



MINISTRY OF RESEARCH, TECHNOLOGY AND HIGHER EDUCATION
ETHICS COMMITTEE OF MEDICAL RESEARCH
Faculty of Medicine Hasanuddin University
Hasanuddin University Hospital
dr. Wahidin Sudirohusodo Hospital, Makassar





Secretariat : 2nd Floor Integrated Laboratory Building Faculty of Medicine Hasanuddin University
 JL.PERINTIS KEMERDEKAAN KAMPUS TAMALANREA KM.10 MAKASSAR 90245.
 Contact Person: dr. Agussalim Bukhari, MMed, PhD, SpGK TELP. 081225704670 e-mail : agussalimbukhari@yahoo.com

APPROVAL LETTER

No : 515/UN4.6.4.5.31/PP36/2021

Date : 27 March 2015

This is certify that the following protocol and related documents have been granted by the IRB for implementation

IRB Protokol No	UH15010021	Sponsor Protocol No	
Principal Investigator	dr. Rosmiaty Z.A	Sponsor	
Title	Serum and Vitreous TGF 1 Levels With or Without Laser Panretinal Photocoagulation in Patients with Prolidratve Diabetic Retinopathy		
Protocol Version No	2	Version Date	25 March 2015
ICF Version No	2	Version Date	25 March 2015
Location	Hasanuddin University Hospital, Dr. Wahidin Sudirohusodo Hospital and Eye Centre orbita Clinic Makassar		
Type of review	<input type="checkbox"/> Exempted <input checked="" type="checkbox"/> Expedited <input type="checkbox"/> Full board	Duration of Approval From 27 March 2015 To 27 March 2016	Frequency of continuing review
IRB Chair	Name Prof.Dr .Suryani As'ad,MD, M.Sc,SpGK(K)	Signature 	
IRB Secretary	Name Agussalim Bukhari,MD,M.Med,PhD, SpGK(K)	Signature 	

Investigator Responsibilities after Approval :

- Submit document amendments for IRB approval before implementing them
- Submit SAE report to the IRB within 24 hours, to be completed within 7 days or as data is complete and SUSAR reports within 72 hours after PI/team is informed
- Submit progress report every 6 months for high-risk study, and yearly for low-risk study
- Submit final report after completion of protocol procedures at the study site
- Report protocol deviation / violation