UNIVERSITI MALAYA

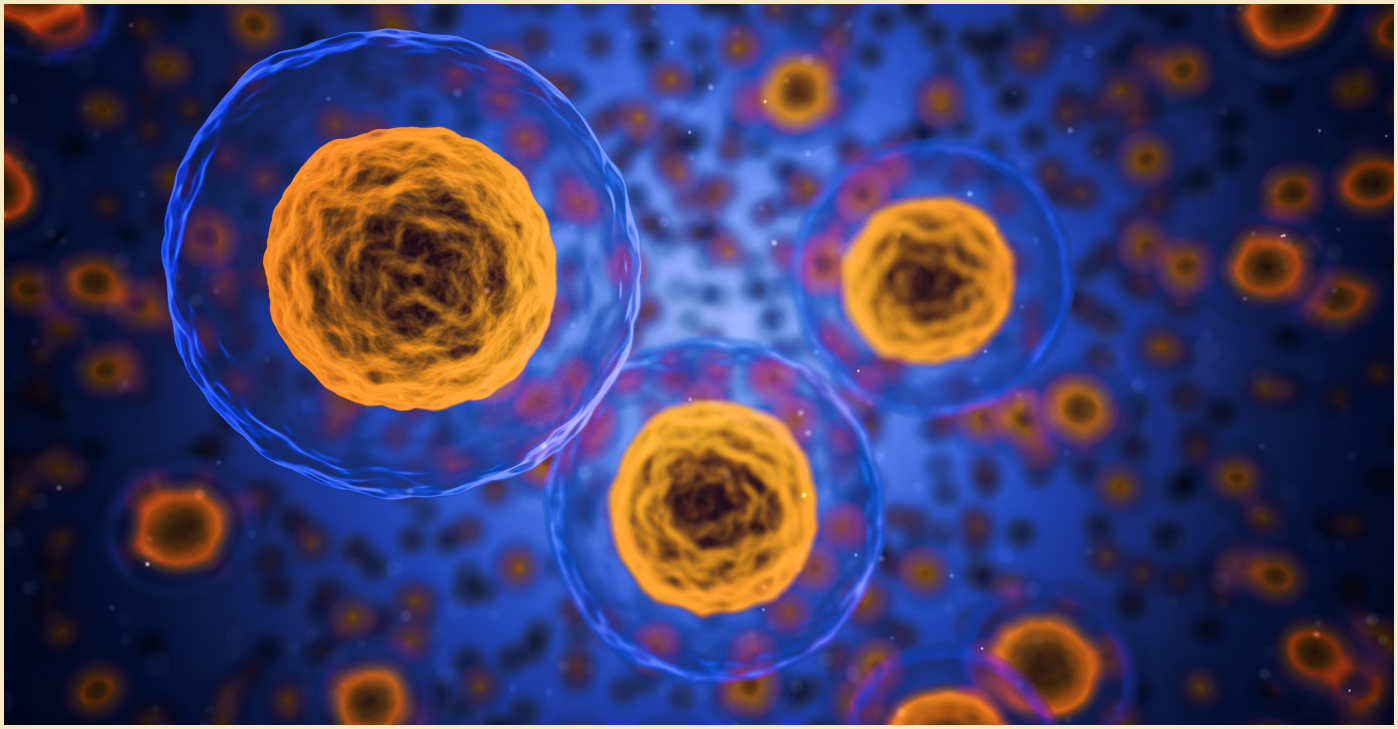
2020 • Issue 4

CELEST NEWSLETTER

CENTRE FOR LAW AND ETHICS IN SCIENCE AND TECHNOLOGY
FACULTY OF LAW, UNIVERSITI MALAYA







Source: www.canva.com

IN THIS ISSUE

Editor's Note

A special note to thank the outgoing Director of CELEST and to welcome our new director.

Featured Article

In this month's newsletter, Dr Mohammad Firdaus Abdul Aziz highlights the promising benefits of stem cell-based therapy to cure many kinds of diseases and the importance of the general public to be aware of the current development of this 21st century medical technology.

eISSN 2637-031X

Editor's Note

It is less than 3 years since the inaugural CELEST Newsletter was published. In that short time, frame we have published 11 articles on various topical topics based on the real-world issues related to law and ethics in the science and technology domain. We are indeed proud of this achievement.

