

**STUDY ON LUMBAR EPIDURAL SINGLE VERSUS
INTERMITTENT INJECTION OF 0.5% BUPIVACAINE
UPON ONSET, LEVEL OF BLOCKADE &
HAEMODYNAMICS IN ORTHOPAEDIC ELECTIVE
LOWER LIMB SURGERIES**

BY

DR TING YUNG CHUEN

**DISSERTATION SUBMITTED IN PARTIAL FULFILMENT
OF THE REQUIREMENTS FOR THE DEGREE OF MASTER
OF MEDICINE (ANAESTHESIOLOGY)**



UNIVERSITI SAINS MALAYSIA

JUNE 2016

ACKNOWLEDGEMENT

I would like to express my greatest gratitude to my supervisor Professor Dr. Nik Abdullah Bin Nik Mohamad, co-supervisor Dr. Wan Nazaruddin Bin Wan Hassan for giving their support & guidance in the progress of conducting this study. They have being very helpful & supportive in providing their inputs and expert opinions so as to enable me to improve as well as complete this study successfully.

It also has been a great pleasure to get assistance & guidance from the lecturers, fellow colleagues and supporting staffs in the Department of Anaesthesiology, School of Medical Science to make this study successful. Therefore I wish to take this opportunity to thank them as well.

Special thanks to Associate Professor Dr. Wan Mohd. Zahiruddin Wan Mohammad from Community and Family Case Study (CFCS) Unit who had given his expert opinions regarding statistics & analysis for my research.

Not to forget my lovely wife, Mariana who had been going through the rains & storms with me throughout the efforts to do this project.

Last but not least, to my family for their support and understanding that without them, the completion of this research was impossible.

TABLE OF CONTENTS

Acknowledgement	ii
Table of Contents	iii
Lists of Tables	vi
Lists of Figures	vii
Abbreviations	viii
Chapter 1: Introduction	1
Chapter 2: Study Protocol	4
2.1 Initial Review of Proposed Ethical Application	5
2.2 Letter of Invitation for Interview by Ethics Committee	7
2.3 Letter of Approval with Correction of Proposed Ethical Application	8
2.4 Letter of Granted Approval for Implementation of Study Protocol	10
2.5 JEPeM-USM/FORM 2(A)2014: REVIEW CHECKLIST	13
2.6 JEPeM-USM FORM 2(B) 2014: REGISTRATION AND APPLICATION FORM	15

2.7 JEPeM-USM FORM 2(C)(ii) 2014: STUDY PROTOCOL ASSESSMENT FORM FOR NON INTERVENTIONAL STUDY	23
2.8 JEPeM-USM FORM 2(d)(ii) 2014 INFORMED CONSENT ASSESSMENT FORM FOR NON INTERVENTIONAL STUDY	26
2.9 Research Proposal	27
Chapter 3: Selected Journal Format	45
Chapter 4: Body	
4.1 Title Page	64
4.2 Abstract	66
4.3 Introduction	67
4.4 Methodology	68
4.5 Results	76
4.6 Discussion	84
4.7 References	87

Chapter 5 : Appendices

5.1 Consent Form (English Version)	91
5.2 Attachment A	96
5.3 Attachment B	98
5.4 Consent Form (Malay Version)	100
5.5 Lampiran S	105
5.6 Lampiran P	107
5.7 Data Collection Form	109
5.8 Curriculum Vitae	113
5.9 Good Clinical Practice Certificate	114

LIST OF TABLES

	Page
Table 1 Demographic profiles of the participants in the study.	77
Table 2 ASA Classification of the participants in the study.	77
Table 3 Changes of MAP for both groups.	78
Table 4 Results of statistical analysis of MAP values of the 2 groups.	79
Table 5 Changes of heart rate for both groups.	80
Table 6 Results of statistical analysis of heart rate values of the 2 groups.	80
Table 7 Results of statistical analysis of time taken to achieve T10 sensory level.	81
Table 8 Results of statistical analysis of changes in sensory block of 2 groups.	81
Table 9 Results of statistical analysis of time taken to achieve Bromage score 1.	82
Table 10 Results of statistical analysis of changes in motor block of 2 groups.	83
Table 11 Table 4.11 Bromage score at the time of T10 sensory blockade is achieved.	83

