

NOTES

OFF WITH THEIR HEADS! HOW CHINA’S CONTROVERSIAL HUMAN HEAD-TRANSPLANT PROCEDURE EXCEEDS THE PARAMETERS OF INTERNATIONAL ETHICAL STANDARDS IN HUMAN EXPERIMENTATION

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I. INTRODUCTION

Frankenstein is possibly the world's most popular mad-scientist story. In Mary Shelley's novel, a doctor reanimates a lifeless body stitched together with beautifully "selected features."¹ When his monster awakens, Dr. Frankenstein finds himself "unable to endure the aspect of the being [he] created" as "breathless horror and disgust filled [his] heart."² As Dr. Frankenstein pieced together body parts to create his monster, a question of personhood arose. Who is Frankenstein's monster? Has Dr. Frankenstein reanimated the person whose head is sewn to the body? Is an entirely new person created—one without a previous identity—that is the sum of all the people that make up his body? Or is the monster's identity created by society's perception of him, and not by the monster at all? Throughout the novel, the monster is not given a name even though he displays numerous human characteristics, such as trying to befriend village people.³ But, upon his rejection by society, he becomes violent.⁴

While *Frankenstein* is a work of fiction, it has inspired a "mad scientist" duo, Sergio Canavero and Xiaoping Ren, to complete the first human head-transplant surgery.⁵ This Note explores head transplants, a theoretically possible medical intervention that would involve two participants: a brain-dead donor with a healthy body, and a mentally sound patient with a failing body. The patient with the functioning brain, but failing body, will receive the healthy body of the brain-dead donor. The patient's failing body will die.

A. *The Name "Head-Transplant"*

Generally, when a person receives a transplant, the name of the transplant procedure refers to the organ or body part the conscious individual is receiving. For example, a person undergoing a hand transplant is receiving a hand. However, in this "head transplant", we see the opposite. The phrase "head transplant" implies that a body is receiving a head. In reality, the head is

¹ MARY SHELLEY, *FRANKENSTEIN* 43 (Bantam Dell, 2003).

² *Id.*

³ *Id.* at 125-28.

⁴ *Id.*

⁵ The reference of Canavero as a "mad scientist" comes from his own embrace of correlations between himself and Dr. Frankenstein and from news outlets. See Erin Brodwin, *A Surgeon Inspired by 'Frankenstein' Claims He Has Completed the First Head Transplant on a Corpse*, *BUS. INSIDER* (Nov. 17, 2017), <http://www.businessinsider.com/human-head-transplant-surgeon-claims-he-did-on-corpse-2017-11> (Where Canavero is cited as being inspired by Dr. Frankenstein to pursue this procedure and to use electricity to reanimate human bodies). See also Sergio Canavero, Xiaoping Ren & C. Yoon Kim, *HEAVEN: The Frankenstein Effect*, *SURGICAL NEUROLOGY INT'L* (Sep. 13, 2016), <http://surgicalneurologyint.com/surgicalint-articles/heaven-the-frankenstein-effect/>.

receiving a body. The recipient's body will inevitably die, but his head will receive a working body and, theoretically, continue living. The donor loses his body and so, his life. Consider this hypothetical: John Smith is a brain-dead patient who is kept alive on life support. His family has donated his body to science. Jacob Jones is a quadriplegic with a fully functioning brain. In fact, he has a high IQ and has made much scientific advancement in physics. Jacob receives the body of John and John will die. In this scenario, it is clear that Jacob is receiving a body transplant, instead of John receiving a head transplant.

The distinction between a head transplant and a body transplant is significant because the name of a medical procedure is significant. The name should clearly identify the thing. It is intended to explain what the doctors are doing, its purpose, and inherently justify the procedure. As this involves a transplant, not a routine medical procedure, it becomes "medically necessary" and a "treatment." By assigning medical nomenclature, society justifies "treating" it—whatever "it" may be—with science because someone identified a problem that was not known or recognized previously.⁶ We have seen this effect in the psychological community, particularly with "disorders" like homosexuality⁷ or female hysteria, which are no longer recognized disorders. This process of assigning medical nomenclature to behavior or biological features is called Medicalization. Medicalization, specifically, is a "process by which some aspects of human life come to be considered as medical problems, whereas before they were not considered pathological."⁸ For example, Kaja

⁶ "Illness is not an 'objective' fact perceived, reacted to and reported similarly by members of all sub-cultures . . . 'social and cultural conditions do influence the development of various types of psychiatric disorders at different social class levels. . . ." Pauline B. Bart, *Social Structure and Vocabularies of Discomfort: What Happened to Female Hysteria?* 9 J. OF HEALTH & SOC. BEHAV. 188 (1968).

⁷ Aversion therapy was frequently used to treat homosexuality. In one case study, this treatment involved placing the patient in a darkened room with no food or drink besides alcohol. Every two hours, the patient was injected with apomorphine, which can cause severe nausea and vomiting, along with a 2 oz. of brandy (a little more than a shot, which is 1.5 oz.). Then, he was shown pictures of nude men. Once the nausea set in, he would listen to a tape that explained homosexuality and its social repercussions, followed by the sounds of someone vomiting. This occurred for 30 hours at a time, with 24-hour breaks in between each 30-hour session. Basil James, *Case of Homosexuality Treated by Aversion Therapy*, BRITISH MED. J. 768-69 (Mar. 17, 1962), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC1957923/pdf/brmedj02859-0056.pdf>. It was not until 1987 that homosexuality disappeared from the Diagnostic and Statistical Manual of Mental Disorders, a book that defines and classifies mental disorders. Vivek Datta, *When Homosexuality Came Out (of the DSM)*, MAD IN AMERICA: SCI., PSYCHIATRY AND SOC. JUST. (Dec. 1, 2014), <https://www.madinamerica.com/2014/12/homosexuality-came-dsm/>.

⁸ Antonio Maturo, *Medicalization: Current Concept and Future Directions in a Bionic Society*, US NAT'L LIBR. OF MED.: NAT'L INSTS. OF HEALTH (Jan. 2012), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3353591/>.

Finkler provides an example of medicalization in her article *Experiencing the New Genetics: Family and Kinship on the Medical Frontier*:

A peasant woman gave birth to two Down's syndrome children in succession. She was counseled to avoid having any more children; however, she refused to regard these children as suffering from an affliction. In fact, she claimed that she preferred such children because they were more docile and more manageable than her other children. The Down's syndrome children were also better field hands than the rest. For this peasant woman, her Down's syndrome children were an asset and unproblematic. By medicalizing their beings, the woman began to perceive her children negatively rather than as positive contributions to the household welfare.⁹

With this "head transplant," there's an implication that the body is the important aspect of a person; a head can be moved, but the body is valuable—everyone needs a functional body. By calling it a head transplant, the head is being equated to a hand, leg, heart, liver, or any other aspect of the body that can be freely removed and replaced to create a better-functioning person. This minimizes the fact that the brain holds very personal and individualized memories, feelings, thoughts, intellect, and that it works in unison with the body to create the personality of an individual. In contrast, a person that receives a hand transplant does not suddenly become a different person or have a hand that thinks and acts on its own.¹⁰

The danger of misnaming this procedure is that it implies those with a dysfunctional body are flawed. In the hypothetical scenario described above, Jacob, the quadriplegic, receives a body despite the fact that he is potentially able to live a safe life in a wheelchair, communicate openly with friends, and have an, arguably, valuable and fulfilling life. His life is not at risk. He will not die from his condition. He is simply displeased with his body and its limitations. This establishes the implication that disabled individuals are suddenly "less" than those that are able-bodied.—those with a deformity in one leg, no problem, just replace the leg.¹¹ Instead of accommodating or

⁹ Kaja Finkler, *Experiencing the New Genetics: Family and Kinship on the Medical Frontier*, in *BIOETHICS AND THE LAW*, 43-44 (3d ed. 2013).

¹⁰ There is some evidence that heart transplant patients do experience a change in personality. One study found that approximately 6% of heart transplant patients (3 people) experienced a distinct change in personality after their transplant. This is, however, in stark contrast to the majority of the 47 patients questioned, where 79% experienced no change to their personality. Brigitta Bunzel et al., *Does Changing the Heart Mean Changing Personality? A Retrospective Inquiry on 47 Heart Transplant Patients*, 1 *QUAL LIFE RES* 251 (1992), <https://link.springer.com/article/10.1007/BF00435634>.

¹¹ Disability rights activists make this same argument in eugenics where certain genes are selected to increase the occurrence of desirable traits. Essentially, genetic testing

appreciating those with disabilities (such as the mother in Kaja Finkler's example above, who preferred her children with Down syndrome) the solution is to treat the head like a hand and move it. The only reason cited for referring to this procedure as a head transplant is because that is the name it was given.¹² Even though it is inaccurate, "it stuck."¹³

The surgery should, rightly, be called a "body transplant" and it will be referred to as such throughout this Note. Furthermore, the person donating the body will be referred to as the "donor" and the person receiving the body as the "recipient."

B. Outline

By allowing the body transplant procedure, China violates the ethical guidelines provided by the World Health Organization (WHO) and the Council for International Organizations of Medical Sciences (CIOMS), both of which recommend an ethical review board evaluate the ethical compliance of research and filter out research that is not scientifically valid.¹⁴ This Note will discuss the many ways China is violating international standards, including their own, by allowing this surgery to occur.

allows parents to make prenatal decisions, including whether they want to carry a child to term—if the child is afflicted with some disease or genetic disorder, they can choose to terminate the pregnancy, to try again, and maybe again, and again, until they have a healthy fetus. For example, screening for children with Down Syndrome—a chromosomal disorder that can cause a range of disabilities from mental handicaps, to physical handicaps, to nothing more than some flattened facial features.

In Iceland, nearly every woman who undergoes prenatal testing and whose fetus receives a diagnosis of Down syndrome decides to end her pregnancy. Each year. . . only a child or two is born with Down syndrome in Iceland. . . In essence, pregnant women in Iceland—and presumably their partners—are saying that life with a disability is not worth living.

Bonnie Rochman, *The Disturbing, Eugenics-like Reality Unfolding in Iceland*, QUARTZ (Aug. 19, 2017), <https://qz.com/1056810/the-disturbing-eugenics-like-reality-unfolding-in-iceland/>.

¹² Helen Thomson, *6 Things You're Dying to Ask About Head Transplants*, NEW SCIENTIST (Feb. 25, 2015), <https://www.newscientist.com/article/dn27035-6-things-youre-dying-to-ask-about-head-transplants/>.

¹³ *Id.*

¹⁴ *International Ethical Guidelines for Biomedical Research Involving Human Subjects*, COUNCIL FOR INT'L ORGS. OF MED. SCI. (2002), https://cioms.ch/wp-content/uploads/2016/08/International_Ethical_Guidelines_for_Biomedical_Research_Involving_Human_Subjects.pdf [hereinafter CIOMS]; *Standards and Operational Guidance for Ethics Review of Health-Related Research with Human Participants*, WORLD HEALTH ORG. (2011), http://apps.who.int/iris/bitstream/10665/44783/1/9789241502948_eng.pdf?ua=1&ua=1 [hereinafter WHO].

Part II will discuss the process of the surgery, how the researchers intend to complete this transplant, and the response from the scientific community to the news of the impending procedure. It will also include an introduction to the participants in this surgery. Part III will address the international standards. Part IV will discuss China's laws and outline their ethical review process.

Part V will include an analysis of the international standards and how the proposed body transplant procedure either does or does not abide by those standards. The applicable Chinese laws will also be compared to international standards. These standards will be categorized into the following sections, in order of discussion: adherence to bioethics; informed consent generally, and as it relates to the donor and the recipient individually; risk and benefit ratios; the scientific design of the study; and the selection of research participants.

Part VI will discuss the international repercussions of this type of research and the potential impacts on medical tourism. Part VII discusses possible remedies available to China and the international community in preventing unethical research. Finally, Part VIII concludes that this procedure, as it stands, is needlessly dangerous and unethical.

II. BACKGROUND

Historically, there have been numerous barriers in advancements to a body transplant procedure, including: vessel anastomosis, immunosuppression, and spinal anastomosis.¹⁵ Vessel anastomosis, involves the difficulties of cutting and repairing injured vessels.¹⁶ In 1908, a physiologist performed a head transplant procedure on a dog where the head of one dog was attached to the neck of another dog, thus creating a two-headed dog.¹⁷ This surgery was successful as the transplanted dog's head showed visual, aural, and reflexive movements after the procedure.¹⁸ The dog's condition deteriorated quickly, however, and the dog was euthanized after only a few hours.¹⁹ In 2015, Xiaoping Ren made a significant change to the procedure by creating a "jugular carotid cross circulation."²⁰ This involved cutting the jugular vein and carotid artery on one side of the body and connecting it to the donor—allowing the blood to continue flowing through the vein and artery on the other side—while

¹⁵ Nayan Lamba et al., *The History of Head Transplantation: A Review*, NCBI (Oct. 14, 2016), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5116034/>. See also *Anastomosis*, MERRIAM-WEBSTER DICTIONARY, <https://www.merriam-webster.com/dictionary/anastomosis> (last visited Jan. 21, 2018) (medical definition of anastomosis: "the surgical union of parts and especially hollow tubular parts").

¹⁶ Lamba et al., *supra* note 15.

