodules varies according to their density, and based on nodule density, they are classified into three types: solid nodules, part-solid nodules, and ground-glass nodules [1]. Currently, lung cancer is the most common and deadliest cancer worldwide, and is also one of the most prevalent malignant tumors in China. Malignant pulmonary nodules are considered an early manifestation of lung cancer; therefore, early detection, early diagnosis, and early treatment are key to improving patient survival.

Current clinical treatment options for pulmonary nodules include surgical resection and ablation techniques, such as radiofrequency ablation, microwave ablation, and cryoablation [3][4]. However, for pulmonary nodules located in special sites, hot or cold ablation may easily damage the pleura, leading to bronchopleural fistula, and often results in incomplete ablation due to the heat sink effect.

Irreversible electroporation (IRE) employs a mechanism and technical application features completely different from other physical ablation methods. This technique delivers high-voltage electrical pulses via electrode needles to create a high-electric-field ablation zone. Within this zone, numerous irreversible nanoscale pores are formed in the cell membrane, disrupting the intra- and extracellular environment balance and inducing apoptosis, thereby permanently destroying tissue cells. During IRE ablation, only the lipid bilayer of the cell membrane within the ablated area is disrupted, while critical structures such as blood vessels are not severely damaged. Owing to this unique ablation characteristic, IRE offers irreplaceable advantages in the treatment of various diseases, including short treatment time, applicability to more complex conditions, preservation of vital structures within the treatment zone, complete ablation, and well-defined ablation margins.

The wideband electric pulse tumor ablation system used in this study is a Class III medical device based on the mechanism of irreversible electroporation (IRE), developed and manufactured by Hangzhou Win-Onco Medical Technology Co., Ltd. (Model/Specification: WK-WN-K-A1). This system has passed the Type Examination for Class III medical devices and the EMC testing conducted by Fangguang Inspection & Testing Co., Ltd., and was found to be compliant. The disposable pulse ablation catheter/disposable pulse ablation needle (Model/Specification: WKN series) has passed the Type Examination for Class III medical devices conducted by the Zhejiang Medical Device Inspection and Research Institute and the EMC testing

conducted by the Hangzhou Medical Device Quality Supervision and Inspection Center of the State Food and Drug Administration, and was found to be compliant. The analysis of product electromagnetic compatibility characteristics conducted by the Key Laboratory of Biomedical Optics of the National Medical Products Administration, Zhejiang Provincial Key Laboratory of Medical Device Safety Evaluation Research, Zhejiang Medical Device Inspection and Research Institute, also concluded compliance. The cytotoxicity test, skin sensitization test, and animal intradermal reaction test conducted by Hangzhou Taige Jietong Testing Technology Co., Ltd. also yielded compliant results.

2. Study Purpose

Evaluation of the safety and efficacy of the wideband electric pulse tumor ablation system for malignant pulmonary nodules.
The investigational device used in this study is the wideband electric pulse tumor ablation system, developed and manufactured by Hangzhou Win-Onco Medical Technology Co., Ltd. This system has passed all registration tests conducted by a qualified medical device quality supervision and inspection center, with all test results meeting the required standards. The product complies with the safety standards for active medical devices in terms of physical, chemical, and biological properties, demonstrating good safety performance.

In accordance with the Measures for the Registration of Medical Devices and the Good Clinical Practice for Medical Device Trials promulgated by the National Medical Products Administration (NMPA), the product has met the requirements for conducting clinical research.

This study has been reviewed and approved by the Ethics Committee of Sir Run Run Shaw Hospital, Zhejiang University School of Medicine (Approval No.: 2025- 0602).

3. What Will Happen If You Take Part In The Study?

The overall duration of this study is expected to be 12 months. For each subject, the expected participation period is approximately 8 months. A total of 4 subjects will be enrolled.

This clinical study is a single- arm trial, meaning that all enrolled subjects will receive irreversible electroporation (IRE) ablation therapy using the wideband electric pulse tumor ablation system. After the IRE ablation procedure, you will be required to cooperate with three follow- up visits, scheduled at 1 month, 3 months, and 6 months post- treatment. The details of the follow- up assessments are described in the next section.

4. What Are The Study Procedures?

Before you decide whether to participate in this clinical study, your study doctor or relevant research staff will inform you about the study. Once you agree to participate, you will be asked to sign the informed consent form. Your study doctor or research staff may then begin the screening procedures to assess your eligibility for participation in this study. The investigator will determine whether you can be enrolled in the study based on the screening examination results and the inclusion/exclusion criteria.

