### A STUDY ON AN APPROPRIATE MODEL OF LAW ON HUMAN EMBRYO STEM CELL RESEARCH IN MALAYSIA

By

Nurlina Binti Rahim (2009927345)

Nur Hamizah Binti Adenan (2009320695)

Mohd Azhier Farhan bin Arisin (2009342009)

Submitted in Partial Fulfillment of the Requirement for the Bachelor in Legal Studies (Hons)

Universiti Teknologi Mara Faculty of Law

March 2012

The students/authors confirm that the work submitted is their own and that appropriate credit has been given where reference has been made to the work of others.

### ABSTRACT

Stem cells which are characterized by its ability to differentiate into specific cells are highly regarded by the scientific community as providing possible treatment for degenerative diseases. Owing to such great advantage to human race, scientific communities around the world have been conducting many research involving human embryonic stem cells. But the popularity of human embryonic stem cells has not only sparks interest among scientific community but also controversial among legislatures due to the employment of method which requires human embryos to be destroyed for extraction of the stem cells. The law to regulate the practices of human embryonic stem cells research among scientist is therefore inevitable to safeguard human subjects from malpractices by research community. The scantiness of proper mechanism to monitor and regulate the practices of human embryonic stem cells research has prompted for a specific legislation to be enacted in Malaysia. This research paper is therefore aims firstly to analyze the lacunae in Malaysia's regulatory scheme, secondly to study the legislative model of law on stem cell research in the United Kingdom and in the United States of America for lesson to be learned and lastly to make recommendations as to which model of law suits Malaysia in the matter of stem cells research. In using largely legislative materials from the UK and the US as well as scholastic journals, this research paper increases understanding of the legal approach in the UK and the US as well as the position in Malaysia.

## **TABLE OF CONTENTS**

Acknowledgement	ii
Abstract	iii
Contents	iv
List of Statutes and Legislation	vi
List of Cases	vii

# **CHAPTER ONE: INTRODUCTION**

1.0	Introduction	1
1.1	Research Background	1
1.2	Objective	3
1.3	Research Questions	4
1.4	Significance of the Research	4
1.5	Literature Review	5
1.6	Research Methodology	9
1.7	Scope and Limitations	9
1.8	Conclusion	10

# CHAPTER TWO: LAW AND POLICIES OF EMBRYO RESEARCH IN MALAYSIA

2.0	Introduction	11
2.1	The Current Legal Position of Embryo Stem Cell Research in Malaysia	12
2.2	The Law on Embryo Stem Cell Research in Malaysia	13
	2.2.1 Medical Act 1971	13
	2.2.2 Human Tissue Act 1974	14
2.3	Policy and Guidelines on Embryo Research in Malaysia	16
	2.3.1 The National Organ, Tissue and Cell Transplantation Policy	16
	2.3.2 The Guidelines on Stem Cell Research and Therapy, 2009	18
	2.3.3 The Guidelines on Assisted Reproduction and Technology	
	(ART) 2006	20
	2.3.4 Majlis Fatwa Kebangsaan	21
2.4 C	Conclusion	22

#### CHAPTER THREE: THE MODEL OF THE UNITED KINGDOM LEGAL FRAMEWORK OF EMBRYO STEM CELL RESEARCH: THE COMMAND & CONTROL MODEL

3.0	Introdu	liction	24
3.1	The Ba	ckground of Embryo Stem Cell Research in the United Kingdom	25
3.2	The H	uman Fertilization and Embryology Authority	26
	3.2.1	The Composition of the HFE Authority	27
	3.2.2	The HFE Authority as a Licensing Authority	30
	3.2.3	The License Condition	31
	3.2.4	Research Involving Embryos	34
	3.2.5	Review on HFE Authority's Power	35
	3.2.6	Sanction in HFEA 1990	36
3.3	Concl	usion	37

## CHAPTER FOUR: THE MODEL LEGAL FRAMEWORK OF HUMAN EMBRYONIC STEM CELLS RESEARCH IN THE UNITED STATES: THE CALIFORNIA SECTORAL COMMAND AND CONTROL MODEL

4.0	Introduction	39
4.1	The Development of Stem Cells Research in the United States	40
	4.1.1 The Advent of Embryonic Research	40
	4.1.2 The Influence of American Economic and Legal Culture on	
	Regulation of Embryo Stem Cell Research	43
4.2	Competency of State and Federal Legislative: Balancing the	
	Legislative Power	43
4.3	Policy and Legislation on Embryo Stem Cell Research in the United States	45
	4.3.1 The Federal level	45
	4.3.2 The State Level: The State of California	46
	4.3.2.1 Permissibility and Funding	47
	4.3.2.2 California Institute of Regenerative Medicine (CIRM)	48
	4.3.2.3 Medical and Ethical Standards	49
4.4	Conclusion	50

# CHAPTER 1 INTRODUCTION

#### **1.0 INTRODUCTION**

In this chapter, we will be discussing the background of our research paper, the research question and the objective of our study. We further discuss our selected materials for use of our study in the literature review. We will also discuss the methodology used in our research as well as the scope and the limitation of our study. The significance of our research and provisional plan will also be highlighted.

#### 1.1 RESEARCH BACKGROUND

Vital organ in our body system such as kidney plays an important role in maintaining one's healthiness. Failure of vital organs to function properly may adversely affects health and often than not lead to mortality. Although ailing vital organs can be transplanted with another same organ through organ transplantation yet the demand for transplant organ is far outweigh the supply. Many serious medical conditions such as cancer and organ failure associated with abnormal cell division and differentiation.<sup>1</sup> Scientists have been working around the clock studying and researching on stem cells that have the potential to reverse the adverse effect of abnormal cell division and differentiation to human health in what it appears to revolutionize medical sciences. Stem cells are biological cells found in multi cellular organisms that serve functions as internal repair system and may develop into many different cells in the body during early stage of life and growth.<sup>2</sup> Stem cells characterized by its ability to replicate itself continuously under numerous cycles of division and may adapt to certain physiologic or experiment conditions.<sup>3</sup> Scientist around the world denotes stem cells unique properties into three namely for being unspecialized cell yet have the full force to give rise into specialized cell types under physiologic condition and capable to divide and renew themselves for long periods.4

<sup>2</sup> Ibid.

Edwards, R.G., ed. 2004. "History of Embryo Stem Cells", (Armsterdam, Elsevier); National Institutes of Health, "Stem Cell Basics: Introduction", available at <u>http://stemcells.nih.gov/info/basics/basics1</u> accessed on 29 May 2012.

<sup>&</sup>lt;sup>3</sup> Ibid.

<sup>&</sup>lt;sup>4</sup> Ibid.