After He Jianku: China’s biotechnology regulation reforms

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Abstract
The unveiling of the world’s first gene-edited twins by biophysics researcher He Jiankui generated much discussion about Chinese legal and ethical frameworks for biotechnology. In response, the highest Chinese legislative body, the National People’s Congress, and the two responsible departments for biotechnology, the Ministry of Science and Technology and the National Health Committee, have undertaken a seemingly far-reaching regulatory reform. The most salient step of this reform is to regulate genetic research and human embryo research in the Chinese Civil Code. This article overviews recent policy developments in China and their respective importance for promoting a governance framework for biomedical research that meets the expectations of the international community. However, this regulatory reform could also set stricter administrative procedures in place for Chinese institutions and their foreign partners, which may impede scientific progress. The concrete impact of this reform on the practice of Chinese scientists will need to be closely scrutinised by Chinese authorities and the international community.

Keywords
Chinese regulatory reforms in biotechnology, Chinese bioethics, the first gene-edited baby, He Jiankui Scandal, The Chinese laws in biotechnology, CRISPR-Cas 9

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Introduction: China confronting bioethics - A dragon in the closet?

Although the worldwide bioethics community had achieved a consensus to postpone clinical germline gene editing on scientific, social and ethical grounds, the Chinese professor He Jiankui ignored all ethical norms including his own. He claims that ‘gene surgery is only permissible when the risks of the procedure are outweighed by a serious medical need’. However, He created two genetically altered babies, neglecting the ‘off-target’ risks of the CRISPR-Cas 9 mechanism that may impair the function of normal genes. His announcement created an uproar in the Chinese scientific and bioethical expert community. One hundred and twenty-two Chinese scientists, some from renowned institutions such as Stanford University, MIT and the German Cancer Research Centre, fiercely condemned He’s behaviour. Concerned that his endeavour might hamper Chinese biomedical research and damage the reputation of other Chinese scientists, they urged authorities to adopt relevant regulations and undertake an inquiry of He’s actions.

In an official statement, the Ministry of Science and Technology (MoST) and the National Health Committee (NHC) stressed that genetically modifying a human embryo for reproductive purposes is explicitly prohibited in China. They said that He had severely violated ethical morality, scientific integrity and relevant regulations. Xu Nanping, the Vice Minister of the MoST, states that according to Article 6 of the Ethical Guiding Principles for Research on the Human Embryonic Stem Cells Research (2003)...

1. Statement by the Organizing Committee of the Second International Summit on Human Genome Editing. Available at: https://www.nationalacademies.org/news/2018/11/statement-by-the-organizing-committee-of-the-second-international-summit-on-human-genome-editing (accessed 11 June 2020); Statement on Governance and Oversight of Human Genome Editing. Available at: https://www.who.int/news-room/detail/26-07-2019-statement-on-governance-and-oversight-of-human-genome-editing (accessed 11 June 2020).
2. J. He et al., ‘Draft Ethical Principles for Therapeutic Assisted Reproductive Technologies’, The CRISPR Journal 2(1) (2018), p. 1. (This article was retracted for the reasons of conflict of interest and ethical violations by the author.)
3. CRISPR stands for the Clustered regularly interspaced short palindromic repeats. CRISPR-Cas 9 can be used to edit genes within organisms.
4. X. Zhang et al., ‘Off-Target Effects in CRISPR/Cas9-Mediated Genome Engineering’, Molecular Therapy – Nucleic Acids 4 (2015), p. 1.
5. ‘The Joint Statement by 122 Chinese Scientists’ Strong Condemnation of the First HIV Immune Genetic Modification’ 122位科学家发联合声明:强烈谴责’首例免疫艾滋病基因编辑’, Science Net 26 November 2018. Available at: http://news.sciencenet.cn/htmlnews/2018/11/420386.shtm (accessed 20 June 2020).
6. Op. cit.
7. National Health Committee, the Ministry of Science and Technology, and the Chinese Association for Science and Technology: Response to Gene-edited Babies. 国家卫生健康委、科技部、中国科协负责人回应“基因编辑婴儿”事件, Xinhua News 29 November 2018, Available at: http://www.nhc.gov.cn/wjw/xwdt/201811/7e433478e87d4bf787a920c8af7d18ac.shtml (accessed 20 January 2020).
(人胚胎干细胞研究伦理指导原则), China prohibits human cloning, research on human embryos 14 days after fertilisation and genetic manipulation of human gametes, zygotes and embryos for reproductive purposes. However, the MoST and the NHC did not release the investigation report for He’s case, which prompted criticism from Chinese bioethicists regarding the inadequacy and transparency of investigation.

On 30 December 2019, He and his accomplices were convicted by the Nanshan District Court of ‘illegal medical practice’ for gene editing human embryos for reproductive purposes and for carrying out illegal reproductive medical activity. He was sentenced to 3 years’ imprisonment and a fine of 3 million RMB (around US$450,000).

Beyond the criminal sanctions, the NHC gave He, Qin Jinzhou and Zhang Renli a life ban on conducting assisted reproductive technology-related services. The MoST prohibited them from applying for any administrative permit relating to research with human genetic resources and from applying for all research funds under their purview. The China Association for Science and Technology also revoked He’s award for the 15th ‘Chinese Youth Science and Technology Prize’. No civil punishment was imposed because the babies’ parents did not file a civil litigation against He.

