



# Evaluations on Pending Regulation on Ethical Review Measures for Biomedical Research Involving Human Subjects and Artificial Intelligence

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**Abstract.** The rapid development of Artificial Intelligence (AI) has extensively promoted medicine, pharmaceutical, and other related fields in recent years. The ethics review is one of the critical procedures of registration to get the medical artificial intelligence products approved and commercialized. The National Health Commission of the People's Republic of China published a consultation paper on the Ethical Review Measures for Biomedical Research Involving Human Beings (Second Version) (the Draft) on March 16th, 2021.

Although the Draft indicated that the Ethics Review Committees need to be set up by the Regional and Institutional level, the review authorities of different levels were not clarified. The suggestion is that three tiers of Ethics Review Committees should be set up in China. The precise scope of review authorities for each level should be identified. Such as the complicated leading technology, gene editing, should be reviewed by National Ethics Review Committees. It will be the job of individual institute Ethics Review Committees to approve the clinical research with less risk such as a new ointment to treat acne. Furthermore, to standardize the research and development of artificial intelligence in healthcare in the age of AI, more clear guidance should be given to data security in the layers of data, algorithm, and application in the ethics review process. In addition, transparency and responsibility, as two of six principles in the Rome Call for AI Ethics promoted by the Pontifical Academy for Life and presented on February 28th, 2020, could be further strengthened in the Draft.

**Keywords:** Biomedical research involving human beings · Data security · Ethics Committees · Ethical Review · Medical artificial intelligence

## 1 Introduction

The rapid development of Artificial Intelligence (AI) has extensively promoted medicine, pharmaceutical, and other related fields in recent years. There is an expectation that the implications of AI can have a significant positive impact on quality of care of patients, disease prevention, diagnosis, and treatment options, in addition to the potential for

efficiency gains and reduction in human error. The research and development of artificial intelligence in healthcare by scientific and commercial organizations are on the fast track. The ethics review is one of the critical procedures of registration to get the products quickly approved and launched.

However, the Standard Operating Procedures for ethics review is not enough to guide the healthy and rapid development of artificial intelligence in healthcare in China. Ethical Review Measures for Biomedical Research Involving Human Beings were enacted by the National Health Commission of the People's Republic of China (NHC) on December 1st, 2016 [1]. However, from a legislative design perspective, it was neither updated timely nor in line with the international trends of AI development. Therefore, it was great that NHC published a consultation paper on the Ethical Review Measures for Biomedical Research Involving Human Beings (Second Version) (the Draft) on March 16th, 2021 [2], and started to collect public comments on the Draft.

## 2 Methods

In order to submit the comments to the Draft and facilitate AI development in China, first, the laws and regulations in the USA and EU were reviewed and compared, then 11 subject matter experts (SMEs) in China were in-depth interviewed (IDI), including lawmakers, regulators, and key members of ethics review committees, heads of Regulatory Affairs in Software as a Medical Device (SaMD) industry, and data scientists. The tailor-made questionnaire for each SME was prepared, interviewed each SME in 75 min from April to June. Coupled with the findings from the global laws and regulations, the opinions of SMEs were summarized and enlighten on the proposed suggestions to the Draft [2].

## 3 Results and Discussion

### 3.1 Ethics Review Committees in Three Tiers (Institutional, Provincial, and National) Should Be Established in China While Identifying the Clear, Precise Scope of Review Authorities for Each Level

The Draft indicated that the Institutional Review Board (IRB) and Regional Ethics Committee (REC) need to be set up for ethics review. The responsibility of IRB was specified as IRB provides an ethical review of human subjects research to be conducted in the institution or delegated institution, to protect the rights and welfare of human subjects of research and to assure that human research is conducted according to applicable national, provincial, and local laws and regulations and the relevant policies. However, the responsibility of REC was not indicated in the Draft, and the review authorities of IRB and REC were not clarified.

Chinese Hospital Association and the Ethics Expert Committee of NHC released the Guidance to Ethics Review Committee for Clinical Research Involving Human Beings in October 2020, but no guidance for the limits of authorities of IRB and REC [3].

The United States of American and European countries set up REC much earlier, the experiences of those countries could be referred to improve and perfect the regulations in China:

**The United States of American.** Several RECs were established in the USA. For example, the Biomedical Research Alliance of New York (BRANY) was founded in 1998 by four nationally-ranked academic medical centers. BRANY IRB was the first IRB in New York to be accredited by Association for the Accreditation of Human Research Protection Program (AAHRPP) in 2006, takes the role of REC to oversee the researches involving human subjects in the region [4, 5].

