Buddhism and the Status of the Human Embryo: 
The Regulation of Human Embryo Research in Thailand

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Summary

This dissertation addresses relevant moral values and legal principles underpinning the regulation of human embryo research. The objective is to propose model legislation to regulate human embryo research in Thailand legitimately and effectively.

When considering the status of human embryos, the key question is application of the sanctity of life principle. As the separation of church and state principle has not been adopted in Thai law, Buddhism is the main factor which influences laws based on sanctity of life principles in Thailand. This dissertation argues that, under Buddhist teachings, an embryo created in vitro does not constitute a human life warranting the protection of the sanctity of life principle unless it is implanted in a woman's uterus. As a result, it can be further argued that research conducted on human embryo created in vitro in Thailand is ethical.

As stated, part of this dissertation is concerned with the regulation of human embryo research in Thailand. In addition, an analysis of two key legislative models regulating human embryo research in the United Kingdom and Australia examines the issues which influenced those legal frameworks. The main issues involve concerns to uphold the sanctity of life principle, preservation of human dignity and the preservation of social foundation. These concerns are addressed and incorporated in the proposed model legislation for the conduct of research involving human embryos in Thailand.
Statement of Authorship

Except where reference is made in the text of the thesis, this thesis contains no material published elsewhere or extracted in whole or in part from a thesis submitted for the award of any other degree or diploma.

No other person’s work has been used without due acknowledgement in the main text of the thesis.

This thesis has not been submitted for the award of any degree or diploma in any other tertiary institution.

Suntaree Buchitchon

14 March 2012
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My interest in this topic arose from news on the abortion debate in Thailand where the argument from the religious point of view stopped decriminalization of the abortion law provisions. This event gave rise to a question: if a human embryo in vivo is protected under the law, would the in vitro human embryo be protected as well? The process of turning this question into a thesis was a challenge for me as I had started my doctoral candidature in another research discipline -- environmental law -- and I was then in the second year of my candidature. Professor Jianfu Chen, my ex-supervisor and, at that time, Head of the Law School, helped me through the process of changing my supervision and research topic.

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Chapter One:

Introduction

1.1 Human Embryo Research in Thailand

Since the birth of the first test tube baby resulting from *in vitro* fertilisation (Louise Brown) in 1978, the degree of protection afforded a human embryo\(^1\) *in vitro* has come to the attention of jurists in many countries. Various ethical debates have taken place regarding the status of *in vitro* human embryos.\(^2\) People’s perceptions regarding the status of human embryos have changed and concerns over the exploitation of human life for scientific development have increased as a result of the development of technologies that allow human embryos to be created outside of human bodies.\(^3\) Many countries have enacted legislation regulating the use human embryos created *in vitro*. However, if a

\(^1\) An embryo is an entity in its earliest stage of development. In humans, it is called an embryo until about eight weeks of development and then it is called a foetus. Gary C Schoenwolf et al, *Larsen’s Human Embryology* (Elsevier Churchill Livingstone, 4\(^{th}\) ed, 2009) 5. However, for the purposes of this dissertation, references to the human embryo incorporate the foetus when appropriate.


proper process is not followed, the consistency of the principles underpinning new legislation may be called into question.4

Thailand is a nation that currently allows research to be conducted into human embryo and stem cell technologies. In the absence of any laws in Thailand either preventing or restricting the conduct of such research, Thailand’s researchers are allowed to conduct embryonic stem cell research and are subject to little regulation in doing so. Currently, research on human embryo is regulated by guidelines that are different among institutions.

It is widely acknowledged that the state has the power to enact laws in order to maintain public order and morality. This power is not absolute but is subject to important principles such as basic human rights and norms which are widely accepted in the jurisdiction. In order to ensure compliance by a particular society with a new set of laws, the regulators need to be able to justify the laws by showing that the objectives of the laws are legitimate.5 This is particularly true in the case of regulations proposed in order to control morally controversial issues, such as human embryo research. In Thailand, the morality of people in the society is widely determined by the Buddhist teachings. In Buddhist beliefs, human life starts at conception in the mother’s womb where the human embryo is entitled to


protection under the sanctity of human life principle. Historically, the interpretation of Buddhist teachings regarding the sanctity of human life has influenced legal principles protecting human embryos in the laws prohibiting abortion in Thailand. However, at the time of Buddha, the science of \textit{in vitro} fertilisation did not exist and there is no teaching which specifically addresses the creation of human life \textit{in vitro}. This dissertation analyses the possible application of Buddhist teachings in relation to the status of human embryos created \textit{in vitro}. The aim is to propose a regulatory regime to be applied for the regulation of human embryo research in Thailand within ethical boundaries of Theravada Buddhist ethics.

1.2 Thailand and Buddhism

Buddhism refers to the religion of the Buddha. However, the word ‘Buddha’ is not an individual person’s name, but rather refers to someone who attains an enlightened state. In this dissertation, the word ‘Buddha’ refers to Siddhartha Gautama, an awakened teacher who was the founder of Buddhism.\(^6\) The teachings of the Buddha are recorded in several canons of scripture. These canons of scripture have been passed down through the generations by oral transmission preserved by a communal chanting.\(^7\) The ‘Pali Canon’ is the most complete of the early canons to be preserved. The Pali Canon is the primary scripture of the


Theravada Buddhist doctrine, which is the main stream of Buddhism in Thailand. The institutions of the Thai monarchy and the Buddhist temple form the basis of Thailand’s political culture. When the previous kings of Thailand, then known as Siam, adopted Theravada Buddhism as the predominant religion, the relationship between the monarchy, politics and Buddhist ethics became deeply rooted in Thailand. The adoption of Hindu-Buddhist cosmology, with its core belief in karma, led to that cosmology being ‘at the core of Siamese Buddhist belief for centuries’.

There is a distinctive Buddhist character to the culture of Thailand. Historically, the precepts of Thai morality have been influenced by Buddhism, Brahmanism and a myriad of indigenous traditions. Thailand became an official Buddhist Kingdom in the reign of King Lithai, also known as Phra Maha Thammaracha I, who composed Traibhumikatha, ‘the first systematic construction of Buddhist cosmology’. Today, Buddhism permeates every level of the social, political and

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12 Ibid.
cultural landscape in Thailand. Traibhumikatha was intended to establish two main precepts: (1) to engender a moral code in accordance with the Buddha’s teachings; and (2) to legitimise the Devaraja or the god-king. The term 'Devaraja', or 'Dhammaraja', in this context means ‘Righteous Ruler’, namely one who not only rules the kingdom in accordance with the natural law of karma but who also represents the divine power of god on earth. This interpretation of Devaraja remains to the present day in Thai traditions surrounding the King and the Thai royal family.

The significance of Traibhumikatha for Thai society declined during the colonial era of the mid-nineteenth century, during the reign of King Mongkut (King Rama IV) and King Chulalongkorn (King Rama V) when the Western powers arrived. In its quest to become more modern, Siam, as it was then known, underwent various changes in its belief system, including the rejection of supernatural mythology which had been incorporated in the Traibhumikatha text. The expansion of trade and commerce with the West was driven by the Thai royal


15 The Colonial Era in this context refers to the period during which Western Countries, such as France, Spain, the United Kingdom, the Netherlands and Portugal, established colonies in Asia in the mid-nineteenth century.
family and Thai elites. King Mongkut developed the traditions of Thailand to reflect the humanism, rationalism and realism of the West. For example, the old tradition of the king as a divine symbol was replaced by the view that the king was an ordinary person who had a duty to his people and the kingdom. Furthermore, King Mongkut also encouraged his people to know the law by confirming that the law is not sacred and should be learned by the people. He published the law in the Royal Gazettes in a systematic way beginning with causes and reasons for making the law.

The reformation period during the reigns of King Mongkut and King Chulalongkorn propelled Siam into the modern age. The process started with the codification of the Penal Code of Thailand 1908. However, it was not until the reign of King Prajadhipok (King Rama VII) that democracy was adopted. However, the ‘Promoters’ of the 1932 Revolution acknowledged the significant role of the monarchy in Thai society by establishing constitutional monarchy as the new system of Thai government. Since then, the position of the monarchy has been retained under the constitution.

16 อรรถจักร สัตยานุรักษ์, การเปลี่ยนแปลงโลกทัศน์ของชนชั้นผู้นำไทยตั้งแต่รัชกาลที่ 4 - พ.ศ. 2475 [Changes of Elites’ Worldview from Rama IV to 1932] (Chulalongkorn University Press, 1995) 9.
17 วิไลเลขา ถาวรธนสาร, ชนชั้นนำไทยกับการรับวัฒนธรรมตะวันตก [Thai Elites and the Reception of Western Culture] (เมืองโบราณ [Muang Boran], 2002) 74.
During the reign of King Wajirawut (King Rama VI), the movement toward modernisation and nationalisation resulted in Thailand becoming a Buddhist nation in which Buddhism and the government were intertwined. This relationship (between Buddhism and government) is reflected in the national motto and tri-colour symbols of the Thai national flag – ‘the Nation, Religion, and the King’.

After that, the relationship between the King, Buddhism and the people became essentially symbiotic.19 Stanley Tambiah, a leading social anthropologist who specialises in the study of Thailand, points out that Buddhism legitimises the polity, whereby the King’s role is to be a patron and protector of Buddhism and the community of monks provide an example of those devoted to dharma.20 These elements brought order to Thailand’s society as a Buddhist kingdom.21 Currently, around 90 per cent of the Thai population are Theravada Buddhist and the influence of Buddhist ethics are prominent in various aspects of day to day life of people in Thailand.22 The notion of justice in the mind of Thai people is largely influenced by Buddhist beliefs. ‘Justice’ in the Thai language is “khwam yuttitham” or “khwam pen than”. The word tham is derived from the Pali word “dhamma” referring to ‘Buddhist teachings on the cosmic law of existence governing all substances and beings in universe according to their intrinsic

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19 Stanley Tambiah, World Conqueror and World Renouncer: A Study of Buddhism and Polity in Thailand Against a Historical Background (Cambridge University Press, 1976).

20 Ibid.


22 Misha, above n 10, 11.
Buddhist teaching is the main principle that justifies the legitimacy of Thai law.

1.3 The Development of Thai Legal System

The history of the Thai legal system can be divided into two eras: pre-codified law and post-codified law. Thai pre-codified law originated from India and the Mon Kingdom and was transformed by the influence of Theravada Buddhist beliefs, “\textit{manudharmmasattham}” or ‘Laws of Manu’. Once Sukhothai was free from the Khmer Kingdom in 1238, the king governed his people according to the main law of \textit{thammasat} (the law derived from \textit{manudharmmasattham}) and the stone inscription, \textit{sila charuek lak thi nueng} (the law written by King Ramkhamheang the Great).

In the Ayutthaya era, the influence of \textit{thammasat} declined and was replaced by enacted laws. The king had the power to legislate necessary provisions in the form of royal decrees, called \textit{ratchasat}. However, the royal decree only applied during the reign of the monarch, meaning that if the content of the royal decree was not reasonable, it would be repealed at the end of the reign. Later, in order to make

\begin{itemize}
\item Misha, above n 10, 2.
\item \textit{Sila charuek lak thi nueng} was written by King Ramkhamheang the Great in 1283 to provide rights and freedoms for people who lived in Sukhothai. This inscription was regarded as the first constitution of the Siamese Kingdom (later known as Thailand).
\end{itemize}
the enacted *ratchasat* stable, the king incorporated them into a part of *thammasat* and proclaimed them as having the same status as *thammasat* which could be enforced after his reign. It can be asserted that, during the Ayutthaya era, the *ratchasat* was the major legislation governing the people in the kingdom while *thammasat* was treated as the constitution which provided general rules of guidance.

After the destruction of Ayutthaya in 1767, the law books of Ayutthaya were lost or damaged. King Taksin, the ruler in the Thonburi Era, attempted to collect and restore them but did not completely succeed as the length of his reign was only fifteen years. King Rama I, in an attempt to restore the kingdom and deliver justice to his people in the Rattanakosin era, appointed a commission to collect the remaining laws of Ayutthaya and draft new provisions reflecting the practical needs of the people in the kingdom. The result was *kotmai trasamduang* or the three sealed laws which was the collection of laws that were promulgated as the main law of the kingdom from 1805 to the codification of Thai law during the 20th century.

In the reign of King Rama III, the Southeast Asian countries were viewed by the West as a region to distribute goods from Europe and exploit natural resources. An ‘open door’ policy was adopted along with an unequal agreement on trade and

26 ว หรีรัศนะ, ประวัติศาสตร์กฎหมายไทย [*Thai Legal History*] (ทำโดยวัฒนาพาณิช [Thai Wattana Panich], 2nd ed, 1983) 47.

27 Ibid 16.
commerce which a Southeast Asian country had to agree to avoid being colonised.\textsuperscript{28} The colonies had to transplant the Western law into their legal systems while the non-colonised countries were affected by a series of treaties of amity and commerce which also influenced their legal systems.\textsuperscript{29} It is true that Thailand was not colonised by any of the Western countries, however, trade and commerce with the West had various effects on Thai society and its legal system. Due to the differences of law and customs between Thailand and the Western countries that traded with the kingdom, an extraterritorial agreement was normally imposed by Western nations which excluded Westerners from the application of local law.\textsuperscript{30} In Thailand, such a clause was included in the Bowring Treaty of 1855, and other treaties concluded with various Western countries\textsuperscript{31} to avoid colonisation and domination by Great Britain.\textsuperscript{32} These extraterritorial rights also protected people from countries which were the colonies of Western countries by consular jurisdiction, and as a result, the power of Siam was significantly limited by these extraterritorial clauses.\textsuperscript{33}

\textsuperscript{28} Anthony Webster, \textit{Gentlemen Capitalists: British Imperialism in Southeast Asia (1770-1890)} (Tauris Academic Studies, 1998) 149.

\textsuperscript{29} M B Hooker, \textit{A Concise Legal History of South-East Asia} (Clarendon Press, 1987) 167.

\textsuperscript{30} John Bassett Moore, \textit{Digest of International Law, Volume 2} (Churchill Livingstone, 2005) 593.

\textsuperscript{31} Such as; with the United States of America in May, 1856; with France in August, 1856; with the Netherlands in December 1860.

\textsuperscript{32} กรมพระยาดํารงราชานุภาพ, \textit{พงศาวดารกรุงรัตนโกสินทรรัชกาลที่ 5 [The Dynastic Chronicles of Rattanakosin: King Rama V]} (บรรณาคารการพิมพ์ [Bunnakarn Publishing], 1959) 211-12.

[A]s a result, Siam was deprived of jurisdiction over hosts of Cambodians, Annamites and Laos from Indo-China, Javanese, Malayans, Burmese, Chinese born in Macao or Hong Kong, and East Indians, even though residing permanently and perhaps doing an extensive business in Siam.34

In an attempt to end the inequality caused by such treaties, King Chulalongkorn (King Rama V) initiated a project to reform the Thai administration of justice and law.35 This project commenced with sending members of the royal family and Thai elites to study law abroad to acquire knowledge from the West, especially from England. King Chulalongkorn considered the political and administrative institutions of the West provided an example for reform.36 However, he doubted that the direct adoption of such a system would do the country little good as long as there was an insufficient number of educated persons to hold positions of responsibility in the executive and the legislature.37 It was not until 1892 that King Chulalongkorn exercised power to transform and modernise the country by establishing twelve ministries in accordance with the royal policy and assigned educated royal family and members of Thai elites to be Ministers.38 The King also considered recommendations from the Belgian lawyer, Gustave Rolin

34 Francis Bowes Sayre, ‘The Passing of Extraterritoriality in Siam’ (1928) 22 American Journal of International Law 70, 73.
38 วิไลเลขา ถาวรธนสาร, above n 17, 92.
Jacquemyns, who was appointed as a general advisor to improve legal procedures and start codification of the law.\(^{39}\)

The process of codification began in 1898. The Commission of Codification of Criminal Law was appointed to examine the existing laws of the country.\(^{40}\) The first task of the Commission was to consider whether common law or civil law should be the basis of the Thai legal system. At the beginning, the common law approach was considered as the Chair of the Commission and senior lawyers were graduates from Law Schools in Great Britain.\(^{41}\) It was concluded at the time that the work would be guided by the codification work of British India.

The objective will not be, as is the case in Japan, in Egypt and in Turkey, to simply blueprint some European codes of law, but to begin by examining the existing laws, to take from it what is still in use (a lot has fallen in disuse), and to improve and organise this as necessary by using as example the codification work of English India.\(^{42}\)

As Rolin Jacquemyns noted, the Commission would not copy any of the European code of laws but examine the laws of other countries as well as Thai law to mirror


\(^{40}\) Ibid.


the people’s character and moral aspirations of Siam. In a later stage of the drafting process, King Chulalongkorn anticipated that Thai pre-codification law, kotmai trasamduang, was more similar to the civil law system than the common law system. Thus, he thought that the civil law system would be more suitable for Thailand. Furthermore, the civil law system could accelerate the process of codification as the government would not have to wait for legal rules to develop from court decisions. Thus, the second phase of Criminal Code (Th) drafting was commenced in 1905 by a new Commission chaired by Monsieur Georges Padoux from France. As a result, Siam has developed its own Criminal Code of 1908 (Th) reflecting existing rules of law contained in kotmai trasamduang complemented with principles adopted from foreign countries.

The drafting of the Civil and Commercial Code was started in the reign of King Rama V and was completed during the reign of King Rama VII. The current court system was adopted in 1935 with the promulgation of the Charter of the Courts of Justice. According to the Charter, there are three levels of Courts of Justice; 1) Courts of First Instance, 2) Courts of Appeal, and 3) Supreme Court. Judges are recruited by the Judicial Commission and appointed by the King from candidates who obtain the required legal qualifications and experience. Supreme Court’s

43 Tips, above n 42, 237–38; See also Georges Padoux, Report on the Proposed Penal Code for the Kingdom of Siam Submitted to His Royal Highness Prince Rajburi Direkrit (1906) 5.

44 หอจดหมายเหตุแห่งชาติ [National Archives of Thailand], หนังสือจากกรมหลวงดํารงราชานุภาพกราบบังคมทูลพระบาทสมเด็จพระจุลจอมเกลาเจาอยูหัวเรื่อทำโคตสําหรับเมืองไทย [Letter from Prince Damrong to King Chulalongkorn on Codification in Thailand] Document No. ถง. 5 622 [ M R 5 Y/22] 13 December 1899, 8–12.

45 See Padoux, above n 43.
decisions are often used as secondary authority following the enacted legislation, however, judicial precedence is not binding in Thailand. However, due to the influence of the common law system during codification, courts are highly influenced by the previous decisions of higher courts.

1.4 Methodology

This research has been conducted using a literature review and secondary historical sources. Most documents have been collected from libraries and electronic resources mainly in Australia, especially from La Trobe University Library. For documents relating to the Kingdom of Thailand, the relevant documents have been collected from the National Archives of Thailand, Sunyathammasak Library from Thammasat University, the National Libraries of Thailand and the Office of Council of State of Thailand.

1.5 Scope and Limitations

In context of this dissertation, the scope is limited to the status of human embryo that related to human embryo research. Other information relevant to issues such as infertility treatment, reproductive cloning and related topics have been mentioned only when necessary. It is conceded that in order to acquire thorough and accurate information needed to be able to adopt legislation regulating human embryo research in Thailand, a detailed determination of public values and standards would be necessary in order to analyse every aspect of the arguments.
for and against human embryo research including its regulation. However, due to
the limited time available to conduct research required for this dissertation, it was
impossible to acquire all the information on regulating human embryo research in
Thailand. Thus, the main focus of this dissertation is on the status of human
embryo that relates to sanctity of life, human rights and human dignity principles.

1.6 Chapter Outlines

This dissertation undertakes a review of the provisions in the Protection of
Children Born from Assisted Reproductive Technology Bill (Th) and discusses
challenges and recommendations for the regulation of human embryo research in
relation to the status of human embryos in Thailand.

Chapter Two: Human Embryo Research and Regulation

Chapter Two provides background information about human embryo research and
its regulation. Human embryo research and hESC research provide great promise
for the therapeutic medication of currently untreatable illnesses and for other areas
of medical science. Nevertheless, human embryo research also raises problems
which have the potential to challenge foundational values of society. The issues
raised by human embryo research usually involve the concern that the derivation
of hESCs unavoidably terminates life. A process that prevents the development of
human embryos arouses concern, as it involves the issue of the sanctity of human
life. As a result, various countries have responded to this challenge with specific
but different laws and policies regulating human embryo research. It is argued in this chapter that it is important to have specific legislation regulating human embryo research in Thailand to address concerns over the protection of human embryo.

Chapter Three: The Moral Status of Human Embryos

Chapter Three discusses the moral status of human embryos through the application of sanctity of human life principle. Sanctity of life is highly valued in many religions and influences various contexts of law. The status of the human embryo and the application of the sanctity of life principle are the main influences on the debate surrounding human embryo research. Essentially a human is, according to the Buddha’s understanding, a womb-born being. Thus, in vitro embryos, if not implanted in the women’s womb, could not come into existence as human beings in the eyes of the Buddha. This inference begs the question of whether an in vitro embryo has the same status as an embryo implanted in a womb. According to this analysis, an embryo created in vitro does not constitute as a human life thus warranting the protection of the sanctity of life principle unless it is implanted in a woman’s uterus. As a result, the legal protection stemming from the sanctity of human life principle should not be applied to the human embryo created in vitro.

Chapter Four: The Legal Status of In Vivo Human Embryos
Chapter Four discusses the legal status of human embryos *in vivo*. This is done by tracing legal recognition of the status of the human embryo created *in vivo* from the abortion law provisions. This discussion, together with recent court cases in which judges have decided between the conflicting claims of the parties, shows how the human embryo is protected in contemporary medical law. In many cases, the moral claim that right to life should be granted to the unborn child is limited. In the case of abortion, the woman’s right to self-determination and her health interests are generally prioritised over the interests of the human embryo and the claim for absolute sanctity of life depending on the stage of gestation. Therapeutic abortion can generally be practised where the pregnancy threatens the woman’s life or her health. In addition, in some jurisdictions, defences for abortion based on the health of the person to be born and the mental health of the pregnant woman are accepted. Furthermore, the human embryo is considered as a part of the pregnant woman and the decision to deny life-saving medical treatment, even when such a decision threatens the life of the viable embryo,\(^46\) must be accorded some respect. In Thailand, the relationship between law and morality is supportive in several ways. Traditionally, Thai law is derived from Buddhist beliefs which are the main determination of Thai morality. Even after the codification process during the 1890s, various provisions of Thai law still reflect Buddhist teachings especially in the provisions regarding the protection of human life.

\(^{46}\) A viable foetus refers to a foetus that has the capacity to survive following the separation from its mother and to live to the point of sustaining independent life. Les Haberfield, ‘The Transplantation of Human Fetal Tissue in Australia: Abortion, Consent and Other Legal Issues’ (1996) 4 *Journal of Law and Medicine* 144, 147-51.
Chapter Five: The Legal Status of In Vitro Human Embryos

This Chapter discusses the legal status of human embryo created in vitro. This is done by the observation of the legal protection grants by the regulation of human embryo research in various countries including the United Kingdom, Australia and Italy. It is found that the status of human embryo in vitro is generally influenced by collective social values. Although Thailand generally prohibits abortion, this dissertation asserts that the underlying principle regulating the human embryo created inside the human body and the human embryo in vitro, are different. Whereas the sanctity of life principle is the main principle governing the law protecting the human embryo against abortion in Thailand, the same application would not be applied to a human embryo created outside human body. The teachings of Buddha can be interpreted as meaning that a human embryo created outside the human body is not yet a human life, thus warranting its exclusion from the sanctity of human life principle.

Chapter Six: Recommendations for the Regulation of Human Embryo Research in Thailand

When considering the appropriateness of human embryo research, the key determination is the application of the sanctity of life principle. In addition, concerns involving human dignity, social foundations and safety are often associated with the question of what kinds of human embryos are suitable for research purposes. The Human Fertilisation and Embryology Act 1990 (UK) and the Research Involving Human Embryos Act 2002 (Cth) are used as legislative
models for the adoption of specific legislation regulating human embryo research in Thailand. The main issues addressed in the chapter include: 1) definition of human embryo, 2) the prohibition in connection with human embryo, 3) stages of embryo development, 4) consent, and 5) the protection of human dignity, social foundations and safety concerns.
Chapter Two:

Human Embryo Research and Regulation

2.1 Introduction

Since the start of the scientific revolution in the early 19th century, significant scientific discoveries and technological innovations have created a wealth of possibilities for improvement in various aspects of day-to-day life. In particular, great advances in biomedical science have progressively benefited human-kind through the introduction of a range of treatments for various life-threatening, debilitating or troubling health conditions. However, the journey from the discovery of possible cures to the therapeutic application of treatments has never been simple.47 Similarly, the journey from the first research conducted involving human embryos to the application of the results of that research in therapeutic medication has not been simple.

This chapter outlines background information on human embryo research and its technologies, including the biology of a human embryo and the methods used to generate and extract human embryonic stem cell (hESC). This discussion highlights the potential applications of the research which gives hope to patients suffering from various conditions that are currently untreated. The discussion

then turns to problems associated with human embryo research and their potential to challenge societal principles and concludes with the importance of legislation regulating human embryo research in Thailand.

### 2.2 Assisted Reproductive Technologies (ART)

The ability to create a human embryo outside the human body has extended the boundaries of biomedical technology because of developments in Assisted Reproductive Technologies (ART) and human embryo research. ART is a technology that was developed to assist people to have children. There are various types of assisted reproductive technologies including *in vitro* fertilisation (IVF), intracytoplasmic sperm injection (ICSI), pre-implantation genetic diagnosis (PGD), use of donor gametes and embryos and surrogacy. ART is considered advanced technology because it consists of medical and laboratory practices which usually involve the woman going through a process of superovulation which stimulates the ovaries to produce multiple eggs at the same time. Once this has occurred, a surgical retrieval procedure will be performed in order to take the eggs for further laboratory procedures to be conducted. After retrieving the eggs, especially in the case of *in vitro* fertilisation (IVF), the eggs are fertilised in a laboratory using the sperm of the partner or a donor. The resulting embryo is

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50 Ibid 138.
normally placed in the woman’s uterus when it is two to five days old and can be
carried to full term.51

It is usual to fertilise more than one egg, in order to increase the chances of one or
more successful pregnancies being achieved from one oocyte collection. In the
past, when the results were poorer, multiple fertilised eggs allowed more than one
embryo to be transferred into the woman’s uterus, which increased the chances of
the birth of a baby.52 However, the process also increased the chance of multiple
births and these have poorer health outcomes for the mother and the babies.
Surplus eggs or embryos must be destroyed or preserved by cryopreservation
which involves eggs or embryos being frozen for use in future attempts at
pregnancy. Surplus ART embryos are defective IVF embryos that are not suitable
for transfer or cryopreserved embryos remaining after the couple have completed
their family or ceased treatment. Surplus ART embryos are sometimes donated
for research purposes.53

Initially, the main reason for creating human embryos *in vitro* was to assist
infertile couples to have children or to select a healthy embryo through pre-
implantation genetic diagnosis (PGD).54 Pre-implantation genetic diagnosis

51 Begum, above n 49; See also, Michel Revel, ‘Bioethics of Human Embryonic Stem Cells and
Cloning for Stem Cells: An Israeli Perspective’ in Joseph G Schenker (ed), *Ethical Dilemmas in
Assisted Reproductive Technologies* (Walter de Gruyter, 2011).

52 Revel, above n 51, 189.

53 Ibid 189.

54 Currently PGD can be used to detect more than 200 diseases, such as Tay Sach’s, Huntington’s
(PGD) is used to select embryos without chromosomal genetic defects to improve success rates of IVF for infertile couples or avoid transmission of serious heritable disorders in fertile couples.55 The diagnostic procedure starts with one cell being obtained from an embryo during the mitotic division stage, usually with the aid of micromanipulator.56 The biopsied cell is then tested for genetic markers, either cytogenetic (chromosomes) or molecular (DNA sequence), to check for chromosomal or genetic diseases.57 Only unaffected embryos are transferred while embryos with genetic defects are destroyed or used for research.

2.3 What is Human Embryonic Stem Cell (hESC) Research?

Stem cell research began in the early 1900’s, when the first stem cells were discovered by European researchers.58 Following the initial discovery of the first disease and hemophilias. Moreover, PGD can be used for human leukocyte antigen (HLA)-matching. See Gayane Ambartsumyan and Amander T Clark, ‘Aneuploidy and Early Human Embryo Development’ (2008) 17(1) Human Molecular Genetics R10, R11.

55 Ibid.


stem cells, it was proven soon after — as a result of research carried out using animal and human models — that stem cells have three abilities: (1) self renewal; (2) the ability to remain in the undifferentiated stage; and (3) the ability to differentiate into specialised cells.\(^5^9\) In 1988, this was demonstrated in practice by using embryonic stem cells taken from mice. It was then demonstrated to a certain extent with the use of hESCs, when harvested functional cells were integrated into adult animals.\(^6^0\) These transplanted cells functioned satisfactorily in many animal models such as mice with a heart malfunction or diabetes, and in rats with brain and spinal cord injuries.

These characteristics found in stem cells led scientists to conduct research into ways to apply this knowledge in therapeutic medication. Bone marrow transplants, which involve the transplant of adult stem cells, have been widely used to treat patients who have received radiation therapy and chemotherapy.\(^6^1\) Adult stem cells are ‘multipotent’, which means that they have a limited ability to


differentiate into other cell types.\textsuperscript{62} As an illustration, adult stem cells collected from blood cells can only regenerate various types of blood cells, but they cannot generate other types of cells in the human body. The ‘multipotent’ characteristic of adult stem cells places certain limitations on their use in therapeutic medications.

In 1998, James Thomson and his colleagues successfully derived hESC from a human embryo that was created \textit{in vitro}.\textsuperscript{63} Research conducted on embryonic stem cells revealed the ‘pluripotent’ potential of the cells to develop multiple variations of cells and body tissues.\textsuperscript{64} Unlike the ‘multipotent’ characteristic of adult stem cells, the ‘pluripotent’ potential of hESCs gives them the ability to be regenerated into any cell type of the human body.\textsuperscript{65} This development led scientists to conduct research into possible cures for currently untreatable diseases such as diabetes, Alzheimer’s and Parkinson’s.\textsuperscript{66}

\section*{2.4 The Biology of a Human Embryo}

\textsuperscript{62} Kiatponsan, ‘Introduction to Stem Cell Medicine’, above n 48, 112.

\textsuperscript{63} Thomson, above n 60.

\textsuperscript{64} See Evans, above n 58.

\textsuperscript{65} Thomson, above n 60, 1145.

An embryo is an entity in its earliest stage of development. In humans, it is called an embryo until about eight weeks of development, after which it is called a foetus.67 A human embryonic stem cell (hESC) is derived from a human embryo before its 14th day of development, by separating the inner cell mass of the blastocyst and culturing the biopsied cell using feeder cells for further research. hESCs and adult stem cells differ in their characteristics; adult stem cells are ‘multipotent’, which means that they have a limited ability to differentiate into other cell types, while hESCs are ‘pluripotent’, which gives them the ability to be regenerated into any type of cell in the human body.

The debate surrounding human embryo research cannot be properly examined without understanding the human embryo itself. This section provides a brief biological outline of the formation of a human embryo and its development from fertilisation to the formation of a blastocyst.

Fertilisation is a complex process that begins with contact between a sperm and an egg, and ends with the breakdown of the male and female pronuclei to form a zygote.68 This process can be illustrated in six stages.

**Basic phases of fertilisation:**69

67 Schoenwolf, above n 1, 5.
• The contact of sperm and a mature oocyte which has a female pronucleus containing the female chromatids.
• The sperm penetrates through the zona pellucid
• Fusion of the plasma membranes of the sperm and oocyte
• Entry of sperm into the cytoplasm of the oocyte
• Formation of the male pronucleus containing the paternal chromatids
• Breakdown of the membranes of the female and male pronuclei to form a zygote.

The approximate duration of the fertilisation process is about 24 hours. The fertilisation phase ends with the formation of the zygote. The resulting zygote contains a combination of the two sets of chromosomes derived from each parent, which produce a new double set of chromosomes. In other words, the resulting zygote is a new identity which is genetically different from its parents.

After the fertilisation phase, the development of the zygote continues with the process of mitotic cell division. Mitotic cell division is the process by which each cell of the zygote separates itself into two identical cells, called

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70 Schoenwolf, above n 1, 41.


72 Schoenwolf, above n 1, 41.
blastomeres. The division starts with one cell zygote dividing into two, then into four, eight and so on. The first mitotic division is complete by about 30 hours after fertilisation. In early stages of division, up to about the eight cells embryo, each blastomere is ‘totipotent’; they can develop into any cell type, including both embryonic and extra-embryonic cells, meaning that they can develop into a whole other embryo. Identical twins can be formed during this and later processes of embryonic development.

The blastomeres start to specialise after this, the outer cells becoming the trophoblast. About five to six days after fertilisation the embryo usually has more than 100 blastomeres and has a cavity separating the inner blastomeres called the inner cell mass from a thin outer trophoblast cell layer. The blastocyst contains the inner cell mass and a thin outer cell layer. The inner cell mass then develops into the embryo proper while trophoblast develops into the placenta and outer membrane of the foetal sac. Human embryonic stem cells (hESC), are usually grown from the inner cell mass of human blastocysts created by IVF. A blastocyst that has had its inner cell mass extracted cannot develop further as a foetus.