I must say that we are indebted to Associate Prof Dr Tay Pek San, the outgoing Director of CELEST. She has recently retired from her teaching position at the Faculty of Law. On behalf of the CELEST member, I would like to thank her for the enormous time and effort that she has invested in laying the foundation of CELEST and the immensely valuable contribution in steering the direction of the centre. Since its inception, Dr Tay Pek San has encouraged its growth including the instigation of the publication of this newsletter. We wish her all the best for her next endeavor and look forward to continue working with her.

I am pleased to announce that Dr Sharon Kaur, has now been appointed by the faculty as the new Director of CELEST. She is a senior lecturer at the Faculty of Law. She has a vast experience in the field of medical law, medical ethics, and research ethics. Through her wide network both at local and international level, we believe the centre can go to the next level under her leadership and we are very much looking forward to working together with her at the helm.

Also, we are grateful for the support from the faculty and the CELEST members . We will continue working to make CELEST a thriving centre for research excellence relating to legal and ethical aspect of science and technology and its newsletter an academically useful that you look forward to reading each quarter.

Respectfully,

Mohammad Firdaus Abdul Aziz, DPhil
Senior Lecturer,
Faculty of Law, Universiti Malaya
firdausaziz@um.edu.my

News

Congratulations to our members on the following:

Appointments

Dr Pardis Moslemzadeh Tehrani was appointed as a member of the Editorial Review Board of International Journal of Digital Crime and Forensics.

Dr Pardis Moslemzadeh Tehrani was appointed as an Ad hoc Editorial Review Board of International Journal of Digital Crime and Forensics (IJDCF).

Dr Mohammad Firdaus Abdul Aziz was appointed as an external reviewer for LLM (Healthcare and Medical Law) Program at Taylor's University.

Dr Mohammad Firdaus Abdul Aziz was appointed as external supervisor for LLM (Medical Ethics and Law) at the University of Hong Kong.

Dr Mohammad Firdaus Abdul Aziz was appointed as a reviewer for the Journal of Science and Engineering Ethics

Dr Sharon Kaur was appointed as a member of the Ethics Advisory Council of the International COVID-19 Data Research Alliance

Articles

Maryam Khalid & Sherin Kunhibava (2020). Fintech Regulatory Sandboxes in Australia and Malaysia: A Legal Analysis. IIUM Law Journal,vol 28(1), pp. 1-35.

Pardis Moslemzadeh Tehrani (2020). States Obligations to Impose Emergency Measures during the COVID-19 Crisis. SHAPE-SEA, 27 March 2020, http://shapesea.com/op-ed/covid-19/states-obligations-to-impose-emergency-measures-during-the-covid-19-crisis/

Akbariavaz, Khalil, and Pardis Moslemzadeh Tehrani (2020). "The Role of International Law in Protection against Attacks on Children's Education Rights in Armed Conflict." J. Pol. & L. 13: 90.

Osama Ismail Mohammad Amayreh, Izura Masdina Mohamad Zakri, Pardis Moslemzadeh Tehrani & Yousef Mohammad Shadi (2020). The Pre-Contractual Obligation to Confidentiality of Information in the Palestinian Civil Code Draft and its Role in Maintaining Economic Contractual Equilibrium. UUM Journal of Legal Studies, vol 10(2), pp. 121-156 ISSN: 01279483

Book

Tay Pek San, Intellectual Property Law in Malaysia (2nd ed.) Thomson Reuters (Sweet and Maxwell). Scheduled for release at the end of October 2020.

Chapter in books

Maryam Khalid & Sherin Kunhibava (2020). Regulating FinTech Through Sandboxes: Entering the UK and Malaysian Regulatory Sandbox. In Albastaki, Y.A., Razzaque, A., and Sarea, A.M., (Eds), Innovative Strategies for Implementing FinTech in Banking, pp. 83-99, Hershey, PA: IGI Global. ISBN: 1799832570

Events

- **25-26 June 2020**

Dr Pardis Moslemzadeh Tehrani served as a Chair at the 19th European Conference on Cyber Warfare and Security, organized by the University of Chester, United Kingdom.

- **27 August 2020**

Dr Pardis Moslemzadeh Tehrani spoke on "Teaching International Law in the Online Classroom: Challenges and Strategies" at the workshop entitled "Teaching International Law: New Strategies to Meet the Challenges of a Dynamic Subject", organized by Multimedia University.

- **2 September 2020**

CELEST, in collaboration with Asia-Europe Institute and the University of Malaya Research Ethics Committee, organized a webinar on 'Digital Data in Social Science Research: Legal and Ethical Concerns'. Our researchers, **Dr Izura Masdina Mohammed Zakri** and **Dr Sik Cheng Peng**, spoke on 'Privacy, data protection and cyber security law' and 'Copyright law in the digital age' respectively. Please refer to the brochure below.

- **18 September 2020**

Dr Sharon Kaur was a panelist in the session on 'Desirable developments and possible solutions for a trustworthy data governance' at the experts online workshop entitled 'Towards trustworthy data governance for healthcare technologies'. The webinar is inscribed within the Future of Health Technologies (FHT) project, a collaboration between ETH Zurich and the National University of Singapore.

- **18 September 2020**

Dr Pardis Moslemzadeh Tehrani presented an article at The 16th ALIN General Meeting & International Conference, Laws for Fading Borders in Asia, entitled"Regulatory Compliance and Data Protection in Contact Tracing Applications under COVID-19".

- **30 September and 2 October 2020**

Dr Sharon Kaur spoke on 'Living Wills in Malaysia' at the 'Living Will, Living Well? Advance Directives Across Asia' workshop organized by the University of Hong Kong.

CELEST
CENTRE FOR LAW & ETHICS IN SCIENCE & TECHNOLOGY

What do you know about stem cell research and therapy?

By Dr Mohammad Firdaus Abdul Aziz
Faculty of Law, Universiti Malaya

Author's Biography

Dr Mohammad Firdaus is a senior lecturer at the Faculty of Law, Universiti Malaya. He is also an academic affiliate at the Centre for Health, Law and Emerging Technologies (HeLEX), Faculty of Law at the University of Oxford. He teaches Medical Law and Ethics and Law and Society at undergraduate level and Healthcare Law and Ethics, Biosafety Law, and Biodiversity Law at postgraduate level. He also teaches Ethical Issues of Emerging Sciences for Master in Health Research Ethics program at the Faculty of Medicine. He is currently researching on the regulation and policy of various emerging technologies such as biobanking, stem cell research and therapy, genetically modified organism as well as supervising research work on abortion law, juvenile criminal justice, and medical treatment for severely impaired neonates. He is also a self-taught artist and his artworks have been featured in an art gallery in Bangsar.

Introduction

Stem cell research and therapy has become a global phenomenon given the potential use of stem cells to develop therapies to cure degenerative diseases that are incurable by conventional medicine. This is due to the unique ability that stem cells have to differentiate into the various cell types of the body while at the same time replicating to maintain stem cells pool in the body.

There are different forms or types of stem cells that exist in our body such as embryonic stem cells and adult stem cells and each type of these stem cells have varying capacity and potency to replicate and differentiate into different cell types that form tissues and organs. Due to its unique ability, stem cells have been used for research purposes in the effort to develop treatment.

Given its promising benefits, there are many clinics across the globe leveraging on the 'hype' of stem cells by offering and marketing stem cell therapies [1]. These clinics are offering many different kinds of treatments for a wide range of diseases and medical conditions. The treatment can be purchased via the Internet [2].

Many of these clinics not only exist in the developed countries such as the USA, Japan, Australia, a few European countries such as Italy and Germany, but also in the newly emerging industrialised countries such as China, India, and Mexico. The escalating claim over the benefits of stem cell therapies have attracted increased attention among patients who are desperately looking for a cure, which has led to the phenomenon known as 'stem cell tourism', whereby these patients travel from their home country to another country that hosts companies that provide stem cell therapies [3].

Unfortunately, most of these 'therapies' lack testing of efficacy and safety. Therefore, this phenomenon gives rise to concerns over the risky situation that these patients may put themselves into as well as their financial and emotional wellbeing.

Stem cell research and application in Malaysia

Malaysia also recognises the importance of this highly promising medical technology. The Academy Sciences of Malaysia commissioned a Task Force to prepare a report about the development of research activities involving stem cells and therapy in Malaysia, which was published in 2009.

It is highlighted in the report that Malaysia sought to venture into this field for two main reasons namely (i) the potential use of cell therapy to address diseases of a rapidly growing population of ageing citizens in the country and (ii) cell therapy can also be leveraged on to promote national development goals especially the commercial aspects. Based on the report, there are quite a number of researchers in the public sector mainly from public universities and government research agencies who are carrying out research work in this field. However, it has been 11 years since the report was published and to date, there is no updated data about the current state-of-art and capacity in developing this field in Malaysia. Also, little is known about the activities in the private sector [4].

