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Certificate of Approval

DSMC IRB
Keimyung University School of Medicine/Dongsan Hospital
Institutional Review Board
Tel :82-53-250-8020
FAX:82-53-252-9006
Dalsung-ro 56, Jung-Gu, Daegu, 700-712, Korea

THE FOLLOWINGS WERE APPORVED:

BOARD ACTION DATED: May.20.2010
STUDY NO :
IRB NO: 10-46

INVESTIGATOR: KYUNG SIK PARK M.D. Ph.D.

SPONSOR:
PROTOCOL NO:
TITLE: Immunohistochemical and immunofluorescence demonstration of enteric nerve, interstitial cells of Cajal, and fibroblast-like cell in the human gastric musculature in diabetes mellitus

☐ Initial review	■ Response for IRB comment	☐ Protocol modification
☐ Safety information	☐ Others	☐ Interim report
☐ End of study report	☐ Cancellation of protocol	☐ Final report

APPROVAL INCLUDES:

1. Protocol
2. ICF

APPROVAL EFFECTIVE PERIOD: May. 20.2010~ May. 19.2011
CONTINUING REVIEW REPORT INTERVAL: Annually

ALL CONDITIONS OF APPROVAL PREVIOUSLY ESTABLISHED BY KMUSM/DSMC IRB
FOR THIS RESEARCH PROJECT CONTINUE TO APPLY.
IF YOU HAVE ANY QUESTIONS, CONTACT DSMC IRB (Tel: 82-53-250-8020)

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This is to certify that the information contained herein is true and correct as reflected in the records of the DSMC Institutional Review Board. **We certify that DSMC IRB is in full compliance with Good Clinical Practice as defined under the Ministry of Food and Drug Safety(MFDS) regulations and the International Conference on Harmonisation (ICH) guidelines.**

Joonkee Lee — **Chairperson**

27/09/2016 — **Date**

ALL DSMC IRB APPROVED INVESTIGATORS MUST COMPLY WITH THE FOLLOWING:

1. Conduct the research as required by the protocol.
2. Use only the Consent Form bearing the DSMC IRB " IRB" stamp.
3. Provide non-Korean speaking subjects with a certified translation of the approved Consent Form in the subject's first language. The translated version must be approved by the DSMC IRB.
4. Obtain pre-approval from the DSMC IRB of any changes in the research activity (except when necessary to protect human subjects; immediately report to the DSMC IRB any such emergency changes for the protection of human subjects).
5. Report to the DSMC IRB the death, hospitalization, or serious illness of any study subject.
6. Promptly report to the DSMC IRB any new information that may adversely affect the safety of the subjects or the conduct of the trial.
7. Provide reports to the DSMC IRB concerning the progress of the research, when requested.
8. Obtain pre-approval of study advertisements from the DSMC IRB before use.
9. Conduct the informed consent process without coercion or undue influence, and provide the potential subject sufficient opportunity to consider whether or not to participate.

MFDS regulations require that the DSMC IRB conduct review of approved research. You will receive Continuing Review Report forms from the DSMC IRB. These reports must be returned even though your study may not have started.

DISTRIBUTION OF COPIES:

SPONSOR:

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CRO:

OTHER:

INSTITUTION:

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