(2012) 16 JUUM 55 - 68

# The Regulatory Regime for Human Embryonic Stem Cell (HESC) Research in Malaysia: A Critique

## (Regim Pengawalseliaan Penyelidikan Sel Stem Embrionik Manusia di Malaysia: Satu Kritikan)

PATRICK FOONG CHEE KUEN

ABSTRACT

*Stem cell research is a scientific breakthrough which has the potential to revolutionise the practice of medicine which will in future improve the quality and length of life of patients. Scientists hypothesise that stem cell therapy will become the basis for treating a number of devastating diseases such as Parkinson's disease, diabetes and heart disease. Given the promise of stem cell therapies, scientists throughout the world are conducting the research using different types of stem cells including human embryonic stem cells (HESC), and adult stem cells. HESC research is controversial as all extractions of stem cells involve the destruction of the human embryo. In view of its contentious nature, the research should be strictly regulated. In this article,there is a critique of the current regulation of HESC research in Malaysia and it considers whether the Malaysian government should adopt an effective regulatory framework to govern the research.*

*Keywords: human embryonic stem cell research, Malaysia, regulatory regime, guidelines, legislation*

ABSTRAK

*Penyelidikan sel stem merupakan satu penerobosan saintifik yang berpotensi untuk merevolusikan amalan perubatan yang berupaya untuk menambahbaik kualiti dan jangka hayat pesakit di masa depan. Para saintis menjangkakan bahawa terapi sel stem akan menjadi landasan bagi rawatan pelbagai penyakit yang serius seperti penyakit Parkinson, kencing manis dan penyakit jantung. Bersandarkan kepada keupayaan terapi sel stem, para saintis seluruh dunia sedang mengendalikan penyelidikan menggunakan pelbagai jenis sel stem termasuklah sel stem embrionik manusia (HESC) dan sel stem matang. Penyelidikan HESC merupakan penyelidikan yang controversial memandangkan kesemua ekstraksi sel-sel melibatkan pemusnahan embrio manusia. Oleh kerana sifatnya yang penuh kontroversi, penyelidikan mengenainya haruslah dikawal. Artikelini mengandungi kritikan terhadap peraturan terkini penyelidikan HESC di Malaysia. Artikel ini juga mempertimbangkan sama ada kerajaan Malaysia harus mengadoptasi satu kerangka pengawalseliaan yang efektif untuk mengawal penyelidikan jenis ini.*

*Kata kunci: penyelidikan sel stem embrionik manusia, Malaysia, regim pengawalseliaan, garis panduan, perundangan*

## INTRODUCTION

Stem cell research includes research involving adult stem cells and HESC.[1]Adult stem cells are found in various tissues in fully developed humans, from babies to adults such as organs that need a constant supply of cells which include blood and lining of the gut. These stem cells have also been found in other organs including skin,[2] bone marrow,[3] nose,[4] testicles[5] and in surprising places like the brain,[6] which is not known to readily replenish its cells. In addition, the cells can be derived from foetal tissues such as umbilical cord blood,[7] amniotic fluid[8] and placenta.[9] Adult stem cell research is not as controversial as HESC research as these cells are derived from fully developed humans. HESC are stem cells derived from two sources of human embryos: (a) excess in vitro fertilisation (IVF)/ assisted reproductive technology (ART) embryos;[10] and (b) cloned embryos created through a process called somatic cell nuclear transfer (SCNT)/ therapeutic cloning which shares the same technology as the creation of Dolly, the first cloned mammal. It is stressed that these embryos are destroyed for the extraction of stem cells while they are at early stage in development.

HESC research is regarded as the epitomy of stem cell research.[11] First, HESC are relatively easy to identify, isolate, maintain and grow in the laboratory. In comparison, adult stem cells are difficult to isolate as they are inconspicuous, hidden deep in tissues, present only in low numbers and they are not found in all tissues.[12] Second, HESC are more flexible than adult stem cells; they are pluripotent, that is, they have the

potential to produce every cell type in the human body to form skin, bones, organs and other body parts that people with injuries or disease in need of transplants might benefit from receiving. Whilst doctors can transplant tissues and organ cells, they are often limited by lack of organ donors. In comparison, adult stem cells are multipotent, that is, they produce limited number of cell types. Thus, the scientific importance of using HESC as research tools is that they have unique properties as they are unspecialised, capable of dividing and renewing themselves for lengthy periods. Potentially, HESC will allow the growth of required tissue when it is needed.

However, there are serious ethical and moral concerns raised by HESC research. The paramount concern is that extraction of the stem cells from a human embryo involves its destruction. There is no easy way to address this concern because the moral status of the human embryo is highly contested. Opponents of the research argue that an embryo has the equivalent legal and moral status of a baby or even an adult. But proponents argue that an early embryo, destroyed on the fifth day after fertilisation for the purpose of the extraction of stem cells, is a hollow microscopic ball of 100-200 cells, not yet differentiated into specific tissues, let alone organs, with no sentience and has none of the attributes thought of as human and it develops 'primitive streak'[13] only on the 14th day after conception.[14]

HESC research raises issues of deep religious significance and it is especially controversial in a nation like Malaysia which is multi-racial, multi-cultural and multi-religious. Islam is the official religion in Malaysia[15] with the majority of the population being Muslims. There are also significant numbers of Christians, Buddhists, Hindus and Sikhs in the country.[16] Internationally, theologians and representatives for the various religious groups argue both in favour of and against HESC research. There is a lack of consensus about the moral status of the human embryo as well as the ethics and morality of research using embryos. The cultural and religious diversity of a society makes the task of reaching a consensus challenging.

It is noted that most debates on HESC research are conducted in western developed countries like United Kingdom (UK), United States of America (USA) and Australia. The majority of the texts on the subject are written in western countries with western perspectives. The policies, guidelines and law in these countries are also highly developed. However, elsewhere, especially in emerging economies including Malaysia, there is limited literature written on this area, thus acknowledging the gap in the literature.

This article examines the present regulation of HESC research in Malaysia[17](which is in the form of national guidelines) and the Malaysian government could consider adopting an effective regulatory framework, which includes legislation, to govern the research based on the regulatory theories of leading academics of Professor Roger Brownsword[18] and Professor John Braithwaite.[19]

## STEM CELL RESEARCH IN MALAYSIA

In Malaysia, the government has identified biotechnology, which includes stem cell research, as one of the core technologies to accelerate the transformation of Malaysia into an industrialised nation and knowledge-based economy.[20] The *National Biotechnology Policy* (NBP), launched in 2005, provides a development framework for the industry. The policy is underpinned by nine Thrusts with Thrust 7 stating the need to:

> Create an enabling environment through continuous reviews of Malaysia's regulatory framework and procedures in line with global standards and best practices..

In 2002, a 'Seminar on Reproductive Cloning of Human Beings' was held where stakeholders representing a cross section of the Malaysian society made presentations.[21] The presenters included doctors, scientists, government officials, academics, lawyers, ethicists and representatives of the some of the main religions of the country.[22] Subsequent to the seminar, a directive was issued by the Malaysian cabinet to the Ministry of Health (MOH) to form a committee on human cloning at the national level, the National Committee on Human Cloning, to advise the Malaysian government on cloning and cloning related issues. This committee, which comprises specialists from various hospitals, is headed by the Director-General of Health.[23]

Most of stem cell research being conducted in Malaysia involves haemopoietic stem cells including bone marrow, cord blood and peripheral blood[24] and Malaysian scientists have recently begun pursuing HESC research.[25] The Institute Medical Research (IMR)[26] is initiating a study known as 'Derivation of Human Embryonic Stem Cell Lines', sponsored by the MOH, which is aimed to derive HESC lines from excess in vitro fertilisation (IVF) embryos to establish the first Malaysian stem cell line.[27] For the propagation and expansion of HESC lines, IMR collaborates with the faculty of medicine of University of Sheffield in the UK and Lembaga Penduduk dan Pembangunan Keluarga Negara (LPPKN).[28] As for the derivation of HESC lines, IMR collaborates with Hospital Tengku Ampuan Rahimah (HTAR) and a private company, Stempeutics Research.[29]

## THE CURRENT REGULATION OF STEM CELL RESEARCH

The Malaysian government has adopted the National Guidelines scheme, also known as soft law, to regulate stem cell research. Guidelines, which are made by government agencies, are advantageous in the regulation of new technologies as they are flexible and can be revised as needed. The amendments can be made slowly, focusing directly on issues that arise as new discoveries are made.

