

## **APPRAISING THE LEGAL AND PHILOSOPHICAL ISSUES IN EUTHANASIA AND XENOTRANSPLANTATION THROUGH INTERNATIONAL LAW**

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**Abstract:** Euthanasia (which can be referred to as “mercy killing” or “letting die”) and xenotransplantation, the efforts to keep alive at all costs through the placing of animal organs into human body has raised legal and philosophical issues. Legal and philosophical issues on right to life and human dignity as entrenched in international legal instruments relating thereto. The main question this article seeks to answer is whether there is a body of international law supporting right to die as opposed to right to live. In discussing the above, this article adopts a theoretical and doctrinal study of primary and secondary sources as contained in the international treaties, conventions and protocols, journal articles, books, newspapers, and materials sourced from the internet. The article observes that though, right to die does not exist in any instruments of international law, euthanasia itself is not an impediment to the right to life if it is supported with robust regulation in ensuring compliance with the free, informed, and clear decision of patient to prevent abuse by medical practitioners. It concludes that in developing the medical innovation of xenotransplantation, adequate and comprehensive global regulations on responsible treatment of animals, and adequate and transparent informed consent are very crucial in ensuring ethical and safe practices.

**Keywords:** *Euthanasia, International Law, Legal, Lens, Philosophical, Xenotransplantation.*

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## I. INTRODUCTION

Two of the most controversial and provocative procedures in modern bioethics are euthanasia and xenotransplantation. Euthanasia could just be considered an addendum to ultimate death. This subject has attracted a lot of debate. This problem generates conflict between theologians and moral thinkers.<sup>1</sup> It questions long-standing moral standards on the dignity of life and the allowed limits of human action, therefore creating great ethical conundrums. Conversely, xenotransplantation, most usually from animals to humans is the transplantation of organs, tissues, or cells from one species, into another.<sup>2</sup> Though it also raises difficult issues regarding interspecies ethics, human identity, and the limits of medical intervention, this approach emerges as possible succour to the urgent shortage of human organs accessible for transplantation.<sup>3</sup>

Ethical and legal questions concerning euthanasia and xenotransplantation highlight their wider social consequences. Both techniques force us to consider basic ideas such as autonomy, dignity, and the sanctity of life. For example, euthanasia questions the function of medical experts as defenders of life and examines the boundaries of personal freedom in choosing one's fate.<sup>4</sup> Xenotransplantation similarly begs ethical issues regarding the handling of animals and the dangers of crossing species borders including genetic contamination and zoonotic illnesses.<sup>5</sup> These methods call for a sophisticated ethical framework that balances personal liberties with group obligations and a legal system fit for handling their inherent risks and moral complexity.

For various reasons, considering euthanasia and xenotransplantation through the prism of international law is crucial. First, given advances in medical research and technology that cut across national boundaries, these activities are progressively worldwide in scope. For instance, under rigorous regulatory systems, euthanasia is legally allowed in nations like the Netherlands and Belgium; yet, xenotransplantation research and clinical trials are subject to varied degrees of control depending on the country.<sup>6</sup> The variances in the legal standard draw attention to the

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<sup>1</sup> Victor Adefarasin. 'Euthanasia: An Act of Mercy or Murder?' (2012) 4 *Journal of Arts and Contemporary Societies*. 69

<sup>2</sup> Nourhan Eissa., et.al. 'Xenotransplantation: Past, Present, and Future Directions' (2022) 5 *Highlights in Bioscience*. 13

<sup>3</sup> Megan Sykes, & David Sachs. 'Transplanting Organs from Pigs to Humans' (2019) 4 *Science Immunology*. 2-3

<sup>4</sup> Sundaresh Menon. 'Euthanasia: A Matter of Life or Death' (2013)54(3) *Singapore Medical Journal*. 118

<sup>5</sup> Joachim Denner., 'Recent Progress in Xenotransplantation, with Emphasis on Virological Safety' (2016) 21 *Annals of Transplantation*. 718

<sup>6</sup> Penney Lewis, *Assisted Dying and Legal Change* (Oxford University, 2007). 1

requirement of a unified global strategy that values cultural variety while guaranteeing ethical consistency.

Furthermore, the philosophical discussions underlining euthanasia and xenotransplantation mirror universal human worries about life, death, and the moral application of medical achievements.<sup>7</sup> These discussions compel us to consider the possibility of such transforming methods co-existing with our ethical standards without compromising the fundamental values sustaining society's cohesiveness. Is it right, for example, to give personal liberty in euthanasia priority while placing group ethical limits on xenotransplantation? How can we weigh the moral expenses of experimental treatments against the necessity to reduce human suffering?

With an eye toward the larger framework of international law, this paper seeks to investigate the moral and legal questions in euthanasia and xenotransplantation. It aims to highlight their common ethical conundrums and special difficulties. While considering the consequences of these arguments for legal harmonization and worldwide policy development, the study will interact with fundamental philosophical ideas including dignity, autonomy, and the sanctity of life. Through this analysis, the debate will help to clarify how society may negotiate the moral complexity of these provocative medical frontiers.

## II. EUTHANASIA: A COMPLEX ISSUE

Euthanasia etymologically derived from the Greek words eu (good) and thanatos (death), refers to the intentional act of putting an end to a person's life to alleviate suffering, especially in cases of terminal illness or intractable pain.<sup>8</sup> This practice is often distinguished from related concepts such as physician-assisted suicide, where the individual ultimately administers the means to their death. In euthanasia, another party, typically a medical professional, directly causes the death of the patient.<sup>9</sup> Philosophical implications of euthanasia are profound, raising critical questions about morality, autonomy, and the ethical dimensions of life and death decisions.

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<sup>7</sup> Nataliia M. Boichenko, & N.A Fialko. 'Legitimation of Euthanasia Decisions: A Philosophical Assessment of the Assisted Life Termination' (2023)24 *Anthropological Measurements of Philosophical Research*. 18-26

<sup>8</sup> Friday Ojonugwa Agbo, Daniel Philemon Saredu, & Ani Ogoma Sunday. 'Examining Euthanasia through the Lenses of Nigerian and Islamic Laws' (2024) 2 *East African Journal of Law, Policy and Globalization*. 54-73

<sup>9</sup> Diyora Suxrobovna Xaydarova, et.al. 'Euthanasia as A Humanistic Problem in Modern Medicine' (2023) 4 *Science And Education*. 57-64

The definition of euthanasia encompasses various nuances that reflect its complex moral landscape. According to Smith,<sup>10</sup> euthanasia involves several key elements: an agent who performs the act, a subject whose life is ended, an intention to cause death, and a causal relationship between the agent's actions and the outcome. This definition underscores the deliberate nature of euthanasia as an intervention aimed at relieving suffering. Furthermore, it is essential to differentiate between euthanasia and other practices such as withdrawing life-sustaining treatment or palliative care, which may not involve an intention to hasten death but rather focus on comfort and quality of life. The legal frameworks governing euthanasia vary significantly across jurisdictions. In countries like the Netherlands and Belgium, both active and passive voluntary euthanasia are legal under strict conditions that emphasize patient autonomy and informed consent.<sup>11</sup> For instance, Dutch law requirement is that patients are faced with unbearable suffering with no hope of improvement and their request for euthanasia is made voluntarily and persistently.<sup>12</sup> In Canada, the legislation permits "medical assistance in dying" (MAID) for individuals suffering from "grievous and irremediable conditions" while maintaining safeguards against potential abuses.<sup>13</sup> These legal frameworks reflect evolving societal attitudes toward end-of-life choices and highlight the importance of balancing individual rights with ethical considerations.

Philosophically, euthanasia raises significant debates surrounding autonomy, dignity, and the sanctity of life. Proponents argue that respecting individual autonomy is paramount; individuals should have the right to decide on their lives and deaths without external interference.<sup>14</sup> This perspective supports that of the liberal ethical theories that give priority to personal freedom and self-determination. Advocates also emphasize the compassionate aspect of euthanasia as a means to alleviate unbearable suffering, arguing that allowing individuals to die with dignity is a moral imperative when faced with terminal illness or severe pain.

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<sup>10</sup> Patrick T. Smith. 'Ramsey on "Choosing Life" At the End of Life: Conceptual Analysis of Euthanasia and Adjudicating End-of-Life Care Options' (2018) 24 *Christian Bioethics*. 151-172

<sup>11</sup> Andreas Fontalis, Efthymia Prousalis, & Kunal Kulkarni. 'Euthanasia and Assisted Dying: What Is the Current Position and What Are the Key Arguments Informing the Debate?' (2018) 111 *Journal of the Royal Society of Medicine*. 408

<sup>12</sup> Pauline S. C. Kouwenhoven, et.al. 'Developments In Euthanasia Practice in the Netherlands: Balancing Professional Responsibility and the Patient's Autonomy'. (2019)25 *European Journal of General Practice*. 44

<sup>13</sup> Peter Driftmire, & Jessica Shaw. 'Medical Assistance in Dying (MAiD) for Canadian Prisoners: A Case Series of Barriers to Care in Completed MAiD Deaths' (2021) 5 *Health Equity*. 850

<sup>14</sup> John Scott, & Mary Scott. 'Suffering As a Criterion for Medical Assistance in Dying' in *Medical Assistance in Dying (Maid) In Canada: Key Multidisciplinary Perspectives* (Jaro Kotalik & David Shannon eds., 2023). 211

Conversely, opponents often invoke the will to live principle, asserting that life is valuable and should not be terminated intentionally.<sup>15</sup> This viewpoint is frequently influenced by religious beliefs that regard life as a gift from a higher power. Critics argue that legalizing euthanasia could result to a slippery slope where vulnerable individuals may be pressurised to choose death.<sup>16</sup> Additionally, concerns about potential abuses of power in medical settings raise ethical questions about whether physicians can be trusted to make life-and-death decisions impartially.

The debate also encompasses practical considerations regarding medical ethics. The Hippocratic Oath traditionally emphasizes preserving life and doing no harm; thus, many healthcare professionals grapple with reconciling their ethical obligations with patients' requests for assisted dying.<sup>17</sup> The Doctrine of Double Effect provides a framework for understanding situations where actions intended to relieve suffering may inadvertently hasten death; however, distinguishing between palliative care and euthanasia remains contentious within medical practice.<sup>18</sup>

## 2.1 Types of Euthanasia

Euthanasia is classified depending on the type of consent and the method of execution:

### 2.1.1 Active euthanasia

This is the intentional act of ending a life; by giving a deadly drug dosage. While supporters, such as James Rachels, justify this practice on the reason of compassion and minimizing suffering, others claim that it amounts to homicide.<sup>19</sup> In a few nations, for example; Belgium, Canada, Switzerland, active euthanasia is restricted to specified situations and the approval of councillors and doctors or other experts.<sup>20</sup> In Belgium, "patients qualify for euthanasia only if they have an incurable illness and experience constant, intolerable physical or mental suffering that cannot be

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<sup>15</sup> Marvin Lim. 'A New Approach to the Ethics of Life: The Will to Live in Lieu of Inherent Dignity or Autonomy-Based Approaches'. (2014) 24 *Southern California Interdisciplinary Law Journal*. 145

<sup>16</sup> Friderik Klampfer. 'Euthanasia Laws, Slippery Slopes, and (Un) Reasonable Precaution', (2019)18 *Prolegomena*. 121

<sup>17</sup> Russo, Raimondo G. *Medical Ethics. Germany*, (Springer Nature Switzerland, Imprint: Springer, 2023). 1

<sup>18</sup> Kasper Raus, Sigrid Sterckx, & Freddy Mortier. 'Can the doctrine of double effect justify continuous deep sedation at the end of life?' In *Continuous Sedation at the End of Life: Ethical, Clinical and Legal Perspectives* (Kasper Raus, Sigrid Sterckx, & Freddy Mortier ed.,2013). 177

<sup>19</sup> James Rachels. 'Active and Passive Euthanasia' In, *Killing and Letting Die* (A. Norcross, & B. Steinbock Eds.,1994). 112

<sup>20</sup> Aluko-Arowolo, S et.al 'Motivations, and Mechanisms of End-of-Life Issues: The Reflections on the Right to, and Not to Die Among Yoruba, Nigeria', (2020) 6 *NIU Journal of Social Sciences*. 178

alleviated. They also have to expressly repeat an explicit request for assisted death, which must be proven thoroughly thought-through and not subject to any outside pressure.”<sup>21</sup>

### 2.1.2 Euthanasia Passive Approach

With passive euthanasia, life-sustaining medications are stopped or withheld, therefore allowing natural death. Although it is sometimes considered less morally controversial, it nevertheless begs discussion on the part intent and responsibility play in accelerating death.<sup>22</sup> Legal under some situations in several nations, passive euthanasia also known as “pulling the plug” is illegal in others.<sup>23</sup>

### 2.1.3 Euthanasia Voluntary

Voluntary euthanasia is carried out under clear individual permission. Philosophical debates here usually centre on respect for autonomy, and people’s freedom to make decisions about their life and death.<sup>24</sup>

### 2.1.4 Euthanasia Non-Voluntary

When someone cannot provide permission as in circumstances of extreme incapacity or coma, non-voluntary euthanasia results. This kind begs moral questions about the risk of misuse and surrogate decision-making.<sup>25</sup>

## 2.2 Legal Framework on Euthanasia

The legal framework on euthanasia differs greatly throughout countries, reflecting religious, ethical, and cultural values:

Netherlands under the Termination of Life on Request and Assisted Suicide (Review Procedures) Act, 2002, the Netherlands became the first nation to legalize euthanasia under tight guidelines.

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<sup>21</sup> Anca Ulea & AFP, ‘Right to Die: Belgium Marks Two Decades Since It Legalised Euthanasia’ Euro News, May 28 2022. <<https://www.euronews.com/2022/05/28/right-to-die-belgium-marks-two-decades-since-it-legalised-euthanasia>> accessed 22 October 2024

<sup>22</sup> Tom L. Beauchamp & James F. Childress. *Principles of Biomedical Ethics* (Oxford University Press, 2019)

<sup>23</sup> Aluko-Arowolo (n 20) 176

<sup>24</sup> Steven Ross, ‘Life's Dominion: An Argument about Abortion, Euthanasia, and Individual Freedom by Ronald Dworkin’ (1994) 25(1) *Metaphilosophy*. 96-101

<sup>25</sup> Peter Singer, *Practical Ethics*. (Cambridge University Press, 2011). 12

The legislation mandates that the patient's request be voluntary and well-considered and that their suffering is intolerable with no hope of improvement.<sup>26</sup>

Belgium enables adults going through continuous, intolerable physical or psychological suffering to be euthanized. Belgium has approved euthanasia for minors under strict guidelines, which fuels worldwide ethical discussions.<sup>27</sup>

The Medical Assistance in Dying (MAID) Act helped Canada to legalize euthanasia in 2016. The 2021 revisions to Canada's MAID law created a two-track approach to procedural safeguards for medical practitioners to follow, based on whether a person's natural death is reasonably foreseeable. This approach to safeguards ensures that sufficient time and expertise are spent assessing MAID requests from persons whose natural death is not reasonably foreseeable while easing procedural safeguards in cases where natural death is reasonably foreseeable.<sup>28</sup>

## 2.3 Philosophical Debates on Euthanasia

### 2.3.1 Autonomy

A key philosophical defense of euthanasia is autonomy. Advocates argue that people should be free to decide when and how they die since this honours their liberty and autonomy.<sup>29</sup> Critics like Leon Kass, however, contend that the sanctity of life limits human autonomy and caution against the social consequences of approving euthanasia.<sup>30</sup>

### 2.3.2 Equity Euthanasia

This is sometimes presented by supporters as a way to honour dignity in the face of the crippling disease. They contend that extended suffering reduces the quality of life and that euthanasia is a kind decision. Opponents such as John Finnis, on the other hand, contend that psychological or physical suffering cannot reduce human dignity since it is natural.<sup>31</sup>

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<sup>26</sup> Agnes van der Heide, Johannes J M van Delden, & Bregje D Onwuteaka-Philipsen. 'End-of-life decisions in the Netherlands over 25 years' (2017) 377 *New England Journal of Medicine*. 492

<sup>27</sup> Caroline Ong. 'Legalising Euthanasia for Children: Dying With 'Dignity' or Killing the Vulnerable?' (2014) 20 *Chisholm Health Ethics Bulletin*. 5

<sup>28</sup> Government of Canada, *Canada's medical assistance in dying (MAID) law*, <[https://www.justice.gc.ca/eng/cj-jp/ad-am/bk-di.html#s3\\_1](https://www.justice.gc.ca/eng/cj-jp/ad-am/bk-di.html#s3_1)> accessed 24 October 2024

<sup>29</sup> Stven Ross (n 24)

<sup>30</sup> Leon R. Kass. 'Neither For Love Nor Money: Why Doctors Must Not Kill', (1989) 94 *Public Interest*. 25

<sup>31</sup> John M. Finnis, *Natural Law and Natural Rights* (Oxford University Press, 2011).48

### 2.3.3 *Life's Sanctity*

Rooted in religious and moral traditions, the idea of the sanctity of life maintains that life is essentially important and should not be intentionally ended. According to Thomas Aquinas's natural law doctrine, life taken against divine law and natural order is against natural law and natural order. Secular ethicists who advocate contextual moral reasoning contest this point of view.<sup>32</sup>

### 2.3.4 *Approaches from utilitarianism*

Emphasizing the decrease of suffering and the maximizing of general well-being. Thinkers like Peter Singer favour euthanasia. They contend that ending life might be ethically permissible when it starts to cause intolerable suffering.<sup>33</sup> Critics warn that utilitarian methods run the danger of devaluating life depending on arbitrary criteria of usefulness.

### 2.3.5 *Slippery Slope Arguments*

Legalizing euthanasia runs the danger of creating abuses, including coercion of vulnerable people or expansion to non-terminal cases, according to critics who warn of a slippery slope. Empirical research from Belgium and the Netherlands offers conflicting results; some show strict protections while others draw attention to worrying developments.<sup>34</sup>

## III. XENOTRANSPLANTATION: A MEDICAL FRONTIER

Xenotransplantation is the process of retrieving organs, tissues, or cells from one species and transplanting them into another. Derived from the Greek "xeno," (foreign) and Latin "transplantare," (to transfer), xenotransplantation entails placing of living cells, tissues, or organs from one specie into another.<sup>35</sup> Most usually, it entails replacing or enhancing human biological processes using animal organs or tissues. The technique seeks to solve the worldwide scarcity of human donor organs, therefore offering a possible answer to the rising demand for life-saving

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<sup>32</sup> Singer (n 25) 12

<sup>33</sup> *Ibid.*

<sup>34</sup> José Pereira. 'Legalizing Euthanasia or Assisted Suicide: The Illusion of Safeguards and Controls' (2011)18 *Current Oncology* 38-45

<sup>35</sup> David K C Cooper, 'A Brief History of Cross-Species Organ Transplantation' (2012) 25 *Baylor University Medical Center Proceedings* 49



transplants.<sup>36</sup> There are more efforts to address human organ scarcity through the generation of human organs within human-pig chimeras<sup>37</sup> and the development of organoids, which are lab-generated human mini-organ prototypes.<sup>38</sup> Although this is not within the scope of our discussion, it is important to point out the rapid development of biotechnology today.

Xenotransplantation has long been seen as the ultimate solution to the high shortage of human organs available for transplantation.<sup>39</sup> This area gained prominence in medical research in the wake of human organ shortage to cater to the patients of end-stage organs. Xenotransplantation came into existence in the 20th century, with kidney xenografts from animals such as pigs, goats, and non-human primate donors like chimpanzees and baboons. However, due to the high mortality of the transplanted organs and the patient, the practice was abandoned.<sup>40</sup>

The first documented of its kind as it relates to heart xenotransplantation took place in 2022 at the University of Maryland Medical Centre (UMMC) with the University of Maryland School of Medicine.<sup>41</sup> However, Mr Benneth, the patient died two months later.<sup>42</sup> Mr. Bennett was in end-stage heart failure and did not qualify for a traditional heart transplant. The procedure was approved by the U.S. Food and Drug Administration under its (compassionate use) provision.<sup>43</sup>

Bartley P. Griffith, MD who carried out the surgery stated that “We are devastated by the loss of Mr. Bennett. He proved to be a brave and noble patient who fought to the end, We extend our

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<sup>36</sup> Bahar Bastani. ‘The Present and Future of Transplant Organ Shortage: Some Potential Remedies’. (2020) 33 *Journal of Nephrology* 227

<sup>37</sup> Julian Koplin, & Julian Savulescu. ‘Time to Rethink the Law On Part-Human Chimeras’, (2019) 6 *Journal of Law and the Biosciences* 37

<sup>38</sup> Inesa Fausch. ‘The Law for Mini-Organ Prototypes in a Dish. Mapping the Legal Status Options for Organoids in Swiss Law’ (2024) 11 *Journal of Law and the Biosciences* 20

<sup>39</sup> Wayne J Hawthorne. ‘Ethical and Legislative Advances in Xenotransplantation for Clinical Translation: Focusing on Cardiac, Kidney, and Islet Cell Xenotransplantation’. (2024)15 *Frontiers In Immunology* 2

<sup>40</sup> OECD, (1999) OECD ‘Proceedings: Xenotransplantation International Policy Issues’. <[https://www.oecd.org/content/dam/oecd/en/publications/reports/1999/03/xenotransplantation\\_g1gh2528/9789264172654-en.pdf](https://www.oecd.org/content/dam/oecd/en/publications/reports/1999/03/xenotransplantation_g1gh2528/9789264172654-en.pdf)> accessed 25 October 2024

<sup>41</sup> Deborah Kotz., UM ‘Medicine Performs Historic Xenotransplantation’ UMB News, 11, January, 2022.<<https://www.umaryland.edu/news/archived-news/january-2022/um-medicine-performs-historic-xenotransplantation.php>> accessed 25 October 2024

<sup>42</sup> Deborah Kotz., ‘IN MEMORIAM: David Bennett, Sr.’ UMB News, 9 March, 2022.<<https://www.medschool.umaryland.edu/news/2022/in-memoriam-david-bennett-sr.html>> accessed 26 October 2024

<sup>43</sup> Deborah Kotz., ‘Lessons Learned from World’s First Successful Transplant of Genetically-Modified Pig Heart into Human Patient’ UMB News, 30 June, 2023. <<https://www.medschool.umaryland.edu/news/2023/lessons-learned-from-worlds-first-successful-transplant-of-genetically-modified-pig-heart-into-human-patient-.html>> accessed 26 October 2024

sincerest condolences to his family.”<sup>44</sup> Muhammad M. Mohiuddin, MD, a Professor of Surgery and Scientific Director of the Cardiac Xenotransplantation Program at UMSOM, expressed optimism that:

*“We have gained invaluable insights learning that the genetically modified pig heart can function well within the human body while the immune system is adequately suppressed. We remain optimistic and plan on continuing our work in future clinical trials.”*<sup>45</sup>

True to their optimistic stance, a 58-year-old patient, Mr. Lawrence Faucette with a terminal heart disease became the second patient in the world to receive a epoch making transplant of a genetically modified pig heart on September 20, 2023. This is the second time in the world that a genetically modified pig heart has been transplanted into a living patient.<sup>46</sup> Mr. Faucette received the transplant on September 20 and lived for almost six weeks after the surgery but died on October 30, 2023.<sup>47</sup>

In the first documented kidney xenotransplantation, Harvard Medical School physician-scientists at Massachusetts General Hospital transplanted a genetically modified pig kidney into a human in early 2024. The patient, 62-year-old Richard Slayman of Weymouth, Massachusetts got the kidney in a four-hour surgery on March 16, 2024.<sup>48</sup> However, barely two months later, Richard Slayman died.<sup>49</sup>

On April 12, 2024, Lisa Pisano, a 54-year-old woman in New Jersey who had heart failure and end-stage kidney disease and was on dialysis, became the second person to receive a genetically modified pig kidney. She was not eligible to receive a human heart and kidney transplant because

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<sup>44</sup> Kotz (n 42)

<sup>45</sup> *Ibid.*

<sup>46</sup> Deborah Kotz., ‘UM Medicine Faculty-Scientists and Clinicians Perform Second Historic Transplant of Pig Heart into Patient with End-Stage Cardiovascular Disease’ UMB News, 22 September 22, 2023. <<https://www.medschool.umaryland.edu/news/2023/um-medicine-faculty-scientists-and-clinicians-perform-second-historic-transplant-of-pig-heart-into-patient-with-end-stage-cardiovascular-disease.html>> accessed 27 October 2024

<sup>47</sup> Deborah Kotz., ‘In Memoriam: Lawrence Faucette’ UMB News, 31 October, 2023 <<https://www.medschool.umaryland.edu/news/2023/in-memoriam-lawrence-faucette.html>> accessed 27 October 2024

<sup>48</sup> Mass General Brigham Communications, ‘In a First, Genetically Edited Pig Kidney Is Transplanted Into Human’ <<https://hms.harvard.edu/news/first-genetically-edited-pig-kidney-transplanted-human>> accessed 27 October 2024

<sup>49</sup> Virginia Hughes. ‘Patient Dies Weeks After Kidney Transplant from Genetically Modified Pig’ The New York Times, 12 May, 2024. <<https://www.nytimes.com/2024/05/12/health/richard-slayman-death-pig-kidney-transplant.html>> accessed 27 October 2024

she had many issues that would have made finding both organ and survival unlikely.<sup>50</sup> Her experimental surgery was performed under the U.S. Food and Drug Administration's Expanded Access program, also referred to as "compassionate use": an option for people with serious disease and few treatment options.<sup>51</sup> However, Lisa Pisano passed away on July 7, 2024.

The heart pump implanted in her failed to supply enough blood to her transplanted pig kidney, and the organ was removed on May 29 2024 when she was put back on dialysis before her death on July 7, 2024.<sup>52</sup> In responding to the incident, Dr. Robert Montgomery, director of the NYU Langone Transplant Institute where the transplant took place, said: "Lisa's contributions to medicine, surgery, and xenotransplantation cannot be overstated. ... Lisa helped bring us closer to realizing a future where someone does not have to die for another person to live."<sup>53</sup> Efforts are being made by scientists and surgeons to ensure the availability of organs for human use through the rearing of genetically modified pigs whose organs are similar to human's.

Philosophically, xenotransplantation brings to the fore the question of identity, ethics, and the core of being human by stretching conventional lines separating humans from animals. Rooted in the interaction between utilitarian goals and deontological principles, the ethical consequences generate great controversy in medicine.<sup>54</sup>

### 3.1 Types of Xenotransplantation

There are two types of xenotransplantation which are: animal to human transplantation and human to animal transplantation. These two are briefly discussed below for clarity purposes as opposed to embarking on a review of the literature on them.

**Animal-to-Human Transplantation:** The most researched variant of xenotransplantation is the animal-to-human one. It involves implanting human patients with pig hearts, kidneys, and pancreatic islet cells. Such methods address zoonotic disease hazards and must overcome

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<sup>50</sup> Tanya Lewis, 'Woman Becomes First Person to Receive Both Pig Kidney Transplant and Heart Pump' *Scientific American* 24 April, 2024. <<https://www.scientificamerican.com/article/woman-receives-genetically-modified-pig-kidney-transplant-after-heart-pump/>> accessed 28 October 2024

<sup>51</sup> *Ibid.*

<sup>52</sup> Maya Davis, 'A Woman Who Received A Pig Kidney Transplant and Heart Pump Dies' CNN 9 July, 2024. <<https://edition.cnn.com/2024/07/09/health/heart-pump-pig-kidney-transplant-death/index.html>> accessed 28 October 2024

<sup>53</sup> *Ibid.*

<sup>54</sup> Bernard E Rollin. 'Ethical and Societal Issues Occasioned by Xenotransplantation.' (2020)10 *Animals* 1

immunological obstacles to stop rejection.<sup>55</sup> The barriers to xenotransplantation are huge but are steadily being overcome by the ability to genetically engineer pigs to make their tissues more resistant to the human immune response.<sup>56</sup>

**Human-to-Animal Transplantation:** Human-to-animal transplantation is less common in research environments but is used there to test medical treatments or investigate human disorders. For research on tumor development and treatment development, for example, introducing human cancer cells into mice generates models. This approach raises issues of animal welfare and the moral limits of scientific inquiry.<sup>57</sup>

### 3.2 Medical Benefits

There are medical benefits in transplantation and they are as follows:

**Fixing Organ Shortages:** Xenotransplantation mostly helps to solve the urgent shortage of human donor organs. Offering a substitute organ supply for transplantation can perhaps save millions of lives per year.<sup>58</sup>

**Developing Biomedical Research:** Xenotransplantation advances creative treatments and helps us to better understand human diseases. It has considerably developed research in oncology, virology, and immunology.<sup>59</sup>

**Expanding Treatment Choices:** For diseases including diabetes, where pig pancreatic islet cells have shown promise in controlling insulin levels, xenotransplantation opens therapy options.<sup>60</sup>

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<sup>55</sup> Daniel Rodger, Daniel J Hurst, & David Kc Cooper. 'Xenotransplantation: A Historical–Ethical Account of Viewpoints' (2023) 30 *Xenotransplantation* 13

<sup>56</sup> Cooper (n 35) 49

<sup>57</sup> Insoo Hyun, 'Moral Permissibility of Transplantation of Human Brain Organoids into Animals'. In: Dederer, HG., Hamburger, D. (eds) *Brain Organoids in Research and Therapy. Advances in Neuroethics*. (Springer, Cham. 2022)193. [https://doi.org/10.1007/978-3-030-97641-5\\_8](https://doi.org/10.1007/978-3-030-97641-5_8)

<sup>58</sup> David K C Cooper, et.al. 'Clinical Pig Kidney Xenotransplantation: How Close Are We?' (2020) 31 *Journal of the American Society of Nephrology* 12

<sup>59</sup> Daniel L Eisenson, Yu Hisadome, & Kazuhiko Yamada. 'Progress in Xenotransplantation: Immunologic Barriers, Advances in Gene Editing, and Successful Tolerance Induction Strategies in Pig-To-Primate Transplantation' (2022)1 *Frontier In Immunology*. <<https://doi.org/10.3389/frtra.2022.989811>> accessed 28 October 2024

<sup>60</sup> David K C Cooper, Lisha Mou, & Rita Bottino. 'A Brief Review of the Current Status of Pig Islet Xenotransplantation' (2024) 15 *Frontier In Immunology*. <<https://doi.org/10.3389/fimmu.2024.1366530>> accessed 29 October 2024

### 3.3 Medical Risks

As beneficial as xenotransplantation is, there are medical risks associated with the procedure and the risks are:

#### 3.3.1 *Rejecting Immunologically*

Because their genetic makeup differs between species, xenografts are prone to hyperacute and chronic rejection. These hazards are being lessened by developments in genetic engineering.<sup>61</sup>

#### 3.3.2 *Zoonic Infections*

One major issue is the possibility of passing animal diseases including porcine endogenous retroviruses (PERVs) to humans. Minimizing these hazards depends on thorough screening and close observation.<sup>62</sup>

#### 3.3.3 *Moral Issues*

Xenotransplantation's use of animals begs ethical concerns about animal suffering, moral status, and the reason for their use in human health.<sup>63</sup>

### 3.4 Legal and Institutional Frameworks Governing Xenotransplantation

#### 3.4.1 *FDA Rules (US)*

Xenotransplantation research and clinical trials underlie the Food and Drug Administration (FDA) supervision in the United States. Emphasizing zoonotic disease control and ethical issues, the FDA mandates thorough preclinical testing to guarantee the safety and efficacy of xenotransplants.<sup>64</sup> The FDA is the sole agency responsible for regulating clinical xenotransplantation trials in the United States of America. It evaluates the risks and benefits of these trials and determines whether

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<sup>61</sup> Qiao Zhou, et.al. 'Current Status of Xenotransplantation Research and the Strategies for Preventing Xenograft Rejection' (2022) 13 *Frontier In Immunology*. doi: 10.3389/fimmu.2022.928173

<sup>62</sup> Denner (n 5)

<sup>63</sup> Rodger (note 55)

<sup>64</sup> FDA, *Source Animal, Product, Preclinical, and Clinical Issues Concerning the Use of Xenotransplantation Products in Humans* U.S. Department of Health and Human Services Food and Drug Administration Center for Biologics Evaluation and Research April 2003 Updated December 2016. <<https://www.fda.gov/media/102126/download>> accessed 25 January 2025

the clinical trials may proceed. This agency has published diverse guidance documents with recommendations for sponsors of clinical xenotransplantation trials.<sup>65</sup>

### 3.4.2 Global Recommendations

Focussing on world health hazards and ethical norms, the World Health Organisation (WHO) offers recommendations on xenotransplantation. It supports openness, worldwide cooperation, and fair access to xenotransplantation technologies.<sup>66</sup>

### 3.4.3 European Union Framework

Under strict criteria to guarantee patient safety and animal welfare, the European Medicines Agency (EMA) controls xenotransplantation. EMA protects public and animal health in the EU Member States, as well as the countries of the European Economic Area, by ensuring that all medicines available on the EU market are safe, effective, and of high quality. EMA serves a community of around 450 million people living in the EU and has been operating since 1995.<sup>67</sup>

## 3.5 Philosophical Debates Surrounding Xenotransplantation

### 3.5.1 Moral Considerations and Species Limitations

Xenotransplantation questions the conventional wisdom of human exceptionalism by blurring the boundaries between animals. Advocates of ethical consistency, such as Peter Singer, contend that whenever animals are utilized for human advantage, their welfare has to take the front stage.<sup>68</sup>

### 3.5.2 Perspectives from Utilitarians

From a utilitarian standpoint, the possibility of saving lives and reducing suffering of xenotransplantation justifies its research. Critics warn against ignoring the possible long-term hazards and moral conundrums for temporary benefit, nevertheless.<sup>69</sup>

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<sup>65</sup> Maria Jorqui-Azofra. 'Regulation of Clinical Xenotransplantation: A Reappraisal of the Legal, Ethical, and Social Aspects Involved' in *Xenotransplantation Methods and Protocols* (Christina Costa ed., 2020). 315

<sup>66</sup> WHO, *WHO Guidance on Xenogeneic Infection/Disease Surveillance and Response: A Strategy for International Cooperation and Coordination*. WHO/CDS/CSR/EPH/2001.2<[https://iris.who.int/bitstream/handle/10665/68888/WHO\\_CDS\\_CSR\\_EPH\\_2001.2.pdf?sequence=1&isAllowed=y](https://iris.who.int/bitstream/handle/10665/68888/WHO_CDS_CSR_EPH_2001.2.pdf?sequence=1&isAllowed=y)> accessed 11 January 2025

<sup>67</sup> European Medicine Agency<<https://www.ema.europa.eu/en/about-us>>accessed 25 January 2025

<sup>68</sup> Singer (n 25)

<sup>69</sup> Chana Erlbaum, 'Xenotransplantation: The Science, the Advantages, the Ethics' (2018) 12(1) *The Science Journal of the Lander College of Arts and Sciences*, 58

### 3.5.3 Deontological Issues

Rooted in Kantian ideas, deontological ethics challenge the morality of utilizing living entities for a purpose. This structure emphasizes the inherent worth of all life forms, animal welfare, and rights, issues of human and animal identity, and concerns relating to fair allocation of organs and appropriate use of resources.<sup>70</sup>

### 3.5.3 Study of Risk-Benefit

Making ethical decisions in xenotransplantation sometimes means balancing hazards against rewards. Advocates of a precautionary approach Cooper et al<sup>71</sup> underline the unknown long-term effects while supporters point out life-saving possibilities.

## IV. INTERNATIONAL LAW AND EUTHANASIA

On 25 January 2021, UN human rights experts expressed alarm at the growing trend to enact legislation allowing access to medically assisted dying based mostly on disability, including in old age.<sup>72</sup> They opined that:

We all accept that it could never be a well-reasoned decision for a person belonging to any other protected group – be it a racial minority, gender, or sexual minority - to end their life because they experience suffering on account of their status.<sup>73</sup>

The experts believe that when access to medical assistance in dying is restricted to those at the end of life or with a terminal illness, people with disabilities, older persons, and especially older persons with disabilities, may be put under pressure to end their lives prematurely due to attitudinal barriers and lack of appropriate care and support.

The fifth paragraph of the preamble of the Universal Declaration of Human Rights provides that:

Whereas the peoples of the United Nations have in the Charter reaffirmed their faith in fundamental human rights, in the dignity and worth of the human person, and in

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<sup>70</sup> Andrew Jt George. 'Ethics, Virtues and xenotransplantation' (2024) 39 *Perfusion* 334

<sup>71</sup> Cooper (n 58) 14

<sup>72</sup> UN, 'Disability is not a reason to sanction medically assisted dying – UN experts' January 25, 2021. <<https://www.ohchr.org/en/press-releases/2021/01/disability-not-reason-sanction-medically-assisted-dying-un-experts>> accessed 26 January 2025

<sup>73</sup> *Ibid.*

the equal rights of men and women and have determined to promote social progress and better standards of life in larger freedom.

Article 1 reiterates the principle of freedom and equality of human beings when it provides that: “All human beings are born free and equal in dignity and rights. They are endowed with reason and conscience and should act towards one another in a spirit of brotherhood”. Also, everyone is entitled to all rights and freedoms without discrimination including equality before the Law.<sup>74</sup>

One of the most important aspects of the Universal Declaration of Human Rights is the right to privacy, life, liberty, and security of person as provided for in Articles 3 & 12 of the Universal Declaration of Human Rights. Although the instrument in its current form does not bind states to its norms, it is however a foundation for several human rights treaties like the International Covenant on Economic, Social and Cultural Rights 1967. The first paragraph of the preamble reiterates the United Nations principles of human rights thus:

Considering that “In accordance with the principles proclaimed in the Charter of the United Nations, recognition of the Inherent dignity and the equal and inalienable rights of all members of the human family is the foundation of freedom, justice, and peace in the world.”

People have the right to self-determination as provided in Article 1(1) of the International Covenant on Economic, Social, and Cultural Rights. The instrument also recognises the right of everyone to the enjoyment of the highest attainable standard of physical and mental health.<sup>75</sup> Article 6(1) of the International Covenant on Civil and Political Rights provides for the right to life “Every human being has the inherent right to life. This right shall be protected by law. No one shall be arbitrarily deprived of his life.”

In the continuation of the second reading of draft General Comment no. 36 on the Right to Life published on 9 April 2018, the members of the United Nations Human Rights Committee agreed that States must prevent suicide, however, the concern of the members was whether or not States had the obligation to assist suicide in case that the person inform his/her consent. This brought about the principles of “human dignity” and “autonomy” it was argued that the wording could not impose an obligation on the States to accept and assist suicide, but for those States who

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<sup>74</sup> Universal Declaration of Human Rights 1948, arts 2 and 7

<sup>75</sup> International Covenant on Economic, Social and Cultural Rights 1967, art 12(1)



accept euthanasia, like Switzerland and Netherlands, they had to provide medical assistance to the individual.<sup>76</sup>

More than fifteen countries have embraced euthanasia. Some of the countries and the dates euthanasia came into existence are: the Netherlands in 2002, Switzerland in 1942, and Belgium in 2002, In 2014, Belgium extended its 2002 euthanasia law to children.<sup>77</sup> Canada 2016, Australia 2017, United States, 11 out of the 50 states recognise euthanasia under the Death with Dignity Act 2016. In Germany, there is a struggle to agree on new legislation after a 2020 federal constitutional court ruled that a ban on assisted suicide violated the rights of citizens to determine the circumstances of their deaths by restricting their ability to seek assistance from a third party.<sup>78</sup> In New Zealand, both euthanasia and assisted dying were legalized in November 2021, under the End of Life Choice Act 2019.<sup>79</sup> Luxembourg legalized euthanasia in 2009.

In 2024, Ecuador's constitutional court decriminalized euthanasia, after delivering judgment in a case presented by a patient with a progressive neurological disease. Seven of the court's nine judges voted in favour of decriminalizing euthanasia on Wednesday 7 February 2024. Doctors in Ecuador are no longer at risk for homicide when ending a seriously ill patient's life at the patient's request.<sup>80</sup>

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<sup>76</sup> United Nations, International Covenant on Civil and Political Rights Human Rights Committee General Comment No. 36 Article 6: right to life. September 3, 2019

<<https://documents.un.org/doc/undoc/gen/g19/261/15/pdf/g1926115.pdf>> accessed 25 January, 2025

<sup>77</sup> Sandra Huenchuan. *The Right to End-of-Life Palliative Care and A Dignified Death* Contribution from UN-ECLAC for the Expert Group Meeting On "Care and Older Persons: Links to Decent Work, Migration and Gender December 5-7, 2017, United Nations Headquarters, New York – Secretariat Building, Conference Room S-2725. <https://www.un.org/development/desa/ageing/wp-content/uploads/sites/24/2017/11/ECLAC-contribution.pdf> accessed 12 January, 2025

<sup>78</sup> Daniel Boffey. 'Assisted Dying Around The World: Where and When It Is Allowed' The Guardian, 19 December, 2023. <<https://www.theguardian.com/society/2023/dec/19/assisted-dying-around-world-where-when-allowed-esther-rantzen>> accessed 12 January, 2025

<sup>79</sup> Alex Dakers. 'Where Assisted Dying Is Legal and How It Works in Other Countries' The Paper, 4 October, 2024<<https://inews.co.uk/news/where-assisted-dying-is-legal-and-how-it-works-in-other-countries-3308244>> accessed 12 January, 2025

<sup>80</sup> Luke Taylor. 'Ecuador Becomes Second Latin American Country to Decriminalise Euthanasia', (2024)384 *BMJ*. doi: <<https://doi.org/10.1136/bmj.q357>> accessed 12 January 2025

#### 4.1 European Court of Human Rights responses to euthanasia

The case of *Mortier v. Belgium*<sup>81</sup> is the first ruling of the European Court of Human Rights on the compliance of euthanasia with the rights protected under the European Convention on Human Rights, and the first ruling on euthanasia for a psychiatric disorder.<sup>82</sup>

The Court considered the above case and opined that:

This was the first case in which the Court had been called upon to examine the compliance with the Convention of an act of euthanasia. It is therefore considered necessary to clarify the nature and scope of a State's obligations under Article 2 in this context before examining whether those obligations had been fulfilled in the present case. The Court therefore had to begin by determining whether such an act could, in certain circumstances, be carried out without contravening Article 2. The question that arose was whether the euthanasia carried out under the Act, by which it was authorized, at the request of the applicant's mother, had been in accordance with Article 2.

Article 2 of the European Convention on Human Rights provides that:

1. Every individual's right to life shall be protected by law. No one shall be deprived of his life intentionally save in the execution of a sentence of a court following his conviction of a crime for which this penalty is provided by law.
2. Deprivation of life shall not be regarded as inflicted in contravention of this Article when it results from the use of force which is no more than necessary:
  - (a) in defence of any person from unlawful violence;
  - (b) to effect a lawful arrest or to prevent the escape of a person lawfully detained;
  - (c) in action lawfully taken for the purpose of quelling a riot or insurrection.

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<sup>81</sup> *Mortier v Belgium* (78017/17 Judgment 4.10.2022)

<sup>82</sup> Marc De Hert M, Loos S, & Van Assche K. 'Euthanasia of A Person with A Psychiatric Disorder Does Not Violate the European Convention on Human Rights (*Mortier v. Belgium* [no. 78017/17])'(2022) 65 *European Psychiatry* 1-2. <<https://doi.org/10.1192/j.eurpsy.2022.2342>> accessed 13 January 2025

The Court admitted that while it is impossible to extract a right to die from Article 2, the right to life enshrined in that provision could not be interpreted to prohibit the conditional decriminalization of euthanasia. The Court went further that the decriminalisation of euthanasia can be compatible with Article 2 where it is accompanied by the provision of law as sufficient safeguards in preventing abuse and ensuring respect for the right to life. In going by the decision of the court, certain conditions must be met before an individual can qualify for euthanasia.

## **V. INTERNATIONAL LAW AND XENOTRANSPLANTATION**

Xenotransplantation issues have taken centre stage in the international arena and this is so because it is a potential solution to the shortage of human organs and eradication of human organ trafficking. This section examines the development of xenotransplantation and the emergence of international regulations on the issue.

### **5.1 Overview of international law governing medical research and innovation**

#### **Universal Declaration on Bioethics and Human Rights**

The Universal Declaration on Bioethics and Human Rights was adopted on 19 October 2005 in Paris, France. Paragraph 3 of the preamble acknowledges that ethical issues raised by the rapid development in science and technology should be examined as regards the dignity of the human person, universal respect for human rights, and fundamental freedoms. The Declaration also recognises that:

The freedom of science and research, scientific and technological developments have been and can be, of great benefit to humankind in increasing, inter alia, life expectancy and improving the quality of life, and emphasizing that such developments should always seek to promote the welfare of individuals, families, groups or communities and humankind as a whole in the recognition of the dignity of the human person and universal respect for, and observance of, human rights and fundamental freedoms.<sup>83</sup>

The Declaration, according to Article 1 addresses ethical issues related to medicine, life sciences, and associated technologies applying to human beings, considering their social, legal, and

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<sup>83</sup> Universal Declaration on Bioethics and Human Rights 2005

environmental dimensions. It also applies and addresses countries, guiding decisions or practices of individuals, groups, communities, institutions, and corporations, public and private. It is the “universal framework of principles and procedures to guide states in the formulation of their legislation, policies or other instruments in the field of bioethics,”.<sup>84</sup> The Declaration could affect national laws and policies on bioethics, even though in its current form it does not bind states to its norms.

The Declaration provides in its Article 2 as follows:

- (i) to provide a universal framework of principles and procedures to guide States in the formulation of their legislation, policies, or other instruments in the field of bioethics;
- (ii) to guide the actions of individuals, groups, communities, institutions, and corporations, public and private;
- (iii) to promote respect for human dignity and protect human rights, by ensuring respect for the life of human beings, and fundamental freedoms, consistent with international human rights law;
- (iv) to recognize the importance of freedom of scientific research and the benefits derived from scientific and technological developments, while stressing the need for such research and developments to occur within the framework of ethical principles set out in this Declaration and to respect human dignity, human rights, and fundamental freedoms;
- (v) to foster multidisciplinary and pluralistic dialogue about bioethical issues between all stakeholders and within society as a whole;
- (vi) to promote equitable access to medical, scientific, and technological developments as well as the greatest possible flow and the rapid sharing of knowledge concerning those developments and the sharing of benefits, with particular attention to the needs of developing countries;
- (vii) to safeguard and promote the interests of the present and future generations;
- (viii) to underline the importance of biodiversity and its conservation as a common concern of humankind.

The Declaration provides that human dignity, human rights, and fundamental freedoms are to be respected without reservation, that is, the interests and welfare of individuals should be put above

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<sup>84</sup> Universal Declaration on Bioethics and Human Rights 2005, art 2(a)

the interest of science and society.<sup>85</sup> The Declaration recognises advancement in scientific knowledge, medical practice, and associated technologies, it is, however, important that its benefits to patients should be uppermost in advancing such, and every effort to minimize harm should be adopted.<sup>86</sup>

The right to autonomy to make decisions and be responsible for such decisions should put the right to autonomy of other people into consideration and where a person is incapable of exercising autonomy, special measures are to be taken to protect such person's rights and interests.<sup>87</sup> Informed consent is also required from patients before medical intervention. Article 6 exhaustively provides for consent as follows:

1. Any preventive, diagnostic, and therapeutic medical intervention is only to be carried out with the prior, free, and informed consent of the person concerned, based on adequate information. The consent should, where appropriate, be express and may be withdrawn by the person concerned at any time and for any reason without disadvantage or prejudice.
2. Scientific research should only be carried out with the prior, free, express, and informed consent of the person concerned. The information should be adequate, provided in a comprehensible form, and should include modalities for withdrawal of consent. Consent may be withdrawn by the person concerned at any time and for any reason without any disadvantage or prejudice. Exceptions to this principle should be made only in accordance with ethical and legal standards adopted by States, consistent with the principles and provisions set out in this Declaration, in particular in Article 27, and international human rights law.
3. In appropriate cases of research carried out on a group of persons or a community, additional agreement of the legal representatives of the group or community concerned may be sought. In no case should a collective community agreement or the consent of a community leader or other authority substitute for an individual's informed consent.

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<sup>85</sup> Universal Declaration on Bioethics and Human Rights, art 3

<sup>86</sup> Universal Declaration on Bioethics and Human Rights, art 4

<sup>87</sup> Universal Declaration on Bioethics and Human Rights, art 5

It is clear from the above that in every circumstance, informed consent is very important in carrying out any medical intervention or scientific research. This is not negotiable. There are also instances where an individual cannot give consent for medical intervention or scientific research on his person, Article 7 provides that:

By domestic law, special protection is to be given to persons who do not have the capacity to consent:

(a) authorization for research and medical practice should be obtained in accordance with the best interest of the person concerned and in accordance with domestic law. However, the person concerned should be involved to the greatest extent possible in the decision-making process of consent, as well as that of withdrawing consent;

(b) research should only be carried out for his or her direct health benefit, subject to the authorization and the protective conditions prescribed by law, and if there is no research alternative of comparable effectiveness with research participants able to consent. Research which does not have potential direct health benefit should only be undertaken by way of exception, with the utmost restraint, exposing the person only to a minimal risk and minimal burden and, if the research is expected to contribute to the health benefit of other persons in the same category, subject to the conditions prescribed by law and compatible with the protection of the individual's human rights.

Refusal of such persons to take part in research should be respected.

It is expected to respect the rights of vulnerable persons and protect their integrity.<sup>88</sup> Ensuring the privacy and confidentiality rights of the person concerned is paramount.<sup>89</sup> "The fundamental equality of all human beings in dignity and rights is to be respected so that they are treated justly and equitably".<sup>90</sup> Andorno<sup>91</sup> opines that even if the UN agencies are unable to guarantee that

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<sup>88</sup> Universal Declaration on Bioethics and Human Rights, art 8

<sup>89</sup> Universal Declaration on Bioethics and Human Rights, art 9

<sup>90</sup> Universal Declaration on Bioethics and Human Rights, art 10

<sup>91</sup> Roberto Andorno. 'Global Bioethics at UNESCO: In Defence of the Universal Declaration on Bioethics and Human Rights' (2007) 33 *Journal of Medical Ethics* 150–154

biomedical advances will always be used for the greatest well-being of humanity, they can contribute to making their use favourable to human dignity and human rights.

## **5.2 The World Health Organisation and Xenotransplantation**

The World Health Organisation has a long-standing interest in xenotransplantation, which came into existence through the publication of the “WHO Guidance on Xenogeneic Infection/Disease Surveillance and Response: A strategy for International Cooperation and Coordination” in 2001.<sup>92</sup> The objective of the document was to “facilitate consideration for the development and implementation of an international xenogeneic infection/disease event surveillance network for efficiently and effectively detecting, reporting and responding to xenogeneic infection and disease events using internationally harmonized, cooperative and coordinated surveillance activities.”

The second World Health Organization “Global Consultation on Regulatory Requirements for Xenotransplantation Clinical Trials” came up on October 17-19, 2011 in Geneva, Switzerland. The purpose of the consultation was to (i) review the current status of xenotransplantation science and practice, (ii) determine whether updates to the Changsha Communiqué’s guidance to WHO, Member State health regulatory authorities, and study investigators and/or sponsors of xenotransplantation trials are required and (iii) discuss and refine draft guidance for infectious disease surveillance, prevention, and response appropriate to support various probable clinical xenotransplantation trial scenarios.<sup>93</sup>

The document noted that:

Unregulated xenotransplantation continues to be advertised and performed in multiple jurisdictions in contravention of the fifty-seventh World Health Assembly Resolution WHA57.18 (Annex 1) urging Member States “to allow xenogeneic transplantation only when effective national regulatory control and surveillance mechanisms overseen by national health authorities are in place”. These trials are ignoring the requirements expressed in the Changsha Communiqué (Annex 2) and run contrary to the spirit and letter of most guidance documents governing

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<sup>92</sup> WHO (n 66)

<sup>93</sup> Second WHO Global Consultation on Regulatory Requirements for Xenotransplantation Clinical Trials, October 17-19 2011, WHO, Geneva, Switzerland. WHO/HTP/EHT/CPR/2011.01

xenotransplantation clinical trials which require regulatory oversight, microbiologic testing, and archived sample repositories for such activities.

