Informed Consent Form

Study Title: International Multicenter Clinical Study on the Application of Artificial Intelligence Digital Physician Based on Large Language Models in Urology

Study ID: XXX

Ethics Approval No.: 2026-K0059

Version No. 1

Version Date: 2026/3/27

1. Introduction

You are being invited to participate in a clinical research study. Before you decide whether to participate, it is important for you to understand why the research is being done and what it will involve. Please read the following information carefully. Feel free to ask questions if anything is unclear or if you would like more information.

2. Study Nature and Randomization

This study uses a randomized design, which means you will be assigned to one of two groups by chance:

AI-Assisted Group (50% chance): Your diagnosis, treatment plan, and preoperative education will be supported by an Artificial Intelligence (AI) Digital Physician.

Conventional Group (50% chance): Your diagnosis, treatment plan, and preoperative education will be provided by your attending urologist following conventional methods.

Randomization will not affect your right to receive standard medical care. Regardless of the group assignment, the final treatment plan will always be determined jointly by senior urology specialists to ensure it meets clinical standards.

3. Potential Benefits

The AI Digital Physician is designed to assist doctors by providing evidence-based information and personalized health education. While the use of this tool may support your physician in delivering more standardized and detailed preoperative education, it is important to understand that this system serves only as an auxiliary tool and does not alter the final diagnosis or treatment plan determined by your physicians. There is no guarantee that participation will lead to a direct improvement in your medical condition.

4. Risks and Management of Adverse Events

Potential Risks: As with any AI-based tool, there is a theoretical possibility of inaccurate or incomplete information. To minimize this, all AI-generated suggestions are reviewed and confirmed by senior physicians before any clinical action is taken.

Management of Adverse Events: If you experience any unexpected discomfort, dissatisfaction, or adverse event related to the AI system,

please report it immediately to your study doctor. You will receive prompt evaluation and necessary medical support free of charge.

Serious Adverse Events (SAEs): In the unlikely event of a serious adverse event directly related to the study intervention, the research team will report it to the ethics committee and relevant authorities, and will take all necessary measures to ensure your safety and rights.

Contact: For any concerns or emergencies, you can reach the research team 24 hours a day using the contact information on page 3.

5. Privacy and Data Use

Your personal information and medical data will be kept strictly confidential.

Data De-identification: All data collected for this study will be anonymized (i.e., any identifying information such as your name will be removed) and replaced with a unique study code.

Storage Period: De-identified data will be retained for 5 years after the study is completed, as required by regulatory standards.

Cross-Border Data Transfer: If applicable, anonymized data may be securely transferred to collaborating research centers in other countries (including ASEAN countries) in compliance with applicable data protection laws and ethical regulations. Such transfers will use encryption and will not include any information that can identify you.

Your Rights: You have the right to request access to, correction of, or deletion of your research-related data. Any such request can be made to the study doctor, who will assist you in accordance with applicable regulations.

6. Withdrawal and Your Rights

Your participation in this study is entirely voluntary. You have the right to withdraw from the study at any time, for any reason, without any penalty or impact on your regular medical care. If you choose to withdraw, your future treatment at this hospital will not be affected in any way.

Withdrawal Procedure:

If you withdraw, you may choose whether you allow the data already collected from you to be used in the study analysis, or if you wish it to be destroyed.

Your study doctor will continue to provide appropriate follow-up care for your safety as clinically necessary.

7. Contact Information

If you have any questions about the study, your rights, or if you experience a medical emergency, please contact:

Research Team (24-hour emergency contact)

Principal Investigator: Zhang Dongjie

Phone: 0771-5356516

Email: ykdyfymnwk@163.com

Ethics Committee (for concerns about study rights)

Committee Name: Li xieping

Phone: 04771-5354579

Email: ykdyfymne@163.com

8. Statement of Consent

I have read and understood the information provided in this Informed Consent Form. I have had the opportunity to ask questions and have received satisfactory answers. I understand that my participation is voluntary and that I may withdraw at any time without any consequences.

I voluntarily agree to participate in this study.

Participant Name (Printed) Participant Signature

Date:

Name of Investigator Investigator Signature

Date:

I confirm that I have provided a copy of this signed and dated Informed Consent Form to the participant.

Investigator Signature

Date: