Informed Consent Form

Study Title: Research on the Application of Federated Learning in the Construction of Deep Learning Models for Renal Tumor Imaging

NCT number: XXX

Lead Institution:

The First Affiliated Hospital of Guangxi Medical University

Participating Institutions:

Nanning Second People's Hospital

Guilin People's Hospital

Liuzhou People's Hospital

Guigang People's Hospital

Wuzhou Red Cross Hospital

Yulin Red Cross Hospital

Beiliu People's Hospital

Principal Investigator: Jiwen Cheng

July 1, 2026

Dear Participant,

You are invited to join a clinical study. This form explains the study so you can decide whether to participate. Please read it carefully and ask the study doctor if anything is unclear. Participation is voluntary. This study has been approved by the Ethics Committee of the First Affiliated Hospital of Guangxi Medical University.

1. Background and Purpose

Renal tumors are common. It is often difficult for doctors to tell whether a renal tumor is benign or malignant using CT alone, especially when the tumor is small. This study evaluates an investigational AI system, CascadeDiagnose Renal Tumor CT, for CT-based renal tumor detection and benign/malignant classification.

The main goals are to assess:

Diagnostic accuracy: AUC, sensitivity, specificity, PPV, and NPV.

Safety: false negative rate, false positive rate, system failure, and potential risks to clinical decisions.

The study also compares AI with radiologists, evaluates small tumors (⩽3 cm), and tests the system across different hospitals and CT scanners. The system is not yet approved for marketing and is used for research only.

2. Study Procedures

If you join the prospective phase:

The study team will check whether you meet the study criteria.

Your routine clinical data, CT images, and pathology results may be collected.

Your CT images will be analyzed locally by the AI system at your hospital.

Radiologists or urologists may review your images first without AI and then with AI assistance.

Only de-identified, encrypted statistical results may be sent to the central aggregation node. Your original CT images and identifiable data will not leave your hospital.

No extra CT scans or blood draws are required for this study.

The study does not use randomization, placebo, or blinding.

The overall study period is planned from August 2026 to July 2028.

3. Risks

Possible risks include:

Privacy risk: Low, but accidental disclosure is possible. Data are de-identified, encrypted, and access-controlled.

AI error: The system may miss a malignant tumor or misclassify a benign tumor as malignant. AI results will not be the only basis for your clinical care.

System failure: The system may fail, crash, time out, or output abnormal results.

Uncertainty/rejection: The system may output “uncertain” or “rejection” if image quality is poor or data are incomplete.

Routine CT risks: Contrast allergy, kidney effects, and radiation exposure from routine CT.

Unknown risks: Some risks may not yet be known.

If you feel unwell, contact your study doctor.

4. Benefits

You may not receive direct medical benefit from this study. The information learned may help improve AI-assisted diagnosis of renal tumors and may help reduce unnecessary kidney surgery in the future.

5. Alternatives

You do not have to join this study. Standard care options may include active surveillance, follow-up imaging, biopsy, surgery, ablation, or other treatments recommended by your doctor. Please discuss these with your doctor.

6. Costs and Compensation

The AI analysis and research data management are free. Routine medical costs, including CT, laboratory tests, hospitalization, surgery, medications, and follow-up, are not covered by this study. No additional compensation is provided unless required by the ethics committee or hospital policy.

7. Injury and Insurance

If you suffer injury related to this study, necessary medical treatment and compensation will be provided according to Chinese law. Compensation does not apply to injury caused by the natural progression of your disease, your negligence, or events unrelated to the study. If applicable, liability insurance has been arranged.

8. Voluntary Participation and Withdrawal

Participation is voluntary. You may refuse or withdraw at any time without giving a reason. This will not affect your medical care or rights. If you withdraw, de-identified data already integrated into the study may continue to be used.

9. Privacy and Confidentiality

Your identifiable information will be replaced by a study ID. The mapping table will be encrypted and stored locally at your hospital. Your original CT images, medical records, and pathology data will remain in your hospital. Only de-identified, encrypted intermediate features may be transmitted through encrypted dedicated lines. Ethics committees and regulators may review records for quality and compliance. Publications will not identify you.

10. Biological Samples

No additional biological samples will be collected for this study. Routine pathology results from clinical care may be used for diagnosis confirmation. Samples will not be used for product development or secondary research without separate consent.

11. Spouse Pregnancy and Separate Consent

Not applicable to this study.

12. Contacts

For study questions, contact:

Name: _Haiqi Liang__

Phone: __+86-18346849794_____

For questions about your rights as a participant, contact:

Ethics Committee, First Affiliated Hospital of Guangxi Medical University

Phone: 0771-5356557

Consent Statement

I confirm that:
I have read and understood this informed consent form and have had the chance to ask questions.
I understand that participation is voluntary, and refusing or withdrawing will not affect my rights or medical care.
I agree that authorized study staff, the ethics committee, and regulators may review my research records, and that my information will be kept confidential.

I agree to participate in this study.
Participant Signature: _____
Date: _____

Investigator Statement

I confirm that I have explained the nature, purpose, requirements, and possible risks of this study to the participant, discussed other treatment options, and provided a copy of this informed consent form.

Investigator Signature: _____
Date: _____