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**Title:** A Need of Shari‘ah Compliant Model of 3D Bioprinting

**Author (s):** Nurmunirah Ramli<sup>1</sup>, Mohammad Naqib Hamdan<sup>1</sup>, Mohd Anuar Ramli<sup>2</sup>, Saiful Izwan Abd Razak<sup>1</sup>, Hussein ‘Azeemi Abdullah Thaidi<sup>3</sup>, Mohd Farhan Md Ariffin<sup>4</sup>, and Norhidayu Muhamad Zain<sup>1</sup>

**Affiliation (s):** <sup>1</sup>Universiti Teknologi Malaysia  
<sup>2</sup>Academy of Islamic Studies, University of Malaya  
<sup>3</sup>Universiti Sains Islam Malaysia, Malaysia  
<sup>4</sup>Universiti Kebangsaan Malaysia

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Department of Islamic Thought and Civilization, School of Social Science and Humanities,  
University of Management and Technology, Lahore, Pakistan

## A Need of *Sharī'ah* Compliant Model of 3D Bioprinting

**Nurmunirah Ramli**

**Mohammad Naqib Hamdan\***

Academy of Islamic Civilization,  
Faculty of Social Sciences and Humanities, Universiti Teknologi Malaysia

**Mohd Anuar Ramli,**

Academy of Islamic Studies, University of Malaya

**Saiful Izwan Abd Razak**

School of Biomedical Engineering and Health Sciences,  
Faculty of Engineering, Universiti Teknologi Malaysia

**Hussein 'Azeemi Abdullah Thaidi,**

Faculty of Syariah and Law,  
Universiti Sains Islam Malaysia, Malaysia

**Mohd Farhan Md Ariffin**

Faculty of Islamic Studies,  
Universiti Kebangsaan Malaysia

**Norhidayu Muhamad Zain**

Academy of Islamic Civilization,  
Faculty of Social Sciences and Humanities,  
Universiti Teknologi Malaysia

### Abstract

One of the credible inventions is 3D Bioprinting or Organ Printing which uses layer by layer fabrication manner and is an emerging and developing technology offered by the research industry and can help the humanity in certain areas of life e.g., health, food, etc. The technology has been found beneficial in wide spectrum within the medical industry in fighting the shortage of organ and tissues donations. It is also helpful for the pharmaceuticals for determining effectiveness of new drugs and the food industry players to develop new type of edible meat for humans' consumption. However, behind all these benefits, there are unresolved issues that need be discussed critically and addressed properly within the ethics, law and orders of Islamic worldview. This study aims to indentify the *Sharī'ah* related issues raised consequent upon the invention of 3D bioprinting. The study uses data collection from scholars' writings, academic journals, and Islamic fatwa related to bioethics. The data are analysed thematically. The results show that there is a loophole in bioethics research on *Sharī'ah* compliant guidelines for the Muslims users with regards to bioprinting usage. It is suggested for the experts to do thorough research on *Sharī'ah* compliant guidelines of bioprinting to be the benchmark guideline for authorities such as JAKIM in Malaysia and other authorities such as the Ministry of Health in treating the Muslim patients.

**Keywords:** 3D Bioprinting, Ethical and legal issues, Organ Printing, *Sharī'ah* Compliance.

### Introduction

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\*Correspondence concerning this article should be addressed to Mohammad Naqib Hamdan, Senior Lecturer, Academy of Islamic Civilization, Faculty of Social Sciences and Humanities, Universiti Teknologi Malaysia at [mohammadnaqib@utm.my](mailto:mohammadnaqib@utm.my)

Science and technology are constantly evolving and becoming more rapid over the last 20 years. Various new technologies have been introduced to facilitate human life. There are inventions that have been successfully grounded and entered the consumer market and they remain so to this day through various evolutions and improvements. However, there are also various inventions and designs of scientists that have not been successfully grounded or entered the consumer market. Among the inventions that are beneficial and remain until today are such as telephones, cars, airplanes and so on. Today, one of the technologies that promises the greatest benefits is three-dimensional (3D) printing. Compared to the previous paper printing technology which can only print books and writings on a large scale, this three-dimensional printing technology is able to print goods in physical form, just like the original goods faster and cheaper. In addition to printing goods, this 3D printing is also used in medicine with bio printing that is able to print tissues and is expected to be able to print organs perfectly.