He’s case also underscored systemic problems of ethics and governance in Chinese private hospitals. In recent years, the Putian Medical Group, which runs 80% of private hospitals in China, has developed an infamous reputation for false advertisements and an excessively commercial ethos. It was therefore unsurprising to learn that a Putian

8. Article 6 of the Ethical Guiding Principles for Human Embryonic Stem Cell Research (2003).
9. X. Zhai et al., ‘Chinese Bioethicists Respond to the Case of He Jiankui’, The Hastings Center February 2019. Available at: https://www.thehastingscenter.org/chinese-bioethicists-respond-case-jiankui/ (accessed 5 July 2020); R. Lei and R. Qiu, ‘Chinese Bioethicists: He Jiankui’s Crime Is More than Illegal Medical Practice’, The Hastings Center 4 January 2020. Available at: https://www.thehastingscenter.org/chinese-bioethicists-he-jiankui-crime-is-more-than-illegal-medical-practice/ (accessed 4 July 2020).
10. The Case of Gene Editing Babies: He Jiankui was Convicted of Illegal Medical Practice and Sentenced to Three Years in Prison. 基因编辑婴儿案贺建奎因非法行医罪被判处3年. Available at: http://www.court.gov.cn/zixun-xiangqing-213381.html (accessed 7 July 2020).
11. Op. cit.
12. Op. cit.
13. Op. cit.
14. The Chinese Association for Science and Technology (CAST) 中国科学技术协会 is a non-governmental organisation of Chinese scientists and engineers. The CAST is a member of the country’s top political advisory body and links the Chinese government with Chinese scientists. Available at: http://english.cast.org.cn/col/col471/index.html (accessed 11 June 2020).
15. S.L. Wee, ‘Scandals Catches Up to Private Chinese Hospitals, After Fortunes Are Made’. The New York Times 15 November 2018. Available at: https://www.nytimes.com/2018/11/15/business/china-private-hospitals-putian.html (accessed 7 July 2020).
16. A. Ramzy, ‘China Investigates Baidu after Student’s Death from Cancer’, The New York Times 3 May 2016, sec. World. Available at: https://www.nytimes.com/2016/05/04/world/asia/china-baidu-investigation-student-cancer.html (accessed 6 July 2020).
hospital, Shezhen Harmonicare, seemed to be implicated in the ethics approval for He’s gene editing project. Although the Harmonicare hospital denied responsibility, the Chinese Clinical Trial Registry attested that it had approved the ethics application related to He’s research.17

He’s case is not the only one that has caught the attention of the international community in recent years. The integrity of some Chinese scientists has also been generally criticised for recurring issues involving plagiarism in scientific publications.18 These scandals have substantially and unfairly overshadowed Chinese scientists’ contribution to biomedical research.

In response to He Jiankui’s case and broader bioethical issues, the Chinese government introduced a series of regulatory reforms that are discussed in the following sections: the first section discusses laws approved by the National People’s Congress and its Standing Committee; the second section touches on department regulations; the third section introduces the conceptual plan of constituting a National Medical Ethics Committee and the fourth section explores questions of legal liability raised by He Jiankui’s case going beyond the court’s decision. Our article anticipates the possible next steps in the reform programme. We conclude with some important considerations for these reforms to succeed in the fifth section.

Laws of the National People’s Congress and its Standing Committee (Laws)

The National People’s Congress (NPC) and its Standing Committee have adopted two laws and reviewed two drafts relevant to biomedical research after the He Jiankui affair: the Civil Code (2021), the Basic Healthcare law, the Criminal Code (proposed amendment) and the Biosecurity Law (draft).

China’s most significant legislative activity in 2020 was the adoption of the Civil Code of the P.R.C.19 In keeping with China’s civil law tradition, the Civil Code represents basic law subordinate to the Constitution of the P.R.C. but superior to other special

17. Chinese Clinical Trial Register (ChiCTR) – The WHO International Clinical Trials Registry Platform, 中国临床试验注册中心 - 世界卫生组织国际临床试验注册平台一级注册机构. Available at: http://www.chictr.org.cn/showprojen.aspx?proj=32758 (accessed 30 May 2020).
18. D. Cyranoski, ‘China Cracks down on Fake Peer Reviews’, Nature News 546, no. 7659 (22 June 2017): 464. Available at: https://doi.org/10.1038/546464a.(accessed 5 July 2020); Z. Zhang, ‘Scientist Cleared of Falsifying Results’, ChinaDaily 3 September 2018. Available at: https://www.chinadaily.com.cn/a/201809/03/WS5b8e8059a310add14f38923c.html (accessed 1 July 2020); For example: Y. Li et al., ‘Internet-scale Secret Sharing Algorithm with Multimedia Applications’, Multimedia Tools and Applications 79(13) (2020), pp. 9669–9669; X. Han et al., ‘Medical Image Encryption Technique in Big Media Environment’, Multimedia Tools and Applications 79(13) (2020), pp. 9655–9655. These two papers were retracted for reasons of authorship, fake peer review, and plagiarism.
19. Explanation of the Draft Civil Code of the P.R.C.中华人民共和国民法典（草案）的说明. Available at: http://www.xinhuanet.com/politics/2020-05/22/c_1126021017.htm (accessed 1 July 2020).
civil laws. Dubbed by many legal scholars as the ‘encyclopedia of social life’, this Code regulates citizens’ civil relations.20

The Chinese Civil Code highlights human rights protection. Article 109 of the Civil Code introduces the constitutional rights of liberty and human dignity.21 The Civil Code is thus heralded as a milestone of Chinese human rights protection.22 Moreover, a separate section, Book Four: Personality Rights (人格权编，Ren Ge Quan Bian), singles out ‘the rights to life, bodily rights, the right to health, the right of name, reputation, portrait, privacy, honour, and other personality interests’, which ensures the dignity of people.23 As far as the authors are aware, the only other country which incorporates a separate book for personality rights in its Civil Code is the Ukraine. Wang Liming, a member of the drafting committee of the Civil Code, stated that the book for personality rights corrects flaws in other Chinese civil laws, which prioritises property rights over personality rights.24

After He’s scandal, the Civil Code’s drafting committee responded swiftly by adding articles to the Book of Personality Rights on the topic of biomedical research and genetic research. Article 1008 requires ethical approval for any such clinical trial along with written consent disclosing the purpose, objectives and potential risks thereof.25 Article 1009 specifies that ‘any medical research activity associated with human gene and human embryo must comply with the relevant laws, administrative regulations and national regulation, must not harm individuals and violate ethical morality and public interest’.26 Wang Yi, the associate director of the Civil Code Research Society of the Chinese Law Society, commented that ‘Article 1009 reiterates and extends the protection of personal liberty and personal dignity’.27 This approach is also supported by Liming Wang, who praised the revision and stressed the necessity of legislating on human genetic and embryonic research in the Civil Code.28 Other voices disagreed. Sun

20. The Chinese Civil Code: the Encyclopaedia of Social Life. 民法典: 社会生活百科全书. Available at: http://www.npc.gov.cn/npc/c30834/202005/530a28f7f2544e14934711371ad6f376.shtml (accessed on 7 July 2020).
21. A. 109 of the Chinese Civil Code (2021).
22. L. Wang, ‘The Chinese Civil Code is the Basic Law of the Market Economy. The Civil Code is the Declaration of Protecting People’s Civil Rights民法典是市场经济基本法 保护公民权利的宣言书’, Beijing News 21 May 2020 Available at: http://www.bjnews.com.cn/inside/2020/05/21/729667.html (accessed 18 June 2020); The constitutional rights of liberty and human dignity can only be used as a case of action if the rights are stipulated in a specific law.
23. Article 990 of the Chinese Civil Code (2021).
24. Wang, ‘The Chinese Civil Code is the Basic Law’.
25. Article 1008 of the Chinese Civil Code (2021).
26. Article 1009 of the Chinese Civil Code (2021).
27. Y. Wang, ‘The 1260 Articles of the Civil Code: from Cradle to Cemetery; from value consensus to laws‘民法典1260条中的生老病死: 从价值共识到法律规则’, Beijing News 24 May 2020. Available at: http://www.bjnews.com.cn/inside/2020/05/24/730856.html (accessed 7 July 2020).
28. The Second Review of the Book of Personality Rights of the Chinese Civil Code which regulates Genetic Research, Face Swapping AI, Clinical Trials, and Personal Information, 基因科研、“AI换脸”、人体试验、个人信息，民法典人格权编草案二审稿都作出规范.
Xianzhong, a renowned civil law scholar and a member of the drafting committee, argued that according to Article 13 ‘civil rights start with birth and end with death’. Sun Xianzhong stated that human cells and genes can be the object of personality rights, but not their subject, and thus should not be introduced in the Book of Personality Rights. Article 1009 is a typical prohibitive provision but was deliberately inserted into the Book of Personality Rights.\(^{29}\)

Shi Jiayou argues that Article 1009 is only applicable to medical and scientific activity, which leaves other activities in a legal vacuum.\(^{30}\)

Article 1009 has shown the Chinese government to be determined to bring human embryonic research under regulatory control, although it fails to specify how this article should apply in civil litigation. As explained by Yang Lixin, another member of the drafting committee, it is not the role of the Civil Code to establish detailed guidelines. Rather, it leaves the responsible departments and the Supreme Court to release more specific guidelines and judicial interpretation.\(^{31}\)

Human genetic and embryonic research have been regulated by different administrative regulations before Article 1009 was introduced. However, none of these regulations provided a legal basis for civil or criminal litigation. Once enacted, Article 1009 will form the legal basis for civil litigation in cases of unethical human genetic or embryonic research. Article 1009 will also trigger legal reforms for other relevant laws, including the civil procedure law and criminal law. For instance, the draft of the 11th Amendment to the Chinese Criminal Code has added three types of crime: the illegal practice of human gene editing, the crime of human embryo cloning and the crime of severe endangering of the security of human genetic resources. These crimes are sanctioned by imprisonment of up to 7 years and a fine. This draft amendment was submitted to the Standing Committee of the National People’s Congress for review on 28 June 2020.\(^{32}\)

China is not the only country to regulate human genetic and embryonic research through its Civil Code and Criminal Code. The Civil Code of France also explicitly prohibits eugenic practices and the alteration of genetic characteristics for modifying

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\(^{29}\) X. Sun, Comments Regarding the Book of Personality Rights of the Civil Code submitted to the Twelfth Session of the Thirteenth Standing Committee of the National People’s Congress. 孙宪忠：关于提交十三届全国人大常委会第十二次会议审议的民法典人格权编的审议意见. Available at: http://iolaw.cssn.cn/zt/sunxianzhong/ (accessed 7 July 2020).

\(^{30}\) J. Shi, ‘The Progress and Limits of the Legislation of the Personality Rights立法的进展与局限’. China Civil and Commercial Law 2 October 2019. Available at: https://www.civillaw.com.cn/zt/t?id=36076 (accessed 1 July 2020).

\(^{31}\) L. Yang, ‘The Chinese Civil Code regulates the virtual property民法典对虚拟财产作出规定在世界上系首个’, China News 24 May, 2020. Available at: http://www.chinanews.com/gn/2020/05-22/9191283.shtml (accessed 7 July 2020).

\(^{32}\) Interpretation of the 11th Amendment to the Criminal Code of the P.R.C.: Seven Points to be Considered，七大看点解析刑法修正案(十一)草案, Xinhua News 28 June 2020 Available at: http://www.ccdi.gov.cn/yaowen/202006/t20200628_220925.html (accessed 20 July 2020).
offspring. Moreover, in France’s Criminal Code, eugenics and reproductive cloning are considered crimes against humanity, sanctioned by imprisonment of up to 30 years and a fine of 7,500,000 euros.

Before the French Civil Code, the French Criminal Law and the Code of Public Health incorporated these provisions, the industry-specific French Bioethics Law established an overarching regulatory framework for the biomedical field. Therefore, the French Civil Code and the Criminal Code only needed to modify or update their provisions in accordance with the Bioethics Law. In contrast, before regulating human gene editing in the Civil Code and the Criminal Code, China had no overarching bioethics regulation. This regulatory vacuum presents a challenge for the implementation of these articles.

Beyond the Civil Code and the Criminal Code, the Standing Committee of the National People’s Congress adopted a specific law called the Basic Healthcare and Health Promotion Law (2019) (基本医疗卫生与健康促进法) in December 2019. This is meant to enhance public healthcare and to implement constitutional rights to health. Personal rights such as health privacy and informed consent are also protected in this Law.

On 14 February 2020, against the backdrop of the coronavirus outbreak, President Xi Jinping stressed the necessity of incorporating biosecurity into China’s national security system and the need for a national biosecurity law, which will improve the mechanisms for major epidemic prevention. In April 2020, the Biosecurity Law underwent its second review at a regular session of the National People’s Congress. National security, public

33. Article 16-4 of the French Civil Code, ‘...Without prejudice to researches aiming at preventing and treating genetic diseases, there may be no alteration of the genetic characters with a view to changing the descent of a person’.
34. Article 214-2 of the French Penal Code, ‘Carrying out any procedure designed to cause the birth of a child genetically identical to another person whether living or deceased is punished by thirty years’ criminal imprisonment and a fine of €7,500,000’.
35. A. Blasimme, D. Caminiti and E. Vayena, The Regulation of Human Germline Genome Modification (Cambridge: Cambridge University Press, 2019), pp. 385–387.
36. The National Health Committee adopted an administrative rule, the Ethical Review Guidelines for Biomedical Research Involving Humans, which is not a comprehensive bioethical regulation as the Bioethics Law in France.
37. The constitutional right to health is to ensure wide access to public health while the civil right to health is to keep individual mental and physical health; Article 1 of the Basic Healthcare and Health Promotion Law (2019).
38. Article 32 and Article 33 of the Basic Healthcare and Health Promotion Law (2019).
39. Xi Jinping Hosted the Twelfth Meeting of the Central Deeping Overall Reform Committee: Improve the major epidemic prevention and control mechanism and Enhance the National Public Health Emergency Management System. Li Keqiang, Wang Huning, and Han Zheng attended. 习近平主持召开中央全面深化改革委员会第十二次会议，完善重大疫情防控体制机制 健全国家公共卫生应急管理体系 李克强王沪宁韩正，Xinhua Press 14 February 2020. Available at: http://www.xinhuanet.com/politics/leaders/2020-02/14/c_1125575922.htm (accessed 7 July 2020).
40. Resubmitting the Draft Biosecurity Law to the Highest Legislative Committee 生物安全法草案再次提请最高立法机关审议, Xinhua News 26 April 2020. Available at: http://www.xinhuanet.com/legal/2020-04/26/c_1125909096.htm (accessed 7 July 2020); Chinese
health and the progress of biotechnology remain the primary goals for this law. As an integral component of national security, biosecurity refers to ‘the State’s ability to effectively respond to threats caused by biological and related factors, to maintain the stable and healthy development of the biological sector, keeping interests relatively free of risk and unthreatened and safeguarding continued development and security’. The Biosecurity Law covers all research and clinical applications of biotechnology, including the prevention and control of major emergent infectious diseases, including outbreaks in animals and plants (Chapter 3); the research, development, and safe application of biotechnology (Chapter 4); laboratory biosecurity (Chapter 5); the safety of human genetic resources and bioresources (Chapter 6); and the prevention of bioterrorism and bioweapon threats (Chapter 7). However, Liu Yinliang contends that protection of genetic resources and biosecurity are two different issues that should not be regulated under a single act. Protection of human genetic resources is to protect these resources from exploitation by foreign countries. However, biosecurity is about preventing any foreign microorganism, animal, plant and virus from interfering with China’s ecological system. This law has outlined the general principles for biosecurity in each chapter and leaves the responsible authorities (which are the MoST and NHC) to adopt specific regulations which to prevent the misuse of biotechnology in the field of research and clinical application. These are discussed in the following sections.

Department administrative regulations

The MoST is mandated to regulate basic research while the NHC regulates clinical research and applications of biotechnology. After the He Jiankui incident, the MoST adopted the Regulations on the Management of Human Genetic Resources (section ‘Regulations on the Management of Human Genetic Resources (2019): Preventing illegal research at the source’). A drafted regulation on the safety management of biotechnology is under the review process by the MoST (Section ‘Regulations on the Safety Management of the Research and Development of Biotechnology (MoST

41. Article 1 of the Draft Biosecurity Law (2019).
42. Article 3 of the Draft Biosecurity Law (2019).
43. Lingqiao Song: Y. Liu and D. Xue, ‘The Biosecurity Act should Grasp for the Essential Problems and Coordinate with Relevant Regulations’, Journal of Beijing University of Aeronautics and Astronautics 32 (5) (2019), pp. 33. ((生物安全法》应把握立法重心和相关法律规范的衔接’
44. Explanation for Drafting the Regulations on the Clinical Application of Innovative Biomedical Technologies 生物医学新技术临床应用说明. Available at: http://www.nhc.gov.cn/zyyj/1659/201902/0f24dce242c24212abc42ab8b539584.shtml (accessed 7 July 2020); L. Song and R. Isasi, The Regulation of Human Germline Genome Modification in the People’s Republic of China (Cambridge: Cambridge University Press, 2019), pp. 472–473; Article 6 of the Regulations on the Management of the Clinical Application of the Innovation Biomedical Technology (2019).
Regulation, draft, 2019’). Meanwhile, as another main authority in this field, the NHC drafted a regulation on the clinical application of innovative biotechnologies (section ‘Regulations on the Management of the Clinical Application of Innovative Biomedical Technologies (NHC Regulation, draft, 2019’).

**Regulations on the Management of Human Genetic Resources (2019): Preventing illegal research at the source**

In 2019, the State Council adopted the Regulations on the Management of Human Genetic Resources (RMHGR), which is the governing regulation on Chinese human genetic resources. Representatives from the MoST and the Ministry of Justice (MoJ) specified that ‘the MoST and the MoJ have drafted the RMHGR to respond to issues generated by the gene-edited babies incident’. This regulation aims to prevent illegal or unethical biotechnological research at the source by overseeing the collection and use of human genetic resources. The other department regulations focus on the safety management of biotechnology research and its clinical applications, which is essential to complete the entire oversight process. These regulations are the *Regulation on the Safety Management of the Research and Development of Biotechnology of the MoST* (2019) (hereafter MoST Regulation) and NHC Regulation, which are discussed in sections ‘Regulations on the Management of the Clinical Application of Innovative Biomedical Technologies (NHC Regulation, draft, 2019’).

The RMHGR retains the administrative licence approach in which collecting, preserving, utilising and providing human genetic resources abroad is subject either to an administrative licence or a filing process. Specific guidelines are in place to regulate each activity. The regulation does not apply to areas such as clinical practice, blood collection, criminal investigations, doping control or the funeral industry.

The collection, preservation and sharing of Chinese human genetic resources abroad are only limited to Chinese entities. Chinese institutions that share genomic data

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45. Ministry of Justice and Ministry of Science and Technology: Answers to Journalists’ Questions regarding the Regulations on the Management of Human Genetic Resources, 司 法部、科技部负责人就〈《人类遗传资源管理条例》〉答记者问. Available at: http://www.gov.cn/zhengce/2019-06/11/content_5399059.htm (accessed 7 July 2020).
46. Op. cit.
47. Administrative Licensing Service Guide for Collecting Chinese Human Genetic Resources (2019) 中国人类遗传资源采集审批行政许可事项服务指南; Administrative Licensing Service Guide for Preserving Human Genetic Resources (2019) 中国人类遗传资源国际合作科学研究审批 行政许可事项服务指南; Administrative License Service Guide for International Cooperative Human Genetic Research (2019) 中国人类遗传资源国际合作科学研究审批 行政许可事项服务指南; Filing Scope and Process for Sharing Human Genetic Data Abroad (2019) 中国人类遗传资源信息对外提供或开放使用备案范围和程序.
48. Article 3 of the Regulations on the Management of Human Genetic Resources (2019).
49. Article 7 of the Regulations on the Management of Human Genetic Resources (2019).
abroad are not subject to an administrative permit, but they need to report to the MoST with a copy of the data.\textsuperscript{50} However, if sharing data abroad may jeopardise the public health, state security or public interest, a security check should be conducted by the MoST.\textsuperscript{51} Foreign entities are only entitled to use human genetic samples by collaborating with a Chinese partner or to employ genomic data shared by a Chinese entity.\textsuperscript{52}

A fine of up to 5 million RMB (US$700,000) or of 10 times the illegal gains (if the illegal gains are over 1 million) is imposed for collecting, preserving or utilising without administrative permit or filing process.\textsuperscript{53} Civil and criminal penalties will be applied in severe cases. The regulation does not specify the situations where civil or criminal penalties apply. However, once the 11th Amendment to the Chinese Criminal Code is enacted, the crime of endangering the security of the human genetic resources will apply.\textsuperscript{54}

Collective interests including public health, public interest and national security remain a primary concern in this regulation, as reflected in many of its articles.\textsuperscript{55} The regulation also stipulates fundamental legal and ethical principles including privacy, ethical review and informed consent.\textsuperscript{56} Fiscal sanctions of up to 5 million RMB (US$700,000) or of 10 times the illegal gains are imposed for human genetic activities without ethical review or appropriate informed consent.\textsuperscript{57}

\textbf{Regulations on the safety management of the research and development of biotechnology (MoST Regulation, draft, 2019).} In 2017, the MoST passed the \textit{Safety Ordinance for Biotechnology Research and Development to Safeguard Biosecurity}.\textsuperscript{58} The Ordinance stratified the risks associated with biotechnologies into three levels, but gene-editing technology was listed under each level without additional information to help assign a gene-editing activity to a specific level.\textsuperscript{59}

After He’s incident, the MoST addressed the lack of clarity in the Ordinance by producing a new \textit{Regulations on the Safety Management of the Research and Development of Biotechnology} (MoST Regulation, draft, 2019). To address the lack of clarity in the Ordinance, the MoST produced new regulations on the safety management of the research and development of biotechnology, which stratified the risks associated with biotechnologies into three levels. However, the Ordinance did not provide specific guidance on how to assign a gene-editing activity to a specific level.

50. Article 28 of the Regulations on the Management of the Human Genetic Resources (2019).
51. Op. cit.
52. Article 7 of the Regulations on the Management of the Human Genetic Resources (2019).
53. Article 36 of the Regulations on the Management of the Human Genetic Resources (2019).
54. Interpretation of the 11th Amendment to the Criminal Code of the P.R.C.: Seven Points to be Considered, 七大看点解析刑法修正案(十一)草案, Xinhua News 2020.
55. For example: Article 8, ‘Collecting, preserving, utilizing, sharing human genetic resources abroad must not harm the public health, national security, and public interest’. Article 16, ‘…The government is entitled to use human genetic resources for public health, national security, and public interests…’ Article 28, ‘…Share genetic data to foreign entities or individuals […] must not harm the public health, national security, or public interest…’
56. Article 9 of the Regulations on the Management of Human Genetic Resources (2019).
57. Article 39 of the Regulations on the Management of Human Genetic Resources (2019).
58. Article 1 of the Safety Ordinance for Biotechnology Research and Development to Safeguard Biosecurity (2017).
59. Article 4 and Appendix of the Safety Ordinance for Biotechnology Research and Development to Safeguard Biosecurity (2017).
The MoST Regulation also focuses on national biosecurity.\(^{60}\) Article 5 stresses that scientific progress and safety are of the same importance, which is inconsistent with the second part of the article stating that research and development activities in biotechnology must not jeopardise national biosecurity, ethics or the public interest.\(^{61}\) Since it focuses on safety management, the new regulation does not focus much on individuals’ personal rights. This regulation remains centred on a three-tier classification of risk levels: high, intermediary and low risk.\(^{62}\) The MoST is mandated to list the research and development activities with high and intermediary risk.\(^{63}\)

Article 2 defines the biotechnology research and development activity, which are ‘activities carried out through the understanding, utilization, and transformation of organisms through scientific and engineering principles’.\(^{64}\) This definition is broad enough to include basic research on human embryonic gene editing which should comply with this regulation. The provincial science and technology authority should review and approve high-risk activities based on the listed criteria, including the research plan, the risk mitigation plan and the emergency plan for security incidents.\(^{65}\) Moreover, only legal persons registered in China are entitled to perform high or intermediary-risk research and development activities.\(^{66}\)

The sanctions provided for in the MoST Regulation are similar to those included in the RMHGR. Violators can be fined up to 10 million RMB (US$1.3 million) or 10 times their illegal gains (if they gained over 1 million RMB). Other administrative sanctions include a temporary or life ban on the research activity or loss of the contravening party’s right to apply for an administrative licence. Those who violate the provisions of these regulations and infringe on the legal interests of others also bear full civil liability for their actions and will also be investigated for criminal responsibility according to the relevant law.\(^{67}\) This Regulation does not apply to clinical applications of innovative biomedical technologies, which are covered by the NHC Regulation as

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60. Article 1 of the Regulations on the Safety Management of the Research and Development of Biotechnology (2019).
61. Article 5 of the Regulations on the Safety Management of the Research and Development of Biotechnology (2019).
62. Article 10 of the Regulations on the Safety Management of the Research and Development of Biotechnology (2019).
63. Article 12 of the Draft Regulations on the Safety Management of the Research and Development of Biotechnology (2019).
64. Article 2 of the Regulations on the Safety Management of the Research and Development of Biotechnology (2019).
65. Article 13 of the Regulations on the Safety Management of the Research and Development of Biotechnology (2019).
66. Article 13 and Article 17 of the Regulations on the Safety Management of the Research and Development of Biotechnology (2019).
67. Article 44 of the Draft Regulations on the Safety Management of the Research and Development of Biotechnology (2019).
discussed in ‘Regulations on the Management of the Clinical Application of Innovative Biomedical Technologies (NHC Regulation, draft, 2019)’.