LIST OF FIGURES

		Page
Figure 1	Changes in MAP over 30 minutes of measurement.	78
Figure 2	Changes in heart rate over 30 minutes of measurement.	79
Figure 3	Changes in sensory block as marked by the spread of dermatome level.	81
Figure 4	Changes in motor blockade as graded by Bromage score.	82

ABBREVIATIONS

ASA	American Society of Anesthesiologist
ANOVA	Analysis of Variance
BMI	Body Mass Index
BP	Blood Pressure
CSF	Cerebrospinal Fluid
ECG	Electrocardiogram
IV	Intravenous
LA	Local Anaesthetics
HUSM	Hospital Universiti Sains Malaysia
MAP	Mean Arterial Pressure
SpO2	Oxygen Saturation

CHAPTER 1

INTRODUCTION

Epidural anaesthesia, a form of regional anaesthesia is not completely associated with lesser adverse effects when compared with general anaesthesia. Unfavourable events potentially can happen from various aspects whether technical, monitoring or late interventions of the side effects and complications.¹¹

The common physiological effects on cardiovascular system are hypotension and bradycardia, which is proportional to the extent of sympathetic nerve blockade. Epidural block-induced sympathectomy occurs at same level of the sensory dermatomes at anterior nerve root fibers autonomic outflow.^{11, 20} The T5-L1 sympathetic fiber blockade increases venous capacitance and decreases systemic vascular resistance, leading to pooling of blood & reduced venous return to the heart.^{1, 16, 20, 25} The resulting hypotensive “functional” hypovolaemia is predominantly contributed by venodilation.¹⁵ Arterial vasodilation significantly contributes towards hypotension when compensatory vasoconstriction is compromised by high sympathetic blockade.

Bradycardia can be due to negative chronotropic effects of high sympathetic blockade of cardioaccelerator fibers of T1-4 or decreased outflow from intrinsic chronotropic stretch receptors in right atrium and great veins as the result of reduced venous return.^{11, 20}

Epidural-induced sympathetic blockade is reflected by changes in haemodynamic parameters such as blood pressure, heart rate or cardiac output in clinical studies.²⁶ There

are affirmative facts that level of analgesia and the cardiovascular effects are related via studies of the distribution of epidural neural blockade which defining the extent of autonomic, sensory & motor blockade. In addition, sympathetic blockade patterns tend to follow those of sensory due to small differential block zones.^{6, 25-26}

Spread of the blockade from epidural anaesthesia is variable among subjects and can be attributed by multiple factors which remain as interesting matters of debate.¹ They can be due to patient's factors (e.g. age, body weight), pharmacological factors (e.g. dose, type, use of adjuncts to local anaesthetics) or anaesthetic technical factors (position, rapid injection).^{1, 4-5, 7, 10, 11-12, 14, 18, 20, 23}

Hypotension and bradycardia are the consequences of epidural anaesthesia which are viewed as the unfavourable adverse effects in clinical practice.²¹ Nevertheless this can be minimized and altered through modifications in usage of local anaesthetics & anaesthetic techniques.

Speed of injection has been the factor of concerned as rapid injection can increase the onset of the blockade.¹ However, to our knowledge, there is no conclusive study which has demonstrated the effects of injection rate of local anaesthetics upon haemodynamic changes.²⁰ The current available studies of epidural anaesthesia are focused on the onset & level of anaesthesia, sensory and motor blockade with wide range of injection rate of 0.06-1.2 ml/s.^{1-3, 8, 11, 15-17, 20, 22-24} The significance of the rate upon blood pressure and heart rate is controversial due to variations in the patient's position, technical aspects of epidural as well as the use of different types of local anaesthetics along with their volumes, concentrations and the use of adjuncts. The aims of this study are to assess the lumbar

epidural injection rate in relation to its effect upon onset and level of blockade, blood pressure and heart rate.