¹⁷ *Id.*

¹⁸ *Id.*

¹⁹ *Id.*

²⁰ *Id.*

maintaining blood flow to the recipient's head.²¹ When this procedure was conducted on mice, it was considered successful, but there was no indication of what was considered successful.²²

Immunosuppression was the next major issue to overcome. This was largely addressed by immunosuppressive agents like corticosteroids in the 1950s-60s, which revolutionized transplant surgery, allowing physicians to successfully perform kidney and heart transplants.²³ Spinal anastomosis presented the final hurdle to overcome. Spinal anastomosis is the fusion of donor-recipient spinal cords.²⁴ In 2014, Ren proposed cutting the spinal cord in a way that preserved the donor brainstem.²⁵ This is different from previous experiments that did not leave the donor brainstem intact.²⁶ Ultimately, Ren's procedure allowed donor mice to continue breathing after transplantation and lengthened survival time.²⁷

A. *The Surgery*

Sergio Canavero and Xiaoping Ren are the two researchers behind this project. Both have conducted transplant procedure experiments and together have conducted the majority of research on this topic.²⁸ As discussed above, Ren has created a process for successfully fusing donor and recipient spinal cords by severing the spinal cords above the brain stem, leaving most of the

²¹ *Id.* Imagine that the veins and artery on one side of the donor body's neck are severed and connected to the corresponding veins and artery of the recipient's neck. This connects the two bodies, so they share a blood supply and have circulation through both bodies. Then the surgeons will fully disconnect the donor body's head and attach the other side of the recipient's neck to the body. This way, the donor body and the recipient's head will share the new blood supply. This makes it easier for the doctors and scientists to connect the donor body to the recipient head without wholly severing the head and hoping neither the body nor the recipient bleed out before the veins and arteries are connected. *See also*, Allen Furr et al., *Surgical, Ethical, and Psychosocial Considerations in Human Head Transplantation*, 41 INT'L J. OF SURGERY 190, 191 (2007), <http://www.sciencedirect.com/science/article/pii/S1743919117300808> (“[T]he first priority will be to maintain blood flow to the recipient head and donor body to minimize tissue ischemia. Interruption of blood flow to the brain for more than a few minutes results in irreversible brain damage.”) *See*, *Myocardial Ischemia*, MAYO CLINIC, <https://www.mayoclinic.org/diseases-conditions/myocardial-ischemia/basics/definition/con-20035096> (last visited Jan. 21, 2017) (defining ischemia as a lack of blood and oxygen to the heart).

²² Lamba et al., *supra* note 15.

²³ *Id.*

²⁴ *Id.*

²⁵ *Id.*

²⁶ *Id.*

²⁷ *Id.*

²⁸ Tom Lamont, *I'll Do the First Human Head Transplant*, THE GUARDIAN (Oct. 3, 2015), <https://www.theguardian.com/science/2015/oct/03/will-first-human-head-transplant-happen-in-2017>.

spinal chord intact.²⁹ This process gave researchers hope in establishing and maintaining life post-transplant without respirators.³⁰

Around the same time, Canavero put forth a head transplant protocol, Head Anastomosis Venture (HEAVEN).³¹ In this protocol, Canavero proposes a very controlled cutting of the spinal cord in order to inflict minimal damage and allow for functioning of the spinal cord after surgery.³² Reviews of this process, however, indicate that while it has been successful in animals including rats, cats, and mice, those animals have different spinal cord circuitry than humans and the precise mechanisms that lead to “re-wiring” is still unclear.³³

1. Protocol

During HEAVEN, the doctors will first induce hypothermia in the donor and recipient.³⁴ Second, the neck of both the donor and recipient will be cut open and the blood vessels of both bodies (still otherwise intact) will be connected via tubes so blood is exchanged between the two bodies.³⁵ Next, the spinal cord on both the donor and recipient is cut and blood vessels are left for connecting the donor body to the recipient head.³⁶ Then, the recipient’s spinal cord is reconnected using polyethylene glycol (PEG), which is similar to glue for the spinal cord.³⁷ Finally, the skin, muscle, and other tissues are attached and the body is kept in a coma to allow time for the individual to recover.³⁸

There is one protocol in particular that Canavero claims will ensure the success of this process: Gemini. HEAVEN is the overarching procedure, and Gemini is a procedure included within HEAVEN. Gemini stems from research conducted by Dr. Richard Borgens in 2004. The research involved

²⁹ Lamba et al., *supra* note 15.

³⁰ *Id.*

³¹ *Id.*

³² *Id.*

³³ *Id.*

³⁴ Lamba et al., *supra* note 15 (inducing hypothermia is a procedure used to protect the transplanted brain. Ren was able to accomplish a head transplant procedure at a less aggressive temperature than other researchers but acknowledges that the optimal time for cooling has not been established).

³⁵ Sky News, *World’s First Head Transplant: What’s Involved?*, YOUTUBE (June 12, 2015), <https://www.youtube.com/watch?v=1IJ7ZBGSykA> (describing this process as cross-circulation).

³⁶ *Id.*

³⁷ *Id.* See also, PZ Myers, *Dangerous and Unethical*, FREETHOUGHT BLOGS (Apr. 10, 2015), <https://freethoughtblogs.com/pharyngula/2015/04/10/dangerous-and-unethical/> (“Slice through long fibers, and you’ve still destroyed long distance connections. He doesn’t say anything about scarring; apparently, polyethylene glycol is magic and will allow the cut ends to fuse neatly.”).

³⁸ Sky News, *supra* note 35.

paraplegic dogs who were treated with PEG injections, which fuse membranes of a cell together.³⁹ Dogs were injected within seventy-two hours of their spinal cord injuries. After two weeks, more than half of the treated dogs were able to walk.⁴⁰ Canavero will utilize the research done by Dr. Borgens and add electro-stimulation in order to accelerate recovery of the severed neurons.⁴¹

This surgical process is plagued with concerns, such as the induced hypothermia. Ren himself acknowledges the lack of information and knowledge on this step because there is currently no established optimal time for cooling.⁴² Furthermore, he acknowledges that the recipient body may suffer complications due to hypothermia, such as hypotension, thrombosis, and bradycardias, but writes off these complications since the body is later discarded.⁴³ In regards to cross circulation, Ren's procedures have proven effective in mice head transplantations, but there is little research into its application on humans.⁴⁴

Another concern involves the fact that Dr. Borgen's research involved dogs with spinal cord compression injuries rather than transection injuries.⁴⁵ A compression injury involves the spinal cord being disrupted from its normal function by bone, blood vessels, or herniated disks compressing the spinal cord.⁴⁶ Transection injuries involve severing the spinal cord. This is significant because while the PEG procedure was successful on dogs with compression injuries, it is not "generalizable to the procedure of spinal cord transection, as would occur in head transplantation."⁴⁷ Furthermore, testing of this procedure has not been conducted on injured humans.⁴⁸ Other researchers tested the Gemini protocol on mice, using PEG after a full transection of the cervical cord.⁴⁹ Results revealed that the group of mice receiving PEG

³⁹ Lamba et al., *supra* note 15.

⁴⁰ *Id.*

⁴¹ *Id.*

⁴² *Id.*

⁴³ *Id.*

⁴⁴ *Id.*

⁴⁵ *Id.*

⁴⁶ Michael Rubin, *Spinal Cord Compression*, MERCK MANUAL (Jan. 22, 2017), <https://www.merckmanuals.com/professional/neurologic-disorders/spinal-cord-disorders/spinal-cord-compression>.

⁴⁷ Lamba et al., *supra* note 15.

⁴⁸ *Id.* (explaining how it has been conducted on uninjured volunteers as a safety trial).

⁴⁹ C-Yoon Kim et al., *GEMINI: Initial Behavioral Results After Full Severance of the Cervical Spinal Cord in Mice*, SURGICAL NEUROLOGY INT'L (Sep. 13, 2016), <http://surgicalneurologyint.com/surgicalint-articles/gemini-initial-behavioral-results-after-full-severance-of-the-cervical-spinal-cord-in-mice/>. See also *Spinal Cord Injury*, JOHNS HOPKINS MED., http://www.hopkinsmedicine.org/healthlibrary/conditions/physical_medicine_and_rehabilitation/spinal_cord_injury_85,P01180 (last visited Jan. 22, 2018) (explaining that cervical refers to a portion of the spine around the neck).

showed partial restoration of motor function after four weeks, compared to the placebo group, which never recovered useful motor activity.⁵⁰ Finally, the spinal cord stimulation (electro-stimulation) Canavero proposes was only successfully applied clinically on individuals with chronic, incomplete spinal cord injuries, not on individuals with acute spinal cord transection as would occur in transplantation.⁵¹

2. Participants

Initially, the recipient was a Russian man named Valery Spiridonov who suffered from “Werdnig-Hoffman Disease, a genetic disorder that destroys muscle and nerve cells.”⁵² Spiridonov is currently wheelchair-bound and has limited control over his bodily movements.⁵³ Spiridonov believed he did not have much of a choice regarding this surgery; without this surgery, he said, “my fate will be very sad.”⁵⁴ He is a scientist and engineer who believes that the surgery will only take place “when all believe that success is 99% possible.”⁵⁵ Ultimately, Spiridonov decided to withdraw from the project after realizing that there was little chance of obtaining an independent life.⁵⁶ Spiridonov describes the reality of declining the surgery as a “weight lifted off [his] chest” and he will seek crowdfunding for a “more conventional treatment.”⁵⁷ Since his withdrawal, an unidentified Chinese man has taken his place.⁵⁸

⁵⁰ Kim et al., *supra* note 49 (demonstrating that placebos are generally used as a control group, meaning they are not given a treatment and are later compared to those that are provided a treatment).

⁵¹ Lamba et al., *supra* note 15.

⁵² Ana S. Iltis, *The First Human Body Transplant – Ethical and Legal Considerations*, HARVARD L. BILL OF HEALTH (May 30, 2017), <http://blog.petrieflom.law.harvard.edu/2017/05/30/the-first-human-body-transplant-ethical-and-legal-considerations/>.

⁵³ *Id.*

⁵⁴ Alan Martin, *Human Head Transplant: Controversial Procedure Successfully Carried out on Corpse; Live Procedure “Imminent”*, ALPHR (Nov. 17, 2017), <https://www.alphr.com/science/1001145/human-head-transplant>.

⁵⁵ *Id.*

⁵⁶ Will Stewart, *Volunteer Set to Become the First Person to Undergo a HEAD TRANSPLANT Admits He Will NOT Now Undergo the Surgery and Says: ‘That’s a Weight Off My Chest’*, DAILY MAIL (June 21, 2017), <http://www.dailymail.co.uk/news/article-4624364/Man-undergo-head-transplant-gives-hope-surgery.html>.

⁵⁷ *Id.*

⁵⁸ *Id.*

B. Backlash from the Medical/Scientific Community

Canavero specifically states that he has not addressed the ethical aspects of HEAVEN but recognizes the potential dissonance in society.⁵⁹ He refers to a story by Thomas Mann where two men behead themselves and magically their heads are restored, but to opposite bodies.⁶⁰ One man's wife, Sita, is unable to decide which is her real husband—the man with her husband's head or the man with her husband's body.⁶¹ Through this story, Canavero recognizes the ethical dilemma where the recipient would maintain his own mind, but should he reproduce, the recipient would produce the genetic offspring of his donor.⁶² Canavero ultimately dismisses this dilemma because “horrible conditions without a hint of hope of improvement cannot be relegated to the dark corner of medicine.”⁶³

It is important to note that Canavero assumes that the essence of a person is in their brain; by moving the person's head, the whole of the person moves with it.⁶⁴ But what truly makes a person? Philosopher Maurice Merleau-Ponty posited that the mind and body are inseparable and create what is known as the “lived body.”⁶⁵ The body is just as much a part of the person as the mind because the mind's perceptions are based on the body's experiences.⁶⁶ He famously said, “I am my body.”⁶⁷ Under this theory, it is much harder to assume that the whole of the person resulting from this operation will be the full consciousness of the recipient.⁶⁸

Response to this procedure has been overwhelmingly negative from fellow researchers, scientists, and doctors. Bioethicist Arthur Caplan calls the

⁵⁹ Sergio Canavero, *HEAVEN: The Head Anastomosis Venture Project Outline for the First Human Head Transplantation with Spinal Linkage (GEMINI)*, SURGICAL NEUROLOGY INT'L (June 13, 2013), surgicalneurologyint.com/surgicalint-articles/heaven-the-head-anastomosis-venture-project-outline-for-the-first-human-head-transplantation-with-spinal-linkage-gemini/.

⁶⁰ *Id.*

⁶¹ *Id.*

⁶² *Id.*

⁶³ *Id.*

⁶⁴ *Id.*

⁶⁵ Maurice Merleau-Ponty (1908-1961), INTERNET ENCYCLOPEDIA OF PHIL., <http://www.iep.utm.edu/merleau/> (last visited Jan. 22, 2018).

⁶⁶ *Id.*

⁶⁷ *Id.*

⁶⁸ See Lizette Borrelli, *Can an Organ Transplant Change a Recipient's Personality? Cell Memory Theory Affirms 'Yes'*, MED. DAILY (July 9, 2013), <https://www.medical-daily.com/can-organ-transplant-change-recipients-personality-cell-memory-theory-affirms-yes-247498> (A theory called “Cellular Memory” posits that long-term memories live within a cell's nucleus, allowing future recall. Essentially, “the behaviors and emotions acquired by the recipient from the original donor are due to the combinatorial memories stored in the neurons of the organ donated.”).

surgery “rotten scientifically and lousy ethically.”⁶⁹ The first area of concern is the fact that the Animal Welfare and Ethics Research Committee shut down similar research with animals for being lethal to animals and being experiments solely “for the sake of experimentation.”⁷⁰ Furthermore, the HEAVEN procedure is not therapeutic. Its goal is prolonging life.⁷¹ Therapeutic surgeries are generally held to a lower standard of safety because they aim to help individuals overcome disease or heal from injury. Non-therapeutic surgeries are held to a higher standard because they do not serve to heal.

Concern for the recipient’s well-being, identity, and psyche is key. First, Canavero presumes that transplanting the head with the brain will automatically transfer the recipient’s personality and consciousness but, “[t]his confusion to the person’s psychological state could possibly lead to serious psychological problems, namely insanity and finally death.”⁷²

Another major concern for skeptics is immunosuppression. In current transplants, considerable amounts of immunosuppressive agents are required to stop the recipient body from rejecting the donation.⁷³ These agents are generally toxic and can lead to cancer, infections, or premature death.⁷⁴ For example, with cystic fibrosis patients, a lung transplant is used as a treatment for severe lung disease to, hopefully, extend a patient’s life and improve their

⁶⁹ Arthur Caplan, *Doctor Seeking to Perform Head Transplant is Out of His Mind*, FORBES (Feb. 26, 2015), <https://www.forbes.com/sites/arthurcaplan/2015/02/26/doctor-seeking-to-perform-head-transplant-is-out-of-his-mind/#633d92535ed3>.

