

## Notice of Review of the Clinical Trial Proposal

IRB Review No.			IRB Approval No.		KHNMC 2022-11-017
Project Title	Optimal concentration of mesenchymal stem cell to promote fracture healing in a rat model of long bone fracture				
	Protocol No.		Version No.		
Principal Investigator		Myung Seo Kim (Assistant Professor, Department of Pediatric, Kyung Hee University Hospital at Gangdong)			
Co-Principal Investigators					
Sponsor		-			

We inform you of the result of the review of your proposal for Clinical Trials which was submitted on the 7th Nov, 2022.

Review date.	8th Nov, 2022		
Review purpose	Reviewing research plan		
Reviewed document list	1. Protocol version 1.0 2. Application for waiver of informed consent process 3. Curriculum Vitae 4. GCP Training Certificate 6. Investigator's Pledge 7. IRB application sheet 8. Application for IRB review exemption		
Review comment	It's allowed to exempt of review.		
Period of interim report	NA	Review result	Approval
The IRB respects the regulation of 'Korea Good Clinical Practice (KGCP)' and international relevant regulations. In case of an 'Adverse Event', the research PI should report to the IRB as soon as possible. IRB does not allow you to do the clinical research not based on the original plan without any approval of change except for the case of adverse event or minor change of administrative procedure such as the change of contact number of monitoring agent, researcher and emergency contact number.			

8th Nov, 2022

IRB Chair Kyung Hee University Hospital at Gangdong (signature)