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73 Ibid.
74 Bongso, above n 59, 831.
75 Schoenwolf, above n 1, 43.
76 Larsen, above n 69, 15; Schoenwolf, above n 1, 43; Keith L Moore, above n 68, 36.
77 Bongso, above n 59.
In a natural gestation, the blastocyst would implant itself into the uterine wall in approximately the sixth day of its development.\(^78\) By hatching out of the clear zona pellucid, which is coated around the blastocyst to prevent the blastocyst from implanting itself into the fallopian tubes, the blastocyst can then implant itself tightly into the uterine lining and develop further into a foetus.\(^79\) The development of the foetus continues until the end of the pregnancy. The likelihood of the successful development of a fertilised egg into a cell at the blastocyst stage is extremely low. Only one in 10 early embryos successfully implant itself in the uterus lining and develop to full term.\(^80\)

2.5 Derivation Methods of Embryonic Stem Cells

Theoretically, there are five methods that can be used for extracting hESC: (a) the classical method; (b) the single blastomere method; (c) the somatic cell nuclear transfer method; (d) the altered nuclear transfer method; and (e) the cytoplasmic hybrids method. Each of these methods encounters problems on ethical and legal grounds.

2.5.1 The Classical Method

\(^78\) Schoenwolf, above n 1, 44.
\(^79\) Ibid 43-45.
\(^80\) John A Robertson, 'In the Beginning: The Legal Status of Early Embryos' (1990) 76 Virginia Law Review 437, 443.
The classical method was the first method developed for embryonic stem cell derivation. The process starts with the separation of the inner cell mass of the blastocyst, which is created in vitro. The biopsied cell is then cultured using feeder cells for further research. The blastocyst that has had its inner cell mass extracted cannot develop any further. In other words, this method of deriving embryonic stem cells prevents the subject blastocyst from developing into a foetus.

2.5.2 The Single Blastomere Method

The single blastomere method was developed by Chung and his colleagues in 2005. This method has been created using technology that is used in pre-implantation genetic diagnosis (PGD). In hESC research, the embryonic stem cell line is derived from the biopsied blastomere before it develops into a blastocyst. The method starts with the biopsied cell/blastomere being obtained from the developing embryo. The cell is then placed in a culture in the laboratory in order to develop another blastocyst that is used to extract stem cell lines for research purposes. Through this approach, a new embryonic stem cell line can be obtained without destroying the original developing embryo.

83 Kiatponsan, above n 81, 896.
84 See above n 57 and accompanying text.
biopsied embryo can still be implanted into the uterine wall and develop to full term. However, successful applications of this method have been conducted using only mice as subjects.

### 2.5.3 The Somatic Cell Nuclear Transfer Method (SCNT)

The SCNT involves a combination of a somatic cell nuclear transfer with the classical method of embryonic stem cell derivation. The process starts with the transfer of an adult human somatic cell nucleus into an oocyte which has had its nucleus removed (a so-called ‘enucleated oocyte’). The oocyte is then electrically stimulated in order to make it fuse, \textit{in vitro}, and develop to the blastocyst stage. Once it reaches this stage, the embryonic stem cell will be extracted from the inner cell mass of the blastocyst. This method has great potential because cells and tissues generated from embryonic stem cells can be matched with the needs of specific patients. The success of the SCNT in mammals was widely recognised with the birth of Dolly the sheep in 1996.\textsuperscript{85} Dolly was the first mammal successfully created by transferring the adult tissue of a ewe into an enucleated egg. There has been a report of a successful use of SCNT in humans. However, this report has since been wholly discredited.\textsuperscript{86}

\textsuperscript{85} Ian Wilmut et al, ‘Viable offspring derived from fetal and adult mammalian cells’ (1997) 385(6619) \textit{Nature} 810, 812–13. Dolly the sheep was born in 1996, but the report about it was only made public in 1997.

\textsuperscript{86} Hwang WS and his colleagues have reported the development of the first human embryonic stem cell line by using the SCNT method in 2005. See Woo Suk Hwang et al, ‘Patient-Specific Embryonic Stem Cells Derived from Human SCNT Blastocysts’ (2005) 308 \textit{Science} 1777, 1777–
2.5.4 The Altered Nuclear Transfer Method

The altered nuclear transfer method was proposed by Meisser and Jeanisch; it is similarly based on the SCNT application. However, the adult somatic cell is modified to turn off the gene that allows implantation of the blastocyst, meaning that the resulting blastocyst cannot implant itself properly into a uterus and therefore cannot develop. However, the blastocyst that is derived from the altered nuclear transfer method can be subjected to hESC research.

2.5.5 The Cytoplasmic Hybrids Method

The cytoplasmic hybrids method is also based on the SCNT application. The embryo is generated by inserting an adult somatic cell into an animal egg (whose nucleus has been removed) and then electrically stimulating them to fuse. The resulting embryo contains a human genetic copy of the original adult cell, which provides embryonic stem cell lines that match the adult cell owner.


88 Cytoplasmic hybrids embryos are created by injecting human somatic nuclear cells into enucleated animal eggs in order to extract embryonic stem cells. This method would avoid the risk to women’s health in eggs harvesting for research purposes. It is currently allowed in the United Kingdom with strict regulation. Cytoplasmic hybrids are sometimes referred to as human admixed embryos or human/animal hybrid embryos. See United Kingdom, House of Commons Science and Technology Committee, Human Reproductive Technologies and the Law, 5th report session (2005).
Summary

In the debate over hESC research, the method of deriving the embryonic stem cells is at the core of the discussion. The research into the therapeutic application of hESCs is viewed as controversial because the derivation methodology terminates the development of the human embryo during the process of extracting the hESCs.\textsuperscript{89} However, human embryo research holds potentials that could not be derived from other types of research and the limitation on such research should only be based legitimate grounds.

2.6 Potential Applications for hESCs

The hESC’s ability to reproduce and differentiate indefinitely into any cell type provides scientists with the hope of developing an ‘unlimited cell source for cell transplantation’.\textsuperscript{90} Furthermore, the unlimited ability of embryonic stem cells to differentiate into any cell type also provides promising potential for drug screening within the pharmaceutical industry. Drug toxicity can be tested with cells derived from hESCs during the drug research and development process.\textsuperscript{91} In addition, disease progression can be studied in cells derived from hESCs that are


disease infected, or whose genes have been manipulated, to aid with new drug discoveries.\textsuperscript{92}

Research carried out on human embryos also has an application in the treatment for infertility. Early human development can be studied in areas such as embryonic tumours, and the causes of birth defects can be explored.\textsuperscript{93} Various models could be generated which simplify the complex processes that take place in the development of human embryos. The potential offered by hESC research has led scientists and clinicians to gain a greater understanding, and to acquire the skills needed for the future applications, of the human embryo research and the hESC technology.\textsuperscript{94} However, these potential applications could not come into existence if human embryo research were prohibited.

Associated with the potential applications are concerns over the appropriateness of the research conducted. The carrying out of research in order to extract hESCs from human embryos drew public attention to moral and social issues.\textsuperscript{95} On the one hand, the potential therapeutic uses for hESC have given hope to patients who suffer from currently untreatable illnesses. On the other hand, the process of extracting hESCs, which stops human embryos from developing further, raises

\textsuperscript{92} Ibid.

\textsuperscript{93} Ibid.

\textsuperscript{94} The successful clinical application in animals has shown the potential curing for diabetes, Parkinson’s disease and spinal cord injury. See Kiatpongsan, 'Introduction to Stem Cell Medicine', above n 48, 112.

\textsuperscript{95} See Brambati, above n 66.
concerns surrounding the need to protect the sanctity of human life, human dignity, and moral codes and beliefs.

2.7 Current Regulation of Human Embryo Research in Thailand: Problems without Specific Legislation Regulating Human Embryo Research in Thailand

Thailand is a nation that currently allows research to be conducted into human embryo and stem cell technologies. In the absence of any laws in Thailand either preventing or restricting the conduct of such research, Thailand’s researchers are allowed to conduct embryonic stem cell research and are subject to little regulation in doing so.

While it is important for research to be sufficiently advanced before application to therapeutic medications, the absence of laws specifically regulating human embryo research may impede the pace of research as well as causing society’s moral codes and beliefs to be questioned.

2.7.1 Ambiguous Nature of the Regulation

In the absence of specific legislation, scientists interested in conducting human embryo research in Thailand might feel reluctant to expand their research into more specific areas for fear of possible litigation in which the existing laws might be applied in an unexpected way to human embryo research. Various questions
have not been answered in Thai law and therefore remain unclear. For example, does Thailand allow research to be conducted on human embryos if that research directly benefits the embryo that is the subject of the research? Does Thailand allow research to be conducted on human embryos if the aim of the research is to produce therapeutic medication for the benefit of others? Does Thailand allow research to be conducted on human embryos if the research will result in the destruction of the subject embryos but at the same time will yield benefits for others? In the absence of specific laws, these questions will remain unanswered until there is litigation, presenting the courts with an opportunity to establish case law on the subject. However, judicial precedent is not binding the court in Thailand but is used as a secondary authority.

Where a novel civil proceeding is commenced before the Thai courts without any specific laws governing the issue, the relevant court would generally consider existing comparable legislation or Thailand’s cultural factors in delivering its judgment and the provisions of the Civil and Commercial Code (Th) would be applied. The Civil and Commercial Code (Th) requires that, in order for research to be conducted on a human subject, the informed consent of the subject is crucial. This informed consent must be obtained from the subject involved prior to the research being commenced.96 However, in the context of human embryo research, the question of whom the informed consent should be obtained from is not easily answered. The question as to whether an in vitro human embryo is considered a human in its own right, or is the property of the owners of the

96 See Civil and Commercial Code (Th) ss 354-452.
gametes, has not been answered in any legislation in Thailand. Obviously, when conducting research on human embryos, it is impossible to obtain the informed consent of the *in vitro* human embryos. In circumstances where research needs to be conducted on human embryos, should informed consent be obtained from the parents or should human embryos be protected under a separate legal regime? In civil litigation, the decision will come down mainly to the exercise of the judges’ discretion. This will leave the decision to judges who may not be familiar with the issues and would not have the benefit of legislative guidance.

This position would create a situation whereby researchers would be fearful of the possibility of litigation and would therefore avoid conducting human embryo research in the Kingdom. It would hinder the development of scientific knowledge that could otherwise be obtained from the research if the boundaries of legal conduct were clearly set out.

**2.7.2 Lack of Ethical and Legal Boundaries**

As well as hindering the conduct of human embryo research that may benefit society, the absence of laws specifically regulating the conduct of the research in Thailand could attract scientists who wish to establish laboratories for the conduct of morally questionable research which cannot be conducted in other countries. For example, in various countries, reproductive cloning is viewed as unethical conduct. However, due to the absence of specific legislation in Thailand regulating human reproductive cloning, Woo Suk Hwang has moved his
laboratory to Thailand to conduct research on human cloning which is prohibited in South Korea.97 This situation would place the social morality of Thailand’s citizens in peril, as the development of the scientific technologies would accelerate while the concerns held regarding the ethics and morality of the people in society would be at risk of being ignored.98 In some cases, researchers have moved their scientific experimentation bases to countries with fewer restrictions, in order to expand their questionable research activities, can be found in various areas of medical science. For example, in Italy, certain types of pre-implantation genetic diagnosis (PGD) are prohibited.99 This legal restriction has driven a number of couples to seek this type of medical service elsewhere and so has resulted in scientists interested in conducting this type of research doing so in jurisdictions where it is permitted.100

In Thailand, research and medical practices conducted by medical practitioners are normally subject to the supervision of the Medical Association of Thailand. The Medical Association has created several codes of conduct governing research involving human embryos. These codes of conduct have been created with the

intention of putting in place certain standards governing various types of research and service practices, as well as limiting the conduct of certain medical practices that are deemed inappropriate. As regards research involving human embryos, the relevant codes of conduct are nos. 1/2540 and 21/2544,\textsuperscript{101} which set out the standards required for services related to reproductive technology. Under these two codes of conducts, services related to reproductive technology may only be conducted by a medical practitioner, and reproductive human cloning is strictly prohibited. The regulatory regime developed by the Medical Association of Thailand, governing research involving human embryos, takes the form of professional regulation. As a result, the standards adopted apply only to medical professionals, with non-compliance resulting in the suspension or revocation of the practitioner’s medical practice licence.

Another attempt to regulate human embryo research can be found in the guidelines of the \textit{National Centre of Genetic Engineering and Biotechnology}.\textsuperscript{102}

In 2003, the \textit{Guidelines to Practices and Issues Concerning Research Involving Humans} were developed by the Biomedical Ethics Research Project and Modern Medicine.\textsuperscript{102}

\textsuperscript{101} ประกาศแพทยสภาที่ 1/2540 [The Medical Association Codes of Conduct 1/2540], เรื่อง มาตรฐานการให้บริการเกี่ยวกับเทคโนโลยีช่วยการเจริญพันธุ์ [The Standard of Assisted Reproductive Services]; ประกาศแพทยสภาที่ 21/2544 [The Medical Association Codes of Conduct 21/2544, เรื่อง มาตรฐานการให้บริการเกี่ยวกับเทคโนโลยีช่วยการเจริญพันธุ์ (ฉบับที่ 2) [The Standard of Assisted Reproductive Services No.2].

\textsuperscript{102} Guidelines to Practices and Issues Concerning Research Involving Humans, โครงการที่ชีวจริยธรรมกับการวิจัยวิทยาศาสตร์การแพทย์สมัยใหม่ [Biomedical Ethics Research Project and Modern Medical Science], แนวปฏิบัติและประเด็นจริยธรรม ทางวิจัยวิทยาศาสตร์การแพทย์สมัยใหม่ที่เกี่ยวข้องกับมนุษย์ [Guidelines to Practices and Issues Concerning Research Involving Humans], October 2003.
Medical Science under the National Centre of Genetic Engineering and Biotechnology.\textsuperscript{103} The Guidelines contain recommendations to be implemented when a research fund is created and financial support is provided for any modern medical scientific research involving human subjects. Under these Guidelines, research may only be conducted on surplus ART embryos and from embryos created by SCNT, as long as they are no more than 14 days old.\textsuperscript{104} However, the regulation of research activities by the use of guidelines is constrained in terms of enforceability. The only practical application of the guidelines is in the ratification of institutions and research centres that submit to the guidelines on a voluntary basis. The result is that a particular type of research may be conducted in one institution while the same type of research is not conducted in another institution because of the different policies and research guidelines adopted by each institution. This scenario creates inconsistencies in the regulation of human embryo research in Thailand.

2.8 The Draft Law: “Protection of Children Born from Assisted Reproductive Technology Bill” — The Bill (Th)

In 2004, the Office of Welfare Promotion, Protection and Empowerment of Vulnerable Groups, Ministry of Social Development, established a committee, chaired by Mrs. Saisuree Chutikul, to study assisted reproductive technology and

\textsuperscript{103} นเรศ ดํารงชัย, ’ชีวจริยธรรมของการวิจัยดานเซลลนกําเนิดจากแนวคิดสูแนวทางปฏิบัติสําหรับประเทศไทย’ [Stem Cell Bioethics: From Theory to the Implementation in Thailand], 29 June 2004).

\textsuperscript{104} Guidelines to Practices and Issues Concerning Research Involving Humans, above n 102.
make recommendations for a law to be enacted protecting children born from the application of that technology. Studies have been conducted since 1 March 2004, involving 36 meetings being held, with both medical practitioners and legal professionals being consulted. Two public hearings have been held to gather information and suggestions.

In October 2007, the Secretariat of the Cabinet approved the draft Protection of Children Born from Assisted Reproductive Technology Bill (Th) — The Bill (Th) — and referred the Bill (Th) to the Council of State further consideration. In November 2010, the Council of State approved the Bill (Th) and referred it to the House of Representatives for consideration. At the present, the Bill (Th) is currently in the process of Parliamentary consideration. Due to the constant change of government in Thailand, the Bill (Th) has not yet been passed by the House of Representatives. The Bill (Th) is concerned mainly with the use of assisted reproductive technology to create a child and surrogacy arrangements. However, there are provisions dealing with the use of human embryos for research purposes.


106 Ibid.

107 Ibid. See also, Thai Law Watch Website <http://thailawwatch.org/bills/assisted-reproductive-technology-bill/> updated 27 September 2011.
Another Bill which is in the process of being drafted is the Research Involving Human Subject Bill (Th).\footnote{Thai Law Watch Website <http://thailawwatch.org/bills/assisted-reproductive-technology-bill/> updated 27 September 2011.} This Bill addresses scientific research that is conducted on human subjects including human cells, human tissues and human gametes.\footnote{สํานักงานเลขานุการ คณะกรรมการวิจัยการสืบพันธุ์ในมนุษย์ กระทรวงสาธารณสุข [The Ethical Review Committee for Research in Human Subjects, Ministry of Public Health], บันทึกหลักการและเหตุผลประกอบร่างพระราชบัญญัติวิจัยที่เกี่ยวข้องกับมนุษย์ บ.ศ. ... [Explanatory Memorandum on Research Involving Human Subject Bill B.E. ...] <http://www.ecmoph.com/files/archives/decreed-prin.pdf> 11 September 2007.} In the current draft, the main focus of the provision is to give guidelines for the ethical review committee of each institution when granting a research licence.\footnote{Ibid.} However, this Bill is not yet settled; it was debated in two public consultations and is currently in the revision process under the Ministry of Public Health, Thailand.\footnote{ ' narc.วิจัยในมนุษย์! ปัญหาหนัก' [Delay of the Research Involving Human Subject Bill], ไทยโพสต์ [Thaipost] (Thailand) 8 October 2011.}

2.9 Concluding Summary

While human embryo research offers many benefits, it also raises many ethical and legal problems which have the potential to undermine fundamental beliefs involving human life and death which are the foundations of civic society. The absence of laws specifically regulating the conduct of human embryo research in Thailand could entice scientists to Thailand to establish laboratories for unethical
and unacceptable research which cannot be conducted in other countries. This situation would place the social morality of Thailand’s citizens in peril as those unethical sciences would be allowed to progressively accelerate while the concerns held for the ethics and morality of the people in society would be put to one side. Furthermore, without specific legislation, scientists interested in conducting human embryo research in Thailand might feel reluctant to extend their research into these areas because of a concern about the possibility of litigation in which the existing law might be interpreted in a way that adversely affects the conduct of the research. Thus, it is important to have specific legislation regulating human embryo research in Thailand in order to address the issues associated with human embryo research.

112 For example, in various countries, reproductive cloning has been viewed as an unethical practice. In addition, in some countries, the creation of cytoplasmic hybrid embryos is prohibited. See Cyranoski, above n 97.
Chapter Three:

The Moral Status of Human Embryos

3.1 Introduction

The discovery of potential uses for human embryo research is like a geographical map on which a new landscape has appeared. To date, much of the ethical and policy debate surrounding human embryo research has focused on the moral status of the human embryo before implantation. When conducting human embryo research, it is necessary to use cells from human embryos, with the inevitable consequence that further development of the embryo is prevented. The question of whether the human embryo should be granted legal protection and the status of a viable person or, at the very least recognised as a potential person, is a highly controversial subject.


The current perception regarding the status of the human embryo has been influenced by theories surrounding the starting point of human life.\(^\text{115}\) In Thailand, prior to the advancements in technology that allowed the creation of human embryos \textit{in vitro}, the generally accepted view about the time at which a human life came into existence was limited by the knowledge that then existed regarding human reproduction. The pregnant woman usually become aware of her pregnancy after the embryo had implanted itself into the uterine wall, which occurs 6–12 days after conception.\(^\text{116}\) After implantation, the existence of a human embryo is recognised by Thai Law. Prior to the creation of human embryos outside the body, there was never any debate in Thailand about the human status of the embryo in the period from conception until implantation into the uterine wall. Currently, in Thailand, the law that protects the life of human embryos is contained in the abortion law. The abortion law only protects the life of human embryos after implantation and does not prohibit the use of an IUD for birth control nor sterilisation, both of which prevent such embryo from getting to the point of implantation.

However, now that technology has developed to the point where human embryos can be created \textit{in vitro}, it is important to revisit social perceptions toward the status of the human embryo. Contrasting views have been expressed by those who believe that an embryo is a human being with a moral status and by those who see


the embryo simply as a combination of human parts and as an appropriate subject for research. These contrasting views regarding the status of human embryos have implications for policies and legislation. Chapter Three discusses the moral status of the human embryo and the sanctity of human life principle, with attention to the Buddhist views of human embryos. As stated before, the Buddhist view represents the morality of Thai people and influences various contexts of Thai society as well as the law.

3.2 Sanctity of Human Life

When considering the appropriateness of human embryo research, the key question concerns the sanctity of life principle which is a common law principle that is the basis of many human rights. The concept of the inviolability of human life, which is an integral part of the sanctity of life principle, refers to the prohibition against the taking of innocent human life, even for merciful reasons. According to this doctrine, it is not always wrong to take a human life in certain circumstances, such as capital punishment or killing a person in self-defence. However, it is wrong to intentionally take an innocent human life.

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The sanctity of life principle is also the basis of arguments surrounding euthanasia and abortion, as well as reproductive technologies. Those who subscribe to the absolutist theory believe that life is sacred and inviolable under all circumstances. According to this principle, concluding that one life is better than another, and taking an innocent life, are unethical and must be avoided. There are two separate tenets underpinning the principle of the sanctity of life: one is that, by being a member of the species of *homo sapiens*, one’s life has special value; the other is that a special value is accorded to human life which possesses certain qualities. For instance, Peter Singer, a leading consequentialist ethicist, believes that a human being can be distinguished from other species by possession of human characteristics such as ‘self-awareness, self-control, a sense of the future, a sense of the past, the capacity to relate to others, a concern for others, communication and curiosity’. To be a human being, in his view, involves not just being a member of the human species, but also being a conscious and rational person. According to this interpretation, an embryo is not a human being as it lacks these capacities and does not have the same human status as an adult human. However, groups who subscribe to the absolutist view of sanctity of life point out that because a human embryo possesses the same

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120 Kuhse, above n 118, 6.


123 Ibid 87.
essential properties that a human possesses then, even though it is still in the developmental stage, it should be afforded the same rights and protections as a human and not be subjected to any research.124

3.2.1 The Equal Value of All Human Life

The concept of the equal value of all human life, which is also an integral part of the sanctity of life principle, refers to the view that all human lives are equal and entitled to the same protections. Regardless of the quality of life or the stage of human development, the sanctity of life doctrine requires that all human lives be granted the same status and protections.125 Under this doctrine, infants as well as disabled persons, for example, have the same status and are entitled to the same protections as humans. The equality of all human life is the dominant argument put forward against the performance of mercy killings.126 According to this

124 For example, George and Gomez-Lobo points out;

Each new human being comes into existence possessing the internal resources to develop immediately exercisable characteristically human mental capacities and only the adverse effects on them of other causes will prevent their full development. In this sense, even human beings in the embryonic, fetal, and infant stages have the basic natural capacity for characteristically human mental functions.


126 Kuhse, above n 118, 9–11.
argument, even though the present or future quality of life may be severely compromised, the killing of such a life should be prohibited.

### 3.2.2 The Source of the Sanctity of Life Principle

Most scholars claim that the sanctity of life principle is grounded in religious beliefs. In the various discussions about the history of the sanctity of life principle, there is general agreement that the traditions of Christianity have had a significant influence on the extent to which people believe in the sanctity of life. Kuhse suggests that the belief that it is wrong to take a human life was not widely held until the religions of Judaism and Christianity began to flourish. She points out that, in ancient Greece and ancient Rome, the taking of a human life was considered acceptable in many different circumstances, including the killing of a deformed infant, abortion, suicide and euthanasia. For example, Aristotle, the great philosopher, wrote in his book, *Politics*, that ‘[a]s to the

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128 Kuhse, above n 118, 16–21. Prior to the nineteenth-century, human life was not understood to start at conception. It was believed that only after ensoulment, the foetus becomes a person. It was after the scientific discovery of the process of fertilisation in nineteenth-century that Catholic Church deemed human life starts at conception. Christine E Gudorf, ‘Contraception and Abortion in Roman Catholicism’ in Daniel C Maguire (ed), *Sacred Rights: The Case of Contraception and Abortion in World Religions* (Oxford University Press, 2003), 69.

129 Kuhse, above n 118, 16–21.

130 Ibid.
exposure and rearing of children, let there be a law that no deformed child shall live’.  

The sanctity of life is highly prized in many religions. The Catholic Church decrees that life has infinite value because it comes from God and is the property of God. Destroying human life is against God’s will. By comparison, Buddhists believe that human life is sacred not because it is the property of a divine being, but because, apart from the fact that all living things cherish their lives, human life is the path to the most precious goal of all life – that of nirvana. Thus, to destroy life is to deprive a person of one of the most valuable resources.

Catholicism


133 S R Goyal, Indian Buddhism after Buddha (Kurumanjali Book World, 2003), 39 However, Parpod Assavavirulhakarn asserts that ‘among religious aims, the most frequent is to become a Buddha, or to be reborn in the time of the future Buddha, Maitreya. A third religious aim is to wish to attain nirvana’. See Assavavirulhararn, above n 14, 175.

134 In arguing against abortion, Lecso stated that ‘…basing on the high value placed upon the human rebirth. “The human rebirth is a life form hard to find and once found, very meaningful; a treasure more precious than a wish-fulfilling gem”’, Phillip A Lecso, ‘A Buddhist View of Abortion’ (1987) 26(3) Journal of Religion and Health 214, 216.
From a Catholic viewpoint, an embryo has the same moral status as a human. Pope Benedict XVI stated that ‘human life is sacred and inviolable at every moment of its existence, including the initial phase which precedes birth’. Thus, according to the Roman Catholic Church, human embryo research that destroys human embryos violates the sanctity of life.

**Judaism**

Judaism deems that an embryo does not have the same moral status as an adult. Although it is regarded as a potential life, it warrants only a certain level of respect and protection not equal to that afforded to an independent life. In the

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135 The Congregation for the Doctrine of the Faith (Donum Vitae) states that ‘[t]he human being is to be respected and treated as a person from the moment of conception: and therefore from that same moment his rights as a person must be recognized…’. See The Congregation for the Doctrine of the Faith, *Instruction Dignitas Personae on Certain Bioethical Questions*, 8 September 2008 <http://www.vatican.va/roman_curia/congregations/cfaith/doc_doctrinali_index.htm>.

136 The Address of His Holiness Benedict XVI to the Participants at the 12th General Assembly of the Pontifical Academy for Life and Congress on “the Human Embryo in the Pre-Implantation Phase”, Clementine Hall, 27 February 2006 <http://www.vatican.va/holy_father/benedict_xvi/index.htm>.

137 In the discussion on abortion, Zoloth stated that ‘[n]ot only does Jewish tradition have a developmental view of the moral status of the embryo and fetus but also the tradition’s focus on life and health for the mother is the primary ground for the debate Moral status of the embryo in Jewish considerations of abortion is based on age and proximity to independent viability’. In this regard, it can be asserted that the human status of an embryo is based on age and viability as well. Laurie Zoloth, “‘Each One an Entire World’: A Jewish Perspective on Family Planning’ in Daniel C Maguire (ed), *Sacred Rights: The Case for Contraception and Abortion in World Religions* (Oxford University Press, 2003), 38.

138 For instance, the Old Testament contains a principle whereby, should a pregnant woman be hurt in a fight between two men and she loses her baby as a result, then those men would be
context of human embryo research, this interpretation can mean that research on human embryos that results in their destruction is not totally objectionable. Furthermore, it has been suggested that, from a Jewish perspective, stem cell research that leads to new medical treatments should be permitted as it provides hope and ‘from a Jewish perspective we have a duty to proceed with that research’.139

Islamic View

There are various views held regarding the moral status of an embryo under Islam. Unlike the Roman Catholic Church, there is no central authority representing Muslim beliefs. Therefore, a range of views can be held depending on the way the religious texts and scriptures are interpreted.140 However, when looking at the Qur’an, the Hadith and the Shari’a (which are the foundations of Islam), the respective texts convey the belief that an embryo attains human status after subject to a fine. However, if the woman were to die, those men would be liable to the death penalty. This principle is found in Exodus, Chapter 21, which implies that the status of the unborn is less than that of an adult human as the penalties applied in each of the two circumstances are not the same.

If men strive together, and hurt a woman with child, so that her fruit depart, and yet no mischief follow; he shall be surely fined, according as the woman’s husband shall lay upon him; and he shall pay as the judges determine. But if any mischief follow, then thou shalt give life for life

The Hebrew law of Exodus 21:22ff quoted in Dunstan, above n 3, 39.


140 Bundren, above n 113, 733-36.
ensoulment, which occurs after the fortieth day of the pregnancy.\textsuperscript{141} It can be inferred from this view that human embryo research is permissible as it is performed on embryos that have developed for less than forty days.

\textit{Buddhism}

The Buddhist view of research involving the destruction of a human embryo is complex.\textsuperscript{142} The sanctity of life is one of the foundation beliefs of Buddhist ethics in both the Theravada and Mahayana doctrines.\textsuperscript{143} Drawing on the belief that all creatures disliked pain and death, the Buddha disapproved of killing or causing injury to all living things.\textsuperscript{144} Buddhism teaches that there are six stages of rebirth: hell, animals, ghosts, titans, humans and gods.\textsuperscript{145} Despite the better conditions of life in the realm of the gods, it is widely perceived in Buddhist communities that the most desirable condition in which to be reborn is as a human being.\textsuperscript{146} This is because the human stage alone provides the opportunity to transcend the realm of

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\textsuperscript{141} Vardit Rispler-Chaim, \textit{Islamic Medical Ethics in the Twentieth Century, Social, Economic and Political Studies of the Middle East} (Brill Academic Pub, 1993), 9-11.
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\textsuperscript{142} An in depth discussion on Buddhist view will take place later in the chapter.
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\textsuperscript{143} According to S R Goyal, there are broadly three Buddhist sects; Hinayana (Theravada), Mahayana and Tantrayana. However, the commonly known sects are Theravada and Mahayana. Goyal, above n 133, 39.
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\textsuperscript{144} This doctrine can be seen in the first percept of layperson in Buddhist Ethics. H Saddhatissa, \textit{Buddhist Ethics: Essence of Buddhism} (G Allen & Unwin, 1970) 87.
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\textsuperscript{146} Ibid 29.
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suffering and to become enlightened like the Buddha.\textsuperscript{147} However, being reborn as a human is considered an exceedingly rare circumstance. In order to be reborn as a human, an individual has to accumulate virtuous karma.\textsuperscript{148} Thus, the sanctity of human life is highly protected in Buddhist ethics. Any actions which result in the destruction of an embryo, such as an abortion, are severely condemned among Buddhist societies.

Apart from the principle of the sanctity of life, the ultimate foundation belief of Buddhist ethics is karma. The Buddha defined karmic actions as moral actions.\textsuperscript{149} Therefore, whether actions are good or bad, action is determined by the intention of the individual. Even though the status of being human is granted at the very beginning, at the moment of fertilisation, the intention behind the destructive action is also given the same weight when considering the arguments for and against human embryo research. The intention to do research for the benefit of others can be accounted for as good karma. Likewise, researchers who conduct research on the human embryo, the result of which is to take the life of a human, can obtain good karma as well as bad karma from such an action.

3.2.3 Compromise of the Sanctity of Life Principle


\textsuperscript{148} Harvey, An Introduction (2000), above n 145, 14-16.

\textsuperscript{149} Ibid 17.
Due to the influence of the Universal Declaration of Human Rights and other international conventions, much of the legal theory governing the regulation of human embryo research is articulated in the form of rights and liberties.\textsuperscript{150} In today’s society, even though the principle of the sanctity of life is accepted internationally, the recognition of principles such as the right to autonomy have seriously challenged the respect held for the sanctity of life principle in various ways.\textsuperscript{151} For example, in the context of the abortion debate, the idea that a woman has the right to seek an abortion when the pregnancy threatens the life of the woman is slowly being accepted around the world.\textsuperscript{152} Furthermore, the principle of individual liberty has resulted in a change of perception, which can be evidenced in decisions to refuse treatment as well as the use of euthanasia in various jurisdictions.

Generally, concerns involving the protection of the sanctity of life in human embryo research are associated with the kind of human embryos that are suitable for research purposes. In countries where \textit{in vitro} embryo is viewed as having the same status as a human, research conducted on such embryos would be contrary to sanctity of life principles. For example, in Italy where an \textit{in vitro} human embryo is viewed as having the same status as a human, research on such embryos is prohibited as it would be an action of treating human life as the means

\textsuperscript{150} Jonathan Herring, \textit{Medical Law and Ethics} (Oxford University Press, 2\textsuperscript{nd} ed, 2008) 19.

\textsuperscript{151} John Keown, above n 125, 253.

to an end. However, in a jurisdiction where *in vitro* human embryo does not have the same status as a human, certain types of research on human embryos would be able to be conducted within the ethical boundaries, where other principles such as human dignity and the public morality would not be violated.

### 3.3 The Protection of Human Dignity, Social Foundations and Safety Concerns

*Preamble to the Universal Declaration on Human Rights*

Whereas recognition of the inherent dignity and of the equal and inalienable rights of all members of the human family is the foundation of freedom, justice and peace in the world ... 

In Kantian theory, the fundamental principle regarding human dignity is that a person should never be treated as a means to an end. In the debates stemming from human embryo research, it has been argued that the research does not respect human dignity. The main concern is that embryos die during the research, in order for hESCs to be generated and that as a result embryos are treated as research objects rather than as humans with their own dignity.