CHAPTER 2

STUDY PROTOCOL

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CHAPTER 2.1 INITIAL REVIEW OF PROPOSED ETHICAL APPROVAL APPLICATION



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

15th November 2015

SEGERA

Dr. Ting Yung Chuen,
Department of Anesthesiology,
School of Medical Sciences,
USM Health Campus.

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

JEPeM Code : USM/JEPeM/15070244

Protocol Title : Study on Lumbar Epidural Single vs. Intermittent Injection of 0.5% Bupivacaine upon Onset, Level of Blockade & Hemodynamics in Elective Orthopedic Elective Lower Limb Surgeries.

Dear Dr,

We wish to inform you that the Jawatankuasa Etika Penyelidikan Manusia, Universiti Sains Malaysia (JEPeM-USM) reviewed your proposed ethical application during its regular meeting on 25th October 2015 (Meeting No.319). Your study has been assigned study protocol code USM/JEPeM/15070244 which should be used for all communication to the JEPeM related to this study.

As a result of the review, the decision of the committee is **PENDING**. This ethical approval application will be presented in the next meeting scheduled on 18th November 2015.

"ENSURING A SUSTAINABLE TOMORROW"

Very truly yours,

Mohd Bazlan Hafidz Mukrim
Secretary
On behalf of Chairperson
Jawatankuasa Etika Penyelidikan (Manusia) USM



6.1.2.1 Study Protocols for Initial Review (PI NOT TO BE INVITED)

6.1.2.1.3

JEPeM Code	USM/JEPeM/15070244
Study Protocol Submission Date	06/07/2015
Study Protocol Title	Study on Lumbar Epidural Single vs. Intermittent Injection of 0.5% Bupivacaine upon Onset, Level of Blockade & Hemodynamics in Elective Orthopedic Elective Lower Limb Surgeries
Principal investigator	Dr. Ting Yung Chuen
Type of review	Full Board Review
Assessment of scientific soundness and assessment of ethical issues	Committee members have decided and agreed to call the PI (in the next meeting scheduled on 18 th November) to present the research application due to absence of the Primary Reviewers to report the feedback of the review to the committee.
Conclusion and recommendations	This ethical approval application will be presented in the next meeting scheduled on 18th November 2015.
Action taken	Decision: Pending.

CHAPTER 2.2 LETTER OF INVITATION FOR INTERVIEW BY ETHICS COMMITTEE



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

03th November 2015

Dr Ting Yung Chuen
Jabatan Anesthesiology
Pusat Pengajian Sains Perubatan
USM Kampus Kesihatan

Universiti Sains Malaysia

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

JEPeM-USM Code: USM/JEPEM/15070244

Protocol Title: Study of Lumbar Epidural Single vs Intermittent Injection of 0.5% Bupivacaine Upon Onset, Level of Blockade & Hemodynamics in Elective Orthopedic Elective Lower Limb Surgeries

Dear Dr :

We wish to inform you that the Jawatankuasa Etika Penyelidikan (Manusia) JEPeM -USM has reviewed your submission received on 06th Julai 2015 . Upon review by the primary reviewers, we found issues requiring your clarifications.

In this regard, our primary reviewer's requests for a clarificatory interview with you during the next deliberated review meeting on **18th November 2015** from 9.00 am till 2.00 pm at the **Meeting Room, Centre for Research Initiatives, USM Health Campus. Your session will be start at 10.45 am.**

Should you have any questions or clarifications regarding the abovementioned matters, please contact the undersigned through the JEPeM-USM Secretariat at 09-7672362/097672354 or jepem@usm.my.

The JEPeM-USM looks forward to your immediate response and action.

Thank you.