In 2006, the *Guidelines on Stem Cell Research* (*Guidelines 2006*)were issued by the MOH[30] and they were revised in 2009. The *Guidelines 2006* stated that the MOH acknowledged the importance of stem cell research and its controversies[31] and it will undertake to encourage and promote stem cell research in the country.[32] It also stated that the MOH recognised that it is crucial for Malaysian scientists and clinicians to be involved in stem cell research within ethical guidelines.[33]

The provisions in *Guidelines 2006* reflected the Islamic *Fatwa*[34] which has officially adopted a position, leaving other religions to deliberate on these issues.[35] The *Guidelines 2006* provided that all stem cell research, whether involving human or animals, must be reviewed by Institutional Review Board (IRB) or Institutional Ethics Committee (IEC) for approval to ensure ethical research and use of stem cells.[36] They permitted the conduct of research involving adult stem cells,[37] stem cells derived from foetal tissues from legally performed termination of pregnancies,[38] non-human stem cells[39] and HESC derived from 64 cell lines maintained in USA.[40] However, they prohibited the creation of human embryos, whether through ART or SCNT, for the purposes of scientific research.[41]

In 2009, the *Guidelines 2006* were updated, entitled the *Malaysian Guidelines for Stem Cell Research and Therapy* (*Guidelines 2009*).[42] The *Guidelines 2009* were prepared by the Stem Cell Research and Ethics Sub-Committee of the National Stem Cell Committee in collaboration with the MOH.[43] Prior to the release of the *Guidelines 2009,* a workshop entitled the 'Scientific Meeting on Stem Cell Research' was held in 2008.[44] Contributions to the workshop, in the form of constructive comments on the draft, came from the Department of Islamic Advancement of Malaysia/ JabatanKemajuan Islam Malaysia (JAKIM), PersatuanPerubatan Islam Malaysia, the Malaysian Consultative Council of Buddhism, Christianity, Hinduism, Sikhism and Taoism (MCCBCHST) and 'all non-governmental organisations (NGOs)' and 'many more'.[45]

Like the *Guidelines 2006*, the *Guidelines 2009* reflect the *Fatwa* on stem cell research with the incorporation of additional guidelines.[46]The *Guidelines 2009* permit the conduct of research involving adult stem cells,[47] stem cells derived from foetal tissues from legally performed termination of pregnancies,[48] non-human stem cells[49] and HESC derived from surplus IVF embryos.[50] However, the deliberate creation of human embryos, whether through ART or SCNT, for the purposes of scientific research is prohibited.[51]

The *Guidelines2009* provide that all stem cell research, whether involving human or animals, must be reviewed by an IRB or an IEC for approval to ensure ethical research and use of stem cells.[52] The IRB and IEC must strictly adhere to the *Guidelines 2009*. A copy of any research proposal must be submitted to the National Stem Cell Research and Ethics Sub-Committee, which retains the right to review the proposal.[53]The *Guidelines2009* prohibit the following activities:[54]

1. Research involving in vitro culture of any intact human embryo, regardless of derivation methods, for longer than 14 days or until the formation of the primitive streak, whichever occurs first;
2. Research in which HESC are introduced into non-human primate blastocysts[55] or in which any HESC are introduced into human blastocysts;
3. Breeding of animals into which HESC have been introduced at any stage of development; and
4. Development of human stem cells or other cells of pluripotent nature fused with cells of non-human origin beyond 14 days, or the formation of primitive streak begins, whichever occurs first.

Consent for blastocyst donation is required from each donor at the time of donation.[56] Donors' consent is required to be sought again when any specific research is being considered.[57] They must be informed of their right to withdraw consent until the blastocyst is used in the cell line derivation.[58] The informed consent process, whether for the purpose of donation of gametes or blastocysts for HESC research, is required to include the following information:[59]

1. A statement that the blastocyst of gametes will be used to derive HESC for research that may include research on human transplantation;
2. A statement that the donation is made without any restriction or direction regarding who may be the recipient of transplants of the cells derived, except in the case of autologous donation;
3. A statement as to whether the identities of the donors will be readily ascertainable to those who derived or work with the resulting HESC lines;

4. If the identities of the donors are retained, even if coded, a statement as to whether donors wish to be contacted in the future to receive information obtained through studies of the cell lines;
5. An assurance that participants in research projects will follow applicable and appropriate best practices for donation, procurement, culture and storage of cells and tissues to ensure the traceability of the stem cells, traceable information must be secured to ensure confidentiality;
6. A statement that derived HESC cells and / or cells lines might be kept for many years;
7. A statement that the research is not intended to provide direct medical benefit to the donors except in the case of autologous donation;
8. A statement that embryos will be destroyed in the process of deriving HESC cells;
9. A statement that neither consenting nor refusing to donate embryos for research will affect the quality of any future care provided to potential donors; and
10. A statement of risks involved to the donors.

Other important provisions in the *Guidelines 2009* include the following:

1. Payment, whether in cash or in kind, for the donation of blastocyst for research purposes is prohibited;[60]
2. The doctor responsible for the infertility treatment and the investigator proposing to use the HESC cells should not be the same person;[61]
3. Laboratories conducting stem cell research shall conform to the required guidelines for good laboratory practices.[62] They shall be GMP compliant as required by the National Pharmaceutical Control Board (NPCB) and shall be certified as GMP compliant by the NPCB;
4. The procurement, management, storage and disposal of stem cells and tissues used in research and clinical trials must be in accordance with the national guidelines;[63]
5. Therapeutic outcomes, adverse effects and tissue integration shall be documented or reported to the National Stem Cell and Ethics Sub–Committee;[64] and
6. All imported stem cells/ tissue products for use in clinical trials and therapy shall be GMP certified and registered by the NPCB.[65]

## CRITIQUE OF THE *GUIDELINES 2009*

The *Guidelines2009* made significant advances to the regulation of HESC research in Malaysia. First, they attempt to address a number of issues relating to stem cells, both research and therapy. Secondly, they were updated three years after they were first drafted and with the incorporation of additional guidelines, being more comprehensive than the *Guidelines 2006*. Thirdly, prior to the release of the guidelines, a workshop was held and there were constructive comments on the draft received from NGOs and religious organisations.

However, a number of critique could be raised in relation to the *Guidelines 2009*. According to Professor Brownsword, for regulators to attain 'regulatory legitimacy', the regulatory position that they adopt must be considered by all 'ethical constituencies' in a society as acceptably legitimate and ethically appropriate.[66] Articulating such a regulatory position is a challenge in a multi-religious society with a plurality of values like Malaysia with each of the main religion of the nation adopting a different interpretation on the moral status of the human embryo. It is noted that Malaysia is a democratic country and in democracies, differences could be settled by reasoned debates. As Michael Kirby explains, 'the very process of consultation and public debate promote a broad community understanding of the issues, an appreciation of different viewpoints and an acceptance of any regulation adopted, even when they give effect to conclusions different from one's own.'[67] Unlike bills which are debated extensively in Parliament, there were no equivalent lengthy debates conducted amongst the various stakeholders prior to the release of the *Guidelines 2009*. While a workshop was conducted, the attendees comprised mostly doctors and other professionals in medical and scientific field.[68] In addition, while constructive comments on the draft were provided by religious organisations and NGOs,[69] no invitation was sent to the general public for their feedback.