However, the phrase ‘human dignity’ can be ambiguous. According to Kantian theory, in order to be entitled to human dignity, one would need to have consciousness and the capacity to reason. This interpretation raises the question of

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whether one needs to have consciousness or just be a member of the *homo sapiens* species in order to be entitled to human dignity. If the consciousness factor is essential in order to be entitled to human dignity, a human embryo would not be so entitled because it does not have any consciousness at the point when hESCs are extracted from it.  

155 In contrast, if being a member of the human species is the only factor needed to be entitled to human dignity, then a human embryo would be entitled to human dignity and would be granted the same respect as a human. These diverse views can be argued endlessly as the grounds for these arguments are based on subjective theories which depend on people’s perceptions. 

Like sanctity of life principles, there are the separate tenets underpinning human dignity: one to the human life itself and the other to the member of *homo sapiens* as a whole. The absolutist view of human dignity includes the protection of the dignity of the human race as a whole. Under this interpretation, research that would erode the dignity of human race, such as the creation of a human-admixed embryo, can be viewed as being contradictory to human dignity.  

156 The Universal Declaration of the Human Genome and Human Rights recognises the absolutist view of human dignity in that ‘[t]he human genome underlies the fundamental unity of all members of the human family, as well as the recognition of their inherent dignity and diversity. In a symbolic sense, it is the heritage of

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156 Baylis, above n 89, 24-25.
humanity’. It is also in the interest of states to respect the dignity of their populace and “not to reduce individuals to their genetic characteristics”.

Concerns involving human dignity and the maintenance of the moral codes and beliefs of society are often associated with the question of what kind of human embryos are suitable for research purposes. In countries where the human embryo is viewed as having the same status as an adult human, research on such embryos would be contrary to the human dignity and morality of people as it would be treating human life as a means to an end. However, in a jurisdiction where the human embryo does not have the same status as a human but is entitled to some protection after a period of development, certain types of research on human embryos can be conducted within ethical boundaries where human dignity and the morality of the people would not be violated. However, the absolutist view on human dignity includes the protection of the dignity of the human race as a whole and views any conduct that would deprive the dignity of human race as a violation of human dignity. The dignitarian view and the human rights view are similar in that they both represent the view that a human has a certain moral status and has

157 *Universal Declaration on the Human Genome and Human Rights* Art 1.

158 *Universal Declaration on the Human Genome and Human Rights* Art 2(b).


To create embryos with the intention of destroying them, even with the intention of helping sick, is completely incompatible with human dignity, because it makes the existence of a human being at the embryonic stage nothing more than a means to be used and destroyed.
rights that cannot be violated. However, the dignitarian approach rejects the claim that free and informed consent can be used to sanction a violation of human dignity, whereas, from the human rights perspective, informed consent by the research subject can be accepted.160

3.4 The Utilitarian View: The Future Life

Utilitarianism counts benefits against harms. Any action is judged to be ethically acceptable only when the weighing scale leans towards the benefits side. However, utilitarians restrict the calculation to those affected by the action who are capable of having interests, experiencing pain or pleasure.161 Thus, in the context of human embryo research, the Utilitarian would not be engaged in the debate as, at the time when the research is to be conducted, the human embryo has not yet developed those senses and therefore lacks the ability to experience pain or pleasure.

However, the assumption that human embryo does not constitute a life is not globally accepted without question. One can assume that embryo is a human life and destroying it would need justifications. Even though some groups claim that human life starts at conception, one of the arguments for the use of surplus ART embryos for human embryo research is that there is no possible future life for the

160 Brownsword, Rights, Regulation, and the Technological Revolution, above n 5, 39.
161 Ibid, 37.
surplus embryos as they are destined to be discarded. This argument has been articulated as follows:

If we accept that these embryos, which are to be discarded, are destined to be destroyed for sound ethical reasons, then the tissue derived from them deserves the same moral status as tissue derived from a deceased infant. In other words, human life is not sacrificed for research purposes. 162

This argument suggests that the debate about when human life begins is not relevant to the extraction of hESCs from surplus ART embryos. It follows the assumption that surplus ART embryos have no future life as they are ‘destined to be destroyed’, thus those embryos are viewed as a group of cells that have no life. To put this argument another way, the use of surplus ART embryos for hESC research is as ethical as are the use of cells that are derived from deceased embryos or people. Therefore, from this view point, the research on surplus ART embryos is viewed as ethical. However, people who subscribe the absolutist theory of the sanctity of human life would have an opposite view point. The sanctity of life doctrine dictates that life is sacred and inviolable under all circumstances and taking an innocent life is unethical and must be avoided. If a human embryo is considered a human life, regardless of its destination, the sanctity of life doctrine would be applied the same way as to a human.

3.5 The Beginning of Human Life

162 Gilbert, above n 91, RA101.
The sanctity of human life in the context of human embryo research cannot be properly assessed without discussing these two questions: when does human life begin and what elements constitute being a human? There is currently no consensus on when human life begins. However, there are those who oppose and those who support human embryo research based on their determination of the beginning of human life. There are three common positions on the status of the human embryo: 1) the pro-life view where ‘[t]he embryo-foetus has full moral status, equal to that of any adult human, from the moment of conception’; 2) the gradualist view where the embryo acquires full human status at birth, however, the embryo gains respect or special status due to its potential to become human and the level of respect increases through time of gestation; 3) the pro-choice view where ‘[t]he embryo-foetus has no intrinsic moral status (i.e. no moral status solely by virtue of its own characteristics). Such status is only acquired at birth or even beyond and, when acquired, is acquired to the full extent possible’.163 For instance, the groups who oppose human embryo research argue that personhood starts at conception when the two gametes combine and are transformed into a zygote which possesses the capability to develop into a human.164 This specific moment has been viewed as the moment at which human life comes into existence. According to this view, the derivation of hESCs is unethical and should be avoided as it destroys the human embryo, which has the same status as a human.165 On the other hand, there are others who do not take the view that

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163 Beyleveld, above n 155, 59–85.

164 Ibid.
human life starts at the moment of conception and assert that the coming into existence of human life is gradual and continuous and therefore cannot be pinpointed with any precision.\textsuperscript{166}

More to the point, in the view of these commentators no discrete point in time or development would seem to give any justification for assuming that the embryo in question was one thing at one point and then suddenly became something different (turning, for example, from non-human to human or non-person to person).\textsuperscript{167}

This point of view rejects the argument that an embryo has the same status as a person from the moment of conception. This perception leads to the conclusion that a human embryo does not have the same status as a human, and that such status will develop during the course of its gradual development.\textsuperscript{168} Therefore, according to this view, it is possible to conduct human embryo research ethically, as for example, if it is conducted on the human embryo before its 14\textsuperscript{th} day of development, as the blastocyst is not fully entitled to the status of being human.

### 3.6 Elements which Constitute Being a Human


\textsuperscript{167} President’s Council on Bioethics, above n 124.

\textsuperscript{168} Strong, above n 166, 436.
In addressing the question of what constitutes being a human, one must consider the various methods of human procreation. The first and traditional method, is the natural fertilisation of a human egg by a human sperm inside a female’s body. In this instance, there is no doubt that the resulting embryo is human because it came into existence naturally without any technological assistance.\(^{169}\)

However, the capacity to create human embryos outside a woman’s body has complicated these issues. Several techniques, which have been successfully applied using animal models, have been introduced for the creation of human embryos. If the fertilisation of a human egg by a human sperm were a prerequisite for being human, then various types of embryos would now be considered non-human.\(^{170}\) By this approach, a SCNT embryo, a cytoplasmic hybrid embryo and parthenogenetically activated oocytes would be excluded from the definition of a human embryo,\(^{171}\) as the biological makeup of the resulting embryo would not be the same as an embryo conceived traditionally, by fertilisation.\(^{172}\)


As an example, the embryo created by SCNT technology could not be considered human as sperm is absent from the process and the resulting embryo is not created via the traditional method of natural fertilisation. Thus, it is possible to conduct research on SCNT embryos without concern over the protection of sanctity of life principles. The use of SCNT technique in the creation of human embryo for research could provide a significant development in medical science. In theory, creating a stem cell line using the SCNT technique provides the ability to create tissue that is matched with the patient’s immune system. A key benefit of this technique is that it avoids the need for use of immunity suppression drugs. This technological advance could provide an unlimited source of cells for transplantation, with cells created specifically for each unique patient. However, the technique of SCNT can also, in theory, generate a human that has genetic material that is identical to the donor of the somatic cell. This process of creating another identical entity is usually called reproductive cloning. The use of SCNT technique to create human embryo arouse controversy in relation to human reproduction as well as human embryo research. On the one hand, the potential to match tissue to specific patients tempts researchers as well as policy makers to be more permissive of research into this field of science. However, the perceived dangers involved in reproductive cloning have led some to call for a total ban on SCNT research. Reproductive cloning is considered unethical in many

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174 Hipp, above n 171, 2.
countries. Those people believe that allowing the application of SCNT will inevitably lead to reproductive cloning being permitted in the future. Furthermore, concerns have been raised by many people over the safety of the procedure as successful reproductive cloning has only ever been reported using animal subjects.

Furthermore, with the advent of new technology, an embryo can now be generated without the use of human eggs or human sperm – this is known as the cytoplasmic hybrid embryo. Following the same argument, a cytoplasmic hybrid embryo would also not be recognised as a human embryo as human gametes are omitted from its creation and scientific research on such embryo would possibly be ethically approved. Currently, female oocytes for research on human embryos are mainly derived from surplus eggs following infertility treatment. Surplus eggs are sometimes donated for research purposes including human embryo research; however, the shortage of donated eggs is increasing due to procedural risks to the woman’s health. As previously discussed in Chapter Two, women undergoing

175 Annas, ‘Regulatory Models for Human Embryo Cloning’, above n 98, 244-46.  
176 For more discussion on human cloning, see Brownsword, ‘Cloning, Zoning and the Harm Principle’, above n 173.  
179 Ibid.
infertility treatment require pharmaceutical stimulation called ovarian stimulation and oocyte retrieval, in order to cause several eggs to mature at the same time. These eggs are then surgically harvested for in vitro fertilisation in laboratories. This maturation process is often painful and requires a great amount of dedication by the women.\(^ {180}\) There are potential risks associated with the ovarian stimulation, which are mainly caused by the use of drugs and procedural issues. The potential risks include ovarian hyper stimulation syndrome (OHSS) infection, as well as bleeding.\(^ {181}\) The use of an animal oocyte has been viewed as the alternative to human oocyte for the creation of a human embryo for research purposes. However, the creation of human admixed embryos attracted a lot of attention from people in various societies.\(^ {182}\) Opposition to this research includes groups who consider that human dignity is infringed by the mixing of human substance with animal gamete. However, if cytoplasmic hybrid embryo is not considered to be a human embryo, then it is possible that the use of animal oocytes in the creation of cytoplasmic hybrid embryo would reduce the number of human oocytes required while maintaining the ability to derive human stem cells for research purposes.\(^ {183}\)


\(^{183}\) Ubaka Ogbogu, Timothy Caulfield and Shane Green, ‘From Human Embryos to Interspecies Creations: Ethical and Legal Uncertainties Surrounding the Creation of Cytoplasmic Hybrids for Research’ (2008) 9 Medical Law International 227, 228.
Summary

The moral status of human embryo is a highly controversial issue. There are various determinations that have been developed reflecting social, historical, moral, and legal contexts. In Thailand, the morality of people is mainly determined by Buddhist ethics. Thus, it is important to discuss Buddhist views on the human embryo in order to ascertain the moral status of the human embryo in Thailand.

3.7 The Buddhist Teachings

The ultimate foundation of Buddhist Ethics is Dharma. Dharma means ‘natural law’, which governs all beings despite their beliefs and values. This universal law was revealed by the Buddha as a law regulating every aspect of life. Damien Keown, the Buddhist bioethicist, explains the law of Dharma in one of his books as follows: “Dharma is neither caused by nor under the control of a supreme being, and the gods themselves are subject to its laws, as was the Buddha”. Dharma represents the truths and the teachings of Buddha, and to understand Dharma is to put an end to suffering, which is the ultimate goal of Buddhism.

Fundamentally, Buddhism involves a belief in reincarnation and an assertion that everyone has been through multiple cycles of birth. In Theravada Buddhist teachings, rebirth is an instantaneous phenomenon following the death of an

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The moment of birth is the rebirth of a pre-existing being. As a demonstration of this belief, the analogy of a man hanging onto a rope that stretches across a river tied to trees on either side has been used. Once he departs, the arrival then occurs. This happens even though the reincarnation does not take place visibly and even though it cannot be established where the next life will take place.

The Buddha defined karmic actions as moral actions. “It is intention, O monks, that I call Karma; having willed one acts through body, speech, or mind”. By this statement, the Buddha showed that all good and bad action is determined by the intention of an individual. In the law of Karma, both good and bad experiences in the present and the future are governed by the moral actions of that individual in the past, be that past hours, past days, past years or even past lives.

According to Buddhist teachings, moral actions have an impact both on the agent and on others. For example, stealing is an action which deprives an owner of his or her possessions. At the same time, stealing also characterises the thief as someone who is unsatisfied with his or her possessions. Human beings have free will and when they make their moral decisions, they are the author of their own character and their own future. Good moral actions lead to good effects while bad moral actions lead to bad effects. There is no supreme being that governs


individuals’ lives other than their own choice of actions. Actions cultivated by greed, hatred and delusion are bad, while actions cultivated by non-attachment, benevolence and understanding are good.

It is hard to predict when the law of karma will manifest its effects; some seeds might give their fruits in this life while others might give their fruits in the next life, or perhaps many lives ahead. However, individuals can always write their own future through their behaviour in the present. They can always resist previous conditioning by cultivating new behaviours through their choice of present actions.

3.7.1 Buddhist Embryology

The development of an embryo during the first month is comprised of four stages, according to Buddhism: Kalala, Abudda, Pesi and Ghana. Each stage involves approximately seven days of development. The first stage, called Kalala, is the stage in which an embryo is described as ‘clear and translucent’. The next stage, called Abudda, sees the embryo become more solid and able to bear more pressure. The development of an embryo, as described by the Buddha, is almost completely compatible with the modern science of embryology. The Kalala stage relates to the stage of the zygote development. The Abudda stage is similar to the implantation of the blastocyst noted by modern science. Drawing on the research of Bhikkhu Samut Thavarathummo in ‘A Comparative Study on Ethics Relating
to Abortion: Theravada Buddhism Viewpoints vis-a-vis Abortion Law’,\textsuperscript{187} this general comparison of Buddhist embryology and modern embryology can be broken down as shown in the following table.

<table>
<thead>
<tr>
<th>Buddhist Embryology</th>
<th>Modern Embryology</th>
<th>Approximate time of embryonic development</th>
</tr>
</thead>
<tbody>
<tr>
<td>Kalala</td>
<td>Zygote development</td>
<td>The first day of fertilisation</td>
</tr>
<tr>
<td>Abudda</td>
<td>Blastocyst development</td>
<td>The seventh day of fertilisation</td>
</tr>
<tr>
<td>Pesi</td>
<td>Embryonic disc development</td>
<td>Day 14 after fertilisation</td>
</tr>
<tr>
<td>Ghana</td>
<td>Primitive streak development</td>
<td>Day 21 after fertilisation</td>
</tr>
<tr>
<td>Pencasakha</td>
<td>The pharyngeal arches development</td>
<td>Day 29 after fertilisation</td>
</tr>
</tbody>
</table>

The above table is derived from the Buddha’s insights into embryo development. It provides details regarding the appearance of a human embryo during each stage of generation. While today’s medical science provides the world with a more exacting insight into the stages of development of the human embryo, a comparison can still be drawn as shown in the table above. Even though the

explanation provided by the Buddha more than 2,000 years ago is not exactly compatible with today’s science, a lot of the teachings do not differ significantly from modern science and the fundamentals of the two can be matched correspondingly.

3.7.2 The Beginning of Human Life in Buddhist Teachings

There are four methods of birth which apply to all living things.

- Egg-born beings (*andaja*)
- Womb-born beings (*jalabuja*)
- Moisture-born beings (*samsedaja*)
- Beings having spontaneous births (*opapatika*)

In the first method, egg-born beings are the creation of life from eggs such as in the birth of snakes and birds, whereas human beings, certain gods, and some animals such as dolphins are womb-born creatures are born by the second method. The third method comprises the birth of certain low forms of life such as worms. Lastly, beings having a spontaneous birth are those beings that are born as fully grown. Generally, they are invisible to the physical human eye: certain gods, ghosts, titans, and hell creatures belong to this class. From these teachings, it can be asserted that a human is a womb-born being indicating that a human life starts in a woman’s womb. According to this interpretation, it would not be possible to conceive and develop a human being outside the mother’s womb and those who
were born from other methods are not humans and belong to other realms of being.

A human life is highly praised in Buddhist view, the Buddha prescribed a severe punishment for any monk or nun who took a human life, even in the womb. The third monastic precept states that this course of action would lead to exile from the monastic community.

An ordained monk should not intentionally deprive a living thing of life even if it is only an ant. A monk who deliberately deprives a human being of life, even to the extent of causing an abortion, is no longer a follower of the Buddha. As a flat stone broken asunder cannot be put back together again, a monk who deliberately deprives a human being of life is no longer a follower of the Buddha.\textsuperscript{188}

This teaching reflects the level of seriousness ascribed to the killing of a human. The Buddha considered that, even in the womb, the unborn baby has the same status as an adult because it constitutes the same set of life's elements. According to Buddhist beliefs, the creation of life needs two elements: (1) the spiritual ($\textit{nama}$) and (2) the physical ($\textit{rupa}$). They are interdependent and cannot survive without each other.\textsuperscript{189} The spiritual element drives, maintains and develops the physical element, while the physical element gives perception to the spiritual

\textsuperscript{188} Pali Canon, Vin.i.97. Cited in Damien Keown, \textit{Buddhist Ethics: A Very Short Introduction}, above n 186, 87.

At the beginning of human life, according to Buddhism, three conditions must be fulfilled. In the Pali Canon, Buddha stated as follows:

Monks, it is on the conjunction of three things that there occurs the descent of an intermediate being into the womb. If the parents come together in union, but it is not the mother’s proper season, and the intermediate being is not present, then there will be no conception. If the parents come together in union and it is the mother’s proper season but [still] the intermediate being is not present [again] there will be no conception. But when the parents come together in union, it is the mother’s proper season and the intermediate being is present, then on the conjunction of these three things the descent of an intermediate being will take place. Then, monks, the mother for nine or ten months carries the foetus in her womb with great concern for her heavy burden. 190

From the above statement, the three conditions of the beginning of life are that:

1. intercourse must take place;
2. it must be the proper fertile period for the woman; and
3. there must be an intermediate being available to be reborn.

The first two conditions are the conditions required to form the physical body while the last condition is the condition required to form the spiritual element. At

190 Pali Canon, M.i.256. Cited in Damien Keown, Buddhism & Bioethics, above n 185, 69.
conception, when intermediate beings transcend into the mother’s womb, the fertilised egg, driven by the spiritual element, will develop into an embryo and develop further to term.\textsuperscript{191} However, if the spiritual element departs, due to its karma, the embryo cannot continue the development to term but will abort from the mother’s womb.\textsuperscript{192}

The teaching on the beginning of human life affirms the importance of the mother’s womb in human life creation. It might be argued that the three conditions that constitute being a human can occur outside the human body, however, the phrase – ‘the descent of an intermediate being into the womb’ – represents the crucial element in conception of a human life which can only occur in the woman’s womb and only when the three conditions are met is a human life conceived.

### 3.7.3 Does a Life Exist in a Human Embryo?

Morality is one of the three divisions of the Eightfold Path and the foundation of the ethical life which leads to Nirvana. To live a moral life is to live in accordance with Dharma. Buddhist morality is expressed in the precepts or moral code. For the lay-person, the most general precepts are the Five Precepts:

I undertake the precept to refrain from harming living creatures.

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\textsuperscript{191} Harvey, \textit{An Introduction} (2000), above n 145, 311.

\textsuperscript{192} Keown, \textit{Buddhism & Bioethics}, above n 185, 84-85.
I undertake the precept to refrain from taking what has not been given.

I undertake the precept to refrain from sexual immorality.

I undertake the precept to refrain from speaking falsely.

I undertake the precept to refrain from taking intoxicants.

These precepts list the actions that a moral person would never do. However, an abstinence from wrongdoing must be motivated by correct reasoning. For example, someone who follows the first precept – refraining from harming living creatures – must be motivated by compassion. Buddhism reveres this quality more than one who refrains from taking a life for fear of the law.

As discussed earlier, a life is composed of two elements, namely the physical and spiritual elements (rupa and nama). Logically, according to the Buddhist view, a combination of cells which has a physical element but which lacks a spiritual element would not count as having a life. Drawing from the analysis in Buddhist teachings on the methods of birth, a human embryo in vitro only possesses physical elements but not spiritual elements. Thus, it can be concluded that a life does not exist in the in vitro human embryo.

3.7.4 The Future Life: Gateway to Life

A human embryo can only possess the status of a human life under Buddhist teachings after it has been implanted successfully in a woman’s uterus. It can be
concluded that a human embryo in vitro does not constitute a human life. This conclusion conforms to scientific research which has proven that a human embryo cannot develop into a human outside a human body. A study conducted by Chui-Yee Fong et al confirmed that an in vitro embryo cannot develop normally outside the human body for more than six to seven days after fertilisation. For some, this type of deliberate inaction is viewed as an act of stopping the gateway to life. Buddha teaches the importance of karma, which is a moral action. Moral actions are regarded as the source of karma. Moral and immoral actions are not only determined by the end result but also the motive and awareness of one's actions. In conducting research on a human embryo, the intention of the scientist is not to deprive the embryo of life (as there is no life), but rather to generate a scientific data that has the potential to help humankind.

Still, the question remains whether there is an obligation to implant a human embryo created in vitro in order to allow it to develop into a human. According to the teachings, each sentient being has its own path according to its karma; only a sentient being that has accumulated the right kind and amount of karma would reincarnate as a human. It has to be understood that a sentient being does not attach itself to a specific physical element. It is not the case that the destruction of a specific physical element will deprive a sentient being of its chance to have a life. If the sentient being has the karma to reincarnate as a human, no matter how

193 See Fong, above n 173. This would confirm the Buddhist teachings that a human life can only develop inside a woman’s womb.

194 Harvey, above n 145.
many *in vitro* human embryos were researched or succumbed, that sentient being would finally find its way into life by virtue of its karma.

### 3.8 Concluding Summary

Human embryo research and hESC research provide potential for the therapeutic medication of currently untreatable illnesses and other areas of medical science. However, human embryo research also raises unique problems which have the potential to challenge fundamental tenets of society involving the sanctity of life. While it is important for research to be well advanced before application to therapeutic medications, the absence of laws specifically regulating human embryo research may distort the pace of research as well as causing society’s moral codes and beliefs to be questioned. In order to ensure compliance by a particular society with a new set of laws, the regulators need to be able to justify the laws by showing that the objectives of the laws are legitimate and impose rules that accord with international and domestic moral standards.\(^{195}\) In Thailand, it is widely acknowledge that Theravada Buddhist ethics are the most prominent ethics determining the morality of people in Thailand. Traditionally, Thai law was derived from Buddhist beliefs and even after the codification, various provisions of Thai law still reflect the Buddhist teachings especially with respect to protecting human life. In determining the status of human embryo in Thailand, according to Buddhist teachings, the protection of the sanctity of life is applied to the human embryo created *in vivo* when it is implanted in the woman’s uterus.

However at the time of Buddha, the science of *in vitro* fertilisation did not exist and the sanctity of human life principle cannot be applied to the human embryo created *in vitro* which is viewed as not having a life.

According to the Buddha’s teachings, a human is a womb-born being where the three factors creating a human life come together. Furthermore, the study of Chui-Yee Fong et al confirms that *in vitro* embryo cannot develop normally outside the human body for more than six to seven days after fertilisation. These findings are consistent with Buddhist teachings that human life creation occurs inside the mother’s womb. Therefore, it can be argued that an *in vitro* human embryo does not constitute a human life and the protection of the sanctity of human life principle does not apply to an *in vitro* human embryo unless it is implanted in the woman’s uterus. Thus, research on human embryo *in vitro* can possibly be conducted in Thailand within ethical boundaries.

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196 Fong, above n 173.
Chapter Four:

The Legal Status of *In Vivo* Human Embryo

4.1 Introduction

‘*Everyone has the right to life, liberty and security of person*’.\(^{197}\)

The main argument against human embryo research stems from the perception that the human embryo is a human being with a right to life. However, in legal contexts, the interpretation of the right to life is ambiguous. There is no international consensus on the definition of life that is protected by the right to life. One question that has been raised is whether the word ‘everyone’ includes the unborn foetus?

In this chapter, the focus is on the legal status of human embryos *in vivo*. As stated earlier, hESCs research unavoidably stop the development of human embryo. This type of research is sometimes viewed as a termination of the early form of human life which has a close similarity to the termination of pregnancy or induced abortion. However, there are still some differences between human embryo research and induced abortion as the human embryos are in different stages of development. While induced abortion can occur after the implantation of

\(^{197}\) *Universal Declaration of Human Rights* Art 3.
human embryo in the uterus which usually takes place after 14 days of development, human embryo research usually takes place before the 14\textsuperscript{th} day. Still the reason behind the restriction to induced abortion and human embryo research stems from the same argument which involve the protection of human life.

The chapter starts with the discussion on the status of human embryo \textit{in vivo} under the abortion law provisions. Abortion law is the field of law that protects human life in its early stage starting from implantation until the labour. The interest that the state claims over the human embryo is that the human embryo belongs to the human race and has the potential to become a person which entitles it to some level of protection but not the same protection as a person.\textsuperscript{198} This legal protection increases as the embryo develops through the stages of gestation.

\textbf{4.2 \textit{In Vivo} Human Embryo: Abortion Law}

It is generally recognised that one of the objectives of provisions in international human rights is to protect human life after birth.\textsuperscript{199} Even though human rights and liberties have evolved to require that certain interests are protected by the law, the


legal notion is that the human embryo warrants some degree of respect, but not a full right to life. This was confirmed by the House of Lords in Attorney-General’s Reference where it was found that the foetus ‘does not have a distinct human personality,’ whose extinguishment gives rise to any penalties or liabilities at common law.’

Legislation in most countries grants the status of personhood upon live birth. In other words, an unborn child is not a legal person. Justice Baker asserted in Paton v Trustees of the BPAS, that a foetus cannot, in English law, have any right of its own at least until it is born and has a separate existence from the mother. His Honour stated:

[Legally a person is not in being until he or she is fully born in a living state. A baby is fully and completely born when it is delivered from the body of its mother and it has a separate and independent existence in the sense that it does not derive its power of living from its mother. It is not material that the child may still be attached to the mother by the umbilical cord; that does not prevent it from having a separate existence.]


201 For example, the European Court stated that ‘the unborn child is not regarded as a “person” directly protected by Article 2 of the Convention and that if the unborn child do have a “right” to “life”, it is implicitly limited by the mother’s rights and interests’. See Vo v France (2005) 10 EHRR 12, [80].


This means the status of rights and the benefit of protection under the law are granted after a live birth to a living infant who was born and living separately from its mother. Thailand shares this principle with other countries and accords personhood after a full live birth.\textsuperscript{204} However, there are many circumstances where the claim to an interest in life should be granted to the unborn child based on the sanctity of life principle.\textsuperscript{205} The common examples can be found in the debates for abortion law reform.\textsuperscript{206} The following section contributes to the discussion on abortion law regimes. This discussion assists in determining the legal recognition of the human embryo that is being recognized in various jurisdictions.

\begin{quote}
\textit{Historical Background of Abortion Law}
\end{quote}

Historically, the common law system derived many offences from religious precepts which treated abortion as an offence. The common law system derived various provisions from canon law and prohibited the termination of pregnancy after quickening,\textsuperscript{207} meaning the moment when the pregnant woman feels

\begin{itemize}
\item \textsuperscript{204} \textit{Civil and Commercial} (Th) s 15.
\item \textsuperscript{205} Catherine S Chilman, ‘The Background of the Present Abortion Controversy’ (1988) 3 \textit{Affilia} 41, 42; Cameron above n 169, 215-16.
\item \textsuperscript{206} For more details, see Rebecca J Cook and Bernard M Dickens, ‘Human Rights Dynamics of Abortion Law Reform’ (2003) 25 \textit{Human Rights Quarterly} 1.
\item \textsuperscript{207} Kerry Petersen, \textit{Abortion Regime} (Dartmouth, 1993), 1.
\end{itemize}
movement in her womb.\textsuperscript{208} Thus, the termination of pregnancy was treated as a crime.\textsuperscript{209}

\textit{The United Kingdom}

\textit{The Offences Against the Person Act 1861} (UK), which was the legislative model for other Western countries in regulating the termination of pregnancy,\textsuperscript{210} stated in section 58 that:

\begin{quote}
Every woman, being with child, who, with intent to procure her own miscarriage, shall unlawfully administer to herself any poison or other noxious thing, or shall unlawfully use any instrument or other means whatsoever with the like intent and whosoever, with intent to procure the miscarriage of any woman whether she be or be not with child, shall unlawfully administer to her or cause to be taken by her any poison or other noxious thing, or shall unlawfully use any instrument or other means whatsoever with the like intent, shall be guilty of felony.
\end{quote}

Under this Act, abortion was prohibited in all circumstances without any exception until the \textit{Infant Life (Preservation) Act 1929} (UK) was passed. This legislation provided legal defence for the doctors acting in good faith, 'to destroy

\begin{flushright}
\textsuperscript{208} Ibid 18.
\textsuperscript{209} Cook, above n 206, 8; See also Chilman, above n 205, 45-46. Chilman asserted that abortion law reform in the U.S. is driven by the attempt to control abortion by medical practitioners.
\textsuperscript{210} Petersen, \textit{Abortion Regime}, above n 207, 21.
\end{flushright}
the life of the child capable of being born alive\textsuperscript{211} in order to save the woman’s life. Subsequently the court in \textit{R v Bourne}\textsuperscript{212} recognised the concept of therapeutic abortion for the first time in England. In this case, the court extended the lawfulness of therapeutic abortion to include psychological trauma to a 14 year-old child who was raped and subsequently become pregnant. The judge ruled that a termination of pregnancy would not be unlawful, under section 58 of the 1861 Act, if a medical practitioner performed it to preserve a woman's life or her physical or mental health.\textsuperscript{213}

After the \textit{Bourne} case, a medical practitioner acting in good faith could perform a lawful abortion if it was needed to preserve a pregnant woman’s health. However, due to the high cost of medical services, this meant that only women of means could have access to safe abortions. As a result there was a high rate of mortality and morbidity amongst women who could not afford to consult medical practitioners. This situation influenced the abortion law reform debate. Currently, the \textit{Abortion Act 1967} (UK) provides that abortion can be obtained up to 24 weeks if two registered medical practitioners are of the opinion the pregnancy would ‘endanger the physical or mental health of the pregnant woman or any existing children of her family’,\textsuperscript{214} or there is a substantial risk that the unborn

\begin{footnotesize}
\begin{itemize}
\item \textsuperscript{211} \textit{Infant Life (Preservation) Act 1929} (UK) s 1(1).
\item \textsuperscript{212} (1939) 1 KB 687.
\item \textsuperscript{213} Even though the \textit{Bourne} case was the ruling of a single judge in the Central Criminal Court, it was greatly respected and has led enormous impact throughout the western countries. Petersen, \textit{Abortion Regime}, above n 207, 61.
\item \textsuperscript{214} \textit{Abortion Act 1967} (UK) s 1(1)(a).
\end{itemize}
\end{footnotesize}
child would ‘suffer from such physical or mental abnormalities as to be seriously handicapped’ if the child were born and this determination can be carried out through the term of pregnancy.\(^{215}\)

**Australia**

In Australia, the criminal law in Australian states and territories also prohibited ‘unlawful’ abortion. In Victoria, the term ‘unlawful’ was clarified in a landmark case *R v Davidson*,\(^{216}\) where a single judge of the Supreme Court of Victoria stated that an abortion could be lawful if the person performing abortion honestly believed on reasonable grounds that the abortion was necessary and proportionate.\(^{217}\) This ruling was later extended by court in New South Wales to include economic and social consequences in the necessity and proportion of the abortion.\(^{218}\) Since then, the State of Victoria and Western Australia have partially

\(^{215}\) *Abortion Act 1967* (UK) s 1(1)(d).


\(^{217}\) Menhennit J held that abortion can be performed when the operation is ‘necessary to preserve the woman from a serious danger to her life or her physical and mental health (not being merely the normal dangers of pregnancy and childbirth) which the continuance of the pregnancy would entail’ and that the abortion is ‘in the circumstances not out of proportion to the danger to be averted’. See *R v Davidson* [1969] VR 667 at 672.

\(^{218}\) *R v Wald* (1972) 3 DCR 25; *K v Minister for Youth and Community Services* [1982] 1 NSWLR 311.
decriminalised abortion law. In Australia, abortion is increasingly viewed as a health matter.

Summary

In many cases, the moral claim that right to life should be granted to the unborn child is limited. In the case of abortion, women’s rights to control their own bodies are generally prioritised over the interests of the human embryos – up to a certain point. Courts have interpreted the law to reflect the rights of women and distinguish the legal claims of the pregnant woman from the moral claims of interest in life of the unborn child. Therapeutic abortion can be practised where the pregnancy threatens the woman’s life or her health. In addition, in some jurisdictions, defences for abortion based on the health of the person to be born and the mental health of the pregnant woman are accepted. Furthermore, the decision to refuse life-saving medical treatment, even when such a decision threatens the life of the viable embryo, has been endorsed. In 1997, the Court of

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219 For example, in recent legislation of Victoria, the Abortion Law Reform Act 2008 (Vic) s 4 states that an abortion can be performed by registered health or medical practitioners for up to 24 weeks of pregnancy. After 24 weeks, the termination of pregnancy can be performed only when two medical practitioners reasonably have the opinion that abortion is appropriate in all circumstances. Abortion Law Reform Act 2008 (Vic). See also, Acts Amendment (Abortion) Act 1998 (WA) s 119; Health Act 1911 (WA) ss 334-335.