The following describes the examinations and procedures you will undergo at each visit during this clinical study.

a) Visit 1: Screening Period (Day －7 to 0)

Before you are enrolled in the study, the following examinations will be performed to determine whether you are eligible to participate. Routine clinical data will be collected, including demographic information, medical history, and current illness history, as well as laboratory tests such as complete blood count, coagulation function, blood biochemistry, tumor markers, infectious disease screening, pregnancy test, and immunological examinations.

1) You will be provided with study information and will have sufficient time to consider whether to participate. After all your questions have been answered, you will sign this informed consent form.
2) The doctor will review your previous medical examinations or records, inquire about your medical history and medication use, and perform a physical examination and vital signs assessment (temperature, blood pressure, heart rate, respiration).
3) You will undergo complete blood count, urinalysis, coagulation function tests, blood biochemistry, and tumor marker tests, and a pregnancy test if necessary.
4) You will undergo electrocardiography (ECG), pulmonary function tests, and contrast- enhanced CT.

b) Visit 2: IRE Treatment Period (Day 0)

If you meet the eligibility criteria based on the above examinations, the study procedures will proceed as follows: Vital signs will be collected as part of routine clinical care during the treatment period.

1) Your vital signs (temperature, blood pressure, heart rate, respiration) will be measured.
2) On- site cytological assessment will be performed if necessary.
3) Treatment will be administered using irreversible electroporation (IRE) ablation.
4) You will be asked how you are feeling, whether you have experienced any health- related problems, and about any other medications or treatments you are using.

c) Visit 3: 30 Days Post- IRE (30 ± 7 days)

This follow- up visit will collect your vital signs as part of routine clinical care.

1) You will be asked how you are feeling, whether you have experienced any health- related problems, and about any other medications or treatments you are using.
2) Your vital signs (temperature, blood pressure, heart rate, respiration) will be measured.
3) You will undergo electrocardiography (ECG), pulmonary function tests, and contrast- enhanced CT.

d) Visit 4: 90 Days Post- IRE (90 ± 7 days)

This follow- up visit will collect your vital signs as part of routine clinical care.

1) A physical examination and ECOG performance status assessment will be performed. You will be asked how you are feeling, whether you have experienced any health- related problems, and about any other medications or treatments you are using.
2) Your vital signs (temperature, blood pressure, heart rate, respiration) will be measured.
3) You will undergo complete blood count, urinalysis, coagulation function tests, blood biochemistry, and tumor marker tests.
4) You will undergo electrocardiography (ECG), pulmonary function tests, and contrast- enhanced CT.
5) Assessment of nodule recurrence.

e) Visit 5: 180 Days Post- IRE (180 ± 15 days)

This follow- up visit will collect your vital signs as part of routine clinical care.

1) A physical examination and ECOG performance status assessment will be performed. You will be asked how you are feeling, whether you have experienced any health- related problems, and about any other medications or treatments you are using.
2) Your vital signs (temperature, blood pressure, heart rate, respiration) will be measured.
3) You will undergo complete blood count, urinalysis, coagulation function tests, blood biochemistry, and tumor marker tests.
4) You will undergo electrocardiography (ECG) and contrast- enhanced CT.
5) Assessment of nodule recurrence.

5. Biological Specimens Collected In The Study

During the study, the data generated from your blood samples and pathological results, as described in the study procedures, will be collected, stored, and used for the purposes stated in this trial. Any intellectual property or potential commercial value arising from the study results will not be shared with you.

6. What Should You Pay Attention To During The Study

1) You are required to visit the hospital according to the follow- up schedule agreed upon with your doctor. Your follow- up visits are very important, as the doctor needs to determine whether the treatment you received is truly effective.

2) At each follow- up visit, please bring any other medications you are taking, including those for other medical conditions that you need to continue taking (including herbal medicines), and report any changes in the medications/treatments you are using (both over- the- counter and prescription).

3) If you need to receive any other treatment, please contact your study doctor in advance.

4) You must promptly inform the study doctor of any discomfort, health changes, or changes in how you feel during the study, even if you think they are not very important.

5) Please consult and follow your study doctor’s recommendations regarding diet and daily routines.

7. Alternative Treatments Outside This Study

Whether or not you choose to participate in this study, you may discuss more details and alternative therapies with your doctor. You may decide not to take part in this study, and this will not have any negative impact on your access to conventional treatment. Currently, for your medical condition, the conventional treatment options include: surgery, cryoablation, radiofrequency ablation, etc.

