

Institutional Review Board of Zhujiang Hospital, Southern Medical University

Ethical Approval Document

Approval No.: 2023-KY-164-01

Date of Issuance: September 5, 2023

Project Title: Clinical Study on the Occlusion of CAD/CAM All-Ceramic Restorations Using Virtual Articulator

Department: Department of Stomatology **Principal Investigator:** Xiao-qing Shen

Sponsor/Origin of the project: Investigator-initiated

Review Category: ☒ Initial ☐ Amendment

Review Method: ☒ Full Committee Review ☐ Expedited Review

Reviewed material: Filing Assessment Form, List of Project Team Members, Project Information List (Excel Spreadsheet), Statement of Funding Source, Curriculum Vitae and Qualification Certificates of the Principal Investigator, Investigator's Declaration of Conflict of Interest, Research Protocol (Version No: V1.0, Version Date: April 10, 2023), Informed Consent Form (Version No: V1.0, Version Date: April 10, 2023), Case Report Form (Version No: V1.0, Version Date: April 10, 2023), Quality Management Plan, Project Risk Pre-assessment and Risk Management Contingency Plan, Human Genetic Resources Project Filing and Registration Form (Excel Spreadsheet), Product Information Manual / Instructions for Use, Initial Review Application Form.

Ethical Review Opinion: In accordance with the ethical principles of the "Measures for the Ethical Review of Biomedical Research Involving Humans" (National Health Commission, 2016), "Good Clinical Practice for Drugs" (National Medical Products Administration, 2020), "Good Clinical Practice for Medical Devices" (National Medical Products Administration, 2022), "Technical Guiding Principles for Clinical Trials of In Vitro Diagnostic Reagents" (National Medical Products Administration, 2021), the "Declaration of Helsinki" (World Medical Association), and the "International Ethical Guidelines for Biomedical Research Involving Humans" (Council for International Organizations of Medical Sciences - CIOMS), this committee has reviewed the ethical issues of the aforementioned study. This committee approves the commencement of the aforementioned study in accordance with the submitted research protocol and related materials.

Chairperson (Signature, Xiao-dan Jiang)

Institutional Review Board of Zhujiang Hospital, Southern Medical University
(Official Seal of the Board)

Date: September 5, 2023

Note: (Please read carefully)

1. Before the clinical research (trial) begins, the applicant is requested to complete the clinical trial registration.
2. This clinical research (trial) is subject to continuing review by the Ethics Committee during its conduct. The applicant is requested to submit a study progress report one month

before the deadline. The next report is due before: August 4, 2024. (The Ethics Committee reserves the right to change the frequency of continuing review based on the actual progress, with the interval not exceeding 1 year.)

3. This ethical approval is valid for 1 year. The applicant is requested to start the clinical research (trial) before September 4, 2024.
4. Please follow the relevant laws and regulations of our country--the "Measures for the Ethical Review of Biomedical Research Involving Humans" (2016) issued by the National Health and Family Planning Commission, the "Good Clinical Practice for Drugs" (2020), the "Good Clinical Practice for Medical Devices" (2022), the "Technical Guiding Principles for Clinical Trials of In Vitro Diagnostic Reagents" (2021) issued by the National Medical Products Administration, the "Declaration of Helsinki" by the WMA, and the "International Ethical Guidelines for Health-related Research Involving Humans" by CIOMS. Conduct the clinical research (trial) in accordance with the protocol approved by this Ethics Committee, and protect the health and rights of the subjects.
5. During the clinical research (trial), any changes to the Principal Investigator, protocol, Informed Consent Form, etc., must be promptly notified to this Ethics Committee for re-review and can only be implemented after approval is obtained.
6. The occurrence of Serious Adverse Events and unexpected events that affect the risk-benefit ratio of the study must be reported to this Ethics Committee in a timely manner.
7. In the event of a protocol deviation, the Sponsor/Monitor/Investigator must promptly submit a protocol deviation report to the Ethics Committee.
8. If the research (trial) is suspended or terminated prematurely during its course, a suspension/termination report must be submitted to the Ethics Committee in a timely manner.
9. Upon completion of the clinical research (trial), the applicant is requested to submit a study completion report.
10. This review conclusion only pertains to the ethical aspects of the study. If the research requires other relevant procedures, such as obtaining approval/filing records from higher authorities, or signing contracts/agreements with relevant hospital departments, please complete the aforementioned procedures before the project commences.

Address: 253 Gongyedadao Road, Guangzhou, China Phone: 020-62783254/020-61643033

Email: zjylxs@126.com / zjyylxjllwyh@163.com

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List of Members of the Institutional Review Board (the second round) for Clinical Drugs, Devices, New Medical Technologies, and Clinical Research

(The table listed the board members' board position, name, gender, employer, major/specialty, department)

Declaration:

This Institutional Review Board is constituted and operates in accordance with ICH-GCP guidelines and applicable Chinese laws. All members are bound by a confidentiality agreement, ensuring that review materials are used exclusively for ethical assessment and are not disclosed to third parties. Materials submitted for review may not be copied or retained. All documents, including Standard Operating Procedures (SOPs), confidential records, notes, and their copies, are the exclusive property of the Board.

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Formal Review Opinion

In accordance with the ethical principles of the "Measures for the Ethical Review of Biomedical Research Involving Humans" (2016) by the National Health and Family Planning Commission; the "Good Clinical Practice for Drugs" (2020), the "Good Clinical Practice for Medical Devices" (2022), and the "Technical Guiding Principles for Clinical Trials of In Vitro Diagnostic Reagents" (2021) by the National Medical Products Administration; the "Declaration of Helsinki" by the WMA; and the "International Ethical Guidelines for Health-related Research Involving Humans" by CIOMS, the Board conducted an expedited review of the project titled "Clinical Study on the Occlusion of CAD/CAM All-Ceramic Restorations Using Virtual Articulator" on September 5, 2023. The result of the review was "Approved." The Board has the following formal review opinion, which requires a submission for the record before the project commences:

Submit a scanned copy of the Project Approval/Filing Assessment Form, which has been signed and stamped by the responsible project approval/filing department.

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