The *Guidelines 2009* are brief. They are also of general application as they apply to both stem cell research and stem cell therapy. In addition, in the context of stem cell research, the guidelines apply to all types of stem cell research, that are, research involving adult stem cells, non-human stem cells and HESC. To achieve clarity, it is recommended that each specific type of research should have its own set of regulations.

The permissibility and prohibition of the types of stem cell research in the *Guidelines2009* are based on the *Fatwa* but there were no reference made to the religious perspectives of other main religions of the country. However, in the *Guidelines2006* the other religions were then required to deliberate on the matter[70] as Islam has already adopted an official position on the matter as reflected in the *Fatwa* issued in 2005. The Malaysian Catholic church follows the official Vatican

position[71] but other religions have yet to adopt any formal position.[72]

The *Guidelines 2009* are silent on the following activities:

1. Human reproductive cloning. The *Fatwa* prohibits this practice but the *Guidelines 2009* make no express provision on this prohibition;
2. The use of fresh embryos in HESC research, for instance, abnormal embryos not suitable for implantation or embryos diagnosed by pre-implantation diagnosis (PGD) as carrying a genetic disease. It is argued that fresh embryos are important and useful source for HESC research and the *Fatwa* permits this activity. Therefore, it is argued that research using these embryos should be permitted and this should be expressly stated in the Guidelines; and
3. The conduct of induced pluripotent stem cells (IPS) research.[73] It is noted that IPS is an important scientific breakthrough in 2006 but the guidelines, which were drafted in 2009, make no reference to this development.

The IRBs and IECs are formally designated to review and approve all stem cell research. Compared to the statutory licensing process in other jurisdictions such as the Australian regulatory framework, the review of stem cell research by IRB or IEC is not as stringent. In the *Guidelines 2009*, the criteria imposed for the approval of the research are general and not comprehensive; they merely require that 'the IRB or IEC must strictly adhere to the National Guidelines …'[74] and 'a copy of research proposal must be submitted to the National Stem Cell Research and Ethics Sub-Committee which retains the right to review the proposal'.[75] In contrast, in Australia, the *Research involving Human Embryo Act 2002* (*RIHE Act 2002*) established the Embryo Research Licensing Committee,[76] whose principal task is to license the use of embryos.[77] There are two stages to the issue of a licence. First, the Licensing Committee must be satisfied that all the required consents have been obtained and the applicant has obtained approval for the activity or project by the Human Research Ethics Committee (HREC), in accordance with the NHMRC National Statement.[78] Secondly, the Licensing Committee is directed to have regard to the following matters in deciding where to issue the licence:[79]

1. Whether the number of excess ART embryos is restricted to that likely to be necessary to achieve the goals of the activity or project proposed in the application;
2. The likelihood of significant advance in knowledge or improvement in technologies for treatment as a result of the use of excess ART embryos proposed in the application, which could not reasonably be achieved by other means;
3. Any relevant guidelines, or relevant parts of guidelines, issued by the NHMRC;
4. The HREC assessment of the application; and
5. Such additional matters as are prescribed by the regulations.

The composition of IRB or IEC is not stated in the *Guidelines 2009*. It is important that the membership of such boards and committees, which make crucial decisions on the approval of stem cell research, comprise of professionals who come from a variety of backgrounds. This is essential to meet the requirements of the concept of tripartism and to avoid regulatory capture.[80] Therefore, the compositions of such boards and committees should comprise of people from a different backgrounds and this should be specifically provided for in the guidelines.

There are no provisions in the *Guidelines 2009*for the monitoring of HESC research to ensure 'regulatory effectiveness', the second regulatory challenge outlined by Brownsword.[81] For instance, inspectors could be appointed to conduct audit in the laboratories to ensure scientists' compliance with the guidelines. In addition, no consequences for breaching the guidelines are prescribed, and the guidelines have no enforcement power.

The *Guidelines 2009* do not include a sunset clause that provides for a mandatory review within a reasonable time frame to ensure 'regulatory connection', Brownsword's third regulatory challenge.[82] He explains that as new technologies develop rapidly, regulatory frameworks may lose connection with the technological state of the art which causes a mismatch, leading to a regulatory crisis. When regulatees do not know with certainty where they stand, a fundamental principle of the Rule of Law is violated- that the current regulatory position should be communicated clearly by regulators to regulatees. Such regulatory void causes regulatees to face uncertainties and encounter challenges in interpreting the legal position. As a consequence, they face a difficult choice: either they assume that their acts are permitted or they assume these acts are prohibited. Especially for law abiding regulates, this uncertainty is unsettling. While it is acknowledged that the *Guidelines 2006* were updated in 2009, it is crucial to make a specific provision, through a sunset clause, in the *Guidelines2009* for a formal mandatory review in future as stem cell research is an innovative area which is dynamic and fast moving.

The *Guidelines 2009* do not provide for the need to maintain a publicly available database on approved research or the need to make regular reports to Parliament. These formal mechanisms, which should be made available to the public such as websites, ensure transparency and accountability.

In summary, the *Guidelines 2009* are brief and general. They do not impose strict controls and safeguards on the use of human embryos in research. They lack mechanisms aimed at transparency and accountability, which may allay public concerns, such as maintaining a publicly available database and making regular reports to Parliament which are accessible by the public. There was no public consultation conducted prior to the release of the guidelines, no inspectorate system to audit the laboratories and no sunset clause provision providing for a mandatory review of the guidelines within a reasonable time frame. It is therefore concluded that the present guidelines do not ensure 'regulatory legitimacy', 'regulatory effectiveness' and 'regulatory connection'.

## BRAITHWAITE'S THEORY OF RESPONSIVE REGULATION

In the formulation of effective regulation of HESC research, Malaysian regulators could apply the responsive regulatory theory, originally conceptualised by Professor Ian Ayres and Professor John Braithwaite in 1992.[83] This theory proposes that 'regulators should be responsive to the conduct of [regulatees] [before] deciding whether a more or less interventionist response is needed'.[84] The first response to proscribed behaviour is to determine how effectively individuals or corporations self-regulate before deciding whether to escalate intervention. Giving primacy to less invasive responses facilitates this approach and 'attempts to solve the puzzle of when to punish and when to persuade.'[85]

The most distinctive part of responsive regulation is Braithwaite's regulatory pyramid (see Figure 1) with each increment step increasingly demanding in its sanctions. The pyramid illustrates the ideal that less punitive measures should be the reaction of first instance to non-compliance of the law. At the base of the pyramid, self-compliance is encouraged. The wide base of the pyramid represents the majority of cases that are handled informally, restorative dialogue-based approach. They are non-punitive responses, that is, they are based on persuasion as well as self-regulation. The narrowing towards the top of the pyramid illustrates the increasingly fewer cases handled by progressively more formal means. Moving up the pyramid, the regulations are increasingly demanding in their sanctions. The key to influencing human behaviour is the inexorability of escalation to punitive responses. Regulators have the capacity to move up and down the pyramid to access the appropriate level of regulation necessary.

As an example, at the base of the pyramid, attempts are made to encourage compliance of the law by persuasion. If this fails, the next step is to issue a warning letter; if this fails to secure compliance, civil monetary penalties are imposed. If this fails, criminal prosecution ensues and penalties like fine will be imposed, if this fails, the licence to operate is suspended

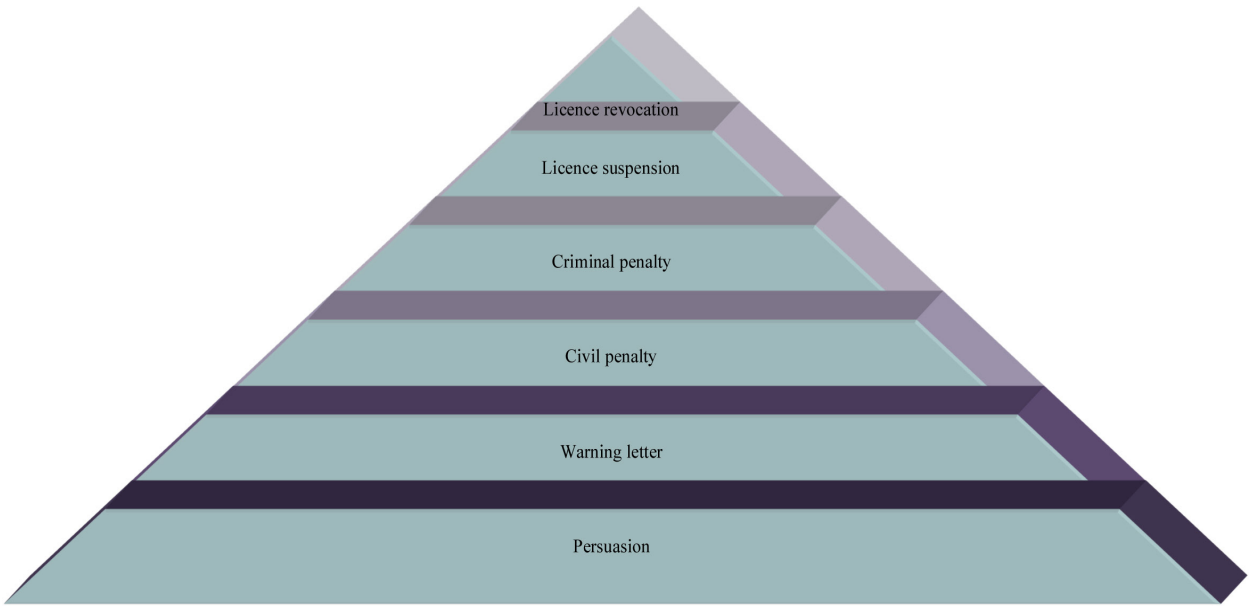


FIGURE1. An example of Braithwaite's enforcement pyramid in the context of a business
*Source* : I. Ayres & J. Braithwaite (1992)

and this fails, arriving at the peak of the pyramid, the licence to do business is revoked and the business must cease.

According to responsive regulatory theory, a 'spectre of punishment [is] threatening in the background but never threatened in the foreground'.[86] The theory claims that if persuasion by itself is to work, stiffer forms of consequences must loom as a real and likely threat. The main point is that the peak of the enforcement pyramid creates downward pressure which causes the majority of the action to occur at the base of the pyramid, that is, in the realms of persuasion and self-regulation.[87] The existence of the capacity to get as tough as is needed can bring about a regulatory culture which is more voluntaristic and less litigious. Braithwaite warns that if the top of the pyramid is lopped off, there will be less prospect of self-regulation and persuasion as an alternative to punishment.[88] The greater the heights of punitiveness to which a regulatory agency can escalate, the greater its capacity to push regulation down to the base of the enforcement pyramid.[89] A truncated pyramid with a truncated range of escalations will exert less downward pressure to keep regulation at its base than a tall pyramid whereas a tall enforcement pyramid can be used to apply great pressure from the heights of its peak to encourage voluntary compliance.[90]

Braithwaite refers to the regulatory agencies as 'the Benign Big Guns that walk softly while carrying very big sticks',[91] that is, while regulators have great powers, they rarely ever use the power of criminal prosecution. Compliance is optimised by regulation that is both tough and forgiving. Forgiveness is advocated for its importance in building commitment to comply in future and punishment is about deterrence. As Braithwaite explains, 'Paradoxically, the bigger and the more various are the sticks, the more regulators will achieve success by speaking softly'.

The second pyramid is the Braithwaite's 'strengths-based pyramid' as illustrated in Figure 2. It is a pyramid of responses to individuals and organisations. This pyramid of support promotes a virtue whereas the pyramid of regulatory strategies restrains vice. Thus, it has features of the provisions of incentives rather than the imposition of punishments. The idea of this pyramid is that as it moves up, it moves to targeting progressively higher rewards on progressively smaller target groups. Starting at the base, strategies are minimally interventionist and minimally costly, yet have the relevance to the widest possible community.[92]

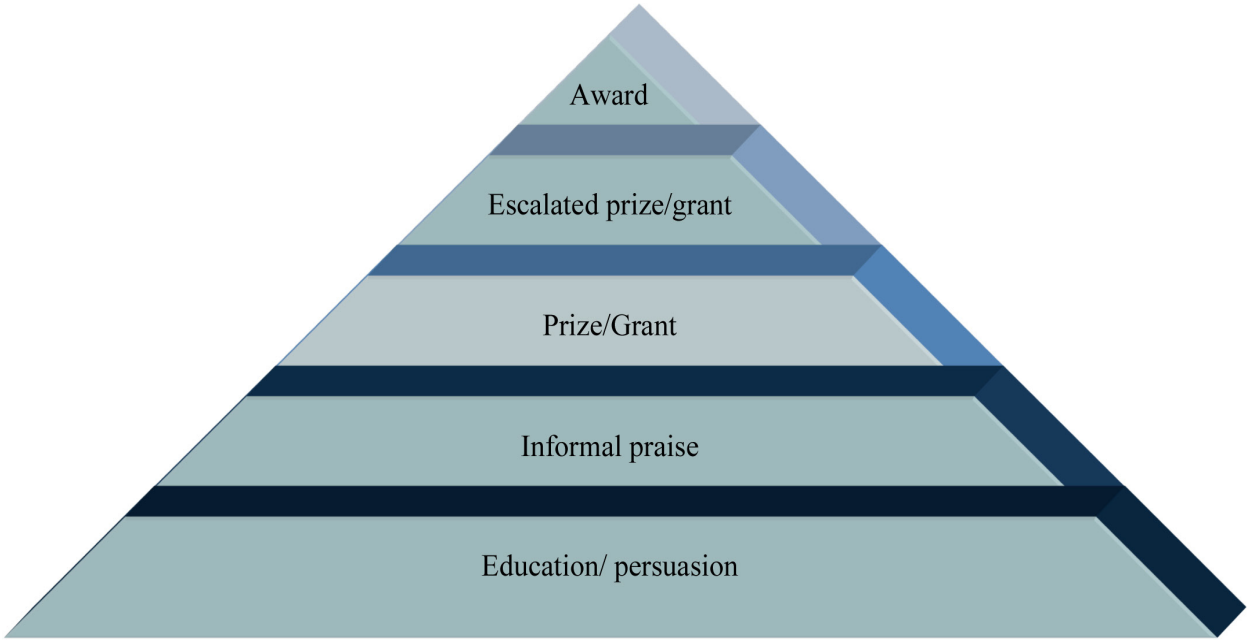


FIGURE 2. A possible approach of a Braithwaite's pyramid of strengths–based pyramid to motivate conduct
*Source* : J. Braithwaite (1990 – 1991)

The responsive regulatory theory suggests that 'regulators should operate with a cooperative default approach'[93] and attempt to seek win-win relationships with their regulatees. They will perform 'well to respond to non-compliance in a way that leaves room for escalating sanctions, for flexibility, and for sensitivity to the nature and character of particular regulatees.'[94]

This article is informed by these two pyramids in the context of regulating HESC research in Malaysia which are complementary. 'Pyramid design is a creative, deliberative activity'[95] and 'regulators that think responsively tend to design very different kinds of pyramids for different kinds of problems ...'[96]The first pyramid of regulatory strategies designed in this article is illustratd in Figure 3 below.

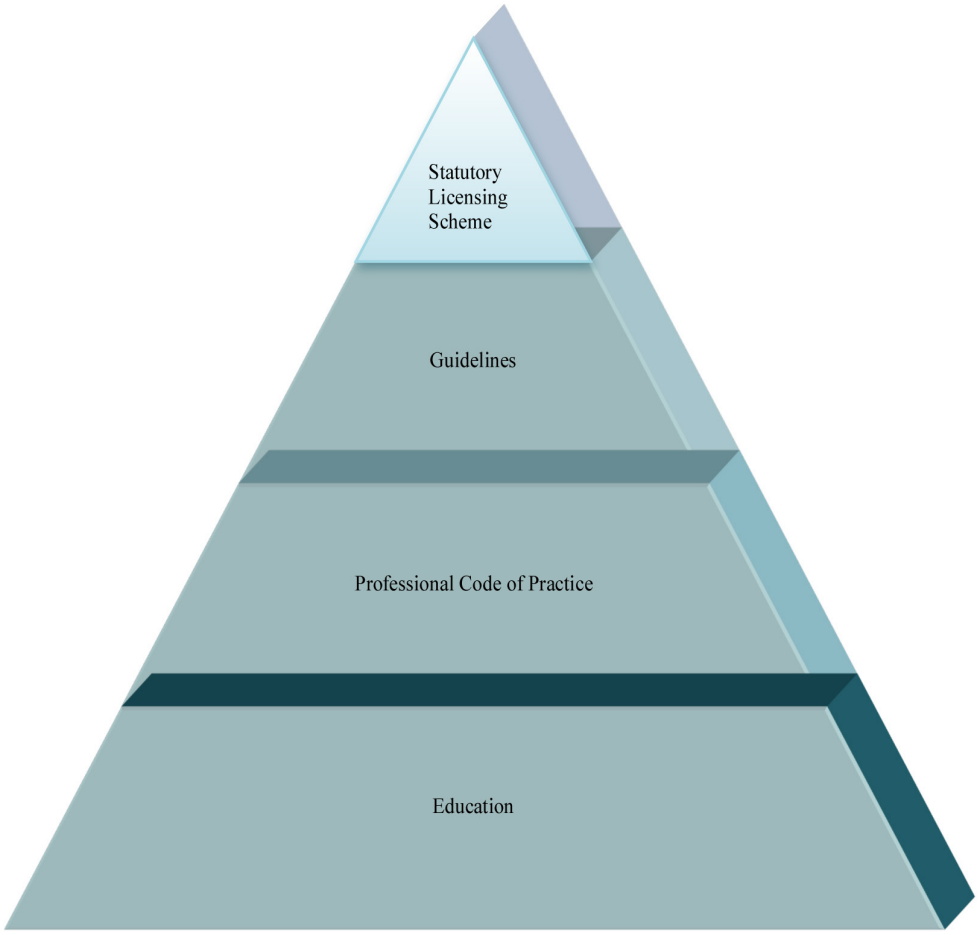


FIGURE 3. A possible approach of a pyramid of regulatory strategies to regulate HESC research
*Source* : J. Braithwaite (2006)

At the base of the pyramid is education. Through education, awareness is created amongst the scientific community about the importance of observing high ethical standards whilst conducting HESC research and the consequences of breaching the regulation. The Australian regulatory framework includes this important component. It is based on a model of 'cooperative compliance' where licence holders are encouraged to cooperate with the National Health Medical Research Council (NHMRC) to comply with the legislation. Emphasis is placed on education and communication as these promote awareness of the responsibilities of both licence-holders and inspectors. A key mechanism for raising such awareness is through information exchange visits, which were made to researchers, licence-holders, human research ethics committee members and other interested organisations. In addition, information is made available through seminars, workshops, websites and publications. In this way, scientists/ researchers are deterred from breaching the law.

On the next rung of the pyramid is professional Code of Practice/ industry self-regulation, the aim being to provide guidance as well as support and advice to scientists. Professional bodies and institutions should adopt industry self-regulation. This practice is encouraged as it sets industry standards for compliance.

Further up the pyramid is the Guidelines scheme, also known as soft law/under legislation, made by government agencies.[97] Guidelines are advantageous in the regulation of new technologies. They are flexible and can be amended as needed. Amendments can be made slowly, focusing directly on issues that arise as new discoveries are made.

Finally, at the apex of the pyramid is statutory licensing scheme where restrictive research on embryos is permitted by statute and criminal offences apply where the activity is carried out without a valid licence. For instance, in Australia, the *RIHE Act 2002* creates a series of offences relating to the use of excess ART embryos without a licence. It is an offence to use an embryo that is not an excess ART embryo,[98] and to breach a licence condition.[99] The seriousness with which the legislature views these offences is reflected in the penalties, with a maximum of five years' imprisonment.

With the strengths-based pyramid model (Figure 2), scientists are motivated to be compliant with regulations. At the base of the pyramid, through education, scientists are informed and motivated to conduct research whilst observing high ethical standards. On the next rung is receiving an informal praise and not everyone is singled out for a special praise. This is followed by receiving prize/ research grant and again not everyone will receive the grant. The next rung is 'escalated' prize/ grant and few will receive, for instance, a $1m dollar grant. Finally at the peak of the pyramid, even fewer will receive an award such as the Nobel prize or being conferred knighthood or being named as the 'Person of The Year' and receiving cash prize.

The two pyramids recommended in the regulation of HESC research comprise the pyramid of regulatory strategies, emotional economy of shame, and the strengths-based pyramid, emotional economy of pride. This pyramid structure provides a useful framework to craft a systematic set of regulations for HESC in Malaysia. The pyramid of regulatory strategies, with its various tiers, creates awareness through education, provides guidance and support through the code of practice and the guidelines scheme complements the strict statutory licensing scheme. The 'strengths-based pyramid', with its features of incentives rather than punishments, provides different varieties of rewards to researchers who have clean ethical records in their conduct of research. With these two pyramids, a range of instruments, which inflict punishment and provide incentives to scientists, effectively control their conduct. As Braithwaite says, 'It's very important to have a mix of support and sanctions.'[100] It is therefore recommended that this regulatory model, which has a combination of instruments that effectively promote the regulatory purposes and a spectre of punishment in the background, is effective in Malaysia.

## MOVING TO THE NEXT LEVEL: CRAFTING A RESPONSIVE REGULATORY REGIME

To effectively govern HESC research, the Malaysian government could consider adopting a different regulatory framework which includes comprehensive legislation. Contentious research must be subject to clear legislative parameters as these controls are essential to safeguard the public interest and allay widespread anxiety. Public confidence would be maintained with consistency, accountability, transparency and the assurance of the observance of high ethical standards by scientists conducting the research. It would mean a society with inhibiting limits and moral scruples. The Australian regulatory framework on research involving human embryos, which includes legislation, serves as a model for Malaysia to adopt. The *RIHE Act 2002* has features mandating the following:

1. A licensing system with strict criteria to fulfil before a licence is granted;[101]
2. A licensing committee that must comprise of professionals representing different backgrounds;[102]
3. A monitoring system by inspectors;[103]
4. Provisions on consequences including penalties imposed on scientists for breach of statutory requirements and licence conditions;[104]
5. Mechanisms that promote transparency and accountability;[105] and
6. Law review within a reasonable time as provided in a sunset clause.[106]

It is acknowledged that Malaysian regulators might encounter different challenges but the general principles stated above are of universal application, recognising it may be necessary to make modifications, where necessary, for them to apply in a society with different culture. An attempt to resolve differences of religious interpretations in multi-religious Malaysia is, and will remain, a challenging task in reaching a consensus. Yet as a democratic country it is necessary that reasoned debates and open forums are conducted to explore the issues fully. It is essential that some process is conducted to ensure all voices are heard. This assists in attaining regulatory legitimacy, Brownsword's first regulatory challenge. With fair and open processes to produce regulatory outputs, regulatees should respect the regulatory regime as good faith regulatory settlements deserve to be respected. Parliament is arguably the best forum for the conduct of debates where contentious issues are fully explored and debated.[107] Like the open court, Parliament is open to visitors. Its debates are broadcasted on television and radio and they are documented in Hansard, parliamentary reports. Parliamentary debates attract media coverage which will then create public awareness in the Malaysian

society. While a seminar on cloning and related issues was held in 2002 where many stakeholders attended, such seminars, held behind 'closed doors' over two days and attracting limited media coverage, are not equivalent to lengthy parliamentary debates conducted in the open.