8. Possible Benefits of Participation

If you agree to participate in this study, treatment of your pulmonary nodules with irreversible electroporation (IRE) may result in remission. However, you may also receive no direct medical benefit from the treatment. Your participation will help advance medical research and understanding of this disease, and may improve future diagnosis and treatment outcomes. We thank you for your willingness to participate in scientific research and for contributing to the advancement of medicine.

9. Risks And Inconvenience Of The Study

If you experience any illness or discomfort during the study, you should immediately inform your study doctor or relevant research staff. The study doctor will evaluate you and, if necessary, you will receive appropriate treatment.

1) The investigational device in this study has not yet obtained a registration certificate; therefore, this is a pre- market study. Based on reports of similar existing devices, the use of irreversible electroporation (IRE) for pulmonary nodule ablation may be associated with the following complications: venous thrombosis, bleeding, arrhythmia, infection, etc. These complications can be detected promptly through imaging examinations and managed appropriately. During the procedure, the investigator will perform real-time monitoring using CT to assess treatment efficacy and detect any injury to critical structures. Post-procedure imaging will be performed immediately to determine whether there is any damage to surrounding structures or post-operative bleeding.

2) Risk of incomplete ablation: The use of IRE for pulmonary nodule ablation may result in incomplete ablation or post- operative recurrence.

3) Risks of blood draw: Risks associated with venipuncture from the arm include temporary discomfort and/or bruising, and may also include infection, bleeding, coagulation issues, or fainting.

4) Risks of electrocardiography (ECG): Minimal discomfort may occur, either during or after the attachment and removal of leads, due to adhesives or suction cups.

5) Unforeseeable risks may arise during the study due to the underlying disease, pre-existing comorbidities, concomitant medications, or other factors. In addition, the investigational intervention may be ineffective, and the disease may continue to progress.

6) During the study, you will be required to attend follow- up visits at the hospital on time and undergo certain examinations, which may cause inconvenience or trouble.

7) Risk to spouse of childbearing potential: You agree to use effective contraceptive measures correctly during the study. If necessary, consult your study doctor or relevant research staff and follow the

contraception guidance.

10. Will I Need To Pay For The Study?

During your participation in this study, the irreversible electroporation (IRE) ablation treatment will be provided to you free of charge, including the free use of the wideband electric pulse tumor ablation system and the disposable pulse ablation catheter/disposable pulse ablation needle. All examinations and tests related to the study protocol are also free of charge, including complete blood count, urinalysis, blood biochemistry, coagulation function, tumor markers, pregnancy test (for female subjects), 12-lead electrocardiography (ECG), pulmonary function tests, contrast-enhanced CT, and histopathological examinations. In addition, you will receive a surgical subsidy of 2,000 RMB, which will be paid at the end of the treatment period.

Furthermore, for each on-site follow-up visit, this study will provide you with a transportation subsidy of 200 RMB per visit. A total of 5 follow-up visits are planned in this study. You will also receive a blood draw subsidy of 200 RMB per blood collection, with a total of 4 blood collections in this study. The transportation and blood draw subsidies will be paid at the end of the follow-up period. If you do not complete all scheduled visits and blood draws, payment will be made based on the number of visits and blood draws actually completed.

After IRE treatment, you may choose other treatment options. These will be part of your routine clinical care, and the associated costs will be borne by yourself. Costs not related to the study, such as treatment and examinations for other concurrent medical conditions, as well as costs for switching to alternative treatments due to lack of efficacy of the investigational treatment, will also be borne by yourself.

11. What Happens If I Am Injured As A Result Of Taking Part In This Study?

If you experience any discomfort, any new changes in your medical condition, or any unexpected events during the study, regardless of whether they are related to the irreversible electroporation (IRE) pulmonary nodule ablation treatment, please notify your doctor immediately. He/she will make a judgment and provide medical management.

If any study-related injury occurs, the investigator will provide prompt diagnosis and treatment to control the risk of complications. Hangzhou Weina Anke Medical Technology Co., Ltd. will bear the corresponding costs of examination and treatment, and will provide compensation in accordance with relevant national laws and regulations. To further protect your rights, this study has purchased insurance for all enrolled subjects. Any costs not covered by the insurance (e.g., amounts below the deductible, etc.) will be borne by the sponsor.

12. What Happens If I Do Not Participate Or Choose To Withdraw

From The Study?

Your participation in this study is entirely voluntary. You may withdraw from the study at any time and for any reason, and this will not affect your relationship with your doctor or your medical treatment and rights.

If you require other diagnostic or therapeutic interventions, or if you do not follow the study plan, or for any other reasonable reason, the investigator may terminate your continued participation in this study.

Prior to withdrawal, the study doctor's processing of your data is lawful. If data collected before withdrawal have already been integrated into the study database, they will continue to be used in this study under the condition of protecting your privacy.

If deemed necessary by the doctor, you may be asked to undergo laboratory tests and physical examinations, which are highly beneficial for protecting your health.

13. Confidentiality Of My Personal Information

During this study, for the purposes of the research, the study team may need to access your medical history and collect personal information such as your past necessary medical records and test results. By signing this informed consent form, you authorize the study team to contact other healthcare providers who have provided you with medical care in order to obtain necessary medical information about you from the period during which they were delivering care to you. Only members of the study team will have access to your medical information and be able to identify you. Without violating confidentiality principles and relevant regulations, monitors authorized by the sponsor, the Ethics Committee, and regulatory authorities may review your original medical records to verify clinical trial data.

During the study, we will collect your personal information and research data. To ensure privacy, we will code information that can directly identify you, such as your name and contact details, so that no one can ascertain your identity. If the results of this study are published in a medical journal or presented at scientific conferences, no information that could identify you will be disclosed.

You may withdraw your permission for the use and sharing of your personal information at any time by contacting your study doctor if needed. If you do so, you will no longer be able to remain in the study. After that, the researchers will no longer collect new health data that can identify you. However, health data already collected may continue to be used and shared with other researchers as described in this informed consent form. To ensure the scientific validity and credibility of this study, you may not be able to access certain study- related records before the study is completed. At the end of the study, you may request to review the health data collected during the study from your study doctor. After reviewing the data, you may point out any errors in your personal information. The information and research data collected or generated during this study will be coded and stored ("research data") and will be kept at the study site for 10 years before being destroyed.

Your information will not be used again in the future outside of the current study.

14. For More Information

You may ask any questions regarding this study at any time. You may directly contact Dr. _____ at Sir Run Run Shaw Hospital, Zhejiang University School of Medicine, at the following telephone number: _____.

15. Ethics Committee

If you have any questions regarding your rights/interests, or if you wish to report any difficulties, dissatisfaction, or concerns encountered during your participation in this study, or if you would like to provide comments or suggestions related to the study, please contact the Medical Ethics Committee of Sir Run Run Shaw Hospital, Zhejiang University School of Medicine.

Address: Medical Ethics Committee, Sir Run Run Shaw Hospital, Zhejiang University School of Medicine
Telephone number: 0571- 86006811

Please keep this document for your records.

Subject Signature Page

Informed Consent Statement:

I have been informed of the purpose, background, procedures, risks, and benefits of this study. I have had sufficient time and opportunity to ask questions, and I am satisfied with the answers provided. I agree to participate in this study.

I have also been informed of whom to contact if I have questions, wish to report difficulties, concerns, or suggestions regarding the study, or need further information or assistance.

I understand that I may choose not to participate in this study or may withdraw from the study at any time without giving any reason.

I understand that if my condition worsens, if I experience a serious adverse event, or if my study doctor determines that continued participation is not in my best interest, he/she may decide to withdraw me from the study. The sponsor or regulatory authorities may also terminate the study during the study period without my consent. In such an event, the study doctor will notify me promptly and will discuss other options with me.

I will receive a copy of this informed consent document, which bears the signatures of both myself and the researcher.

I understand that participation in this study requires the use of my personal information and biological samples, and I consent to the use and processing of my personal information and biological samples for the purposes described in this informed consent form.