⁷⁰ Anto Čartolovni & Antonio Spagnolo, *Ethical Considerations Regarding Head Transplantation*, NCBI (June 15, 2015), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4476134/>.

⁷¹ *Id.* (Despite applications that this procedure could be used therapeutically, Canavero’s intent is to prolong life in those with degenerative disorders.) *But see* Furr et al., *supra* note 21. (“The goal of body-to-head transplantation (BHT) is to sustain the life of individuals who suffer from terminal disease, but whose head and brain are healthy. Ideally BHT could provide a lifesaving treatment for several conditions where none currently exists.”).

⁷² Čartolovni & Spagnolo, *supra* note 70.

[T]he person will encounter huge difficulties to incorporate the new body in its already existing body schema and body image that would have strong implications on human identity. Even memories of the role the former body played in the creation of the subjects [sic] identity would encounter possible conflict with a new donor given body, because the identity would reflect itself in the corporeality that does not exist anymore.

Id.

⁷³ Caplan, *supra* note 69.

⁷⁴ *Id.*

health.⁷⁵ Cystic fibrosis is a fatal genetic disease that currently has no cure.⁷⁶ Lung transplants provide an opportunity to extend the lives of patients, with many seeing a year or more of life after the transplant.⁷⁷ For them, the risks associated with the procedure and the side effects of immunosuppressive agents are warranted because without the procedure, they may die much sooner.⁷⁸

III. INTRODUCTION TO ETHICAL RESTRAINTS ON HUMAN EXPERIMENTATION

In response to the horrors of World War II, it became necessary to implement restrictions on human experimentation.⁷⁹ This movement started with the Nuremberg Code, which set out basic requirements for human experimentation, including, but not limited to: voluntary consent, that research not be random and unnecessary in nature, that experiments be based on results from animal experimentation, that experiments avoid unnecessary physical and mental suffering and injury, that no experiment be conducted where there is “reason to believe that death or disabling injury will occur”, and that the degree of risk should not exceed the humanitarian importance of solving the problem.⁸⁰

Throughout time, the rules set forth in the Nuremberg Code have set the groundwork for consensus ethical guidelines. International bodies, such as the WHO, United Nations Educational, Scientific and Cultural Organization (UNESCO), and the Council for International Organizations of Medical Sciences (CIOMS) have released ethical guidelines for research on human subjects.⁸¹ While not binding, these documents guide international bioethics on

⁷⁵ *Weighing the Benefits and Risks*, CYSTIC FIBROSIS FOUND., <https://www.cff.org/Life-With-CF/Treatments-and-Therapies/Lung-Transplantation/What-to-Consider-Regarding-a-Lung-Transplant/Weighing-the-Benefits-and-Risks/> (last visited Jan. 22, 2018) [hereinafter *Benefits and Risks*].

⁷⁶ *What is Cystic Fibrosis?*, CYSTIC FIBROSIS CANADA, <http://www.cysticfibrosis.ca/about-cf/what-is-cystic-fibrosis> (last visited Jan. 22, 2018). See also *Benefits and Risks*, *supra* note 75 (stating that among people with CF, more than 80 percent of lung transplant recipients are still alive after one year, and more than 50 percent are alive after nine years).

⁷⁷ *Benefits and Risks*, *supra* note 75.

⁷⁸ *Id.*

⁷⁹ See *Research & Economic Development: History of Research Ethics*, U. OF MISSOURI-KANSAS CITY, [http://ors.umkc.edu/research-compliance-\(iacuc-ibc-irb-rsc\)/institutional-review-board-\(irb\)/history-of-research-ethics](http://ors.umkc.edu/research-compliance-(iacuc-ibc-irb-rsc)/institutional-review-board-(irb)/history-of-research-ethics) (last visited Jan. 22, 2018) (explaining that concentration camp prisoners were used for medical experiments by German physicians without their consent, leaving most of them dead or permanently crippled).

⁸⁰ *The Nuremberg Code* (1949), <https://history.nih.gov/research/downloads/nuremberg.pdf>.

⁸¹ CIOMS, *supra* note 14; WHO, *supra* note 14; *Universal Declaration on Bioethics and Human Rights*, UNITED NATIONS EDUC., SCI. & CULTURAL ORG. (Oct. 19, 2005), <http://>

research and the operating of Ethical Review Committees (ERCs) or Institutional Review Boards (IRBs). These committees/boards ensure that researchers, institutions, and others abide by accepted standards of research and ensure human safety and willing participation.⁸² This Note focuses primarily on two publications, one from the WHO and the other from CIOMS.

In 2011, the WHO published *Standards and Operational Guidelines for Ethics Review of Health Related Research with Human Participants*, providing guidance to research ethics committees (RECs), organizations that oversee research, and researchers themselves.⁸³ Additionally, the document is intended to provide guidance on the research ethics review process. It was not designed to “take a substantive position on how specific ethical dilemmas in health-related research should be resolved.”⁸⁴ Chapter Three of the WHO publication outlines the standards for determining “the ethical acceptability of research protocols” by providing a checklist for the ethical review boards.⁸⁵ This checklist requires ERBs consider: the scientific design of the study, risks and benefits, how the population of participants are recruited and selected, inducements and financial benefits, how the participant’s privacy and confidentiality are protected, informed consent, and community considerations.⁸⁶

The CIOMS published a set of guidelines called *International Ethical Guidelines for Biomedical Research Involving Human Subjects*, which reflects changes and advances in biomedical research ethics. The guidelines relate to the “ethical justification and scientific validity of research; ethical review; informed consent; vulnerability of individuals”; and more.⁸⁷ The goal is to define national policies for adoption in other countries.⁸⁸

IV. CHINA’S LAWS

China has a relatively short history with bioethics. It was not until the 1980s that courses on bioethics became obligatory for medical students. Moreover, the first textbook on the subject was not published in China until 1983.⁸⁹ “[T]he Ministry of Public Health released its first guidelines on medical ethics” in the mid-1980s; “however, these guidelines were not legally

www.eubios.info/udbhr.pdf [hereinafter UDBHR].

⁸² *Id.*

⁸³ WHO, *supra* note 14, at xi.

⁸⁴ *Id.* at xiii.

⁸⁵ *Id.* at 12.

⁸⁶ *Id.* at 13-14.

⁸⁷ CIOMS, *supra* note 14, at 1.

⁸⁸ *Id.*

⁸⁹ Wolfgang Hennig, *Bioethics in China: Although National Guidelines are in Place, Their Implementation Remains Difficult*, 7(9) EMBO REP. 850 (2006), https://www.researchgate.net/publication/6837240_Bioethics_in_China.

binding”⁹⁰ Even today, they are simply “professional guidance” instead of mandated procedures.⁹¹ In the 1990s, leading university-affiliated hospitals began establishing research ethics committees.⁹² This marked the beginning of ethical review programs in China.⁹³ Currently, the National Health and Family Planning Commission “is responsible for organizing inspection and supervision of the ethical review of biomedical research activities involving human research participants.”⁹⁴ At a provincial level, the National Expert Committee on Medical Ethics researches major ethical issues, provides advice for policymakers, and evaluates the work of expert committees.⁹⁵

A. Ethical Review Process in China

China’s National Health and Family Planning Commission released *Measures for Ethical Review in Biomedical Research Involving Humans* in 2016.⁹⁶ This document explains the many types of research activities that fall within the scope of an ethical review and also describes the ethical review process.⁹⁷ Generally, research on humans, psychological behavior, or any other disease, pathogen, or diagnosis falls within the scope of the ethical review committee.⁹⁸ Human experiments involving new medical techniques are also within the scope, and are particularly relevant to this operation.⁹⁹ In China, when an ERC receives an application for review, the committee first organizes the review to focus on twelve points:

- (1) qualification, experience and technical competence of researchers;
- (2) scientific basis of the research plan, compliance with ethical principles and, for TCM¹⁰⁰ projects, reflection of traditional practices and experience;
- (3) exposure of research participants to risks and expected benefits of research (risk-

⁹⁰ *Id.*

⁹¹ *Id.*

⁹² Zhang Xinqing et al., *The Chinese Ethical Review System and its Compliance Mechanisms*, TRUST: EQUITABLE RES. P’SHIPS 1, 5 (2014), <http://trust-project.eu/wp-content/uploads/2016/03/Chinese-Ethics-Review-System.pdf>.

⁹³ *Id.*

⁹⁴ *Id.* at 7.

⁹⁵ *Id.* at 8.

⁹⁶ *Id.* at 6.

⁹⁷ *Id.* at 8.

⁹⁸ *Id.*

⁹⁹ Xinqing et al., *supra* note 92, at 4. (“According to preliminary estimates, every year in China more than 800 new drugs enter human trials, with approximately 500,000 human research participants participating in them, raising concern for the protection of the rights and interests of human research participants.”).

¹⁰⁰ *Id.* at 7 (TCM stands for Traditional Chinese Medicine).

benefit ratio); (4) comprehensibility of information provided in the informed consent form, and appropriateness of the process of obtaining informed consent; (5) protection of confidentiality of research participants' personal and related information; (6) appropriateness and fairness of inclusion and exclusion of research participants; (7) informing research participants of their rights and interests, including withdrawal without reason, and protection from discrimination; (8) indemnification of reasonable expenses incurred by research participants, and reasonable and lawful compensation for harm caused to research participants due to participation; (9) securing of informed consent by qualified or trained researchers, and readiness to answer questions regarding safety; (10) measures to prevent and respond to any risk that research participants may be exposed to; (11) conflict of interest; and, (12) public opinion.¹⁰¹

Next, the ERC evaluates 7 key factors to determine whether to approve a research project. These seven factors are: “(1) adherence to bioethics; (2) scientific soundness of the research plan; (3) fair selection of research participants; (4) reasonable risk-benefit ratio; (5) signing of proper informed consent form; (6) respect for research participants' rights; and (7) compliance with norms on research integrity.”¹⁰²

China's current regulations are based on the Declaration of Helsinki¹⁰³ in addition to the CIOMS guidelines.¹⁰⁴ Despite having regulations extraordinarily similar to the Western world, China still struggles to comply and is

¹⁰¹ *Id.* at 11. See also *Ethical Governance of Biological and Biomedical Research: Chinese—European Co-operation*, BIONET (Mar. 2010), <http://www.lse.ac.uk/researchAndExpertise/units/BIONET/pdfs/BIONET%20Final%20Report1.pdf> [hereinafter *Ethical Governance*].

At the BIONET workshop on stem cell research held in Shanghai in October 2007, workshop participants debated what would constitute ‘public opinion’ (e.g., on the status of the human embryo) on stem cell research in China in the absence of large-scale or longitudinal national surveys, focus group research or qualitative research among the public or donors. . . . [S]ince China is such a large nation, some participants questioned whether it would be possible to identify a single ‘public view.’

Id.

¹⁰² Xinqing et al., *supra* note 92, at 12.

¹⁰³ *Declaration of Helsinki - Ethical Principles for Medical Research Involving Human Subjects*, WORLD MED. ASS'N, <https://www.wma.net/policies-post/wma-declaration-of-helsinki-ethical-principles-for-medical-research-involving-human-subjects/> (last visited Jan. 22, 2018).

¹⁰⁴ Hennig, *supra* note 89.

continuously criticized for lack of compliance.¹⁰⁵ There are several reasons China has trouble complying with their own standards. For example, some ERCs do not have an established standard of operating procedure and, therefore, use their discretion.¹⁰⁶ The regulations and guidelines also do not provide answers to issues that arise on a day-to-day basis.¹⁰⁷ For example, in the process of informed consent, researchers may struggle to determine whether a patient is given sufficient time and care, whether a patient is given the opportunity to consider the risks and benefits, or whether the informed consent process involves more than just a signature.¹⁰⁸ Other ERCs simply may not comply with their standard operating procedures because the procedures are not comprehensive, the members are unfamiliar with the procedures, or there is a lack of standardization, poor management, or a lack of infrastructure.¹⁰⁹ This is exacerbated by the fact that a small percentage of ERC members are people with backgrounds in ethics.¹¹⁰ Many have backgrounds in medical science, and all receive training in good clinical practice, but not all are educated in ethics or jurisprudence.¹¹¹

China has made strides in ethical reviews, but not enough to match the compliance standards in the United States or Europe.¹¹² Even though China is not required to abide by international standards, the semblance of their laws and procedures to those of Europe and the United indicate, at least facially, an intent that their laws be evaluated similarly to those standards. In the 80s, "some biological and medical research institutions in China started to set up ethics commissions" inspired by strict international rules when conducting international joint research programs.¹¹³ Since then, China has made an effort to comply with "internationally recognized ethical norms."¹¹⁴ For example, ERCs have started providing training to their members and researchers on

¹⁰⁵ *Id.*

Hongyun Huang, a Beijing neural surgeon, treats patients with spinal-cord injuries or various neurodegenerative diseases by transplanting fetal brain tissue to the spinal cord. The publication of his method has been rejected by several international scientific journals on the basis of the argument that the data do not meet international safety standards and that necessary controls are lacking—a conclusion that has recently been supported by three internationally recognized neurologists.

Id.

¹⁰⁶ Xinqing et al., *supra* note 92 at 12.

¹⁰⁷ *Ethical Governance*, *supra* note 101.

¹⁰⁸ *Id.*

¹⁰⁹ Xinqing et al., *supra* note 92 at 12.

¹¹⁰ *Id.*

¹¹¹ *Id.*

¹¹² *Id.* at 4-5.

¹¹³ *Id.*

¹¹⁴ *Id.*

ethics.¹¹⁵ These trainings focus on informed consent, acceptable risk-benefit ratios, privacy protection, and justice.¹¹⁶ Considering the facts of the body transplant procedure, it is not difficult to see how that procedure fits within these standards. The participant has given informed consent. The risk-benefit ratio can include the potential benefit to society if this surgery is successful (considering that one's life may be sacrificed, but thousands of others saved or bettered). The privacy of the participants is being maintained (since the resignation of Spiridonov, there has been no information regarding the identity of either the donor or the recipient). Finally, justice is served under the rationale that the transplant does benefit the recipient because, if the procedure is successful, he has an opportunity at an improved quality of life.

