Jawatankuasa Etika Penyelidikan (Manusia), JEPeM-USM is in compliance with the Declaration of Helsinki, International Conference on Harmonization (ICH) Guidelines, Good Clinical Practice (GCP) Standards, Council for International Organizations of Medical Sciences (CIOMS) Guidelines, World Health Organization (WHO) Standards and Operational Guidance for Ethics Review of Health-Related Research and Surveying and Evaluating Ethical Review Practices, EC/IRB Standard Operating Procedures (SOPs), and Local Regulations and Standards in Ethical Review.

Thank you.

"ENSURING A SUSTAINABLE TOMORROW"

Very truly yours,

PROF. DR. HANS AMIN VAN ROSTENBERGHE

Chairperson

Jawatankuasa Etika Penyelidikan (Manusia) JEPeM

Universiti Sains Malaysia



Jawatankuasa Etika Penyelidikan Manusia USM (JEPeM) Human Research Ethics Committee USM (HREC)

Date of meeting Venue

: 24 June 2015

: Meeting Room, Centre for Research Initiatives,
Clinical and Health Sciences, USM Kampus Kesihatan.
: 9.00 a.m – 3.30 p.m
: 310

Meeting No

Universiti Sains Malaysia

Universiti Sains Malaysia
Kampus Kesihatan,
16150 Kubang Kerian,
Kelantan. Malaysia.
T: 609 - 767 3000 samb. 2354/2362
F: 609 - 767 2351
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www.jepem.kk.usm.my

Members of Committee of the Jawatankuasa Etika Penyelidikan (Manusia), JEPeM Universiti Sains Malaysia who reviewed the protocol/documents are as follows:

Member (Title and Name) Chairperson: Professor Dr. Hans Amin Van Rostenberghe Deputy Chairperson: Professor Dr. Mohd Shukri Othman		Occupation (Designation)	Male/ Female (M/F)	Tick (✓) if present when above items were reviewed
		Chairperson of Jawatankuasa Etika Penyelidikan (Manusia), JEPeM USM Deputy Chairperson of Jawatankuasa Etika Penyelidikan (Manusia), JEPeM USM	M	(Chairperson) (Deputy Chairperson)
Membe	ers:			
1.	Dato' Haji Ellias Zakaria	Lecturer, School of Humanities	М	1
2.	Dr. Hjh. Selasawati Haji Ghazali	Deputy Director (Medical), Hospital Raja Perempuan Zainab II, Kota Bharu, Kelantan	F	1
3.	Professor Dr. Narazah Mohd Yusoff	Lecturer, Advanced Medical and Dental	F	1
4.	Professor Dr. Zeehaida Mohamed	Lecturer, School of Medical Sciences	F	1
5.	Associate Professor Oleksandr Krasilshchikov	Lecturer, School of Health Sciences	М	1
6.	Associate Professor Dr. Lee Yeong Yeh	Lecturer, School of Medical Sciences	М	7
7.	Associate Professor Dr. Nor Azwany Yaacob	Lecturer, School of Medical Sciences	F	1
8.	Associate Professor Dr. Suzina Sheikh Abd Hamid	Lecturer, School of Medical Sciences	F	1
9.	Associate Professor Siti Hawa Ali	Lecturer, School of Health Sciences	F	1
10.	Dr. Azlan Husin	Lecturer, School of Medical Sciences	М	1
11.	Dr. Win Mar @ Salmah	Lecturer, School of Medical Sciences	F	1
12.	Mr. Harry Mulder	Community Representative	М	1
13.	Mrs. Zawiah Abu Bakar	Community Representative	F	-

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PROFESSOR DR. HANS AMIN VAN ROSTENBERGHE
Chairnerson

Chairperson Jawatankuasa Etika Penyelidikan (Manusia), JEPeM Universiti Sains Malaysia



Jawatankuasa Etika Penyelidikan Manusia USM (JEPeM) Human Research Ethics Committee USM (HREC)

Universiti Sains Malaysia

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Kampus Kesihatan, 16150 Kubang Kerian, Kelantan. Malaysia. T: 609 - 767 3000 samb. 2354/2362

27th October 2015

Miss Nurul Shafira Adi
Department of Pediatric
School of Medical Sciences

Universiti Sains Malaysia 16150 Kubang Kerian, Kelantan.

10130 Rubang Kenan, Kelantai

JEPeM Code : USM/JEPeM/15040130
Protocol Title : The Effects of Guided Imagery and Relaxation on Children with Cancer: A

Randomized Controlled Trial.

Dear Dr.,

We wish to inform you that your study protocol has been reviewed and is hereby granted approval for implementation by the Jawatankuasa Etika Penyelidikan Manusia Universiti Sains Malaysia (JEPeM-USM). Your study has been assigned study protocol code **USM/JEPeM/15040130**, which should be used for all communication to the JEPeM-USM related to this study. This ethical clearance is valid from **November 2015** until **October 2016**.

The following documents have been approved for use in the study.

1. Research Proposal

In addition to the abovementioned documents, the following technical document was included in the review on which this approval was based:

- 1. Patient Information Sheet and Consent Form (Malay version)
- 2. Data Collection Sheet (Maklumat Am [Kanak-Kanak/Pesakit])

Attached document is the list of members of JEPeM-USM present during the full board meeting reviewing your protocol.

While the study is in progress, we request you to submit to us the following documents:

- Application for renewal of ethical approval 60 days before the expiration date of this
 approval through submission of JEPeM-USM FORM 3(B) 2014: Continuing Review
 Application Form. Subsequently this need to be done yearly as long as the research goes on.
- Any changes in the protocol, especially those that may adversely affect the safety of the participants during the conduct of the trial including changes in personnel, must be submitted or reported using JEPeM-USM FORM 3(A) 2014: Study Protocol Amendment Submission Form.
- Revisions in the informed consent form using the JEPeM-USM FORM 3(A) 2014: Study Protocol Amendment Submission Form.
- Reports of adverse events including from other study sites (national, international) using the JEPeM-USM FORM 3(G) 2014: Adverse Events Report.
- Notice of early termination of the study and reasons for such using JEPeM-USM FORM 3(E) 2014.
- 6. Any event which may have ethical significance.
- 7. Any information which is needed by the JEPeM-USM to do ongoing review.
- Notice of time of completion of the study using JEPeM-USM FORM 3(C) 2014: Final Report Form.

Please note that forms may be downloaded from the JEPeM-USM website: www.jepem.kk.usm.my