**Peking University First Hospital Ethics Committee**

**Review Approval Document**

**Number of EC review: Number of EC archiving:**

**Date approved by the EC: The approval document is valid until: Frequency of periodical continuing review:**

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| --- | --- | --- | --- |
| Name of protocol |  | | |
| NMPA approval number |  | | |
| Sponsor |  | | |
| Department |  | Investigator |  |
| **The composition and working procedures of this EC comply with GCP and relevant regulations of China** | | | |
| EC review method：□Convened review Date of meeting: Place of meeting:  □Expedited review Review date: | | | |
| Review EC member | See the attached " Sign-in Form of EC Meeting", in which the EC member XXXX avoided | | |
| Review comment | Approval to conduct the clinical research in accordance with the above approved documents. | | |
| Notes:  1. This clinical research should be implemented within 1 year from the date of approval by the EC. If it is not implemented within the time frame, this review approval document should be automatically cancelled.  2. The research should be carried out in accordance with the research protocol approved by the EC, and must comply to the principles of GCP and the Declaration of Helsinki.  3. Since the date of approval of the research, the EC should conduct regular continuing review (the review frequency may be changed according to the actual progress); please submit the "Application Form of Periodical Continuing Review" one month before the expiration of the periodical continuing review.  4. During the research process, if any modifications are made to the research protocol and informed consent form and other related documents, please submit the relevant materials specified in the "Application Form of Modification Review" and the "List of Documents for Review". After being reviewed and approved by the EC, they can be implemented.  5. In the case of serious adverse events or unexpected adverse events that affect the risk-benefit ratio of the research, a written notification should be made to the EC while reporting to the NMPA. You can use NMPA’s "Serious Adverse Event Report Form" or the "Serious Adverse Event / Suspected Unexpected Serious Adverse Reaction Report Form" published by our EC or other report forms with relevant content, but the report in foreign language requires a Chinese abstract. The EC has the right to make new decisions based on its evaluation.  6. Non-compliance or protocol violation should submit "Report Form of Non-compliance/Protocol violation" in time.  7. Early termination of research should submit "Report Form of Early Termination of Research" in time.  8. Submit the "Report Form of Research Conclusion " and summary report of clinical research after the research is completed.  9. Report the important decisions of other ECs in writing in time. | | | |
| Signature of Chairman or Deputy Chairman:  Peking University First Hospital Ethics Committee(seal)  Date: | | | |

Address of EC: No.8 Xishiku street, Xicheng District, Beijing Post Code: 100034

Tel: 010-66119025

**List of EC Review Documents**

Number of EC Review:

XXXXX

Name of Protocol:

XXXXXX

Review Documents:

1. XXXXX

2. XXXXXX

**Peking University First Hospital Ethics Committee**  (seal)

Date: