Notice by the National Health Commission, the Ministry of Education, the Ministry of Science and Technology, and the National Administration of Traditional Chinese Medicine of Issuing the Measures for Ethical Review of Life Science and Medical Research Involving Human Being

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Notice by the National Health Commission, the Ministry of Education, the Ministry of Science and Technology, and the National Administration of Traditional Chinese Medicine of Issuing the Measures for Ethical Review of Life Science and Medical Research Involving Human Being

国家卫生健康委、教育部、科技部、国家中医药局关于印发涉及人的生命科学和医学研究伦理审查办法的通知

(No. 4 [2023] of the National Health Commission)

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The people's governments of all provinces, autonomous regions, and municipalities directly under the Central Government; all ministries and commissions of the State Council and all institutions directly under the State Council; and the China Association for Science and Technology:

各省、自治区、直辖市人民政府，国务院各部委、各直属机构，中国科学技术协会：

The Measures for Ethical Review of Life Science and Medical Research Involving Human Being, as deliberated and adopted by the National Science And Technology Ethics Committee, are hereby issued for your diligent implementation in light of the work reality, with the consent of the State Council.

《涉及人的生命科学和医学研究伦理审查办法》已经国家科技伦理委员会审议通过。经国务院同意，现印发给你们，请结合工作实际，认真组织实施。

National Health Commission	国家卫生健康委
Ministry of Education	教育部
Ministry of Science and Technology	科技部
National Administration of Traditional Chinese Medicine	国家中医药局
February 18, 2023	2023年2月18日
Measures for Ethical Review of Life Science and Medical Research Involving Human Being	涉及人的生命科学和医学研究伦理审查办法

Chapter I General Principles

第一章　总 则

Article 1 For the purposes of protecting life and health of human being, safeguarding personal dignity, respecting and protecting the legitimate rights and interests of research participants, promoting the sound development of life science and medical research, and regulating the ethical review of life science and medical research involving human being, these Measures are developed in accordance with the Civil Code of the People's Republic of China, the Basic Healthcare and Health Promotion Law of the People's Republic of China, the Law of the People's Republic of China on Scientific and Technological Progress, the Law of the People's Republic of China on Biosecurity, and the Regulation of the People's Republic of China on the Administration of Human Genetic Resources, etc.

第一条　为保护人的生命和健康，维护人格尊严，尊重和保护研究参与者的合法权益，促进生命科学和医学研究健康发展，规范涉及人的生命科学和医学研究伦理审查工作，依据《中华人民共和国民法典》《中华人民共和国基本医疗卫生与健康促进法》《中华人民共和国科学技术进步法》《中华人民共和国生物安全法》《中华人民共和国人类遗传资源管理条例》等，制定本办法。

Article 2 These Measures shall apply to the ethical review of life science and medical research involving human being in medical and health institutions, institutions of higher learning and research institutes, among others, in the territory of the People's Republic of China.

第二条 本办法适用于在中华人民共和国境内的医疗卫生机构、高等学校、科研院所等开展涉及人的生命科学和医学研究伦理审查工作。

Article 3 For the purposes of these Measures, “life science and medical research involving human being” refers to the following research activities carried out with biological samples and information data (including health records, behaviors, etc.) with human beings as subjects or users (collectively referred to as “research participants”):

第三条 本办法所称涉及人的生命科学和医学研究是指以人为受试者或者使用人（统称研究参与者）的生物样本、信息数据（包括健康记录、行为等）开展的以下研究活动：

(1) Carrying out activities of research on human reproduction, growth, development and senescence by physics, chemistry, biology and traditional Chinese medicine and other means.

（一）采用物理学、化学、生物学、中医药学等方法对人的生殖、生长、发育、衰老等进行研究的活动；

(2) Carrying out activities of research on human physiological and psychological behaviors, pathological phenomena, etiology and pathogenesis of diseases, as well as prevention, diagnosis, treatment and rehabilitation of diseases by physics, chemistry, biology, traditional Chinese medicine, psychology and other means.

（二）采用物理学、化学、生物学、中医药学、心理学等方法对人的生理、心理行为、病理现象、疾病病因和发病机制，以及疾病的预防、诊断、治疗和康复等进行研究的活动；

(3) Carrying out activities of experimental research on human subjects by using new technologies or new products.

（三）采用新技术或者新产品在人体上进行试验研究的活动；

(4) Carrying out activities of collecting, recording, using, reporting or storing biological samples, information data (including health records, behaviors, etc.) and other scientific research materials on life science and medical problems involving human being by epidemiology, sociology, psychology, and other means.

（四）采用流行病学、社会学、心理学等方法收集、记录、使用、报告或者储存有关人的涉及生命科学和医学问题的生物样本、信息数据（包括健康记录、行为等）等科学研究资料的活动。

Article 4 The ethical review work and relevant personnel shall comply with the Constitution, laws and relevant regulations of the People's Republic of China. In life science and medical research involving human being, participants shall be respected, the principles of benefiting, non-harm and justice shall be followed, and the right to privacy and personal information shall be protected.

第四条 伦理审查工作及相关人员应当遵守中华人民共和国宪法、法律和有关法规。涉及人的生命科学和医学研究应当尊重研究参与者，遵循有益、不伤害、公正的原则，保护隐私权及个人信息。

Chapter II Ethical Review Committee

第二章 伦理审查委员会

Article 5 As subjects assuming the management responsibilities for the work of ethical review, medical institutions at or above Grade II and health institutions at or above the level of districted cities (including disease prevention and control, maternal and child health care, blood collection and supply institutions, etc.) carrying out life science and medical research involving human being, institutions of higher learning, scientific research institutes and other institutions shall set up ethical review committees to conduct ethical review of life science and medical research involving human being, and provide bioethics education and training for researchers, students, scientific research managers and other relevant personnel carrying out life science and medical research involving human being on a regular basis.

第五条 开展涉及人的生命科学和医学研究的二级以上医疗机构和设区的市级以上卫生机构（包括疾病预防控制、妇幼保健、采供血机构等）、高等学校、科研院所等机构是伦理审查工作的管理责任主体，应当设立伦理审查委员会，开展涉及人的生命科学和医学研究伦理审查，定期对从事涉及人的生命科学和医学研究的科研人员、学生、科研管理人员等相关人员进行生命伦理教育和培训。

Article 6 Institutions shall take effective measures and provide resources to ensure the independence of the ethical review committees.

第六条 机构应当采取有效措施、提供资源确保伦理审查委员会工作的独立性。

Article 7 An ethical review committee shall conduct ethical review of life science and medical research involving human being, including initial review and follow-up review; accept and coordinate complaints of research participants to ensure that the research will not make research participants face unreasonable risk; and organize and provide relevant ethical review training, and provide ethical consultation.

第七条 伦理审查委员会对涉及人的生命科学和医学研究进行伦理审查，包括初始审查和跟踪审查；受理研究参与者的投诉并协调处理，确保研究不会将研究参与者置于不合理的风险之中；组织开展相关伦理审查培训，提供伦理咨询。

Article 8 Members of an ethical review committee shall be selected from experts in the fields of life science, medicine, bioethics, law and other fields as well as from social elites. The number of members shall not be less than seven, and there shall be members of different genders. Ethnic minority members shall be considered for regions inhabited by ethnic groups.

第八条 伦理审查委员会的委员应当从生命科学、医学、生命伦理学、法学等领域的专家和非本机构的社会人士中遴选产生，人数不得少于7人，并且应当有不同性别的委员，民族地区应当考虑少数民族委员。

Members of an ethical review committee shall have appropriate capacity for ethical review and receive training on ethical knowledge on life science and medical research as well as relevant laws and regulations on a regular basis.

伦理审查委员会委员应当具备相应的伦理审查能力，定期接受生命科学和医学研究伦理知识及相关法律法规知识培训。

If necessary, an ethical review committee may retain independent consultants to provide professional advice on particular issues under review and research. Independent consultants shall neither participate in voting and nor have conflict of interest.

必要时，伦理审查委员会可以聘请独立顾问，对所审查研究的特定问题提供专业咨询意见。独立顾问不参与表决，不得存在利益冲突。

Article 9 The term of office of a member of an ethical review committee shall not exceed five years and a member may be reappointed. An ethical review committee shall have one chairman and several deputy chairmen, who shall be recommended or elected through consultation by members of the ethical review committee and appointed by the institution.

第九条 伦理审查委员会委员任期不超过5年，可以连任。伦理审查委员会设主任委员1人，副主任委员若干人，由伦理审查委员会委员协商推举或者选举产生，由机构任命。

Article 10 Members of an ethical review committee, independent consultants and their staff members shall enter into confidentiality agreements, pledging to keep confidential the sensitive information known during the ethical review.

第十条 伦理审查委员会委员、独立顾问及其工作人员应当签署保密协议，承诺对伦理审查工作中获知的敏感信息履行保密义务。

Article 11 An ethical review committee shall accept management of the institution and supervision by the research participants.

第十一条 伦理审查委员会应当接受所在机构的管理和研究参与者的监督。

Article 12 An ethical review committee shall establish the working system and standard operating procedures for ethical review, improve the management mechanism for conflict of interest and the quality control mechanism for ethical review, and ensure the independence, objectivity and fairness of the ethical review process.

第十二条 伦理审查委员会应当建立伦理审查工作制度、标准操作规程，健全利益冲突管理机制和伦理审查质量控制机制，保证伦理审查过程独立、客观、公正。

An ethical review committee shall establish an ethical review system in advance for emergencies such as epidemic outbreaks and specify the time limit for review.

伦理审查委员会应预先制定疫情暴发等突发事件紧急情况下的伦理审查制度，明确审查时限。

Article 13 An institution shall undergo the recordation formalities within three months from the date of formation of an ethical review committee, and upload the information to the National Medical Research Registration and Recordation Information System. Medical and health institutions shall undergo the recordation formalities with their practicing registries. Other institutions shall undergo the recordation formalities with competent authorities at higher levels according to their administrative affiliations. An ethical review committee shall submit the work report of the ethical review committee for the previous year to the recordation authority before March 31 of each year.