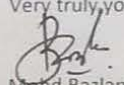

"ENSURING A SUSTAINABLE TOMORROW"

Very truly yours,

MOHD BAZLAN HAFIDZ MUKRIM

Secretary
Jawatankuasa Etika Penyelidikan (Manusia) JEPeM
Universiti Sains Malaysia

CHAPTER 2.3 LETTER OF APPROVAL WITH CORRECTION OF PROPOSED ETHICAL APPLICATION



 	Jawatankuasa Etika Penyelidikan Manusia USM (JEPeM) Human Research Ethics Committee USM (HREC)	
6 th December 2015		Universiti Sains Malaysia Kampus Kesihatan, 16150 Kubang Kerian, Kelantan, Malaysia. T 099 - 767 3000 samb 2354/2352 F 099 - 767 2351 E: jepem@usm.my www.jepem.lk.usm.my
 Dr. Ting Yung Chuen, Department of Anesthesiology, School of Medical Sciences, USM Health Campus.		
 JEPeM Code : USM/JEPeM/15070244 Protocol Title : Study on Lumbar Epidural Single vs. Intermittent Injection of 0.5% Bupivacaine upon Onset, Level of Blockade & Hemodynamics in Elective Orthopedic Elective Lower Limb Surgeries.		
Dear Dr,		
<p>We wish to inform you that the Jawatankuasa Etika Penyelidikan Manusia, Universiti Sains Malaysia (JEPeM-USM) reviewed your proposed ethical application during its regular meeting on 18th November 2015 (Meeting No.320). Your study has been assigned study protocol code USM/JEPeM/15070244 which should be used for all communication to the JEPeM related to this study.</p>		
<p>As a result of the review, the decision of the committee is APPROVED WITH CORRECTION. Recommended revisions and/or clarifications are summarized in the 'conclusion and recommendations' part in the provided attachment.</p>		
Please note that revisions requested by the JEPeM-USM should:		
<ol style="list-style-type: none">1. Be integrated into a revised STUDY PROTOCOL and related documents in one printed copy2. Be SUMMARIZED in a cover letter indicating in which page of the revised study protocol the respective revision may be found;3. Modified part should be <u>underlined</u> and bold.		
<p>Please note that the cut-off date for submission of revised study protocol is on 18 January 2016. Also, please note that resubmissions can only be accepted within 30 working days from the date of this letter. Failure to respond within 30 working days from the date of this letter will inactivate the application and study protocol will be archived. Subsequent submissions will be processed as initial review. Should you have any questions or clarifications regarding the abovementioned recommendations, please contact the undersigned through the JEPeM Secretariat at 09 7672352/2354 or jepem@usm.my</p>		
The JEPeM-USM looks forward to your immediate response and action.		
"ENSURING A SUSTAINABLE TOMORROW"		
Very truly yours,		
		
Mohd Bazlan Hafidz Mukrim Secretary On behalf of Chairperson Jawatankuasa Etika Penyelidikan (Manusia) USM		
		
<hr/>		
<USM/JEPeM/15070244> Dr. Ting Yung Chuen		Page 1

6.1.2.2 Study Protocols for Initial Review (PI TO BE INVITED)

6.1.2.2.6

JEPeM Code	USM/JEPeM/15070244
Study Protocol Submission Date	06/07/2015
Study Protocol Title	Study on Lumbar Epidural Single vs. Intermittent Injection of 0.5% Bupivacaine upon Onset, Level of Blockade & Hemodynamics in Elective Orthopedic Elective Lower Limb Surgeries.
Principal investigator	Dr. Ting Yung Chuen
Type of review	Full Board Review
Conclusion and recommendations	<p>This ethical approval application will be approved only after the researcher have submit all the correction/clarification as listed:</p> <ol style="list-style-type: none"> 1. Subject recruitment/Specimen collection and processing – Detailed out in the research proposal. 2. Serious Adverse Events (SAE) – Need to be mentioned and documented in the research proposal. 3. Risks – Need to mention clearly in the research proposal. What is the extra risk if subjects taking part in this study? 4. Patient/Participant Information Sheet and Consent Form (PIS and CF) (including translation) – a. Make the PIS and CF more simplify to be understandable to the laymen. 5. b. Risks – need to modify the “Risks” part. Need an introductory sentence. What is the extra risk if subjects taking part in this study? 6. c. Leave out the sentence regarding compensation part for the subjects in this study (in the PIS and CF).
Action taken	Decision: Approved with correction. All the submitted correction will be review again at the level of Secretary and Chairperson.

CHAPTER 2.4 LETTER OF GRANTED APPROVAL FOR IMPLEMENTATION OF STUDY PROTOCOL

 	Jawatankuasa Etika Penyelidikan Manusia USM (JEPeM) Human Research Ethics Committee USM (HREC)
6th January 2016 <i>6/1/2016</i> Dr. Ting Yung Chuen Department of Anesthesiology School of Medical Sciences Universiti Sains Malaysia 16150 Kubang Kerian, Kelantan.	Universiti Sains Malaysia Kampus Kesihatan, 16150 Kubang Kerian, Kelantan, Malaysia. T: 609 - 767 3000 <i>samb. 2354/2392</i> F: 609 - 767 2351 E: <i>jepem@usm.my</i> <i>www.jepem.kk.usm.my</i>
JEPeM Code : USM/JEPeM/15070244 Protocol Title : Study on Lumbar Epidural Single vs. Intermittent Injection of 0.5% Bupivacaine upon Onset, Level of Blockade & Hemodynamics in Elective Orthopedic Elective Lower Limb Surgeries.	
Dear Dr.,	
<p>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/15070244, which should be used for all communication to the JEPeM-USM related to this study. This ethical clearance is valid from January 2016 until December 2016.</p>	
<p>The following documents have been approved for use in the study.</p> <ol style="list-style-type: none">1. Research Proposal	
<p>In addition to the abovementioned documents, the following technical document was included in the review on which this approval was based:</p> <ol style="list-style-type: none">1. Patient Information Sheet and Consent Form (English version)2. Patient Information Sheet and Consent Form (Malay version)3. Patient Data Form	
<p>Attached document is the list of members of JEPeM-USM present during the full board meeting reviewing your protocol.</p>	
<p>While the study is in progress, we request you to submit to us the following documents:</p> <ol style="list-style-type: none">1. 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.2. 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.3. Revisions in the informed consent form using the JEPeM-USM FORM 3(A) 2014: Study Protocol Amendment Submission Form.4. Reports of adverse events including from other study sites (national, international) using the JEPeM-USM FORM 3(G) 2014: Adverse Events Report.5. 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.8. Notice of time of completion of the study using JEPeM-USM FORM 3(C) 2014: Final Report Form.	
<hr/>	
<div style="display: flex; justify-content: space-between;"><Approval><Dr. Ting Yung Chuen><USM/JEPeM/15070244Page 1 of 2</div>	

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

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

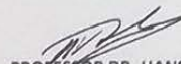
Date of meeting : 18 November 2015
Venue : Meeting Room, Centre for Research Initiatives,
Clinical and Health Sciences, USM Kampus Kesihatan.
Time : 9.00 a.m – 2.00 p.m
Meeting No : 320

