

## A bio-civil code for China: articles 1006–1009 of the new Chinese Civil Code

Vera Lúcia Raposo, Liu Sijia\*

**ABSTRACT:** Amongst the many achievements of the first Chinese Civil Code, one of the most discussed is the provision of the so-called biorights. This paper focuses on articles 1006 to 1009, which mainly cover the new regulations on bioethics, biorights and new technologies, to show the breakthroughs made by the Chinese Civil Code. Despite the incomplete solutions provided for the referred norms and its blurred content, the code is a most welcome innovation in a country still seeking a bioregulation capable of handling its astonishing scientific achievements.

**KEYWORDS:** Bioregulation, biorights, Chinese Civil Code, human body, medical technologies, personality rights

**SUMMARY:** 1. The Inclusion of Biorights in the Chinese Civil Code – 2. Legal Status of Human Biological Materials and Legal Power over Them – 2.1. The Power to Make Decisions on Biological Materials – 2.2. The ‘Collective Decision’ Principle – 2.3. The Ban on Trading Human Cells, Tissues and Organs – 3. Clinical Experiments and the Protection of the Human Subject – 3.1. Control over Clinical Experiments and Ethical Review – 3.2. Informed Consent as A Requirement for Clinical Experiments Involving Humans – 3.3. The Ban on Any Payment in Clinical Experiments – 4. Scientific Experimentation with Embryos, Genes and ... Something Else – 4.1. A Traditionally Conservative Framework – 4.2. Types of Research Targeted – 4.3. Limits on Research – 4.3.1. Existing Regulations – 4.3.2. Human Health – 4.3.3. Moral Principles – 4.3.4. Public Interests – 5. Subsequent Developments – 6. Conclusive Notes

### 1. The Inclusion of Biorights in the Chinese Civil Code

In 2020, the National People’s Congress approved the first Chinese Civil Code (CCC). This codification is the most significant breakthrough in personality rights protection in Chinese history. The personality rights<sup>1</sup> chapter (Book Four, Personality Rights, Chapter II) was the subject of the greatest controversy during the legislative process,<sup>2</sup> one of the reasons being the provision, for the first time in China, of the so called ‘biorights’.

\* Vera Lúcia Raposo: NOVA School of Law – NOVA University of Lisbon, Lisbon, Portugal. Centre for Research on Law and Society (CEDIS), FutureHealth / WhatNext.Law. Mail: [vera.lucia.raposo@novalaw.unl.pt](mailto:vera.lucia.raposo@novalaw.unl.pt). Liu Sijia: Post-doctoral researcher, Sun-Yat Sen University Law School, China. Mail: [liusijiaruc@foxmail.com](mailto:liusijiaruc@foxmail.com). The article was subject to a blind peer review process.

<sup>1</sup> This paper uses the concept of ‘personality rights’ as rights that protect the individual in its specific individuality, that is, they protect the legal person’s physical, psychological, and moral identity, together with the external expression of that identity. Cf. B. BEIGNIER, *Le Droit De La Personnalité*, PUF, Que sais-je?, 1992.

<sup>2</sup> See K. LIU, *Comments on Several Important Theoretical Issues about the Chapter on Personality Rights*, in *Peking University Law Journal*, 32, 2020, 883.

This paper concentrates on articles 1006 to 1009 of the CCC,<sup>3</sup> which cover the new regulations on medical ethics, science, and technology. These norms were added to Book Four, Personality Rights, Chapter II in April 2019 after the first gene-edited babies were born at the end of 2018.<sup>4</sup>

Criticisms quickly arose, mainly regarding systematization. Some scholars argued that most articles in this chapter have no firm, logical or systematic links and that this fragmentation could lead to a chaotic and disordered sequence of legislation.<sup>5</sup> This objection is well-grounded, as chapter II includes different norms regarding actual biorights, as well as norms stating the rights to life, safety and dignity, and even norms on sexual harassment and freedom of movement, without clear criteria of connection between them.

From a substantive perspective, scholars claimed that rights to body and health are essentially non-disposable; therefore, articles regulating human clinical trials and body/organ/tissue/cell donation could not be defined as rights that could be easily disposed or transferred.<sup>6</sup> However, this is ungrounded criticism. Even though many jurisdictions maintain a conservative approach to legal powers over one's own body,<sup>7</sup> it is common to recognize rights involving the human body, body parts and biological materials, so this concern might be outdated.

Despite the controversy, these provisions were ultimately included in the CCC, creating personality 'biorights'<sup>8</sup> that feature brand-new perspectives for China regarding human experimentation, clinical trials and reproductive techniques. Although China has been a preeminent player in the scientific domain, these matters were previously very poorly regulated.<sup>9</sup> Thus, bioregulation is absolutely necessary.

<sup>3</sup> These rights are included in Chapter II, about the rights of life, inviolability and integrity of person, and health.

<sup>4</sup> V. RAPOSO, *The First Chinese Edited Babies: A Leap of Faith in Science*, in *JBRA Assisted Reproduction*, 23, 2019, 197.

<sup>5</sup> See H. ZOU, *Re-discussion on the Civil Law Expression of Personality Right*, in *Journal of Comparative Law*, 4, 2016, 1; Also see H. ZOU, *Why Personality Right Can't Be A Separate Part of Civil Code?* in *Website of Institute of Law, China Academy of Social Sciences*, 23 April 2020, at [http://iolaw.cssn.cn/zxzp/201801/t20180124\\_4656241.shtml](http://iolaw.cssn.cn/zxzp/201801/t20180124_4656241.shtml) (last visited on 13/6/2023).

<sup>6</sup> *Ibidem*; Especially see the Research Group for the Civil Code legislation, Chinese Academy of Social Sciences, *Why We Should Strongly Oppose Personality Rights to be a Separate Part of Civil Code?* in *Website of Institute of Law, China Academy of Social Sciences*, 23 February 2018, at [https://www.sohu.com/a/222156411\\_169411](https://www.sohu.com/a/222156411_169411) (last visited on 13/6/2023).

<sup>7</sup> For instance, by banning profit made using the body. In the framework of international law see article 21 of the Convention for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine and article 4/2/c of the European Charter of Fundamental Rights.

<sup>8</sup> The expression 'biorights' is used to refer to rights involving a power of disposal and protection over the body, body parts and biologic components (cells, genes, fluids). See C. TIMOTHY, B. MURDOCH, *Genes, Cells, and Biobanks: Yes, There's still a Consent Problem*, in *PLoS Biology* 15, 2017, e2002654; Referring to a 'biorights movement', see M. HAYDEN, *The Burgeoning "Biorights Movement": Its Legal Basis, What's at Stake, and How to Respond*, in *Boston College Law Review*, 59, 2018, 1775. Also about biorights in the Chinese legal framework, please see the medium and long-term youth development plan (2016-2025) enacted by the State Council of China, which clearly states that China protects the legal rights of youth to enjoy assisted reproductive technology, as well as a series of biorights to dispose their cells, tissues, organs and remains in legitimate ways. This paper will assume that all biorights are personality rights, but that not all personality rights are biorights, as it is the case of the right to honour, the right to a name or the right to marry.

<sup>9</sup> There were some regulations, but not enough in quantity and quality to handle the fast scientific growth. Cf. J. LI ET AL, *Experiments that Led to the First Gene-edited Babies: The Ethical Failings and the Urgent Need for Better*

The CCC does not provide specific solutions for most of the issues – this is probably not even a task for a civil code,<sup>10</sup> but it opens the path for future regulation. The CCC's incursion into these domains creates the expectation of future standards with more concrete norms. The authors understand that most of the norms at stake are supposed to be developed in subsequent regulations, so our criticism is not based on the fact that they are incomplete concrete solutions, but on the fact that some of them are incomplete even as principles. It remains to be seen, though, how much the new expected norms will add to the (extremely general and vague) content of the Civil Code.<sup>11</sup>

## 2. Legal Status of Human Biological Materials and Legal Power over Them

The CCC includes two norms regarding the legal status of human genetic materials and legal power over them, as follows.

### Article 1006

A person with full capacity for civil conduct has the autonomy to decide to donate his human cells, human tissues, human organs and remains in accordance with the law. No organization or individual may force or induce any person to make donation or deceive any person into making donation. A person with full capacity for civil conduct agreeing to make donation in accordance with the provisions of the preceding paragraph shall adopt the written form and may make a will. The spouse, grownup children or parents of a natural person who has not expressed dissent from the donation may jointly decide on the donation in writing after his death.<sup>12</sup>

### Article 1007

Trading in human cells, human tissues, human organs, and remains in any form is prohibited. Any sale or purchase in violation of the provisions of the preceding paragraph is invalid.