...due to the unique ability that stem cells have to differentiate into the various cell types of the body while at the same time replicating to maintain stem cells pool in the body...Given its promising benefits, there are many clinics across the globe leveraging on the 'hype' of stem cells by offering and marketing stem cell therapies. These clinics are offering many different kinds of treatments for a wide range of diseases and medical conditions.

In terms of the application of stem cell therapy in Malaysia, the government through the collaboration between Institute of Medical Research (IMR) and National Cancer Council (MAKNA) has founded the Malaysia Stem Cell Registry in 2020. The registry acts as a database of volunteers who are potential stem cells donors. The registry plays an important role to match potential donors with patients who need stem cell transplants. Since its inception, there are a number of successful cases of stem cell therapy reported in the country. However, this initiative is currently confined to blood disorder. Nonetheless, one could see that there is a possibility that the scope of the registry could be expanded to include other diseases in the future.

On September 30th, 2019, The Star reported a celebration of a two-time stem cell donor, Zahari Mansur, who donated his bone marrow stem cells (from his blood) to both his sisters, Zabiha and Zawiah on two different occasions. Zabiha was the recipient of Zahari's stem cells in 2009 after he was identified by Ampang Hospital as a suitable donor to save his sister who was suffering from myelofibrosis. His bone marrow stem cells were used to help regenerate his sister's bone marrow. One year later, he once again called up to save another sister of his, Zawiah who had acute myeloid leukemia [5].

Institute of Medical Research (IMR) and National Cancer Council (MAKNA) has founded the Malaysia Stem Cell Registry in 2020. The registry acts as a database of volunteers who are potential stem cells donors...Since its inception, there are a number of successful cases of stem cell therapy reported in the country. However, this initiative is currently confined to blood disorder.

Another example of a successful stem cell-based therapy is the case reported in 2016 involving a one-year old boy, Muhammad Yusuff, who was suffering from a severe lung infection and not having immune system, which is a very rare case known as 'bubble boy disease'. His condition was cured using bone marrow stem cells transplanted from his father. The procedure took place at the University Malaya Medical Centre (UMMC) [6].

Malaysia is also a host for quite a number of foreign companies that offer stem cell therapies for many other medical conditions. An empirical study in 2012 showed that there are concerns among key stakeholders (policy makers, stem cell researchers, ethicists) in Malaysia given the increasing number of clinics providing stem cell therapies which are not known of its effectiveness [7].

Some of the concerns highlighted in the study include the level of knowledge and awareness among the members of the public; whether or not they are well informed about the technology and 'therapy' they receive. Also, the stakeholders are worried in case of any unfortunate events, the reputation of this promising technology in Malaysia would also be tainted [8].

Regulation in Malaysia

Malaysia has yet to introduce legislation that is primarily regulating stem cell research and therapy. Currently, it can be said that stem cell research and therapy is under-regulated. In the absence of specific legislation, this field is presently regulated through guiding rules, namely the National Guidelines for Stem Cell Research and Therapy which was issued in 2006 and later revised in 2009 [9,10].

In general, these guidelines are non-binding in nature and arguably less effective to be comprehensively enforced across the board. The scope of these guidelines is rather limited to research and therapy that involves government staff and facilities, and work on human subjects. It is unclear as to how entities in the private sector are being regulated.

Apart from these guidelines, there are also other circulars and guidelines introduced by the medical council specifically for licensed medical practitioners who are involved in this field, which have legal mandate and can be imposed on medical practitioners in Malaysia. In addition, medical interventions involving stem cells in the private clinical setting carried out by licensed medical practitioners can be subject to the umbrella act governing private practice, which is the Private Healthcare Facilities and Services Act 1998.

Nonetheless, in 2017, the then Minister of Health, Datuk Seri Dr S. Subramaniam urged Malaysians to be cautious in making their decision if they consider to undergo any stem cell-based therapy. He made it clear that the application of stem cells in Malaysia is limited to certain medical conditions. According to him, the general public need to be cautious of stem cell therapies that are being offered to treat different kinds of medical conditions that have not been approved by mainstream science [11].

In view of the proliferation of stem cell therapies being offered in the country, there is an urgent need to revisit the current regulatory framework in Malaysia [12,13]. One can argue that Malaysia should consider enacting a specific legislation to regulate this promising field, which may take some time to materialise. Another option, which could be a faster route would be to amend the existing relevant acts such as the Human Tissue Act 1974 to incorporate stem cells and its revolutionary therapies.