220 Petersen, Abortion Regime, above n 207, 9.

221 Haberfield, above n 46, 153.


Appeal, in *Re MB*,\(^{224}\) affirmed the right to autonomy of the pregnant woman and prioritised her right over the interests of the foetus.\(^{225}\) However, in this case, the court found that the pregnant woman was incompetent to make her own decision due to her phobia of needles and allowed a caesarean section in her best interests.

Most countries provide protection to the viable embryo *in vivo*. In *Vo v France*,\(^{226}\) the interests of a viable foetus were recognised by the law, however, the court asserted that such protection is not accorded at the same level as a person with an absolute right to life. Thus, in this case, the court concluded that private law remedies for the involuntary negligent termination of life of a viable foetus are sufficient for preserving its life.\(^{227}\)

Furthermore, in the recent decision of the Human Rights Committee (HRC) in *Llantoy Huaman v Peru*,\(^{228}\) the HRC asserted that a human embryo does not have an absolute right to life and affirmed that the denial of access to safe abortion


\(^{225}\) The court asserted that ‘Although it may seem illogical that a child capable of being born alive is protected by the criminal law from intentional destruction, and by the Abortion Act from termination otherwise than as permitted by the Act, but is not protected from the decision of a competent mother not to allow medical intervention to avert the risk of death, this appears to be the present state of the law’. *Re MB* [1997] 8 Med. LR 217, 226. The case was upheld in the case of *St George’s Healthcare NHS Trust v S, R v Collins ex parte S* (1998) that a pregnant woman is not denied her right to autonomy and self-determination and the unborn child is not a separate person from its mother.

\(^{226}\) (2005) 10 EHRR 12.


\(^{228}\) 13 IHRR 355 (2006).
where the continuation of pregnancy is likely to cause serious impairment to the mental health of the woman is a violation of human rights. In this case, the HRC found the restrictive abortion provisions of Peru in violation of human rights where ‘[t]he omission on the part of the State in not enabling the mother to benefit from a therapeutic abortion was, in the Committee’s view, the cause of the suffering she experienced’ and that the restriction amounted to the mental trauma of a minor who was three months pregnant with a diagnosed ‘anencephalic’ foetus.

4.3 The Abortion Law Regime in Thailand

Under Thai law, a human embryo is not considered a separate entity from its mother until live birth, as it is not granted separate human status until live birth. However, an embryo is entitled to certain protection under the law, as well as having rights which can be exercised after a full live birth has taken place. The most common example can be found in the provisions of the Civil and Commercial Code (Th) dealing with the law of succession, namely sections 15(2) and 1604, which give a right to a legitimate child to inherit the properties of a deceased relative even though the deceased relative passed away before the child was born.

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230 Llantoy Huaman v Peru 13 IHRR 355 (2006), [6.3].

was born.232 Another example can be found in abortion law provisions under the *Criminal Code* (Th). Sections 301–305 of the *Criminal Code* (Th) prohibit abortion. A woman who performs an abortion on herself and any other person who performs abortion for a woman are subject to criminal penalties.233 When judging whether a criminal offence has been committed, the criminal intention of the offender is a crucial factor in determining whether the action results in the offender being found guilty or not guilty. In the context of the offence against abortion in Thailand, it must be proven that the woman (or the other person who performed the abortion, as the case may be) has criminal intention by knowing that the woman was pregnant and intended to cause the miscarriage. Furthermore, it is important that the woman must be pregnant at the time the abortion procedure was conducted in order to be guilty of a felony.234

In Thailand, abortion has long been illegal since the adoption of the codification system in 1908. The last reform of abortion law occurred in 1957 to permit therapeutic abortion where pregnancy is the result of a crime such as in cases of rape or when it is necessary to protect the woman.235 The main reason for which therapeutic abortion can be legally performed in Thailand is when there is a conflict with the fundamental rights of the woman, in which case the law grants a

232 Under section 1604, a natural person can be an heir only when he or she has, at the time of the death, legal personality or is capable of rights under section 15 of the *Civil and Commercial Code* (Th).

233 *Criminal Code* (Th) ss 301-305.

234 *Criminal Code* (Th) s 59.

doctor the discretion to perform a therapeutic abortion subject to first obtaining the woman’s consent.\textsuperscript{236} The only two exceptions to the prohibition on the performance of therapeutic abortions involve abortions conducted by a medical practitioner, with the woman’s consent: (1) when the abortion is necessary for the sake of the woman’s health; or (2) if the woman has become pregnant as a result of a criminal offence.\textsuperscript{237} Where the woman denies consent for abortion, even if such abortion is a necessary medical procedure in the woman’s best interests, the practitioner would still be prohibited to perform an abortion.

However, there are debates over the interpretation of section 305(1). These concern whether abortion can be conducted when the abortion is necessary to preserve the woman’s health and whether the term ‘woman’s health’ includes the physical and mental health of the woman. In response, the Medical Council of Thailand issued professional regulation guiding medical practitioners clarifying that abortion can be performed to protect the mental health of the pregnant woman where severe stress is caused by the diagnosis of a deformed foetus.\textsuperscript{238}

It has been suggested on several occasions that the abortion laws of Thailand should be reformed.\textsuperscript{239} However, more liberal laws governing abortion have not

\textsuperscript{236} Criminal Code (Th) s 305.

\textsuperscript{237} Criminal Code (Th) s 305.

\textsuperscript{238} Boland, above n 223, 114.

\textsuperscript{239} There have been attempts to reform the restrictive abortion laws since the 1970s. See Andrea Whittaker, ‘Abortion Law Reform Advocacy in Thailand’ 46(2) Society for International
yet been adopted in Thailand due to strong opposition from within Thai society. Advocacy for abortion law reform in Thailand was initiated in the 1970s when Dr Suporn Koetsawang raised public awareness over the safety of illegal abortions which were secretly practised.\textsuperscript{240} Since then, several lawyers, academics and some parliamentary members have lobbied for law reform. Various campaign channels were used and received wide media coverage. A public seminar describing the medical and social consequences of the restriction on abortion was held and all participants favoured the reform of the law.\textsuperscript{241} In 1980, amendments to the abortion law were proposed to Parliament. The amendment bill was initially rejected, but after progressive lobbying, the bill was resubmitted to Parliament. On 29 September 1980, the Abortion Bill was passed by the House of Representatives by 79 votes to 3 with 219 MPs abstaining.\textsuperscript{242} However, a coalition of religious and conservative groups, leaded by Chamlong Srimuang, launched an effective campaign against the law reform based on Thai cultural and Buddhist religious values. The result was the rejection of the Bill in December 1981 by the Senate by a vote of 141 to 1 with 83 absent.\textsuperscript{243} Since then, a number of attempts to reform abortion law in Thailand have been initiated, but rejected by conservative religious forces.

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\textsuperscript{240} Whittaker, ‘Abortion Law Reform Advocacy in Thailand’, above n 239, 73.

\textsuperscript{241} Ibid 74.

\textsuperscript{242} Ibid.

\textsuperscript{243} Ibid.
Even though access to safe abortion is viewed in various jurisdictions as the right of a woman, resistance for a more liberal abortion law due to the belief in Buddhist teachings is the main obstacle to abortion law reform in Thailand. Abortion is viewed as unethical conduct in Thailand due to the moral standards adopted by Thai people, being moral standards which are derived from Buddhist ethics. Buddhism teaches that human life starts at conception \textit{in vivo}. As a result, any conduct that results in depriving a human of life, including abortions, is viewed as immoral conduct which should therefore be avoided.

\textit{Summary}

Abortion by a medical practitioner acting in good faith can be legitimately conducted as a general medical practice in many jurisdictions.\textsuperscript{244} However, in Thailand, the sanctity of life principle is given a higher priority than the well being of the child and the law prohibit abortion even when the born child would be seriously handicapped. There are only a few statutory exceptions allowing an abortion to be performed to preserve the woman’s health and where the pregnancy is a result of a criminal offence. In determining the status of the \textit{in vivo} human embryo in Thailand, it is clear that the human embryo is not a separate person from its mother until the completion of a full live birth;\textsuperscript{245} however, the protection of sanctity of life, which is influenced by Buddhist teachings, is applied to the

\textsuperscript{244} See for example, Royal Australian and New Zealand College of Obstetricians and Gynaecologists (RANZCOG), \textit{Termination of Pregnancy: A Resource for Health Professionals} (November 2005) 5.

\textsuperscript{245} \textit{Civil and Commercial Code} (Th) s 15.
human embryo created in vivo when it is implanted in the woman’s uterus. Abortion without legitimate excuse is prohibited under the provisions of the Criminal Code (Th).

From these provisions, it can be concluded that the underlying legal principles established in Thailand are: (1) under the Civil and Commercial Code (Th) section 15, the human embryo is not a separate person from its mother until the completion of a live birth; (2) under the law governing succession, a child is deemed to have the right to inherit property from a deceased relative if the child is born alive within 310 days after the date of death of the deceased relative; and (3) under the provisions of the Criminal Code (Th) dealing with the protection of the sanctity of life, the human embryo is protected against abortion without a legitimate reason.246 After many years of discussions about possible reforms of abortion laws, the Thai people’s views regarding the status of human embryos still reflect the ethics of Buddhist philosophy.

As stated, discussion of the abortion provisions raises the possibility of a hierarchy of fundamental rights where the sanctity of life and interests of the in vivo human embryo prevails over the right to autonomy and self-determination of the pregnant woman in Thailand. However, there is no issue of a conflict of interests between the pregnant woman and the human embryo because the human embryo for research is created outside the woman’s body. The questions that remain then are: should the human embryo created in vitro be accorded an interest

246 Criminal Code (Th) ss 301-305.
in life and the protection of the sanctity of life and is there a right to life of the human embryo created _in vitro_? Or should the human embryo created _in vitro_ be recognised as a different entity from an _in vivo_ human embryo?

### 4.4 Concluding Summary

This chapter finds that legislation in most countries grants the status of personhood at live birth and an _in vivo_ embryo does not have the same status as an adult human. However, the law recognises the interests in life of the unborn child which increases through time and grants a certain level of protection to the unborn child after a period of gestation.

In most jurisdictions, therapeutic abortion can be performed to preserve the woman’s physical and mental health and where there is a substantial risk that that the child born would be seriously handicapped. In Thailand, sanctity of life principles are given a higher priority and abortion can only be performed to preserve the woman’s health or where the pregnancy is a result of criminal offences but does not extend to where there is a risk that the child born would be seriously impaired. This represents the influence of Buddhist teaching regarding the sanctity of human life and the legal protection of the human embryo created _in vivo_.

However, the status of human embryo _in vitro_ is viewed as differently from _in vivo_ embryo under Buddhist teachings. In Thailand, Buddhist teachings affirm the
importance of the mother’s womb in the human life creation and *in vitro* embryo is not viewed as a human being. As a result, research conducted on the human embryo created *in vitro* can be allowed ethically in Thailand without contradicting the sanctity of human life principle. However, it cannot be concluded that all forms of human embryo research should be legally permitted in Thailand.
Chapter Five:

The Legal Status of *In Vitro* Human Embryo

5.1 Introduction

This Chapter discusses the legal status of a human embryo created *in vitro*. This is done by making observations about the legal protection that is granted by regulations governing the conduct of human embryo research in various countries, including the United Kingdom, Australia and Italy. The regulations in these three jurisdictions represent the regulation of human embryo research from the permissive, moderate and restrictive ends. Despite the different approaches, it seems clear that the status of a human embryo *in vitro* is generally influenced by arguments about human research regulation, commercial and financial interest, and regulatory alternatives.

5.2 *In Vitro* Human Embryo: Assisted Reproductive Technology and Human Embryo Research

Abortion and human embryo research are similar in that both are morally controversial issues concerning the sanctity of human life and the status of the human embryo. However, in the case of abortion, protection of the sanctity of life in the human embryo is not absolute but relative to the rights of the pregnant woman. In the case of human embryo research, the human embryo has never been
implanted in the woman’s body and thus there is no conflict of interest between the autonomy of the woman and the human embryo. There are three views that afford status to a human embryo: (1) the embryo is human and entitled to full human rights; (2) the human status of an embryo is developmental through the gradual process of its growth; and (3) the embryo is a collection of cells.247

5.2.1 The United Kingdom: Permissive Approach to Human Embryo Research Regulation

The history of the Human Fertilisation and Embryology Act 1990 (UK) can be traced back to 1982, when a Committee of Inquiry was appointed to prepare a report on the extent to which reproductive technologies had developed. The inquiry was required after the successful birth of the first test tube baby resulting from \textit{in vitro} fertilisation, Louise Brown.248 This was viewed as a great achievement after a long period of research into reproductive technologies.249 Against this background, concerns were raised about ethical issues involved in the rapid development of scientific research, which led to the conclusion that this type of research be regulated.

\begin{footnotesize}
\begin{enumerate}
\item Ibid.
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\end{footnotesize}
When the Warnock Report was presented to the United Kingdom government, it was debated in the House of Commons in November 1984. Subsequently, several private members’ Bills were introduced in 1985, 1986 and 1987. None of these were passed despite an overwhelming majority of votes being in favour of the original Bill at its first reading in the House of Commons.\(^{250}\) Six years later, specific legislation governing assisted reproductive technology was finally passed through Parliament in November 1990. The Warnock Report was the blueprint for the \textit{Human Fertilisation and Embryology Act 1990} (UK), and the recommendations made in the Warnock Report have been reflected in the Act. The provisions of the \textit{Human Fertilisation and Embryology Act 1990} (UK) provided protection for human embryos by creating a broad framework under the licensing regime mandated by the HFEA. Unless conducted pursuant to a licence issued under this regime, the use or storage of gametes and the creation of embryos outside the body are prohibited under the Act.\(^{251}\) Although it is considered that this was a facilitative regime, the Act failed to keep pace with the rapid pace of change in the area of human embryo research.

An inquiry into the \textit{Human Fertilisation and Embryology Act 1990} (UK) was conducted by the House of Commons Science and Technology Select Committee. In 2005, a report titled \textit{Human Reproductive Technologies and the Law} was

\(^{250}\) The private members’ Bills were introduced by MPs Enoch Powell, Ken Hargreaves and Alistair Burt respectively. See Robert G Lee and Derek Morgan, \textit{Human Fertilisation & Embryology} (Blackstone, 2001), 57.

\(^{251}\) \textit{Human Fertilisation and Embryology Act 1990} (UK).
presented. The aim of the report was to investigate the challenges presented by advancing technologies, changes in ethical attitudes and the public’s perception towards those technologies.

In light of the Committee’s Report, the Department of Health undertook a review of the Human Fertilisation and Embryology Act 1990 (UK). Over 500 submissions were made in response to public consultations conducted by the Government. In March 2006, the Report on the Consultation on the Review of the Human Fertilisation and Embryology Act 1990 (UK) was published. The result was the enactment of the Human Fertilisation and Embryology Act 2008 (UK) which came into force in October 2009. The Human Fertilisation and Embryology Act 2008 (UK) makes several amendments to the Human Fertilisation and Embryology Act 1990 (UK) with the aim of keeping up with the pace of scientific developments. This development has resulted in the United Kingdom being the country with the most liberal approach to the regulation of human embryo research as well as the lead position in the development of human embryo research.

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254 The provisions of the Act were rolled out in three phases. Phase one (involving part 2 of the Act and the revised definition of ‘parenthood’) came into effect in April 2009. Then, in October 2009, the amendments to the 1990 Act came into effect. Then finally, phase three, involving the parental orders, came into effect in April 2010.

255 Will be discussed in details later in the Chapter.
The Status of Human Embryo In Vitro

In the United Kingdom, the *in vitro* human embryo does not have the same status as a human. The determination of *in vitro* human embryo was officially considered by the Committee, chaired by Dame (now Baroness) Mary Warnock, who was charged with the responsibility for examining and gathering evidence of the new assisted reproductive technology of *in vitro* fertilisation in order to make recommendations regarding the regulation of this technology.\(^{256}\) The Committee conducted an investigation into the ethical implications the technology has for society as a whole and set for itself the task of addressing the minimum legally permissible regime.

The status of human embryo was confirmed by the Warnock Committee, which stated in the Report of the Committee of Inquiry into Human Fertilisation and Embryology that: ‘[t]he human embryo *per se* has no legal status. It is not, under law in the United Kingdom, accorded the same status as a child or an adult, and the law does not treat the human embryo as having a right to life.’\(^{257}\) In acquiring information to be used to formulate its recommendations, the Committee considered more than 600 responses from various sources, including medical

\(^{256}\) The Committee conducted an investigation into the ethical implications that the technology has for society as a whole and set for itself the task of addressing the question: ‘what is legally permissible may be thought of as the minimum requirement for a tolerable society’. United Kingdom, *Report of the Committee of Inquiry into Human Fertilisation and Embryology*, Cmnd 9314 (1984), 3.

\(^{257}\) Ibid 62–63.
associations, religious affiliates, as well as the legal profession.\(^{258}\) In July 1984, the Warnock Report was presented to the United Kingdom Parliament. The report took into account the ethics of society, the possible future advantages and harms that could come from using the technology and the pluralistic characteristics of the United Kingdom society. The report asserted that, in a pluralistic society such as the United Kingdom, with more than one set of principles governing people’s perceptions, it was vital to set up a monitoring scheme and create regulations specifically governing this area of reproductive technology. Moreover, as well as making recommendations regarding infertility treatments and related issues,\(^{259}\) the Committee recommended there should be some level of protection provided by the law for embryos of ‘the human species’.\(^{260}\) This recommendation had significant implications for the conduct of human embryo research.

The status of *in vitro* human embryos was affirmed in the *Evans*,\(^{261}\) where Wall J pointed out in the High Court that:

> There is no direct authority on the point in relation to embryo,

\(^{258}\) Ibid 95.

\(^{259}\) Ibid. The report also initially addressed the fertility treatments and related issues, which were the main part of the issues considered by the Committee.

\(^{260}\) Ibid 84, Recommendation 42.

\(^{261}\) Natallie Evans v Amicus Healthcare Ltd, Howard Johnston, Royal United Bath Hospital NHS Trust, The Secretary of State for Health, the Human Fertilisation and Embryology Authority; Lorraine Hadley v Midland Fertility Services Ltd, Wayne Hadley, Royal United Bath Hospital NHS Trust, The Secretary of State for Health, the Human Fertilisation and Embryology Authority [2003] EWHC 2161 (Fam), [2004] 1 FLR 67. (*Evans* case).
but there is abundant domestic authority, binding on me, that a foetus, at whatever stage of its development, has no existence independent of its mother. If a foetus has no right to life under article 2, it is difficult to see how an embryo can have such a right.262

Thus, ‘[t]he embryo … cannot be considered a person, or to have a "qualified" right to life.’ 263 However, the Warnock Committee recognised that the human embryo possesses the unique ability to develop into a human being and this unique ability means that the human embryo should be entitled to certain protections under the law.264

Under the provisions of the Human Fertilisation and Embryology Act 1990 (UK), unless conducted pursuant to a licence issued under the Human Fertilisation and Embryology Authority (HFEA), the use or storage of gametes and the creation of embryos outside the body are prohibited.265 However, the HFEA can grant a licence for research that fall within the scope provided by the Human Fertilisation

262 Evans case, [175].

263 Evans case, [178].

264 United Kingdom, Report of the Committee of Inquiry into Human Fertilisation and Embryology, Cmd 9314 (1984) 63. However, it has been argued that ‘if an unborn child is not a legal person, it cannot seriously be argued that a frozen two, four, or eight-cell embryo is a legal person with all the legal consequences stemming from such recognition by the law’. Andrew Grubb, ‘The Legal Status of the Frozen Human Embryo’ in Andrew Grubb (ed), Challenges in Medical Care (Wiley, 1991), 75. Still, one of the reasons put forward to justify embryo protection was that an in vitro embryo (as opposed to and in vivo embryo) has never been carried by a woman, thus no question of conflict with the mother’s right which prevent legal protection in the case of in vivo embryos. Lee, above n250, 83.

265 Human Fertilisation and Embryology Act 1990 (UK) (as amended) s 3.
and Embryology Act 1990 (UK).266

The Definition of Human Embryo

The Human Fertilisation and Embryology Act 1990 (UK) had to be amended in 2008 because the definition of the embryo was too limited to keep pace with science. Under the previous version of the Human Fertilisation and Embryology Act 1990 (UK), a human embryo was defined as ‘a live human embryo where fertilisation is complete’ and that ‘fertilisation is not complete until the appearance of a two cell zygote’.267 This definition was enacted before the science of creating embryos in vitro had developed to the point at which embryos could be created using means other than fertilisation such as SCNT. The HFEA took a purposive position and confirmed that SCNT embryos are human embryos, thus falling within the licensing regime administered by the HFEA; ‘both Ministers and the Authority … are content that the Act does allow the HFEA to regulate nuclear replacement into an unfertilised egg through its licensing system.’268 The HFEA purposive interpretation of the Act was affirmed by the House of Lords in R (on the application of Quintavalle) v Secretary of State for Health.269 In this case, Lord Bingham stated:

266 Human Fertilisation and Embryology Act 1990 (UK) (as amended) s 25(1).

267 Human Fertilisation and Embryology Act 1990 (UK) s 1.


Does the creation of live human embryos by CNR [SCNT] fall within the same genus of facts as those to which the expressed policy of Parliament has been formulated? In my opinion, it plainly does. An embryo created by \textit{in vitro} fertilisation and one created by CNR [SCNT] are very similar organisms. The difference between them as organisms is that the CNR [SCNT] embryo, if allowed to develop, will grow into a clone of the donor of the replacement nucleus which the embryo produced by fertilisation will not. But this is a difference which plainly points towards the need for regulation, not against it.\textsuperscript{270}

Lord Millet also made a similar observation:

Once it is accepted that the embryo is defined by reference to what it is and not by reference to the process by which it is created, all need for updating falls away. The result is to bring within the regulatory scope of the Act embryos produced by a process which was unknown to Parliament when the Act was passed. But such embryos are in all respects save the method of their creation indistinguishable from other embryos. They are alive and human, and accordingly possess all the features which Parliament evidently considered make it desirable to regulate their use for treatment or research.\textsuperscript{271}

Thus, the creation of SCNT embryos was addressed by the HFEA licensing authority, even though the \textit{Human Fertilisation and Embryology Act 1990} (UK) did not mention the SCNT technique of embryo creation. However, this purposive position was questioned on various grounds.\textsuperscript{272} In an earlier discussion, the main argument was that the SCNT technique does not involve fertilisation, meaning

\textsuperscript{270} \textit{R (on the application of Quintavalle) v Secretary of State for Health} [2003] UKHL 13, 15(1).

\textsuperscript{271} \textit{R (on the application of Quintavalle) v Secretary of State for Health} [2003] UKHL 13, 49.

\textsuperscript{272} For a discussion on the regulation of the SCNT technique in the 1990 Act, see Lee, above n 250, 93-96.
that the resulting embryo would not fall within the definition of ‘human embryo’ under the *Human Fertilisation and Embryology Act 1990* (UK). At the same time, the use of the SCNT technique to create cytoplasmic hybrid embryos was not specifically regulated under the *Human Fertilisation and Embryology Act 1990* (UK) before the amendment in 2008. The definition of the human embryo did not cover cytoplasmic hybrid embryos as they are not created by fertilisation. In addition, the method used to create those embryos does not involve ‘replacing a nucleus of a cell of an embryo’ as the ‘cell’ that is being replaced is a ‘cell’ of an animal, not a human embryo. Those opposed to the conduct of the research argued that the HFEA could not issue licences for the creation of cytoplasmic hybrid embryos as they did not fall within the scope of the authority bestowed on the HFEA.273 On the other hand, drawing on the judgment in the *Quintavalle* case,274 the HFEA issued a guidance note recording how it interprets its jurisdiction to issue licences for the creation of cytoplasmic hybrid embryos. It argued that, under the Code of Practice, the HFEA is authorised to issue licences for any research that ‘involves the creation, keeping or using of human embryos outside the body’ and that cytoplasmic hybrid embryos are considered to be human

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273 In early 2008, the HFEA granted two licences to two separate research institutes allowing for the creation of cytoplasmic hybrid embryos. Following the issuance of the first two licences, the first cytoplasmic hybrid embryos were created by the team at the University of Newcastle in April of the same year. These two licences created a large amount of criticism regarding the authority of the HFEA to issue licences. See Irene Nemes, ‘Therapeutic Cloning in Australia: One Small Stem from Man, One Giant Leap for Mankind’ (2008) 16 *Journal of Law and Medicine* 139, 140; ‘Legal Challenge to Hybrid Embryos’, *BBC News* (UK) 9 April 2008; Emily Jackson, *Medical Law: Text, Cases and Materials* (Oxford University Press, 2nd ed, 2010), Chapter 12.

274 *R (on the application of Quintavalle) v Secretary of State for Health* [2003] UKHL 13.
embryos, thus also falling within the scope of the authority bestowed on the HFEA.275

The definition of ‘human embryo’ in the Human Fertilisation and Embryology Act 1990 (UK) as amended by the Human Fertilisation and Embryology Act 2008 (UK) includes all live human embryos regardless of how they were created. The Act states:

1 Meaning of “embryo” and “gamete”

(1) In this Act (except in section 4A or in the term “human admixed embryo”) —

(a) embryo means a live human embryo and does not include a human admixed embryo (as defined by section 4A (6)), and

(b) references to an embryo include an egg that is in the process of fertilisation or is undergoing any other process capable of resulting in an embryo.276

The revision was intended to ensure that all human embryos are afforded the same protection under the law. It can be seen that the definition of the human embryo in the Human Fertilisation and Embryology Act 1990 (UK) includes ‘an egg that is in the process of fertilisation or is undergoing any other process capable of resulting in an embryo’ which creates some ambiguity as to what is an ‘embryo’


276 Human Fertilisation and Embryology Act 1990 (UK) s 1(b) as amended by the Human Fertilisation and Embryology Act 2008 (UK) s 1(2).
as it is very broadly defined. However, this definition has significant implications for the SCNT technique of embryo creation, as it includes every entity that is developed in vitro.\(^{277}\)

*The Protection of Human Dignity, Social Foundations and Safety Concerns*

The *Human Fertilisation and Embryology Act 1990* (UK) allows a licence for the creation of human-admixed embryos for research purposes and addresses the possible harm to society from the creation of babies whose DNA has been mixed with animal DNA,\(^{278}\) by prohibiting the implantation of human-admixed embryo into a woman’s uterus.\(^{279}\) The provision that allows for such creation has advanced the notion that ethical boundaries should be limited. The point was

\(^{277}\) Section 1(2)(a) ‘references to embryos the creation of which was brought about in vitro (in their application to those where fertilisation or any other process by which an embryo is created is complete) are to those where fertilisation or any other process by which the embryo was created began outside the human body whether or not it was completed there.’ *Human Fertilisation and Embryology Act 1990* (UK) s 1(2)(a) as amended by the *Human Fertilisation and Embryology Act 2008* (UK) s 1(3).

\(^{278}\) Apart from allowing the creation of cytoplasmic hybrid embryos, the *Human Fertilisation and Embryology Act 1990* (UK) (as amended) allows for the creation of true hybrids which are created by fertilisation of a human egg with animal sperm or *vice versa* and the creation of chimeras, which are a integration of animal and human cells. Unlike cytoplasmic hybrid embryos, these human admixed embryos would have more than one per cent animal DNA. *Human Fertilisation and Embryology Act 1990* (UK) s 4A as amended by the *Human Fertilisation and Embryology Act 2008* (UK) s 4(2). Dr. Lyle Armstrong, the research’s team leader, reported preliminary data on the research of creating human hybrid embryos at a lecture at the Knesset in Israel on the 27th March 2008. ‘Hybrid Embryos Statement’, *Press Release* (Newcastle University) 1 April 2008 <http://www.ncl.ac.uk/press.release/item/1207065299>.

made in debate in the House of Lords in 19 May 2008 when discussing the
Human Fertilisation and Embryology Bill (UK). However, it has been argued that
public concern about hybrid babies can be controlled through the use of laws and
licensing regimes.\textsuperscript{280}

[T]he Authority has decided that there is no fundamental reason to
prevent cytoplasmic hybrid research. However, public opinion is
very finely divided with people generally opposed to this research
unless it is tightly regulated and it is likely to lead to scientific or
medical advancements.\textsuperscript{281}

It can be asserted that the \textit{Human Fertilisation and Embryology Act 1990} (UK)
adopted a consequences approach by focusing on the benefit accruing from such
research and providing other methods of regulation to address social risks
concern. The provision of the \textit{Human Fertilisation and Embryology Act 1990}
(UK) that address the concern of society involving the risk of the creation of new
species is section 3ZA which separates the 'permitted embryo' from other embryos
created for research purposes. It states:

\begin{quote}
Permitted eggs, permitted sperm and permitted embryos

(1) This section has effect for the interpretation of section 3(2).

(2) A permitted egg is one —
\end{quote}


(a) which has been produced by or extracted from the ovaries of a woman, and
(b) whose nuclear or mitochondrial DNA has not been altered.

(3) Permitted sperm are sperm —
(a) which have been produced by or extracted from the testes of a man, and
(b) whose nuclear or mitochondrial DNA has not been altered.

(4) An embryo is permitted embryo if —
(a) it has been created by the fertilisation of a permitted egg by permitted sperm,
(b) no nuclear or mitochondrial DNA of any cell of the embryo has been altered, and
(c) no cell has been added to it other than by division of the embryo’s own cells.

By the definition in the Act, an embryo is created by fertilisation of a permitted egg (derived from a woman’s ovary)\(^{282}\) and permitted sperm (derived from the testes of a man).\(^{283}\) By extension, a permitted embryo is an embryo created by fertilisation. The determination of whether such an embryo is a permitted embryo is placed in the hands of scientific researchers which confirms that the protection does not stem from the principle that the \textit{in vitro} human embryo is entitled to right to life, but that such provision has been developed to serve the objective of maintaining the social foundations and protecting the safety of the resulting child. Together with the provision that limits the time of \textit{in vitro} human embryo development, the prohibition on placing scientifically modified embryos into a

\(^{282}\) Human Fertilization and Embryology Act 1990 (UK) s 3ZA(2) as amended by the Human Fertilization and Embryology Act 2008 (UK) s 3(5).

\(^{283}\) Human Fertilization and Embryology Act 1990 (UK) s 3ZA(3) as amended by the Human Fertilization and Embryology Act 2008 (UK) s 3(5).
woman’s uterus would ensure that permission for human embryo research would not result in the risk of the creation of new human species or the change of social structure.

The Prohibition in Connection with Human Embryo

In the United Kingdom, HFEA is the key administrative body for the Human Fertilisation and Embryology Act 1990 (UK). The HFEA has authority to grant licences permitting the conduct of human embryo research and assisted reproductive treatments in accordance with the Act. Under this regulatory regime, a wide range of reproductive treatments, embryo storage techniques and human embryo research activities can be conducted under licence. This approach facilitates an interpretation of the Human Fertilisation and Embryology Act 1990 (UK) that accommodates the rapid pace of change in scientific and social developments. Section 3(3) of the Human Fertilisation and Embryology Act 1990 (UK) outlines the types of research activities involving human embryos that are prohibited and section 23 and 24 leave a more descriptive provision to the Code of Practice to be developed by the HFEA. The provisions of the Act that bestow on HFEA the authority to adopt the Code of Practice also bestow on the HFEA the power to review and revise the provisions of the Code of Practice in

284 Kerry Petersen, ‘The Regulation of Assisted Reproductive Technology: A Comparative Study of Permissive and Prescriptive Laws and Policies’ (2002) 9 Journal of Law and Medicine 485, 487 and 497. However, there are some observations and criticisms that the HFEA is more influenced by scientists working in the field than the ethics of biological science. Comment on Reproductive Ethics (CORE), <http://corethics.org/>.
order to reflect current scientific developments and changes in social perceptions, and to monitor and control the conduct of research through its licensing system.\textsuperscript{285} Even though the Code of Practice is not legally binding, the HFEA’s enforcement powers stem from its power to vary or revoke licences due to non-compliance of the terms governing those licences.\textsuperscript{286} This approach balances the possible benefits that will derive from allowing the creation and use of human embryos for research against the possible harms that the research will render.

In the United Kingdom, the HFEA will consider each research application to determine whether such research is necessary or desirable.\textsuperscript{287} The application to use human embryos for research needs to satisfy the requirement outlined in paragraph 3(5) schedule 2 of the \textit{Human Fertilisation and Embryology Act 1990} (UK) — ‘[n]o licence under this paragraph is to be granted unless the Authority [HFEA] is satisfied that any proposed use of embryos or human admixed embryos is necessary for the purposes of the research’. The licence committee must be satisfied that the research could not be carried on without the use of human embryos. Furthermore, paragraph 3A clarifies the jurisdiction of the HFEA in granting a research licence. It states:

\begin{quote}
3A (1) A licence under paragraph 3 cannot authorise any activity unless the activity appears to the Authority —
\end{quote}

\textsuperscript{285} \textit{Human Fertilisation and Embryology Act 1990} (UK) (as amended) ss 23-24.

\textsuperscript{286} \textit{Human Fertilisation and Embryology Act 1990} (UK) (as amended) s 25(1).

