



연세대학교 강남세브란스병원 임상연구심의위원회
Yonsei University, Gangnam Severance Hospital, Institutional Review Board

2F, 235, Dogok-ro, Gangnam-gu, Seoul, 06230, Korea
Tel. 82 2 2019 4601~3,4631, Fax.82 2 2019 4605

MAR-09-2018
IRB # 3-2018-0011

This is to inform that the following research has been reviewed and approved by Gangnam Severance Hospital, Institutional Review Board.

Protocol No. : -
Protocol Title: **Secondary Endoscopic Submucosal Dissection for Locally Recurrent or Incompletely Resected Gastric Neoplasms**
Principal Investigator Name/Department : Jung, Da Hyun / Department of Gastroenterology

Sponsor : -

Approval Issued : 2018-03-09
Expiration Date : 2019-03-08

Risk Level : I II III IV
Type of Review : Initial review response for IRB comment protocol modification
 safety information others interim report
 end of study report cancellation of protocol final report

Documents Approved(Contents of Review) :

1. Study protocol
2. Case Report Form
3. The IRB application Form(Exemption)
4. Curriculum Vitae

Quorum : Panel#1
Attendees : Panel #1 (Expedited review)

Result of Review : Approved Approved with modification
 Deferred Disapproved Tabled
 Suspension Termination

Comment : The IRB application Form (Exemption), Exemption of informed Consent Form (ICF)

This IRB is organized and operates according to ICH-GCP and the applicable laws and regulations. Investigators of this research did not take part in the approval process.

Gangnam Severance Hospital
Principle Chair, Institutional Review Board



Approval conditions for all Gangnam SEV Human Research Protocols

1. Gangnam SEV Research Policies :

All individuals engaged in human subjects research are responsible for compliance with all applicable Gangnam SEV HRPP(Human Research Protection Program). The principal investigator of the research is ultimately responsible for assuring all study team members review and adhere to applicable policies for the conduct of human subject research.

2. Principal Investigator recordkeeping responsibilities :

Principal investigators are responsible for keeping protocol and study records. The following web pages should be reviewed for more information about the PI's recordkeeping responsibilities, and preparation and maintenance of research files. See <http://ocr.yuhs.ac/Gangnam/GN/Center/Vision.aspx>

3. Protocol Expiration :

The Gangnam SEV IRB approval expiration date is listed above. As a courtesy, approximately 6 weeks prior to expiration of this approval, the IRB Office will send an e-mail reminding you to apply for continuing review. It is your responsibility to apply for continuing review and receive continuing approval for the duration of the study. Lapses in approval should be avoided to protect the safety and welfare of enrolled subjects.

4. Modifications & Amendments :

No changes are to be made to the approved protocol or the approved, stamped consent form without prior review and approval of the Gangnam SEV IRB. All changes(e.g., a change in procedure, number of subjects, personnel, study locations, new recruitment materials, study instruments, etc.) must be prospectively reviewed and approved by the IRB before they are implemented.