☐**Agree** ☐**Disagree, and cannot participate in this study**

Subject Signature：_____ Date：_____

Guardian Signature：_____Relationship with Subject（ ） Date：_____

（For subjects who are incapacitated or have limited legal capacity, the signature and date of the legal guardian are required）

Impartial Witness Signature：_____ Date：_____

（If the subject cannot read the consent form, an impartial witness must sign and date to confirm that the investigator explained all content to the subject and the subject agreed to participate.）

Investigator Signature：_____ Date：_____

方案编号：**WNAK-PN-A1-2025-1**

方案版本号和日期：**V1.1/2025 年 10 月 10 日**

评估微纳秒协同电脉冲肿瘤消融系统治疗恶性肺结节安全性、有效性的 FIM 试验

知情同意书

申办方：杭州维纳安可医疗科技有限责任公司

临床试验机构：浙江大学医学院附属邵逸夫医院

主要研究者：陈恩国

尊敬的先生/女士：

我们将邀请您参加一项临床试验研究。在您决定是否参加这项研究之前，请尽可能仔细阅读以下内容，它可以帮助您了解该项研究内容、为何要进行这项研究以及本研究可能给您带来的益处、风险和不适等。如有任何疑问或疑虑，可以与研究人员进行讨论，您可以与亲朋好友商量后再做决定。本次研究已通过浙江大学医学院附属邵逸夫医院伦理委员会审查，遵从中国相关法规和赫尔辛基宣言等保护受试者权益的伦理原则。

1. 研究背景

肺结节是（pulmonary nodule, PN）指肺内直径小于或等于3CM的类圆形或不规则形病灶，影像学表现为密度增高的阴影，可单发或多发，边界清晰或不清晰的病灶。不同密度的肺结节，其恶性概率不同，依据结节密度将肺结节分为三类：实性结节、部分实性结节和磨玻璃密度结节。目前肺癌是世界上最常见、死亡率最高的癌症，也是我国最常见的恶性肿瘤之一。恶性肺结节被认为是肺癌的早期形态，因此早期发现、早期诊断与早期治疗是提高病人生存率的关键所在.

目前临床对肺结节的治疗手段包括外科手术和消融治疗，消融技术包括射频消融、微波消融和冷冻消融；冷热消融用于特殊部位肺结节容易损伤胸膜造成支气管胸膜瘘且常因热沉效应致消融不彻底。

不可逆电穿孔（IRE），具有与其他物理消融方法完全不同的原理和技术应用特点。该技术通过电极针高压电脉冲释放形成高场强消融区域，使消融区域覆盖的组织细胞膜上产生多个不可逆的纳米级孔道，引起细胞内外环境失衡，造成细胞凋亡，从而永久性的破坏组织细胞。其消融过程中只对消融区域内细胞膜脂质双分子层进行破坏，对消融范围内血管等重要结构不会产生严重损害。因为这种消融特性，使得不可逆电穿孔治疗在多种疾病治疗中，具有不可替代的优势，如治疗时间短、可适应更多复杂的病情、保存治疗区内重要结构等治疗彻底、边界清晰等。本研究所采用的微纳秒协同电脉冲肿瘤消融系统为杭州维纳安可医疗科技责任有限公司所研制生产（型号规格：WK-WN-K-A1），其是基于不可逆电穿孔作用机制的第三类医疗器械。其已通过了方圆广电检验检测股份有限公司的第三类医疗器械型式检验和EMC检测，结论为合格。一次性使用脉冲消融导管/一次性使用脉冲消融针（型号规格：WKN系列）已通过浙江省医疗器械检验研究院的第三类医疗器械型式检验和国家食品药品监督管理局杭州医疗器械质量监督检验中心的EMC检验，结论为合格；浙江省医疗器械检验研究院浙江省

医疗器械安全性评价研究重点实验室国家药品监督管理局生物医学光学重点实验室产品电磁兼容特性分析检测，结论为合格；杭州泰格捷通检验技术有限公司的细胞毒性试验、皮肤致敏试验、动物皮内反应试验，结论为合格。

2. 研究目的

评估微纳秒协同电脉冲肿瘤消融系统消融恶性肺结节安全性和有效性。本研究使用的是杭州维纳安可医疗科技有限责任公司研制生产的微纳秒协同电脉冲肿瘤消融系统，其已通过具有资质的医疗器械质量监督检验中心的各项注册检验，检验结果均为合格，产品在物理、化学、生物学等方面符合有源类医疗器械的安全标准，安全性能良好。按照国家药品监督管理局（NMPA）颁布的《医疗器械注册管理办法》及《医疗器械临床试验质量管理规范》等法律法规的要求，该产品已具备实施临床研究的条件。本研究已经得到浙江大学医学院附属邵逸夫医院伦理委员会审查同意（批件号: ）。

