

SNUDH Institutional Review Board

#101, Daehak-ro, Jongno-gu, Seoul, 03080, Rep. of KOREA, Tel: +82-2-2072-3147, FAX: +82-2-2072-3058

No. 20_COA_002

Certificate of Approval

Initial Approval date : Apr. 04th 2019

THE FOLLOWING WERE APPROVED:

BOARD ACTION DATE : Apr. 04th 2019

SNUDH_IRB PRO No. CRI19004

Principal Investigator : Prof. Ki-Tae Koo

Sponsor : Ministry of Trade, Industry and Energy

Study Title : Diagnosis of chronic periodontitis using biomarkers and oral bacteria in saliva

ALL CONDITIONS OF APPROVAL PREVIOUSLY ESTABLISHED BY SNUDH_IRB
FOR THIS RESEARCH PROJECT CONTINUE TO APPLY.

CONTINUING REVIEW REPORT INTERVAL: One year

IF YOU HAVE ANY QUESTIONS, CONTACT SNUDH_IRB AT 82-2-2072-3147

THIS IS TO CERTIFY THAT THE INFORMATION CONTAINED HEREIN IS TRUE AND CORRECT AS REFLECTED IN THE RECORDS OF THE SEOUL NATIONAL UNIVERSITY DENTAL HOSPITAL INSTITUTIONAL REVIEW BOARD (SNUDH_IRB). **WE CERTIFY THAT SNUDH_IRB IS IN FULL COMPLIANCE WITH BIOETHICS AND SAFETY ACT AS DEFINED UNDER THE REPUBLIC OF KOREA MINISTRY OF HEALTH AND WELFARE (MOHW) REGULATIONS AND THE INTERNATIONAL CONFERENCE ON HARMONISATION (ICH) GUIDELINES.**

Yang Jo Seol

Chairperson: **Prof. Yang-Jo Seol, D.D.S, Ph.D.**

Jul, 1, 2020

(Date)



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ALL SNUDH_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 SNUDH_IRB "APPROVED" 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 SNUDH_IRB;
4. Obtain pre-approval from the SNUDH_IRB of any changes in the research activity (except when necessary to protect human subjects; immediately report to the SNUDH_IRB any such emergency changes for the protection of human subjects;
5. Report to SNUDH_IRB the death, hospitalization, or serious illness of any study subject;
6. Promptly report to the SNUDH_IRB any new information that may adversely affect the safety of the subjects or the conduct of the trial;
7. Provide reports to the SNUDH_IRB concerning the progress of the research, when requested;
8. Obtain pre-approval of study advertisements from the SNUDH_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.

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

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