Western Institutional Review Board (WIRB) is an independent central IRB located in Puyallup, Washington, oversees overall human participant research at Wayne State University (WSU) and its affiliates registered under the Wayne State Federal wide Assurance (FWA). WIRB also takes the role of REC, cooperated with more than 100 research centers and pharmaceutical companies to review their research projects in the region [4, 6].

**The United Kingdom.** The United Kingdom Ethics Committees Authority (UKECA) was founded in 2004 to authorize and oversee the operation of IRBs in the UK; UKECA identifies IRBs by three types. The type II IRB takes the responsibilities of REC to review and approve the researches in its region [4, 7].

**Sweden.** Six RECs were established by geographical location [8]. Therefore, the principal investigator (PI) of a multiple center clinical trial should get approval from one REC where PI's institution locates in. Then the approval is effective national wide.

Those countries have the practice of RECs. However, no specific guidance is developed to link the risk levels of the research with the review authorities of ethics committees at each level.

In the age of AI, biomedical research projects have become more complex, the potential risks are more difficult to be forecasted. To be more efficient, biomedical researches with risks at different levels should be reviewed and approved by ethics committees at a different levels. Three tiers of ethics review committees should be established in China. They are Institutional Review Board (IRB), Provincial Ethics Committee (PEC), and National Ethics Committee (NEC). For example, the clinical research of a new ointment to treat acne has less risks, IRB could review and approve it independently. The risks of some research are not high, but unique populations such as psychiatric patients are involved, or about certain diseases such as rare diseases or organ transplantations, IRB should review first and then submit to PEC for approval. The complicated leading technology, such as Assisted Reproductive Technology (ART), Gene editing, Mitochondrial Replacement Techniques (MRT), Interspecies Cloning, etc., have high risks, should be preliminary reviewed by IRB, second reviewed by REC, finally approved by NEC (Table 1).

### 3.2 The Guidance About Data Security in Ethics Review Should Be Clearly Described in the Draft

The Draft has minimal guidance to IRB in data security, majorly focuses on data sharing and secondary utilization. In the age of AI, more AI will be involved in biomedical research, such as Software as a Medical Device (SaMD), data security has been an essential topic. Strengthening data security and privacy protection is the key to researching,

**Table 1.** The Scope of Review Authorities of the Ethics Committees in Different Level

Risk levels	IRB	REC	NEC
Researches with low or medium risks	Approval		
Researches with low or medium risks: Special population: psychiatric patients etc Special diseases: rare diseases, organ transplantations etc	Review	Approval	
Researches with high risks [9]: Assisted Reproductive Technology (ART), Gene Editing, Mitochondrial Replacement Techniques (MRT), Interspecies cloning, etc.	Preliminary review	Second review	Approval

developing, and applying medical artificial intelligence. The USA and some European countries have adopted policies for critical privacy data related to medical, such as increasing the difficulty of cracking by strong encryption and establishing strict data access procedures and authorities [10].

The research of medical artificial intelligence products is inseparable from patients’ health data and medical record data. Therefore, the Draft should give more explicit guidance to ethics review in data security in the kind research. The Draft should identify the ethics review requirement for data security and privacy protection, including the qualification of the research personnel who may have direct contact with the research data, infrastructure, access control technologies, etc., to ensure data security and privacy protection in the data layer, algorithm layer, and application layer in the entire research process [11].

**3.3 Transparency and Responsibility Should Be Supplemented into the Principles of Ethics Review**

The Draft identified eight principles of ethics review in biomedical research. They were Compliance, Informed Consent, Control Risk, Fairness, Free and Compensation, Privacy Protection, Special Protection, and Public Interests [2].

Transparency and responsibility were the principles in almost all the regulations and guidelines related to AI Ethics in the USA and European countries [12]. The “Rome Call for AI Ethics” promoted the use of Artificial Intelligence-based on Transparency, Inclusion, Responsibility, Impartiality, Reliability, Security, and Privacy principles [13]. The Call, promoted by the Pontifical Academy for Life and presented on February 28, 2020, had as first signatories the President of Microsoft Brad Smith, the Vice President of IBM John Kelly III, the Director-General of the Food and Agriculture Organization of the United Nations (FAO) Qu Dongju and the Minister for Innovation of the Italian Government Paola Pisano.

