Protocol Title：（Efficacy and Safety of the RDI Mode in Endoscopic Submucosal Dissection: a Multicenter, Randomized Controlled Study）

Informed Consent Form

Protocol No.：2025.12.01

Protocol version：3.0，2025.12.01

ICF Version：3.0，2025.12.01

Please read the following information carefully

You are being invited to take part in a clinical research study. This informed consent form gives you information to help you decide whether or not to participate. Please read it carefully and feel free to ask the study staff any questions—you will receive detailed answers. You may take as much time as you need to decide, based on your own situation.

1. Study background and aims

Endoscopic submucosal dissection (ESD) has become the standard minimally invasive treatment for early esophageal, gastric and colorectal neoplasia. However, intra-operative bleeding remains a key factor that prolongs procedure time, reduces en-bloc resection rates and increases adverse events. Because conventional white-light endoscopy (WLE) offers limited contrast, it is often difficult to identify deeper vessels and pinpoint bleeding sites; visibility drops further when the field is obscured by blood, making hemostasis less efficient.

Red dichromatic imaging (RDI) is a newly developed image-enhanced endoscopic modality that improves visualization of deeper vessels and active bleeding spots, shortens hemostasis time and may enhance overall procedural efficiency.

Although retrospective series suggest potential advantages of RDI for controlling ESD-related bleeding and for delineating the submucosal plane, high-quality multicenter randomized controlled data comparing RDI with standard WLE are lacking. No RCT has yet evaluated whether RDI improves critical outcomes such as en-bloc resection rate, procedure time, complication rate or operator mental workload while avoiding selection bias.

Therefore, we are conducting a multicenter, randomized controlled trial to systematically compare the efficacy and safety of RDI versus WLE when either modality is used throughout the entire ESD procedure. A total of 158 participants will be enrolled across three hospitals in China, with recruitment ending on 30 November 2027.

2. Study procedure

If you agree to take part, you will be prepared in the usual way and then randomly assigned (by computer-generated random numbers) to either the study group (RDI group) or the control group (conventional white-light endoscopy group). The imaging mode used throughout your ESD procedure will be determined by this random assignment.

RDI group: the submucosal dissection will be performed entirely under red dichromatic imaging (RDI); white-light mode may be used only for observation and marking.

White-light endoscopy (WLE) group: the whole ESD will be completed with white-light endoscopy; RDI will not be activated.

The entire procedure will be video-recorded, and any complications will be monitored closely during and after the operation.

3. Risks and discomforts

All of your information will be kept strictly confidential. Your endoscopic examination and treatment will follow the usual clinical routine; using either imaging mode will not add any extra risk for you.

4. Potential Benefits

Your endoscopic examination and treatment will be performed by highly experienced gastro-intestinal endoscopists, and you will receive close monitoring before, during, and after the procedure. The findings of this study may also help future patients.

5. Study Costs

ESD and all associated drugs and devices are part of standard care; their cost is the same whether or not you join the study. The research involves no extra charges and provides no additional compensation.

6. Responsibilities of Participants

As a study participant, you are expected to: Provide truthful information about your medical history and current physical condition; inform the study physician of any discomfort you experience during the study; notify the study physician if you have taken part in any other research recently or are currently enrolled in another study.

7. Voluntary participation

You are free to decline to take part or to withdraw from the study at any time simply by informing the investigator. Your data will then be excluded from the analysis, and your medical care and rights will not be affected in any way.

The study physician may also discontinue your participation if you require alternative treatment, fail to follow the study plan, suffer a study-related injury, or for any other medical or administrative reason.

8. Confidentiality

If you decide to take part, all information about your participation and any personal data collected during the study will be kept strictly confidential. Regulatory authorities or members of the Ethics Committee may review your records on-site, as required by regulations, to ensure the study is conducted properly. When the results of this research are published, no information that could identify you personally will be disclosed.

9. Injury of Participants

If you are injured as a result of taking part in this study, you will receive immediate medical care. Any additional medical costs and compensation for damages will be provided in accordance with Chinese law.

This study protocol and the informed consent form have been reviewed and approved by the Institutional Ethics Committee of this hospital.

If you become aware of any protocol violations during the study, you may report them directly to the Ethics Committee. Tel: +86-20-3837 9764 E-mail: zslyllb@mail.sysu.edu.cn.

If you agree to participate voluntarily, you will be asked to sign this informed consent form to confirm that you have understood the study information and consent to take part.

You may obtain updated information about the study and its progress at any time.

For study-related questions, any discomfort or injury during the study, or issues concerning participants' rights, please contact Dr. Jiachen Sun at +86 178 7676 7620.

Subject Informed Consent – Signature Page

I have read this informed consent form.

I have had the opportunity to ask questions and all my questions have been answered.

I understand that my participation is voluntary.

I may choose not to take part or may withdraw at any time simply by informing the researcher, without penalty or retaliation; my medical care and rights will not be affected.

The study physician may discontinue my participation if I require alternative treatment, fail to follow the study plan, suffer a study-related injury, or for any other reason.

I will receive a signed copy of this informed consent form.

Name of subject：_____

Signature of subject：_____

Signature of legally authorized representative：_____

Relationship of legally authorized representative to subject：_____

Date：_____

I have accurately explained this document to the participant, who has read the informed consent form, and I confirm that the participant had the opportunity to ask questions. I certify that his/her consent was given voluntarily.

Name of Investigator：_____

Signature of Investigator：_____

Date：_____

（*Note: If the participant is illiterate, a witness must also sign. If the participant lacks capacity, a legally authorized representative must sign.*）