Informed Consent Form Official Study Title: An Observational Study of Percutaneous Glomerular Filtration Rate (TGFR) in the Early Warning of Contrast-induced Acute Kidney Injury During the Peri-examination Period of Emergency Enhanced CT NCT Number: Not Yet Assigned Document Date: 15 September 2026 Document Version: V2 Study Site: The Second Affiliated Hospital, Zhejiang University School of Medicine

Informed Consent Form

An Observational Study on Transdermal Glomerular Filtration Rate (TGFR) for Early Warning of Contrast - Associated Acute Kidney Injury (CA - AKI) During Peri - Examination Period of Emergency Contrast - Enhanced CT

Study Site: The Second Affiliated Hospital, Zhejiang University School of Medicine

Version: V2

Patient Name: _____ Ward: _____ Bed No.: _____

Medical Record No.: _____

Dear Patient,

You are invited to participate in an observational clinical study titled "An Observational Study on Transdermal Glomerular Filtration Rate (TGFR) for Early Warning of Contrast - Associated Acute Kidney Injury (CA - AKI) During Peri - Examination Period of Emergency Contrast - Enhanced CT". Before you decide whether to take part, please read this document carefully. It will help you understand this research, its purpose, study procedures, duration, potential benefits, risks and inconveniences of participation.

I. Study Background and Objectives

1. Study Background

Contrast - associated acute kidney injury (CA - AKI) refers to acute kidney injury occurring within 48 - 72 hours after administration of iodinated contrast media. Its incidence is approximately 2% - 6% among general hospitalized patients. The risk rises significantly in patients with chronic kidney disease, diabetes, cardiac insufficiency and advanced age. According to the 2020 consensus jointly released by the American College of Radiology (ACR) and the National Kidney Foundation (NKF), patients with lower baseline estimated glomerular filtration rate (eGFR) carry higher CA - AKI risk (approximately 5% for eGFR $\geqslant$60 mL/min/1.73 m^2 and approximately 30% for eGFR <30 mL/min/1.73 m^2). Patients with CKD stage 3 - 5 (eGFR <60 mL/min/1.73 m^2) are defined as high - risk populations.

Currently, clinical diagnosis of AKI mainly depends on serum creatinine (SCr) and urine output. However, serum creatinine is affected by muscle mass, age, sex, volume status and medications. Baseline SCr values are often unavailable in emergency settings. Moreover, obvious elevation of SCr only occurs when glomerular filtration rate (GFR) decreases by more than 50%, resulting in a diagnostic delay window of 48 - 72 hours. Novel biomarkers such as Cystatin - C, NGAL and KIM - 1 have inconsistent cut - off values and are prone to interference by inflammation. They require invasive blood sampling and are difficult to implement for continuous bedside monitoring in emergency scenarios.

Transdermal Glomerular Filtration Rate (TGFR) is a novel non - invasive bedside technology for continuous dynamic monitoring of glomerular function. It obtained marketing approvals from the U.S. FDA and China NMPA in 2025 (NMPA registration No. 20253070094). The TGFR system consists of the MB1000 transdermal GFR monitor, skin sensor and relmapirazin injection. Relmapirazin is a non - radioactive, non - iodinated small - molecule fluorescent tracer. After intravenous injection, it is freely filtered by glomeruli without tubular reabsorption or secretion. The skin sensor records changes in

transcutaneous fluorescence intensity at a frequency of 2.5 times per second. Built - in software converts fluorescence decay rate into GFR values, providing average GFR over the monitoring period as well as snapshot GFR readings approximately every 15 minutes. No blood drawing or urine collection is required. Sino - US pivotal phase III trials demonstrated that TGFR achieved a P30 accuracy of 94% versus measured GFR in adult patients with stable renal function (normal or impaired). No serious or severe adverse events were observed.

Against this background, this study will be the first to compare the predictive performance of TGFR versus baseline eGFR for CA - AKI among patients undergoing emergency contrast - enhanced CT. We will mainly evaluate whether TGFR can detect abnormal changes earlier than eGFR and whether it provides superior early diagnostic performance. This work will lay a foundation for future large - sample validation of TGFR as an early warning tool for CA - AKI.

2. Study Objectives

This study aims to evaluate the predictive performance of an 8 - 10 - hour peri - examination TGFR monitoring versus baseline eGFR for CA - AKI in patients receiving emergency contrast - enhanced CT. "TGFR abnormality" is defined as a ⩾15% drop in snapshot GFR relative to the subject's own baseline, confirmed by two consecutive snapshot GFR readings (approximately 30 minutes apart). This threshold references GFR decline cut - offs for early warning of subclinical AKI, which is more sensitive than the approximate 25% GFR decline corresponding to KDIGO AKI stage 1. Two key dimensions will be assessed:

The time lead (in hours) of TGFR - detected abnormalities compared with eGFR - defined abnormalities according to KDIGO criteria.

Diagnostic performance (AUROC, sensitivity, specificity, positive and negative predictive values with 95% confidence intervals) of peri - examination TGFR versus baseline eGFR for predicting CA - AKI.

II. Study Procedures

Baseline assessment: collect demographic information, underlying comorbidities, recent medications (NSAIDs, ACEI/ARB, diuretics, etc.), baseline SCr, BUN, eGFR, blood pressure, heart rate, volume status, clinical indication for contrast - enhanced CT, contrast media type and planned dose.

Initiate dynamic TGFR monitoring 2 - 3 hours before contrast - enhanced CT. Snapshot GFR values will be recorded every 15 minutes until monitoring completion. The total single monitoring duration is 8 - 10 hours. You are expected to remain relatively supine and avoid extensive physical activity during monitoring.