3. 如果参加研究，将发生什么？

本研究整体预计 12 个月，对每位受试者而言预计持续 8 个月，共 4 名受试者参加。本次临床研究为单臂研究，单臂研究意味着入选的所有受试者均将接受微纳秒协同电脉冲肿瘤消融系统进行不可逆电穿孔消融治疗，不可逆电穿孔消融术后需要您配合 3 次随访。在不可逆电穿孔治疗后第 1、3、6 个月时各有一次随访。随访的具体内容在下一节。

4. 研究的具体流程是怎样的？

在您决定是否参加本次临床研究前，您的研究医生或研究相关人员将会告知您有关本研究的相关信息。一旦您同意参与研究，您须签署知情同意书，您的研究医生或研究相关人员可开始进行筛选程序，审查您参与本项研究的资格。**研究者会根据筛选期检查结果和入排标准来判断您是否可以入组本研究。**

如下是向您介绍在本次临床研究过程中，每次访视时您将要进行的检查和流程。

a) 访视 1，筛选期（-7 至 0 天）

您入选研究前，将接受以下检查以确定您是否可以参加研究。收集您常规诊疗的人口学资料、既往病史、现病史，血常规、凝血功能、血生化、肿瘤标志物、传染病筛查、妊娠试验、免疫学检查等检测。

1) 将为您提供研究信息，您有足够的时间来考虑是否参与本研究，在您所有的问题得到答复后，您将签署本知情同意书；
2) 医生将阅读您既往的检查或医疗记录、询问您的病史、用药情况，进行体格

检查和生命体征检查（体温、血压、心率、呼吸）；

3) 您需要进行血常规、尿常规、凝血功能、血生化、肿瘤标志物，必要时进行妊娠试验；

4) 您将接受心电图检查、肺功能检查、增强 CT 检查；

b) 访视 2，IRE 治疗期（0 天）

若您以上检查合格，将按以下步骤进行研究：治疗期将收集您常规诊疗的生命体征。

1) 将测量您的生命体征（体温、血压、心率、呼吸）；

2) 必要时进行现场细胞学评估；

3) 使用不可逆电穿孔消融术进行治疗；

4) 询问您感觉如何，如您是否出现任何健康相关问题；以及您正在使用的其它任何药物和治疗；

c) 访视 3，IRE 术后 30 天（30±7 天）

本次随访将收集您常规诊疗的生命体征。

1) 询问您感觉如何，如您是否出现任何健康相关问题；以及您正在使用的其它任何药物和治疗；

2) 对您进行生命体征检查（体温、血压、心率、呼吸）；

3) 您将接受心电图检查、肺功能检查、增强 CT；

d) 访视 4，IRE 术后 90 天（90±7 天）

本次随访将收集您常规诊疗的生命体征。

1) 进行体格检查、ECOG 评分，询问您感觉如何，如您是否出现任何健康相关问题；以及您正在使用的其它任何药物和治疗；

2) 对您进行生命体征检查（体温、血压、心率、呼吸）；

3) 您需要进行血常规、尿常规、凝血功能、血生化、肿瘤标志物；

4) 您将接受心电图检查、肺功能检查、增强 CT；

5) 结节复发情况评估。

e) 访视 5，IRE 术后 180 天（180±15 天）

本次随访将收集您常规诊疗的生命体征。

1) 进行体格检查、ECOG 评分，询问您感觉如何，如您是否出现任何健康相关问题；以及您正在使用的其它任何药物和治疗；

2) 对您进行生命体征检查（体温、血压、心率、呼吸）；
3) 您需要进行血常规、尿常规、凝血功能、血生化、肿瘤标志物检查；
4) 您需要接受心电图、增强 CT 检查；
5) 结节复发情况评估。

5. 研究中收集的生物标本

在研究过程中，研究步骤所描述的您的血液样本及病理结果所产生的数据将会是为了本试验告知的目的而被采集、保存和使用，研究结果产生的知识产权或潜在商业价值不会分享给您。

6. 研究中有哪些需要注意的问题？

1) 您需要按医生和您约定的随访时间来医院就诊。您的随访非常重要，因为医生将判断您接受的治疗措施是否真正起作用；
2) 您在每次随访时都将正在服用的其他药物带来，包括您有其他疾病须继续服用的药物（包括中草药），报告所服用药物/治疗（非处方药和处方药）的任何变化；
3) 如您需要进行其他治疗，请事先与您的医生取得联系；
4) 需要您及时告知研究医生研究期间任何不适或健康以及感觉变化，甚至是您认为不是很重要的问题；
5) 请您咨询并遵守您的研究医生提出的饮食、起居建议。