\textsuperscript{287} \textit{Human Fertilisation and Embryology Act 1990} (UK) (as amended) s 3A (1).
(a) to be necessary or desirable for any of the purposes specified in sub-paragraph (2) (“the principal purposes”) 
(b) to be necessary or desirable for the purpose of providing knowledge that, in the view of the Authority, may be capable of being applied for the purposes specified in sub-paragraph (2)(a) or (b), or 
(c) to be necessary or desirable for such other purposes as may be specified in regulations.

(2) The principal purposes are —
(a) increasing knowledge about serious disease or other serious medical conditions, 
(b) developing treatments for serious disease or other serious medical conditions, 
(c) increasing knowledge about the causes of any congenital disease or congenital medical condition that does not fall within paragraph (a), 
(d) promoting advances in the treatment or infertility, 
(e) increasing knowledge about the causes of miscarriage, 
(f) developing more effective techniques of contraception, 
(g) developing methods for detecting the presence of gene, chromosome or mitochondrion abnormalities in embryos before implantation, or 
(h) increasing knowledge about the development of embryos.288

Schedule 2 Paragraph 3A of the Human Fertilisation and Embryology Act 1990 (UK) allows various types of research to be licensed by the HFEA. The HFEA can authorise research it considers to be necessary or desirable for one of the specified research purposes which include the creation and the use of human

embryos for research into stem cell therapies and research which is undertaken to increase knowledge about serious diseases and other serious medical conditions and the development of treatments for them.\textsuperscript{289} This provision covers a broad range of applications that can be licensed for research, giving the HFEA an authority to determine the matter under its discretion.\textsuperscript{290}

\textit{Stages of Embryo Development}

Despite the criticisms levelled at the permissive nature of the licensing regime, and even though a wide range of research activities can be licensed in the United Kingdom, certain activities which are specifically prohibited by the \textit{Human Fertilisation and Embryology Act 1990} (UK) cannot be licensed. The prohibited activities for which the HFEA is not authorised to grant research licences are listed in section 3(3) of the Act which includes the keeping or using of an embryo after the appearance of the primitive streak.

\textsuperscript{289} \textit{Human Fertilisation and Embryology Act 2008} (UK) para 3A(2)(a) sch 2 as amended by \textit{Human Fertilisation and Embryology Act 2008} (UK) para 6 sch 2.

\textsuperscript{290} The broad language of the Act allows the interpretation of the HFEA to license various types of research activities such as PGD for abnormality of embryos, HLA typing to test the embryo for tissue compatibility with existing child, and for the license of creating SCNT embryos for research purposes. See further \textit{Quintavalle v Human Fertilisation and Embryology Authority} [2003] EWCA Civ 667; \textit{R (on the application of Quintavalle) v Secretary of State for Health} [2003] UKHL 13; \textit{R (on the application of Quintavalle) v Secretary of State for Health} [2005] UKHL 28.
The types of research activities involving human embryos that are prohibited under the *Human Fertilisation and Embryology Act 1990* (UK) include, according to section 3(4):

For the purposes of subsection (3)(a) above, the primitive streak is to be taken to have appeared in an embryo not later than the end of the period of 14 days beginning with the day on which the process of creating the embryo began, not counting any time during which the embryo is stored.\(^{291}\)

This means that an *in vitro* embryo cannot be kept outside the body for more than 14 days from the day on which the gametes were mixed (excluding the time at which the embryo was stored). The *Human Fertilisation and Embryology Act 1990* (UK) has developed a permissive framework to the regulation of human embryo research. The human embryo is recognised under the United Kingdom legislation as having no legal rights but is entitled to a certain level of protection under the law. Despite controversies, the *Human Fertilisation and Embryology Act 1990* (UK) has introduced a licensing regime which allows research to be conducted on human embryos for up to 14 days after the embryo is created. The timeline was formulated based on the biology of human embryos. Cunningham states:

This line was drawn because up to that point – when the “primitive streak” appeared – the development of the cells was largely confined to

\(^{291}\) *Human Fertilisation and Embryology Act 1990* (UK) s 3(4) as amended by the *Human Fertilisation and Embryology Act 2008* (UK) s 3(4).
those subsequently to become the placenta rather than the foetus and only after about the fourteenth day did it become clear that one or more babies might eventually result. 292

Consent

One prerequisite to the use of human embryo for research purpose is consent. In the United Kingdom, an application to use human embryo for research must provide that the gamete or tissue providers have consented, in writing, to donate them for research purpose. 293 In giving consent, the donor must be provided with relevant information and opportunity to receive counselling. The HFEA 8th Code of Practice para 22.7 provides as follow:

For any research project, the centre should ensure that before donors give their consent to their gametes or embryos, or cells used to create embryo, being used in research, they are given oral information, supported by relevant written material, that confirms:

- the specific research project and its aims
- details of the research project, including likely outcomes and how any individual donation will impact on the overall project
- whether the embryos will be reversibly or irreversibly anonymised, and the implications of this
- whether donors will be given any information that is obtained during the research and is relevant to their health and welfare


293 Human Fertilisation and Embryology Act 1990 (UK) (as amended) sch 3 para 2.
• that donors are expected to have an opportunity to ask questions and discuss the research project
• that donating gametes or embryos to research in the course of treatment services will not affect the patient’s treatment in any way
• that patients are under no obligation to donate gametes and embryos for research and that their decision whether to do so will have no repercussion for any treatment they may receive
• that only fresh or frozen gametes and embryos not required for treatment can be used for research
• that research is experimental, and so any gametes and embryos used and created for any research project must not be used in treatment
• that donors may specify conditions for the use of the gametes or embryos
• that after the research has been completed, all donated gametes and embryos will be allowed to perish, and
• that, for any individual who donates cells for creating embryos for research, consent to use these cells includes consent to do so after the individual’s death, unless stated otherwise.\textsuperscript{294}

Consent can be withdrawn at any time until the embryo has been used for the research.\textsuperscript{295} In the case of donation for the creation of human embryos for extracting hESCs, the potential donors must be informed ‘that any stem cell lines created may continue indefinitely and be used in many different research projects’\textsuperscript{296} and of the intention to bank any stem cell lines derived from their

\textsuperscript{294} Human Fertilisation and Embryology Authority, the United Kingdom, \textit{Code of Practice 8th Edition} (2009) [22.7].

\textsuperscript{295} \textit{Human Fertilisation and Embryology Act 1990} (UK) (as amended) sch 3 para 4.

\textsuperscript{296} For current development of the \textit{Human Fertilisation and Embryology Act 1990} (UK), see
embryos. However, there are some cases where informed consent cannot be obtained from the donors. The *Human Fertilisation and Embryology Act 1990* (UK) provides that the creation of embryos without consent can be accepted where the conditions outlined in schedule 3 are met. These are: 1) the child with parental responsibility; 2) adults who lack capacity and 3) if the cells of the person is stored before the Act came into force, and they have since died. However, in order to use cells from a deceased person, it must be established that scientific research will be adversely affected to a significant extent.

### 5.2.2 Australia: Moderate Approach to Human Embryo Research

In Australia, the state of Victoria was the first to enact legislation regulating the conduct of research into human embryos. However, instead of studying the legislation passed in all of the states and territories in Australia, this dissertation will focus on the development of the legislation at the Commonwealth level. Even though regulating assisted reproductive technologies do not fall within the scope

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297 Ibid. The HFEA will not grant research licence unless the researchers have made commitment to deposit a sample of each stem cell line with the UK stem cell bank.


300 *Infertility (Medical Procedures) Act 1984* (Vic).
of the Commonwealth’s legislative power,\textsuperscript{301} the COAG has agreed to the creation of uniform regulation across the country meaning that, when the Commonwealth Parliament passed a law regulating human embryo research, the states and territories would have to enact corresponding legislation.\textsuperscript{302} Currently, most states and territories have passed legislation mirroring the Commonwealth statute by virtue of the Council of Australian Governments (COAG) agreement.\textsuperscript{303}

\textsuperscript{301} According to s 51(xx) of the \textit{Commonwealth Constitution}, the Australian Federal Parliament has no power to pass legislation relating to human embryo research.

\textsuperscript{302} COAG is an organisation providing a forum for discussion amongst the attorneys-general of the states and territories, with the aim of promoting the adoption of consistent legislation by the parliaments of the states, territories and the Commonwealth. See further Council of Australian Government website \textless http://www.coag.gov.au\textgreater .

\textsuperscript{303} Australian Capital Territory–\textit{Human Cloning and Other Prohibited Practices Act 2003 No 20} and \textit{Research Involving Human Embryos (New South Wales) Act 2003 No 21} (ACT);

New South Wales–\textit{Human Cloning and Embryo Research Act 2004} (NSW);

Northern Territory–Legislation is currently being drafted in the Northern Territory;

Queensland–\textit{Research Involving Human Embryos} and \textit{Prohibition of Human Cloning Act 2003} (Qld);

South Australia– \textit{Prohibition of Human Cloning for Reproduction Act 2003} and \textit{Research Involving Human Embryos Act 2003} (SA);

Tasmania– \textit{Human Cloning for Reproduction and Other Prohibited Practices Act 2003 (No. 51 of 2003) and Human Embryonic Research Regulation Act 2003 (No. 52 of 2003)} (Tas);

Victoria– \textit{Research Involving Human Embryos Act 2008} and \textit{Human Cloning for Reproduction 2008} (Vic);

Western Australia–\textit{Human Reproductive Technology Act 1991(WA)}.

The regulation of human embryo research at the Commonwealth level can be traced back to 1985 when the Human Embryo Experimentation Bill 1985 (Cth) was introduced by Senator Brian Harradine.\textsuperscript{304} Even though this bill was not passed, its provisions focused attention on the need to regulate human embryo research. A year later, in 1986, the Select Committee Report, \textit{Human Embryo Experimentation in Australia (Tate Report)},\textsuperscript{305} recommended consistent regulation at the federal level with the co-operation of the states and territories. Despite the recommendations, a national protocol was not created until 2002 and the passing of laws regulating human embryonic research was left to each state. In June 2002, the Research Involving Embryos and Prohibition of Human Cloning Bill 2002 (Cth) was introduced into the House of Representatives of the Commonwealth Parliament. The Bill proposed that human cloning be prohibited, but that experimentation on surplus ART embryos be allowed, subject to regulatory oversight. While there was considerable support for the prohibition of human reproductive cloning, there was much controversy surrounding embryonic experimentation due to the conflicting views held on the subject.\textsuperscript{306} However, the wording of the original bill did not allow the members of parliament who opposed either human cloning or all forms of research involving human embryos, but not both, to oppose only that aspect of the bill. As a result, the bill was split into two separate bills: the Prohibition of Human Cloning Bill (Cth) and the Research Involving Human Embryos Bill (Cth).\textsuperscript{307}

\textsuperscript{304} Chalmers, above n 2, 245.

\textsuperscript{305} Senate Select Committee on the Human Embryo Experimentation Bill 1985, \textit{Human Embryo Experimentation in Australia}, 1986.

\textsuperscript{306} Chalmers, above n 2, 240.
In considering the bills, members of Parliament were permitted to have a ‘conscience vote’, which allows voting in line with personal values and beliefs rather than according to party lines. Both bills were passed by the House of Representatives and then, in mid-November, the Prohibition of Human Cloning Bill (Cth) was passed by the Senate, followed by the Research Involving Human Embryos Bill (Cth), which was passed in December. The *Prohibition of Human Cloning Act 2002* (Cth) and the *Research Involving Human Embryos Act 2002* (Cth) thus became law.

The *Research Involving Human Embryos Act 2002* (Cth) and the *Prohibition of Human Cloning Act 2002* (Cth) each included a provision which required an independent review of its operation to be carried out by 19 December 2005, being two years after the Acts received Royal Assent. Hence, in June 2005, the Legislative Review Committee chaired by the Hon. John Lockhart, a former Federal Court judge, was appointed to review the Acts.\(^{308}\) In the process of legislative review, the Lockhart Committee recognised the diversity of social and moral values held within society and stated that all views would be given recognition in the regulatory compromise:

> [I]n considering whether certain activities should be made illegal, the social and moral value that some communities attach to the human embryo needs to be balanced against the social and moral value that

\(^{307}\)Ibid 248.

other communities attach to the treatment of disease and to helping people to have a family.\textsuperscript{309}

The Lockhart Committee took into account the importance of scientific development as well as the ethical issues surrounding human embryo research and presented the Report to the Minister of Ageing.\textsuperscript{310} The previous version of the Research Involving Human Embryos Act 2002 (Cht) only allowed for research to be conducted on surplus ART embryos as, at that time, there was a sufficient supply of stem cells being derived from surplus ART embryos.\textsuperscript{311} However, it was considered by the Lockhart Committee that the stem cell sciences had moved to the point where the creation of SCNT embryos to generate hESCs was required. The Lockhart Committee stated:

[T]he Committee note that, based on the submissions of experts working in the field, embryonic stem cells have potentially useful applications in other areas of medical research, such as for studying cell differentiation in healthy and diseased tissues (disease modelling studies) and for drug screening. Such studies could increase understanding of disease processes and lead to cures for diseases through other means apart from cellular therapies. The Committee’s view is that there is scientific merit in the use of embryonic stem cells for this type of research.\textsuperscript{312}

\textsuperscript{309} Ibid xiii.


\textsuperscript{311} Ibid 30.

In October 2006, the Bill reflecting the recommendations of the Lockhart Committee, the Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Bill 2006 (Cth), was introduced into the Senate by Senator Kay Patterson. It was passed by a majority vote in the Senate and the Bill was passed in the House of Representatives one month later. Almost all recommendations of the Lockhart Committee were reflected in the Research Involving Human Embryos Act 2002 (Cth) as amended, except for the recommendation to allow the creation of cytoplasmic hybrid embryos for the production of hESC. The Research Involving Human Embryos Act 2002 (Cth) was under a legislative review again in 2010 under the Committee chaired by Honourable Peter Heerey. The Report of the Committee set out 33 recommendations. While the Committee recommends some changes to the legislation, the basic structure of the provision in the Act is viewed as adequately regulating the issues.

The Status of Human Embryo In Vitro

In 1999, the Australian House of Representatives Standing Committee on


314 It was 34 votes for and 32 votes against in the Senate and 82 votes for and 62 votes against in the House of Representatives. See Nemes, above n 273, 142.


316 Ibid.
Constitutional and Legal Affairs was asked to conduct an inquiry into human cloning and embryonic research.\(^{317}\) A public inquiry was established, with Kevin Andrews as Chairman. The focus of the Committee’s review was whether any benefits accrued from cloning technologies and whether ‘it is ethical to conduct research involving cloning techniques which destroy embryos, and, if so, to what degree’. The result was a report titled *Human Cloning: Scientific, Ethical and Regulatory Aspects of Human Cloning and Stem Cell Research* (Andrews Report),\(^{318}\) which was published in 2001, followed with the enactment of the *Prohibition of Human Cloning Act 2002* (Cth) and the *Research Involving Human Embryos Act 2002* (Cth).

The Australian *Research Involving Human Embryos Act 2002* (Cth) recognises an embryo as an entity which has the potential to become a human, but is not yet a human being. This reflects the view that the human embryo is not entitled to human status at conception; however, the human status of the human embryo will develop gradually during its development and full human status will be accorded after a live birth.\(^{319}\) Later in 2005, the Lockhart Committee was appointed to undertake a review of the *Research Involving Human Embryos Act 2002* (Cth). In this review, the Lockhart Committee recommended the creation of SCNT embryo


for research purpose while restricting the creation of IVF embryo for research. This recommendation stems from the perception that a human embryo created by the fertilisation of a human egg by a human sperm is significantly connected to a family unit and has the status of a potential child, while a SCNT embryo is created purely for research purposes.\textsuperscript{320}

\textbf{[T]he former [fertilised embryos] having the social significance of being formed within the context of a family unit; the later [embryos created by other means] not having that significance, but rather being the product of research, suitable for research or therapeutic uses.}\textsuperscript{321}

Reflecting this review, the provisions of the \textit{Research Involving Human Embryos Act 2002} (Cth) prohibit the creation of human embryo by the fertilisation of a human egg with a human sperm for other purpose than to assist reproduction.\textsuperscript{322} However, if the fertilised embryo is not suitable for transfer into a woman, it may be used for research purposes.\textsuperscript{323}

\begin{itemize}
\item \textsuperscript{320} Ibid 73.
\item \textsuperscript{321} Ibid 71.
\item \textsuperscript{322} \textit{Research Involving Human Embryos Act 2002} (Cth) s 20(1)(b) as amended by \textit{Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006} (Cth) s 15 sch 2.
\item \textsuperscript{323} The law prohibits the creation of fertilised embryo for research purposes but allows for surplus ART embryos to be donated for research. \textit{Research Involving Human Embryos Act 2002} (Cth) ss 20 (1)(a)-(c) as amended by \textit{Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Act 2006} (Cth) s 15 sch 2.
\end{itemize}
The Definition of Human Embryo

In Australia, the definition of human embryo is outlined in section 7(1) of the Research Involving Human Embryos Act 2002 (Cth). The definition states:

*human embryo* means a discrete entity that has arisen from either:
(a) the first mitotic division when fertilisation of a human oocyte by a human sperm is complete; or
(b) any other process that initiates organised development of a biological entity with a human nuclear genome or altered human nuclear genome that has the potential to develop up to, or beyond, the stage at which the primitive streak appears; and has not yet reached 8 weeks of development since the first mitotic division.

The definition of a human embryo in Australian legislation attempts to include various methods of embryo creation as well as avoid including an entity that has no potential to develop into a human being into the definition of human embryo.324 This definition replaces the prior version before the amendment in 2006 which recognised the human status of an embryo following the development of the two pro nuclei stage—an event prior to the first mitotic division—that hindered research conducted on embryos during the fertilisation process up to the first mitotic division.325

The Protection of Human Dignity, Social Foundations and Safety Concerns


325 For example, research on the culture and maturation of oocytes. See Cooper, above n 310, 38.
In Australia, the suggestion that the creation of human admixed embryos be permitted was considered by the Lockhart Committee. Comments and suggestions were put forward for legislation permitting the creation of cytoplasmic hybrid embryos due to concerns over the exploitation of women for oocytes. At the end of the review process, the Committee recommended that the legislation should permit the creation of human admixed embryos for research purposes despite the community concern that was put forward regarding the creation of human-animal hybrid embryos. The Committee stated:

In order to reduce the need for human oocytes, transfer of human somatic cell nuclei into animal oocytes should be allowed, under licence, for the creation and use of human embryo clones for research, training and clinical application, including the production of human embryonic stem cells, as long as the activity satisfies all the criteria in the amended Act and these embryos are not implanted into the body of a woman or allowed to develop for more than 14 days.

The Committee recommended that cytoplasmic hybrid embryos should be allowed to be created for research purposes. Acknowledging the vital need for human oocytes for the creation of human embryos for research, the Committee recommended that allowing the use of animal oocytes in the creation of human embryos would reduce the need to use, and potentially exploit, women to obtain

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327 Ibid xxiii, recommendations 17 and 24.

oocytes to be used for hESC research.\textsuperscript{329} However, during the debate over the provisions of the Prohibition of Human Cloning for Reproduction and the Regulation of Human Embryo Research Amendment Bill 2006 (Cth), this recommendation was rejected on the grounds of concerns that were raised over the violation of human dignity. As a consequence, the \textit{Research Involving Human Embryos Act 2002} (Cth) specifically prohibits researchers from creating a chimeric embryo\textsuperscript{330} or creating and developing a hybrid embryo without a licence.\textsuperscript{331} The only application involving the development of human–animal hybrid embryos that is allowed under section 20(1)(f) of the \textit{Research Involving Human Embryos Act 2002} (Cth) is the fertilisation of an animal egg by a human sperm for the purposes of testing sperm quality, as long as it is performed in an accredited ART centre under licence.\textsuperscript{332} However, section 23B(3) of the \textit{Prohibition of Human Cloning for Reproduction Act 2002} (Cth) permits the creation of cytoplasmic hybrids embryo for research purpose, subject to a

\begin{itemize}
\item As discussed earlier, women undergoing infertility treatment require ovarian stimulation, in order to cause several eggs to mature at the same time and surgically harvested for \textit{in vitro} fertilisation. This maturation process is often painful and requires a great amount of dedication of the women. See Eugster , above n 180, 576; Mertes, above n 181, 630-33; Baylis, above n 89, 28.
\end{itemize}

According to section 8(1) of the \textit{Prohibition of Human Cloning for Reproduction Act 2002} (Cth), the \textbf{chimeric embryo} means:

\begin{itemize}
\item (a) a human embryo into which a cell, or any component part of a cell, of an animal has been introduced; or
\item (b) a thing declared by the regulations to be a chimeric embryo.
\end{itemize}

\begin{itemize}
\item \textit{Prohibition of Human Cloning for Reproduction Act 2002} (Cth) (as amended) ss 18, 23B.
\item \textit{Research Involving Human Embryos Act 2002} (Cth) (as amended) s 20(1)(f).
\end{itemize}
licence. Nonetheless, such creation is not possible as NHMRC is not authorised
to grant a licence for the creation of cytoplasmic hybrids embryos. In 2011, it
was recommended by the Legislative Review Committee that section 23B(3) of
the Prohibition of Human Cloning for Reproduction Act 2002 (Cth) should be
revised to reflect section 20(1)(f) of the Research Involving Human Embryos Act
2002 (Cth).\(^\text{335}\)

The Prohibition in Connection with Human Embryo

In Australia, the Research Involving Human Embryos Act 2002 (Cth) created a
Licensing Committee within the structure of the NHMRC. The committee had
bestowed on it the authority to grant licences authorising the conduct of research
on human embryos in both the private and public sectors. Before granting a
licence, the Licensing Committee must be satisfied that:

- all necessary consents have been obtained;\(^\text{336}\)
- the project has been approved by the Human Research Ethics Committee
  (HREC) forming part of the researcher’s institution;\(^\text{337}\)


\(^{334}\) Research Involving Human Embryos Act 2002 (Cth) (as amended) s 20(1).


\(^{336}\) Research Involving Human Embryos Act 2002 (Cth) (as amended) s 21(3)(a).

\(^{337}\) Research Involving Human Embryos Act 2002 (Cth) (as amended) s 21(3)(c).
In contrast to the United Kingdom legislation, the prescriptive provisions of the *Research Involving Human Embryo Act 2002* (Cth) have been criticised as preventing the development of human embryo research in Australia.338 Section 21(4) of the Act outlines the conditions which the NHMRC Licensing Committee has to consider before granting a research licence. It states:

(a) restricting the number of excess ART embryos, other embryos or human eggs, to that likely to be necessary to achieve the goals of the activity or project proposed in the application;

(b) the likelihood of significant advance in knowledge or improvement in technologies for treatment as a result of the use of excess ART embryos or human eggs, or the creation or use of other embryos, proposed in the application, which could not reasonably be achieved by other means;

(c) any relevant guidelines, or relevant parts of guidelines, issued by the CEO of the NHMRC under the *National Health and Medical Research Council Act 1992* and prescribed by the regulations for the purposes of this paragraph;

(d) the HREC assessment of the application mentioned in paragraph (3)(c); and such additional matters (if any) as are prescribed by the regulations.

(e) such additional matters (if any) as are prescribed by the regulations.339

Only a few applications have been approved under the regulation of the *Research Involving Human Embryo Act 2002* (Cth) due to the long process and proofs that

338 Nemes, above n 273, 140-41.

339 *Research Involving Human Embryos Act 2002* (Cth) (as amended) s 21(4).
researchers have to provide when applying for research licence.\(^{340}\) In response, the recent legislative review Committee chaired by Honourable Peter Heerey recommended that the term ‘significant advance’ in section 21(4)(b) of the *Research Involving Human Embryos Act 2002* (Cth) ‘should not be the subject of legislative definition’.\(^{341}\) This approach should facilitate research by allowing more human embryo research licences to be granted under the *Research Involving Human Embryos Act 2002* (Cth).\(^{342}\)

**Stages of Embryo Development**

In Australia, as discussed earlier, the Lockhart Committee took the view that the human status of human embryo will develop gradually during the development of the embryo. This approach is reflected in the provision that limits the period allowed for developing a human embryo outside a woman’s body. In section


\(^{342}\) *Research Involving Human Embryos Act 2002* (Cth) (as amended) ss 21(3)(a)-(c), 21(4).
20(1A) of the *Research Involving Human Embryos Act 2002* (Cth), the limit placed on this time period is 14 days after the embryo’s creation.343

*Consent*

In Australia, informed consents from responsible people are needed before a licence can be granted for research on the human embryo.344 These consents must be separated from consents to any treatment. In donating surplus ART embryos for research, two consents must be obtained. One is that the embryo is excess to treatment and another is that the embryo can be used in research. Only after the consent that the embryo is excess to treatment is obtained can the researcher seek consent for the use of the embryo for research.345 The relevant Guidelines state:

> Under the RIHE Act (s 21), before a licence can be issued for the use of an excess ART embryo in research, the Licensing Committee must be satisfied that appropriate protocols are in place to obtain proper consent from each person responsible for the embryo (as defined in the RIHE Act; see also paragraph 17.14).

> Researchers must report in writing to the Licensing Committee that such consent has been obtained and must disclose any restrictions to

343 *Research Involving Human Embryos Act 2002* (Cth) (as amended) s 20(1A).

344 Under the *Research Involving Human Embryos Act 2002* (Cth) (as amended) s 8, responsible person include the gamete providers and their spouses, the woman for whom the embryo was created for and her spouse or partner (if different from the gamete provider) and each person whose reproductive material, genetic material or cell was used in the creation of the embryo.

which the consent is subject. The protocols must also enable compliance with any restrictions of the consent.

Under the terms of the National Statement, proper consent for research must be informed, competent, voluntary, specific and, for this purpose, it must be in writing. Researchers must comply with the National Statement in respect of all these conditions, and must also follow the specific guidance provided in paragraphs 17.18 and 17.19 of these guidelines.

As for all other ART research (see paragraph 15.5), the process of providing information and obtaining consent for research on excess ART embryos must be clearly separated from the clinical care of the embryos or embryo donors.346

Under the Guidelines, the consent must be specific for the purpose, nature and scope of the research to ensure a clear understanding that in the case of destructive embryo research it might not be possible to report the fate of the embryo.347 Apart from the duty to provide a full explanation of the nature of the proposed research, the Guidelines recommend a ‘cooling-off’ period where destructive embryo research must not be acted upon for a fixed period of time. This period is designed to give time for full consideration by the donor and allows time to withdraw consent. Under the Guidelines as revised in 2007, it is recommended that researchers should wait at least two weeks after obtaining the consent.348 This ‘cooling-off’ period has a significant impact on research that requires the use of fresh human embryos as the human embryo is only allowed to develop in vitro for

346 Ibid [17.16].

347 Such as in the case of harvesting embryonic stem cell where researcher is not required to consult about the fate of the stem cells. Ibid [17.17].

348 Ibid [17.19].
14 days. The Guidelines only require consent from responsible people before the using embryo for research purposes; thus researchers have a discretion to obtain consents and allow for a cooling-off period before using the gametes or cells to create the embryo for the consented research. However, destructive embryo research on a ‘fresh embryo’ that is created by fertilisation of human egg with human sperm (IVF embryo) would not be possible. This is because the Research Involving Human Embryos Act 2002 (Cth) prohibits the creation of IVF embryos for research purposes while the Guidelines requires that consent can only be obtained after the embryo has been declared an excess ART embryo and requires two weeks cooling-off period before destructive embryo research can be conducted. The descriptive nature of the provisions of the Research Involving Human Embryos Act 2002 (Cth) limits the possibilities for scientific advance in connection with human embryo research. However, such principles enable the state to maintain the ethical boundaries in society.

5.2.3 Italy: Prohibitive Approach to Human Embryo Research Regulation

The standard of the regulation of human embryo research in Italy is at the restrictive end of the regulatory spectrum. Prior to the passing of legislation

349 Research Involving Human Embryos Act 2002 (Cth), (as amended) s 20(1).

350 National Health and Medical Research Council, Australian Government, Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research 2004 (as Revised in 2007 to Take into Account the Changes in Legislation), (2007) [17.13].

351 Ibid [17.19].
specifically addressing human embryo research, the use in Italy of assisted reproductive technology was free from any controls or restrictions.\textsuperscript{352} However, after 2004, when the Repubblica Italiana 40/2004, law number 40/2004 (Law Forty) came into force, the liberal approach to reproductive therapies came to an end.

Even though the Italian Republic has proclaimed itself to be a liberal and pluralist state, the power held by the traditional fascists and the Catholic Church has limited the scope for the practical expression of the liberalist ideals. It has been suggested that ‘strong elements of legal continuity with fascism remained despite the reintroduction of democracy and the rights and liberties contained in the Constitution’.\textsuperscript{353} In addition, the role of the Christian Democratic Party as the main Government party in the Italian Republic contributes to the high level of resistance to the concept of pluralism proclaimed in the Constitution. It has even been suggested that the Christian Democratic Party considers its duty is to block the coming into being of the pluralist polity provided in the Constitution.\textsuperscript{354} The Christian Democratic Party aligns itself with the principles of the Church, thus increasing its level of support in the Catholic electorates.\textsuperscript{355} In 1981, the Christian

\textsuperscript{352} Ingrid Metzler, ‘“Nationalizing Embryos”: The Politics of Human Embryonic Stem Cell Research in Italy’ (2007) \textit{2 BioSocieties} 413, 416; Bundren, above n 113, 730.

\textsuperscript{353} John Foot, \textit{Modern Italy} (Palgrave Macmillan, 2003), 65.

\textsuperscript{354} Patrick Hanafin, \textit{Conceiving Life: Reproductive Politics and the Law in Contemporary Italy} (Ashgate, 2007), 18.

\textsuperscript{355} John F Pollard, \textit{The Vatican and Italian Fascism, 1929-32: A Study in Conflict} (Cambridge University Press, 1985).
Democrats supported the stance taken by Pope John Paul II against the passing of a law legalising abortion law, when the Catholic Church attempted to have Law 194 on abortion repealed. The Pope’s argument in *Evangelium Vitae* focuses on the idea that laws should not reflect the majority’s views on morality but that they should reflect the morality of the Church.

Italy and the Catholic Church are interconnected, but are at the same time independent sovereign states. Their relationship is regulated by the *Italian Constitution* and the *Lateran Pacts*, which established the Vatican City. Under the Lateran Pacts, Italy recognises the ‘full ownership, exclusive dominion, and sovereign authority and jurisdiction of the Holy See over the Vatican’, 356 thus prohibiting Italy from interfering with the Vatican’s affairs. However, there is no provision prohibiting the Vatican from interfering with Italy’s affairs.

Italy used to separate the regulation of reproductive treatments into two parts; different regulatory regimes were put in place for the regulation of research conducted in private and public research centres.357 Before 2004, public fertility centres in Italy were prohibited from producing more embryos than could be transferred during each attempt of insemination, but such prohibition did not apply to private fertility centres.358

356 *Lateran Pacts of 1929, the Kingdom of Italy and the Holy See* (ratified 7 June 1929), Art. 3.
357 Metzler, above n 352, 416.
358 *Ministero della Sanita 1985.*
When there was no specific legislation regulating the conduct of human embryo research in private centres in Italy, Italian researchers were free to engage in any kinds of human embryo research.³⁵⁹ However, a ministerial decree introduced in 1997 banned the use of the cloning technology, resulting in prohibition on the creation of SCNT embryos.³⁶⁰ Still, the techniques of IVF embryo creation, the production of surplus embryos, embryo freezing and gamete donations were allowed and commonly conducted in Italy.³⁶¹ In addition, research on hESCs that were derived from fertilised embryos was allowed, in the absence of specific legislation.

However, in February 2004, the Italian parliament has passed the Repubblica Italiana, the law number 40/2004 (the Law Forty) to regulate assisted reproductive technologies in exceptionally strict manner. The Law has passed by narrowly voted of 277 to 222.³⁶² Since then human embryos are under the protection of the law and the derivation hESC has been succinctly prohibited.

Before the legislation, Italy has famous reputation as the ‘Wild West’ of assisted reproduction. Celestine Bohlen, a New York Times Journalist, reported in 1995 that ‘Italy is virtually the only country in Europe that still has no law, no controls, not even any minimum regulations governing more than 100 private clinics that

³⁵⁹ Metzler, above n 352, 423.
³⁶¹ Metzler, above n 352, 423.
perform various fertilization procedures.\textsuperscript{363} The creations of children from insemination after the death of the father as well as the surrogate motherhood had been widely conducted in Italian jurisprudence.\textsuperscript{364} The situation was seen as generating the vital need to have a legislation establishing legal protection for the child born through the use of the technology.\textsuperscript{365}

The Status of Human Embryo In Vitro

Italian regulation under the Repubblica Italiana 40/2004 (Law Forty) protects the ‘rights of all subjects involved, including the concepito’\textsuperscript{366} – a reference to the rights of the human embryo in vitro being protected under the law. Law Forty contains a long list of prohibitions against any scientific intervention with human embryos that is not directed toward therapy, even if there is a consequent risk of the child being born with chronic disease.\textsuperscript{367} The provision was tested in an Italian court in May 2004 when a couple who were both carriers of the genetic condition beta thalassemia, sought approval of pre-implantation genetic diagnosis

\textsuperscript{363} Cited in Boggio, above n 100, 1153.


\textsuperscript{365} Ibid.

\textsuperscript{366} Repubblica Italiana 40/2004 Art 1(1).

