

From,

Dr. Saravanabhavan Thangavel,

Scientist-E,

Centre for Stem Cell Research (a unit of InStem, Bengaluru),

Christian medical college campus,

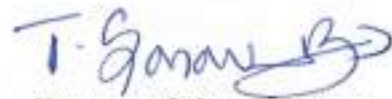
Vellore – 632002.

To whomever it may concern

The project submitted for the Sun Pharma Science Foundation Science Scholar Awards has received "Ethical Clearance" from the concerned authorities and the ethical approval for the same are attached along with this document.

Place: Vellore

Date : 30-08-2023



Signature of PhD supervisor

Dr. Saravanabhavan Thangavel, Ph.D.,
Assistant Investigator
Centre for Stem Cell Research (CSCR),
(A Unit of InStem, Bengaluru)
Christian Medical College Campus,
Bagayam, Vellore - 632 002, Tamil Nadu, India.



**OFFICE OF RESEARCH
INSTITUTIONAL REVIEW BOARD (IRB)
CHRISTIAN MEDICAL COLLEGE, VELLORE, INDIA**

CDSCO - Ethics Committee Registration No: ECR/326/INST/TN/2013, DHR Provisional Registration No: EC/NEW/INST/2020/818

Dr. George Thomas, B. Ortho., Ph.D.,
Chairperson, Ethics Committee

Dr. Prasanna Samuel, M.Sc., Ph.D.,
Secretary, Research Committee

Prof. Keith Gomez, MA (S.W.), M.Phil.,
Deputy Chairperson, Ethics Committee

Dr. Biju George, MD, DML,
Chairperson, Research Committee

Dr. Succena Alexander, MD, DML, FASN.,
Secretary, Ethics Committee, IRB
Additional Vice-Principal (Research)

Ref: IRB - A50 - 30.06.2021

July 29, 2021

Dr. Saravanabhavan Thangavel,
Department of CSCR,
Christian Medical College,
Vellore 632 004.

Ref: IRB Min No. 11807 (other) dated: 30.01.2019

Dear Dr. Saravanabhavan Thangavel,

The Institutional Review Board (Silver, Research and Ethics Committee) of the Christian Medical College, Vellore, reviewed and discussed the following amendments for the study titled "In vivo efficacy and safety studies of CSCR-ST04, the gene edited autologous hematopoietic stem cells for the gene therapy of β -hemoglobinopathies" on June 30, 2021.

(1) Information Sheet - for sickle cell disease patients

(2) Addition of Physicians:

Dr. Alok Srivastava,
Professor

Department of Haematology /
Head CSCR

Dr. Fouzia N.A
Associate Professor,
Department of Haematology

(3) Addition of Research Coordinators (Haematology):

Mr. Navien Kumar. R,
Mr. Christopher Benjamin

The following Institutional Review Board (Silver, Research & Ethics Committee) members were present at the meeting (Zoom) held on June 30, 2021 at 8.00 am in the New IRB Room, Christian Medical College, Bagayam, Vellore-632002.

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INSTITUTIONAL REVIEW BOARD (IRB)
CHRISTIAN MEDICAL COLLEGE, VELLORE, INDIA**

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Dr. George Thomas, D. Ortho., PhD,
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Dr. Prasanna Samuel, M.Sc., Ph.D.,
Secretary, Research Committee
Prof. Keith Gomez, MA (SW), MPhil,
Deputy Chairperson, Ethics Committee

Dr. Biju George, MD, DM,
Chairperson, Research Committee
Dr. Suceena Alexander, MD, DM, FASN,
Secretary, Ethics Committee, IRB
Additional Vice-Principal (Research)

ETHICS COMMITTEE MEMBERS			
Name	Qualification	Designation	Affiliation
Dr. George Thomas	D Ortho, PhD	Orthopaedic Surgeon, St. Isabella Hospital, Chennai, Chairperson, Ethics Committee, IRB, Chennai	External, Clinician
Mrs. Pattabiraman	BSc, DSSA	Social Worker, Vellore	External, Lay person
Dr. Suceena Alexander	MD, DM, FASN	Professor, Nephrology, Additional Vice Principal (Research), Member Secretary (Ethics Committee), IRB, CMC, Vellore.	Internal, Clinician
Rev. Joseph Devaraj	BSc, BD	Chaplaincy Department, CMC, Vellore	Internal, Social Scientist
Dr. Jayaprakash Muliylil	MBBS, MD, MPH, Dr PH (Epid), DMHC	Retired Professor, Vellore	External, Scientist & Epidemiologist
Mr. C. Sampath	BSc, BL	Advocate, Vellore	External, Legal Expert
Mr. Samuel Abraham	MA, PGDBA, PGDPM, M. Phil, BL	Sr. Legal Officer, Vellore	External Legal Expert
Mrs. Ilavarasi Jesudoss	M Sc (Nursing)	Deputy Nursing Superintendent, College of Nursing, CMC, Vellore	Internal, Nurse
Dr. Laxmi G	MBBS, MD,	Assistant Professor, Pharmacology, CMC, Vellore.	Internal, Pharmacologist
RESEARCH COMMITTEE MEMBERS			
Dr. Biju George	MBBS, MD,DM	Professor, Haematology,	Internal, Clinician
Dr. DJ. Christopher	DTCD, DNB, FRCP (Glasg), FCCP (USA)	Professor, Pulmonary Medicine, CMC, Vellore	Internal, Clinician
Dr. Sridhar Gibikote	DMRD, DNB	Professor, Radiology, CMC, Vellore	Internal, Clinician