Universiti Sains Malaysia
Kampus Kesihatan,
10150 Kubang Kerian,
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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)	Occupation (Designation)	Male/ Female (M/F)	Tick (✓) if present when above items, were reviewed
Chairperson : Professor Dr. Hans Amin Van Rostenberghe	Chairperson of Jawatankuasa Etika Penyelidikan (Manusia), JEPeM USM	M	✓ (Chairperson)
Secretary: Mr. Mohd Bazlan Hafidz Mukrim	Research Officer	M	✓
Members :			
1. Professor Dr. Nik Hazlina Nik Hussain	Lecturer, School of Medical Sciences	F	✓
2. Professor Dr. Zeehaida Mohamed	Lecturer, School of Medical Sciences	F	✓
3. Associate Professor Dr. Mohtar Ibrahim	Lecturer, School of Medical Sciences	M	✓
4. Associate Professor Siti Hawa Ali	Lecturer, School of Health Sciences	F	✓
5. Associate Professor Oleksandr Krasilshchikov	Lecturer, School of Health Sciences	M	✓
6. Dr. Teguh Haryo Sasongko	Lecturer, Human Genome Center	M	✓
7. Mr. Harry Mulder	Community Representative	M	✓
8. Mr. Hj. Ismail Hassan	Community Representative	M	✓

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.


PROFESSOR DR. HANS AMIN VAN ROSTENBERGHE
Chairperson
Jawatankuasa Etika Penyelidikan (Manusia), JEPeM
Universiti Sains Malaysia



CHAPTER 2.5 JEPeM-USM/FORM 2(A): REVIEW CHECKLIST

JEPeM-USM FORM 2(A)2014: REVIEW CHECKLIST

6/04/2014

For JEPeM-USM Secretariat Purposes Only	
Protocol Code	
Is the submission complete?	<input type="checkbox"/> Yes <input type="checkbox"/> No
Completeness Verified By	
Date of Verification	

Review Checklist (To be filled by Principal Investigator [PI])

STUDY PROTOCOL INFORMATION

Study Protocol Title:	Study on Lumbar Epidural Single vs. Intermittent Injection of 0.5% Bupivacaine Upon Onset, Level of Blockade & Hemodynamics in Elective Orthopedic Elective Lower Limb Surgeries
Principal Investigator:	Dr. Ting Yung Chuen
Study Protocol Submission Date:	

Compulsory documents

- ☒ JEPeM-USM FORM 2(A)2014 Review Checklist
- ☒ JEPeM-USM FORM 2(B)2014 Registration and Application Form
- ☒ JEPeM-USM FORM 2(C)2014 Study Protocol Assessment Form
- ☒ JEPeM-USM FORM 2(D)2014 Informed Consent Assessment Form
- ☒ Full study protocol
- ☒ Study subject information sheet
- ☒ Study subject informed consent form
- ☒ Brief [1 page] CVs of researchers

Study-specific Documents (if applicable)

- ☐ Research tool materials
- ☐ Previous ethical review approvals/clearances
- ☐ Assent form
- ☐ Notification Letter to related governmental office for studies with specific needs

For Clinical Trial

- ☐ Investigator's Brochure
- ☐ Basic Product Information Document
- ☐ Letter of indemnity/ insurance coverage
- ☐ Assent form in local language
- ☒ Good Clinical Practice (GCP) Certificate of PI, Co-I
- ☐ Recruitment advertisements
- ☐ Material Transfer Agreement
- ☐ Memorandum of Agreement
- ☐ Clinical Trial Agreement
- ☐ Financial Contract
- ☐ Statement of Publication Rights

- ☐ Site Resources Checklist for Clinical Trial Outside USM By USM Personnel [JEPeM-USM FORM 2(E)2014]
- ☐ Site Resources Checklist for Clinical Trial Outside USM By non-USM Personnel [JEPeM-USM FORM 2(F)2014]
- ☐ Clearance or permit from respective regulatory authorities
- ☐ Proof of fee payment

Untuk kegunaan Setiausaha JEPeM-USM sahaja:

(For Secretary of JEPeM-USM Purposes Only)

Permohonan ini akan dibincangkan dalam mesyuarat:

(This application will be evaluated in the meeting of):

[] **Expedited Ethical Review Meeting**

Panel penilai (Primary Reviewers):

1.

2.

[] **Deliberated Ethical Review Meeting**

Panel penilai (Primary Reviewers):

1.

2.