Like negotiations, open debates might lead to consensus, albeit a provisional one, among regulatees. When regulators regulate with the grain, this leads to regulatory effectiveness, Brownsword's second regulatory challenge. He explains that regulators should act on the basis of consensus as they perform better when they act with the backing of regulatees rather than without it; thus, the 'regulatees who internalise the regulations and their purpose outperform other regulatees who mechanically apply the prescribed standards and have not internalised the spirit of the regulations and therefore not disposed to comply or are disposed not to comply.'[108] In addition, a legislative provision on the monitoring system where inspectors are assigned the responsibility of monitoring licensees' compliance with the law will lead to regulatory effectiveness. A sunset clause provision in the legislation that mandates a law review within a reasonable time frame will ensure regulatory connection.

The best practice regulatory framework for Malaysia might incorporate the following features:

1. The regulation of HESC is separate from that governing other research such as research involving adult stem cells, cells from aborted foetus and non-human stem cells.[109] Of these types of research, HESC is the most contentious research. It is proposed that there should be *sui generis* legislation to govern the use of human embryos for the purpose of extracting HESC.
2. The proposed legislation should apply to public research, private research and collaborative research, whether between national institutions or between national and international institutions.
3. Human reproductive cloning should be prohibited and any attempt to undertake this activity should be subject to criminal penalty. This reflects the *Fatwa* issued by the National Fatwa Committee of Malaysia that human reproductive cloning is prohibited[110]and this is also in accordance with the position taken by the international community.[111]
4. A moratorium should be imposed on SCNT research. The *Fatwa* rules that the deliberate creation of a human embryo by SCNT for research purposes is prohibited on the basis of *sad al zaraie*/ closing all doors on evil.[112] It remains to be seen whether this prohibition will be lifted in the future. Arguably, SCNT will not lead to evil consequences with adequate regulation and the *Shariah/* Islamic jurisprudence aims to strike a balance between the inherent good of the act and its possible evil consequences. In addition, it is stressed that Islamic religious leaders have adopted a liberal interpretation of the concept of ensoulment, with the majority interpreting that ensoulment occurs on the 120th day after conception.[113] In future Islamic conferences, the issue might be revisited that could lead to the issuance of a fresh *Fatwa* which would permit the creation of an embryo through the SCNT process for research purposes.[114]
5. The use of fresh embryos, for instance abnormal embryos not suitable for implantation or embryos diagnosed by pre-implantation diagnosis (PGD) as carrying a genetic disease should be legalised for the purposes of extracting HESC for research purposes. The *Fatwa* permits the practice of PGD.[115]
6. A licensing scheme should be introduced for research involving excess IVF embryos. This reflects the existing *Fatwa,*[116] which provides that only licensed researchers are permitted for the use of excess IVF embryos for research. The licence should be issued by an authority like the NHMRC Licensing Committee in Australia. The legislation should establish this authority to regulate the research. This authority should be independent of the government, health authorities or research institutions.
7. Membership of the licensing body should comprise of members from various backgrounds that reflect the diverse demographic groups in Malaysia. This could prevent the possible problem of regulatory capture and corruption. To resolve this problem, the concept of tripartism advocated by Professor Braithwaite explains that 'three heads are better than two in ensuring all the arguments are properly considered, bringing about different experience and perspectives to enrich regulatory deliberation.'[117] Appointing a good mix of people that come from diverse backgrounds on the proposed licensing committee is a powerful deterrent to the problem of regulatory capture.
8. Licences for research should be issued only if strict conditions are satisfied. Before issuing a licence, the licensing committee will have to be satisfied that there is approval for the research granted by an institutional research ethics review committee such as the IRB or the IEC. The ethics review committee will see whether the embryos are excess to ART needs

of the woman and her spouse and whether all the required consents have been obtained.

9. Consent should be provided by the egg/ embryo donor and her spouse and it should be evidenced in writing by both parties. This provision, however, does not apply to unmarried couples living as partners[118] as Islam justifies practices only within the confines of a valid marriage.
10. The licensing committee must be satisfied that the research proposal fulfils the purposes of research by the observation of the principles of necessity, that is, the research represents a significant knowledge or improvement in technologies for treatment and secondly, the principle of proportionality, that is, the number of embryos used for the research is restricted to that likely to be necessary.
11. Inspectors should be appointed to monitor scientists' compliance with licence conditions.[119] Their role is to make regular visits to licensed research premises to conduct audit. This provision is to ensure regulatory effectiveness. It is proposed that the monitoring and compliance framework be based on a model of cooperative compliance, which encourages licence holders to cooperate with the licensing body to comply with the legislation. Emphasis is placed on education and communication to promote awareness of the responsibilities of licence holders as well as inspectors and this is achieved through information exchange visits, seminars, workshops, websites and publications.[120]
12. The consequence of breach of licence should be revocation of licence by the licensing committee.
13. The legislation should provide for criminal penalties such as fines and imprisonment imposed for breach of regulations.[121]
14. The licensing authority should have regular consultations with all stakeholders including scientists, researchers, industry and the general public. Consultations will promote awareness of the issues and encourage consensus.[122]
15. An annual report should be prepared to Parliament.[123] This ensures transparency and accountability. The reports must outline all licences issued, the purposes for which they were granted and the outcome of the research.[124] In addition, it is proposed that there is a publicly available database containing all current information on all licences issued as well as licence conditions.[125] All research should be published.
16. A sunset clause should be incorporated in the legislation that provides for review of legislation and the review should be conducted within a reasonable time frame,[126] taking into considerations the latest developments of the science. The review, as well as the swift implementation of the recommendations, will ensure regulatory connection.

## CONCLUSION

The Malaysian government could consider adopting a regulatory framework, which includes comprehensive legislation, to effectively regulate HESC research. The proposed framework, based on Braithwaite's regulatory theory, would comprise a pyramid of regulatory strategies and a strengths-based pyramid that incorporates a range of instruments of punishment as well as incentives to scientists to control their conduct. As Brownsword proposed:

> Regulators ... need to be clear about their objectives and smart in their approach ... the more that regulators are able to act with the grain of regulatees' values, the more likely it is that their intervention will be effective.[127]

As a moderate Muslim country, this plan of action is serves as a model not only for the Muslim world[128] but also for other developing countries especially emerging economies.[129]The proposed regulatory framework in this article attains'regulatory legitimacy', exhibits'regulatory effectiveness' and maintains'regulatory connection'. With the regulatory pyramid (emotional economy of shame), incorporating a range of regulatory instruments, employed as 'sticks' to inflict punishment and the strengths-based pyramid (emotional economy of pride), comprising of a variety of rewards/ incentives which serve as 'carrots' and thereby promotes the regulatory purposes, these are effective means of controlling scientists conducting HESC research. With a spectre of punishment threatening in the background but never threatened in the foreground, Braithwaite's 'Benign Big Guns' project an image of invisibility by carrying different varieties of big sticks as well as giving away various incentives. They could and would achieve success by walking and speaking softly.

## NOTE

[1] A good source of reference on the science of stem cells is 'Understanding Stem Cells: An Overview of the Science and Issues from the National Academies' (2006) National Academies Press.

[2] J. Li et al, 'Mice cloned from Skin Cells' (2007) *Proceedings of the National Academy of Sciences of the United States of America,* p 2738-2743.

[3] 'Department of Health, Stem Cell Research: Medical Progress with Responsibility' (2000) *Report from the Chief Medical Officer's Expert Group,* p19.

[4] Australian Scientists Grow Adult Stem Cells from Nose (2005) http://www.stemcellnews.com/articles/ stem-cells-adult-from-nose.htm(21 April 2009).

[5] T. Skutella et al, 'Generation of Pluripotent Stem Cells from Adult Human Testis' (2008) 456 *Nature,* p 344-349.