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Dr. Biju George, MD., DM.,
Chairperson, Research Committee

Dr. Succena Alexander, MD., DM., FASN.,
Secretary, Ethics Committee, IRB
Additional Vice-Principal (Research)

Dr. Abhay Gahukamble	MS, D Ortho, DNB (Ortho)	Associate Professor, Paediatric Orthopaedics, CMC, Vellore	Internal, Clinician
Dr. Prasanna Samuel	M. Sc, PhD	Lecturer, Biostatistics, CMC, Vellore	Internal, Statistician
Dr. Thomas V Paul	MD, DNB, PhD	Professor, Endocrinology, CMC, Vellore	Internal, Clinician
Dr. RV. Shaji	M.Sc, PhD	Professor, Hematology, CMC, Vellore	Internal, Basic Medical Scientist
Dr. Sivakumar Balasubramanian	M. Tech, PhD	Professor of Bio-Engineering, CMC, Vellore	Internal, Basic Medical Scientist
Dr. Santhanam Sridhar	DCH, DNB	Professor, Neonatology, CMC, Vellore	Internal, Clinician
Dr. Nihal Thomas	MD, MNAMS, DNB(Endo), FRACP (Endo) FRCP(Edin) FRCP (Glasg)	Professor,	Internal, Clinician
Dr. Manoranjitham Sathyaseelan	MSc., PhD	Professor and Head of Psychiatric Nursing, CMC, Vellore	Internal Nurse
Dr. Sujith J Chandy	MHBS., MD., PhD., FRCP (E)	Professor, Clinical Pharmacology, CMC, Vellore	Internal, Pharmacologist
Dr. Jacob John	MD, MPH	Professor, Community Medicine, CMC, Vellore	Internal, Clinician
Dr. Ajith Sivadasan	MD, DM	Professor, Neurological Sciences, CMC, Vellore	Internal, Clinician

We approve the above amendment as presented.

Yours sincerely,

Dr. Succena Alexander
Secretary (Ethics Committee)
Institutional Review Board.

Dr. Succena Alexander, MD, DM, FASN.
Secretary - (Ethics Committee)
Institutional Review Board
Christian Medical College,
Vellore - 632 002, Tamil Nadu, India.

IRB Min No. 11807 (other) dated: 30.01.2019

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INSTITUTIONAL ANIMAL ETHICS COMMITTEE
CHRISTIAN MEDICAL COLLEGE, VELLORE

Dr. Anna B. Pulimood
Chairperson

Dr. Joe Varghese
Member Secretary

Date: 06/03/2019

Dr. Saravanabhavan Thangavel,
Assistant Investigator,
Centre for Stem Cell Research,
CMC, Vellore.

Sub: Proposal for IAEC approval (NEW) - "In vivo efficacy and safety studies of CSCR-ST04, the gene-edited autologous hematopoietic stem cells, for the gene therapy of β -hemoglobinopathies."

Ref: IAEC no: 1/2019

Dear Dr. Saravanabhavan Thangavel,

Your application to the Institutional Animal Ethics Committee (IAEC) titled "In vivo efficacy and safety studies of CSCR-ST04, the gene edited autologous hematopoietic stem cells for the gene therapy of β -hemoglobinopathies." has been reviewed by the IAEC at the meeting held on 02/03/2019.

The following members of the IAEC were present at the meeting:

1. Dr. A. Yasotha, CPCSEA Main Nominee
2. Dr. D. Sivaraman, Scientist from outside the institute
3. Dr. B.R. Senthilkumar, Socially aware member
4. Dr. Christhunesa Christudass, Scientist
5. Dr. K. Imayrasi, Veterinarian
6. Dr. Joe Varghese, Secretary

After discussion, 128 (one hundred and twenty-eight) NBSG-W mice have been approved for a period of 1 year.

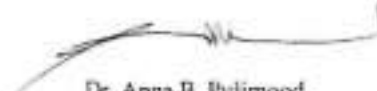
The IAEC approval number for the study is 1/2019

You are required to maintain all records as per Form D, ensure humane treatment of animals and submit final report to the IAEC.

With best wishes,

Yours sincerely,


Dr. A. Yasotha
CPCSEA Main Nominee


Dr. Anna B. Pulimood
Chairperson


Dr. Joe Varghese
Member Secretary

