伦理审查批件
IEC Approval Letter

[2021]伦审字（0125）号 Review date: March 02, 2021

项目名称 Protocol Title	Construction of transitional nursing scheme and application in ne urosurgical ICU based on SEC model		
研究类型 Type of study	☐Drug clinical trial ☐Clinical trials of medical devices ☐Clinical trials of in vitro diagnostic reagents ■Non-registered clinical study		
申办者 Sponsor	Union Hospital Affiliated to Tongji Medical College, Huazhong University of Science and Technology		
合同研究组织 CRO	NO		
试验产品 Study product	NO		
NMPA 批件号 Approval Number by NMPA	NA		
研究单位 site	Union Hospital Affiliated to Tongji Medical College, Huazhong University of Science and Technology		
主要研究者/科室 PI/Department	Yunxin Zhan/ Nursing department		
Review category	■Initial review ☐reexamine		
Review mode	■Conference review ☐Expedited review		
censor	17 people should arrive, 14 people actually, 0 people avoided, please refer to the meeting sign-up sheet.		
Voting result	agree	14 votes	Voting result ■agree
	Agree after the necessary amendments	0 votes	☐Agree after the necessary amendments
	disagree	0 votes	☐disagree
	Terminate or suspend the agreed research	0 votes	☐Terminate or suspend the agreed research
Review document	See the attachment。		
Follow-up review frequency	☐ 3 months ☐ 6 months ■ 1 year		
Validity period of approval	■ 1 year		

Union Hospital Affiliated to Tongji Medical College, Huazhong University of Science and Technology

Medical Ethics Committee (seal) :

Signature of Director/Deputy Chairman:

Review date: March 02, 2021

Ethics review approval	Start date	Revision date
UHCT-IEC-SOP-016-03-01（未经允许不得分发或复印）	February 22, 2021	February 10, 2021

The composition and working procedures of the Ben Lun Council follow ICH-GCP, China GCP and relevant la ws and regulations. Note: (Please read carefully)

1. All research content involving the export of human genetic resources or subject to special approval by relevant departments according to state regulations must be reported to relevant departments in accordance with relevant state regulations and regulations, and clinical research can only be carried out after approval.
2. The study shall be conducted in accordance with the protocol agreed by the Ethics Committee, and shall comply with the principles of GCP and the Helsinki Protocol to protect the health and rights of the subjects.
3. Any amendment to the agreed clinical research protocol, informed consent, recruitment materials and other related documents shall be submitted to the Ethics Committee in time for amendment application and can only be implemented after re-examination and approval.
4. Serious adverse events or unexpected adverse events occurring in the Center shall be reported to the Ben Lun Board in a timely manner, and the Ethics Committee has the right to make a new decision based on its evaluation.
5. According to the opinions of the Ethics Committee on the frequency of follow-up review, no matter whether the trial is started or not, please submit the follow-up review report one month before the expiration of the follow-up review date. The Ethics Committee has the right to change the follow-up review frequency according to the actual situation.
6. Suspension/early termination of clinical studies, the suspension/termination report shall be submitted to the Ethics Committee in a timely manner.
7. Any non-compliance/violation of the program shall be reported to the Ethics Committee in writing.
8. At the end of the clinical trial, a final report shall be submitted for review by the Ethics Committee.
9. This ethical approval shall be valid for one year from the date of approval, and shall be void if it is not implemented within the time limit.

* The validity period of the ethical review approval refers to the period of time from the date of approval of the ethics committee to carry out the clinical study. If the clinical study is not conducted within the validity period of the ethical review approval, a new application for ethical review is required. If a clinical study is conducted within the validity period of the ethical review approval, this ethical review approval is valid.

Annex (review document) :

1. Source of funding for the project
2. Research Proposal (V1.0, February 24, 2021)
3. Informed consent (V1.0, February 24, 2021) 4. Principal investigator qualification
5. Conflict of Interest statement
6. List of researchers of the Center and their division of labor
7. Declaration of Conformity
8. Attachment of Principal investigator qualification

华中科技大学同济医学院附属协和医院 医学伦理委员会

Ethics review approval	Start date	Revision date
UHCT-IEC-SOP-016-03-01（未经允许不得分发或复印）	February 22, 2021	February 10, 2021