# Informed consent

## Enhancing CBCT-Guided Pulmonary Nodule Puncture Efficiency with generative AI

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| Title | Enhancing CBCT-Guided Pulmonary Nodule Puncture Efficiency with generative AI |
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| Trial Principal Investigator<br><br>Other investigator(s) | Prof. Bo Du<br>Dr. Huangxuan Zhao<br><br>Dr. Lei Chen |
| Subsidising party <if applicable> | Not applicable |

**Dear friend:**

We invite your participation in a study on the clinical application of a Generative AI Based Puncture Surgery Navigation System (GPS) to guide lung puncture. This study will be conducted at the Union Hospital, Tongji College, Huazhong University of Science and Technology (Wuhan Union Hospital), and it is estimated that 220 subjects will volunteer to participate. This study has been reviewed and approved by the Ethics Committee of Wuhan Union Hospital.

This informed consent form provides you with information to help you decide whether or not to participate in this clinical research study. Your participation in this study is voluntary. This study has been reviewed by the Ethics Committee of our research institution.

Please read it carefully and if you have any questions, please address them to the investigator in charge of the study.

**Objectives:**

Constructing a lung puncture guidance system for high-quality CBCT images based on a generative deep learning approach to guide interventional procedures and reduce the number of punctures, radiation dose, and procedural complications.

**Research process and methods:**

If you agree to participate in this study, we will number each subject and

create a case file. We will collect and archive your chest plain CT images before you undergo the lung puncture and your CBCT images during the surgery for easy viewing at future checkups or review. We promise to respect your privacy and the information will not be disclosed to the public. Your information and images are limited to this study.

**Potential advantages:**

In this study, only the chest plain CT images before you were treated with lung puncture procedure and the CBCT images generated during the interventional procedures were collected and did not cause any secondary damage to you. This project was conducted to improve the quality of CBCT images generated during interventional procedures with a puncture navigation system to provide a puncture path, better guide the interventionalists to perform the procedure, improve the success rate of the procedure, and reduce the number of intraoperative punctures, surgical complications, and radiation dose to the patient during the procedure.

**Potential risks:**

This study will not cause you any secondary harm, and all risks are consistent with those arising from conventional interventional procedures.

**Privacy issue:**

If you decide to take part in this study, your personal information about your participation in the trial and in the trial is confidential. All information will be confidential to you. Information that identifies you will not be

disclosed to anyone outside of the research team unless you give your permission. At the end of the study, I will destroy the forms that contain your information. your images will remain in the radiology department's computer system and I will not be able to destroy them. To ensure that the study is conducted in accordance with the regulations, members of the government administration or the Ethics Review Committee will have access to your personal data at the research unit if necessary and as required. A commitment to confidentiality will also be required when the results of this study are published.

**Fees and reimbursements:**

You will receive a one-time living allowance of ¥200 if you are willing to be enrolled in this study after you have been informed of the treatment and examination. In the event of damages related to this clinical study, you may receive free treatment and/or appropriate reimbursement. The cost of treatment will be provided by the Department of Radiology, Wuhan Union Hospital.

**Voluntary participation and free withdrawal:**

As a subject, you may decide voluntarily whether to participate or not to participate in the study by keeping yourself informed of the information materials and research progress related to this study. After participation, regardless of whether an injury occurs or is serious, you may choose to request withdrawal from the study at any time by notifying the investigator,

your data will not be included in the results of the study, and any of your medical treatment and rights will not be affected as a result. If continuing to participate in the study would cause you serious harm, the investigator will also discontinue the study.

However, while participating in the study, you are asked to provide truthful information about your medical history and current physical condition, and tell the doctors about any discomfort you experience during the study.

**Contact Information:**

If you have questions related to this study, or if you experience any discomfort or injury during the study, or if you have questions about the rights of participants in this study, you may contact Lei Chen at +86-15971480677.

**Signature:**

I have read this informed consent form and my doctor_____ (signature) has explained the purpose, content, risks, and benefits of this clinical trial to me in detail, answered all of my questions, and I understand this clinical research study, and I am volunteering to participate in this study.

Your signature: _____ Date: _____

Signature of investigator: _____ Date: _____

Researcher contact number: _____

*(Note: the signature of a witness is required if the subject is illiterate and the consent of an agent is required if the subject is incapacitated).*