This bio printing technology is very useful because it can overcome the problem of lack of organ and tissue donation, besides being able to reduce the risk of the body's rejection of new organs transplanted into the patient's body because it has the same genetic information as that of the patients because it is printed from their own cells. It can also be used in the pharmaceutical field to test the level of effectiveness of a drug compared to the old method that makes animals as experimental material. Another use of this bio printing is to print animal meat as food to humans to overcome problems arising from animal husbandry such as environmental pollution, lack of protein resources and so on. The meat produced through this method is also known as cultured meat.

However, despite all the benefits of regular 3D bio printing, there are some problems that arise and need to touch on Islamic ethics and law. Among the problems that arise is the safety of the organs or tissues printed by bio printers whose level of hygiene and safety is unknown. In fact, there is a possibility of the sale of printed organs or tissues, whether they are sold in the open market or in the black market illegally. This is because, so far, there is no clear guide from the legal and Islamic aspects related to this issue.

## 2. Literature Review

### 2.1 What is Bioprinting?

For further discussion on the matters, the paper will start off by finding the definition of 3D Bioprinting. Even though there is no definitive definition for Bioprinting, the first definition was presented in International Conference at University of Manchester Institute of Science and Technology (which is now known as University of Manchester, UK) during September 2009 as: "the use of material transfer processes for patterning and assembling biologically relevant materials – molecules, cells, tissues, and biodegradable biomaterials – with a prescribed organisation to accomplish one or more biological functions."<sup>1</sup>

Even though this definition is broad, Chua stated that the open definition brought out bioprinting to be considered as a set of techniques rather than a single approach. So long the technique which can transfer biological materials onto a substrate that ending up with 3D structures, thus it can be accepted as a bioprinting technique. Therefore, the main aim of bioprinting is to manufacture living functional tissues and organs to be transplanted into human bodies.<sup>2</sup> This brings towards an absolute definition by Mironov et al. who have defined bioprinting as specific as "a computer-aided layer by

<sup>1</sup>Chee Kai Chua and Wai Yee Yeong, "Bioprinting," *World Scientific* (2015), <https://doi.org/10.1142/9193>.

<sup>2</sup>*Ibid.*

layer additive biofabrication of functional 3D tissue and organ constructs based on digital model with using tissue spheroids as self-assembling building blocks.”<sup>3</sup>

In essence, bioprinting can be known as a biomedical application of rapid prototyping technology or additive manufacturing.<sup>4</sup> In technical term, this definition is much related to define 3D bioprinting as organ printing.

## 2.2 History of Bioprinting

According to Rezende et al., bioprinting has started its existence for the past one decade or more. It can be easily started with 3D printing as an additive manufacturing technique which is in essence based on computer-aided design and computer-aided manufacturing (CAD/CAM). Within 3D printing process, a two-dimensional (2D) pattern with a defined thickness will be printed by selectively adding the selected materials and 3D structures are built by piling up 2D patterns in layers. There will be automated additive process which allows 3D scaffolds to have accurate controlled architecture that are reproducibility and repeatability.<sup>5</sup>

Later on, the application of 3D printing has been applied in medical image data. Among known start off applications are magnetic resonance imaging (MRI) and computerized tomography to create patient-specific implants. In near years, the advancements in 3D printing-based approaches have allowed living cells to be embedded in the printing process as a whole. Hence, the part of living cells alongside applicable biomaterials and supporting biochemical factors to be embedded within a 3D structure has been made possible. From there, much complex 3D tissue/organ printing techniques has been developed such as dispensing, droplet, and stereolithography (SLA) techniques and applied to reproduce the complex micro-architecture, substances of the extracellular matrix (ECM) and multiple cell types in sufficient resolution.

Therefore, 3D printing has evolved into 3D tissue / organ printing which directly print living cells and specific functions of 3D printed tissue / organ analogues. The process is kicked off with design of desired tissue / organ model using 3D CAD software. All sorts of information were accessed from the medical image data including structural (external shape and internal architecture) and biological design of a 3D tissue/organ model. Another option is by doing mirroring the configuration of normal tissue / organ as a model design. After selecting 3D printing techniques to be used, the cell types (differentiated, pluripotent, or multipotent stem cells), biomaterials (synthetic or natural polymers and decellularized ECM (dECM)), and secondary biochemical factors need be selected, and the outline of these printing components is built within the 3D tissue/organ model. All parts of the components will be printed specifically according to its geometrical and in-depth size that matches all substances in a complete tissue / organ. Hence, 3D printing has proven its outstanding potential in the creation of tissue / organ implant which can be utilized for organ shortages that suits to the current need of humanity.

## 2.3 Techniques of Bioprinting

According to Christian Mandrycky et al. (2016), none of bioprinting technology is able to produce all types including complex parts of synthetic tissue. However, of four known types of bioprinting techniques i.e., inkjet printing, laser assisted printing, extrusion printing and

<sup>3</sup>Vladimir Mironov et al., “Organ Printing: Promises and Challenges,” *Regenerative Medicine* 3, no. 1 (January 2008): 93-103, <https://doi.org/10.2217/17460751.3.1.93>.

<sup>4</sup>Rodrigo A. Rezende et al., “Organ Printing as an Information Technology,” in *Procedia Engineering*, 2015, <https://doi.org/10.1016/j.proeng.2015.07.023>.

<sup>5</sup>Ibid.

stereolithography printing have their own strengths, weaknesses and differences. The comparisons can be seen from what has been summarized by Mandrycky et al., as per the following Table 1.<sup>6</sup>

Table 1. Comparison of Four Types Bioprinting Techniques

| Parameters                           | Inkjet                           | Laser-assisted                      | Extrusion                               | Stereolithography                   |
|--------------------------------------|----------------------------------|-------------------------------------|-----------------------------------------|-------------------------------------|
| Cost                                 | Low                              | High                                | Moderate                                | Low                                 |
| Cell Viability                       | >85%                             | >95%                                | 40% - 80%                               | >85%                                |
| Supported Viscosities                | 3.5 to 12 mPa/s                  | 1 to 300 mPa/s                      | 30 mPa/s to above $6 \times 10^7$ mPa/s | No limitation                       |
| Resolution                           | High                             | High                                | Moderate                                | High                                |
| Quality of vertical structure        | Poor                             | Fair                                | Good                                    | Good                                |
| Cell Density                         | Low<br><10 <sup>6</sup> cells/ml | Medium<br><10 <sup>8</sup> cells/ml | High (cell spheroids)                   | Medium<br><10 <sup>8</sup> cells/ml |
| Representative materials for bioinks | Alginate, PEGDMA, Collagen       | Collagen, Matrigel                  | Alginate, GelMA, Collagen               | GelMA, GelMA-PEGDA hybrid hydrogel  |

#### 2.4 Success Rate of Bioprinting Techniques

Smith (2016), in his research has stated that functional tissues such as skin, blood vessels, cartilage, the bladder and the uterus has been successfully obtained by a few groups of researchers. As for example, researchers at the Scripps Research Institute able to produce artificial cartilage which contained human chondrocytes in a hydrogel<sup>7</sup>. Other than that, some researchers at Cornell University have managed to create aortic valve conduits that are built from various cell types and patterned cell distribution<sup>8</sup>. Other success can be referred to following table 2 as per Reported Application by Mandrycky et al. in his literature summary.<sup>9</sup>

Table 2. Summary of Comparison of four Bioprinting Techniques

| Parameters | Inkjet | Laser-assisted | Extrusion | Stereolithography |
|------------|--------|----------------|-----------|-------------------|
|------------|--------|----------------|-----------|-------------------|

<sup>6</sup>Christian Mandrycky et al., "Research Review Paper 3D Bioprinting for Engineering Complex Tissues," *Biotechnology Advances*, 2016, <https://doi.org/10.1016/j.biotechadv.2015.12.011>.

<sup>7</sup>Suraj Kannan, "The 3D Bioprinting Revolution," *Harvard Science Review*, 2014, <https://harvardsciencereview.org/2014/05/01/the-3d-bioprinting-revolution/>.

<sup>8</sup>Bin Duan et al., "3D Bioprinting of Heterogeneous Aortic Valve Conduits with Alginate/Gelatin Hydrogels," *Journal of Biomedical Materials Research Part A* 101A, no. 5 (May 2013): 1255-64, <https://doi.org/10.1002/jbm.a.34420>; Kannan, "The 3D Bioprinting Revolution."

<sup>9</sup>Mandrycky et al., "Research Review Paper 3D Bioprinting for Engineering Complex Tissues."

| Reported Application | Tissue engineering (blood vessel, bone, cartilage, and neuron) | Tissue engineering (blood vessel, bone, skin, and adipose) | Tissue engineering (blood vessel, bone, cartilage, neuron, muscular, tumor) Controlled release of biomacromolecules Organ-on-a-chip | Tissue engineering (blood vessel and cartilage) Organ-on-a-chip |
|----------------------|----------------------------------------------------------------|------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------|
|----------------------|----------------------------------------------------------------|------------------------------------------------------------|-------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------|

### 3. Method

This research uses thematic methodology upon bioprinting current practice and past success. Literature reviews with regards to bioprinting and its ethics and legal opinion will be analysed and critically reviewed upon the same theme in finding the structure of bioprinting usage in current era. Different opinions and facts will be extracted from various kinds of literature of research and finding loopholes which can be ideally suggested for best practices of bioprinting.

### 4. Result and Discussion

#### 4.1 Ethics

There are basically two types of ethics in the current modern world. They are the Western ethics and religious ethics. Even though there hasn't been any specific writing or definitive description of these two, for the sake of ease of reference, this research analyzes the issue based on these two terms.

#### 4.1.1 Western Ethics

**4.1.1.1 Playing Nature:** There are concerns regarding the practice of bioprinting that would perhaps disrupt nature process or playing with nature in simple form by humans in various forms. The question such as to whether the tissue / organ printing will be used to replace diseased and injured tissue only or can it be used for human long-life benefit such as to fight negative consequences of human aging. Hence there would be high chance that the tissue / organ printing technology can be misused to extend human lifespan due to human greed.

In living example such as professional sports, with longing of long service in the industry or maintaining winning, some sportsmen might use bioprinted tissues for performance enhancement by gaining unnatural advancement of human capabilities. Other example such as in cosmetic industry, plastic surgeons may use organ printing technology to print body parts or tissues that are more artistically pleasing to substitute undesirable parts or diseased tissues offered for rich or affording patients to obtain easy wealth.<sup>10</sup>

Hence, there are possibilities that human will disrupt the nature process through the extension of lifespan and advancement of human capabilities through organ printing processes and advantages.

**4.1.1.2 Bioethics:** Another concern which has arisen among the researches was the ethical behavior of donors and receivers upon the existence of bioprinting technology. "Will humans' behaviour regressively change due to the enhancement?" According to Patuzzo, the use of

<sup>10</sup>Mathew Varkey and Anthony Atala, "Organ Bioprinting: A Closer Look At Ethics And Policies," *Wake Forest Journal of Law and Policy* 5, no. 2 (2014): 275-98.

enhancement is well described by the theory of “morality of wellbeing.”<sup>11</sup> The theory entailed that the morality of any meliorative intervention and its dutifulness need be included with regard to the related increase of both individual and social well being.

In contrast, human advancement can be described as repulsive aspects due to its capacity to irreversibly weaken men in their naturality together with their morality.<sup>12</sup> According to this insight, human advancement can also encompass humility, responsibility and solidarity among souls. Personal difficulties would not also be read as part of human experience, but as a mindful failure to cope with the performative standards.<sup>13</sup> With bearing in mind, under the rule of greater efficiency and productivity, policies and external powers can harm those human rights which become the pillar of our nature in liberal societies.<sup>14</sup> Furthermore, it increases the chances by means of certain uses of human enhancement with irreversible effects that will stop us to be what we would have been as we would be pre-automated by some others’ interests. In consequence, social interaction will be at stake.<sup>15</sup>

However, the debate has been enormously widening into the basic understanding of “morality of wellbeing.” The first argument mentioned that the advancement of human capacities ideally needs to correspond to one step improvement of quality of life. It is where majority of the humans would do good, better than harm and keep healthy wellbeing secured. Nonetheless, there are a few concerns such as intervention of market interest or capital intervention which will change humans’ behavior and interception that will cause misuse of the enhancement.<sup>16</sup>

#### 4.1.2 Religious Ethics

**4.1.2.1 Playing God:** One of the known religious disapprovals to modern biotechnology such as bioprinting is the “playing God” exclamation. By definition, “Play God” means to neglect God’s creation, and to do changes upon things that are “natural.”<sup>17</sup> Basically, “Playing God” has been widely used against the practice of anesthesia against pain, the birth control pill, transplantation medicine and diagnosing brain death, stem cell research, genetic engineering, and synthetic biology.<sup>18</sup> However, if doctors and scientists do not “Play God,” positive progress would not happen and humans would be devastated with lots of deaths and failures in saving human lives. Hence, the researchers have suggested that “Playing God” would be much better with ethical consideration in mind for the practitioners.<sup>19</sup>

<sup>11</sup>Sara Patuzzo et al., “3D Bioprinting Technology: Scientific Aspects and Ethical Issues,” *Science and Engineering Ethics*, June 28, 2017, <https://doi.org/10.1007/s11948-017-9918-y>.

<sup>12</sup>Kass Leon, *Leon Kass, Life, Liberty, and the Defense of Dignity: The Challenge for Bioethics* (San Francisco: Encounter Books, 2002), <https://philpapers.org/rec/KASLLA>.

<sup>13</sup>Sandel Michael J., *The Case Against Perfection: Ethics in the Age of Genetic Engineering* (Cambridge: Harvard University Press, 2007).

<sup>14</sup>Fukuyama Francis, *Our Posthuman Future: Consequences of the Biotechnology Revolution* (New York: Farrar, Strauss and Giroux, 2002), <https://www.amazon.com/Our-Posthuman-Future-Consequences-Biotechnology/dp/0312421710>.

<sup>15</sup>Habermas Jürgen, *The Future of Human Nature*, 1st ed. (Oxford: Blackwell Publishing, 2003).

<sup>16</sup>Patuzzo et al., “3D Bioprinting Technology: Scientific Aspects and Ethical Issues.”

<sup>17</sup>Jasper L. Tran, “To Bioprint or Not to Bioprint,” *SSRN Electronic Journal* 17, no. 1 (2015): 123-78, <https://doi.org/10.2139/ssrn.2562952>.

<sup>18</sup>Peter Dabrock, “Playing God? Synthetic Biology as a Theological and Ethical Challenge,” *Systems and Synthetic Biology* 3, no. 1-4 (December 10, 2009): 47-54, <https://doi.org/10.1007/s11693-009-9028-5>.

<sup>19</sup>Tran, “To Bioprint or Not to Bioprint.”

## 4.2 Religious Scholars perspective

### 4.2.1 Islam

Shari'ah, known as Islamic law, has wide concern regarding the benefits to both individual and community, which aims to sustain and guard the essential values to obtain a more suitable condition of human life<sup>20</sup>. One of the components is Maqāsid al-Shari'ah which has been known as the knowledge of the objectives or the goals that Allah (s.w.t) has notified in formulating the laws of Islam. Allah (s.w.t) has regulated a particular legislation, that has suggested good values that come out from the legislation and all harms are removed with it. The Maqāsid al-Shari'ah is important for all Islamic jurists and are bases from a clear and detailed scripts from the Holy Qur'an and *Sunnah*.<sup>21</sup> Hence, based on the researchers' view, bioprinting can act for the purpose of preserving human life where Islam has provided a crystal view of it. In Islam, there is strict forbiddence for the act of killing humans and this command can be read from many verses in the Holy Qur'an and *Sunnah* such as in Surah al-Isra' verse 33 and al-An'am verse 131. Through the method of *Sadd al-Dhara'i* (blocking the means), also a part of the method to preserve *Hifz al-Nafs* (preventing anything that could lead towards killing a soul) and this can guide best for the tissue / organ printing objectives.<sup>22</sup>

### 4.2.2 Christianity

According to a research summary, the Catholics and Orthodox Christians forbid the usage of stem cell or hESCs, therapeutic, and reproductive cell cloning since they believe that life starts from conception. While Protestant Christianity accept the research on HESCs and therapeutic cloning but prohibit reproductive cloning.<sup>23</sup> Based on current progress, there hasn't been any specific writing that prove religious Christians would accept Bioprinting as life saving. But most of the Christians scholars have written about its' ethical usage in current modern practice.