7. 本次研究之外的替代诊疗方法

无论您是否参与本研究，您都可以与您的医生了解讨论更多的细节与替代疗法。您可以选择不参加本项研究，这对您获得常规治疗不会带来任何不良影响。目前针对您的健康情况，常规的治疗方法有：外科手术、冷冻消融、射频消融等。

8. 参加这项研究可能获得什么益处？

如果您同意参加本研究，通过不可逆电穿孔治疗您的肺结节可能可以获得缓解。同时，您的疾病也可能没有获得直接的医疗受益。您的参与有助于医学对此类疾病的进一步研究和认识，在未来提高疾病的诊疗水平。在此，我们为您能够参与科学研究，并为医学的发展做出贡献表示感谢！

9. 参加这项研究可能有什么风险和不便？

如果您在研究期间出现任何疾病或不适，您应立即告知您的研究医生或研究相关人员。研究医生将会对您进行评估，如有必要，您将接受适当的治疗。

1) 本研究器械尚未获得注册证，因此本研究属于上市前研究，根据既往同类器械的报导情况，使用不可逆电穿孔技术进行肺结节消融可能出现以下并发症：静脉血栓形成、出血、心律失常、感染等；这些并发症都可以通过影像学检查及时发现并进行处理。研究者会在术中通过CT进行实时监测，及时了解治疗效果以及是否出现重要结构的损伤；会在术后进行即时的影像学检查，以确定周边结构是否存在损伤及有无术后出血现象。
2) 消融不彻底风险:使用不可逆电穿孔技术进行肺结节消融,可能存在消融不彻底、术后复发的情况;
3) 抽血的风险：从胳膊静脉抽血的风险包括短暂的不适和/或青紫，也可能出现感染、出血、凝血或晕厥的情况；
4) 心电图检测的风险：可能会在连接和摘除导线时或之后，因粘合剂和吸盘而引起极轻微的不适；
5) 由于疾病本身以及其他已经存在的合并症或者药物的联合应用等原因，研究中可能会出现无法预知的风险。此外，研究干预可能出现无效，病情继续发展的情况；
6) 您在研究期间需要按时到医院随访、做一些检查，这些也都可能给您造成麻烦或带来不方便；
7) 育龄期配偶的风险：您应同意在研究期间正确地使用有效的避孕措施，必要时咨询您的研究医生或研究相关人员，依从避孕指导。

10.参加这项研究我需要支付费用吗？

参加本项研究期间，将免费为您进行不可逆电穿孔消融治疗，包括免费试用微纳秒协同电脉冲肿瘤消融系统和一次性使用脉冲消融导管/一次性使用脉冲消融针，本试验方案相关的检验检查项目也是免费的包括血常规、尿常规、血生化、凝血功能、肿瘤标志物、妊娠试验（女性）、12-导联心电图、肺功能、增强CT、组织或病理学检查。另外还将给予您2000元手术补贴，手术补贴将于治疗期结束发放。

此外，每次来院访视，本研究还将依照200元/次随访给予您一定的交通补贴，本研究共计5次访视；依照200元/次给予您一定的采血补贴，本研究共计4次采血。交通补贴、采血补贴将在随访结束时发放。如果您没有完成所有的访视和采血，则按照已完成

的访视向您支付费用。

不可逆电穿孔治疗后，您可选择其它治疗方式，这属于您的常规诊疗项目，相关费用需要您自己承担。与研究无关的费用，如您同时合并其他疾病所需的治疗和检查，以及因治疗无效而改用其他治疗的费用，将由您自己承担。

11.如果由于参加本研究而受到损害，将如何处理？

如果在研究期间出现任何不适，或病情发生新的变化，或任何意外情况，不管是否与不可逆电穿孔肺结节消融治疗有关，均请您及时通知您的医生，他/她将对此做出判断和医疗处理。

如发生与本研究相关的损害时，研究者会对您进行及时的诊断和治疗，以控制并发症的风险，杭州维纳安可医疗科技有限责任公司则会承担相应的检查和治疗费用，并依照相应国家法律法规进行赔偿。为进一步保障您的权益，本研究为参加研究的所有受试者购买了保险，保险不覆盖的部分（例如未达到起赔偿额等情况）由申办方承担。