\textsuperscript{367} Article 13 of Law Forty forbids ‘production of human embryos for research or experimentation purposes…’. The only research that Law Forty allows on human embryos is clinical research that is conducted in the interests of the health and development of that embryo, in circumstances where there is no alternative method. Repubblica Italiana 40/2004 Art 13. Translated by Giuseppe Benagiano and Luca Gianaroli in Giuseppe Benagiano and Luca Gianaroli, ‘The New Italian IVF Legislation’ (2004) 9(2) Reproductive BioMedicine Online 117, 121.
application for embryo selection to ensure the embryo to be implanted would not have the condition.\textsuperscript{368} The judge ruled the application was not permissible under the Law Forty and all fertilised eggs must be implanted in the woman’s body.\textsuperscript{369} This ruling infers the legal protection owed to the life of \textit{in vitro} human embryo overrides the interests of the woman and the health interests of the future child. Interestingly, the \textit{Italian Law 194/78} provides for pregnancy interruption in the circumstance where there may be ‘expectations of anomalies or malformations of the child about to be born’.\textsuperscript{370} In other words, parents may choose to have an abortion after implantation due to the potential effect of a genetic disease on the newborn child, in order to protect the mental and physical health of the mother. This provision creates circumstances whereby Law Forty requires all embryos to be implanted, but then another law allows the woman to have an abortion afterwards. As a consequence, the woman concerned has to undergo a medical procedure to avoid having children who have inherited a genetic disease. It can be argued that, in Italy, \textit{in vitro} human embryos are entitled to more protection than human embryos \textit{in vivo} because the hierarchy of rights of the woman is prioritised

\textsuperscript{368} \textit{Tribunale di Catania, 1 sezione civile}, 3 May 2004; cited in Patrick Hanafin, \textit{Conceiving Life: Reproduction Politics and the Law in contemporary Italy} (Ashgate, 2007), 66.

\textsuperscript{369} Ibid. The couple argued that the Law was incompatible with Article 2 and Article 32(2) of the \textit{Italian Constitution} which guarantee inviolable human rights. In response, the judge stated that under Article 2, there is no fundamental right to have a child of one’s desires. The interest in this case is not the health of any child born as a result of the assisted reproduction but rather the couple’s wish to have a child that is a healthy one and such interest is not guaranteed in the \textit{Italian Constitution}. Furthermore, the judge stated that the obligation to transfer all fertilised eggs into the womb did not fall within the scope of unconsented medical treatment stated in Article 32(2) of the \textit{Italian Constitution} and dismissed all of these claims.

\textsuperscript{370} \textit{Italian Law 194/78} Art 4, cited in Fineschi, above n 364.; See also Boggio, above n 100, 1155.
5.3 Concluding Summary

In summary, the right to life of human embryo *in vitro* is determined by collective social values which were influenced by arguments about human research regulation, commercial and financial interests and regulatory alternatives. Most jurisdictions maintain that the human embryo *in vitro* has no right to life to avoid contradiction in the law. However, in order to legitimately regulate human embryo research, the state acknowledges public concern and grants special status to human embryos and entitles them to legal protection under the law. Some jurisdiction view that an adequate protection is provided when human embryo is treated with respect. The legislative determination of the status of *in vitro* human embryos derives from the moral values of the society through various channels including public consultation and the research conducted by a specific committee.\(^{371}\) However, in Italy, the Italian government took into account the moral viewpoint that reflected Catholic belief, when enacting Law Forty.\(^ {372}\)

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\(^{372}\) Metzler, above n 352, 418.
In Thailand, the morality of people in society is widely determined by Buddhist teachings. As discussed in a previous chapter, in Buddhist belief, human life starts at conception in the mother’s womb where the human embryo is entitled to protection under the sanctity of human life principle. Historically, the interpretation of Buddhist teachings regarding the sanctity of human life has influenced legal principles protecting human embryos in the provisions prohibiting abortion in Thailand. However, at the time of Buddha, the science of *in vitro* fertilisation did not exist and there is no teaching which specifically addresses the creation of human life *in vitro*. Thus, the absence of a specific Buddhist principle leaves room for interpretation of Thai morality regarding the sanctity of life of *in vitro* human embryos.
Chapter Six:

Challenges and Recommendations for the Regulation of Human Embryo Research in Thailand

6.1 Introduction

The analyses in previous chapters find that under Theravada Buddhist ethics an *in vitro* embryo does not constitute as human life in Thailand. However, it does not follow that human embryo research should be left unregulated. In theory, *in vitro* human embryos can be developed into a human being if implanted in a woman’s uterus. Thus, regardless of having a life or not, the use of *in vitro* human embryo should be limited to necessity and should not be left unregulated. To date, there has been no law regulating human embryo research and researchers and medical practitioners in Thailand have been worked in a legal vacuum. Thus, it is proposed in this dissertation that legislation is required for the regulation of human embryo research in Thailand.

One challenge confronting the proposed regulation of modern technological advancements is the pace of technological change that the legislation needs to address. New issues surrounding the appropriateness of human embryo

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373 In the area of medical research, it has been said that the ideal type of regulation is that which regulates unethical practices while at the same time maintaining sufficient flexibility to accommodate the rapidly changing environment of science. Henry T Greely, ‘Banning “Human
research constantly emerge as advances are made in the area of stem cell science. Hence, the effectiveness of the regulation depends on the ability of the regulation to keep up with scientific advancements while at the same time maintaining the stability and consistency of the law. However, it is important to note the contradiction between the stable and consistent nature of legislation and the fast pace of technological developments cannot be easily reconciled.\textsuperscript{374} It is argued in this dissertation that, the provisions of the Protection of Children Born from Assisted Reproductive Treatment Bill (Th) are not applicable to the regulation of human embryo research in Thailand. This can be remedied either by revising the Bill or developing a new specific statute regulating human embryo research which would require all types of human embryo research to be regulated under a licensing regime administered by a statutory authority.

### 6.2 Guidelines v Legislation

There are different regulatory approaches that can be adopted to influence behaviour. Lawrence Lessig has characterised the approaches taken by regulators into four modes of regulations. These are: (1) the law; (2) social norms; (3) the market; and (4) code.\textsuperscript{375} Currently, in Thailand, the research into human embryos is regulated using guidelines and codes of conduct. Nevertheless, the situation


remains unclear and the boundaries have not been clearly defined. The following table shows the differences that exist between the regulation of hESC research by guidelines and by legislation. Even though guidelines provide flexibility and enable the regulation to compete with technological developments, regulation by legislation can fill the gaps that exist with the current situation in Thailand, by providing legal boundaries.

<table>
<thead>
<tr>
<th></th>
<th>Guidelines</th>
<th>Legislation</th>
</tr>
</thead>
<tbody>
<tr>
<td>The Policy Developers</td>
<td>No specific authority that can impose a regulation on both public and private sectors</td>
<td>The Parliament has specific authority to enact the law through the process according to the Constitution.</td>
</tr>
<tr>
<td>The Enforcement</td>
<td>There is no specific authority that can enforce the guidelines in all sectors.</td>
<td>The legislation can create a specific authority that is responsible for enforcing the law in all sectors.</td>
</tr>
<tr>
<td>The Sanction</td>
<td>Guidelines cannot impose criminal penalties.</td>
<td>Legislation can impose both criminal penalties and monetary sanctions.</td>
</tr>
<tr>
<td>The Amendment</td>
<td>The process of amending guidelines would be</td>
<td>Legislation is enacted through the Parliament,</td>
</tr>
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</table>
easier as it would not require much process.
so amendments would need the Parliament’s consideration as well.
Thus, it would take more time and resources.

6.3 Law and Legitimacy

The concept of legitimacy is used in several different contexts. For instance, one may say that a particular regulation is legitimate because it is effective, necessary and worthy of support. On the other hand, one may argue that a particular regulation is morally wrong and not worthy of support, thus arguing that such regulation lacks legitimacy. In order to achieve legitimacy, the regulation must be supported by legitimate regulatory purposes and those purposes must not violate accepted moral, legal and ethical standards.

When regulators seek to ‘legitimate’ their objectives, they might appeal to a broad range of public interest or national interest purposes (economic, medical,

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377 Legitimacy is conceptualised as an attitude or belief that individuals hold about something, affecting the extent to which that thing is considered worthy of the individuals’ support. Christine Horne, ‘A Social Norms Approach to Legitimacy’ (2009) 53(3) American Behavioural Scientist 400, 401.
educational, security, and so on) which they claim merit respect on the part of their regulatees.\textsuperscript{378}

In a pluralist society with more than one set of values and interests, it is difficult for legislators to appeal to the entire range of public interests. It should not be assumed that one claim that the law is legitimate can apply to all segments of society.\textsuperscript{379} In the context of human embryo research, it might not be enough for regulators to appeal for public support based only on the assertion that the research will benefit medical treatments. This is because certain applications of human embryo research are judged, by various groups of people, to be in violation of certain ethical or moral standards.\textsuperscript{380} For example, if human embryo research is always considered immoral, regardless of the mode of its application and the harms outweighing the benefits gained, then the law can only prohibit all applications of human embryo research. However, theoretically, human embryo research can lead to great benefits while the possible harms caused and the ethical issues involved are still subject to debate. Thus, the blanket prohibition of human embryo research would be resisted by society, just as society would resist outright permission.

Living in a democratic country means that citizens are required to comply with any law that is democratically made. The challenge for regulators seeking to

\textsuperscript{378} Brownsword, Rights, Regulation, and the Technological Revolution, above n 5, 9.


\textsuperscript{380} See Brownsword, above n 173.
regulate emergent technologies is the legitimacy of the regulation, which in turn depends on the ability of the regulators to keep pace with scientific advances while at the same time maintaining stability and consistency in the law. Additionally, the acceptance and support of the public are essential preconditions to a particular law achieving legitimacy. While regulators may appeal to the public interest in order to justify their actions, their actions also need to be seen as legitimate on moral and ethical grounds.\footnote{Brownsword, \textit{Rights, Regulation, and the Technological Revolution}, above n 5, 9-10.} Brownsword states:

While legitimation envisages a broad set of potentially justifying reasons for regulatory action, we engage a much narrower class of justifying reasons if we question the ‘legitimacy’ of regulatory purposes and practices. Here, the question is whether an adequate moral or ethical justification is available. … To put this another way, whereas regulators might purport to ‘legitimate’ their actions by appealing to a wide range of public interest reasons, they must appeal specifically to moral or ethical reason if they are to defend the ‘legitimacy’ of their actions.\footnote{Ibid 10.}


The rights and liberties, recognized by this Constitution expressly, by implication or by decisions of the Constitutional Court, shall be protected and directly binding on the National Assembly, the Council
of Ministers, the Courts, and other State organs in enacting, applying and interpreting laws.\textsuperscript{384}

The restriction of such rights and liberties as recognised by the Constitution shall not be imposed on a person except by virtue of provisions of the law specifically enacted for the purpose determined by this Constitution and to the extend of necessity and provided that it shall not affect the essential substance of such rights and liberties.\textsuperscript{385}

In Thailand, the recognition of rights, human dignity, liberty and equality of people are currently protected under the \textit{Constitution of the Kingdom of Thailand B.E 2550 (2007) (Th)}. Any restriction of these rights and liberties is prohibited and the state has a duty to exercise its power in accordance with the provisions in the \textit{Constitution} (Th).

\textbf{6.4.1 Right of Privacy}

``A person’s family rights, dignity, reputation and the right of privacy shall be protected."\textsuperscript{386}

The right of privacy is protected under section 35 of the \textit{Constitution} (Th). Privacy allows personal autonomy and creates a space where individual can

\begin{flushleft} 
\textsuperscript{384} \textit{Constitution of the Kingdom of Thailand B.E. 2550 (2007) s 27.} \\
\textsuperscript{385} \textit{Constitution of the Kingdom of Thailand B.E. 2550 (2007) s 29.} \\
\textsuperscript{386} \textit{Constitution of the Kingdom of Thailand B.E. 2550 (2007) s 35.} 
\end{flushleft}
determine their personal aspects of life. In 1973, the United States Supreme Court in the landmark case of *Roe v Wade*, in this case the court found that a Texas criminal abortion statute violated the due process clause of the Fourteenth Amendment because it interfered with a woman’s right to privacy.

In the debate over human embryo research, the right to privacy could play an important role in Thailand. Currently it is perceived by the law that a human embryo is not a human being but rather a part of the pregnant woman. Thus, in the debate over human embryo research, it can be argued that, if the owners of the gamete owners consent to research being conducted on their embryos, their decisions to make contributions to research should be respected. However, the opposing view of human embryo research argues that even though the human embryo is not yet a human being, it has potential to become a human. Thus, the right to privacy should not override the interests in life of the embryo, with the result that it must be protected from any research that deprives its life.

6.4.2 Right to Research and Dissemination of Research

A person shall enjoy an academic freedom.

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389 See below, Chapter 3.

390 Gilbert, above n 162.
Education, training, learning, teaching, researching and disseminating such research according to academic principles shall be protected; provided that it is not contrary to his or her civic duties or good morals.\(^{391}\)

Section 50 of the *Constitution* (Th) protects academic freedom to conduct research and disseminate the results of the research. The regulation of human embryo research is viewed as an intervention to such rights. In arguing that human embryo research should be permitted, Luca Coscioni, the president of the Luca Coscioni Association,\(^{392}\) stated as follows:

Every patient has the civil right to avail himself of the progress of scientific research. The right to health, to recovery or, anyhow, to a reduction of suffering, have to be respected. They must not be violated by a dogma-law of a state that blocks the freedom to do research, of finding out about the world of life and nature, in the name of faith.\(^{393}\)

It is recognised that the state has a duty to protect the rights and liberties of its citizens and must justify interference with them. However, research involving human embryos raises problems which have potential to challenge foundation values of society and social security in various contexts. As a result, it can be argued that the state has authority to enact the law to regulate the use of this technology for public interests. However, legal intervention must be limited to

\(^{391}\) *Constitution of the Kingdom of Thailand B.E 2550 (2007)* s 50.

\(^{392}\) The Luca Coscioni Association is a cross-party association of politicians, scientists and patients suffering from chronic diseases in Italy.

\(^{393}\) Luca Coscioni quoted in Metzler, above n 181, 419.
necessity and must not violate the fundamental rights outline in the Constitution (Th).

6.4.3 Right to Health and Medical Treatment

The State shall pursue directive principles of State policies in relation to Social Affairs, Public Health, Education and Cultural Affairs, as follows:

…

(2) to promote, support and develop the health system based upon the fostering of health that leads to a sustainable state of happiness of the people, provide and promote public health services that meet the standard thoroughly and efficiently, promote participation by private individuals and communities in the development of health and the provision of public health services, provided that persons who, under the duty to provide such services, have performed the duty in accordance with the professional standard and ethics, shall be protected.394


The right to health and medical treatment is also protected under international convention such as in:

Article 25 Universal Declaration on Human Rights

(1) Everyone has the right to a standard of living adequate for the health and wellbeing of himself and of his family, including food, clothing, housing and medical care and necessary social services, and the right to security in the event of unemployment, sickness, disability, widowhood, old age or other lack of livelihood in circumstances beyond his control.

Article 12 International Covenant on Economic, Social and Cultural Rights

1. The States Parties to the present Covenant recognise the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.
In the context of this dissertation, references to the rights to health and to receive medical treatment refer to the rights held by citizens stemming from the fact that their respective states are under an obligation to perform certain duties. One of the duties which a state has toward its citizens is the need to provide them with basic health care. It could be argued that states are obliged to allow the conduct of human embryo research as a result of their citizens’ rights to health and access to medical treatment. As any knowledge gained from the conduct of human embryo research has the potential to improve therapeutic medication, the failure of a state to support the development of hESC technologies could be viewed as a denial of the rights of its citizens to health and access to medical treatment.

However, it might be argued that in the inter-connected world of globalisation, technology and knowledge can be transferred, and the treatment developed from countries where human embryo research is permitted would be easily made available in the countries where such research is prohibited. However, the

2. The steps to be taken by the States Parties to the present Covenant to achieve the full realization of this right shall include those necessary for:

(a) The provision for the reduction of the stillbirth-rate and of infant mortality and for the healthy development of the child;

(b) The improvement of all aspects of environmental and industrial hygiene;

(c) The prevention, treatment and control of epidemic, endemic, occupational and other diseases;

(d) The creation of conditions which would assure to all medical service and medical attention in the event of sickness.

accessibility to such treatment would be limited to people with economic advantages as the cost of transferring the knowledge and technology would be high and this can be viewed as discrimination against a person on the ground of economic or social standing.\textsuperscript{396}

6.5 The \textit{National Health Act 2007 (Th) and The Statute on the National Health System 2009 (Th)}

The \textit{National Health Act 2007 (Th)} was enacted in 2007 after “the National Health System” report was publicized and proposed a reform on the health system in the \textit{Constitution 1997} in year 2000. The \textit{National Health Act 2007 (Th)} serves as a tool to set guidelines on the national health development in which all parties in society have to participate. The Act states that;

Section 6. A woman’s health in aspect of her gender and reproductive system which is of specific characteristics, complicate and influential to

\textsuperscript{396} \textit{Constitution of the Kingdom of Thailand (Th) s 30.}

All persons are equal before the law and shall enjoy equal protection under the law.

Men and women shall enjoy equal rights.

Unjust discrimination against a person on the grounds of the different in origin, race, language, sex, age, disability, physical or health condition, personal status, economic or social standing, religious belief, education or constitutionally political view, shall not be permitted.

Measure determined by the State in order to eliminate obstacles to or to promote person’s ability to exercise their rights and liberties in the same manner as other persons shall not be deemed as unjust discrimination under paragraph three.
her total life span, shall be harmoniously and appropriately promoted and protected.

The health of a child, a disabled person, an elderly person, and a socially deprived person, as well as, groups of people with specific health characters, shall also be relevantly and appropriately promoted and protected. 397

The task to promote health is recognised as the State responsibility. Furthermore, section 4 of the Statute on the National Health System 2009 (Th) guarantees the right to health as one of the fundamental rights of the people of Thailand. It imposes the duty of the state to “promote and support education and exchange of learning of the individuals, families, and communities in order to generate knowledge and skills in the way of life and promotion of health”. 398

6.6 Approaches to the Regulation of Human Embryo Research

Drawing from LeRoy Walters’s classification, 399 it is possible to examine the regulatory regimes governing human embryo research of several different nations. Amongst these regimes, it is possible to classify three separate types of regulatory approaches.

397 National Health Act 2007 (Th) s 6.
398 Statute on the National Health System 2009 (Th) s 26.
6.6.1 All Forms of Human Embryo Research and Technology are Prohibited by the Law

This approach prohibits the conduct of research on a human embryo and the creation of hESC lines. Nations taking this position risk the loss of potential knowledge that could be obtained from research conducted on both human embryos and hESCs. In addition, this position ignores the responsibility of the state to develop potential medical treatments for its citizens. However, this position endorses the claim that a human embryo has the right to life. This policy is mainly based on the ethical standpoint whereby the status of a human embryo is the same as that of a human.400

The nation to which this approach applies might prohibit research being conducted on human embryos, but allow research to be conducted on imported hESC lines. This approach reveals an inconsistency in the policy that underpins the legislation regulating hESC research. On the one hand, it is considered unethical to conduct research on an embryo, while on the other, it is considered ethically acceptable to import embryonic stem cell lines that are derived from the destruction of human embryos. The argument put forward supporting this approach is based on the distinction between performing unethical practices on

400 Ibid.
the one hand and, on the other, benefiting from the unethical practices of others.  

6.6.2 All Forms of Human Embryo Research and Technology are not Prohibited by the Law

This approach is found mainly in nations that have no regulations specifically governing the conduct of human embryo research. In the absence of specific laws, all types of human embryo research practices are allowed de facto. Compared to the other approaches, this would be the most liberal approach towards the conduct of human embryo research and the development of hESCs. However, the controversial issues surrounding the research cannot be resolved while the social ethics remain prejudiced. This is because no attempt has been made in these nations to balance the differing interests and viewpoints of the people in the particular society. Moreover, the ethical questions that surround the debate over human embryo research have not been answered. At certain levels, it is foreseeable that the moral codes of the nations taking this approach will be questioned, as the reasons for doing so might be conflicted with existing legal principle or social ethics within the nation.

6.6.3 Some Forms of Human Embryo Research and Technology are Prohibited by the Law

Most nations that have specific regulations governing human embryo research have adopted this third regulatory approach. This approach functions by balancing the interests of all people in the society, as well as seeking a compromise regarding the ethical and legal controversies that surround the conduct of human embryo research. This is done in order to find common ground among the majority of people in the society.

The various current regulatory models reveal there are different categories of regulation governing the conduct of human embryo research. These are made up of:

1. nations that permit human embryo research to be conducted on surplus ART embryos that remain after reproductive treatment;

2. nations that permit human embryo research to be conducted on embryos created by the fertilisation of a human ovum by a human sperm for research purposes (IVF embryos);

3. nations that permit human embryo research to be conducted on embryos created by somatic cell nuclear transfer for research purposes (SCNT embryos); and

4. nations that permit human embryo research to be conducted on human admixed embryos that have been created for research purposes.

It is important to note that each nation may have more than one of the types of regulation categorised in this section of the dissertation. A mixture of more than
one type of regulation governing human embryo research can be found in various countries. For example, the United Kingdom permits human embryo research on (1) surplus ART embryos; (2) IVF embryos; (3) SCNT embryos; and (4) human admixed embryos. In other words, the United Kingdom approach represents a mixture of all types of regulation noted above. By way of contrast, Australia allows research to be conducted on embryos that are (1) surplus ART embryos, as well as on (3) SCNT embryos, but prohibits (2) the creation of IVF embryos for research purposes, as well as (4) the creation of human admixed embryos for research purposes.

Nations that permit human embryo research on embryos that are surplus to requirements following reproductive treatments

These nations permit research to be conducted on embryos that are surplus to requirements following the completion of infertility treatments (i.e. surplus ART embryos). Provided that surplus ART embryos are discarded at the end of the cryopreservation frozen period as required by law, such embryos can be of great benefit to the scientific community in the development of biomedical technologies.

Nations that permit human embryo research on embryos created by the fertilisation of a human ovum by a human sperm for research purposes

402 Human Fertilization and Embryology Act 1990 (UK) (as amended).

403 Research Involving Human Embryo Act 2002 (Cth) (as amended).
The nations to which this approach applies are made up of nations who permit research to be conducted on embryos created for research purposes by in vitro fertilisation (IVF embryos). The creation of IVF embryos for research purposes raises several ethical issues, but those in favour of this approach argue that surplus ART embryos are continuously discarded during treatment. If it is considered ethical to create more embryos than can actually be transferred during ART treatment and thus to destroy the excess embryos, it follows that the creation of embryos for research purposes that could potentially benefit all of humankind should be considered ethically acceptable as well.404

Nations that permit human embryo research on embryos created by somatic cell nuclear transfer for research purposes

The nations to which this approach applies allow research to be conducted on embryos created for research purposes by somatic cell nuclear transfer (SCNT embryos). The SCNT technique is one of the most controversial techniques involved in human embryo research.405 Various countries oppose the creation of an embryo using SCNT due to the connotations of reproductive cloning as well as the ethics involved in creating embryos solely to destroy them.406 However, there

405 Bioethics Advisory Committee, Singapore, Ethical, Legal and Social Issues in Human Stem Cell Research, Reproductive and Therapeutic Cloning, (2002); Cameron, above n 169.
are countries that support the SCNT technique. One of the supporting arguments for creating SCNT embryo for research purposes is the different status of the IVF embryo and the SCNT embryo, as one is created as a future child while another is created as a group of cultured cells that could not develop into human being as implantation would not be allowed.407

Nations that permit human embryo research on human admixed embryos which have been created for research purposes

The nations to which this approach applies permit research to be conducted on embryos created by combining a human genome with an animal substance or vice versa. This approach is at the extreme end of the permissive regulatory scale and raises the most number of ethical issues.408 There are currently four main types of ‘human admixed embryos’: (1) true hybrids, created by the fusion of human and animal gametes; (2) cytoplasmic hybrid embryos, created by transferring the nucleus of a human cell into an animal oocyte whose nucleus has been removed; (3) transgenic human embryos, being human embryos into which animal DNA has been integrated; and (4) chimeric human embryos, being human embryos into which animal cells have been integrated.409 The mixing of a human genome with animal substances stirs the public’s emotions and raises questions about human

407 Skene, above n 317, 137.


409 See further Behringer, above n 182.
dignity. Even so, the shortage of donated eggs and the exploitation of women for oocytes have tempted certain countries to take this approach when regulating human embryo research.

6.7 The Recommendations for Law Reform in Thailand: Reviewing the Protection of Children born from Assisted Reproductive Technology Bill (Th) – The Bill

A key factor in regulating science is the pace of its development. However, legal definitions in the Bill have failed to reflect scientific developments to cover various types of embryos such as embryos created by SCNT. The Bill is restricted to embryos that are created by fertilisation. Under the Bill, a human embryo is defined as ‘a combination of human egg and human sperm from fertilisation to eight weeks of development’. As already noted, the SCNT technique involves nucleus replacement into an oocyte and fertilisation is not involved. Thus, SNCT is excluded from the list of activities afforded protection under the Bill. As a

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411 The United Kingdom is one of the countries that allow the creation of human-animal admixed embryos for research purposes in 2008. *Human Fertilization and Embryology Act 1990* (UK) s 4A as amended by *Human Fertilization and Embryology Act 2008* (UK) s 4(2).

412 Section 1 of the *Human Fertilisation and Embryology Act 1990* (UK) refers to a human embryo as ‘a live human embryo where fertilisation is complete’.

413 The English translation of the Protection of Children Born from Assisted Reproductive Technology Bill (Th) in this dissertation was translated by the author based on the Thai version that was submitted to the House of Representatives on 26 April 2011.
consequence, the use of SCNT technique to create human embryo for research purpose including the creation of cytoplasmic hybrid embryos and true hybrid embryo would not be regulated under the Bill because they are not created by the fertilisation of egg and sperm.

When the previous version of the *Human Fertilisation and Embryology Act 1990* (UK) was debated in the Parliament, the science of using SCNT and the creation of human-admixed embryos were unknown. For this reason, the House of Lords adopted a purposive interpretation of the provision of the Act. However, in the case of Thailand, the Bill has been developed at the time when there is clear evidence of scientific advances in the creation of human embryo *in vitro* to include various methods of human embryos creation. Thus, the legislators should not rely on the interpretation of the judges in deciding whether SCNT embryo and the human-admixed embryo are regulated under the law of Thailand as the interpretation of intention of the Parliament would be questionable since the science has been known for some time.

If the definition of ‘embryo’ in the Thai Bill is to be interpreted strictly, only surplus ART embryos are allowed for research and researchers could not create human embryo for any purpose other than to assist reproduction.414 Unless human embryos *in vitro* are afforded special status by Thai society, this restriction of the rights and liberties of people cannot be justified as the moral standard (determined by Theravada Buddhist ethics) is not violated by such research.

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414 *The Draft Protection of Children Born from Assisted Reproductive Technology Bill (Th) s 31.*
Because the human embryo created in vitro does not constitute a human life thus warranting it the protection of the sanctity of human life principle, the restriction on research conducted on the in vitro human embryo must be based on other compelling principles.

6.7.1 Definition of Human Embryo

The definition of a human embryo is an important part of the legislation regulating human embryo research. Even though human embryo is not recognised as having moral or legal status in Thailand, the use of human embryo should be limited to necessity. Human embryo is viewed as a gateway to a human life, albeit that there is no moral obligation imposed, the use of human embryo should be regulated with adequate protection. It is important that the definition includes all human embryos regardless of how they are created to protect them from unnecessary research. At the same time, the definition must not include human cells or cellular structures that have not been considered as human embryos so as to avoid distorting scientific advances without legitimate claim.415

Thailand could adopt the Australian amended definition of a ‘human embryo’ to include all human embryos under the regulation of the legislation while being able to facilitate research on entities that are not recognised as human embryos. This new definition would ensure that all research involving human embryos would be regulated in accordance with social ethics and legal principles.

415 Findlay, above n 324, 906.
**human embryo** means a discrete entity that has arisen from either:

(a) the first mitotic division when fertilisation of a human oocyte by a human sperm is complete; or

(b) any other process that initiates organised development of a biological entity with a human nuclear genome or altered human nuclear genome that has the potential to develop up to, or beyond, the stage at which the primitive streak appears;

and has not yet reached 8 weeks of development since the first mitotic division.

Furthermore, Thailand should adopt the United Kingdom model of dividing the regulation of human embryos into two regimes; one for embryos for reproduction (IVF embryos for ART treatment) and one for embryos for research.\(^{416}\) This would ensure that the interests of the child-to-be are protected while research on human embryos can be permitted by a designated authority on case by case basis.\(^{417}\)

### 6.7.2 The Protection of Human Dignity, Social Foundations and Safety Concerns

**The Statute on the National Health System**

*Section 7* The health system must promote human value and dignity and must attach importance to fairness and equity in society.

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\(^{416}\) See above, Chapter 5 of the dissertation.

\(^{417}\) This position is proposed by Martin H Johnson to avoid a biological definition of human embryo while being able to effectively regulate human embryo research. See Martin H Johnson, ‘Escaping the Tyranny of the Embryo? A New Approach to ART Regulation Based on UK and Australian Experiences’ (2006) 21 *Human Reproduction* 2756, 2760.
The protection of human dignity is recognised by the Statute on the National Health System 2009 (Th). In order to protect human dignity, one must not treat human life as a mean to an end and not to erode the dignity of human race.

In Thailand, the creation of human admixed embryos is prohibited under the Bill (Th).\textsuperscript{418} Even though the \textit{in vitro} human embryo does not have the status of a human being, the creation of a human admixed embryo is viewed as unethical and violates human dignity in absolute terms. Thus, the restriction on the creation of human admixed embryo can be justified as legitimate in Thailand. To do otherwise would put Thailand at risk of following a slippery slope toward the creation of human admixed babies, which is unacceptable and poses a risk to the world at large.

\textbf{6.7.3 The Prohibition in Connection with Human Embryo}

In Thailand, recognising that human embryo does not have a human status in both moral and legal senses but entitled to some protection, the use of human embryo for research should only be allowed when there is no alternative ways to achieve the same goal. Such goal should be limited to increasing knowledge and developing treatments which cannot be achieved from other types of research.

\textsuperscript{418} The Draft Protection of Children Born from Assisted Reproductive Technology Bill (Th) ss 34-35.
Furthermore, it is recommended that the legislation should appoint a national committee to be responsible for reviewing research applications and granting licences for research involving human embryos in Thailand. The Bill (Th) creates the Protection of the Children Born from ART Committee (“ART Committee”) having authority to advise the Ministry in relation to the development and the issues arise from ART. However, the ART Committee would not have authority to grant licences for human embryo research. Unlike the authority of the HFEA under the *Human Fertilisation and Embryology Act 1990* (UK), the ART Committee only has the authority to develop policies in relation to the use of surplus ART embryos.\(^{419}\) The use of sperms, oocytes, and embryos under the Bill (Th) are subject to the Code of Conduct to be developed by the Medical Council of Thailand which also needs the approval from the ART Committee.\(^{420}\) Thus, the new legislation should bestow licensing authority to the ART Committee with the power to adopt a Code of Practice for the determination of an application for a licence to conduct human embryo research. Furthermore, the Bill (Th) limits the applicants for research to medical practitioners only.\(^{421}\) As certain types of human embryo research will be concerned with the non therapeutic sciences, a qualified researcher with appropriate training should be able to participate in research activities. It is recommended that the revised Bill (Th) should allow for research to be conducted by a qualified researcher with appropriate training and leave more

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\(^{419}\) The Protection of Children Born from Assisted Reproductive Technology Bill (Th) ss 7(3)-(5).

\(^{420}\) The Protection of Children Born from Assisted Reproductive Technology Bill (Th) s 37.

\(^{421}\) The Protection of Children Born from Assisted Reproductive Technology Bill (Th) s 30 prohibits person other than medical practitioners providing assisted reproductive treatment including keeping, using and destroying gametes and human embryos.
details to be addressed in the Code of Practice which is to be adopted within the ART Committee framework.422

6.7.4 Stages of Embryo Development

The Protection of Children Born from Assisted Reproductive Technology Bill (Th) provides that surplus ART embryos may be used for research purposes for up to 14 days after the embryos’ creation.423 The 14 days limit of human embryo development outside the human body represents the existing legal standard that protects the in vivo human embryo in Thailand. Abortion law in Thailand grants protection toward human embryos from the time of pregnancy acknowledgement.424 As discussed in Chapter 3, in natural gestation, where the embryo is conceived traditionally inside the woman’s body, the early signs of pregnancy usually involve a delay in or the missing of a menstruation, nausea and/or morning sickness.425 These symptoms are usually experienced six to fourteen days after conception, being the period during which the embryo implants itself in the uterine wall and after which legal protection is granted.426 Furthermore, scientific study shows that human embryo cannot develop in vitro

422 This provision reflects the same principle as adopted by the Human Fertilisation and Embryology Act 1990 (UK) (as amended) ss 16-17.

423 The Draft Protection of Children Born from Assisted Reproductive Technology Bill (Th) s 32.

424 In Thailand, abortion is prohibited. However, pregnancy acknowledgement is the primary requirement in the offender being found guilty or not guilty. Criminal Code (Th) s 59.

425 As discussed earlier, see ‘Pregnancy Symptoms Early Signs of Pregnancy’, above n 116, 56.

426 This implication comes from the fact that contraception is not an offence under Thai law which means that prior to the implantation, the human embryo is not protected by any provisions.
for more than 14 days.\textsuperscript{427} Thus, the limit of 14 days development outside the human body would not hinder the development of human embryo research. At the same time, this limit is justified as legitimate as it is applied in accordance with moral standards of Thai society. Not only would the time limit protect the sanctity of human life, it would also protect society from possible harm derived from any unknown result of \textit{in vitro} embryo creation such as the “slippery slope” toward the creation of cloned or human admixed babies.