Will regulation obstruct the development of stem cell therapy?

It must be pointed out that the role of regulation is not to hamper development of this technology and to impose unnecessary obstacles on businesses to commercialise stem cell therapy. Regulation is vital to ensure that this technology is applied ethically and safeguard public safety as well as to protect the reputation of this revolutionary field. This is demonstrated by many countries that have heavily invested in developing stem cell research legitimate therapies, they have also established regulation to ensure translational research from bench to bedside is appropriately governed and overseen [14].

In view of the proliferation of stem cell therapies being offered in the country, there is an urgent need to revisit the current regulatory framework in Malaysia...Regulation is vital to ensure that this technology is applied ethically and safeguard public safety as well as to protect the reputation of this revolutionary field.

However, there is a risk of hampering the development if the regulation is not carefully designed and can cause a bureaucratic system and disconnection with what is happening in the real world. It can be argued that if Malaysia aspired to join the leading countries in this field such as the UK, Japan, and South Korea, it is important for us to learn from these countries in establishing a regulatory framework that can facilitate ethical development. Having an established regulation is also important to secure public trust. Public trust is vital and without which it may affect public funding. To secure public trust, measures to safeguard the public from being manipulated and deceived by bogus stem cell providers are crucial and need to be incorporated in the regulation.

Public awareness

The issue of lack of awareness among the public has been widely discussed by scholars. A few studies have been carried out to find out the level of awareness among the general public in many countries. For instance, a study in Japan was reported in 2006 demonstrating that not many Japanese are aware of stem cells even after the ground-breaking news of the discovery of induced-pluripotent stem cells by a world-renowned Japanese scientist, Shinya Yamanaka that was thought could potentially replace the use of the ethically controversial human embryonic stem cells [15}. One could question if the general public in one of the leading nations in stem cell research has lack of awareness, what about the level of awareness in lower- and middle-income countries such as Malaysia? As mentioned earlier, an empirical study in 2012 highlighted the concerns among the stakeholders over the level of awareness among Malaysian public amidst the proliferation of stem cell therapies being offered in the country [16].

One could question if the general public in one of the leading nations in stem cell research has lack of awareness, what about the level of awareness in lower- and middle-income countries such as Malaysia?

In view of this situation, a group of researchers is conducting an online survey to find out the level of the general public's understanding on stem cell research and therapy and to explore whether or not the general public has access to information on the existing stem cell treatment offered by both local and foreign companies in the country. It is hoped that through this study, a more effective regulatory system can be explored to facilitate the members of the public to better understand stem cell research and therapy and be able to make informed decisions before undergoing stem cell therapies.

The online survey can be accessed at https://bit.ly/2EqVFnA.

References

1. Knowles, L. P. (2010). Stem cell hype and the dangers of stem cell "tourism". Stem Cell Network for the Public, Ethics and Policy.
2. Lau, D., Ogbogu, U., Taylor, B., Stafinski, T., Menon, D., & Caulfield, T. (2008). Stem cell clinics online: the direct-to-consumer portrayal of stem cell medicine. Cell stem cell, 3(6), 591-594.
3. Levine, A. D. (2010). Stem cell tourism: assessing the state of knowledge. Scripted, 7, 274.
4. Bin Abdul Aziz, M. F., Morrison, M., & Kaye, J. (2018). Regulating human stem cell research and therapy in low-and middle-income countries: Malaysian perspectives. New Genetics and Society, 37(1), 2-20.
5. John Barry (2019) https://www.thestar.com.my/metro/metro-news/2019/09/30/stem-cell-hero-saves-sisters-lives
6. Tan Shiow Chin (2017) https://www.thestar.com.my/lifestyle/health/2017/04/16/haplo-identical-bone-marrow-transplant
7. see above no 4.
8. ibid.
9. ibid.
10. Gopalan, N., Nor, S. N. M., & Mohamed, M. S. (2020). Regulation of stem cell technology in Malaysia: current status and recommendations. Science and engineering ethics, 1-25.
11. The Star (2017) https://www.thestar.com.my/news/nation/2017/11/22/exercise-caution-with-trial-stem-cell-therapies
12. see above no. 10
13. see above no. 4
14. ibid
15. Sleeboom-Faulkner, M. (2011). Regulating cell lives in Japan: avoiding scandal and sticking to nature. New Genetics and Society, 30(3), 227-240.
16. see above no. 4.