### 2.1. The Power to Make Decisions on Biological Materials

Article 1006 of the CCC recognizes that each person has the autonomy to decide to donate his/her cells, tissues, organs and remains in accordance with the law.<sup>13</sup>

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*Governance*, in *Journal of Zhejiang University Science (B)*, 20,2019, 32; R. LEI, R. QIU, *Fight for Regulation and its Enforcement on Stem Cell Therapy in China*, in *International Journal of Cell Science & Molecular Biology*, 6,2019, 28.

One of the last regulations in this regard is the Basic Healthcare and Health Promotion Law. See E. IP, *The Political Determinants of China's New Health Constitution*, in *Medical Law Review*, 29, 2021, 3.

<sup>10</sup> About the relation between the law and the development of bioethics, see R. CHADWICK, D. WILSON, *The Emergence and Development of Bioethics in the UK*, in *Medical Law Review*, 26(2), 2018, 183.

<sup>11</sup> The authors would like to make it very clear that the criticism to (some) Chinese solutions cannot be mistaken for the blind adoption of a so-called 'western perspective' (if there is such a thing as a 'western perspective').

<sup>12</sup> The expression 'human cells' used in these two norms also includes human gametes such as sperm, eggs and other germ cells.

<sup>13</sup> See arts 7-8 of the 2007 Regulation. Also see *The Official Analytical Notes on WHO Human Cells, Tissues and Organs Transplantation Guiding Principle 2008*, Note 6, Ministry of Health, China, 2008, at

The idea of autonomous donation is not entirely new, as it was already present in a 2007 administrative regulation – the Regulation on Human Organ Transplantation (hereinafter, the 2007 Regulation). The 2007 Regulation was the first national-level regulation that settled some of the legal issues on human organ donation,<sup>14</sup> and it recognized the power to freely donate in its Article 8. A similar trend is present in the newly revised Regulation on the Administration of Human Genetic Resources (hereinafter, the 2019 Regulation), which replaced the previous measures and upgraded the former regime to a national-level administrative regulation governed by the State Council.<sup>15</sup>

Article 1006 expands the scope of the ‘human biological materials’ (人体生物材料) that can be donated to include not only human organs but also human cells, tissues and remains.<sup>16</sup> Never before had Chinese laws granted citizens such powers over their bodies.<sup>17</sup> Although some previous regulations and normative documents (the 2007 Regulation and the 2019 Regulation) include provisions for the collection, use and export of human genetic resources by administrative entities, such specific provisions had not been made for individual citizens. Article 1006 of the CCC is a norm of citizen empowerment over the human body in a jurisdiction known to be restrictive in this regard, as it can be demonstrated by legal familism in medical informed consent,<sup>18</sup> the illegality of euthanasia;<sup>19</sup> the collection of organs from convicted individuals without consent;<sup>20</sup> the limitations on surrogacy,<sup>21</sup> among other examples. Some of these features can be found in other jurisdictions, but it is difficult to find them all in one same jurisdiction.<sup>22</sup>

Moreover, Article 1006 is understood by Chinese scholars as a remarkable milestone for altruism in China, as it establishes a legal framework that will enable people to contribute to the medical industry

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<http://www.nhc.gov.cn/cmsresources/mohyzs/cmsrsdocument/doc2072.pdf> (last visited on 17/8/2020), though the latter is only an internal guiding document.

<sup>14</sup> See the 2007 Regulation in Chinese, State Council, China, 2007, at [http://www.gov.cn/flfg/2007-04/06/content\\_575602.htm](http://www.gov.cn/flfg/2007-04/06/content_575602.htm) (last visited on 13/6/2023).

<sup>15</sup> The 1998 Measures (ineffective nowadays) were only a temporary normative document, at administrative level, while the 2019 Regulation (effective) has become an administrative regulation issued and governed by the State Council. See the 2019 Regulation official English translation, State Council, China, 2019, at <http://en.pkulaw.cn/display.aspx?cgid=089bca0349d42372bdfb&lib=law> (last visited on 14/8/2020).

<sup>16</sup> Donation on remains is newly added issue in art 1006 of CCC in 2020.

<sup>17</sup> See the discussion on the self-determination right and personal dignity entitled by the CCC in S. WEN, *Personal Freedom from the Perspective of Chinese Civil Code*, in *Law and Social Development*, 3, 2022, 30.

<sup>18</sup> V. RAPOSO, *Lost in “Culturation”: Medical Informed Consent in China (From A Western perspective)*, in *Medicine, Health Care and Philosophy*, 22, 2019, 17.

<sup>19</sup> Y. WANG ET AL, *Assisted Suicide and Euthanasia: A Comparative Analysis of Dutch and East Asian Cases*, in *The American Journal of Bioethics*, 22, 2022, 74.

<sup>20</sup> N. PAUL ET AL, *Human Rights Violations in Organ Procurement Practice in China*, in *BMC Medical Ethics*, 18, 2017. Some of these features can be found in other jurisdictions, but it is difficult to find them all in the same jurisdictions.

<sup>21</sup> C. WANG, *China Could Not Easily Say “Open” for Surrogacy*, in *Legal Daily Online*, 2 February 2017, at <http://opinion.people.com.cn/n1/2017/0204/c1003-29057272.html> (last visited on 8/6/2022).

<sup>22</sup> A matter where Chinese law is rather liberal is abortion, not out of respect for people’s rights over their bodies, but because of the one-child policy, that was in place for many years. V. RAPOSO, Z. MA, *An Ethical Evaluation of the Legal Status of Foetuses and Embryos under Chinese Law*, in *Developing World Bioethics*, 20, 2019, 43.

and help patients in need.<sup>23</sup> It is also a way for the Chinese government to fight the underground trade in human biological materials. In line with the international trend of human rights protection, in 2015, China banned the use of organs from criminals sentenced to death.<sup>24</sup> Nonetheless, it is estimated that China still has the largest underground human organ market in East Asia,<sup>25</sup> mostly supplied by the black market.<sup>26</sup> As China does not have a tradition of voluntary organ donation, its donation rates are among the lowest in the world (2 donations per million people, compared with 37 per million in Spain),<sup>27</sup> which raises many questions about the source of the other transplanted organs.

Although the Chinese government has had some success in registering new legal donors, many people are still waiting for transplants, which is the greatest reason for rampant underground trading. With the new CCC donation mechanism taking effect, every citizen is entitled to donate his/her human biological materials freely. In addition, acts of forcing or inducing people to donate will be strictly punished by the CCC, which could be a good start for cleaning up China's transplant industry.

Currently, the legal rights and obligations of donors of biological materials are still ambiguous, as they are not expressly stated in the CCC or in the existing regulations. For instance, can prisoners – especially those sentenced to death – donate sperm to their wives or to third-party institutions freely and without restriction?<sup>28</sup> Can research institutions collect biological materials left by patients in hospitals?<sup>29</sup> Can Chinese individuals donate cells/tissues/organs to international research institutions without contravening the regulations? Overall, what legal power do people have over their genetic resources?<sup>30</sup> More detailed judicial interpretations of the CCC are needed to clarify these questions.

## 2.2. The 'Collective Decision' Principle

A particularity of the Chinese regime is the recognition of the power to make joint decisions in matters related to health and the body. This principle is commonly applied in medical issues to allow relatives

<sup>23</sup> L. YANG, *The Innovation and Development of Personality Rights Legislation in Chinese Civil Code*, in *Studies In Law and Business*, 37, 2020, 18.

<sup>24</sup> M. CHENG, N. WINFIELD, *UN: China Moves to Stop Taking Organs from Prisoners*, in *Seattle times*, 10 February 2017, at [https://www.seattletimes.com/nation-world/un-china-takes-steps-to-stop-taking-organs-from-prisoners/\(last visited on 13/6/2023\)](https://www.seattletimes.com/nation-world/un-china-takes-steps-to-stop-taking-organs-from-prisoners/(last%20visited%20on%2013/6/2023)).

<sup>25</sup> B. ROGERS, *The Nightmare of Human Organ Harvesting in China*, *The Wall Street Journal*, 5 February 2019.

<sup>26</sup> E. U. OCHAB, *United Nations Concerned About Organ Harvesting In China*, in *Forbes*, July 8, 2021, <https://www.forbes.com/sites/ewelinaochab/2021/07/08/united-nations-concerned-about-organ-harvesting-in-china/?sh=7fca555c42dd> (last visited on 13/6/2023).

<sup>27</sup> Q. ZHAO, C. BAO, *The First Organ Donation Guidebook has been Published*, in *People's Daily Online*, 23 August 2015, at [http://bj.people.com.cn/n/2015/0823/c14545-26087308.html\(last visited on 18/8/2020\)](http://bj.people.com.cn/n/2015/0823/c14545-26087308.html(last%20visited%20on%2018/8/2020)).

<sup>28</sup> The matter was discussed long ago, by X. KOU, *Research on the Procreation Right of the ones condemned to Death Penalties*, in *Hebei Law Science*, 21, 2003, 28; Also see X. CHEN, *Probing into the Issue of the Right to Procreate for Death Penalty*, in *Hebei Law Science*, 27, 2009, 126; Especially see the latest discussion by Y. LI, Z. SU, *On the Reproductive Rights of Inmates*, in *Science of Law(Journal of Northwest University of Political Science and Law)*, 36, 2018, 182-185.

<sup>29</sup> The answer to this question depends on the classification of those materials as abandoned things (*res nullius*). Cf. J. PILA, *Property in Human Body Parts: An Old Legal Question for a New Technological Age*, in D. ORENTLICHER, T. K. HERVEY (eds), *The Oxford Handbook of Comparative Health Law*, 2021.

<sup>30</sup> See W. LI, J. CHEN, *Institutional Framework for the Management of Human Genetic Resources in China*, in *Human Gene Therapy*, 32, 2021, 1495.

to be informed about the patient's medical condition (together with the patient or even instead of the patient) and ultimately to make the final decision, eventually against the patient's wishes.<sup>31</sup>

Article 1006 of the CCC extends this principle to organ donations, granting the power to decide to the close relatives of the deceased, that is, the spouse, grownup children<sup>32</sup> or parents. This solution dates back to Article 8 of the 2007 Regulation, which established the collective decision principle, according to which the close relatives of any citizens in China have decisive power regarding the donation of the organs of a dead relative. As long as the deceased did not object to donation while alive, the spouse, grownup children or parents can make a joint decision regarding the donation of the deceased's organs.<sup>33</sup>

This collective decision principle was clarified and reconfirmed in the CCC, which is the second-highest legal text in the legal hierarchy.<sup>34</sup> The aim is to give to those who did not agree to donate while alive a last opportunity to do so.<sup>35</sup> Relatives can only agree to donate if the deceased did not express dissent while alive. *A contrario*, if the deceased expressed the wish to donate his/her cells, tissues and organs in writing (as required by this norm), relatives cannot oppose this decision.

Some scholars in China have argued that if a person has not expressly agreed to donation, he/she should be assumed to disagree with the donation, and thus, close relatives should show respect for the deceased and not decide to donate. By stipulating otherwise, the lawmakers of the CCC adopted a "wishful deduction".<sup>36</sup> China is a typical Confucian country deeply influenced by two core values: 'Benevolence(仁)' and 'Filial Piety(孝)'.<sup>37</sup> In The Classic of Filial Piety(孝经), there is a famous preaching saying that "Our bodies – to every hair and bit of skin – are received by us from our parents, and we must not presume to injure or wound them. This is the beginning of filial piety".<sup>38</sup> There has always been a tradition of 'honourable burials (厚葬)' in Chinese history, as Confucian culture considers that honourable and decent corpse presentation reflects filial piety from the next generations, which

<sup>31</sup> This is a widely discussed issue, both in China (V. RAPOSO, *Lost in "Culturation": Medical Informed Consent in China (From A Western perspective)*, *op. cit.*, 17) and abroad (A. SEIDLEIN, S. SALLOCH, Who Cares About Care? Family Members as Moral Actors in Treatment Decision Making, in *The American Journal of Bioethics*, 20, 2020, 80).

<sup>32</sup> 'Grownup children' refers to persons attaining the age of eighteen. See art. 17 of CCC.

<sup>33</sup> Y. WU ET AL, *Cadaveric organ donation in China: A Crossroads for Ethics and Sociocultural Factors*, in *Medicine (Baltimore)*, 97,10, 2018, e9951.

<sup>34</sup> See the Legislation Law of the People's Republic of China Chapter II- Laws, National People's Congress of China, 2015, at LAWINFOCHINA [https://www.pkulaw.com/en\\_law/6da217477d512dabdbf.html](https://www.pkulaw.com/en_law/6da217477d512dabdbf.html) (last visited on 13/6/2023).

<sup>35</sup> B. ZHANG, *Lawyer's Reading: These Articles in CCC are quite Warm*, in *Health Times*, 28 May 2020, at <https://news.sina.com.cn/c/2020-05-28/doc-iiircuyvi5562242.shtml> (last visited on 13/6/2023).

<sup>36</sup> The expression belongs to X. DAI, *We Should not Hurry in Encouraging the Donation of Remains, To Avoid the Rights of the Deceased Being Ignored*, in *Procuratorial Daily*, 29 August 2019. Also see W. TANG, *Cautious Principles shall be Adopted for Donation of Remains*, in *Qilu Evening News*, 26 August 2019.

<sup>37</sup> In filial piety in family relations, see Q. LIU, "Wrong" cases and "wrong" plaintiffs: intergenerational relationships and legal consciousness in China, in *Journal of Law and Society* 50, 2023, 10-12.

<sup>38</sup> The Classic of Filial Piety occupies an important position in Chinese classical education as one of the most popular foundational texts through to late imperial China, at <https://ccontext.org/xiao-jing/zh?en=on> (last visited on 13/6/2023).

means their offspring can have a flourishing living in the future.<sup>39</sup> The idea that the corpse of your close relatives should not be incomplete and indecent<sup>40</sup> is a deep-rooted ethical concept for thousands of years in China. However, due to this legal solution, older people may worry that their remains will be donated for purely economic reasons.<sup>41</sup>

Despite the criticism, the CCC gave relatives the power to decide about donations of human biological materials, for several reasons. First, it was considered that many factors can influence the willingness to donate, and therefore no expression does not mean objection.<sup>42</sup> Second, protecting the deceased is believed to be essentially the same as protecting the close relatives of the deceased.<sup>43</sup> Thus, if the spouse, grownup children and parents jointly agree with the donation, their agreement means that they do not feel harmed by it. Thirdly, this solution was adopted as an incentive to encourage donations based on social charity and public welfare.<sup>44</sup> As stated by Zhang Lei, “[d]onating organs to people in need continues another life”.<sup>45</sup> The strong influence of Confucianism and the family’s decision-making power<sup>46</sup> might have strongly influenced this solution. In traditional Chinese thinking, the most important decisions are made by the family, not the individual, as is clear in the matter of consent for medical treatment.<sup>47</sup>

The principle of collective decision making is particularly troubling regarding gamete donation (as mentioned before, the solution also applies to gametes). Post-mortem gamete donation has long been discussed,<sup>48</sup> and the primary controversy concerns whether the surviving partner can use the sperm of the deceased to create the family they would have had if not for the male’s death (the use of the oocytes of a deceased wife by her partner is much rare, but also exists).<sup>49</sup> In the west, such a solution has been criticized under the argument that it gives to a third party (the surviving spouse or companion) the power to decide about the genetic material of the deceased person, a decision considered particularly personal and therefore that can only be taken by the individual.<sup>50</sup> It is believed, however,

<sup>39</sup> See N. BAI, F. SUN, C. YUE, *Analysis on Present Situation and Restricting Factors of Relique Donation in China*, in *The Journal of Chinese Medical Ethics*, 18, 2005, 59.

<sup>40</sup> *Ibidem*.

<sup>41</sup> See N. ZHU, *Can the Close Relatives Make A Joint Decision after Death without Opposing the Donation of the Body? Committee Member: Be Cautious When It Comes to Ethics!*, in *Legal Daily*, 26 August 2019.

<sup>42</sup> About the presumed consent principle in organ donation, see D. HAN, W. YU, *On the Self-determination Right and National Obligations in Human Organ Transplant*, in *Law Review*, 3, 2011, 31.

<sup>43</sup> Stating this argument, see the latest article by Y. YUAN, *The Protection of Personality Identity of the Deceased from the Horizon of the Civil Code*, in *The Journal of East China University of Political Science and Law*, 4, 2022, 165-180.

<sup>44</sup> L. ZHANG, *Human Organ Donation has Risen to the Legal Level: If It is not Refused during his Lifetime, Close Relatives can Jointly Decide to Donate*, in *Beijing Evening News* 25 May 2020.

<sup>45</sup> *Ibidem*.

<sup>46</sup> See J. NIE, R. FITZGERALD, *Connecting the East and the West, the Local and the Universal: The Methodological Elements of a Transcultural Approach to Bioethics*, in *Kennedy Institute of Ethics Journal*, 26, 2016, 219.

<sup>47</sup> V. RAPOSO, *Lost in “Culturation”: Medical Informed Consent in China (From A Western perspective)*, *op. cit.*, 17.

<sup>48</sup> M. PARKER, *Till Death Us Do Part: The Ethics of Postmortem Gamete Donation*, in *Journal of Medical Ethics*, 30, 2004, 387.