Synchronized blood sample testing: research nurses will collect blood samples (approximately 3 - 5 mL per time point) for SCr, BUN and eGFR measurement before contrast - enhanced CT, and at 24 h, 48 h and 72 h after contrast administration. Hourly urine output and total 24 - hour urine volume during peri - examination period will be documented. These blood draws are for research purposes; they will not duplicate, or will only add minimal volume to, routine clinical blood tests.

Document hydration regimens during peri - examination period, actual contrast media type and dose, concomitant medications affecting renal function, hypotension/shock

events and adverse events. Follow - up on renal recovery and survival status will be performed via outpatient visit, telephone or electronic medical records up to 28 days after contrast - enhanced CT.

III. What You Will Need to Do If You Participate in This Study

Complete baseline assessments, 8 - 10 - hour peri - examination TGFR monitoring and four scheduled blood collections as required by the study protocol.

Keep relatively still during monitoring; avoid strenuous movements and pulling the sensor.

Promptly inform study physicians of any discomfort, changes in concurrent medications or changes in clinical condition.

Cooperate with outpatient, telephone or electronic - medical - record - based 28 - day follow - up after discharge, and provide relevant information on renal function.

IV. Potential Benefits of Participation

Continuous GFR assessment: beyond routine blood tests, you will receive continuous renal function evaluation from 2 - 3 hours before CT to 5 - 6 hours after CT (total 8 - 10 hours) via the transdermal GFR monitoring system. This overcomes the limitation of intermittent blood sampling which cannot capture dynamic changes in kidney function between blood draws.

Potentially earlier detection of renal impairment: serum creatinine typically rises significantly only after GFR drops by more than 50%, creating a diagnostic delay of 48 - 72 hours. Transdermal monitoring yields continuous GFR trends on the same day, providing reference for clinicians to identify potential kidney injury signals earlier than conventional approaches.

Potential earlier initiation of interventions: dynamic GFR data obtained during the study may serve as reference for your attending physician to evaluate contrast - related renal impact, adjust hydration strategies and manage nephrotoxic medications. Early protective measures may be initiated if early renal decline is observed.

Reduced missed detection: conventional peri - examination evaluation relies on intermittent blood draws, and some early GFR declines may be missed due to long sampling intervals. Continuous transdermal monitoring helps minimize such missed cases and enables more comprehensive assessment of your renal function.

V. Possible Adverse Reactions, Risks and Mitigation Measures

1. Possible Adverse Reactions

Tracer - related reactions: rare mild allergic reactions such as rash, pruritus and flushing.

Skin - related reactions: local erythema, itching or irritant contact dermatitis at sensor application sites.

Device - related events: sensor detachment or signal abnormality which may require re - positioning.

Transient urine discoloration: bright - orange urine due to tracer excretion via kidneys; this represents normal metabolic phenomenon.

2. Risk Prevention and Management

Allergy history will be carefully assessed before procedures. Subjects with known hypersensitivity to the tracer or device components will not receive TGFR monitoring.

Sensors will be applied over intact skin. Skin irritation will be managed by immediate

sensor removal and local symptomatic treatment if needed.

Sensors and connecting components will be properly secured to reduce displacement and detachment. Abnormal conditions will be handled promptly by trained personnel.

All procedures will be performed by standardized - trained medical staff.

In case of serious adverse events, emergency protocols will be activated and managed by emergency and critical care physicians.

Emergency Contact Person & Phone: _____

VI. Cost Statement

Compared with routine clinical care, the additional tracer (relmapirazin injection) and sensor consumables for peri - examination TGFR monitoring will be provided by the research team. You will incur no extra costs for these items.

VII. Research - Related Compensation and Injury Remedy

This is a non - interventional observational study. TGFR monitoring will not alter your routine clinical management. Additional tracer and sensor supplies are provided free of charge. No compensation will be offered for study participation. If you suffer research - related harm, remedies will be handled in accordance with relevant national laws and hospital regulations.

VIII. Alternative Options

If you decline to join this study, there is no specific alternative research procedure. Your routine clinical treatment and CT examination will not be affected in any way.

IX. Confidentiality of Your Personal Information

Your medical records, including research - related medical files and laboratory reports, will be stored in hospital according to regulations. Investigators, ethics committee members, monitors, auditors and regulatory authorities may access your medical records. Unauthorized third parties will not have access. Study results published in public reports will not disclose your personal identifiers. Every reasonable effort will be made to protect your medical privacy within legal limits.

X. Right to Withdraw from the Study

Your participation is entirely voluntary. You may refuse to participate or withdraw from the study at any time without giving reasons. This will not change your relationship with clinical staff, nor will it compromise your medical care or any other legitimate interests.

XI. Institutional Review Board (Ethics Committee)

This study has been reviewed and approved by the Human Research Ethics Committee of The Second Affiliated Hospital, Zhejiang University School of Medicine. For questions regarding research ethics and participant rights, you may contact the Ethics Committee:

Tel (daytime): 0571 - 87783881; On - call (night): 13757118366; Email: HREC2013@126.com

I confirm that I have read and fully understood this informed consent form. I voluntarily agree to participate in this research study and consent to my medical data being used for research publication.

Participant Signature: _____ Contact: _____

Date: _____

Legal Representative Signature (if applicable): _____ Relationship to Participant: _____

Contact: _____ Date: _____

Witness Signature (if applicable): _____ Contact: _____ Date: _____

I confirm that I have explained the full details of this study to the participant, including research - related benefits, risks and subject rights. A signed copy of this informed consent has been provided to the participant.

Investigator Signature: _____

Mobile Contact: _____ Date: _____