**Transparency.** To realize the principle of transparency depends on the explicability, verifiability, and predictability of algorithms of medical artificial intelligence products

[14]. Therefore, when the biomedical research related to medical artificial intelligence is reviewed, the Ethics Committees should ensure that healthcare professionals know how and why medical artificial intelligence makes specific decisions in the research protocol design.

**Responsibility.** The principle of responsibility means that the Ethics Committees should review if a transparent responsibility system has been established for technology research and development, in order to ensure the technology researchers and design departments can be held accountable from the technical level when medical artificial intelligence product leads to the conflict of human ethics or law [14].

The ethical review of the research related to medical artificial intelligence products has the universality with AI, transparency and responsibility are critical principles of AI ethics, so both should be supplemented into the principles of the Draft.

## 4 Conclusions

To facilitate the rapid and healthy development of artificial intelligence in healthcare in China, an updated Ethical Review Measures for Biomedical Research Involving Human Beings is essential. On top of the Draft released on March 16th, 2021, suggest establishing Ethics Committees in three tiers with the different authorities. Furthermore, give more explicit guidance on data security in ethics review. In addition, supplement the principles of transparency and responsibility. If the Draft could adopt the suggestions, the efficiency of ethics review will be improved, the human subjects in the biomedical research will be safer, and the process of registration, approval, and commercialization will be expedited. Then China could be one of the most advanced countries in artificial intelligence in healthcare soon.

## References

1. The National Health Commission of the People's Republic of China (NHC), The ethical review measures for biomedical research involving human beings, 12th October 2016. <http://www.nhc.gov.cn/cms-search/xxgk/getManuscriptXxgk.htm?id=84b33b81d8e747eaaf048f68b174f829>. Accessed 23 Aug 2021
2. The National Health Commission of the People's Republic of China (NHC), The ethical review measures for biomedical research involving human beings (second version, the Draft), 16th March 2021. <http://www.nhc.gov.cn/cms-search/xxgk/getManuscriptXxgk.htm?id=beb66b1525e64472b1a9b8921ed1aedf>. Accessed 23 Aug 2021
3. Chinese Hospital Association and the Ethics Expert Committee of NHC, The guidance to ethics review committee for clinical research involving human beings (v2020), 26th October 2020. <http://cctmis.org/zcfg/zc/809.html>, Accessed 23 Aug 2021
4. Wang, J.: Development and orientation of regional ethics committee. In: 2018 Annual Conference of Pharmaceutical Clinical Evaluation Research Professional Committee, pp. 45–49. China Pharmaceutical Association (2018)
5. Corporate Overview of BRANY (Biomedical Research Alliance of New York). <https://www.brany.com/corporate-overview/>. Accessed 23 Aug 2021
6. Introduction of Western Institutional Review Board (WIRB). <https://research.wayne.edu/irb/wirb>. Accessed 23 Aug 2021

7. Ji, P.: UK research ethics review system introduction and implication. *Med. Philos.* **41**(9), 30–33 (2020)
8. Wang, Y., He, Y., Luo, X., Ma, X., Zhang, N.: The discussion of ethical review program construction in clinical research. *Chinese Med. Ethics* **28**(6), 916–918 (2015)
9. The National Health Commission of the People's Republic of China (NHC), Regulation on the administration of clinical application of new biomedical technologies, 26th February 2019. <http://www.nhc.gov.cn/wjw/yjzj/201902/0f24ddc242c24212abc42aa8b539584d.shtml>. Accessed 23 Aug 2021
10. Xie, X., He, X., Zhang, L., Li, W., Gao, Y.: Analysis on the key points of ethical review concerning medical artificial intelligence research. *Chin. Med. Eth.* **34**(7), 844–850(2021)
11. Li, L.: *Data Ethics and Algorithm Ethics*, 1st edn, pp. 83–93. Science Press, Beijing (2019)
12. The National Committee of Artificial Intelligence Standardization, Report to Risk Analysis of AI Ethics, pp. 3–6 (2019). <https://pan.baidu.com/s/1uqfLuQB0jEDG0AIDlwWEAA,pascode:c91b>. Accessed 23 Aug 2021
13. The Pontifical Academy for Life, Rome Call for AI Ethics. <http://www.academyforlife.va/content/pav/en/news/2020/intelligenza-artificiale-2020.html>. Accessed 23 Aug 2021
14. The National Committee of Artificial Intelligence Standardization, Report to Risk Analysis of AI Ethics, pp. 31–32 (2019). <https://pan.baidu.com/s/1uqfLuQB0jEDG0AIDlwWEAA,pascode:c91b>. Accessed 23 Aug 2021