<sup>49</sup> ETHICS COMMITTEE OF THE AMERICAN SOCIETY FOR REPRODUCTIVE MEDICINE, *Posthumous Retrieval and Use of Gametes or Embryos: An Ethics Committee Opinion*, in *Fertility and Sterility*, 110, 1, 2018, 45

<sup>50</sup> S. SIMANA, *Creating Life After Death: Should Posthumous Reproduction Be Legally Permissible Without the Deceased’s Prior Consent?*, in *Journal of Law and the Biosciences*, 5, 2018, 329–354.

that the surviving partner has compelling reasons to claim the power to take a such intimate decision on behalf of the deceased one, based on the existence of a common parental project, eventually a project 'ratified' by the deceased while still alive.<sup>51</sup> Based on this argument, some jurisdictions allow post-mortem reproduction under strict conditions, but the Chinese solution goes much further, attributing the power to decide about the gametes of the deceased to several relatives of his/her relatives, including the wife/husband, but also other people.

Issues are likely to arise regarding the parents of the deceased person<sup>52</sup> (assuming it will be extremely rare to have grown-up children taking these decisions). The extension of the power to decide to the deceased's parents – which is not an entire novelty, as it can also be found in other jurisdictions, Israel for instance<sup>53</sup> – is based on the idea that parents are entitled to take decisions about their prospective grandchildren. However, the interest in having grandchildren cannot be equated with the interest in having children. The latter is the basis of reproductive rights and under certain requirements, its violation can be argued in court.<sup>54</sup> In contrast, though the interest in having grandchildren is socially accepted (and even encouraged), it cannot be considered a legal right. Therefore, there are no sound legal grounds to allow grandparents to take reproductive decisions about the gametes of their deceased offspring.

Eventually, this solution may lead to the birth of children genetically related to the deceased in a new and different family without his/her expressed consent.

### 2.3. The Ban on Trading Human Cells, Tissues and Organs

One of the basic principles ruling human genetic resources in China is the prohibition of profiting from the body and its components. This principle can be found in the first systematic administrative rules on regulating assisted reproductive biological materials, the 2001 Measures for the Management of Human-Assisted Reproductive Technology (hereinafter, the 2001 Measures). According to its rules, gametes, zygotes and embryos cannot be traded in any way. Likewise, surrogacy is strictly forbidden in China, whether for profit or not.<sup>55</sup>

In 2003, a set of administrative rules called Ethical Guiding Principles for the Research of Human Embryonic Stem Cells (hereinafter, the 2003 Guiding Principles)<sup>56</sup>, jointly enacted by the Ministry of Science and Technology and the Ministry of Health, further expanded the scope of this prohibition:

<sup>51</sup> K. KNAPLUND, *Reimagining Postmortem Conception*, in *Georgia State University Law Review*, 37, 2021, 905.

<sup>52</sup> About the intervention of the deceased' parents in this decision, see S. SIMANA, *Creating Life After Death: Should Posthumous Reproduction Be Legally Permissible Without the Deceased's Prior Consent?* *op. cit.*, 329–354.

<sup>53</sup> In Israel grandparents are allowed to decide about the use of the sperm of their diseased sons. Cf. Y. HASHILONI-DOLEV, Z. TRIGER, *The Invention of the Extended Family of Choice: the Rise and Fall (to date) of Posthumous Grandparenthood in Israel*, in *New Genetics and Society*, 39, 2020, 250.

<sup>54</sup> For instance, *Devika Biswas v Union of India & Others* (2012) 95, about forced sterilization; *Artavia Murillo et al ('In Vitro Fertilization') v Costa Rica* (2012) IACHR, about the ban on the use of in vitro fertilization.

<sup>55</sup> See the 2001 Measures in Chinese Ministry of Health, China, Beijing, 2001, at [http://www.gov.cn/govweb/fwxx/bw/wsb/content\\_417654.htm](http://www.gov.cn/govweb/fwxx/bw/wsb/content_417654.htm) (last visited on 12/8/2020). On this issue, see V. RAPOSO AND U. WAI, *Surrogacy in Greater China: The Legal Framework in Taiwan, Hong Kong, Macao, and Mainland China*, in *UCLA Pacific Basin Law Journal*, 34, 2017, 135.

<sup>56</sup> See the 2003 Guiding Principles in Chinese Ministry of Health and Ministry of Science, China, Beijing, 2003, at [https://www.nsf.gov.cn/nsfc/cen/pfzl/pufanew/20110801\\_13.htm](https://www.nsf.gov.cn/nsfc/cen/pfzl/pufanew/20110801_13.htm) (last visited on 12/8/2020).



embryonic tissues, blastocysts and other related cells were also banned from trading and for-profit scientific research.

Likewise, the 2007 Regulation stipulated that no organization or person may trade human organs in any way or may engage in any activity related to the trade of human organs. Any donation of human organs must be made free of charge and made under the principle of free will, that is, no organization or person may force, cheat, or entice others to donate their organs.

The 2019 Regulation clearly states that foreign organizations and individuals or related institutions cannot collect, store, use or export human genetic resources in China without official approval from the Human Genetic Resources Administration of China.<sup>57</sup> In light of the 2019 Regulation, any form of trading in human genetic resources is strictly banned, pursuant to article 10.

The Human Genetic Resources Administration of China, governed by the State Council, is the deciding national organ, and is responsible for reviewing and approving the legitimate uses and export of human genetic resources in China.<sup>58</sup> The precondition for approval is the argued purpose, which must be the pursuit of reasonable and legal scientific research.<sup>59</sup> The Chinese government also encourages Chinese scientific research institutions, colleges and universities, medical institutions and enterprises to preserve human genetic resources, and provides policy support for relevant scientific research and international collaborations.<sup>60</sup>

Another exception occurs when the use of human genetic resources in scientific research carries a reasonable cost or expense for the donor (resulting from such use), in which case compensation is allowed because it is not considered trading.<sup>61</sup> Reasonable compensation for donors' transportation, work delay, refrigeration and even nutrition expenses is permitted. The CCC does not clearly state this point, but article 10 of the 2019 Regulation stresses that the reasonable cost generated by the use of and research on human genetic resources is not regarded as trading. Article 5 of the 2003 Ethical Principle also stipulates that sperm, eggs and embryo donations should be made for the purpose of helping people, and any trading is strictly prohibited. However, according to the norm, donors can be given 'the necessary work-delay, transportation and medical check compensation, as an encouragement for participating in social charity'. Moreover, different provinces in China can use different measures, including subsidies or material rewards, to flexibly promote the donation of human biological materials.

<sup>57</sup> Arts 21-28 of the 2019 Regulation.

<sup>58</sup> The Administration Office of Human Genetic Resources is an internal organ affiliated to the Ministry of Science and Technology of PRC since 1998. See the website of Ministry of Science and Technology, at [http://www.most.gov.cn/bszn/new/rlyc/fwzn/\(last visited on 29/9/2020\)](http://www.most.gov.cn/bszn/new/rlyc/fwzn/(last visited on 29/9/2020)).

<sup>59</sup> Arts 22-27 of the 2019 Regulation.

There are several cases handled by the Ministry of Science and Technology in the past few years: Sanction No.1 (2015) to Huashan Hospital affiliated to Fudan University for illegally cooperating with Oxford University on Chinese human genetic resources research; Sanction No.2 (2015) to BGI Shenzhen for illegally delivering key information about Chinese human genetic resources to foreign research partners online; Sanction No.1 (2016) to Wuxi AppTec for illegally exporting 5,165 human serum samples to overseas institutions falsely referring to it as "dog plasma"; Sanction No.1 (2018) to Astra Zeneca Shanghai for cooperating with Chinese Biotech companies without approval; Sanction No.2 (2018) to Amoy Diagnostics for receiving 30 gene samples from Astra Zeneca Shanghai without approval; Sanction No.3 (2018) to Q2 Solutions Beijing for receiving 567 gene samples from Astra Zeneca Shanghai without approval).

<sup>60</sup> Arts 16-18 of the 2019 Regulation.

<sup>61</sup> Art 10 of the 2019 Regulation.

Article 1007 of the CCC bans any kind of trade on cells, tissues and organs, and provides no exception.<sup>62</sup> For this reason, the norm has been considered “the strictest containment of trading on human biological materials” in history.<sup>63</sup>

### 3. Clinical Experiments and the Protection of the Human Subject

#### Article 1008

Where clinical experiments need to be conducted for the development of new drugs and medical devices or the development of new prevention and treatment methods, with the approval of the competent department and the consent of the ethics committee upon examination, the subjects or their guardians shall be notified of the experiment purpose, use, possible risks and other details according to the law, and their written consent shall be obtained. For clinical experiments, no experiment fee shall be collected from any subject.

#### 3.1. Control over Clinical Experiments and Ethical Review

The statement in Article 1006 of the CCC, “approval of the competent department and the consent of the ethics committee”, is not a novelty in China. It corresponds to a long tradition involving ethics committees.