### 4.2.3 Other religions

There haven't been any specific writings in other faiths such as Judaism, Buddhism and Hinduism's opinion with regards to bioprinting.

## 4.3 Law

### 4.3.1 Intellectual Property

Another legal issue arose with regard to the bioprinting practice that it would be an intellectual property. There is an argument mentioned that intellectual property is able to protect all steps in the bioprinting process, from the first step till its' machine and every detailed item involved. This can be done through Patent system. Some laws such as United States Code permits patents on "any new and useful process, machine, manufacturing or composition of matter." Based on this definition, products of nature are not patent-permissible. However, variations of naturally occurring organisms can be patented. Based on the US Supreme Court's landmark decision on *Association for Molecular*

<sup>20</sup>Mohd Anuar Ramli et al., "The Realization of Islamic Jurisprudence Transformation in the Classical and Contemporary Fiqh Issues," *Al-Qanatir: International Journal of Islamic Studies* 12, no. 1 (2018): 10-21, <https://al-qanatir.com/index.php/qanatir/article/view/128/99>.

<sup>21</sup>Hamdan MA et al., "The Application of Maqasid-Oriented Approach in Islamic Bioethics: A Case Study on Fatwa Related to Cosmetic, Plastic and Reconstructive Surgery," *IJUM Medical Journal Malaysia* 20, no. 1 (January 5, 2021), <https://doi.org/10.31436/imjm.v20i1.1781>.

<sup>22</sup>Ahmad Syukran bin Baharuddin et al., "Three-Dimensional (3D) Bioprinting of Human Organs in Realising," *Perintis UTM* 4, no. 2 (2014): 27-42.

<sup>23</sup>S. Vijayavenkataraman, W.F. Lu, and J.Y.H. Fuh, "3D Bioprinting – An Ethical, Legal and Social Aspects (ELSA) Framework," *Bioprinting* 1-2 (March 2016): 11-21, <https://doi.org/10.1016/j.bprint.2016.08.001>.

*Pathology vs. Myriad Genetics Inc.*”, the Court held that patents on isolated, naturally occurring DNA segments were not valid. They have ruled that the patented research work did not create or alter any of the genetic information encoded in the genes. “However, patents on complementary DNA, which is synthetically created DNA, are valid because complementary DNA are not natural products of nature.” Based on this argument, patents for human organs will not be valid since it doesn’t change the original, but it is still not crystal clear whether an artificially created substance added printed organ would be patent-eligible.<sup>24</sup>

In Malaysia, intellectual properties law includes patent, copyrights, trademark and design. It started with the passing bill of Inventions Ordinance 1871 back in 1871 under British colonialism. The main act of the 1871 Enactment permitted the application of exclusive rights for any inventions which were new. It also included full ranges of rightful rights of an item including compulsory licensing, cessation of privileges and revocation of privileges. Later on, the Straits Settlement’s Council passed the Telegraphic Copyright Ordinance 32. The Ordinance provided the private right to the person receiving a telegram news to issue it to public which then known as Copyright. The duration of protection provided by this Ordinance is up to 48 hours from the time of first publication. There would be no individual able to print or publish the news without any consent in writing from the person who received the news. This Ordinance has been introduced to Labuan up till 1951 when it has been repealed, revoked and cancelled. Different practices of local Trademarks and Copyright law has been practiced by states under Federated Malay Union. Till today, the Patent Act, Trade Marks Act 1976 and the Trade Practices Act 1972 are still practiced in Malaysia. (Ida Madieha A. Ghani, 1995).