[6] 'Understanding Stem Cells: An Overview of the Science and Issues from the National Academies', p 8.

[7] 'Understanding Stem Cells: An Overview of the Science and Issues from the National Academies', p 4.

[8] A. Trounson, 'A Fluid Means of Stem Cell Generation' (2007) 25 *Nature Biotechnology* p 62-63.

[9] Discarded Placentas Deliver Researchers Promising Cells similar to Embryonic Stem Cells (2005) http://www.bio-medicine.org/biology-news/Discarded-placenta-deliver-researchers-promising-cells-similar-to-embryonic-stem-cells-1575-3/(21 April 2009).

[10] This is a major source of HESC for use in medical research. The embryos are stored in IVF clinics, specifically in the freezers of the clinics. The IVF process requires the retrieval of a woman's eggs through a surgical procedure after undergoing an intensive regimen of fertility drugs which stimulate her ovaries to produce multiple mature eggs. Typically, doctors fertilise all of the eggs in order to maximise the chance of producing a viable embryo that could be implanted in the womb. Because not all the fertilised eggs are implanted, this has resulted in a large bank of excess embryos stored in freezers. After a certain date in storage in freezers, these embryos are destroyed.

[11] K. Hochedlinger 'Your Inner Healers' Scientific American'(2010) p 29-35 at p 35. HESC research continues apace in USA as money is flowing in California from the Californian Institute for Regenerative Medicine (CIRM).

[12] See 'Understanding Stem Cells: An Overview of the Science and Issues from the National Academies', p 7.

[13] Primitive streak is a structure that forms during embryonic development.

[14] National Health Medical Research Council, 'Human Embryo'-A Biological Definition (DP) (2006) http://www.nhmrc.gov.au/_files_nhmrc/file/research/embryos/ reports/humanembryo.pdf(10 May 2010) at 10.

[15] Article 3 of the Federal Constitution of Malaysia.

[16] According to the Department of Statistics Malaysia, the demographics of the Malaysian population are 60.4% Muslims, 19.2% Buddhists, 9.1%, Christians, 6.3% Hindus and others which include Sikhs. See http://www.statistics.gov.my/portal/index.php?lang=en (13 May 2010).

[17] Sources of information in this article include interviews conducted with the Malaysian government bodies such as the Ministry of Health and Attorney General Chambers. This study has received ethical approval from the Tasmanian Social Science Human Research Ethics Committee in 2007. Interviews were audio-recorded with consent forms signed by the interviewees.

[18] Professor Roger Brownsword, of Kings College London, is a prominent expert in issues of technology, ethics and law. He has written extensively on the regulatory challenges of modern technologies. He has long been associated with the UK's House of Commons Science and Technology Committee. This committee's role is to ensure that the UK Government policy and decision-making are based on good scientific and engineering advice and evidence. A face-to-face interview was conducted with Brownsword to seek his insight of these difficult issues as well as options in attempting to resolve themon 18 November 2009 in his office in the Law Faculty, Kings College London.

[19] Professor John Braithwaite is a renowned social scientist in Australia National University (ANU). He has won a number of international awards for his research on restorative justice and responsive regulation. A face-to-face interview was conductedon 19 October 2009 with Braithwaite in his office in ANU.

[20] Malaysian Biotechnology Corporation, The Malaysian Biotechnology Country Report (2009/ 2010) is available online at http://www.biotechcorp.com.my/Documents/AboutBiotechCorp/country%20report%20double.pdfat ES-1 accessed (13 May 2010). The biotechnology industry comprises of three sectors: agricultural, health care and industry. Out of 349 biotechnology companies identified in 2009, 38.4% of them are involved in healthcare with an investment of US $235.1 million. Stem cell research and therapy in Malaysia is estimated to be worth US $157 million with a year on year growth estimated at 12%, see 3-26 of the report.

[21] The seminar was jointly organised by Malaysian Foreign Ministry and Institute of Strategic and International Studies (ISIS) Malaysia, a government think tank organisation. It was held in a hotel in Kuala Lumpur on 6 and 7 February 2002.

[22] In the seminar, presentations were made by representatives of Islam, Catholicism and Hinduism.

[23] Interview with EncikRadzi bin Harun and EncikRushdan bin Mohamed, Senior Federal Counsels of the International Affairs Division, Attorney General's Chambers office, PersiaranPerdana, Precinct 4, Putra Jaya, 27 December 2007.

[24] *Guidelines 2009,* p 12.

[25] Interview with Dr. Nooraini Baba, Director of Medical Health Division, Ministry of Health office, Komplex E, Putrajaya, 10 December 2009.

[26] The IMR is the research arm of the MOH. See http://www.imr.gov.my/index.php(12 May 2010).

[27] http://www.metro.com.my/imr.html(12 May 2010). Metro IVF, a fertility clinic, is assisting in this programme by providing excess IVF embryos.

[28] Interview with Dr. Nooraini Baba.

[29] Interview with Dr. Nooraini Baba. See http://www.stempeutics.com/html/research-Human.htm, 'First world-class stem cell research facility launched in Malaysia, http://www.biotechcorp.com.my/ Documents/MediaRoom/Stempeutics-Press-Release.pdfaccessed (17 May 2010) and http://www.biotechcorp.com.my/Pages/StempeuticsResearchMalaysia.aspx?AudienceId=1?AudienceId=1(17 May 2010).

[30] http://www.tesma.org/downloads/Guidelines_stemcell_research.pdf(13 August 2009). The document is 18 pages and the specific guidelines on stem cell research are found on at page 14. The rest of the document contains information on the science of stem cells, the ethical debates and the *Fatwa* on stem cell research.

[31] *Guidelines 2006,* p 6.

[32] *Guidelines 2006,* p 14.

[33] *Guidelines 2006,* p 6.

[34] In Islam, there are *Fatwas*, legal opinion issued by a *mufti*/ expert, demonstrating a ruling within Islamic law based on evidence as a response to question The *Fatwa* on stem cell research is found at 16-17 of *Guidelines 2006*.

[35] *Guidelines 2006*, p 14.

[36] *Guidelines 2006*, p 14. According to Dr. Nooraini in the interview, the terms IRB and IEC are used interchangeably. This is the usual form of ethical oversight of research involving humans throughout the world

[37] *Guidelines 2006,* p 14.

[38] *Guidelines 2006,* p 14.

[39] *Guidelines 2006,* p 14.

[40] *Guidelines 2006,* p 14. The 64 federally funded HESC lines in USA are available for distribution to scientists throughout the world.

[41] *Guidelines 2006,* p 14.

[42] The updated *guidelines* are available on http://www.moh.gov.my/images/ gallery/Garispanduan/Stem_Cell/stem_cell_therapy.pdf(15 May 2010).

[43] *Guidelines 2009,* p 2.

[44] The workshop was held on 4-6 May 2008 in Kota Bahru, see p 65-69 of *Guidelines 2009.*

[45] See acknowledgement at p 70 of *Guidelines 2009*. It is not clear in *Guidelines 2009* which NGOs provided the comments on the draft and it is also not clear what 'many more' comprises of.

[46] The *Fatwa* is found at p 47-51 of *Guidelines 2009.*

[47] No 5 at p 30 of *Guidelines 2009.*

[48] No 6 at p 30 of *Guidelines 2009.*

[49] For instance, stem cells from animals. No 7 at p 30 of *Guidelines 2009.*

[50] No 8 and no 9 at p 30 and 31 of *Guidelines 2009.*

[51] No 10 at p 31 of *Guidelines 2009.*

[52] No 2 at p 29 of *Guidelines 2009.*

[53] No 3 at p 29 of *Guidelines 2009.*

[54] No 15 at p 35 of *Guidelines 2009.*

55 A blastocyst is an early embryo (day five after fertilisation) comprising of 100-200cells.

[56] No 13 at p 32 of *Guidelines 2009.*

[57] No 13 at p 32 of *Guidelines 2009.*

[58] No 13 at p 32 of *Guidelines 2009.*

[59] No 14 at p 32-34 of *Guidelines 2009.*

[60] No 12 at p 32 of *Guidelines 2009.*

[61] No 11 at p 32 of *Guidelines 2009.*

[62] No 16 at p 36 of *Guidelines 2009.*

[63] No 18 at p 37 of *Guidelines 2009.*

[64] No 19 at p 37 of *Guidelines 2009.*

[65] No 17 at p 36 of *Guidelines 2009.*

[66] R. Brownsword, *Rights, Regulation and Technological Revolution*, Oxford University Press, New York, 2008. p31-131.