Tandatangan Pengerusi

(Signature of Chairman)

Tarikh:

(Date)

CHAPTER 2.6 JEPeM-USM FORM 2(B): REGISTRATION AND APPLICATION FORM



JEPeM-USM FORM 2(B)2014: REGISTRATION AND APPLICATION FORM

06/04/2014

For JEPeM-USM Secretariat Purposes Only	
Protocol Code	

Registration and Application Form

For Initial Review and Resubmission

(Please fill in or tick whenever appropriate)

Please print in A4 size paper

SECTION I: APPLICATION INFORMATION	
1. Study Title	Study on Lumbar Epidural Single vs. Intermittent Injection of 0.5% Bupivacaine Upon Onset, Level of Blockade & Haemodynamics in Elective Orthopaedic Elective Lower Limb Surgeries
2. Type of Submission	<input checked="" type="checkbox"/> Initial Review <input type="checkbox"/> Resubmission [Version and date of version must be inserted as a document footer for all resubmissions]
3. Date of Submission:	
4. Study Category	<input checked="" type="checkbox"/> Research involving human participants <input type="checkbox"/> Research involving non-human living vertebrates <input type="checkbox"/> Others (indicate):
5. Type of study:	<input checked="" type="checkbox"/> Specify based on FOR/SEO : <hr/> <input type="checkbox"/> Clinical Trial Type 1 <input type="checkbox"/> Clinical Trial Type 2 <input type="checkbox"/> Post Marketing Surveillance <input type="checkbox"/> Others, please indicate:
6. Category of Principal Investigators <i>Please refer to Sections II-IV</i>	<input type="checkbox"/> 6.1 USM Lecturer/Researcher (This category requires completion of SECTION IIB: SCIENTIFIC REVIEW APPROVAL and SECTION III: PTJ ENDORSEMENT) <input checked="" type="checkbox"/> 6.2 USM Post/Graduate Student (Master/Doctorate) (This category requires completion of SECTION IIA: SUPERVISOR APPROVAL and SECTION IIB: SCIENTIFIC REVIEW APPROVAL)

	<input type="checkbox"/> 6.3 Other USM staffs (Nurse, Administrative Staff, etc.) <i>(This category requires completion of SECTION IIB: SCIENTIFIC REVIEW APPROVAL and SECTION III: PTJ ENDORSEMENT)</i> <input type="checkbox"/> 6.4 Non-USM <i>(This category requires completion of SECTION IV: AUTHORIZATION AND ACKNOWLEDGEMENT OF REVIEW below)</i> <input type="checkbox"/> 6.5 Others, please specify:
7. Purpose of study	<input checked="" type="checkbox"/> Academic requirement (Thesis, Dissertation, Training Requirement) <input type="checkbox"/> Independent research work <input type="checkbox"/> Multi-institutional or multi-country collaboration <input type="checkbox"/> Others (indicate):
8. Study Duration	6 months
9. Involvement of special populations or vulnerable groups	<input type="checkbox"/> Not involving special populations or vulnerable groups <input type="checkbox"/> Children (under 18) <input type="checkbox"/> Indigenous People <input type="checkbox"/> Elderly <input type="checkbox"/> People on welfare/social assistance <input type="checkbox"/> Poor and unemployed <input type="checkbox"/> Homeless persons <input type="checkbox"/> Refugees or displaced persons <input type="checkbox"/> Prison Inmate or other institutionalized individuals <input type="checkbox"/> Subordinates <input type="checkbox"/> Patients currently under your care <input type="checkbox"/> Patients in emergency care <input type="checkbox"/> Patients with incurable diseases <input checked="" type="checkbox"/> Others (indicate): Patients going for surgery under regional anaesthesia
10. Hosting Institution (University/School/Department/Unit/Center where the PI is employed)	NAME OF HOSTING INSTITUTION : UNIVERSITI SAINS MALAYSIA
	TYPE OF HOSTING INSTITUTION
	<input checked="" type="checkbox"/> USM <input type="checkbox"/> Non-USM Malaysia <input type="checkbox"/> Non-USM outside Malaysia