In current years, Patent law in Malaysia is well practiced. It also has a specific exclusion for methods of medical treatment. The paragraph on this matter in Patent Act 1983 is as follow:

- (1) Notwithstanding the fact that they may be inventions within the meaning of S.12, the following shall not be patentable:
- (d) methods for the treatment of human or animal body by surgery or therapy, and diagnostic methods practised on the human or animal body:

provided that this paragraph shall not apply to products used in any such methods.<sup>25</sup>

Hence, bioprinting as methodology for medication might not be able to be patented and only it’s product can be patented as new in Malaysia. Hence, bioprinted organ / tissue can be patented.

#### 4.3.2 Organ Trade

According to Marina’s literature review on organ trafficking in Malaysia, due to phenomenal organ shortages in Malaysia (especially of kidneys), the researchers have concluded that some Malaysians seek to undergo organ transplantation abroad, predominantly in two countries: China and India. Increasingly, scholars have suggested that bioprinting may be used to produce more complex organs such as hearts, livers and kidneys, thereby revolutionizing organ transplantation and addressing organ shortages worldwide.<sup>26</sup> The researchers in their literature suggest that bioprinting is not only the cure to organ shortages problem that arose but also a solution to the

<sup>24</sup>Varkey and Atala, “Organ Bioprinting: A Closer Look At Ethics And Policies.”

<sup>25</sup>Patents Act 1983 (Act A863, as amended up to Patents (Amendment) Act 2003), Intellectual Property Corporation of Malaysia.

<sup>26</sup>Marina Abdul Majid, “Combating Malaysia’s Involvement in Worldwide Organ Trafficking by Tapping into the Potential of Bioprinting,” *GATR Global Journal of Business Social Sciences Review* 7, no. 1 (February 21, 2019): 61-74, [https://doi.org/10.35609/gjbsr.2019.7.1\(8\)](https://doi.org/10.35609/gjbsr.2019.7.1(8)).

worldwide problem of illegal organ harvesting related to transplantation tourism. While Andreas<sup>27</sup> as well as Li and Faulkner<sup>28</sup> are optimistic that 3D printing in general may bring a fullstop to illegal global transfers, thus reducing transnationally organized crime across borders that supply illegal goods including human organs. However, Vermeulen et al. caution that bioprinting may brought the founding of a new black market of biofabricated organs.<sup>29</sup>

#### 4.3.3 Blueprint

One problem that may arise in organ printing is when the patients' own cells get damaged on account of medical reasons and cannot be used to bioprint the organ and this then lead to seek help from other party or donor. Hence, question of ownership will then arise. Among questions that will be of great concern:

- Will the organ that is printed using the donor's cells belong to the donor?
- Or does it belong to the third party involved like the clinician or Bioprinting Company or the hospital?
- Or is it a shared ownership?

First the problem of ownership has been an issue with tissue-engineered products but it becomes much complex when it is about bioprinted organs. People's perception changes when we talk of organs rather than tissues. People will appreciate a functional organ like a kidney or heart than a tissue graft. Second, there might be different ranges for different type of organs under different conditions. For example, a brain donor with a heart or brain made out of their cell would be marked as high class if his or her mental health is stable despite of his bone's graft or orthopedic constructs. Such convolutions need be resolved and understood before making a guideline for the ownership of bioprinted organs.<sup>30</sup>

For practice in Malaysia, the ownership of the blueprint can be the same as the right of a patent which has been underlined under Section 18 of Patent Act 1983, Right to a patent:

- (1) Any person may make an application for a patent either alone or jointly with another.
- (2) Subject to section 19, the rights to a patent shall belong to the inventor.
- (3) Where two or more persons have jointly made an invention, the rights to a patent shall belong to them jointly.
- (4) If two or more persons have separately and independently made the same invention, and each of them has made an application for a patent, the right to a patent for that invention shall belong to the person whose application has the earliest priority date.<sup>31</sup>

<sup>27</sup>Andreas Peter, "The Global Illicit Economy 2030," in *Global Flow Security Working Papers*, ed. Brattberg Erik and Hamilton Daniel S., 1st ed. (Washington DC: The Paul H. Nitze School of Advanced International Studies, 2014), 1–8.