As the Chinese medical system has developed and improved at the beginning of the 21<sup>st</sup> century, both Western medicine and traditional Chinese medicine (TCM) have been regulated. According to the 2010 Management Regulations for Ethical Review of Traditional Chinese Medicine Clinical Research, issued by the China State Administration of Traditional Chinese Medicine (CSATCM), TCM clinical trials are to be reviewed based on the following criteria: (a) the research design must be in accordance with the research aim and applicable scientific principles; (b) the risk to human subjects must be reasonable and controlled; (c) the selection of subjects must be fair;<sup>64</sup> (d) informed consent for subjects must be complete and sufficient; and (e) the involved research institutions must guarantee the protection of subjects’ privacy, especially when they are minority groups.

Two sets of rules are significant milestones for protecting human subjects in scientific experimentation: the 2016 Measures for Ethical Review of Biomedical Research Involving Human Beings (hereinafter, the 2016 Measures) and the latest 2019 Pharmaceutical Administration Law. The 2016 Measures are a set of administrative rules at the lowest level of the legal hierarchy, yet they are regarded as the “Chinese edition of the Declaration of Helsinki”.<sup>65</sup>

<sup>62</sup> It is not clear if the previously referred exceptions still apply, since article 1007 of the CCC is silent in this regard. It is expectable that local authorities still allow some exceptions, but further clarification in this regard is necessary.

<sup>63</sup> J. LING, *The Protection of Personality Rights in the Internet Era – Highlight Analysis of Personality Chapter of Chinese Civil Code*, in *People’s Court Daily*, 17 July 2020.

<sup>64</sup> This clause means the recruitment of subjects must be fair among the targeted population in terms of risk and benefit control, instead of recruiting only within certain groups, such as younger people or healthy people. The goal is that the selected subjects fairly represent the targeted population.

<sup>65</sup> See Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects, adopted by the 18th World Medical Association General Assembly, Helsinki, Finland, June 1964.

The main achievement of the 2016 Measures is the modification on the compositions of ethics committees, targeted to provide higher protection to participants in clinical trials and achieve procedural justice.<sup>66</sup> The 2016 Measures precisely define what comprises biomedical research involving human beings and stipulate the composition and responsibilities of ethics committees. Ethics committee members in Chinese medical institutions should be selected from various areas (biomedicine, law, sociology and other related fields) and include at least seven individuals. Every decision should be made with the support of at least half of the members. No ethics committees in China may accept applications submitted by scientific research projects in violation of applicable national laws and regulations. If a medical or health institution does not have an ethics committee, it may not carry out any biomedical research involving human beings. When compared with the previous legal standard, the 2016 Measures further refine the procedures to be followed and clarify the responsibilities of all parties involved. Any institution or individual that causes personal injury to a human subject during experimentation will be held liable under the rules of strict liability and, potentially, criminal liability. Notably, the 2016 Measures clearly state that “medical and health institutions without ethics committee shall not carry out biomedical research involving human beings”. A claimed added value of the 2016 Measures is their international insight,<sup>67</sup> but it is not clear which exact foreign laws served as an inspiration or how they conditioned the Measures. Overall, the 2016 Measures are considered in China the most comprehensive protection of the rights of human subjects in clinical experimentation. However, this model is not immune to criticism. Ethics review is one major concern.<sup>68</sup> In the aftermath of the deep administrative reform of 2015, most tasks related to ethical review were transferred from the National Health and Family Planning Commission to the review committees of individual institutions. However, the rules allow such review committees to have different compositions, different operating modes and even different criteria. In the absence of clear, uniform guidelines, the various ethics committees around the country have different capacities and degrees of expertise to evaluate the matters submitted to their assessment, and some are clearly not capable of supervising research.<sup>69</sup> It is hoped that the regulatory momentum surrounding the CCC will change this scenario.

### 3.2. Informed Consent as A Requirement for Clinical Experiments Involving Humans

Article 1008 of the CCC states that the subject (or his/her guardians, in cases of minors or people with mental disabilities) must be provided with relevant information about the clinical experiment and give

<sup>66</sup> In the 2016 Good Clinical Practice for Medical Devices, very similar norms can be found to protect subjects’ rights and safety in clinical trials of medical devices.

<sup>67</sup> Cf. Y. Zuo, *The New Edition of the 2016 Measures will be Enacted in October, 1<sup>st</sup>, 2016*, in *Xinmin Evening News*, 3 October 2016, at <https://news.ifeng.com/c/7fbFyfg410F> (last visited on 11/6/2021); Y. Cai, *Deficiencies and Suggestions of Measures for Ethical Review of Biomedical Research Involving Human Beings*, in *Chinese Medical Ethics*, 32, 2019, 1238.

<sup>68</sup>X. ZHANG, W. ZHANG, Y. ZHAO, *The Chinese Ethical Review System and Its Compliance Mechanisms 2016*, at <http://trust-project.eu/wp-content/uploads/2016/03/Chinese-Ethics-Review-System.pdf> (last visited on 22/8/2020).

<sup>69</sup> According to LI ET AL, this was the case of the ethics committee of the Shenzhen HarMoniCare Women and Children’s Hospital, that against all applicable national and international standards approved the experiment led by He Jiankui, later culminating in the birth of the genetically edited babies. See LI ET AL, *Experiments that Led to the First Gene-edited Babies: The Ethical Failings and the Urgent Need for Better Governance*, *op. cit.*, 32-38.

their written consent based on it. Written informed consent was already a requirement under Article 21 of the 2019 Pharmaceutical Administration Law,<sup>70</sup> as ensuring the autonomy and willingness of the participants is essential in clinical experiments.

### 3.3. The Ban on Any Payment in Clinical Experiments

Article 1008 of the CCC states that “[f]or clinical experiments, no experiment fee shall be collected from any subject”. This rule was absent from the Article 21 of the 2019 Pharmaceutical Administration Law, and its exact meaning is unclear. The wording seems to indicate that participants in clinical experiments cannot be asked to pay a fee for their participation, which makes no sense, as participation in an experiment is a risk for the subject and a benefit for the scientific community and for the human community as a whole. Therefore, the participant should be the beneficiary of the payment, not the promoter of the clinical trial. The norm does not prohibit payment for participation in clinical trials, and in daily practice it is actually common to offer substantial compensation to attract suitable participants.<sup>71</sup> This practice is in clear contradictions with international ethical and legal standards, that ultimately ban making a profit with one's own body.<sup>72</sup> Moreover, is also in contradiction with Articles 1007 and 1008 of the CCC, grounded on that same core idea.

A ‘payment’ should be distinguished from a ‘compensation’. A ‘payment’ refers to an economic amount, received in exchange for a good or service, directly related to the quantity and/or quality of the good or service provided. It is generally considered that individuals cannot make a profit with their bodies (*rectius*, with their body parts, cells, fluids, and organs), and thus payments in this domain are now allowed. A compensation, in turn, aims to reimburse direct expenses and eventually also makes up for the inconvenience (e.g., the time lost).<sup>73</sup> In the European Union, it is allowed compensation for damages<sup>74</sup> and for expenses and loss of earnings.<sup>75</sup> The US goes one step further and allows compensation to be taken as an encouragement to participate in an activity performed in the common good.<sup>76</sup> None of these solutions is a payment for a good or service. The features of the Chinese ‘inducement’

<sup>70</sup> See art 21 of 2019 Pharmaceutical Administration Law: “For a clinical trial on pharmaceuticals, the objective, risk, and other particulars of the clinical trial shall be truthfully made known and explained to any of its subjects, or his or her guardian, an informed consent document voluntarily signed by the subject, or his or her guardian, shall be obtained, and effective measures shall be taken to protect the lawful rights and interests of the subject.”

<sup>71</sup> See M. ZHU, W. SHEN, *The Current Situation, Problems and Countermeasures of the Protection of the Rights and Interests of Drug Testers*, in *Medical Information*, 33, 2020, 20; X. ZHONG, *Driven by Interests, Every Link may be Fraudulent. Unannounced Visits to China’s Drug Testing Lake*, in *Democracy & Legal System Daily*, 24 June 2018.

<sup>72</sup> See, for instance, art 21 of the Convention for the protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine; Art 3 of the Charter of Fundamental Rights of The European Union; Art 4 of the Universal Declaration on the Human Genome and Human Rights.

<sup>73</sup> E. KOOL ET AL, *What Constitutes a Reasonable Compensation for Non-commercial Oocyte Donors: An Analogy with Living Organ Donation and Medical Research Participation*, in *Journal of Medical Ethics*, 45, 2019, 736.

<sup>74</sup> Art 76 of Regulation (EU) No 536/2014 and On Clinical Trials on Medicinal Products for Human Use, and Repealing Directive (2001/20/EC).

<sup>75</sup> Art 32/1/d and 33/d of Regulation (EU) No 536/2014.

<sup>76</sup> Food and Drug Administration, *Payment and Reimbursement to Research Subjects*, US Food and Drug, January 2018, at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/payment-and-reimbursement-research-subjects> (last visited on 16/7/2021).

– the amount paid, the additional medical benefits involved<sup>77</sup> – are something in between the undue motivation and the effective payment.