Some countries are developing regulatory frameworks for xenotransplantation, for example, the European Union has the Advanced Therapy Medicinal Products (ATMPs) Regulation (EC) No 1394/2007 and Reflection Paper on the Classification of Advanced Therapy Medicinal Products, the Reflection paper defines products containing animal cells or tissues for human administration as Advanced Therapeutic Medicinal Products (ATMPs) (Andriichuk, 2024). Also, in the United States of America, xenotransplantation is regulated by the Food and Drug Administration in the U.S. Department of Health and Human Services. The regulatory framework is “Source Animal, Product, Preclinical, and Clinical Issues Concerning the Use of Xenotransplantation Products in Humans-Guidance for Industry” as updated in 2016.

The Third WHO Global Consultation on Regulatory Requirements for Xenotransplantation Clinical Trials was organized in collaboration with the IXA and the EMA in Changsha, China, in December 2018. The principles and recommendations of the “Changsha Communiqué” were extensively reviewed and discussed by different working groups mandated with the following topics: (a) xenozoonosis; (b) regulatory; (c) biorepository; (d) transgenic pig facilities; (e) biomaterials and encapsulation; and (f) immunosuppression and tolerance induction.

The guidance document from the Second Global Consultation (Geneva, 2011) was included in these discussions.<sup>94</sup> The draft was submitted to WHO in February 2019 for WHO and World Health Assembly consideration. It is yet to be finalized.

## **VI. PHILOSOPHICAL ISSUES AT THE INTERSECTION OF EUTHANASIA AND XENOTRANSPLANTATION**

Euthanasia and xenotransplantation offer a rich ground for philosophical investigation covering topics such as dignity, autonomy, and the sanctity of life at their junction. While seeking to alleviate human suffering and enhance the quality of life, both methods question strongly held moral, ethical, and cultural norms. Whereas xenotransplantation aims to extend life by using animal organs or tissues, euthanasia is the deliberate ending of a life to alleviate suffering. This

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<sup>94</sup> Ralf Reinhard Tönjes. ‘Aspects of Regulation of Xenotransplantation in Europe’ (2024) 37 *Transplant International*. doi: 10.3389/ti.2024.13349



juxtaposition begs important issues about the nature of life, the morality of medical intervention, and the limits of human agency.

## 6.1 Philosophical Debate Surrounding the Intersection

### 6.1.1 Respect

Both euthanasia and xenotransplantation centre on dignity as a fundamental idea. Within the framework of euthanasia, dignity usually refers to the right to die in line with one's ideals and free from intolerable pain.<sup>95</sup> Euthanasia, according to supporters, enables people to escape protracted suffering and loss of autonomy, therefore preserving dignity.<sup>96</sup>

Dignity arises in two forms in xenotransplantation: animal and human dignity. Using animals as organ sources begs moral issues regarding the moral standing of animals and whether their exploitation for human advantage contradicts their dignity.<sup>97</sup> While some advocate against the instrumentalization of animals, which may undermine respect for all life forms, others contend that reducing human suffering justifies such activities. The junction of these two methods magnifies these arguments. For example, would the use of xenotransplantation to increase the life span of a terminally sick patient compromise the patient's dignity if it just helps to prolong suffering? On the other hand, may it be considered as maintaining dignity by giving a possibility for significant rehabilitation?

Rollin<sup>98</sup> a supporter of animal instrumentalization opines that:

...societal ignorance of both science and ethics militates strongly against rational solutions to ethical issues, and even elevates non-issues to the highest rank of ethical concerns, for example, "violating God's will" or operating "against nature." Such a mistake, as our discussion indicates, can impede using biotechnology to save human life and alleviate suffering.

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<sup>95</sup> Akshat Hegde, 'Balancing Personal Autonomy and the Right to Life in Euthanasia' (2024) 6(4) *International Journal of Legal Science and Innovation*. 62

<sup>96</sup> Monica Verhofstadt, et.al. 'Ethical Perspectives Regarding Euthanasia, Including in the Context of Adult Psychiatry: A Qualitative Interview Study Among Healthcare Workers in Belgium', (2024) 25 *BMC Medical Ethics*. <https://doi.org/10.1186/s12910-024-01063-7> .

<sup>97</sup> Rollin (n 54) 1

<sup>98</sup> *Ibid.* at 8-9.

These issues continue to generate discussions without arriving at a universal consensus.

### 6.1.2 *Individuality*

Another fundamental concern is autonomy, that is, the right to self-determination. Advocates of euthanasia stress the need for personal decision-making on when and how one should die.<sup>99</sup> Conversely, Xenotransplantation raises issues of permission, especially in experimental or high-risk settings. Patients have to balance the possible advantages against unknown hazards, which might make autonomous decision-making difficult.<sup>100</sup>

The social consequences of these behaviors at the junction hamper autonomy even further. A terminally sick patient might choose euthanasia, for instance, instead of a high-risk xenotransplant. This begs issues regarding whether actual autonomy is used when systematic elements like access to healthcare, society stigma, or the psychological weight of experimental therapies shape decisions.

### 6.1.3 *Sanctity of Life*

Often used against euthanasia, which some claim devalues human life by allowing its deliberate termination, is the sanctity of life. Xenotransplantation similarly encounters resistance based on the sanctity of animal life, particularly from religious or cultural viewpoints that regard some animals as holy.<sup>101</sup>

The junction of these methods questions conventional ideas of purity. For example, is it acceptable to forbid euthanasia based on respect for life while allowing animal life to be sacrificed for xenotransplantation? The conflict between maintaining the sanctity of animal life and saving human life by xenotransplantation highlights the complexity of this ethical ground.<sup>102</sup>

## VII. CONCLUSION

The right to life surpasses the right to die. We have discussed the legal and philosophical issues surrounding euthanasia and xenotransplantation through the lens of international law. We believe

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<sup>99</sup> Ross (n 24)

<sup>100</sup> Ion Arrieta Valero. 'Autonomies in Interaction: Dimensions of Patient Autonomy and Non-adherence to Treatment' (2019)10 *Frontiers In Psychology*. 1. doi: 10.3389/fpsyg.2019.01857

<sup>101</sup> Rollin (n 54) 8

<sup>102</sup> Cooper (n 58) 12

that the right to life takes precedence, the United Nations Human Rights Committee in its “General comment No. 36 on article 6: right to life”, last line of paragraph 12 states that “The intentional taking of life by any means is permissible only if it is strictly necessary in order to protect life from an imminent threat” paragraph 10 mentioned that such exceptional measures should be established by law and accompanied by effective institutional safeguards designed to prevent arbitrary deprivations of life.<sup>103</sup>

Euthanasia did not in itself constitute an interference with the right to life if it was accompanied by robust legal and institutional safeguards to ensure that medical professionals were complying with the free, informed, explicit, and unambiguous decision of their patient, to protect patients from pressure and abuse.

Xenotransplantation has come to stay and its development should be a top priority for the United Nations through the World Health Organization. In further developing this medical innovation, adequate international regulations should be provided for its smooth operations, that is, comprehensive global regulations about the responsible treatment of animals, and adequate and transparent informed consent are very important in ensuring ethical and safe practices.

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<sup>103</sup> United Nations (n 76)