Regulations on the management of the clinical application of innovative biomedical technologies (NHC Regulation, draft, 2019). In its public announcement of the NHC Regulation on 26 February 2019, the NHC stated that all clinical research and translational research involving innovative biomedical technologies would require administrative approval to avoid a repetition of the He scenario.68 The NHC Regulation (2019) also touches on potential problems such as privacy concerns, biosecurity threats, public safety and ethics.69 It classifies clinical research on gene editing into two levels: (1) high risk and (2) low and intermediate risk.70 All research involving technologies with high risk, including gene transfer technology, gene editing technology, stem cell technology, somatic cell technology, mitochondrial replacement transfer and assisted reproductive technology must be approved by the NHC after a review of the project’s scientific and ethical aspects.71 In the future, clinical research on gene editing should require the NHC’s approval. Clinical research with low and intermediate risk requires an administrative licence from the provincial health department instead of the NHC’s approval.72 In this sense, all clinical research on innovative biomedical technology will be subject to two review processes: an internal review carried out by the medical institution and a final permit provided by either the provincial or national medical administration based on the level of risk.

The NHC Regulation also sets out the professional requirements to be considered principal investigator of a clinical research project. Only researchers who are licensed medical practitioners and with a recognised high-level academic position (associate professor at minimum) are qualified to be considered principal investigator.73 However, the NHC Regulation does not mention any credential requirements for the other researchers involved in a project.

Article 12 specifies research requirements for institutions. Only top grade (Sanjia) hospitals are eligible to conduct clinical research involving innovative biomedical technologies.74 The hospital must also meet other requirements for research facilities.
infrastructure, technicians’ qualifications, quality assurance, ethical requirements and subjects’ health benefits.75

The NHC Regulation stipulates that the medical institution is the responsible body and the director of the medical institution is the first responsible person.76 Since the NHC’s authority is limited to medical institutions and medical professionals, those who are not medical professionals are beyond the scope of the Regulation. Non-medical institutions, such as educational and research institutions, should collaborate with a medical institution on any clinical research project involving innovative biomedical technologies. In such cases, the collaborating medical institution is the responsible entity and must comply with this Regulation.77

Chapter 6 covers legal sanctions. For medical institutions, administrative sanctions include a notice of criticism, a warning78 or a fine of up to 100,000 RMB (US$15,000). The director of a medical institution and other responsible medical practitioners can receive the following sanctions: suspension of research, revocation of their licence and a fine of up to 100,000 RMB (around US$15,000) or 20 times the amount of the illegal profit (if there is one).79

Conceptual reform plans: National ethics committee for science and technology (国家科技伦理委员会)

The Ethical Review Guidelines for Biomedical Research Involving Humans (2016) requires the establishment of an ethical committee for medical institutions conducting biomedical research. However, Huang jiefu (former Vice Minister of National Health Committee) pointed out that He’s case underscored the Ethical Review Guidelines are lacking clear-cut sanctions, which cause a widespread problem of weak enforcement. Huang thus called for a national ethics committee.80 In July 2019, the proposal of a national ethics committee to oversee research raising significant ethical controversy,

75. Article 12 of the Regulations on the Management of the Clinical Application of Innovative Biomedical technologies (2019).
76. Article 13 of the Regulations on the Management of the Clinical Application of Innovative Biomedical technologies (2019).
77. Article 23 of the Regulations on the Management of the Clinical Application of Innovative Biomedical technologies (2019).
78. Notice of criticism and warning are typical reputational sanctions that influences on one’s reputation, honour and credentials. These sanctions are commonly endorsed by administrative institutions. See X. Zhu, W. Jin and L. Tang, The Chinese Administrative Law Study 中国行政法学 (Beijing: Tsing Hua University Press, 2005), pp. 239.
79. Chapter 6, Sanctions of the Regulations on the Management of the Clinical Application of Innovative Biomedical Technologies (2019).
80. H. Zhang and S. Leng, ‘Outrage Grows Over Gene Edited Twins Experiment, Peers Critical of Scientist’s Defense’, The Global Times 28 November 2018. Available at: http://www.globaltimes.cn/content/1129476.shtml (accessed 7 July 2020); J. Huang, An Urgent Need for a National Bioethics Committee. 我国亟需在国家层面成立权威的生命科学伦理委员会 The Global Times 29 November 2018. Available at: https://mil.sina.cn/2018-11-29/detail-ihmutuec4590688.d.html (accessed 7 July 2020).
such as projects involving gene-editing technology, was approved at the 9th Meeting of the Central Committee for Deeping Overall Reforms of the Central Communist Party.\footnote{81}

The National Ethical Review Committee for Science and Technology (NERC) will be mandated to strengthen China’s overall regulatory framework by ‘providing guidance and coordination and by promoting the establishment of a comprehensive scientific and technological ethics governance system with comprehensive coverage and a clear direction.’\footnote{82} Renzong Qiu, a renowned bioethicist from the Chinese Academy of Social Science, stated that the NERC will play a role similar to that of the Nuffield Council on Bioethics in the United Kingdom.\footnote{83} Qiu suggested that the committee should include the expertise of the widest variety of professionals, including scientists, physicians, ethicists, philosophers, lawyers and policy advisers. The committee will examine emerging biotechnologies and formulate policy recommendations thereafter.\footnote{84} It is reported that the constitution of the NERC and the drafting of the implementation policy are ongoing.\footnote{85}

**Revisiting the He case: Whose responsibility?**

The court hearing involving He and his accomplices was not made accessible for unclear ‘privacy reasons’, raising questions about the legitimacy and procedural fairness of the trial.\footnote{86} A better alternative would have been to make the court decision public with any private information redacted. Only fragmented pieces of information were revealed in Xinhua News\footnote{87} and the Supreme Court of the P.R.C. website, where official statements from the government are posted. He was convicted of ‘illegal medical practice’ because he was not a licensed clinical doctor but carried out clinical research on humans according to Article 336 of the Criminal Code of the P.R.C. This leaves an open question regarding the outcome had He been a licensed clinician. In this case, what legal ground, if any, could have been invoked to penalise his actions? Therefore, this section addresses questions raised by the court’s decision and possible legal liabilities for He and his accomplices. It then expands the discussion on the moral responsibility of collaborating scientists.

