

NOTIFICATION LETTER

OF SMC IRB REVIEW SUMMARY

Investigator : Jong Man Kim, M.D., Ph.D.
Professor, Dept. of Transplantation Surgery, SMC

SMC IRB File No. : 2020-09-077

Protocol Title : Surgical treatment outcomes of primary hepatic sarcomas

Approval

Contingent approval

* Please append details or summarize reason(s) for determination below:

This retrospective study is to investigate surgical treatment outcomes (recurrence rate, survival rate, etc.) of primary hepatic sarcomas. It is considered less than minimal risks to subjects and meets the requirement set forth in the category 5 of Expedited Review Request Form. The IRB determination for this research is "**Approval**".

Acquiring participant's consent (1) seems to be realistically impossible and does not influence integrity of research (2) there would be no reasons that participant would deny providing his or her consent, even though consent is waived, research involves no more than minimal risk to the participants. Therefore, participant's consent can be waived.

SMC IRB approved this research for one year interval.

To continue the research after the expiration of IRB approval, the PI must submit "Research Progress Report (www.e-IRB.com → Log-in → e-IRB Main Bar → Download Forms → Reference Room)" for the continuing review after Aug. 07, 2021.

Date of Review : Oct. 08, 2020

Institutional Review Board
Samsung Medical Center
#81, Irwon-Ro, Gangnam-Gu, Seoul, Korea, 135-710



CONTENTS OF IRB REVIEW

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DOCUMENT REVIEWED

1. Research Protocol (Justification of ICF waiver included)
2. Case Report Form
3. Investigator Declaration Form

Issued by


Seil Jang
IRB Secretary for Administration
Samsung Medical Center

Jan. 13, 2021
Date



IRB Information

Institution : Samsung Medical Center (SMC)
Address : #81 Irwon-ro, Gangnam-gu, Seoul, Korea
IRB President : Prof. Hojoong Kim, M.D., Ph.D.
Dept. of Pulmonary and critical care medicine

SMC IRB abides by the guideline of ICH and GCP.

SMC IRB and the Institution are registered at Office for Human Research Protections (OHRP), U.S. Dept. of Health & Human Services, U.S.A..

Related SMC IRB registration and accreditation information is as follows.

* Identifier No. (U.S. OHRP)

Organization : IORG0000545 - Samsung Med Ctr
Assurance : FWA00002750
IRBs : IRB #1 : IRB00000877
IRB #2 : IRB00005489
IRB #3 : IRB00005490
IRB #4 : IRB00005491
IRB #5 : IRB00006642
IRB #6 : IRB00006643
IRB #7 : IRB00008480
IRB #8 : IRB00008481
IRB #9 : IRB00011389
IRB#10 : IRB00011390



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Samsung Medical Center has earned the accreditation from the Association for the Accreditation of Human Research Protection Programs, Inc. (AAHRPP) on June 16, 2006.

This research protocol is reviewed by expedited review process.