However, in China, there are also reports of people paying to participate in trials and other experimental procedures,<sup>78</sup> expecting to benefit from medical treatments that they would not normally have access to.<sup>79</sup> Patients participating in ‘innovative therapies’ that have not been fully validated as conventional treatments often do it out of resignation, as they have no other choice. The charging of high fees to people who are already very miserable<sup>80</sup> should be the target of Article 1008 CCC, as it contravenes the original legislative intent – the ‘humanistic care’ – reflected in the CCC.<sup>81</sup>

#### 4. Scientific Experimentation with Embryos, Genes and ... Something Else

##### Article 1009

Medical and scientific research activities concerning human genes and human embryos, among others, shall be carried out according to the laws and administrative regulations, and relevant provisions issued by the state, without endangering human health, violating moral principles, or damaging public interests.

##### 4.1. A Traditionally Conservative Framework

China is traditionally conservative regarding the scientific practices allowed under the law. It remains to be seen whether the existing prohibitions effectively restrict real-life scientific activities, but recent events seem to indicate that they do not.<sup>82</sup>

Consider for example assisted reproductive technologies (ART), a domain in which 2003 witnessed the implementation of several regulations: the 2003 Technical Rules of Human-assisted Reproductive Technology (hereinafter, the 2003 Technical Rules), the 2003 Basic Criteria of Human-assisted Reproductive Technology and the 2003 Ethical Principle of Human-assisted Reproductive Technology

<sup>77</sup> Y. HU, *Indebted Chinese Students, People Seeking Easy Money Scramble to Become Paid Drug Testers*, in *Global Times*, 30 July 2018, at <http://edu.people.com.cn/n/2014/0810/c1006-25437515.html> (last visited on 13/6/2023).

<sup>78</sup> The most infamous case (but not the only one) involves a student called Wei Zexi suffering synovial sarcoma, a rare form of cancer, and in despair he paid around 200,000 yuan (more or less 24,600 euros) to pay for an experimental immunotherapy treatment advertised in internet. The treatment was a failure and the patient eventually died. See D. CYRANOSKI, *Chinese Hospitals Set to Sell Experimental Cell Therapies*, in *Nature*, 569, 2019, 170.

Also see A. ABKOWITZ, J. CHIN, *China Orders Baidu to Revamp Advertising Results in Online Searches*, in *The Wall Street Journal*, 9 May 2016.

<sup>79</sup> See V. RAPOSO, L. DU, *Stem Cell Based Products in Europe and in China: Where are We and Where Should we Go?*, in *European Pharmaceutical Law Review*, 4, 2020, 161.

<sup>80</sup> See commentary: *The Death of Wei Zexi, Several Neglected Basic Facts*, in *Today's News Sohu*, Issue 1868, 3 May 2016, at <http://news.sohu.com/s2016/dianji-1868/> (last visited on 16/6/2021).

<sup>81</sup> See L. LV, *Civil Code: Governing Medical Research and Ensuring the Good Direction of Science and Technology*, in *Tianjin Daily*, 20 July 2020.

<sup>82</sup> Referring the specific case of gene editing, see LI ET AL, *Experiments that Led to the First Gene-edited Babies: The Ethical Failings and the Urgent Need for Better Governance*, *op. cit.*, 32-38.

(hereinafter, the 2003 Ethical Principle).<sup>83</sup> Both the 2003 Technical Rules and the 2003 Ethical Principle are a series of departmental rules for interpreting the 2001 Measures issued by Ministry of Health to further regulate and standardize ART. These norms explicitly ban practices such as cloning, the creation of human chimeric embryos, and the genetic manipulation of human gametes, zygotes and embryos. Donation of and research on embryos without the informed consent of the embryos' biological parents are illegal. Likewise, in the 2003 Guiding Principles, the ways stem cells can be obtained for research are strictly limited to voluntary donation, natural or selective abortion, surplus gametes or blastocysts resulting from *in vitro* fertilization procedures and somatic cell nuclear transfer (SCNT). Any sale or purchase of human embryonic stem cells is illegal.<sup>84</sup>

In 2008, the Law on Progress of Science and Technology<sup>85</sup> (a comprehensive law that regulates all science and technology development in China) raised legal control over scientific research to a new level. This law allowed the prohibition of scientific research and technological development that could undermine national security, harm public interests, endanger human health or violate moral principles and ethics.<sup>86</sup> This provision can be seen as the embryonic form of Article 1009 in the new CCC.

More detailed provisions based on the principles stated above can be found in a recent regulation issued by the Ministry of Science and Technology, the Interim Measures for Handling Violations of Science and Technology (hereafter, the Interim Measures), which was implemented in September 2020.<sup>87</sup> This administrative rule stipulates that the Ministry of Science and Technology is the overall planning, coordination, supervision and guidance body, and the provincial-level administrative departments affiliated with the Ministry of Science and Technology are the actual organs that deal with violations.<sup>88</sup> For those who are suspected of violating the Communist Party discipline and government disciplines,<sup>89</sup> or of committing crimes, more serious criminal judicial procedures will be initiated by the relevant authorities.<sup>90</sup> The Interim Measures provide penalties for 64 types of scientific research violations and are considered a clear and timely response to scientific dishonesty and illegal behaviours, as the Law on Progress of Science and Technology requires detailed guidelines to regulate scientific

<sup>83</sup> See the 2003 Ethical Principle, Chinese Ministry of Health, Beijing, 2003, at <https://www.pkulaw.com/chl/0f3d2020161a456dbdfb.html> (last visited on 12/8/2020).

<sup>84</sup> Art 7 of the 2003 Guiding Principles.

<sup>85</sup> See Law of the People's Republic of China on Scientific and Technological Progress, the Ministry of Science and Technology, 2007, from LAWINFOCHINA, at [https://www.pkulaw.com/en\\_law/3c5dd7c5cdd4702bbdfb.html](https://www.pkulaw.com/en_law/3c5dd7c5cdd4702bbdfb.html) (last visited on 1/12/2020).

<sup>86</sup> *Ibidem*, Art 29.

<sup>87</sup> See the Interim Measures for handling violations of science and technology, Ministry of Science and Technology, 1 September 2020, at: [https://www.safea.gov.cn/xxgk/xinxifenlei/zc/gz/202112/t20211210\\_178498.html](https://www.safea.gov.cn/xxgk/xinxifenlei/zc/gz/202112/t20211210_178498.html) (last visited on 13/6/2023).

<sup>88</sup> *Ibidem*, Art 2, 3 and 11.

<sup>89</sup> Sometimes the violation of a law can simultaneously violates the Chinese Communist Party discipline and government disciplines, as in China the Party can also inspect and rectify illegal activities. Relevant organizations in China such as Central Commission for Discipline Inspection will investigate and penalize such disciplinary offence. *Ibidem*, Art 12.

<sup>90</sup> *Ibidem*.

activities. This was also the first time that China revised relevant laws and regulations on scientific research and technology development to make them more detailed and practicable.<sup>91</sup>

#### 4.2. Types of Research Targeted

Article 1009 of the CC imposes some limits on “[m]edical and scientific research activities”, but it is not clear to which types of research these limits apply. The norm expressly refers to research “concerning human genes and human embryos”, but adds “among others”, creating doubt regarding the exact scope of this provision and the amount of room for interpretation by analogy. For instance, one may wonder whether research involving foetuses is included, even though in China there is no proper legal differentiation between embryos and foetuses.<sup>92</sup> In addition, research involving human stem cells, a hot topic in China due to the well-known investments in regenerative<sup>93</sup> and precision medicine,<sup>94</sup> still lacks a clear legal framework, and it unclear whether this type of research is a target for Article 1009 CCC.

#### 4.3. Limits on Research

##### 4.3.1. Existing Regulations

Existing regulations – laws and administrative regulations, and relevant provisions issued by the state – are a clear limit on research. In the 2019 Pharmaceutical Administration Law and the 2019 Regulations for the Implementation of the Drug Administration Law, Chinese lawmakers stipulated a series of strict administrative and criminal punishments for researchers conducting illegal experiments involving human subjects.

It can be asked why it is necessary to state that research cannot violate the existing norms. It goes without saying that they constitute a legal boundary, so Article 1009 of the CCC is merely stating something that is implicit in the very idea of the rule of law.

##### 4.3.2. Human Health

The reference to human health in Article 1009 is surprising unless this norm is intended to regulate experimentation with human individuals in addition to that with human biologic materials and embryos. This norm is not clear in its scope, and human health can also be considered to refer to future generations. For example, the case of the two gene-edited babies has raised questions regarding the health risks to their offspring.<sup>95</sup>

<sup>91</sup> S. XIE, *Seal “Pandora’s box” with Science and Technology Ethics*, in *Shenzhen Special Zone Daily*, 10 October 2019.