12.如果不参加或中途选择退出研究，将会发生什么？

参与本项研究是完全自愿的，您可以在研究过程中的任何时间因任何原因退出本研究，这都不会影响您和医生间的关系，不会影响您的医疗待遇与权益。

如果您需要其他诊断/治疗，或者您没有遵守试验计划，或者有任何其他合理原因，研究者可以终止您继续参与本项试验。

退出之前，研究医生对您的数据处理是合法的，退出之前的数据如果已经整合到研究项目中，在保护您隐私的前提下仍将继续在本研究中使用。

如果医生认为需要，您也可能被要求进行实验室检查和体格检查，这对保护您的健康十分有利。

13.我的个人信息是保密的吗？

本研究期间，出于本研究目的，研究团队可能需要接触您的病史，收集您过去必要的医疗记录和检测结果等个人信息。在您签署本知情同意书后，就代表您允许研究团队去联系给您提供其他医疗帮助的提供者，以获得在他们为您提供医护服务期间的关于您必要的医疗信息。只有研究团队的成员能接触您的医疗信息，并识别您的身份。在不违反保密原则和相关法规的情况下，申办者授权的监查员；伦理委员会；监管部门会可以查阅您的原始医学记录以核实临床试验数据。

研究过程中，我们将收集您的个人信息和研究数据，为保证隐私我们将姓名、联系

方式等可以直接识别您的这部分数据编码，以便任何人无法确定您的身份。如果在医学期刊上发表或在科学会议上汇报本研究的结果，也不会披露可识别您身份的信息。

您许可的个人信息使用和分享权限，在任何时候都可以收回，如有需要，可通过联系您的研究医生。如果这样做，您将无法继续停留在研究中。在这之后，研究者将不会再收集能识别出您个人信息的新健康数据。然而，对于已经收集到的健康数据，将可能会被继续使用和分享给其他研究者，正如该知情同意书中描述的一样。为了确保这项研究的科学性和可信度，在该研究结束之前，您可能不能够查看到一些与研究相关的记录。当研究结束时，您可以向研究医生提出查看健康数据的要求，这些健康数据就是研究过程中收集的，在您查看之后，可以提出任何关于您个人信息的错误。在本研究期间收集或产生的个人信息和研究过程产生的数据会进行编码后保存（“研究数据”），保存在研究中心 10 年后销毁。

除本次研究外，将来不会再次利用到您的这些信息。

14.我将如何获得更多的信息？

您可以在任何时间提出有关本项研究的任何问题，您可以直接与浙江大学医学院附属邵逸夫医院的 张勇杭 医生联系，联系电话：15858760211。

15.伦理委员会

如果您有与自身权利/权益相关的任何问题，或者您想反映参与本研究过程中遭遇的困难、不满和忧虑，或者想提供与本研究有关的意见和建议，请联系浙江大学医学院附属邵逸夫医院医学伦理委员会，地址：浙江大学医学院附属邵逸夫医院医学伦理委员会，联系电话：0571-86006811。

请您保留这份资料。

受试者签字页

知情同意声明：

我已被告知此项研究的目的、背景、过程、风险及获益等情况。我有足够的时间和机会进行提问，问题的答复我很满意，同意参加本研究。

我也被告知，当我有问题、想反映困难、顾虑、对研究的建议，或想进一步获得信息，或为研究提供帮助时，应当与谁联系。

我知道我可以选择不参加此项研究，或在研究期间的任何时候无需任何理由退出本研究。

我已知道如果我的状况更差了，或者我出现严重的不良事件，或者我的研究医生觉得继续参加研究不符合我的最佳利益，他/她会决定让我退出研究。无需征得我的同意，资助方或者监管机构也可能在研究期间终止研究。如果发生该情况，研究医生将及时通知我，研究医生也会与我讨论我的其他选择。

我将得到这份知情同意书的副本，上面包含我和研究者的签名。

我了解参与本研究必须要使用我的个人信息和生物样本，我同意按照本知情同意书所述的目的使用和处理我的个人信息和生物样本。

☐同意 ☐不同意，无法参与本研究。

受试者签名：陈瑞龙 日期：2025.11.14 9:30

监护人签字：_____与受试者关系（ ） 日期：_____

（适用于受试者无行为能力/限制行为能力时，则需监护人签名和签署日期）

公正见证人签字：_____ 日期：_____

（适用于受试者不能阅读该知情同意书时，则需一名公正见证人见证研究者已将知情同意书的所有内容告知了受试者，受试者表示了同意参加的意愿，公正见证人需签名和签署日期）

研究者签名：[illegible] 日期：2025.11.14 9:30