As China has made considerable strides in medical research and development, they continue to lead the medical industry and strive to be the best. They have permitted other controversial procedures in the past—for example, using prisoners to harvest organs.¹¹⁷ China now faces criticisms that the only reason for allowing this surgery to occur is so that, in the off chance it succeeds, they can boast the medical advancement before other countries take credit.¹¹⁸ There is added concern that the participants, specifically the donor of the body, have not consented and may not, in fact, be dead.¹¹⁹ China does not currently have a uniform standard for determining death.¹²⁰ On the other hand, the United States has adopted the Uniform Determination of Death Act, which defines death as “when there is either an irreversible cessation of circulatory and respiratory function or there is an irreversible cessation of all brain function.”¹²¹

¹¹⁵ *Id.*

¹¹⁶ Xinqing et al., *supra* note 92.

¹¹⁷ James Griffiths, *Report: China Still Harvesting Organs from Prisoners at a Massive Scale*, CNN (June 24, 2016), <http://www.cnn.com/2016/06/23/asia/china-organ-harvesting/index.html>.

¹¹⁸ It is our suspicion that the authorities in China supporting this procedure are doing so wagering that a successful transplant will demonstrate to the world the dazzling level of technological achievement in the country. Perhaps it will. At a minimum, this procedure reveals that Chinese authorities believe there is no cost too high for raising China's profile on the world stage.

Karen Rommelfanger & Paul Boshears, *Human Head Transplants are About to Happen in China: But Where are the Bodies Coming From?*, NEWSWEEK (Nov. 16, 2017), <http://www.newsweek.com/head-transplant-ethics-why-china-why-now-712331>. (Chinese doctor who will perform the first head transplant denies surgery to have ethical conflicts. Canavero also claims that the procedure will cost approximately \$100 million and will require several dozen surgeons and specialists).

¹¹⁹ *Id.*

¹²⁰ *Id.*

¹²¹ Uniform Determination of Death Act, 6 S.C. Juris. § 4 (2018).

V. ANALYSIS

Ultimately, these factors and different methods of evaluation can be summed up into a number of categories worth further discussion: informed consent, risk and benefit ratio, the scientific validity and scientific design, the selection and privacy of the research participants, and the research's adherence to bioethics. These topics will be discussed in greater detail throughout this Note.

While other factors for review may be at issue in this procedure, there is either not enough concern from the community as a whole, not enough information to evaluate these factors, or these factors simply do not appear to apply. For example, the confidentiality of the participants does not appear to apply to the case. Currently, there is no information as to the names of either the donor or the recipient. As mentioned, the original recipient, Spiridonov, has since withdrawn. When Spiridonov was the intended recipient, there was considerable publicity surrounding his decision. He was featured on programs and websites including CBS¹²², DailyMail¹²³, Al Jazeera¹²⁴, and FOX¹²⁵, to name a few. Clearly, Spiridonov's involvement was not kept confidential. There is, however, no evidence that his name or image was released without his permission, making any claims of violating his privacy rights moot. If he voluntarily disclosed his involvement in the procedure, there are no privacy concerns. The newest recipient, however, has not been identified.

Furthermore, the indemnification of expenses incurred by the participants is not discussed. The surgery itself is expected to cost upwards of \$20 million.¹²⁶ There is no information about how the recipient will pay for the procedure and follow-up care. Alternatively, there is no indication of whether such expenses are incurred by the researchers and their supporters.

¹²² Ashley Welch, *Russian Man Volunteers for First Human Head Transplant*, CBS NEWS (Aug. 29, 2016), <https://www.cbsnews.com/news/russian-man-volunteers-for-first-human-head-transplant/>.

¹²³ Will Stewart, *Disabled Human Guinea Pig is Selling 'World's First Head Transplant' Mugs and T-shirts Pay for £14m Operation Himself*, DAILYMAIL (Feb. 5, 2016), <http://www.dailymail.co.uk/news/article-3432084/Disabled-human-guinea-pig-selling-world-s-head-transplant-mugs-t-shirts-pay-14m-surgery-HIMSELF.html>.

¹²⁴ *Neurosurgeon to Attempt World's First Head Transplant*, AL JAZEERA (June 13, 2015), <http://www.aljazeera.com/news/2015/06/neurosurgeon-attempt-world-head-transplant-150613072123910.html>.

¹²⁵ Crystal Bonvillian, *Who is Valery Spiridonov? 5 Things to Know About Russian Volunteer for First Human Head Transplant*, BOSTON 25 NEWS (Aug. 30, 2016), <http://www.fox25boston.com/news/who-is-valery-spiridonov-5-things-to-know-about-russian-volunteer-for-first-human-head-transplant/432852114>.

¹²⁶ Jaden Jane, *World's First Human Head Transplant All Set in December, Man from Russia Volunteered*, THE SCI. TIMES (Mar. 28, 2017), <http://www.sciencetimes.com/articles/11181/20170328/worlds-first-human-head-transplant-all-set-in-december-man-from-russia-volunteered.htm>.

A. *Adherence to Bioethics*

First, the Chinese requirements include that the research adhere to the standards of bioethics. According to CIOMS, there are three basic ethical principles that should be evaluated where human subjects are involved: respect for persons, beneficence, and justice.

Respect for persons incorporates two ethical considerations: respect for autonomy, meaning “those who are capable of deliberation about their personal choices should be treated with respect for their capacity for self-determination” and protection of persons with impaired or diminished autonomy, meaning those with diminished capacity should be protected from harm or abuse.¹²⁷ In some situations, a person needs extensive protection. This includes prohibiting or excluding individuals from research that could harm them.¹²⁸ Generally, respect for an individual just requires that a person participates in research voluntarily.¹²⁹ Using prisoners as subjects is an example of lacking respect for persons because the prisoners may feel coerced to agree to research.¹³⁰

Beneficence is an obligation to maximize benefits and minimize harm.¹³¹ This means that the research should be sound and the investigators competent, but also that there should be no deliberate infliction of harm on the participants.¹³² Consider the Hippocratic oath to “do no harm” as an example of beneficence.¹³³ This obligation falls primarily on researchers who serve as medical practitioners. They have a responsibility to evaluate and address when it’s acceptable to place a research participant at risk and when it is not.¹³⁴

Finally, justice requires a person to act in regard to what is morally right.¹³⁵ One way to understand this principle is to consider the idea that “equals should be treated equally.”¹³⁶ This also means minimizing the risk to

¹²⁷ CIOMS, *supra* note 14.

¹²⁸ *The Belmont Report: Ethical Principles and Guidelines for the Protection of Human Subjects of Research*, NAT’L COMMISSION FOR THE PROTECTION OF HUM. SUBJECTS OF BIOMEDICAL RES. AND BEHAV. RES. B(1) (Apr. 18, 1979), <https://www.hhs.gov/ohrp/regulations-and-policy/belmont-report/read-the-belmont-report/index.html>.

¹²⁹ *Id.*

¹³⁰ *Id.*

¹³¹ *Id.*

¹³² CIOMS, *supra* note 14.

¹³³ *Greek Medicine*, NAT’L LIBR. OF MED., NAT’L INSTS. OF HEALTH: HIST. OF MED. DIV., https://www.nlm.nih.gov/hmd/greek/greek_oath.html (last updated Jan. 22, 2018).

¹³⁴ *The Belmont Report*, *supra* note 128, at B(2).

¹³⁵ CIOMS, *supra* note 14.

¹³⁶ *The Belmont Report*, *supra* note 128, at B(3).

vulnerable subjects.¹³⁷ According to the Belmont Report, there are some formulations for determining the ways burdens and benefits should be distributed: “(1) to each person an equal share, (2) to each person according to individual need, (3) to each person according to individual effort, (4) to each person according to societal contribution, and (5) to each person according to merit.”¹³⁸

These requirements may not seem facially relevant, particularly justice, but they are basic tenants of bioethics. Respect for autonomy provides a basis for evaluating informed consent. Beneficence is a basis for a risk/benefit analysis, and justice is a basis for ensuring that participants with diminished capacity are not bearing the weight of this procedure.

For example, a research institute associated with John Hopkins University established a nontherapeutic research program where lead paint abatement was performed in different homes.¹³⁹ Essentially, the program divided certain homes into classes where different levels of abatement were done to the homes.¹⁴⁰ Landlords received public funding and were encouraged to rent their homes to families with young children.¹⁴¹ The children’s blood was then analyzed to determine how effective the different abatement methods were.¹⁴² It was expected and contemplated that the children would “accumulate lead in their blood from the dust, thus helping the researchers to determine the extent to which the various partial abatement methods worked.”¹⁴³ Though the families gave consent, a U.S. Court held that the parents could not consent to this type of research because it placed children in a “potentially hazardous nontherapeutic research surrounding[.]”¹⁴⁴

This case provides an example of research that violates all three of the principles discussed. First, there is a clear lack of respect for persons because the children faced adverse consequences from a situation in which they either did not give their consent or were unable to do so. Second, the children suffered harm when they inhaled and ingested lead dust, which strongly cuts

¹³⁷ CIOMS, *supra* note 14.

Risk to vulnerable subjects is most easily justified when it arises from interventions or procedures that hold out for them the prospect of direct health-related benefit. Risk that does not hold out such prospect must be justified by the anticipated benefit to the population of which the individual research subject is representative.

Id.

¹³⁸ *The Belmont Report*, *supra* note 128 at B(3).

¹³⁹ *Grimes v. Kennedy Krieger Institute, Inc.*, 782 A.2d 807 (Md. 2001).

¹⁴⁰ *Id.*

¹⁴¹ *Id.*

¹⁴² *Id.*

¹⁴³ *Id.* at 812.

¹⁴⁴ *Id.* at 814.

against the principle of beneficence. Finally, there was no justice because children overwhelmingly bore the brunt of the adverse effects of the research.

B. *Informed Consent*

All research involving humans requires informed consent.¹⁴⁵ Informed consent is defined as: “a decision to participate in research, taken by a competent individual who has received the necessary information; who has adequately understood the information; and who, after considering the information, has arrived at a decision without having been subjected to coercion, undue influence or inducement, or intimidation.”¹⁴⁶

China has strict laws regarding informed consent. To achieve informed consent, researchers must fully inform participants of the experimental risks of a research project, the goals of the procedure, and the methods to be used in that procedure.¹⁴⁷ There are three major portions to informed consent: (1) information, (2) understanding, and (3) voluntariness.¹⁴⁸

Full information means that the researchers provide the subjects with complete and accurate information as known before the trial begins, which is the prerequisite for subjects to make rational decisions on whether to participate in the research.¹⁴⁹

The researchers first determine the scope of information required based on the best interests of the subjects.¹⁵⁰ Then, they inform the subjects of those risks, including those that may cause a person to reconsider participating in the study. Next, researchers inform the subject of all available information regarding the experiment.¹⁵¹ There are certain protocols that researchers must follow when conducting their studies. For example, the subjects must be aware that they can leave the procedure at any time without reason, and that their personal information will remain confidential.¹⁵² Furthermore, the subject must be aware of the purpose of the experiment and the expected benefits and risks, they must have sufficient time to decide whether or not to participate, and they may receive treatment or compensation.¹⁵³ Finally, the Chinese ERCs are required to ensure that informed consent was obtained by qualified

¹⁴⁵ CIOMS, *supra* note 14.

¹⁴⁶ *Id.*

¹⁴⁷ Xiang Yu & Wei Li, *Informed Consent and Ethical Review in Chinese Human Experimentation: Reflections on the “Golden Rice Event,”* 33 BIOTECHNOLOGY L. REP. 155, 156 (2014).

¹⁴⁸ *Id.*

¹⁴⁹ *Id.*

¹⁵⁰ *Id.*

¹⁵¹ *Id.*

¹⁵² *Id.*

¹⁵³ *Id.*

or trained researchers with readiness to answer questions regarding the patient's safety.¹⁵⁴

The Chinese requirements are very similar to those outlined by the WHO and CIOMS. All require disclosure of risks and benefits and assurances that information will stay confidential. However, some differences still exist. For example, the Chinese do not require a disclosure of who is funding the research, which is required by CIOMS.¹⁵⁵

For "understanding," the participants merely have to sign a consent form indicating that they understand the medical interventions and all the related circumstances.¹⁵⁶ This standard is disappointing because it does not require any evaluation methods to ensure that the participant truly understands the risks. Researchers are, however, encouraged to "avoid ambiguous content and fuzzy speech; avoid inducement or coercion; and obtain the autonomous consent of the subjects."¹⁵⁷

Finally, for a participant to voluntary consent, they must have a "full understanding of the research's nature, purpose, procedures, benefits, and risks."¹⁵⁸ This category focuses on the participant's capacity to give consent. If they are incapacitated or otherwise unable to consent, then this standard is not met.¹⁵⁹ Informed consent can only be exempted in three situations: "(1) emergencies, (2) compulsory health care, and (3) situations where direct patient disclosure is inappropriate."¹⁶⁰

When an ERC evaluates informed consent, they evaluate the following aspects: (1) whether the rights and interests of the subject meet the standards of "Good Clinical Practice"; (2) whether subjects understand the purpose and methods of the experiment and whether there are emergency measures in place for potential problems; (3) whether subjects are able to withdraw at any time; (4) whether the trial design protects the subjects from damage as best as possible; (5) whether subjects indicate informed consent; and (6) whether the researchers respect the subjects opinions on participation.¹⁶¹

These factors do not deviate from those in the international community. For example, the WHO requires informed consent for all procedures unless informed consent is waived by the Research Ethics Committees when deemed consistent with international and national standards.¹⁶²

¹⁵⁴ *Id.*

¹⁵⁵ *Id.*

¹⁵⁶ Yu & Li, *supra* note 147.