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81. Scientific Ethics: we will have ‘butlers’ 科技伦理，从此有了’大管家’. *Science Net* 29 July. Available at: http://news.sciencenet.cn/htmlnews/2019/7/428834.shtm (accessed 7 July 2020).
82. Op. cit.
83. H. Jia. ‘China Approves Ethics Advisory Group After CRISPR-babies Scandal’, *Nature News* 8 August 2019. Available at: https://www.nature.com/articles/d41586-019-02362-5 (accessed 7 July 2020).
84. Op. cit.
85. The road map for exploring the ethics for science and technology 探索科技伦理治理的路线图 *The Science Net*, 5 June 2020, Available at: http://news.sciencenet.cn/htmlnews/2020/6/440961.shtm (accessed 31 August 2020).
86. The Case of Gene Editing Babies.
87. Xinhua News is an official state-run press agency of the P.R.C.
According to Article 336 of the Criminal Code, the crime of illegal medical practice only occurs when these illegal practices have had severe consequences. The Supreme Court Interpretation on Illegal Practice of Medicine Cases (2016) provides an interpretation of severe circumstances which includes four possible situations and one umbrella clause:

1. Causing mild disability, or damage to organ tissue, that leads to ordinary dysfunction;
2. Causing Category A infectious diseases to spread, become epidemic, or cause the danger of spreading or becoming epidemic;
3. Using fake or shoddy medicines, or medical materials or instruments that do not meet national standards, sufficiently to seriously harm human health;
4. Engaging in the illegal practice of medicine after having already twice received administrative punishment from the administrative departments of health for practicing medicine illegally;
5. Other situations where the circumstances are serious.  

He’s behaviour does not fall into any of the first four categories, but the umbrella clause at section (5) of the Supreme Court Interpretation would seem to apply. The 11th Amendment to the Chinese Criminal Code incorporates a crime of illegal practices on human gene editing which may bring more clarity to similar cases in the future.

Since criminal liability does not provide for civil compensation, the gene-edited babies and their parents may also be eligible to file a civil action. The Civil Code of the P.R.C. provides a few options for civil actions. From a contractual perspective, according to Article 143, a civil juristic act is only valid if individuals express a genuine intention without violating mandatory provisions enacted through laws or regulations. Deceived by a forged ethical approval letter, the parents would likely have made a different decision if they had received clear and complete information about the risks and benefits of the procedure. In addition, the consent form for He’s experiment misled the parents by stating it was an AIDS vaccine project. The parents seemed to be under undue inducement since He committed to pay them US$40,000 in return. Also, since He was convicted of ‘illegal medical practices’ in violation of the mandatory provision of the Criminal Code, the informed consent he obtained from the parents is presumably invalid.

88. The Supreme Court’s Interpretation on Illegal Medical Practice (2016) 最高法院关于非法行医事件案解释. Available at: http://www.court.gov.cn/zixun-xiangqing-33031.html (accessed 7 July 2020); Also see The Supreme Court’s Interpretation on Illegal Medical Practice 非法行医事件案解释. Available at: https://www.chinalawtranslate.com/interpretation-on-illegal-practice-of-medicine-cases/ (accessed 7 July 2020).
89. Interpretation of the 11th Amendment to the Criminal Code of the P.R.C.: Seven Points to be Considered, 七大看点解析刑法修正案 (十一) 草案, Xinhua News.
90. Chinese Clinical Trial Register (ChiCTR).
91. P. Belluck, ‘Chinese Scientist Who Says He Edited Babies’ Genes Defends His Work’, New York Times 28 November 2018. Available at: https://www.nytimes.com/2018/11/28/world/asia/gene-editing-babies-he-jiankui.html (accessed 7 July 2020).
He and his accomplices collected the parents’ germ cells in a deceptive way, which violated their right to physical integrity.\textsuperscript{92} Physical integrity is protected as part of bodily rights in the Civil Code.\textsuperscript{93} Therefore, parents might be eligible to claim compensation for an infringement of their bodily rights. According to the Supreme Court’s Interpretation on Problems regarding the Ascertainment of Compensation Liability for Emotional Damages in Civil Torts, the parents might also be eligible for emotional damages following the violation of their physical integrity.\textsuperscript{94} Article 1183 of the Civil Code confirms the claim for emotional damage caused by bodily injury. However, the limitation period for emotional damage is 3 years after learning that one’s rights were violated.\textsuperscript{95}

Gene editing may cause off-target effects to other genes, which might influence the twins’ health or even shorten their lives.\textsuperscript{96} Besides, a possible complication of an edited gene may create a mutated protein with unknown functions.\textsuperscript{97} Therefore, these babies or their legal representatives may also have civil recourse by invoking their right to mental and physical health under Article 1004 of the Civil Code.

According to Articles 1179, both parents and twins may be eligible for damages for medical treatment, nursing cost, travel expenses, meals, hospitalisation and loss of income. In case of disability, remedies for assistive devices and disability compensation should also be made to the plaintiff.