\textbf{6.7.5 Consent}

In the case where a public health professional practitioner demands to use a service receiver as subject of experiment in a research, he or she shall inform the service receiver in advance and the consent must be permitted in writing before carrying out the experiment. Such consent may be revoked at any time.\textsuperscript{428}

Apart from respecting the liberty of the donor in contributing to research, consent represents the donors’ determination on the status of embryo. However, under the Bill (Th), there is no provision outlining the requirement for informed consent prior to the use of human embryo for research purposes. The only applicable provision is section 32 where a medical practitioner can seek approval from the ART Committee for the use of surplus ART embryo. Under this provision, the ART Committee will have to develop guidelines for research approval which will

\textsuperscript{427} Cameron, above n 169, 217.

\textsuperscript{428} \textit{National Health Act 2007} (Th) s 9.
be announced in the Royal Gazette after the Bill (Th) has been passed into law.\footnote{The Protection of Children Born from Assisted Reproductive Technology Bill (Th) s 32.}

It is recommended that there should be a specific provision in the Bill (Th) requiring informed consent to be obtained prior to the use, creation and research on human gametes, cells, and embryos in the regulation on human embryo research in Thailand.

**6.8 Concluding Summary**

It is widely acknowledged that the state has the power to enact laws in order to maintain public order and the morality of the people. However, this power is not absolute, but is subject to certain important principles such as human rights and social conventions relevant to each jurisdiction. To tackle the problems which have arisen from research involving the human embryo, Thai regulators need to set a clear boundary clarifying the permitted and prohibited applications of human embryo research while maintaining the moral and ethical values of Thai society. However the regulation of human embryo research would place restriction to certain rights and liberties of people in the society. Thus, the legitimacy of the law is the essential condition providing justification for such intervention.

Even though the status of *in vitro* human embryo is not recognised as having a right to life, it is still important for Thailand to enact a specific legislation regulating human embryo research in Thailand. The adoption of specific legislation regulating human embryo research would eliminate the inconsistency
of the current law and provide a tool to control the research within ethical boundaries. The provisions of the *Human Fertilisation and Embryology Act 1990* (UK) and the *Research Involving Human Embryos Act 2002* (Cth) provide appropriate legislative models for Thailand in adopting legislation addressing human embryo research. It is recommended that the Bill (Th) should be revised in various aspects. For example, the definition of human embryo should reflect scientific advances and include all methods of embryo creation to be regulated under the Bill (Th). Furthermore, the law should create an authority or empower the ART Committee to responsible for enforcing the law and granting licences for research involving human embryos. In granting a research licence, the committee should adopt a Code of Practice which includes the provision to ensure that all required consents have been obtained prior to research. This regime would facilitate the development of human embryo research as well as accommodate moral and ethical concerns within the accepted social and individual boundaries. However, as a responsible member of the world community, it is recommended that the creation of human admixed embryos should not be allowed in Thailand in order to restrict the possibility of the creation of human admixed babies.
CHAPTER SEVEN:

CONCLUSION

7.1 Introduction

Advances in biomedical science and technological innovation have progressively benefited human kind by introducing possibilities for the treatment of various health conditions. The ability to create a human embryo outside the human body has extended the boundaries of biomedical technology with developments in Assisted Reproductive Technologies (ART) and human embryo research. It soon became evident that research conducted on \textit{in vitro} embryos had wider potential for therapeutic medications of currently untreatable diseases as well as the development of infertility treatments and drug research within the pharmaceutical industry.\textsuperscript{430}

While human embryo research offers many benefits it also raises ethical and legal problems. The issues raised by human embryo research mainly involve the sanctity of human life, human dignity, human rights, moral codes and beliefs. As a result, various countries have responded to this challenge with specific but different laws and policies regulating human embryo research; whereas other countries have not passed any specific legislation regulating human embryo

\textsuperscript{430} Gilbert, above n 162, RA102.
research. This dissertation posed the question: how should the law in Thailand regulate human embryo research?

To date, no consistent legal model regulating human embryo research has been developed internationally. Individual countries regulate the conduct of human embryo research in various ways, ranging from restrictive to permissive approaches reflecting, in each case, the social, legal and cultural aspects of the various nations. While restrictive regulation might prevent the development of technologies, excessively permissive regulation might create social problems. An extreme illustration of the inappropriate application of scientific research can be found in various science-fiction movies and novels. A well-known novel written by Aldous Huxley, titled *Brave New World*, is an example of a social structure that has been changed in response to scientific advancements. However, overly restrictive regulation would also not be beneficial. If other countries are able to provide their citizens with access to treatments that have been developed as a result of human embryo research, countries that prohibit human embryo research risk having their citizens accuse them of removing their opportunity to access such treatments or of forcing citizens to pay a high price to access those treatments elsewhere.

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431 Bundren, above n 113, 731.

This dissertation has argued that in Thailand a distinction can be made between human embryos created \textit{in vivo} and human embryos created \textit{in vitro}. While the sanctity of life principle is prioritised over reproductive autonomy and is the paramount principle in the abortion context in Thailand, the same approach does not apply to human embryos created outside the human body because Buddhist teachings imply that an embryo created \textit{in vitro} does not constitute a human life warranting the protection of the sanctity of life principle unless implanted in a woman's uterus. On the other hand, an examination of two legislative models regulating human embryo research in the United Kingdom and Australia shows that several other concerns in addition to sanctity of life were addressed. The additional concerns involve the protection of human dignity, societal foundations and the safety concerns, each of which need to be addressed when developing legislation that purports to regulate the conduct of research involving human embryos.

Generally speaking, the Thailand \textit{Constitution} protects academic freedom to conduct research and disseminate the results. However, human embryo research can be distinguished from other areas of scientific research because it raises unique concerns. To tackle the problems arising from human embryo research, Thai regulators need to set a clear boundary clarifying the permitted and prohibited applications of human embryo research while maintaining the Thai moral standards. Thus, if the regulators can justify that the regulatory intervention
is necessary and the regulation is supported by moral or ethical reason, they can claim that such regulation is legitimate and worthy of support.433

This dissertation analysed the moral and legal status of the human embryo with the aim of reviewing the Protection of Children Born from Reproductive Technology Bill (Th). It finds that the key determinant in the adoption of a permissive or prohibitive approach to legislation regulating research involving the human embryo, arises from different interpretations of the status of the human embryo and the hierarchy of rights and principles relating to human embryo research in each jurisdiction. The dissertation finds that legitimacy and law effectiveness depend on the stability of the principle behind the legislation and the ability to deliver the intended outcomes.

7.2 Summary of Research Findings

When considering the status of human embryos recognised by the law, the key determinant is the application of the sanctity of life principle. The status accorded by the law to human embryos can be divided into three different categories, as follows: 1) as having the same status as a human; 2) as having the potential to become a human but not yet being a human; or 3) as having no human status and thus no right to legal protection. In the case of Thailand, a distinction is made between human embryos created in vivo and human embryos created in vitro because the Buddhist teachings assert that a human life is created in the woman’s

433 Roger Brownsword, Rights, Regulation, and the Technological Revolution, above n 5, 9-11.
uterus. In this context, it may be concluded that an embryo created *in vitro* does not constitute a human life due to the absence of spiritual element and warrant the protection of the sanctity of human life principle unless it is implanted in a woman’s uterus.

The regulatory approach adopted by each jurisdiction to the issue of human embryo research is determined by the status accorded to human embryos. In jurisdictions where the human embryo is viewed as having the same status as an adult human, such as in Italy, all research applications involving human embryos are prohibited, with criminal penalties being imposed on those who break the law. However, in Australia and the United Kingdom where a human embryo is recognised as having the potential to become a human but not yet having the status of a human being, certain research applications are allowed.

In Australia, the creation of human embryos via the fertilisation of a human egg by a human sperm for research purposes is prohibited, because a ‘*fertilised human embryo*’ is viewed as having moral and social significance, being formed with a view to becoming a family member. As a result, the creation of human embryos by fertilisation for research purposes contradicts the moral standards of society. On the other hand, the ‘*SCNT embryo*’ is viewed as a different entity with no potential for human life, as it was never meant to be implanted. As a result, the creation of SCNT embryos for research purposes is allowed in Australia. Conversely, in the United Kingdom, the law is more permissive and research on human embryo is allowed under a strict licensing regime of the HFEA.
On the other hand, concerns involving human dignity and the maintenance of the safety and moral code of society are often raised when discussing the appropriateness of the creation of human admixed embryos and the use of SCNT or the cloning method of embryo creation. While Australia addresses human dignity and safety concerns by prohibiting the creation of human admixed embryos, the United Kingdom asserts that the creation of human admixed embryos does not violate human dignity and maintains that limiting the time of development of human admixed embryos to no longer than 14 days is an adequate method of addressing safety and morality concerns. By way of contrast, both Australia and the United Kingdom allow the use of the SCNT technique to create human embryos for research purposes and address the morality and safety concerns by also limiting the time of development of the embryo to no longer than 14 days.

In Italy where the human embryo is perceived as having the same status as a human, any destructive research on the human embryo is prohibited. No more than three embryos can be created at a time and all of them must be implanted in the woman’s uterus.\footnote{Repubblica Italiana 40/2004 Art 14(2).} Law Forty prohibits the creation of more embryos than can be transferred in one course,\footnote{Repubblica Italiana 40/2004 Art 14(2).} as well as prohibiting embryo selection through pre-implantation genetic diagnosis (PGD).\footnote{Repubblica Italiana 40/2004 Art 13(3)(b).} In addition, embryo freezing and the screening of embryos for genetic or chromosomal defects are forbidden under the
Thus, there is no excess ART embryo available for research and the creation of human embryos for research purposes is forbidden under Law Forty.

By holding that a human embryo created in vitro is not recognised as having the same status as a human embryo created in vivo, all research applications including research on fertilised human embryos, the creation of human admixed embryos and the creation of SCNT embryos for research purposes are allowed for up to 14 days from the embryo’s development in Thailand. This time limit is determined based on the time when the in vivo human embryo is protected by the provisions of abortion law in Thailand. However, due to international concerns over the creation of human admixed embryos regarding the human dignity and the safety of the society, it is recommended that the creation of human admixed embryos should be prohibited.

Regarding the question of how human embryo research should be regulated, emphasis must be placed on how the law is enforced. It is suggested that Thailand should create a specific authority responsible for enforcing the law, monitoring research applications and granting licences for human embryo research backed up by criminal sanctions as a means of ensuring compliance with the legislation. The dissertation proposes the appointment of a specific committee to discharge functions relating to the grant, variation, suspension and revocation of licences to carry on the human embryo research activity. Furthermore, the Committee should

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437 Repubblica Italiana 40/2004 Art 13, 14.
maintain a code of conduct to facilitate the pace of scientific advance while being able to control research within acceptable boundaries.
APPENDIX ONE: The Protection of Children Born from Assisted Reproductive Technology Bill (Th)

ช่วง

พระราชบัญญัติ

คู่ความของเด็กที่เกิดโดยอาศัยเทคโนโลยีช่วยการเจริญพันธุ์ทางการแพทย์

พ.ศ. ....

โดยที่เป็นการสมควรกำหนดมาตรการคู่ความของเด็กที่เกิดโดยอาศัยเทคโนโลยีช่วยการเจริญพันธุ์ทางการแพทย์

พระราชบัญญัตินี้มีบทบัญญัติบางประการเกี่ยวกับการจัดการสิทธิและเสรีภาพของบุคคลซึ่งมาตรา ๒๓ ประกอบกับมาตรา ๔๓ และมาตรา ๔๕ ของรัฐธรรมนูญแห่งราชอาณาจักรไทย บัญญัติให้กระทำได้โดยอาศัยอำนาจตามบทบัญญัติแห่งกฎหมาย

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มาตรา ๑ พระราชบัญญัตินี้เรียกว่า
“พระราชบัญญัติคู่ความของเด็กที่เกิดโดยอาศัยเทคโนโลยีช่วยการเจริญพันธุ์ทางการแพทย์ พ.ศ. ....”

มาตรา ๒
พระราชบัญญัตินี้ให้ใช้บังคับเมื่อพ้นกำหนดหนึ่งปีถัดจากวันประกาศในราชกิจจานุเบกษาเป็นต้นไป
มาตรการ ๒ ให้ทำการบัญชีข้อมูล

“อะไร” หมายความว่า เฉลิมสิบฟันเมื่อของพนักงาน

“เทียบ” หมายความว่า เฉลิมสิบฟันเมื่อของพนักงาน

“เทคนิค” หมายความว่า การจดบันทึกลงทันการแพทย์ หมายความว่า กรรมวิธีใด ๆ

ทางวิทยาศาสตร์การแพทย์ที่น่าสนใจและขอออกจากงานภายนอก

 เพื่อให้เกิดการตั้งครรภ์โดยไม่เป็นไปตามธรรมชาติ รวมถึงการผสมเลือม

“การผสมเลือม” หมายความว่า

การนำสิ่งเช้าไปในวัยระยะสิบฟันเมื่อของพนักงานเพื่อให้เกิดการตั้งครรภ์ โดยไม่มีการร่วมประโยชน์

“การตั้งครรภ์ที่มี” หมายความว่า

การตั้งครรภ์โดยอาศัยเทคโนโลยีช่วยการเจริญพันธุ์ทางการแพทย์

โดยพนักงานที่รับตั้งครรภ์แทนมีข้อตกลงไว้กับสามีและบริษัทที่จะเป็นด้วยกฎหมายก่อนตั้งครรภ์ว่าจะทำให้

กับครรภ์เป็นบรรดาของสามีและบริษัทที่จะเป็นด้วยกฎหมายนั้น

“ตัวอย่าง” หมายความว่า

อุ้มและป้องกันของพนักงานซึ่งรวมกันจะเกิดการปฏิบัติไปจะถูกแปลเปลี่ยน

“ทารก” หมายความว่า ตัวอย่างของพนักงานที่มีอยู่กินร่างแปลเปลี่ยน

ไม่ว่าอยู่ในหรือนอกองค์กรของพนักงาน

“ชอบ” หมายความว่า จำนวนข่าย จำนวน แจก และแปลเปลี่ยน หรือให้

เพื่อประโยชน์ในการคำหรือประโยชน์อื่นใดที่มีควรได้สำหรับตนเองหรือผู้อื่น

และหมายความรวมถึงการเสนอข่ายด้วย

“คณะกรรมการ” หมายความว่า

คณะกรรมการคู่ควรต้องติดต่อกันโดยอาศัยเทคโนโลยีช่วยการเจริญพันธุ์ทางการแพทย์

“รัฐมนตรี” หมายความว่า รัฐมนตรีผู้รักษาการตามพระราชบัญญัตินี้

มาตรการ ๔

ให้ศูนย์ที่มีอำนาจพิจารณาพักยาคัดเลือกวัณและควบคุมร่างกฎหมายว่าด้วยการจัดตั้งศาลเยาว

ชนและครอบครัวและวิธีพิจารณาคัดเลือกวัณและครอบครัวมีอำนาจพิจารณาพักยาคัดเลือกว่า
ขั้นตอนนี้
เฉพาะครั้งที่เกี่ยวกับความเป็นไปตามมาตรการของผู้ที่เกิดโดยอาศัยเทคโนโลยีช่วยการเจริญพันธ์ทางการแพทย์ตามพระราชบัญญัตินี้

ในการนี้ให้ผู้ที่เกิดโดยอาศัยเทคโนโลยีช่วยการเจริญพันธ์ทางการแพทย์ตามพระราชบัญญัตินี้
ให้เสนอปัญหาต่อส่วนใหญ่เครื่องมือคู่มือผู้วินิจฉัย ค่าวินิจฉัยของประชาชนผู้ใดให้เป็นที่สุด

มาตรา ๔
ให้รัฐมนตรีรักษาการกระทรวงการพัฒนาสังคมและความมั่นคงของมนุษย์และรัฐมนตรีรักษาการกระทรวงส
าราษฎร์รักษาการตามพระราชบัญญัตินี้

หมวด ๑

คณะกรรมการคุมครองเด็กที่เกิดโดยอาศัยเทคโนโลยีช่วยการเจริญพันธ์ทางการแพทย์


มาตรา ๖ ให้มีคณะกรรมการคุมครองเด็กที่เกิดโดยอาศัยเทคโนโลยีช่วยการเจริญพันธ์ทางการแพทย์

"คณะกรรมการคุมครองเด็กที่เกิดโดยอาศัยเทคโนโลยีช่วยการเจริญพันธ์ทางการแพทย์"

หรือเรียกโดยย่อว่า "กคพ."

ประกอบด้วยปลัดกระทรวงสาธารณสุข เป็นประธานกรรมการ

นายแพทย์สถาน

เป็นรองประธานกรรมการผู้แทนกระทรวงการพัฒนาสังคมและความมั่นคงของมนุษย์

ผู้แทนกรมอนามัย ผู้แทนคณะกรรมการคุมครองเด็กแห่งชาติ

ประธานราชวิทยาลัยการแพทย์แห่งประเทศไทย ประธานราชวิทยาลัยจิตแพทย์แห่งประเทศไทย

ประธานราชวิทยาลัยสุตินิเรชแพทย์แห่งประเทศไทย เป็นกรรมการโดยตำแหน่ง

และผู้ทรงคุณวุฒิจำแนกตามข้อรัฐมนตรีรักษาการกระทรวงสาธารณสุขแต่งตั้งจากผู้ซึ่งมีความรู้ความร

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ชัยวานุษย์และมีประสิทธิการณ์เป็นที่ประจักษ์ในด้านเทคโนโลยีช่วยการจัดกิจหน้าส่งองค์
ด้านวิชาพื้นฐานสอดคล้องกับกฎหมายของสภ.และด้านสังคมต่อเนื่องเป็นกรรมการ
ให้ยศบัณฑิตสภ.สนับสนุนบริการสาธารณะเป็นกรรมการและเลขานุการ
และให้ยศบัณฑิตสภ.สนับสนุนบริการสาธารณะต่อเนื่องชี้ขาดการของกรรมสิทธิ์สภ.จ้านราย
ไม่แก่ลงอยู่เป็นผู้ช่วยเลขานุการ

มาตรการ ๓ ให้คณะกรรมการมีอำนาจหน้าที่ดังต่อไปนี้

(๑)
เสนอความเห็นต่อรัฐมนตรีในการกำหนดนโยบายคู่คองต้องเกิดโดยอาศัยเทคโนโลยีช่วยการจัด
กิจหน้าส่งองค์การแพทย์

(๒)
เสนอความเห็นต่อรัฐมนตรีในการพัฒนาหรือแก้ไขปัญหาเกี่ยวกับเทคโนโลยีช่วยการจัดกิจหน้าส่งองค์การแพทย์

(๓) ประกาศกำหนดหลักเกณฑ์ วิธีการ
และขอเลือกในการขออนุญาตและการอนุญาตเกี่ยวกับการใช้ตัวอื่นที่เหลือซึ่งจากเกิดรักษากว่า
การมีบุตรยากของสำมิและภาระที่ชอบด้วยกฎหมายเพื่อการศึกษาวิจัยตามมาตรา ๑๒

(๔)
พิจารณาอนุญาตเกี่ยวกับการใช้ตัวอื่นที่เหลือซึ่งจากเกิดรักษากว่าการมีบุตรยากของสำมิและ
ภาระที่ชอบด้วยกฎหมายเพื่อการศึกษาวิจัยตามมาตรา ๑๒

(๕)
ให้ความเห็นชอบต่อแพทย์ในการออกประกาศเกี่ยวกับการให้บริการเทคโนโลยีช่วยการจัดกิจหน้าส่ง
แยกการแพทย์ตามพระราชบัญญัตินี้ ทั้งนี้
ประกาศของแพทย์ให้ใช้บังคับได้เมื่อประกาศในราชกิจจานุเบกษา
(๖) ควบคุม ตรวจสอบ

หรือจำกัดดูแลให้การให้บริการเทคโนโลยีข่าวการเจริญพันธ์ทางการแพทย์เป็นไปตามพระราชบัญญัตินี้

(๗) ส่งเสริมและสนับสนุนการศึกษาวิจัยทางวิทยาการแพทย์

หรือวิทยาการที่เกี่ยวกับเทคโนโลยีข่าวการเจริญพันธ์ทางการแพทย์

(๘) จัดทำรายงานผลการดำเนินงานเกี่ยวกับเทคโนโลยีข่าวการเจริญพันธ์ทางการแพทย์เสนอต่อรัฐมนตรีฯ

รองนายทะเบียนรัฐมนตรี

(๙) ปฏิบัติการอื่นตามที่รัฐมนตรีหรือคณะรัฐมนตรีมอบหมาย

มาตรา ๔ กรรมการผู้ทรงคุณวุฒิมีวาระการดำรงตำแหน่งคราวละสี่ปี

กรรมการผู้ทรงคุณวุฒิซึ่งพ้นจากตำแหน่งตามวาระอาจได้รับแต่งตั้งอีกได้

มาตรา ๕ นอกจากการพ้นจากตำแหน่งตามวาระ

กรรมการผู้ทรงคุณวุฒิพ้นจากตำแหน่งเมื่อ

(๑) ตาย

(๒) ลาออก

(๓) เป็นบุคคลล้มละลาย

(๔) เป็นคนไร้ความสามารถหรือคนเสมือนไร้ความสามารถ

(๕) ได้รับโทษจำคุกโดยคำพิพากษาถึงที่สุดให้จำคุก

เว้นแต่เป็นโทษสำหรับความผิดที่ได้กระทำโดยประมาทหรือความผิดหนี้ซึ่ง

(๖) รัฐมนตรีว่าการกระทรวงสาธารณสุขให้ออกเบี้ยเลี้ยงจากมีความประพฤติไม่เหมาะสมตามข้อเสนอของคณาการที่หนึ่ง

มติของคณะกรรมการที่ให้เบี้ยเลี้ยงไม่โดยว่าสังหารในสามของจำนวนกรรมการทั้งหมดที่มีอยู่
มาตรานี้

ในการให้บริการผู้ทรงคุณวุฒิพิจารณาค้านแนวทงก่อนหารายไว้รับสมัครวิธีการสรรหา更适合ต้องยื่นสมัครเช่นเดียวกันด้วยกันด้วยแนวทงและให้ผู้ได้รับผู้จัดตั้งแห่งด้านที่วางนั้นอยู่ใน
คำหนังสือกับมรรยาทที่มีอยู่แล้วจะมีการแต่งตั้งกรรมการผู้ทรงคุณวุฒิได้แต่งตั้งไว้แล้ว

ในการให้บริการผู้ทรงคุณวุฒิพิจารณาค้านแนวทงก่อนหาราย
ให้คณะกรรมการประกอบด้วยกรรมการทั้งหมดที่มีอยู่แล้วว่าจะมีการแต่งตั้งกรรมการผู้ทรงคุณวุฒิตามความในวรรคหนึ่ง

มาตรานี้

หากยังมิได้มีการแต่งตั้งกรรมการผู้ทรงคุณวุฒิใหม่
ให้กรรมการผู้ทรงคุณวุฒิซึ่งพิจารณาค้านแนวทงตามมรรยาทที่วางนั้นอยู่ในคำหนังสือเพื่อดำเนินงานต่อไปจนกว่า
กรรมการผู้ทรงคุณวุฒิซึ่งได้รับแต่งตั้งใหม่จะเข้ารับหน้าที่

มาตรานี้

การประชุมคณะกรรมการต้องมีกรรมการมาประชุมไม่น้อยกว่ากึ่งหนึ่งของจำนวนกรรมการทั้งหมดจึง
จะเป็นองค์ประชุม

ในการประชุมคณะกรรมการให้ทราบถึงการเป็นประธานในที่ประชุม
สำหรับประธานกรรมการไม่มาประชุมหรือไม่อาจปฏิบัติหน้าที่ได้
ให้รองประธานกรรมการเป็นประธานในที่ประชุม
รองประธานกรรมการไม่มาประชุมหรือไม่อาจปฏิบัติหน้าที่ได้
ให้ที่ประชุมเลือกกรรมการคนหนึ่งเป็นประธานในที่ประชุม สำหรับการประชุมในคราวนั้น

การวิพากษ์ปัญหาของที่ประชุมแต่ละคนจะสามารถปฏิบัติได็เป็นอย่างยิ่งให้ถือเสียงข้างมากกรรมการคน
หนึ่งให้มีเสียงเหนือในการลงคะแนน ถ้าคะแนนเสียงเท่ากัน
ให้ประธานในที่ประชุมออกเสียงเพื่อชั่วขณะมีเสียงเท่ากันเป็นเสียงชั่วคราว
มาตรการ ๑๓
คณะกรมการจะตั้งคณะอนุกรรมการเพื่อพิจารณาและเสนอความเห็นในเรื่องหนึ่งเรื่องใดหรือปัญหาที่เกี่ยวข้องโดยมีอำนาจตามที่คณะกรมการมอบหมายก็ได้

การประชุมคณะอนุกรรมการให้แก่มาตรการ ๑๓ มาใช้บังคับโดยอนุโลม

มาตรการ ๑๔ ให้กองการประกอบโรคศิลปะ กรมสนับสนุนบริการสุขภาพ
ท่าหน้าที่สนับสนุนการดำเนินงานของคณะกรมการ โดยให้มีอำนาจหน้าที่ดังต่อไปนี้
(๑) ปฏิบัติงานธุรการทั่วไปของคณะกรมการ
(๒) ประสานงานและร่วมมือกับส่วนราชการ
หน่วยงานของรัฐและเอกชนที่เกี่ยวข้องในการดำเนินงานเกี่ยวกับเทคโนโลยีช่วยการเจริญพันธุ์ทางการแพทย์ที่อยู่ในอำนาจหน้าที่ของคณะกรมการ

(๓) ดำเนินการจัดทำทะเบียนหน่วยงานหรือองค์กรที่ดำเนินงานเทคโนโลยีช่วยการเจริญพันธุ์ทางการแพทย์และทะเบียนผู้ขอรับบริการ

(๔) ดำเนินการรวบรวมข้อมูลและผลการวิจัยและวิเคราะห์ข้อมูลเกี่ยวกับการดำเนินงานเทคโนโลยีช่วยการเจริญพันธุ์ทางการแพทย์

(๕) ปฏิบัติการอื่นตามที่คณะกรมการมอบหมาย

หมวด ๒

การให้บริการเกี่ยวกับเทคโนโลยีช่วยการเจริญพันธุ์ทางการแพทย์

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มาตรการ ๓๕ ผู้ประกอบวิชาชีพเวชกรรมซึ่งเป็นผู้ให้บริการเกี่ยวกับเทคโนโลยีช่วยการเจริญพันธุ์ทางการแพทย์ บุพธรัชภูมิสินิกิจ
t้องถึงคุณสมบัติและคุณสมบัติตามมาตรฐานในการให้บริการเกี่ยวกับเทคโนโลยีช่วยการเจริญพันธุ์ทางการแพทย์ ตามที่แพทยสภาโดยความเห็นชอบของคณะกรรมการประกาศกำหนด

มาตรการ ๓๖ กลุ่มให้บริการเกี่ยวกับเทคโนโลยีช่วยการเจริญพันธุ์ทางการแพทย์ ผู้ให้บริการเกี่ยวกับเทคโนโลยีช่วยการเจริญพันธุ์ทางการแพทย์จะต้องจัดให้มีการตรวจและประเมินความพร้อมทางด้านการจิตใจ และสภาพแวดล้อมของผู้รับบริการและของผู้บริจาคอสูจิหรือไข่ที่จะนำมาใช้ดำเนินการรวมทั้งการป้องกันโรคที่อาจมีผลกระทบต่อเด็กที่จะเกิดมาด้วย ทั้งนี้ ตามหลักเกณฑ์ วิธีการ และเงื่อนไขที่แพทยสภาโดยความเห็นชอบของคณะกรรมการประกาศกำหนด

มาตรการ ๓๗ การสร้างเกียรติคุณไข่พ่อพ่อจากตัวอ่อน หรือทำให้สืบสานสภาพการเป็นตัวอ่อน ต้องดำเนินการตามหลักเกณฑ์ วิธีการ และเงื่อนไขที่แพทยสภาโดยความเห็นชอบของคณะกรรมการประกาศกำหนด แต่จะกำหนดให้เกียรติคุณไข่พ่อพ่อจากตัวอ่อนที่มีอายุเกินกว่าสิบสี่สัปดาห์แล้วปฏิบัติไม่ได้ทั้งนี้ อายุของตัวอ่อนไม่นับรวมระยะเวลาในการแช่แข็งตัวอ่อน

มาตรการ ๓๘ ในการให้บริการเกี่ยวกับเทคโนโลยีช่วยการเจริญพันธุ์ทางการแพทย์ผู้ให้บริการเกี่ยวกับเทคโนโลยีช่วยการเจริญพันธุ์ทางการแพทย์อาจทำarkanขั้นตอนที่อาจเกิดขึ้นได้ตามความจำเป็นและสมควรทั้งนี้ ต้องไม่เป็นการกระทบในลักษณะที่อาจทำให้เข้าใจได้ว่าเป็นการเลือกเพศการตรวจวิจัยเจลตามมาตรฐาน ให้เป็นไปตามหลักเกณฑ์ วิธีการ และเงื่อนไขที่แพทยสภาโดยความเห็นชอบของคณะกรรมการประกาศกำหนด
มาตรการ ๓๓ ภายใต้ฝ่ายพิจารณา ๑๕ และมาตรการ ๑๖
การพนักงานต้องกระทำต่อหัวหน้าที่มีอำนาจที่ชอบตัวยกกฎหมายและเป็นไปตามมาตรฐานการให้บริการ
ที่เกี่ยวกับการพนักงานที่เฉพาะสภาพโดยความเห็นชอบของคณะกรรมการประกาศกำหนด

มาตรการ ๒๐
การพนักงานโดยใช้สิทธิของผู้บริจาคต้องได้รับความยินยอมเป็นหนังสือจากสภามิและอธิบดีที่ชอบตัว
ยกกฎหมายที่ประสงค์ให้มีการพนักงาน
การให้ความยินยอมตามวรรคหนึ่ง ให้เป็นไปตามหลักเกณฑ์ วิธีการ
และเงื่อนไขที่เฉพาะสภาพโดยความเห็นชอบของคณะกรรมการประกาศกำหนด

หมวด ๓

การตั้งคณะกรรมการ

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มาตรการ ๒๑ ภายใต้ฝ่ายพิจารณา ๑๕ และมาตรการ ๑๖
การดำเนินการให้มีการตั้งคณะกรรมการต้องเป็นไปตามเงื่อนไขดังต่อไปนี้

(๑) สำมิตรและบริษัทที่ชอบด้วยกฎหมายซึ่งบริษัทไม่อาจตั้งคณะกรรมการต้องประสงค์จะมีบริษัทโดยให้ผู้ถืออำนาจตั้งค์
กรรบร ต้องมีความพร้อมทั้งทางด้านการจัดระเบียบและจิตใจที่จะเป็นยึดตามมาตรฐานของเด็ก

(๒) ผู้ถืออำนาจตั้งค์กกรรบร
หนทางมีศักยภาพหรือผู้แทนสิ่งของสำมิหรือบริษัทที่ชอบด้วยกฎหมายตาม (๑) และ

(๓) ผู้ถืออำนาจตั้งค์กรรบรต้องเป็นผู้ถือกรรมและมีแบบอำนาจแล้วทำนั้น
ถ้าผู้ถืออำนาจสำมิตรจะต้องได้รับความยินยอมจากสภามิตัว
แพทยสภาโดยความเห็นชอบของคณะกรรมการอาหารประกาศกำหนดเงื่อนไขเพิ่มเติมได้ตามที่เห็นสมควร

มาตรา ๒๒ การดำเนินการให้มีการตั้งครรภ์แทนตามพระราชบัญญัตินี้ให้กระท่าได้สองวิธี ตั้งต่อไปนี้

(๑) ใช้ตัวย่อยที่เกิดจากสูจิและไข่ของสัณวาและบริบารที่ชอบมีกฎหมายที่ประสงค์จะให้มีการตั้งครรภ์แทน

(๒) ใช้ตัวย่อยที่เกิดจากสูจิหรือไข่ของสามีหรือบริบารที่ชอบมีกฎหมายที่ประสงค์จะให้มีการตั้งครรภ์แทนกับสูจิหรือไข่ของผู้อื่น ทั้งนี้ ห้ามใช้ไข่ของหญิงที่รับตั้งครรภ์แทน

มาตรา ๒๓ ห้ามดำเนินการให้มีการตั้งครรภ์แทนเพื่อประโยชน์ทางการค้า

มาตรา ๒๔ ให้แพทยสภาโดยความเห็นชอบของคณะกรรมการประกาศกำหนดหลักเกณฑ์วิธีการ

และเงื่อนไขที่เกี่ยวกับการกำหนดเงื่อนไขนี้ในการบังคับให้สุขภาพของหญิงที่รับตั้งครรภ์แทนในขณะตั้งครรภ์และการคลอดและหลังคลอด

มาตรา ๒๔ ห้ามมีให้ผู้ใดกระทำการเป็นคนกลางหรือนายหน้าโดยเรียกเงินหรือรับทรัพย์สินหรือประโยชน์อื่นใด

เพื่อเป็นการตอบแทนในการจัดการหรือช่วยให้มีการรับตั้งครรภ์แทน

มาตรา ๒๖ ห้ามมีให้ผู้ใดโฆษณาหรือใช้คำให้เพียงใดด้วยการใด ๆ ว่ามีหญิงที่ประสงค์จะเป็นผู้รับตั้งครรภ์แทนผู้อื่น