¹⁵⁷ *Id.*

¹⁵⁸ *Id.*

¹⁵⁹ *Id.*

¹⁶⁰ Jane Hickman, *Ethics Committee Information: China*, DUKE CLINICAL RESEARCH INST. (Aug. 26, 2013), <https://www.nihcollaboratory.org/sites/CbyC/Lists/ETHICS%20COMMITTEE%20INFORMATION/DispForm.aspx?ID=3>.

¹⁶¹ Yu & Li, *supra* note 147.

¹⁶² WHO, *supra* note 14, at 14.

According to CIOMS, the process of obtaining informed consent begins when initial contact is made with a potential subject and continues throughout the study.¹⁶³ Informed consent must be given to the person manifesting consent in a way that suits their level of understanding, and the investigator must be sure the subject adequately understood the information.¹⁶⁴

CIOMS outlines all of the necessary information that must be communicated to a potential subject.¹⁶⁵ There are twenty-six different pieces of information that must be provided to the potential subject, including, but not limited to: the individual is right to withdraw at any time without penalty or loss of benefits; the purpose of the research is and what the procedures are; the expected duration of the individual's participation; "any foreseeable risks, pain or discomfort, or inconvenience to the individual... including risks to the health or well-being of a subject's spouse or partner"; the direct benefits to the subjects; the expected benefits to the research community; whether the resulting products or interventions will be available to subjects; any current available alternatives to the intervention; whether biological specimens will be disposed of or stored for possible future use; and, that an ethical review committee has approved the research.¹⁶⁶ These guidelines serve to illustrate the numerous concerns an ERC will have in evaluating whether a subject has given informed consent. All of these factors must be disclosed (along with others) to potential participants.

Furthermore, investigators are required to "refrain from unjust deception, undue influence, or intimidation."¹⁶⁷ Deception, in particular, is not permitted when it would "disguise the possibility of the subject being exposed to more than minimal risk."¹⁶⁸ Intimidation, on the other hand, completely invalidates informed consent. Particularly where the study has a therapeutic component, the participants "must [be] assure[d] that their decision on whether to participate will not affect the therapeutic relationship or other benefits to which they are entitled."¹⁶⁹ Finally, researchers should not give unjustifiable assurances about the benefits or risks of the research. Risks, in particular, should be given in a completely objective format and include all the pain or discomfort the procedure may entail and any possible hazards.¹⁷⁰ While it is generally not necessary to inform participants of every risk, there is a reasonable person standard required to consider what information is necessary.¹⁷¹

¹⁶³ CIOMS, *supra* note 14.

¹⁶⁴ *Id.*

¹⁶⁵ *Id.*

¹⁶⁶ *Id.*

¹⁶⁷ *Id.*

¹⁶⁸ *Id.*

¹⁶⁹ CIOMS, *supra* note 14.

¹⁷⁰ *Id.*

¹⁷¹ *Id.*

Consider the Tuskegee Trials as an example of what a lack of informed consent looks like. In this experiment, the participants were told they were receiving a treatment for bad blood, but in reality, they were not treated for anything. They were given placebo medications to make them believe they were receiving treatment.¹⁷²

None of the men was [sic] asked to consent to take part in a medical study. They also weren't told that "bad blood" actually was a euphemism for syphilis. Instead, doctors purposely hid the study's purpose from the men, subjecting them during the study's early months to painful spinal taps and blood tests.¹⁷³

The outright lies Canavero told former volunteer Spiridonov show that there has been clear deception. When Spiridonov was still intended to be the recipient, there was evidence that Canavero told him that there was a 90% chance of success that he would walk and be able to have sex again.¹⁷⁴ When Spiridonov later realized that was unlikely, he withdrew from the procedure.¹⁷⁵ Canavero deceived Spiridonov and made unjustified claims regarding the progress of his own research.¹⁷⁶ With the success of the transplant surgery on cadavers, Canavero claimed, "[t]he first human head transplant, in the human mode, has been realised [sic]."¹⁷⁷ He went on to explain,

¹⁷² Jay Reeves, *For Tuskegee Syphilis Study Descendants, Stigma Hasn't Faded*, AP (May 10, 2017), <https://apnews.com/c92d731d511042a98493b0dcb1bd1d26>.

¹⁷³ *Id.*

¹⁷⁴ Sam Kean, *The Audacious Plan to Save This Man's Life by Transplanting His Head: What Would Happen If It Actually Works?*, THE ATLANTIC (Sep. 2016), <https://www.theatlantic.com/magazine/archive/2016/09/the-audacious-plan-to-save-this-mans-life-by-transplanting-his-head/492755/> ("Canavero claims that the surgery has a '90 percent plus' chance of success, and has promised Spiridonov the ability to walk and have sex afterward.").

¹⁷⁵ Stewart, *supra* note 56.

¹⁷⁶ PZ Myers, *supra* note 37.

But I can fault Canavero for exploiting him and lying to him. This procedure will not work. If it was a good procedure, show me a dog that has undergone it, walking across the stage with a transplanted body. Try it with monkeys first. But he can't: the result would be, at best, a shambling horror, an animal driven mad with pain and terror, crippled and whimpering, and a poor advertisement for his experiment. And most likely what he'd have is a collection of corpses that suffered briefly before expiring.

Id.

¹⁷⁷ Tim Collins & Harry Pettit, *World's First Human HEAD Transplant Is 'Successfully' Carried Out on a Corpse (Now All He Needs to Do Is Try It on a Live Person)*, DAILYMAIL (Nov. 17, 2017), <http://www.dailymail.co.uk/sciencetech/article-5092769/World-s-human-head-transplant-carried-out.html>.

[f]or too long nature has dictated her rules to us. We're born, we grow, we age and we die. For millions of years humans has [sic] evolved and 110 billion humans have died in the process. That's genocide on a mass scale. We have entered an age where we will take our destiny back in our hands.¹⁷⁸

This claim alone, that Canavero was prepared to undergo a procedure with someone's life at stake, when he was only successful on cadavers, is concerning. Professor Catherina Becker told "The Sun" that, "[a]ctual success of a head transplant must be measured by long term survival of head and body with the head controlling motor function. This can obviously not be assessed in a corpse and for all we know, would also not occur in a living human."¹⁷⁹ It is deceptive to inform a recipient that the procedure has a likelihood of success when those claims are unsubstantiated by evidence.

There is a stark difference between being able to successfully wire someone who is dead and who will not have to live with the consequences of the procedure, and someone who is actively living. The difference could be compared to taking an engine out of a car and replacing it with another engine. The mechanic can go through all of the motions and secure everything, but he will not know that the car will run until he turns it on. Canavero is the mechanic that has managed to successfully piece together the human body, but he has not demonstrated that that body will function once it is done to a living human being.

1. Donor

Informed consent requires a discussion on the quality of the informed consent given by the donor. While this argument is conjecture, due to a lack of information on the donor or the consent he provided, it is unlikely that the donor expected, before whatever caused his brain-dead status, that he or his body was destined for this procedure. It is implausible that he intended to consent to someone else's consciousness fathering his children; potentially using his body, organs, blood, and cells; and to someone else using his body as a whole. If his body was donated to science or medicine, it is possible he thought that his body, in parts, would be separated to save the lives of many, not simply alter the life of one.¹⁸⁰ It also draws speculation to the nature of

¹⁷⁸ *Id.*

¹⁷⁹ Andrea Downey & Shaun Wooller, *Head Case 'Dr. Frankenstein' Performs World's First Successful Human Head Transplant*, THE SUN (Nov. 17, 2017), <https://www.thesun.co.uk/news/4936767/dr-frankenstein-performs-worlds-first-successful-human-head-transplant/>.

¹⁸⁰ If the donor is a woman, then the recipient could literally bear the children of the donor. See also, Sergio Canavero, *Sex in Heaven*, SURGICAL NEUROLOGY INT'L (April 27, 2016), <http://surgicalneurologyint.com/surgicalint-articles/sex-in-heaven/>.

any involvement his family might have in this procedure—did they consent to his body being used in this way? How will they feel about his biological children being born to another, etc.?

For example, in “Bodies: The Exhibition,” human bodies are treated so they do not rot and are displayed with skin pulled back or veins showing to display the inner structures of the human body.¹⁸¹ This exhibition came under scrutiny questioning where the specimens came from. The exhibit reports the bodies were deceased and unclaimed, from China, and research.¹⁸² It is possible, therefore, that the body being used for this body transplant procedure is similar—an unclaimed body that has been donated to research by default. In the United States, there are more regulations through the Uniform Anatomical Gift Act (UAGA), which requires the researchers to make efforts to notify the family and receive consent. If they do not get consent, then the bodies are available for use as an organ donor only.¹⁸³

2. *Death?*

In evaluating whether the donor is capable of giving consent, it is important to determine whether the donor is considered alive or dead. Death is defined as the “cessation of all vital functions and signs.”¹⁸⁴ Death can be classified in two different ways: brain death or cardio-respiratory death.

The donor is considered brain-dead, which is defined as a body “showing no response to external stimuli . . . and a flat reading on a machine that measures the brain’s electrical activity.”¹⁸⁵ In many countries, brain death is considered death.¹⁸⁶ In the United States, for example, states have adopted the Uniform Determination of Death Act, which defines death as: “An individual is considered legally dead when there is either an irreversible cessation

The fact that the gonads belong to the body donor is actually a facilitator for the whole enterprise. Imagine the parents of the brain dead body donor – racked by sorrow and despair for their loss – who are told that, once the new being will start reproducing, his or her offspring will actually be their (the donor’s parents) descendants! Life out of death.” I offer another personal view: There is no way that I would uphold “sterilization” of the donor body. HEAVEN is about bringing life and allowing life to spread. At the same time, HEAVEN is not a cure for infertility!

Id.

¹⁸¹ *Learn More*, BODIES: THE EXHIBITION, <http://www.premierexhibitions.com/exhibitions/4/4/bodies-exhibition/learn-more> (last visited Oct. 28, 2018).

¹⁸² *Id.*

¹⁸³ Mark Angelo & Daniel Simon Lefler, *Applied Ethics in Health Care Administration: A Case Study of Organ Donation in an Unidentified Person*, J. OF HOSP. ADMIN. (2016), <http://www.sciedu.ca/journal/index.php/jha/article/view/9096>.

¹⁸⁴ *Death*, BLACK’S LAW DICTIONARY (7th ed. 1999).

¹⁸⁵ *Id.*

¹⁸⁶ *Id.*

of circulatory and respiratory function or there is an irreversible cessation of all brain function.”¹⁸⁷

Although the donor is considered brain-dead, he or she is still pronounced alive, because heart and lung functions are maintained on a machine until transplant surgery is ready. While there are not clear laws on the process of determining death in China, the determination of death is nonetheless important. For example, consider a case in the United States where parents of a child born with anencephaly want to donate the organs of their child before the child has formally died. Anencephaly is a birth condition that causes underdevelopment of a child’s brain and skull.¹⁸⁸ These children will often die.¹⁸⁹ Some parents choose to donate the child’s organs since death is imminent. In this case, the hospitals have an interest in taking the child’s organs before brain death because they will be better for transplantation.¹⁹⁰ If the hospital waits until the child dies, the organs could deteriorate and become potentially unusable.¹⁹¹ A U.S. Court considered whether the parents of an anencephalic child could donate the child’s organs, but the court ultimately rejected the notion because the child is still living.¹⁹² This ruling is relevant because if the donor body in this procedure is still living, or is in a persistent vegetative state instead of truly brain dead, then there is a possibility that use of his organs would violate international standards of death.

When a patient dies, there should be family consent before physicians or other entities make use of the body. The death of a family member is already traumatic. It follows that use of that loved one’s body without knowledge or consent can be even more traumatic for a family. For example, take the Henrietta Lacks’ case in 1951. Lacks went to her doctor with symptoms of cervical cancer.¹⁹³ The doctor took a sample of her tissues which were used for testing.¹⁹⁴ Henrietta later died.¹⁹⁵ The cancer cells that the doctor took, however, thrived.¹⁹⁶ They were very invasive, could cling to air particles and

¹⁸⁷ Uniform Determination of Death Act, 6 S.C. Juris. §4 (2018).

¹⁸⁸ *Anencephaly*, ST. LOUIS CHILDREN’S HOSP., <http://www.stlouischildrens.org/diseases-conditions/anencephaly> (last visited Jan. 22, 2018).

¹⁸⁹ *Id.*

¹⁹⁰ *In re T.A.C.P.*, 609 So. 2d 588, 591 (Fla. 1992) (citing Stephen Ashwal et al., *Anencephaly. Clinical Determination of Brain Death and Neuropathologic Studies*, 6 PEDIATRIC NEUROLOGY 233, 239 (1990)).

¹⁹¹ *Id.*

¹⁹² *Id.* at 595.

¹⁹³ Jane Dailey, “*The Immortal Life of Henrietta Lacks*” by Rebecca Skloot, CHI. TRIB. (Nov. 17, 2010), <http://www.chicagotribune.com/lifestyles/books/chi-the-immortal-life-of-henrietta-111710-story.html>.

¹⁹⁴ *Id.*

¹⁹⁵ *Henrietta Lacks Biography*, BIOGRAPHY.COM, <https://www.biography.com/people/henrietta-lacks-21366671> (last visited Nov. 5, 2018).

¹⁹⁶ Dailey, *supra* note 193.

gloves, and live in any environment.¹⁹⁷ At the time, this was a major discovery. The researchers began sending Lacks' tissues out to other labs for study, which were used to test polio vaccines.¹⁹⁸ Her family, however, never knew this, and they also never received any form of compensation for the unauthorized use of Lacks' cells.¹⁹⁹ Furthermore, when a post-doctoral student asked Lacks' husband permission to test the blood of Henrietta's children, her husband recalled, "[t]hey said they got my wife and she [sic] part alive. They said they been doin [sic] experiments on her and they wanted to come test my children see [sic] if they got that cancer killed [sic] their mother."²⁰⁰ Clearly, Lacks' husband was confused and wholly uninformed of the procedure, its scope, and its importance.

Confusion similar to that of the Lacks family's is understandable and would likely be shared if a similar incident happened to any other family, considering the lack of express consent and total lack of knowledge. Furthermore, if these procedures violate theirs or the donor's religion, culture, or morality, then the family may suffer additional trauma. For example, it could be extremely traumatizing believing that a loved-one is not at peace in death, but rather has been dismembered and is still "alive", as his body is being used by the head and brain of another person entirely. It may further traumatize them to learn that their loved-one's offspring are being born to another person without their knowledge, consent, or ability to interact with the resulting children.

In the Chinese culture, many "believe that burial brings peace to the deceased" and the souls of the "dead stay and protect their descendants."²⁰¹ Even the gravesites are chosen based on *fengshui* so that an energy can form and influence the whole family.²⁰² Based on these widespread beliefs, the family of the donor could likely consider this procedure abhorrent and violative of their loved-one's spirit and soul. It would deprive their loved one of true peace and stop him from protecting those still living.

3. Recipient

Unfortunately, there is also very little information regarding the current recipient. Because his identity is unknown, there is little information regarding the recipient's selection or physical limitations before the procedure. Without more information about the donor or recipient, and what details each

¹⁹⁷ *Id.*

¹⁹⁸ *Id.*

¹⁹⁹ *Id.*

²⁰⁰ *Id.*

²⁰¹ Gavin Van Hinsbergh, *A Grave Day-the Culture of Death!*, CHINA HIGHLIGHTS (Feb. 21, 2017), <https://www.chinahighlights.com/travelguide/article/death-culture.htm>.

²⁰² *Id.*

party was provided with, it is difficult to discern whether each party has truly given informed consent.

Canavero relies on the informed consent standard to validate this procedure, but there is an issue of whether a person can legally consent to this procedure at all. There is a certainty of death for the participant if there are any flaws in the procedure. Here, the procedure is expected to fail. Under Chinese law, a procedure that is highly likely to fail could be legally treated as a pseudo-euthanasia or physician-assisted suicide and subsequently prosecuted.

Euthanasia and physician-assisted suicide are illegal in China under Articles 232 and 233 of the Criminal Law of the People's Republic of China. Article 232 of the Criminal Code in China stipulates a punishment of three to 10 years of fixed-term imprisonment for intentional homicide for relatively minor circumstances, and at least 10 years and up to the death penalty for more serious circumstances.²⁰³

Because this surgery has a high likelihood of failure, the surgery itself could qualify as a form of euthanasia or physician-assisted suicide of both the donor and the recipient. Spiridonov previously claimed that he “didn’t sign up for expensive euthanasia.”²⁰⁴ Without seeing a “moving, living monkey, a moving, living rat [that survives] the operation for several months”, he would not do the procedure.²⁰⁵ Although Canavero previously promised Spiridonov the possibility of walking,²⁰⁶ Spiridonov followed through with his claim and eventually withdrew from the procedure once he realized the probability of success was low.²⁰⁷ Further, many researchers have speculated that the procedure could result in Spiridonov developing “uncontrollable phantom limb pain [and] insanity.”²⁰⁸

²⁰³ *Euthanasia & Physician-Assisted Suicide (PAS) Around the World*, PROCON.ORG (July 20, 2016), <https://euthanasia.procon.org/view.resource.php?resourceID=000136#> China; See also Nita Farahany, *Can You Legally Consent to a Head Transplant?* WASH. POST (Aug. 25, 2016), https://www.washingtonpost.com/news/volokh-conspiracy/wp/2016/08/25/can-you-legally-consent-to-a-head-transplant/?utm_term=.9206c044972b (explaining that Canavero could potentially face criminal sanctions if the procedure fails and he is considered negligent).

²⁰⁴ Kean, *supra* note 174, at 13.

²⁰⁵ *Id.* (alteration in original).

²⁰⁶ *Id.*

²⁰⁷ Stewart, *supra* note 56.

²⁰⁸ James Giordano & Nita Farahany, *Weighing the Ethical Implications of the First Head Transplant*, AIR TALK (Aug. 25, 2016), <http://www.scpr.org/programs/airtalk/2016/08/25/51575/weighing-the-ethical-implications-of-the-first-head/>. See also Kean, *supra* note 174 (noting that “Canavero claims that the surgery has a ‘90 percent plus’ chance of success and has promised Spiridonov the ability to walk and have sex afterward.”).

The greatest justification for this procedure is that the living party consented; however, this justification sets a bad ethical precedent to allow controversial and dangerous surgeries simply because patients have consented. Great Britain seems to have accepted the notion that consent is not an iron-clad justification for allowing controversial or dangerous surgeries. They have barred patients from certain surgeries that would be inappropriate or futile, despite the patient's consent. Charlie Gard, for example, was a child that was terminally ill. His parents wanted to take Gard to the United States for an experimental procedure.²⁰⁹ Great Britain, noting that the experimental procedure was futile and would only result in more pain for Gard, prevented Gard's parents from pursuing the experimental treatment in the United States and instead insisted that the child should be allowed to pass in peace.²¹⁰

There are examples in many other countries of doctors refusing to allow certain necessary surgeries for a variety of reasons.²¹¹ Even if the patient is willing to take the risk, the doctors can still refuse treatment. For example, some surgeons refuse to operate on patients that are using nicotine, alcohol, or other drugs.²¹² If surgeons can prevent patients from consenting to a controversial procedure, and if Great Britain can bar a family from seeking potentially life-saving treatment for their child, then certainly China could bar the head transplant participants from consenting to the procedure.

C. Risks & Benefits

According to both CIOMS and the WHO, an investigator has a responsibility to "ensure potential benefits and risks are reasonably balanced and risks are minimized."²¹³ The risks have to be minimized and must be reasonable in relation to the potential benefits of the study, while harm should be evaluated for all participants. Risks include physical, psychological, social, and financial harm.²¹⁴

Some procedures anticipate a therapeutic benefit (beneficial interventions) and must be justified by the expectation that the procedure will be as advantageous to the subject as any available alternative.²¹⁵ Where there is not a prospect of direct therapeutic benefit, the risks to the person must be

²⁰⁹ Katherine Lam, *Charlie Gard Case: Parents Withdraw Application to Bring Sick Baby to US*, FOX NEWS (July 24, 2017), <http://www.foxnews.com/world/2017/07/24/charlie-gard-case-parents-withdraw-application-to-bring-sick-baby-to-us.html>.

²¹⁰ *Id.*

²¹¹ See generally, Sandeep Jauhar, *When Doctor's Slam the Door*, N.Y. TIMES MAGAZINE (Mar. 16, 2003), <http://www.nytimes.com/2003/03/16/magazine/when-doctor-s-slam-the-door.html> (positing different reasons as to why doctors have refused surgeries).

²¹² *Id.*

²¹³ CIOMS, *supra* note 14.

²¹⁴ WHO, *supra* note 14.

²¹⁵ CIOMS, *supra* note 14.

outweighed by the “importance of the knowledge to be gained,” and “the well-being of the [person] should take precedence over the interests of science.”²¹⁶ Beneficial interventions are generally justified by the expectation that they will be as advantageous to the participant as any other reasonable alternative procedure.²¹⁷ Non-beneficial interventions rest on the justification of the knowledge to be gained—they are not more advantageous compared to other procedures and are purely for the sake of research or furthering knowledge.²¹⁸ To evaluate the benefits of a procedure, there must be adequate laboratory testing demonstrating a probability of success without undue risk and the risks to the subject must be minimized.²¹⁹

Even under Chinese laws, the ERC should evaluate the extent to which a participant is exposed to risks and the benefits of the research as a whole.²²⁰ They must also take measures to prevent and respond to any risk that research participants may face.²²¹ Finally, the Nuremberg Code included a provision that restricted experimentation on humans “where there is a prior reason to believe that death or disabling injury will occur.”²²²

One difference between the international guidelines and Chinese law, is that Chinese law allows the public to voice their opinion on the matter.²²³ This could create a skewed effect where the benefit to the public seems to outweigh the risks to the participants because there is so much outcry for the research the individual participant’s safety is compromised. Because of the backlash and controversy arising from this procedure and the fact that China allows public opinion to weigh in on the ethicality of a procedure, this procedure should be quashed.

The risks in this body transplant are substantial. First, the probability for success is very low. In the 1970s, Dr. Robert White transplanted a monkey’s head onto the body of another monkey. The monkey, however, was left

²¹⁶ *Id.*

²¹⁷ *Id.*

²¹⁸ *Id.*

²¹⁹ *Id.*

²²⁰ Xinqing, *supra* note 92.

²²¹ *Id.*

²²² *The Nuremberg Code*, *supra* note 80.

²²³ See *Ethical Governance*, *supra* note 101 (showing the difficulties of evaluating public view:

At the BIONET workshop on stem cell research held in Shanghai in October 2007, workshop participants debated what would constitute ‘public opinion’ (e.g., on the status of the human embryo) on stem cell research in China in the absence of large-scale or longitudinal national surveys, focus group research or qualitative research among the public or donors. What is more, since China is such a large nation, some participants questioned whether it would be possible to identify a single ‘public view’.

Id.

paralyzed and ultimately died nine days later.²²⁴ If the surgery goes awry, there is a 100% chance that both participants will die. There is no exit strategy available.²²⁵ Professor Jan Schnupp, from the University of Oxford, told *The Sun* that, “[t]he expected therapeutic value for the patient would be minimal, while the risks of graft rejection related side effects or death, as a consequence of a mishap during the operation, are huge.”²²⁶

Furthermore, “[t]here is no evidence that the connectivity of cord and brain would lead to useful sentient or motor function following head transplantation.”²²⁷ Dr. Canavero also admits that he is not concerned with the safety of the brain—which is at serious risk for irreparable damage by being kept in a hypothermic state for too long, by being detached from a blood supply for too long, or completely altering the neural inputs.²²⁸ He claims, “I am pretty sure the brain has the capacity to adapt and to fit into the new body by remapping and rewiring Plus, the patient will be submitted to immersive virtual reality, which is a way to recreate in the brain this image of a whole body.”²²⁹ However, there is evidence the person will have difficulties adjusting to the new body based on the results from people that received face and hand transplants.²³⁰

In November 2017, the surgery was conducted on corpses. Canavero and Ren claim the procedure a success. The surgery, however, has been criticized for having little practical significance. This is because the operation on cadavers will not necessarily translate when a person’s life depends on it.²³¹ Additionally, the operation on cadavers has no basis for determining whether that person will be able to function or survive.²³² Ren, for example, claims that the surgery could be “a solution for all clinically incurable diseases.”²³³

²²⁴ Honor Whiteman, *The First Human Head Transplant: ‘It Will Be a Success,’* MED. NEWS TODAY (Oct. 15, 2015), <https://www.medicalnewstoday.com/articles/301073.php>.

²²⁵ Didi Kirsten Tatlow, *Doctor’s Plan for Full-Body Transplants Raises Doubts Even in Daring China*, N.Y. TIMES (June 11, 2016), https://www.nytimes.com/2016/06/12/world/asia/china-body-transplant.html?_r=0.

²²⁶ Downey & Wooller, *supra* note 179.

²²⁷ Sarah Fecht, *No, Human Head Transplants Will Not Be Possible by 2017*, POPULAR SCI. (Feb. 27, 2015), <https://www.popsci.com/no-human-head-transplants-will-not-be-possible-2017>.

²²⁸ Whiteman, *supra* note 224 (“The brain would be completely confused . . . [n]ot only would it be unethical because we don’t have the science, it would be unethical to even think about this because of the significant risk of creating someone who would be insane, demented, or tortured.”).

²²⁹ Whiteman, *supra* note 224.

²³⁰ Cartolovni & Spagnolo *supra* note 70.

²³¹ Wang Xiaodong, *Surgeons Transplant a Human Head*, CHINA DAILY (Nov. 21, 2017), http://www.chinadaily.com.cn/china/2017-11/21/content_34797003.htm.

²³² *Id.*

²³³ Zhuang Pinghui, *Chinese Surgeon Tackles Head Transplant Critics in Countdown to World First*, SOUTH CHINA MORNING POST (Nov. 20, 2017), <http://www.scmp.com/news>

While this could be true, it also establishes a concern that such a risky, lengthy, expensive, and outlandish procedure would be used exactly as a horror movie may suggest. A wealthy individual finds he has some sort of incurable disease like sterility and with enough money, can just trade their body for a new one.

There are benefits to the surgery for those that suffer from quadriplegia, but such surgery is not the only option available. The research cited by Canavero and Ren indicates that their research could be used to cure those with serious spinal cord injuries, allowing such individuals to walk again. The risks of participants being used purely for their bodies in experimental research is not far from the practices seen in the Tuskegee study.

Furthermore, the participant receiving a new body is not terminally ill, yet they are expected to risk their lives for a medically unnecessary procedure. There is no recourse. The options are: the surgery works, which is highly unlikely, or the surgery does not and the recipient dies. There is no rescue procedure should things go unplanned. The risks in this case massively outweigh the highly speculative benefits.

However, that is not to say there are no possible benefits. The recipient could experience an improved life—though the probability of that is low. There are also benefits to the scientific community. This procedure could open doors to further research on spinal cord injuries, transplants of larger portions of the body, and nerve reconnection. Historically, there has been criticism of many transplant procedures, namely heart and face transplants.²³⁴ Despite the controversy, those procedures have been completed and now are more common practice.

Canavero may seem reckless, but Christiaan Barnard, a South African who performed the first human heart transplant, technically killed the first donor, a brain-dead woman, by taking her off life support without her family's permission and giving her an injection of potassium to render her legally dead. The recipient survived for just 18 days. Richard Lawler, who performed the first kidney transplant, was shunned in certain circles and endured rebukes from a national urological organization, even though the surgery succeeded. More recently, face and hand transplants polarized the surgical community. Critics argued that such procedures were unethical because they wouldn't save lives, and recipients would have to take immunosuppressant drugs that would raise their risk of developing diseases. A few prophesied dire social consequences of face

/china/society/article/2120596/chinese-surgeon-tackles-head-transplant-critics-count-down-world.

²³⁴ Kean, *supra* note 174.

transplants: donor families stalking recipients, and markets emerging to buy and sell comely faces. But face and hand transplants proved quite successful, with few downsides.²³⁵

Often, controversial surgeries have a high risk of failure. There are some stark differences, however, between the above described transplants and the proposed body transplant. The heart surgery was conducted on an individual that was dying—without that heart, she would have died anyway (though the ethical issues of expediting that death are not lost). The face transplant, however, did not involve many issues of inevitable death. There was a possibility of failure, but those did not inevitably result in immediate death. This is not true with the head transplant procedure. Furthermore, the validation Canavero and Ren receive from successfully transplanting the heads of cadavers is concerning. The cadaver is already deceased, has no life to lose, and has no sensory or immunosuppressive issues to consider. Transplanting the heads of cadavers just shows that the procedure is physically possible—something that has been known since the first several attempts at body transplants.²³⁶

D. Scientific Design

According to the WHO, the scientific design and conduct of the study is only ethically acceptable if the study relies on valid scientific methods. If the research exposes participants to harm with no possibility of benefit, then it is not considered scientifically valid.²³⁷ Under the CIOMS guidelines, research involving human subjects should focus on discovering new ways to benefit people's health.²³⁸ This means that the research should respect and protect subjects of research.²³⁹ Finally, it places a duty on investigators and sponsors to ensure that studies are scientifically valid.²⁴⁰

Currently, before an experiment can be conducted, it must pass through an ethical review board or committee. According to CIOMS, “[t]he investigator must obtain their approval or clearance before undertaking the research. The ethical review committee should conduct further reviews as necessary in the course of the research, including monitoring of the progress of the study.”²⁴¹ Medical research “must conform to generally accepted scientific principles, and be based on a thorough knowledge of the scientific literature . . . and

²³⁵ *Id.*

²³⁶ Collins & Pettit, *supra* note 177.

²³⁷ WHO, *supra* note 14, at 13.

²³⁸ CIOMS, *supra* note 14.

²³⁹ *Id.*

²⁴⁰ *Id.*

²⁴¹ *Id.*

where indicated, animal experimentation.”²⁴² The ERC is ultimately responsible for safeguarding rights. Scientists and researchers have a set of requirements to abide by, but the true burden rests on the ERC who must thoughtfully review proposed research studies.²⁴³ Finally, under CIOMS, an ERC will not have authority to impose sanctions on researchers who violate ethical standards and can only withdraw ethical approval.²⁴⁴ Governmental, institutional, professional, or other authorities must impose sanctions as a last resort.²⁴⁵

The following two studies show the harm that can arise from conducting experiments on people not only without their consent, but without scientific validity backing up the research. In both of these cases, there was no scientific research that made it seem plausible that the procedures would succeed.

First, the Tuskegee experiment previously mentioned. In 1932, the U.S. Public Health Service conducted a study involving 600 black men.²⁴⁶ Of those men, 399 had syphilis and 201 did not.²⁴⁷ This study was ethically problematic in many ways, including informed consent issues, discussed briefly above.²⁴⁸ The lack of informed consent in this case was so distressing that the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research passed regulations requiring researchers “to get voluntary informed consent from all persons taking part in studies done or funded by the Department of Health, Education, and Welfare.”²⁴⁹ The participants in the study were told they were being treated for “bad blood,” but were never actually treated for syphilis or anything else. Instead, they were simply studied to determine how syphilis affects the human body.²⁵⁰ What was more reprehensible, was the fact that after penicillin became a known cure for syphilis, the researchers did not administer or offer it to the participants.²⁵¹ The conclusion of the research that was deemed too important to stop, was simply that those with syphilis died at a faster rate than those without.²⁵²

Another example is the CIA’s mind control experiments, MK/Ultra, in the 1980s that left participants “emotionally crippled for life.”²⁵³ This experiment

²⁴² *Id.*

²⁴³ *Id.*

²⁴⁴ *Id.*

²⁴⁵ *Id.*

²⁴⁶ *U.S. Public Health Service Syphilis Study at Tuskegee: The Tuskegee Timeline*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/tuskegee/timeline.htm> (last visited Aug. 30, 2017).

²⁴⁷ *Id.*

²⁴⁸ *Id.*

²⁴⁹ *Id.*

²⁵⁰ *Id.* (“Bad blood” is a colloquial term for many ailments including syphilis, anemia, and fatigue).

²⁵¹ *Id.*

²⁵² Reeves, *supra* note 172.

²⁵³ *MK-ULTRA/Mind Control Experiments*, CENT. INTELLIGENCE AGENCY, <https://www.>

consisted of 130 research programs across the United States in prisons, hospitals, and universities.²⁵⁴ In these experiments, unsuspecting individuals were given LSD and other drugs to see what effect “it would have on certain personality types.”²⁵⁵ An intelligence expert and author, John Marks explained that, “[t]here was an age-old dream in the intelligence business about making people do things against their will, to give you information, to perform acts they didn’t want to perform. And the CIA secretly was looking for a pill or a ray or some technique, a panacea, if you will, which would allow them to manipulate people against their will.”²⁵⁶

One man, a participant in the study, Russell Kirk, explained in an interview that he had never taken drugs before, but “knew something was wrong” because he got very depressed and slashed his wrists.²⁵⁷ Kirk was a prison inmate in Atlanta, GA at the time and was given stitches and put in “the hole.”²⁵⁸ When asked why he slit his wrists, Kirk claims he did not know and he “just felt like [he] didn’t want to live any longer.”²⁵⁹ While in “the hole,” Kirk chewed on his vein until he passed out, then was placed in a straitjacket.²⁶⁰ After being taken out of the straitjacket, he tried to hang himself with a blanket.²⁶¹ Another victim of the MK/Ultra, James Knight, and a fellow inmate, stated in an interview as part of the same series that he has experienced loss of memory and flashbacks to the time he was on LSD.²⁶² Knight also attributes his violence to the MK/Ultra experience:

I was a bootlegger when I started, and I never been in no crime of violence or anything like that. And I got convicted. And I’ve cut several since then and pistol-whipped two or three since then. And it’s just changed—it’s just changed me altogether. In fact, no longer than September I was on furlough and I went home and I beat my wife real bad.²⁶³

[cia.gov/library/readingroom/docs/CIA-RDP88-01070R000301530003-5.pdf](https://www.cia.gov/library/readingroom/docs/CIA-RDP88-01070R000301530003-5.pdf) (approved for release Jan. 1, 2006) [hereinafter MK/Ultra Article].

²⁵⁴ *Id.*

²⁵⁵ *MK/Ultra*, CENT. INTELLIGENCE AGENCY, <https://www.cia.gov/library/readingroom/docs/CIA-RDP88-01070R000100570008-5.pdf> (approved for release Mar. 14, 2007) [hereinafter Central Intelligence Article].

²⁵⁶ *Id.* at 2.

²⁵⁷ *Id.* at 1-2.

²⁵⁸ *Id.* at 2.

²⁵⁹ Central Intelligence Article, *supra* note 255, at 2.

²⁶⁰ *Id.*

²⁶¹ *Id.*

²⁶² *Id.*

²⁶³ *Id.*

In Tuskegee, a viable cure for syphilis had become available, but the testing continued. In the CIA studies, they were trying out multiple drugs for the sake of seeing how and if the drugs could be used to control someone's mind. The importance of relying on scientifically valid evidence and experimentation not only protects the participants from potentially dangerous and life-threatening experiments, but also ensures that the researchers do not conduct senseless experiments that have more chance of harming their participants than helping them.

These examples show that great harm can come to study participants, even if the experiments are deemed scientifically valid or for a worthwhile purpose. For example, the Stanford Prison Experiment was considered, at its outset, ethically acceptable by its Institutional Review Board (IRB).²⁶⁴ This experiment involved male college students that were randomly separated into two groups, playing the roles of prisoners or guards.²⁶⁵ The guards were instructed to consider themselves as real guards at a real prison and while they should not harm the prisoners, they should make prisoners feel powerless.²⁶⁶ The goal of the experiment was to focus on how individuals adapt to being in a powerless situation.²⁶⁷ By day six of the experiment, the participants "endured cruel and dehumanizing abuse at the hands of their peers. At various times, they were taunted, stripped naked, deprived of sleep and forced to use plastic buckets as toilets."²⁶⁸ The experiment ended over a week earlier than anticipated.²⁶⁹

While there is no available evidence regarding whether this body transplant procedure has been in front of a Chinese ERC, Canavero and Ren would have had to receive approval or clearance from the ERC before starting research.²⁷⁰ Because the procedure has been highly publicized both internationally and in China, there is an implication that China has sanctioned the procedure. An IRB in the United States would not permit this research without convincing animal data and evidence of the ability to fuse human spinal cords.²⁷¹ Currently, most of Canavero's research has been conducted on

²⁶⁴ *Frequently Asked Questions*, STANFORD PRISON EXPERIMENT, <http://www.prison-exp.org/faq/> (last visited Sept. 23, 2018).

²⁶⁵ *Id.*

²⁶⁶ Romesh Ratnesar, *The Menace Within*, STANFORD ALUMNI (Aug. 2011), https://alumni.stanford.edu/get/page/magazine/article/?article_id=40741.

²⁶⁷ *Id.*

²⁶⁸ *Id.*

²⁶⁹ *Id.*

²⁷⁰ CIOMS, *supra* note 14.

²⁷¹ Iltis, *supra* note 52. See also Kim Hjelmgaard, *Italian Doctor Says World's First Human Head Transplant 'Imminent'*, USA TODAY (Nov. 20, 2017), <https://www.usatoday.com/story/news/world/2017/11/17/italian-doctor-says-worlds-first-human-head-transplant-imminent/847288001/> (Canavero stated, "No American medical institute or center would pursue this, and there is no will by the U.S. government to support it.").

rodents and has not been published in scientific journals.²⁷² The researchers recognize that this experiment falls outside the traditional standards of ethical review because Canavaro explicitly rejects the peer review process, which is the foundation of most Western research.²⁷³ He blames the scientific community for stifling progress. Canavaro argues that his research has a high success rate. Overwhelming information from the scientific community, however, expresses serious doubt that the procedure will be successful. Moreover, even if the procedure is successful, there are doubts, that the recipient will have a better life. If anything, his life will be significantly diminished and painful.²⁷⁴ Canavaro and Ren are conducting a study as reprehensible as all three of the experiments discussed in this section. They are without adequate research or evidence, raising questions of whether this procedure is even feasible. Finally, they are placing a person's life unalterably at risk solely for the sake of experimentation.

E. Research Participants

In China, the ERC is required to evaluate the “appropriateness and fairness of inclusion and exclusion of research participants.”²⁷⁵ This requirement is similar to a guideline from CIOMS that limits the involvement of vulnerable persons in research. There must be special justification for “inviting vulnerable persons to serve as research subjects.”²⁷⁶ Vulnerable persons are those incapable of protecting their own interests due to “insufficient power, intelligence, education, resources, strength, or other needed attributes.”²⁷⁷ In particular, CIOMS recognizes that individuals with disabling or life-threatening diseases are particularly vulnerable and require protection.²⁷⁸ This same guideline also outlines what ethical justifications investigators should provide to the ERC. These justifications include: whether the research can be carried out by others that are less vulnerable; whether “the research is intended to

²⁷² Iltis, *supra* note 52.

²⁷³ Xiaoping Ren & Sergio Canavaro, *Human Head Transplantation. Where Do We Stand and a Call to Arms*, NCBI (Jan. 28, 2016), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4743270/>.

²⁷⁴ Martin, *supra* note 54.

This procedure will not work . . . the result would be, at best, a shambling horror, an animal driven mad with pain and terror, crippled and whimpering, and a poor advertisement for his experiment. And most likely what he'd have is a collection of corpses that suffered briefly before expiring.

Id.

²⁷⁵ Xinqing et al., *supra* note 92.

²⁷⁶ CIOMS, *supra* note 14.

²⁷⁷ *Id.*

²⁷⁸ *Id.*

obtain knowledge that will lead to improved diagnosis, prevention or treatment of diseases or other health problems characteristic of, or unique to, the vulnerable class;” whether the research subjects will be given access to products available as a result of this research; whether the procedures expect health-benefits exceeding those associated with routine medical examination; and the agreement of vulnerable participants is supplemented by permission of their legal guardians.²⁷⁹

In an effort to provide care to those same vulnerable patients, some countries and states within the United States have laws regarding compassionate use of a drug or procedure. “Compassionate use” is a treatment that “is not properly regarded as research, but it can contribute to ongoing research into the safety and efficacy of the interventions used.”²⁸⁰ According to CIOMS and the Declaration of Helsinki (from which this guideline is derived), physicians should be allowed to treat such patients with therapies not yet licensed for general availability.²⁸¹

Essentially, if life-saving procedures or drugs are available to a person with a life-threatening disease or disorder, then physicians may use any of those means, including experimental drugs and procedures to try and preserve that person’s life. For example, consider a person who is imminently dying from cancer and there is a new drug still in its early phase of testing that has not yet been approved by the FDA for human use. Compassionate use means the dying person could take that drug, even though it is risky to take a drug that has not completed testing. As an example, in some U.S. states, compassionate use has been utilized to allow the use of medical marijuana by those that are “seriously ill.”²⁸² Compassionate use essentially allows the seriously ill and his or her primary caregiver to be exempt from state criminal laws prohibiting the use or cultivation of cannabis.²⁸³

The class at hand is certainly a vulnerable class because the researchers are targeting people with severe physical limitations. If the procedure works, it aims to help that group of individuals as well as provide information and guidance on helping those with other spinal cord injuries. Family members of potential recipients argue that even though this procedure sounds impossible, it “may save us.”²⁸⁴ There is an argument that the procedure should be considered equivalent to a compassionate use—their lives are so limited already that there is no real harm that could come from the procedure. The potential for error, however, outweighs these hopes. Currently, all recipient candidates

²⁷⁹ *Id.*

²⁸⁰ *Id.*

²⁸¹ *Id.*

²⁸² *The Compassionate Use Act of 1996: The Medical Marijuana Initiative*, CAL. MED. ASS’N (1996), <https://medicalmarijuana.procon.org/sourcefiles/CMAonMJ.pdf>.

²⁸³ *Id.*

²⁸⁴ Tatlow, *supra* note 225.

must be living and have fully functional brains. The goal of a body transplant is to preserve personality, brain functions, and provide a better body. This means that the body recipients must not be deteriorating mentally. To risk the potential for life and happiness for almost certain death or a permanent vegetative state is unfounded and misguided.

VI. INTERNATIONAL REPERCUSSIONS

Even though international standards are pronounced in every country, enforcement and actual compliance with these standards in China are still lacking. In 2014, a survey of Chinese hospitals found that “according to the 2,877 [ethics-related] papers published by those hospitals, only 21.8% of projects passed ethical review.”²⁸⁵ This is dangerous because companies, researchers, and scientists seeking to experiment on others with few repercussions, have the opportunity to abuse the lax standards in countries such as China and inevitably harm their own citizens. This not only harms individual citizens at risk—who potentially lack money, education, or simply the resources to seek healthcare—but it also creates the societal standard that those in less fortunate countries are subpar or less important to more Western societies. For example, India recently introduced new legislation preventing commercial surrogacy.²⁸⁶ Before that, however, poor women were given the opportunity to serve as surrogate mothers for foreigners wanting a child.²⁸⁷ The change in legislation stems from the exploitation of these poor women by the wealthy.²⁸⁸

This body transplant procedure could produce a similar problem—poor families who lose a young family member could be offered large sums of money for that body to be used in a transplant procedure by the wealthy. If other countries enact strict laws prohibiting or limiting body transplant procedures, they could stimulate or create a market in China and other countries that allow it. As a result, the problem becomes one of regulation in the countries that do not want the procedure to occur. To protect the poor from exploitation, countries could adopt a requirement that the bodies used in the procedures be altruistic donations. Although altruistic donations currently refer to living-organ donations (where the donor continues to live after the organ donation), the same principle could be applied to posthumous body donations. Instead of selling a body or receiving compensation, the families could donate the body as an act of altruism.

²⁸⁵ Xinqing et al., *supra* note 92.

²⁸⁶ Roli Srivastava, *Indian Surrogate Mothers Grab Last Chance to Make Babies Ahead of Impending Ban*, REUTERS (Jan. 19, 2017), <https://www.reuters.com/article/us-india-women-surrogacy/indian-surrogate-mothers-grab-last-chance-to-make-babies-ahead-of-impending-ban-idUSKBN1530FL>.

²⁸⁷ Shashank Bengali, *India Scales Back 'Rent-a-Womb' Services*, L.A. TIMES (Jan. 25, 2016), <http://www.latimes.com/world/asia/la-fg-india-surrogacy-20160125-story.html>.

²⁸⁸ *Id.*

A. Medical Tourism

Controversial procedures are not new to China. The country is regularly in the news for permitting controversial treatments and procedures where other countries will not. For example, in 2005, a Chinese neurosurgeon injected nasal tissue from fetuses into the brains of patients afflicted with ALS and spinal cord injuries.²⁸⁹ A German doctor, whose patient traveled to China specifically for this procedure, scolded his patient upon return for trying an unproven treatment.²⁹⁰ The Chinese neurosurgeon, Dr. Huang, “is confused over why the Western academic world won’t recognize him,”²⁹¹ which is the same sentiment expressed by Dr. Canavaro and Dr. Ren. Dr. Huang’s results are mostly anecdotal because his results rely on self-reports from the patients, which are generally an unreliable measure for researchers.²⁹² Instead, critics argue Dr. Huang should use magnetic resonance imaging or electrical recordings of muscle activity to show the changes in the neural circuitry of the patients.²⁹³ Ultimately, Huang “says he is going to give up trying to convince a Western scientific community that, he is convinced, is prejudiced against him. ‘It’s their loss. If they believed my results, it could dramatically change clinical practice.’”²⁹⁴ The story from Dr. Huang is remarkably similar to the sentiment felt by Dr. Canavaro and Dr. Ren. Frustrated with the Western standards of medicine, peer review, and animal testing, they believe that moving forward with their own procedure is perfectly acceptable despite the majority of the world telling them it is not. However, it presents an important situation: Medical tourism.

Medical tourism occurs when a person travels from one country to another for the purpose of seeking medical care.²⁹⁵ This phenomenon occurs when an individual seeking medical care/treatment can find better medical care/treatment in another country, compared to the individual’s country. Examples of engaging in medical tourism include seeking medical care in another country can be done cheaper or because the procedure is simply not allowed in the patient’s home country.²⁹⁶ China has already emerged as a popular location for medical tourism because of its high-tech medical facilities, shorter waiting

²⁸⁹ David Cyranoski, *Paper Chase*, 437 NATURE 810 (2005), http://library.wur.nl/WebQuery/file/cogem/cogem_t44d85c1f_001.pdf.

²⁹⁰ *Id.*

²⁹¹ *Id.*

²⁹² *Id.*

²⁹³ *Id.*

²⁹⁴ *Id.*

²⁹⁵ *Medical Tourism*, CTRS. FOR DISEASE CONTROL & PREVENTION, <https://www.cdc.gov/features/medicaltourism/index.html> (last updated Dec. 5, 2016).

²⁹⁶ *Id.*

periods for procedures, and medical personnel that are generally trained in the United States.²⁹⁷ There are considerable ethical concerns involved in medical tourism where the procedure or treatment sought is considered dangerous, or inappropriate, according to other countries.²⁹⁸ Should citizens be prevented from seeking procedures that are dangerous, illicit, or not approved by their country of citizenship? That would mean restricting the freedom of citizens, which is generally frowned upon. On the other hand, it also means protecting citizens from dangerous medical procedures that are unsupported by science.²⁹⁹ Allowing controversial, unsupported procedures opens the door to many more ethical concerns than those discussed in this Note.

VII. POSSIBLE REMEDIES

There are some ways China could come into compliance with these international standards. First, they could require researchers to conduct more thorough, peer reviewed, research. They could improve enforcement by having punitive regulations or laws for those that violate the standards of ethical conduct. China could also improve the education of ERC members, institutions, researchers, and doctors. This would mean implementing a “comprehensive training system for research ethics committees in order to ensure that committee members receive regular training in biomedical research ethics and related laws and regulations, and have the required knowledge and skill to perform their duty of ethical review.”³⁰⁰ Even simple changes, like “improving and

²⁹⁷ *Reasons Behind the Booming Medical Tourism in China*, HEALTHSTATUS, https://www.healthstatus.com/health_blog/wellness/reasons-behind-the-booming-medical-tourism-in-china/ (last visited Jan. 22, 2018).

²⁹⁸ See Dominic Wilkinson, *Medical Tourism for Controversial Treatment Options*, PRAC. ETHICS (July 19, 2017), <http://blog.practicaethics.ox.ac.uk/2017/07/medical-tourism-for-controversial-treatment-options/>. This blog describes various scenarios where a country may have an interest in preventing its citizens from traveling for medical procedures. For example, should it be permitted for parents to travel to another country to receive treatment for their child if the doctors in their country refuse to provide that treatment? The author then changes the hypothetical to, what if the parents are seeking female genital cutting for their 2-year-old daughter, which is something the mother had done as a child, and they plan to travel to Sudan for the procedure? Or, what if the child is terminally ill with a neurodegenerative disorder? Should his parents be allowed to take him to Belgium to access euthanasia? In all of these scenarios, the patients are receiving elective surgery—not lifesaving surgery. In the latter scenario, there is no saving at all, the parents are seeking to terminate their son’s life. These scenarios are not far from the body transplant surgery discussed in this Note.

²⁹⁹ *Id.*

³⁰⁰ Xinqing et al., *supra* note 92.

The scope of training should include the principles and norms of ethics and related laws and regulations and activities, geared to improving trainees’ ability to identify, analyze and resolve ethical issues. The methods of training should be diverse, to include discussion, case analysis, and ethics workshops, among others. Committee members should be

standardizing the procedural rules, and focusing on the scientific basis and ethical implications. . . under review, especially the scientific and ethical aspects related to risks and benefits, and research participant's rights and interests" would make a significant difference in the productivity and effectivity of the ERCs and help minimize the detrimental impact of bad research.³⁰¹

To sum up, China should put in place a comprehensive training system for research ethics committees in order to ensure that committee members receive regular training in biomedical research ethics and related laws and regulations, and have the required knowledge and skills to perform their duty of ethical review. . . . [H]ealth authorities and medical journals should issue written documents to include medical ethical review as part of the review of submissions. . . . [T]he scope of training should include the principles and norms of ethics and related laws and regulations and activities, geared to improving trainees' ability to identify, analyze, and resolve ethical issues. . . . [C]ommittee members should be assessed as to their ethical knowledge and skills on a regular or irregular basis.³⁰²

Between 2006 and 2009, a project called BIONET operated between Europe and China. BIONET examined the challenges of ethical governance.³⁰³ They evaluated questions of ethical regulation and deemed it necessary that laws and regulations become a part of any ethical framework.³⁰⁴ The project saw problems with implementation, however. Translating laws into practice led to misunderstandings and regulating one aspect of the system did not guarantee that every aspect would cooperate.³⁰⁵ Furthermore, science journals had a role in that system, "as published research should not only be scientifically rigorous but also ethically sound."³⁰⁶ Journals have a responsibility to not allow scientists that conduct reprehensible research to publish that research in their journals, as it creates the impression that this research is

assessed as to their ethical knowledge and skills on a regular or irregular basis.

Id.

³⁰¹ *Id.* at 13.

³⁰² *Id.* at 17.

³⁰³ *Ethical Governance*, *supra* note 101, at 2.

³⁰⁴ *Id.* at 13.

³⁰⁵ *Id.* ("At the same time, it became equally clear that regulation was only one part of ethical governance systems which were better thought of as governance networks consisting of scientists, clinicians, regulators, patients, publics, civil society organisations (sic), venture capitalists, research councils, biotechnology companies, scientific journals, etc.").

³⁰⁶ *Id.*

socially acceptable. Journals should also be encouraged to publish material on ethical review.³⁰⁷

By bringing more attention to the many ethical violations in China, there is “[i]ncreased ... scrutiny ... guarantee[ing] the implementation of governmental rules and regulations.”³⁰⁸ China was harvesting organs from prisoners without the world’s attention for many years. Once it was highlighted, they succumbed to the criticism and came into compliance.³⁰⁹ Unfortunately, this took many years to accomplish. Here, there is an opportunity to stop this procedure before it happens.

Finally, there are numerous avenues the international community could take to ensure that appropriate legislation is enacted in China. For example, China is a member of UNESCO, which can create legally binding treaties between countries.³¹⁰ If another country enters into a treaty with China to establish legally-required enforcement of certain bioethical standards, then China could be held accountable for violations of that treaty. There are also numerous international publications that indicate an intent by the UN,³¹¹

³⁰⁷ Xinqing et al., *supra* note 92.

³⁰⁸ Henning, *supra* note 89.

³⁰⁹ Simon Denyer, *China Used to Harvest Organs from Prisoners. Under Pressure, That Practice is Finally Ending*, WASH. POST (Sept. 15, 2017), https://www.washingtonpost.com/world/asia_pacific/in-the-face-of-criticism-china-has-been-cleaning-up-its-organ-transplant-industry/2017/09/14/d689444e-e1a2-11e6-a419-eeffe8eff0835_story.htm?utm_term=.9864195818bb.

The use of prisoners’ organs had left China a global pariah in the transplant field. Relying on prisoners caught in a corrupt and inhumane legal system, China had built the world’s second-largest transplant industry after the United States’. It was effectively an unregulated system in which organs were being delivered not to the most deserving recipients but to the highest bidders. Vast profits were generated as medical ethics were set aside.

Id.

³¹⁰ *What Types of Legal Instrument Does UNESCO Use at the International Level to Protect the Cultural Heritage?*, UNESCO, <http://www.unesco.org/new/en/culture/themes/illicit-trafficking-of-cultural-property/unesco-database-of-national-cultural-heritage-laws/frequently-asked-questions/international-legal-instruments/> (last visited Jan. 22, 2018).

³¹¹ U.N. Educ., Sci., & Cultural Org. [UNESCO], *Universal Declaration on Bioethics and Human Rights*, General Conference of UNESCO, 33d sess. (Oct. 19, 2005), <http://unesdoc.unesco.org/images/0014/001428/142825e.pdf#page=80>. For example, *The Universal Declaration on Bioethics and Human Rights*

[c]alls upon Member States: (a) to make every effort to adopt measures, whether of a legislative, administrative or other character, to give effect to the principles set out in the Declaration, in accordance with international human rights law; such measures should be supported by action in the sphere of education, training and public information

Id.

WHO,³¹² CIOMS, and UNESCO³¹³ to create a uniform method of evaluating the ethicality of human experimentation. However, it is important to note that all of these publications are non-binding on the member countries of those organizations. Creating a legally binding treaty could give the international community an avenue of ensuring ethical standards are met in every country, thus minimizing the risks of exploitation, medical tourism, and unethical procedures.

VIII. CONCLUSION

The procedure itself is controversial and not supported by enough scientific evidence to be allowed in many other countries. However, if China utilizes the rules and regulations they have in place, train their personnel better, and enact some form of enforcement there is a possibility that this procedure could become less detrimental to society and less exploitive of the poor and uneducated.

If this body transplant procedure is successful, it will require other countries to decide whether they want to allow the procedure within their own borders and if not, what they will do when their citizens travel abroad for the procedure. The procedure would force governments to evaluate the definition of family. Governments would have to determine whether someone is more connected to those that intended their birth than to those they are biologically related to. Another issue is whether the biological family of the donor body should have visitation with the resulting children. Families whose children are born with a donor's DNA will have many other issues to face. These implications impact the families of both the donor and the recipient.

The body transplant surgery has not yet occurred. With enough pressure from the international community, it is possible to stop the surgery from occurring until more research is published, peer reviewed, and a review board is able to thoroughly ensure informed consent and a lack of undue risk.

³¹² *Declaration of Helsinki*, WORLD MED. ASS'N OF DECLARATION OF HELSINKI (adopted 2000), <http://www.who.int/bulletin/archives/79%284%29373.pdf>.

³¹³ UDBHR, *supra* note 81.