Along with other recent developments in China, the He Jiankui case has spurred the Chinese government to further develop its policies on scientists’ accountability in biomedical research. However, it should not be forgotten that the project also involved some American scientists. Michael Deem, He’s doctoral supervisor, was listed as the senior author on the paper ‘Birth of twins after genome editing for HIV resistance’.\textsuperscript{98} Likewise, in 2004, South Korean scientist Woo Suk Hwang made headlines worldwide by allegedly cloning human embryos. Hwang was later accused of illegally collecting eggs from junior employees and faking data.\textsuperscript{99} In his retracted article, American scientists from

\textsuperscript{92} J. Cohen, ‘Did CRISPR help—or harm—the first-ever gene-edited babies?’ \textit{Science AAAS} 1 August 2019. Available at: https://www.sciencemag.org/news/2019/08/did-crispr-help-or-harm-first-ever-gene-edited-babies (accessed 7 July 2020).

\textsuperscript{93} Article 1003 of the Chinese Civil Code (2021).

\textsuperscript{94} Interpretation of the Supreme People’s Court on Problems regarding the Ascertainment of Compensation Liability for Emotional Damages in Civil Torts. Available at: http://www.lawinfochina.com/display.aspx?lib=law&id=1802&CGid (accessed 7 July 2020).

\textsuperscript{95} Article 188 of the Chinese Civil Code (2021).

\textsuperscript{96} H. Ledford, ‘CRISPR Babies: When will the World be Ready?’ \textit{Nature} 570(7761) (2019), pp. 293–296.

\textsuperscript{97} D. Cyranoski, ‘The CRISPR-baby Scandal: What’s Next for Human Gene-editing’, \textit{Nature} 566(7745) (2019), pp. 440–442.

\textsuperscript{98} J. Cohen, ‘The Untold Story of the ‘Circle of Trust’ Behind the World’s First Gene Edited Babies’, \textit{Science AAAS} 1 August 2019. Available at: https://www.sciencemag.org/news/2019/08/untold-story-circle-trust-behind-world-s-first-gene-edited-babies (accessed 1 July 2020).

\textsuperscript{99} W.S. Hwang et al., ‘Patient-Specific Embryonic Stem Cells Derived from Human SCNT Blastocysts’, \textit{Science} 308(5729) (2005), pp. 1777–1783.
Pittsburgh University are listed as co-authors. Should scientists who become aware of unethical research overseas do more to stop it or blow the whistle? Greely listed the dilemmas scientists confront in these cases, including the principle of confidentiality in science, loss of relationship and social conditioning. Another problem is the lack of a sophisticated international mechanism to let scientists warn of unethical or illegal research in other jurisdictions. With the increase of international genomic projects, researchers from different countries should collaborate more closely not only to advance scientific progress but also to improve ethical compliance.

**Conclusion: A way forward**

He Jiankui’s highly mediatised misconduct, along with other recent ethical controversies in Chinese biomedical science, has ignited a systemic reaction from the NPC and its Standing Committee to the NHC and MoST. Their new policies cover the entire research and application process, from the collection, preservation and utilisation of human genetic resource to clinical application. This situation even led Chinese President, Jinping Xi, to stress the importance of establishing actionable ethics standards and ensuring the scientific community’s compliance. In addition, personality rights are now protected in a separate book of the *Chinese Civil Code*, marking a milestone in the Chinese history of human rights protection.

Pressure from the international community also played a role in forcing Chinese policies to align with international bioethical principles such as ethical review, privacy protection and informed consent. As Greely observes, ethical rules in China are now similar to those of many developed countries. However, the real challenge is how to translate these globally recognised ethical rules into reality. More specific enforcement guidelines and courts’ interpretations of these policies should be in place to ensure a meaningful implementation of the new regulatory framework. In addition, most of the documents pertaining to this regulatory reform have been enacted for less than one year or are only at the planning stage. The present lack of empirical data on the enforcement of these policies may cast doubt over the efficiency of the reforms. Thus, government and researchers should thus assess the new regulatory framework’s capacity to address problems of research integrity and scientific misconduct on a regular basis. We also note that there are few public information campaigns or education programs for scientists who are key players in the regulatory reform of biotechnology. Training programs and

100. H.T Greely, ‘CRISPR’d Babies: Human Germline Genome Editing in the ‘He Jiankui affair’, *Journal of Law and the Biosciences* 6(1) (2019), pp. 171–173. Available at: https://academic.oup.com/jlb/article/6/1/111/5549624 (accessed 7 July 2020); H.T Greely, ‘How should science respond to CRISPR’d Babies?’ *ISSUES in Science and Technology* xxxv(3) (2019). Spring 2019. Available at: https://issues.org/how-should-science-respond-to-crisprd-babies/ (accessed 31 August 2020).

101. V.J. Dzau and M. McNutt and C. Bai, ‘Wake-up call from Hong Kong’, *Science* 362(6420) (2018), pp. 1215–1215.

102. Greely, ‘CRISPR’d Babies: Human Germline Genome Editing in the ‘He Jiankui affair’, p. 181.
public engagement fora should be integral components of the reform. This measure will help equip scientists with bioethical tools to critically examine their scientific activities.

The lack of transparency in China’s handling of He’s case has commonly been identified as problematic. Critical materials such as the court decision and official investigation reports are not available for the public and experts to view, which may result in continuing mistrust between China and other jurisdictions. The Chinese government thus should aim for more transparency in disclosing its policies and investigation reports with other countries.

Concerns for biosecurity are demonstrated in the draft Biosecurity Law, the draft MoST Regulation and the RMHGR. The stricter administrative permit process on the critical research or application of biotechnology to Chinese entities or Chinese legal persons may impede future international collaborations. More complex administrative processes, from collecting genetic resources for research to running clinical trials, may also increase the burden on scientists. These confounding interests of ethics, security and national ownership/competitiveness could create misunderstandings and conflicting priorities for Chinese scientists. Individuals’ personal rights, national security and biotechnological progress are three main objectives of the current reform. But the Chinese government should aim to balance these aims in a way that will be conducive to policy interoperability and securing the trust of the international community.

The criminal conviction of He Jiankui and the ensuing legal reforms seem to signal to Chinese scientists that they must be more cautious about issues of ethics and scientific integrity to avoid potential administrative, civil and criminal sanctions. However, some parts of the message remain unclear for the moment, and scientists may be tempted to use that lack of clarity to test the seriousness and limits of the reforms. Policies and regulations are in place, but the path ahead, for better or worse, largely remains theirs to trace.

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103. Op. cit., pp. 180–181.