[67] M. Kirby, New Frontier in R. Brownsword & K. Yeung (eds), *Regulating Technologies,* Hart Publishing, Oxford & Portland, 2008, p 387.

[68] At p 65-69 of *Guidelines 2009.*

[69] At p 70 of *Guidelines 2009.*

[70] At p 14 of *Guidelines 2006.*

[71] Interview with Reverend Clarence Dass, pastor of Fatima church, Jalan Sultan Abdul Samad, Kuala Lumpur, 10 January 2008.

[72] The religions that have not adopted any formal position are Buddhism, Hinduism and Sikhism.

[73] IPS are adult cells that have been reprogrammed into a pluripotent embryonic-like state. They display key properties of self-renewal and the ability to mature into many different cell types.

[74] No 2 at p 29 of *Guidelines 2009.*

[75] No 3 at p 29 of *Guidelines 2009.*

[76] Section 13 of *RIHE Act 2002.*

[77] Section 20 of *RIHE Act 2002.*

[78] Section 21(3) of *RIHE Act 2002.*

[79] Section 21(4 of *RIHE Act 2002.*

[80] On tripartism as a means to prevent regulatory capture, Braithwaite advocates this concept which is a process involving a thirdplayer in the regulatory process, for instance, relevant public interest groups. It fosters the participation of these groups by granting them access to all the information available to the regulator, a seat at the negotiating table with the regulatory agency and regulate, and the authority to sue or prosecute. It is therefore important to have multi-players in the field.

[81] On this challenge, see R. Brownsword, *Rights, Regulation and Technological Revolution*, p133-159.

[82] R. Brownsword, *Rights, Regulation and Technological Revolution*, p 160.

[83] I. Ayres & J. Braithwaite, *Responsive Regulation,* Oxford University Press, New York/ Oxford, 1992.

[84] On the explanations of the fundamentals of the theory, see J. Braithwaite, *Regulatory Capitalism*, Edward Edgar Publishing, Cheltenham & Northampton, 2008, p 88-139 at p 88.

[85] Braithwaite explains that what motivated him and Ayres to formulate this theory is due to the frustration with the 'see sawing' in policy making between two groups of people; on one hand, a group who argues that business people only understand the bottom line and therefore must be punished for lawbreaking and on the other hand, a group who claims that business people are responsible people who can be persuaded to comply with the law.

[86] See J. Braithwaite, *Regulatory Capitalism*, p 94.

[87] J. Braithwaite, 'Convergence in Model of Regulatory Strategy' (1990-1991) 2 *Current Issues Criminal Justice*, p 59-65 at p 64.

[88] J. Braithwaite, 'Convergence in Model of Regulatory Strategy', p 64.

[89] J. Braithwaite, 'Convergence in Model of Regulatory Strategy', p 65.

[90] J. Braithwaite, 'Convergence in Model of Regulatory Strategy', p 65.

[91] J. Braithwaite, 'Convergence in Model of Regulatory Strategy', p 59.

[92] See J. Braithwaite, *Regulatory Capitalism*, p 109-139.

[93] See R. Brownsword, *Rights, Regulation and Technological Revolution*, p 138.

[94] R. Brownsword, *Rights, Regulation and Technological Revolution*, p 138.

[95] J. Braithwaite, 'Responsive Regulation and Developing Economies' (2006) 43 *World Development*, p 888.

[96] J. Braithwaite, 'Responsive Regulation and Developing Economies', p 888.

[97] For instance, National Health Medical Research Council (NHMRC) guidelines in Australia.

[98] Section 11 of *RIHE Act 2002.*

[99] Section 12 of *RIHE Act 2002.*

[100] Interview with Professor Braithwaite.

[101] Section 20-28 of *RIHE 2002*

[102] Section 13-19 of *RIHE 2002*

[103] Section 33-41 of *RIHE 2002.*

[104] Section 10-12 of *RIHE 2002*

[105] Section 18-19 of *RIHE 2002.*

[106] Section 47 of *RIHE 2002.*

[107] The parliamentary debate on the bill on cloning and stem cell research in Australia is the longest debate ever held.

[108] R. Brownsword, *Rights, Regulation and Technological Revolution*, p 148.

[109] These different types of stem cell research are found in the same set of guidelines.

[110] http://www.islam.gov.my/portal, (3 June 2010).

[111] Article 11 of Universal Declaration on the Human Genome and Human Rights 1997.

[112] http://www.islam.gov.my/portal, (3 June 2010).

[113] Another school of thought interpretsensoulment to occur on the 40th day after conception which is also a liberal interpretation.

[114] This is also the opinion of Dr. Musa bin Nordin, President of Malaysia's Federation of Islam Medical Association, in an interview, Damansara Specialist Hospital, Jalan SS20/10, Petaling Jaya, 7 January 2008.

[115] http://www.islam.gov.my/portal (3 June 2010).

[116] http://www.islam.gov.my/portal (3 June 2010).

[117] Interview with Professor Braithwaite.

[118] The *Guidelines 2009* apply only to legally married couples and do not extend to partners.

[119] This is a natural feature of ensuring compliance with the law.

[120] This is a feature of the Australian regulatory model which is influenced by Braithwaite's theory.

[121] This is the highest rung of the regulatory pyramid.

[122] This is the lowest rung of the regulatory pyramid, that is, education. Brownsword has also expressed the importance of conducting open discussions among all stakeholders.

[123] In Australia, the report is prepared bi annually, that is, every six months.

[124] This is similar to the Australian position.

[125] This is similar to the Australian position.

[126] In Australia, the review is conducted three years after the enactment of the legislation.

[127] R. Brownsword, *Rights, Regulation and Technological Revolution*, p 143.

[128] In addition, Malaysia was then the President of Organization of the Islamic Conference (OIC). The OIC is the second largest inter-governmental organization after the United Nations which has membership of 57 states spread over four continents. The organisation is the collective voice of the Muslim world and ensuring to safeguard and project the interests of the Muslim world in the spirit of promoting international peace and harmony among various people of the world.

[129] Interview with Dr. Musabin Nordin.

## REFERENCES

Ayres, I. & Braithwaite, J. 1992. *Responsive Regulation*. Oxford: Oxford University Press.

Braithwaite, J. 1990. Convergence in model of regulatory strategy. *Current Issues in Criminal Justice*. 2: 59-65.

Braithwaite, J. 2008. *Regulatory Capitalism*. Cheltenham & Northampton: Edward Edgar Publishing.

Brownsword, R. 2008. *Rights, Regulation and Technological Revolution*. New York: Oxford University Press.

Kirby, M. 2008. New Frontier. In *Regulating Technologies*, edited by Brownsword, R. &Yeung, K. Oxford & Portland: Hart Publishings.

Ministry of Health. 2006. Guidelines on Stem Cell Research.

Ministry of Health. 2009. Malaysian Guidelines for Stem Cell Research and Therapy.

The National Academies. 2006. *Understanding Stem Cells: An Overview on the Science and Issues from the National Academies*. Washington, D.C. : National Academies Press.

Patrick Foong Chee Kuen
University of Tasmania
Law Faculty
Sandy Bay Hobart 7005 Tasmania Australia
E-mail **:** pckfoong@gmail.com/ ckfoong@utas.edu.au