หรือมีบุคคลที่ประสงค์จะให้หญิงเป็นผู้รับตั้งครรภ์แทน

ไม่ว่าจะได้กระทำเพื่อประโยชน์ทางการค้าหรือไม่ก็ตาม
หมวด ๔

ความเป็นปัจจัยและมารยาทของเด็กที่เกิดโดยอาศัยเทคโนโลยีช่วยการเจริญพันธุ์ทางการแพทย์

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มาตรานี้ เลิกที่เกิดจากสุข ไข้ หรือตัวอย่างของผู้บริจาค
แล้วแต่กรณีโดยใช้เทคโนโลยีช่วยการเจริญพันธุ์ทางการแพทย์ตามพระราชบัญญัตินี้
ไม่ว่าจะกระทบโดยการให้บริการที่ชอบด้วยกฎหมายของสัมพันธ์หรือจะมีบุตรเป็นผู้ต้องครอง
หรือให้ผู้บริจาคต้องรับผิดในเรื่องการชอบด้วยกฎหมายของสัมพันธ์หรือการที่ชอบด้วยกฎหมาย
รายซึ่งประสงค์จะมีบุตรแม้ว่าสัมพันธ์หรือการที่ชอบด้วยกฎหมายซึ่งประสงค์จะมีบุตรถึงแก่ความตายก่อน
แล้วเกิด

ขายหรืออุ้มท้องที่บริจาคสุขหรือไข้ซึ่งนำมาใช้ปฏิสนธิเป็นตัวอย่างเพื่อการต้องครองหรือผู้บริจา
คตัวอย่าง และเด็กที่เกิดจากสุข ไข้ หรือตัวอย่างที่บริจาคดังกล่าว
ไม่มีสิทธิ์และหน้าที่ระวางกันตามประมวลกฎหมายแพ่งและพาณิชย์ว่าด้วยครอบครัวและบรรด

มาตรานี้

ในกรณีที่สามและบริการที่ชอบด้วยกฎหมายที่ประสงค์ให้มีการต้องครองแทนที่จะเก่งความตายก่อนแล้วเลิก
ให้ผู้เกิดที่รับเด็กนั้นเป็นผู้ปกครองเด็กนั้นจนกว่าจะมีการต้องผู้ปกครองชิ้นใหม่ ทั้งนี้
ให้ผู้ที่รับเด็กนั้นแทน หน่วยงานเจ้าหน้าที่ตามกฎหมายว่าด้วยการคุ้มครองเด็ก ผู้มีส่วนได้เสีย
หรือหน่วยงานอื่นที่มีอำนาจของต้องคุ้มครองให้เด็กนั้นเป็นผู้ปกครองได้
และในการต้องผู้ปกครองต้องทำให้ศาลคำนึงถึงความพ่อถูก และประโยชน์ของเด็กนั้นเป็นสำคัญ
มาตรา ๒๔
ให้ผู้แทนผู้มีอำนาจตามมาตรา ๒๓ ปฏิบัติตามระเบียบที่กำหนดไว้ในระเบียบหนังสือนายทะเบียน
ในวาระที่ไม่ขัดหรือแย้งกับระเบียบที่มีผลใช้บังคับในขณะนั้น

หมวด ๕
การควบคุมการดำเนินการเกี่ยวกับเทคโนโลยีช่วยการเจริญพันธุ์ทางการแพทย์

มาตรา ๓๐
ห้ามมีให้ผู้ใดซึ่งมิใช่ผู้ประกอบธุรกิจพัฒนาระบบการเจริญพันธุ์ทางการแพทย์ รวมถึงรับผิดรับผิดชอบใดๆซึ่งมีผลเสียต่อสุขภาพหรือให้ผลสัตว์พันธุ์ทางการแพทย์ให้เป็นตัวอย่าง

มาตรา ๓๑ ห้ามมีให้ผู้ใดสร้างตัวอย่างเพื่อใช้ในกิจการใด ๆ
เว้นแต่เพื่อใช้ในการบันทึกข้อมูลทางการแพทย์หรือเรียนรู้ที่ชอบด้วยกฎหมาย

มาตรา ๓๒
ผู้ประกอบธุรกิจพัฒนาระบบการเจริญพันธุ์ทางการแพทย์ที่ประสงค์จะใช้ตัวอย่างเพื่อผลิตซึ่งผลิตภัณฑ์หรือผลิตภัณฑ์มีผลเสียต่อสุขภาพหรือสร้างตัวอย่างเพื่อการศึกษาวิจัยต้องได้รับอนุญาตจากคณะกรรมการ
หลักเกณฑ์ วิธีการ
และเงื่อนไขในการขออนุญาตและการอนุญาตให้เป็นไปตามที่คณะกรรมการประกาศกำหนดในราชกิจจานุเบกษา

การศึกษาวิจัยตัวอย่างที่มีอาจเกิดขึ้นในสัตว์สัตว์เลี้ยงใหม่ที่ทำมาได้ ทั้งนี้สัตว์เลี้ยงตัวอย่าง
อาจมีผลต่อสัตว์เลี้ยงในกรณีเช่นทั่วไปตัวอย่าง
มาตรานี้จะทำให้ผู้โดยสารสามารถตั้งค่าได้เพื่อที่จะให้เกิดขึ้นได้โดยผู้โดยสารสามารถสื่อสารกับผู้โดยสารร่วมกันได้ในระหว่างการใช้งาน

มาตรานี้จะทำให้ผู้โดยสารได้รับดี ใช้ได้ดี

หรือสามารถสื่อสารได้ดีโดยผู้โดยสารสื่อสารกับผู้โดยสารได้โดยผู้โดยสารสื่อสารกับผู้โดยสารได้ในระหว่างการใช้งาน

มาตรานี้จะทำให้ผู้โดยสารได้รับดี ใช้ได้ดี

มาตรานี้จะทำให้ผู้โดยสารได้รับดี ใช้ได้ดี

มาตรานี้จะทำให้ผู้โดยสารได้รับดี ใช้ได้ดี

มาตรานี้จะทำให้ผู้โดยสารได้รับดี ใช้ได้ดี
การให้ความยินยอมตามวรรคหนึ่ง ให้เป็นไปตามหลักเกณฑ์ วิธีการและเงื่อนไขที่แพทย์สภารายความเห็นชอบของคณะกรรมการประกาศกำหนด

มาตรา ๓๙
ผู้ประกอบวิชาชีพเวชกรรมผู้ใดให้บริการเกี่ยวกับเทคโนโลยีช่วยการเจริญพันธุ์ทางการแพทย์ผู้ใดไม่ปฏิบัติตามมาตรฐานในการให้บริการเกี่ยวกับเทคโนโลยีช่วยการเจริญพันธุ์ทางการแพทย์ตามมาตรา ๓๔
ให้ถือว่ากระทำผิดจรรยาวิธีเวชกรรมตามกฎหมายว่าด้วยการประกอบวิชาชีพเวชกรรม

มาตรา ๔๐ ผู้ประกอบวิชาชีพเวชกรรมผู้ใดไม่ปฏิบัติตามมาตรา ๓๖ มาตรา ๓๗ มาตรา ๓๘ มาตรา ๓๙ มาตรา ๔๐ มาตรา ๔๒ มาตรา ๔๓ หรือมาตรา ๔๗
ให้ถือว่ากระทำผิดจรรยาวิธีเวชกรรมตามกฎหมายว่าด้วยการประกอบวิชาชีพเวชกรรม

หมวด ๖
บทกำหนดโทษ

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มาตรา ๔๑
ผู้ประกอบวิชาชีพเวชกรรมผู้ใดให้บริการเกี่ยวกับเทคโนโลยีช่วยการเจริญพันธุ์ทางการแพทย์โดยไม่มีคุณสมบัติตามที่แพทย์สภารายความเห็นชอบของคณะกรรมการประกาศกำหนดตามมาตรา ๓๔ ต้องระวางโทษจำคุกไม่เกินหนึ่งปี หรือปรับไม่เกินสองแสนบาท หรือทั้งจำทั้งปรับ
มาตรการ ๔๒ ผู้ใดฝ่าฝืนมาตรา ๒๓ ต้องเว้นโทษจำคุกไม่เกินสิบปี
และปรับไม่เกินสองแสนบาท

มาตรการ ๔๓ ผู้ใดฝ่าฝืนมาตรา ๒๕ มาตรา ๒๖ หรือมาตรา ๓๕
ต้องเว้นโทษจำคุกไม่เกินห้าปี หรือปรับไม่เกินหนึ่งแสนบาท หรือทั้งจำทั้งปรับ

มาตรการ ๔๔ ผู้ใดฝ่าฝืนมาตรา ๒๗ มาตรา ๓๓ หรือมาตรา ๓๘
ต้องเว้นโทษจำคุกไม่เกินสิบปี หรือปรับไม่เกินสองแสนบาท หรือทั้งจำทั้งปรับ

มาตรการ ๔๕ ผู้ใดฝ่าฝืนมาตรา ๒๙ มาตรา ๓๖ หรือมาตรา ๓๙
ต้องเว้นโทษจำคุกไม่เกินสามปี หรือปรับไม่เกินหนึ่งแสนบาท หรือทั้งจำทั้งปรับ

มาตรการ ๔๖ ผู้ใดฝ่าฝืนมาตรา ๓๑ มาตรา ๓๒ หรือมาตรา ๔๐
ต้องเว้นโทษจำคุกไม่เกินสามปี หรือปรับไม่เกินหนึ่งแสนบาท หรือทั้งจำทั้งปรับ

บทเฉพาะกาล

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มาตรการ ๔๗
ผู้ประกอบบริษัทจับหนี้ชนเป็นผู้รับมิได้ชอบหรือให้บริการเกี่ยวกับเทคโนโลยีช่วยการจับหนี้เพลิง
เร่งการispershipตามประกาศกรมأشخاصด่วนมาตรฐานการให้บริการเทคโนโลยีช่วยการจับหนี้เพลิงอยู่
ก่อนวันที่พระราชบัญญัติงี้ใช้บังคับ เมื่อใดแจง

ราชวิทยาลัยสุสานีฟองประเทศไทยในกําหนดวันเบ็ดวันที่พระราชบัญญัติงี้ใช้บังคับให้
คํานวณการต่อไปได้
จนกว่าจะมีประกาศแพทยสภาโดยความเห็นชอบของคณะกรรมการเกี่ยวกับคุณสมบัติและมาตรฐานในการให้บริการเกี่ยวกับเทคโนโลยีช่วยการเจริญพันธุ์ทางการแพทย์ตามมาตรา ๑๔ ใช้บังคับ

มาตรา ๔๔ ข้อบังคับ ระเบียบ

หรือประกาศของแพทยสภาเกี่ยวกับการให้บริการเทคโนโลยีช่วยการเจริญพันธุ์ทางการแพทย์
ซึ่งใช้บังคับอยู่ในวันที่พระราชบัญญัตินี้ใช้บังคับ

ให้คงใช้บังคับได้ต่อไปเท่าที่ไม่ขัดหรือแย้งกับพระราชบัญญัตินี้ ถึงนั้น

จนกว่าจะมีประกาศที่ออกตามพระราชบัญญัตินี้

มาตรา ๔๗ ให้ผู้ที่ได้รับการตั้งครรภ์แทนก่อนวันที่พระราชบัญญัตินี้ใช้บังคับหรือกรรมาธิการที่ดำเนินการให้มี
การตั้งครรภ์แทน หรือพนักงานอัยการ

มีสิทธิยื่นคำร้องต่อศาลให้มีคำสั่งให้ผู้ที่ได้รับการตั้งครรภ์แทนก่อนวันที่พระราชบัญญัตินี้ใช้บังคับ
เป็นบุตรชอบด้วยกฎหมายของสามีและกรรมาธิการที่ดำเนินการให้มีการตั้งครรภ์แทนเป็นคำตัดสินที่สุดในเกิด
ทั้งนี้

ไม่ว่าสามีและกรรมาธิการที่ดำเนินการให้มีการตั้งครรภ์แทนจะเป็นสามีและกรรมาธิการชอบด้วยกฎหมายหรือไม่
แต่ทั้งนี้จะธงเป็นเหตุเสียชีวิตของบุคคลภายนอกผู้ทำการโดยสุจริตในระหว่างเวลาตั้งแต่เดิมเกิด
นั้นถึงเวลาที่ศาลมีคำสั่งว่าเป็นบุตรไม่ได้

ผู้รับสนองพระบรมราชโองการ

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นายกรัฐมนตรี
APPENDIX TWO: The Most Relevant Australian Provisions

Research Involving Human Embryos Act 2002 (as amended)

Part 1—Preliminary

7 Definitions

(1) In this Act:

*human embryo* means a discrete entity that has arisen from either:

(a) the first mitotic division when fertilisation of a human oocyte by
    a human sperm is complete; or

(b) any other process that initiates organised development of a
    biological entity with a human nuclear genome or altered human
    nuclear genome that has the potential to develop up to, or
    beyond, the stage at which the primitive streak appears;
    and has not yet reached 8 weeks of development since the first mitotic
    division.

*hybrid embryo* means:

(a) an embryo created by the fertilisation of a human egg by animal
    sperm; or

(b) an embryo created by the fertilisation of an animal egg by human
    sperm; or
(c) a human egg into which the nucleus of an animal cell has been introduced; or

(d) an animal egg into which the nucleus of a human cell has been introduced; or

(e) a thing declared by the regulations to be a hybrid embryo.

unsuitable for implantation, in relation to a human embryo, means a human embryo that:

(a) is diagnosed by preimplantation genetic diagnosis as unsuitable for implantation, in accordance with the Ethical Guidelines on the Use of Assisted Reproductive Technology in Clinical Practice and Research (2004), issued by the CEO of the NHMRC; or

(b) is determined to be unsuitable for implantation in the body of a woman, in accordance with objective criteria specified in guidelines issued by the CEO of the NHMRC under the National Health and Medical Research Council Act 1992 and prescribed by the regulations for the purposes of this paragraph.

(2) For the purposes of the definition of human embryo in subsection (1), in working out the length of the period of development of a human embryo, any period when the development of the embryo is suspended is to be disregarded.

(3) A reference in this Act to an embryo (including a human embryo) is a reference to a living embryo.
(4) A reference in this Act to a human egg is a reference to a human oocyte.

(5) A reference in this Act to a human embryo does not include a reference to:

(a) a hybrid embryo; or

(b) a human embryonic stem cell line.

Part 2—Regulation of the use of excess ART embryos, other embryos and human eggs

Division 1—Interpretation

8 Definitions [see Note 2]

In this Part:

*accredited ART centre* means a person or body accredited to carry out assisted reproductive technology by:

(a) the Reproductive Technology Accreditation Committee of the Fertility Society of Australia; or

(b) if the regulations prescribe another body or other bodies in addition to, or instead of, the body mentioned in paragraph (a)—that other body or any of those other bodies, as the case requires.

*proper consent*, in relation to the use of an excess ART embryo or a human egg, or the creation or use of any other embryo, means consent
obtained in accordance with guidelines issued by the CEO of the NHMRC under the National Health and Medical Research Council Act 1992 and prescribed by the regulations for the purposes of this definition.

**responsible person** means: [see Note 2]

(a) in relation to an excess ART embryo:

(i) each person who provided the egg or sperm from which the embryo was created; and

(ii) the woman for whom the embryo was created, for the purpose of achieving her pregnancy; and

(iii) any person who was the spouse of a person mentioned in subparagraph (i) at the time the egg or sperm mentioned in that subparagraph was provided; and

(iv) any person who was the spouse of the woman mentioned in subparagraph (ii) at the time the embryo was created; or

(b) in relation to an embryo other than an excess ART embryo—
each person whose reproductive material, genetic material or cell was used, or is proposed to be used, in the creation or use of the embryo; or

(c) in relation to a human egg—the woman who was the biological donor of the egg.
9 Meaning of excess ART embryo

(1) In this Part:

**excess ART embryo** means a human embryo that:

(a) was created, by assisted reproductive technology, for use in the assisted reproductive technology treatment of a woman; and

(b) is excess to the needs of:

(i) the woman for whom it was created; and

(ii) her spouse (if any) at the time the embryo was created.

(2) For the purposes of paragraph (b) of the definition of **excess ART embryo**, a human embryo is excess to the needs of the persons mentioned in that paragraph at a particular time if:

(a) each such person has given written authority for use of the embryo for a purpose other than a purpose relating to the assisted reproductive technology treatment of the woman concerned, and the authority is in force at that time; or

(b) each such person has determined in writing that the embryo is excess to their needs, and the determination is in force at that time.

Division 2—Offences

10 Offence—use of excess ART embryo

(1) A person commits an offence if the person intentionally uses an excess ART embryo, unless:
(a) the use by the person is authorised by a licence; or

(b) the use by the person is an exempt use within the meaning of subsection (2).

Maximum penalty: Imprisonment for 5 years.

(2) A use of an excess ART embryo by a person is an exempt use for the purposes of subsection (1) if:

(a) the use consists only of:

(i) storage of the excess ART embryo; or

(ii) removal of the excess ART embryo from storage; or

(iii) transport of the excess ART embryo; or

(b) the use consists only of observation of the excess ART embryo; or

(c) the use consists only of allowing the excess ART embryo to succumb; or

(d) the use is carried out by an accredited ART centre, and:

(i) the excess ART embryo is not suitable to be placed in the body of the woman for whom it was created where the suitability of the embryo is determined only on the basis of its biological fitness for implantation; and

(ii) the use forms part of diagnostic investigations conducted in connection with the assisted reproductive technology treatment of the woman for whom the excess ART embryo was created; or
(e) the use is carried out by an accredited ART centre and is for the purposes of achieving pregnancy in a woman other than the woman for whom the excess ART embryo was created; or

(f) the use is of a kind prescribed by the regulations for the purposes of this paragraph.

(3) Despite subsection 13.3(3) of the *Criminal Code*, a defendant does not bear an evidential burden in relation to any matter in subsection (1) or (2) of this section.

(4) In subsection (2):

*diagnostic investigation*, in relation to an excess ART embryo, means any procedure undertaken on embryos for the sole purpose of diagnostic investigations for the direct benefit of the woman for whom it was created.

*observation*, in relation to an excess ART embryo, includes taking a photograph of the embryo, or taking a recording of the embryo from which a visual image can be produced.

### 10A Offence—use of other embryos

A person commits an offence if:

(a) the person intentionally uses an embryo; and

(b) the embryo is:

   (i) a human embryo created by a process other than the fertilisation of a human egg by a human sperm; or
(ii) a human embryo created by a process other than the fertilisation of a human egg by a human sperm that contains genetic material provided by more than 2 persons; or

(iii) a human embryo created using precursor cells taken from a human embryo or a human fetus; or

(iv) a hybrid embryo; and

(c) the use by the person is not authorised by a licence.

Maximum penalty: Imprisonment for 5 years.

Note: The creation or development of embryos mentioned in this section is prohibited under Part 2 of the Prohibition of Human Cloning for Reproduction Act 2002, unless authorised by a licence under this Act.

10B Offence—certain activities involving use of human eggs

A person commits an offence if:

(a) the person undertakes research or training involving the fertilisation of a human egg by a human sperm up to, but not including, the first mitotic division, outside the body of a woman for the purposes of research or training in ART; and

(b) the person is not authorised by a licence to undertake the research or training.

Maximum penalty: Imprisonment for 5 years.
11 Offence—use of embryo that is not an excess ART embryo

A person commits an offence if:

(a) the person intentionally uses, outside the body of a woman, a human embryo:

(i) that was created by fertilisation of a human egg by a human sperm; and

(ii) that is not an excess ART embryo; and

(b) the use is not for a purpose relating to the assisted reproductive technology treatment of a woman carried out by an accredited ART centre, and the person knows or is reckless as to that fact.

Maximum penalty: Imprisonment for 5 years.

12 Offence—breaching a licence condition

(1) A person commits an offence if the person intentionally engages in conduct, knowing that the conduct contravenes a condition of a licence that applies to the person, or reckless as to whether the conduct contravenes a condition of such a licence.

Maximum penalty: Imprisonment for 5 years.

(2) In this section:

engage in conduct means:

(a) do an act; or

(b) omit to perform an act.
12A Person not liable for conduct purportedly authorised

(1) To avoid doubt, a person is not criminally responsible for an offence against this Act in respect of particular conduct if:

(a) the conduct by the person is purportedly authorised by a provision of a licence; and

(b) the licence or the provision is invalid, whether because of a technical defect or irregularity or for any other reason; and

(c) the person did not know, and could not reasonably be expected to have known, of the invalidity of the licence or the provision.

(2) In this section:

*licence* includes a purported licence.

Division 4—Licensing system

20 Person may apply for licence

(1) A person may apply to the NHMRC Licensing Committee for a licence authorising one or more of the following:

(a) use of excess ART embryos;

(b) creation of human embryos other than by fertilisation of a human egg by a human sperm, and use of such embryos;

(c) creation of human embryos other than by fertilisation of a human egg by a human sperm that contain genetic material provided by more than 2 persons, and use of such embryos;
(d) creation of human embryos using precursor cells from a human embryo or a human fetus, and use of such embryos;

(e) research and training involving the fertilisation of a human egg by a human sperm up to, but not including, the first mitotic division, outside the body of a woman for the purposes of research or training in ART;

(f) creation of hybrid embryos by the fertilisation of an animal egg by a human sperm, and use of such embryos up to, but not including, the first mitotic division, if:

(i) the creation or use is for the purposes of testing sperm quality; and

(ii) the creation or use will occur in an accredited ART centre.

(1A) To avoid doubt, paragraphs (1)(a), (b), (c) and (d) do not permit the NHMRC Licensing Committee to authorise any use of an excess ART embryo or other embryo that would result in the development of the embryo for a period of more than 14 days, excluding any period when development is suspended.

(2) An application under subsection (1):

(a) must be made in accordance with the requirements (if any) specified in writing by the NHMRC Licensing Committee; and

(b) must be accompanied by the fee (if any) prescribed by the regulations.
21 Determination of application by Committee [see Note 1]

(1) This section applies if a person has made an application under section 20 for a licence.

(2) The NHMRC Licensing Committee must decide, in accordance with this section, whether or not to issue the licence.

(3) The NHMRC Licensing Committee must not issue the licence unless it is satisfied of the following:

(a) that appropriate protocols are in place:

   (i) to enable proper consent to be obtained before an excess ART embryo or human egg is used, or other embryo is created or used under the licence (see paragraph 24(1)(a)); and

   (ii) to enable compliance with any restrictions on such consent;

(c) that the activity or project proposed in the application has been assessed and approved by a HREC that is constituted in accordance with, and acting in compliance with, the NHMRC National Statement on Ethical Conduct in Research Involving Humans (1999), as in force from time to time.

(4) In deciding whether to issue the licence, the NHMRC Licensing Committee must have regard to the following:

(a) restricting the number of excess ART embryos, other embryos or human eggs, to that likely to be necessary to achieve the goals of the activity or project proposed in the application;
(b) the likelihood of significant advance in knowledge or improvement in technologies for treatment as a result of the use of excess ART embryos or human eggs, or the creation or use of other embryos, proposed in the application, which could not reasonably be achieved by other means;

(c) any relevant guidelines, or relevant parts of guidelines, issued by the CEO of the NHMRC under the *National Health and Medical Research Council Act 1992* and prescribed by the regulations for the purposes of this paragraph;

(d) the HREC assessment of the application mentioned in paragraph (3)(c);

(e) such additional matters (if any) as are prescribed by the regulations.
1 Meaning of “embryo” and “gamete”

(1) In this Act (except in section 4A or in the term “human admixed embryo”)—

(a) embryo means a live human embryo and does not include a human admixed embryo (as defined by section 4A(6)), and
(b) references to an embryo include an egg that is in the process of fertilisation or is undergoing any other process capable of resulting in an embryo.

(2) This Act, so far as it governs bringing about the creation of an embryo, applies only to bringing about the creation of an embryo outside the human body; and in this Act—

(a) references to embryos the creation of which was brought about in vitro (in their application to those where fertilisation or any other process by which an embryo is created is complete) are to those where fertilisation or any other process by which the embryo was created began outside the human body whether or not it was completed there, and
(b) references to embryos taken from a woman do not include embryos whose creation was brought about in vitro.
(3) This Act, so far as it governs the keeping or use of an embryo, applies only to keeping or using an embryo outside the human body.

(4) In this Act (except in section 4A)—

(a) references to eggs are to live human eggs, including cells of the female germ line at any stage of maturity, but (except in subsection (1)(b)) not including eggs that are in the process of fertilisation or are undergoing any other process capable of resulting in an embryo,

(b) references to sperm are to live human sperm, including cells of the male germ line at any stage of maturity, and

(c) references to gametes are to be read accordingly.

(5) For the purpose of this Act, sperm is to be treated as partner-donated sperm if the donor of the sperm and the recipient of the sperm declare that they have an intimate physical relationship.

(6) If it appears to the Secretary of State necessary or desirable to do so in the light of developments in science or medicine, regulations may provide that in this Act (except in section 4A) “embryo”, “eggs”, “sperm” or “gametes” includes things specified in the regulations which would not otherwise fall within the definition.

(7) Regulations made by virtue of subsection (6) may not provide for anything containing any nuclear or mitochondrial DNA that is not human to be treated as an embryo or as eggs, sperm or gametes.
3 Prohibitions in connection with embryos

(1) No person shall bring about the creation of an embryo except in pursuance of a licence.

(1A) No person shall keep or use an embryo except—

(a) in pursuance of a licence, or

(b) in the case of—

(i) the keeping, without storage, of an embryo intended for human application, or

(ii) the processing, without storage, of such an embryo, in pursuance of a third party agreement.

(1B) No person shall procure or distribute an embryo intended for human application except in pursuance of a licence or a third party agreement.

(2) No person shall place in a woman—

(a) an embryo other than a permitted embryo (as defined by section 3ZA), or

(b) any gametes other than permitted eggs or permitted sperm (as so defined).

(3) A licence cannot authorise--

(a) keeping or using an embryo after the appearance of the primitive streak,

(b) placing an embryo in any animal, or
(c) keeping or using an embryo in any circumstances in which regulations prohibit its keeping or use.

(4) For the purposes of subsection (3)(a) above, the primitive streak is to be taken to have appeared in an embryo not later than the end of the period of 14 days beginning with the day which the process of creating the embryo began, not counting any time during which the embryo is stored.

3ZA Permitted eggs, permitted sperm and permitted embryos

(1) This section has effect for the interpretation of section 3(2).

(2) A permitted egg is one—

(a) which has been produced by or extracted from the ovaries of a woman, and

(b) whose nuclear or mitochondrial DNA has not been altered.

(3) Permitted sperm are sperm—

(a) which have been produced by or extracted from the testes of a man, and

(b) whose nuclear or mitochondrial DNA has not been altered.

(4) An embryo is a permitted embryo if—

(a) it has been created by the fertilisation of a permitted egg by permitted sperm.
(b) no nuclear or mitochondrial DNA of any cell of the embryo has been altered, and  
(c) no cell has been added to it other than by division of the embryo’s own cells.

(5) Regulations may provide that—  

(a) an egg can be a permitted egg, or  
(b) an embryo can be a permitted embryo, even though the egg or embryo has had applied to it in prescribed circumstances a prescribed process designed to prevent the transmission of serious mitochondrial disease.

(6) In this section—  

(a) “woman” and “man” include respectively a girl and a boy (from birth), and  
(b) “prescribed” means prescribed by regulations.

4 Prohibitions in connection with genetic material not of human origin

(1) No person shall—  

(a) store any gametes, or  

(i) any sperm, other than partner-donated sperm which has been neither processed nor stored,  

(ii) the woman’s eggs after processing or storage, or  

(iii) the eggs of any other woman.
(1A) No person shall procure, test, process or distribute any gametes intended for human application except in pursuance of a licence or a third party agreement.

(2) A licence cannot authorise storing or suing gametes in any circumstances in which regulations prohibit their storage or use.

(3) No person shall place sperm and eggs in a woman in any circumstances specified in regulations except in pursuance of a licence.

(4) Regulations made by virtue of subsection (3) above may provide that, in relation to licences only to place sperm and eggs in a woman in such circumstances, sections 12 to 22 of this Act shall have effect with such modifications as may be specified in the regulations.

(5) Activities regulated by this section or section 3 or 4A of this Act are referred to in this Act as “activities governed by this Act”.

4A Prohibitions in connection with genetic material not of human origin

(1) No person shall place in a woman—

(a) a human admixed embryo,

(b) any other embryo that is not a human embryo, or

(c) any gametes other than human gametes.

(2) No person shall—

(a) mix human gametes with animal gametes,

(b) bring about the creation of a human admixed embryo, or
(c) keep or use a human admixed embryo, except in pursuance of a licence.

(3) A licence cannot authorise keeping or using a human admixed embryo after the earliest of the following—

   (a) the appearance of the primitive streak, or
   (b) the end of the period of 14 days beginning with the day on which the process of creating the human admixed embryo began, but not counting any time during which the human admixed embryo is stored.

(4) A licence cannot authorise placing a human admixed embryo in an animal.

(5) A licence cannot authorise keeping or using a human admixed embryo in any circumstances in which regulations prohibit its keeping or use.

(6) For the purposes of this Act a human admixed embryo is—

   (a) an embryo created by replacing the nucleus of an animal egg or of an animal cell, or two animal pronuclei, with—

      (i) two human pronuclei,
      (ii) one nucleus of a human gamete or of any other human cell, or
      (iii) one human gamete or other human cell,

   (b) any other embryo created by using—

      (i) human gametes and animal gametes, or
      (ii) one human pronucleus and one animal pronucleus,
(c) a human embryo that has been altered by the introduction of any sequence of nuclear or mitochondrial DNA of an animal into one or more cells of the embryo,

(d) a human embryo that has been altered by the introduction of one or more animal cells, or

(e) any embryo not falling within paragraphs (a) to (d) which contains both nuclear or mitochondrial DNA of a human and nuclear or mitochondrial DNA of an animal (“animal DNA”) but in which the animal DNA is not predominant.

(7) In subsection (6)—

(a) references to animal cells are to cells of an animal or of an animal embryo, and

(b) references to human cells are to cells of a human or of a human embryo.

(8) For the purposes of this section an “animal” is an animal other than man.

(9) In this section “embryo” means a live embryo, including an egg that is in the process of fertilisation or is undergoing any other process capable of resulting in an embryo.

(10) In this section—

(a) references to eggs are to live eggs, including cells of the female germ line at any stage of maturity, but (except in subsection (9)) not including eggs that are in the process of fertilisation or are
undergoing any other process capable of resulting in an embryo, and

(b) references to gametes are to eggs (as so defined) or to live sperm, including cells of the male germ line at any stage of maturity.

(11) If it appears to the Secretary of State necessary or desirable to do so in the light of developments in science or medicine, regulations may—

(a) amend (but not repeal) paragraphs (a) to (e) of subsection (6);

(b) provide that in this section “embryo”, “eggs” or “gametes” includes things specified in the regulations which would not otherwise fall within the definition.

(12) Regulations made by virtue of subsection (11)(a) may make any amendment of subsection (7) that appears to the Secretary of State to be appropriate in consequence of any amendment of subsection (6).

SCHEDULE 2

Licences for research

3 (1) A licence under this paragraph may authorise any of the following—

(a) bringing about the creation of embryos in vitro, and

(b) keeping or using embryos, for the purposes of a project of research specified in the licence.
(2) A licence under this paragraph may authorise mixing sperm with the egg of a hamster, or other animal specified in directions, for the purpose of developing more effective techniques for determining the fertility or normality of sperm, but only where anything which forms is destroyed when the research is complete and, in any event, no later than the two cell stage.

(3) A licence under this paragraph may authorise any of the following—

(a) bringing about the creation of human admixed embryos in vitro,

and

(b) keeping or using human admixed embryos, for the purposes of a project of research specified in the licence.

(4) A licence under sub-paragraph (3) may not authorise the activity which may be authorised by a licence under sub-paragraph (2).

(5) No licence under this paragraph is to be granted unless the Authority is satisfied that any proposed use of embryos or human admixed embryos is necessary for the purposes of the research.

(6) Subject to the provisions of this Act, a licence under this paragraph may be granted subject to such conditions as may be specified in the licence.

(7) A licence under this paragraph may authorise the performance of any of the activities referred to in sub-paragraph (1), (2) or (3) in such manner as may be so specified.

(8) A licence under this paragraph may be granted for such period not exceeding three years as may be specified in the licence.
(9) This paragraph has effect subject to paragraph 3A.

**Purposes for which activities may be licensed under paragraph 3**

3A (1) A licence under paragraph 3 cannot authorise any activity unless the activity appears to the Authority—

(a) to be necessary or desirable for any of the purposes specified in sub-paragraph (2) (“the principal purposes”),

(b) to be necessary or desirable for the purpose of providing knowledge that, in the view of the Authority, may be capable of being applied for the purposes specified in subparagraph (2)(a) or (b), or

(c) to be necessary or desirable for such other purposes as may be specified in regulations.

(2) The principal purposes are—

(a) increasing knowledge about serious disease or other serious medical conditions,

(b) developing treatments for serious disease or other serious medical conditions,

(c) increasing knowledge about the causes of any congenital disease or congenital medical condition that does not fall within paragraph (a),

(d) promoting advances in the treatment of infertility,

(e) increasing knowledge about the causes of miscarriage,
(f) developing more effective techniques of contraception,
(g) developing methods for detecting the presence of gene, chromosome or mitochondrion abnormalities in embryos before implantation, or
(h) increasing knowledge about the development of embryos.
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