

BAGAYAM, VELLORE 632 002, INDIA

Dr. George Thomas, D Ortho, PhD Chairperson, Ethics Committee

Dr. B. Antonisamy, M.Sc, PhD, FAMS, FRCS Secretary, Research Committee

Prof. Keith Gomez, BSc, MA (S.W), M.Phil Deputy Chairperson, Ethics Committee Dr. Alfred Job Daniel, D Ortho, MS Ortho, DNB Ortho Chairperson, Research Committee & Principal

Dr. Nihal Thomas
MD, MNAMS, DNB(Endo), FRACP(Endo), FRCP(EDIN)
Deputy Chairperson
Secretary, Ethics Committee, IRB
Additional Vice Principal (Research)

February 5, 2013

Ms. Serin Anna Isaac Final year BPT student Department of Physical Rehabilitation and Medicine Christian Medical College Vellore 632 002

Sub:

FLUID Research grant project NEW PROPOSAL:

Mirror therapy and transcutaneous electrical nerves stimulation for management of phantom limb pain in amputees – a single blinded randomized controlled trial. Ms. Serin Anna Isaac, Final year BPT student, PMR, Dr. George Tharion, PMR,

Ms. Merlyn, Mr. Jebaraj Fletcher, Ms. Merlyn, PMR, Dr. Rohit Bhide,

Ms. Rajalakshmi, Mr. Andrew Babu, PMR.

Ref: IRB Min. No. 8132 dated 19.12.2012

Dear Ms. Serin Anna Isaac,

I enclose the following documents:-

- 1. Institutional Review Board approval
- 2. Agreement

Could you please sign the agreement and send it to Dr. Nihal Thomas, Addl. Vice Principal (Research), so that the grant money can be released.

With best wishes,

Dr. Nihal Thomas

Secretary (Ethics Committee)

Institutional Review Board

Dr Nihal Thomas

MBBS MD MNAMS DNB (Endo) FRACP(Endo) FRCP(Edin)
Secretary (Ethics Committee)

Institutional Review Board



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Ref: IRB Min. No. 8132 dated 19.12.2012

Dear Ms. Serin Anna Isaac,

The Institutional Review Board (Silver, Research and Ethics Committee) of the Christian Medical College, Vellore, reviewed and discussed your project entitled "Mirror therapy and transcutaneous electrical nerves stimulation for management of phantom limb pain in amputees – A Single Blinded Randomized Controlled Trial." on December 19, 2012.

The Committees reviewed the following documents:

1. Format for application to IRB submission

2. Information Sheet and Consent Form (English, Tamil and Hindi)

3. Cvs of Drs. Ms. Serin Anna Isaac, George Tharion, Ms. Merlyn, Ms. Merlyn, Ms. Rajalakshmi, Mr. Andrew Babu, PMR.

4. A CD containing documents 1 - 3



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The following Institutional Review Board (Silver, Research & Ethics Committee) members were present at the meeting held on December 19, 2012 in the CREST/SACN Conference Room, Christian Medical College, Bagayam, Vellore 632002.

Name	Qualification	Designation	Other Affiliations
Dr. George Thomas	MBBS, D Ortho, PhD	Chairperson (IRB) & Orthopaedic Surgeon, St.Isabel Hospital, Chennai & Former Editor, Indian Journal of Medical Ethics	External, Clinician
Dr. Poonkuzhali	MSC, PhD	Professor, Haematology,CMC	Internal, Basic Medical Scientist
Dr. Biju George	MBBS, MD, DM	Professor, Haematology, CMC	Internal, Clinician
Rev. Arul Dhas	MSc, BD, DPC, PhD(Edin)	Chaplain, CMC	Internal, Social Scientist
Dr. Denny Fleming	BSc (Hons), PhD	Honorary Professor, Clinical Pharmacology, CMC.	Internal, Pharmacologist
Dr. L. Jeyaseelan	MSc, PhD, FRSS	Professor Dept. of Biostatistics, CMC	Internal, Statistician
Dr. Vinod Joseph Abraham	MBBS, MD, MPH	Professor, Community Medicine, CMC	Internal, Clinician
Dr. Sukriya Nayak	MBBS, MS	Professor, General Surgery, CMC	Internal, Clinician
Dr. Molly Jacob	MBBS, MD, PhD	Professor, Biochemistry, CMC	Internal, Clinician



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Mrs. Pattabiraman	BSc, DSSA	Social Worker, Vellore	External,
			Lay person
Mr. Sampath	BSc, BL	Advocate	External,
N. T. 11 1 1	DI	D. C. LY	Legal Expert
Mr. Harikrishnan	BL	Retired Lawyer,	External,
		Vellore	Legal Expert
Mrs. Mary Johnson	M.Sc	Professor, Child Health	Internal,
, ,		Nursing, CMC.	Nurse
Dr. DJ Christopher	BSc, MBBS, DTCD,	Professor, Pulmonary	Internal,
*	DNB, FCCP	Medicine, CMC	Clinician
Dr. Suresh Devasahayam	BE, MS, PhD	Professor,	Internal
		Bioengineering, CMC	
Dr. Jayaprakash Muliyil	BSC, MBBS, MD,	Retired Professor,	External
	MPH, DrPH(Epid),	Vellore	
	DMHC		
Dr. P. Zachariah	MBBS, PhD	Retired Professor	External
Mrs. Selva Titus Chacko	MSc	Professor, Medical	Internal,
e .	h	Surgical	Nurse
		Nursing, CMC	1
Prof. Keith Gomez	BSc, MA (S.W),	Deputy Chairperson	External,
	M. Phil (Psychiatry	(IRB) & Students'	Social Scientist
	Social Work)	Counsellor, Loyola	1 15
	Social Work)	College, Chennai	
D. Antoniosano	M.Sc PhD FAMS, FRCS	Professor & Head	Internal,
Dr. Antonisamy	W.SC FIID FAMS, FRCS	Dept. of Biostatistics &	Statistician
	1	1	Statistician
		Secretary IRB (EC),	
D. Mil. 175	MD MOLAMO DNID/E - 1-1	CMC	Internal,
Dr. Nihal Thomas	MD MNAMS DNB(Endo)	Secretary IRB	Clinician
	FRACP(Endo) FRCP(Edin)	(EC)& Dy.	Cimician
		Chairperson (IRB),	
		Professor of	
		Endocrinology	
		& Addl. Vice Principal	
× 2		(Research), CMC.	



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We approve the project to be conducted as presented.

The Institutional Ethics Committee expects to be informed about the progress of the project, any serious adverse events occurring in the course of the project, any changes in the protocol and the patient information/informed consent. And on completion of the study you are expected to submit a copy of the final report.

A sum of Rs. 14,300/- (Rupees Fourteen Thousand Three Hundred only) will be granted for Six Months

The study has to be registered under Clinical Trial Registry India (CTRI) http://ctri.nic.in

Yours sincerely

Dr. Nihal Thomas

Secretary (Ethics Committee)

Institutional Review Board

Dr Nihal Thomas

MBBS MD MNAMS DNB (Endo) FRACP(Endo) FRCP(Edin)

Secretary (Ethics Committee)

Institutional Review Board

CC: Dr. George Tharion, Department of Physical Rehabilitation and Medicine.