<sup>92</sup> See V. RAPOSO, Z. MA, *An Ethical Evaluation of the Legal Status of Foetuses and Embryos under Chinese Law*, in *Developing World Bioethics*, *op. cit.*, 43.

<sup>93</sup> Y. LI ET AL, *Regulations on Cell Therapy Products in China: A Brief History and Current Status*, in *Regenerative Medicine*, 14, 2019, 791.

<sup>94</sup> J. CHEN ET AL, *Precision Medicine Research and Biobanking in China*, in *Open Access News*, 14 November 2019, at <https://www.openaccessgovernment.org/precision-medicine-biobanking-in-china/77789/> (last visited on 18/1/2021).

<sup>95</sup> J. SHI, W. PANG, *Civil Law Regulation on Human Gene Editing Activities: Taking the Application of Article 1009 of Civil Code as an Example*, in *Journal of Northwest University (Philosophy and Social Science Edition)*, 50, 2020, 46.

Another possible interpretation is that Article 1009 refers to the health of scientists and researchers who carry out human experimentation,<sup>96</sup> but it is difficult to envisage how their health would be at risk.

We must wait for official judicial interpretations to clarify the norm.

#### 4.3.3. Moral Principles

Article 1009 of the CCC clearly states that scientific research cannot be carried out in violation of moral principles. The norm highlights the value of morality and the power of ‘soft law’. China has a long tradition of “valuing public law and devaluing private law”.<sup>97</sup> The tasks pursued by personality rights, namely the protection of the individual, were supposedly assigned to the latter,<sup>98</sup> but they have been assigned to soft law and morality instead.

Article 1009 stipulates several important ‘red lines’ based on morality<sup>99</sup> and law. These two criteria seem to have been raised to almost the same height with the increasing emphasis on the effect of soft power in civil law.

Scientific research on human genes and embryos is not considered an ordinary medical activity, as it heavily involves medical ethics and moral particularities.<sup>100</sup> According to Article 1009 of the CCC, any scientific research activity that violates ethics and morality is illegal.

The principle of ‘public order and good morals’ (公序良俗)<sup>101</sup> plays an important role in protecting public interests and the social ethos. In the 1260 articles of the CCC, the expression ‘public order and good morals’ appears eight times, indicating its exceptional importance. In the Chinese legal context, ‘public order’ refers to general social interests, including national interests, economic order and social public interests. ‘Good morals’ refers to general moral concepts or good moral practices, including social morality, business ethics and a good social ethos.<sup>102</sup> This principle is a kind of standby clause for use when national interests, social interests or good morals are threatened, but the CCC lacks detailed binding provisions to regulate such harmful conduct. When scientific research on human genes and/or embryos threatens social morality and the social ethos, leading to a huge outcry in society and even to

<sup>96</sup> L. YANG, *From Right of Life and Health to Life Right, Body Right and Health Right – Innovative Norms of Material Personality Right in The Civil Code*, in *Journal of Yangzhou University (Humanities and Social Sciences Edition)*, 24, 2020, 37.

<sup>97</sup> See J. XIA, *On the Public Law Nature of Chinese Traditional Legal Culture*, in *The Jurist*, 2, 2000, 3; also see S. LI, X. JIANG, M. JIANG, *The Modernization of Chinese Legal Concept*, in *Chinese Journal of Law*, 3, 1996, 45.

<sup>98</sup> M. DU, *Legislative Response to the Relationship between Private Law and State – from the Perspective of China's Civil Code Compilation*, in *Local Legislation Journal*, 5, 2020, 97.

<sup>99</sup> The concept ‘morality’, as used in this regard, refers to ‘biological morality’ (the basic morals and respect towards life) and ‘professional morality’ (the idea that scientist and doctor must obey to basic moral principles during experimentations). See J. SHI, W. PANG, *Civil Law Regulation on Human Gene Editing Activities: Taking the Application of Article 1009 of Civil Code as an Example*, *op. cit.*, 47.

<sup>100</sup> Y. CHEN, *Responding to Social Concerns and Regulating Human Gene and Embryo Research*, in *Science And Technology Daily*, 25 July 2019.

<sup>101</sup> There are six principles throughout the CCC considered as basic principles to regulate civil activities: principle of good faith, principle of fairness, principle of free will, principle of public order and good customs, principle of legality and principle of saving resources and protecting environment. See arts 6-10 of CCC.

<sup>102</sup> See L. YANG, *From Right of Life and Health to Life Right, Body Right and Health Right – Innovative Norms of Material Personality Right in The Civil Code*, *op. cit.*, 37.



the distortion or collapse of values, the principle of ‘public order and good morals’ can be used to consider the legal effects of the conduct in question.<sup>103</sup>

Under Western law and Western thinking, the autonomy between law and morals is the cornerstone of legal reasoning: some moral acts are illegal, and some immoral acts are legal. There are overlaps, but there is no clear correlation between the two vectors.<sup>104</sup> In contrast, China has a long tradition of intertwining of law and morality.<sup>105</sup> Therefore, instead of adjudicating rights and imposing compensations for their violation, Chinese judges, lawyers and scholars are concerned about the notions of virtue and harmony.<sup>106</sup> While the West tries to fight morality intrusions into the legal world, under the rule that the law is different from morals, the East (China) brings both concepts together and glorifies morals over the law.

Article 1009 had been highly praised in China. It is said that the norms demonstrate the importance of “moral power”<sup>107</sup> and reveals “humanistic consideration”<sup>108</sup> in regulating personality rights. Moreover, the use of morality to places limits on medical research (and to safeguard human health and public interests) has been pointed out as a sign of the ‘humanistic nature’<sup>109</sup> of medical activities. For these reasons, Article 1009 is seen by many Chinese scholars as great progress<sup>110</sup> and an important step forward.<sup>111</sup> No one seems concerned about abuses in the application of the standard due this unclear and (too) extensive reference to an alleged morality as a limit in investigation.

<sup>103</sup> One famous case in which such this principle intervened is the one in which 11 families frequently marry and divorce, in Zhejiang Province. In Mar. 2019, 11 families from Lishui City, Zhejiang Province, in common agreement married and divorced 23 times within only 15 days in order to defraud the government. Their marriage and divorce formalities were legitimate and official, so no legal wrongful could be found. However, the conducts were considered a serious violation of national interests and basic social morality, because their aim was to receive state compensation. It was argued that the marriages and the divorces should be legally void, and the 11 families are currently being prosecuted for fraud by local procuratorate. See K. MA ET AL, *To get More Demolition Compensation, 11 Families Married and Divorced 23 Times within only 15 Days*, in *Ifeng News*, 23 September 2019 <https://news.ifeng.com/c/7qCyd4sKZYu> (last visited on 25/8/2020).

<sup>104</sup> The relation between law and morals is one of the most complex controversies of the legal world. It won't be developed, since it is not related with the topic of this paper, but see R. POUND, *Law and Morals – Jurisprudence and Ethics*, in *North Carolina Law Review*, 23, 1945, 185. A more recent approach see S. KODAMA, *La Distinction que Fait Bentham entre Droit et Morale, et Son Importance Actuelle*, in *Revue D'études Benthamiennes*, 2019, at <http://journals.openedition.org/etudes-benthamiennes/6378> (last visited on 18/1/2021).

<sup>105</sup> R. LITTLEJOHN, Q. LI, *Chinese and Western philosophy in Dialogue*, in *Educational Philosophy and Theory*, 53, 2021, 10.

<sup>106</sup> P. HUANG, *Morality and Law in China, Past and Present*, in *Modern China*, 41, 2015, 3.

<sup>107</sup> See J. SHI, W. PANG, *Civil Law Regulation on Human Gene Editing Activities: Taking the Application of Article 1009 of Civil Code as an Example*, *op. cit.*, 47.

<sup>108</sup> See L. LV, *Civil Code: Governing Medical Research and Ensuring the Good Direction of Science and Technology*, *op. cit.*

<sup>109</sup> Y. LI, *Gene Technology Norms in the Chapter of Personality Rights in Civil Code*, in *Procuratorial Daily*, 6 July 2020.

<sup>110</sup> See L. LV, *Civil Code: Governing Medical Research and Ensuring the Good Direction of Science and Technology*, *op. cit.*

<sup>111</sup> See S. XIE, *Seal “Pandora's box” with Science and Technology Ethics*, *op. cit.*

#### 4.3.4. Public Interests

‘Public interest’ is a widely used concept in various jurisdictions,<sup>112</sup> although there is no consensus on its details in terms of politics, economics, philosophy and law.<sup>113</sup>

In civil law, public interests generally refer to the interests of unspecified social members or groups.<sup>114</sup> In China, Zhang Qianfan defines public interests as “the union of personal interests”, as “society is the product of people’s gathering”.<sup>115</sup>

In the CCC, ‘public interests’ (公共利益) appears eight times (Articles 117, 243, 358, 999, 1009, 1020, 1025 and 1036),<sup>116</sup> including five times in the personality rights chapter, and once each in articles 132, 185 and 534.<sup>117</sup> The CCC also uses the expression ‘social public interests’ (社会公共利益) to emphasize its social nature and boundaries with personal interests, even if these two expressions have little difference in the Chinese context.<sup>118</sup>

The meaning of ‘public interest’ can change according to the legal context. Considering the background of Article 1009, it is reasonable to conclude that public interests in scientific experimentation include not only the normal interests of current generations, but also the potential interests of future generations. Chinese scholars have systematically stated that the abuse of genetic technology may cause irreparable damage to all humanity, not limited to current living persons or social groups.<sup>119</sup> Chinese lawmakers might have felt the need to address these concerns.

