

No.	Time Point	Key Event	Core Compliance Statement
1	2025.03.21	Finalization of Version 4.0 of the study protocol <i>Modified Clown Therapy for Reducing Anxiety During Nebulization in Children: A Randomized Controlled Trial</i> , with complete and clear core content including study design, ethical norms, subject protection mechanism, study endpoints, inclusion and exclusion criteria	The study protocol fully complies with China's Good Clinical Practice (GCP) guidelines and the ethical requirements of the <i>Declaration of Helsinki</i> , providing a standardized and traceable implementation basis for subsequent ethical review and study execution
2	2025.04.07	Formal ethical approval for this study was granted by the Ethics Committee of the First Affiliated Hospital, Zhejiang University School of Medicine, with the official approval letter issued (Approval No.: IIT20250032C-R1)	The study has completed the full-process ethical review by the institutional ethics committee before the enrollment of the first subject, which fully complies with the core ethical principle of "ethical approval prior to study initiation" for clinical research, and is the core legal basis for the compliance of this study
3	2025.04.14	The legal guardian of the first enrolled subject signed the <i>Informed Consent Form</i> approved by the Ethics Committee, the first subject was officially enrolled, and the study was officially launched	Strictly abided by the pediatric research specification of "informed consent prior to enrollment and intervention", fully protected the legal rights and interests of pediatric subjects (vulnerable groups in medical research), and there was no violation of enrollment before informed consent
4	2025.06.23	Completed the enrollment of all 200 subjects, officially closed the enrollment channel, and the whole process was strictly implemented in accordance with the inclusion and exclusion criteria approved by the Ethics Committee	The whole enrollment process was completely consistent with the requirements of the original protocol approved by the Ethics Committee. There was no violation of out-of-scope enrollment, unauthorized adjustment of inclusion and

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			exclusion criteria, and no major protocol deviation affecting the scientificity of the study
5	2025.10.22	Completed the retrospective registration of the full study information in the Chinese Clinical Trial Registry (ChiCTR), and obtained the official registration number: ChiCTR2500110887	All information submitted in the retrospective registration (including study protocol, inclusion and exclusion criteria, intervention measures, study endpoints, statistical analysis plan, etc.) is 100% consistent with the original study protocol approved by the Ethics Committee and the content of the submitted manuscript. No unauthorized modification of the core study content was made, and there is no risk of academic misconduct such as selective reporting of results