<sup>28</sup>Phoebe Li and Alex Faulkner, "3D Bioprinting Regulations: A UK/EU Perspective," *European Journal of Risk Regulation* 8, no. 2 (June 21, 2017): 441–47, <https://doi.org/10.1017/err.2017.19>.

<sup>29</sup>Niki Vermeulen et al., "3D Bioprint Me: A Socioethical View of Bioprinting Human Organs and Tissues," *Journal of Medical Ethics* 43, no. 9 (September 2017): 618–24, <https://doi.org/10.1136/medethics-2015-103347>.

<sup>30</sup>Vijayavenkataraman, Lu, and Fuh, "3D Bioprinting – An Ethical, Legal and Social Aspects (ELSA) Framework."

<sup>31</sup>"Laws of Malaysia- Act 291, Patents Act 1983," <https://www.myipo.gov.my/wp-content/uploads/2016/09/PATENT-ACT-1983-ACT-291.pdf>

#### 4.4 Consent

Other related problem of bioprinting is consent. The donor needs to be informed and provide his / her consent on the usage of his / her cell. This would prevent the use of donated cells or tissues for other purposes than the intended ones (as informed to the donors). It is compulsory for donors to be clearly informed on how the donated cells or tissues will be used in research or for transplantation. Such act is important since there would be possibilities that there are donors who have reservations of certain practices. Let's say if their cells are to be used for research cloning or for constructing a tissue that will be tested in vivo in a porcine model and at the same time they are Catholic Christians whom disbelieve in cloning. Based on their religious and cultural beliefs and moral perspectives, it would be highly unethical if the donated cells or tissues are used for the said purposes which contradict with their belief and are not be briefed to the them i.e., the donors beforehand and before consent is obtained.<sup>32</sup>

#### 4.5 *Sharī'ah* Compliant

To discuss with regard to *Sharī'ah* compliance, one need to verify the very meaning of *Sharī'ah*. In essence, *Sharī'ah* is an Islamic law based on the tenets of the Holy Qur'ān and *Sunnah*. It prescribes both religious and secular duties which includes punitive penalties for law breaking. The Muslim individual need comply with *Sharī'ah* that cover all spheres of his life. In nature, *Sharī'ah* would always work hand in hand with essence of humanity.<sup>33</sup>

With this definition, it is empirical that *Sharī'ah* Compliance is a systematic outline of human interactions which are guided by the Muslims scholars' interpretation of the Holy Qur'ān and *Sunnah*. In modern practice, there are several *Sharī'ah* Compliant's guideline or structure within the Muslim and non-Muslim community. They are Halal Tourism system, Islamic Banking *Sharī'ah* Compliant System, Halal Hotel *Sharī'ah* Compliant System and Food and Beverage Halal System that can be a stepping stone to derive *Sharī'ah* Compliant System for other industry as well.

### 5. Conclusion

The advancement of the technology of 3D bioprinting has been basically a life-saving innovation and its existence has huge potential and has been much felt by the scientists and clinicians. It may save many shortages cases which had occurred across the globe and nationwide. Many lives can be saved with doctors and scientists "Playing God" with the technology and follow all the ethical and social aspects of Bioprinting practices.

Even though bioprinting ethically and legally has been successfully translated in the conventional market and research, there is still a loophole missing as the marketing of the technology for 1.9 billion Muslims globally is concerned<sup>34</sup>. With an ELSA framework for 3D bioprinting technology has been prudently explained, a complete *Sharī'ah* Compliant system for Bioprinting has yet to be developed in order for the authorities to help the Muslims mobilised the usage of Bioprinting in masses market.

Hence, this paper would call for a *Sharī'ah* Compliant Model of 3D Bioprinting to be initiated as it is very important for the Muslims to live along with non-Muslims as well as for the sake of the growth of humanity and its existence within the current humanity system.

<sup>32</sup>Vijayavenkataraman, Lu, and Fuh.

<sup>33</sup>Nurul Farhan Osman, "'Shariah Compliance,'" Amanie: Global Islamic Finance Advisors, 2017.

<sup>34</sup>"Muslim Population by Country 2021," *World Population Review*, 2021, <https://worldpopulationreview.com/country-rankings/muslim-population-by-country>.

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