In addition, although ‘public interest’ does not equate to ‘national interest’ in the Chinese legal context, the ‘Chinese-style public interest’, as stated in Article 1009, might also include concerns related to national interests, as it is believed that most medical or scientific activities involving human genes or embryos may bring unforeseen risks to a whole country, especially in the field of biological safety.<sup>120</sup> This is why China enacted the Biosecurity Law of the People’s Republic of China in October 2020 in the aftermath of the COVID-19 pandemic.<sup>121</sup>

## 5. Subsequent Developments

In the aftermath of the CCC some regulations have emerged, as a concretization of the CCC bionorms.

<sup>112</sup> S. LIANG, *Public Interest and Interest Measurement Theory*, in *Tribune of Political Science and Law*, 34, 2016, 3.

<sup>113</sup> Y. WANG, S. GUAN, *Take Seriously the Public Interest in the General Rules of Civil Law*, in *Social Sciences in Chinese Higher Education Institutions*, 6, 2016, 77.

<sup>114</sup> S. LI, *On the Public Interest in General Provisions of Civil Law*, in *Policy Research & Exploration*, 2, 2019, 45.

<sup>115</sup> Q. ZHANG, *The Constitution of Public Interest*, in *Journal of Comparative Law*, 5, 2005, 7.

<sup>116</sup> Articles 117, 243 and 358 are about the land expropriation and compensation; articles 999, 1009, 1020, 1025 and 1036 are about personality rights protection.

<sup>117</sup> Article 132 is a general provision for civil subjects; article 185 deals with the protection of the right to honour of heroes and martyrs; article 534 refers to the legality of contract.

<sup>118</sup> Actually, ‘public interests’ and ‘social public interests’ have almost the same meaning in the CCC, as underlined by S. LIANG, *Public Interest and Interest Measurement Theory*, *op. cit.*, 3.

<sup>119</sup> See J. SHI, W. PANG, *Civil Law Regulation on Human Gene Editing Activities: Taking the Application of Article 1009 of Civil Code as an Example*, *op. cit.*, 47.

<sup>120</sup> *Ibidem*.

<sup>121</sup> See X. PAN, *The Enactment of Biosecurity Law Means that Biosafety Is an Important Part of National Security*, in *People’s Daily*, 18 October 2020.

The core idea stated in Articles 1007 and 1009 is now formally received into the Chinese Criminal Law (Amendment (XI) to the Criminal Law of the People's Republic of China). The newly added Article 334A states:

“Whoever, in violation of the relevant provisions issued by the state, illegally collects the human genetic resources of China or illegally transports, mails, or carries the human genetic materials of China out of China, endangering public health or social and public interests, shall, if the circumstances are serious, be sentenced to imprisonment of not more than three years, limited incarceration, or probation and a fine or be sentenced to a fine only; or if the circumstances are especially serious, be sentenced to imprisonment of not less than three years nor more than seven years and a fine”.

This is the first time that the Chinese government criminalizes “acts of smuggling and illegally collecting human genetic resources (非法采集、走私人类基因资源罪)”. The target seems to be the extinction of the well-known black market on human organs.<sup>122</sup>

Another addition is Article 336A:

“Whoever implants any genetically edited or cloned human embryo into the body of a human being or animal or implants any genetically edited or cloned animal embryo into the body of a human being shall, if the circumstances are serious, be sentenced to imprisonment of not more than three years or limited incarceration and a fine or be sentenced to a fine only; or if the circumstances are especially serious, be sentenced to imprisonment of not less than three years nor more than seven years and a fine”.

This article is also a breakthrough in Chinese criminal law history, as it is the first time human gene editing and human cloning reach the criminal level, under the crime of illegally implanting genetically edited or cloned embryos (非法植入基因编辑、克隆胚胎罪). This innovation was a clear formal response to the already mentioned He Jiankui incident, which took place in 2018. He Jiankui was charged with illegal medical practice (非法行医罪)<sup>123</sup> due to the lack of a more specific criminal regulation at the time.

Another legal consequence of the bionorms included in the CCC is the Biosecurity Law of the People's Republic of China. This law has an extremely wide scope: biology technology, pandemics and infectious diseases, human genetic resources and biological resources, bioterrorism and biological weapons. Biosecurity was previously a pressing concern in China, and it was fuelled by the pandemic outbreak.<sup>124</sup> Also worth mentioning are the Guiding Principles of Human Assisted Reproductive Technology Application Planning (2021)<sup>125</sup> that came to shed some light on a matter with very little regulation. The guiding principles most directly related to the new bionorms are the ones that impose to local

<sup>122</sup> BBC News, *Chinese Doctors Jailed for Illegal Organ Harvesting*, in *BBC News*, 27 November 2020, at <https://www.bbc.com/news/world-asia-china-55097424> (last visited on 15/6/2021).

<sup>123</sup> Art 336 of National People's Congress, *Chinese Criminal Law Amendment 2021 (XI)*.

<sup>124</sup> China Laws Portal Team, *China's First Biosecurity Law: Infectious Disease Control, Laboratory Biosafety and Biological Warfare Prevention*, in *China Justice Observer*, 1 November 2020, at <https://www.chinajusticeobserver.com/a/chinas-first-biosecurity-law> (last visited on 15/6/2021).

<sup>125</sup> See the General Office of National Health Commission, the Notice of Issuing Guiding Principles of Human Assisted Reproductive Technology application planning 2021, National Health Commission, 22 January 2021, at <http://www.nhc.gov.cn/fys/s3581/202101/444d6fab7c0c4e608c89c99a2e914edd.shtml> (in Chinese) (last visited on 15/6/2021).

governments the duty to control the number of reproductive centres and the way they operate, and seriously sanction the institutions with major misconducts and technical hazards. Moreover, the Guiding Principles strictly prohibit the commercialization and industrialization of ART services and claim as core idea the concept of common welfare.<sup>126</sup>

## 6. Conclusive Notes

The CCC, which has been in development since 2014, will become the first ever codified legislation in China, and will replace the current amalgamation of various laws, especially in the private sector. One of its main achievements is the inclusion of the first bioregulation and biorights.

The development of a biolaw framework is very welcome in China. The 2018 incident involving He Jiankui and the genetically edited babies<sup>127</sup> clearly indicated the existence of a legal gap in the domain of biolaw and biorights.

Nonetheless, it is not enough, and more detailed standards are required in the future. It frequently mixes law and morality (as in Article 1009 CCC); many of its norms are unclear in their scopes and consequences (the rules on scientific research with biological material); some of its solutions might lead to unpredictable consequences (the power granted to relative to dispose of the deceased's gametes).

The advent of the first CCC, with its aim of protecting and managing the "life code"<sup>128</sup> (生命密码), may become the most significant piece of bioregulation and bioethics legislation in China.

<sup>126</sup> The Guidelines do not expressly refer to surrogacy, but their provisions, as well as their timing, indicate that one of its aims is to avoid surrogacy scandals, as the one involving the famous Chinese actress Zheng Shuang (See S. SNG, *Chinese Actress Zheng Shuang Loses Fans and Endorsement Deals over Surrogacy Scandal*, in *The Straits Times*, 21 January 2021, at <https://www.straitstimes.com/life/entertainment/actress-zheng-shuang-loses-fans-and-endorsement-deals-over-surrogacy-scandal> (last visited on 15/6/2021)).

<sup>127</sup> Cf. H. GREELY, *CRISPR'd Babies: Human Germline Genome Editing in the "He Jiankui" affair*, in *Journal of Law and the Biosciences*, 6, 2019,111; R. LEI, R. QIU, *Ethical and Regulatory Issues in Human Gene Editing: Chinese Perspective*, in *Biotechnology and Applied Biochemistry*, 67, 2020, 880.

<sup>128</sup> The expression was taken from the official analysis from the Ministry of Justice and the Ministry of Science and Technology: *Managing Human "Life Code" (Human Genetic Resources) well-2019 Regulation*, at [http://www.gov.cn/zhengce/2019-06/12/content\\_5399732.htm](http://www.gov.cn/zhengce/2019-06/12/content_5399732.htm) (last visited on 15/8/2020).