第十三条 机构应当在伦理审查委员会设立之日起3个月内进行备案，并在国家医学研究登记备案信息系统上传信息。医疗卫生机构向本机构的执业登记机关备案。其他机构按行政隶属关系向上级主管部门备案。伦理审查委员会应当于每年3月31日前向备案机关提交上一年度伦理审查委员会工作报告。

The recordation documents of an ethical review committee shall include:

伦理审查委员会备案材料包括：

(1) the list of members and their resumes;

（一）人员组成名单和委员工作简历；

(2) the bylaws of the ethical review committee;

（二）伦理审查委员会章程；

(3) the working system or relevant working rules; and

（三）工作制度或者相关工作规程；

(4) other relevant materials required by the recordation authority.

（四）备案机关要求提供的其他相关材料。

In the event of any change in the aforesaid information, an institution shall update the information with the recordation authority in a timely manner.

以上信息发生变化时，机构应当及时向备案机关更新信息。

Article 14 If an institution fails to establish an ethical review committee for carrying out life science and medical research involving human being or the ethical review committee is incompetent for the review, the institution may entrust ethical review to a competent ethical review committee of an institution or a regional ethical review committee in writing. The entrusted ethical review committee shall conduct follow-up review of the research reviewed. A medical and health institution shall entrust ethical review to an ethical review committee of a medical and health institution at a level not lower than its level or a regional ethical review committee.

第十四条 机构开展涉及人的生命科学和医学研究未设立伦理审查委员会或者伦理审查委员会无法胜任审查需要的，机构可以书面形式委托有能力的机构伦理审查委员会或者区域伦理审查委员会开展伦理审查。受委托的伦理审查委员会应当对审查的研究进行跟踪审查。医疗卫生机构应当委托不低于其等级的医疗卫生机构的伦理审查委员会或者区域伦理审查委员会开展伦理审查。

The provincial competent health departments shall, in conjunction with the relevant departments, develop measures for the formation and administration of regional ethical review committees. Regional ethical review committees shall undergo recordation formalities with provincial competent health departments and upload the information to the National Medical Research Registration and Recordation Information System.

省级卫生健康主管部门会同有关部门制定区域伦理审查委员会的建设和管理办法。区域伦理审查委员会向省级卫生健康主管部门备案，并在国家医学研究登记备案信息系统上传信息。

Chapter III Ethical Review

第三章 伦理审查

Article 15 Ethical review shall be generally conducted by meeting of the ethical review committee.

第十五条 伦理审查一般采取伦理审查委员会会议审查的方式。

Article 16 An ethical review committee shall require researchers to provide necessary materials for a review, and carry out ethical review and issue review opinions within 30 days after the acceptance.

第十六条 伦理审查委员会应当要求研究者提供审查所需材料，并在受理后30天内开展伦理审查并出具审查意见。

In case of emergency, an ethical review shall be conducted in a timely manner. In the case of an epidemic outbreak and other emergencies, ethical reviews shall be carried out and review opinions shall be issued generally within 72 hours, and the requirements for and quality of the ethical review shall not be reduced.

情况紧急的，应当及时开展伦理审查。在疫情暴发等突发事件紧急情况下，一般在72小时内开展伦理审查、出具审查意见，并不得降低伦理审查的要求和质量。

Article 17 Life science and medical research involving human being shall have scientific and social value without violating relevant laws and regulations of the state, follow internationally recognized ethical norms, without harming public interests, and satisfy the following basic requirements:

第十七条 涉及人的生命科学和医学研究应当具有科学价值和社会价值，不得违反国家相关法律法规，遵循国际公认的伦理准则，不得损害公共利益，并符合以下基本要求：

(1) Risk control. The scientific and social benefits of the research shall not override considerations of personal safety and health rights of research participants. The risk-benefit ratio of a research shall be reasonable to minimize the possible risks of research participants.

（一）控制风险。研究的科学和社会利益不得超越对研究参与者人身安全与健康权益的考虑。研究风险受益比应当合理，使研究参与者可能受到的风险最小化；

(2) Informed consent. The right of research participants or their guardians to know and independently decide to participate in a research shall be respected and protected, the informed consent procedure shall be strictly implemented, deception, inducement, coercion and other methods shall not be allowed to be used to make research participants or their guardians agree with participating in a research, and research participants or their guardians shall be allowed to exit from a research unconditionally at any stage.

（二）知情同意。尊重和保障研究参与者或者研究参与者监护人的知情权和参加研究的自主决定权，严格履行知情同意程序，不允许使用欺骗、利诱、胁迫等手段使研究参与者或者研究参与者监护人同意参加研究，允许研究参与者或者研究参与者监护人在任何阶段无条件退出研究；

(3) Fairness and impartiality. Research participants shall be selected in a fair and reasonable manner, the inclusion and exclusion criteria shall be based on clear scientific evidence, and the benefits, risks and burdens of research shall be distributed in a fair and reasonable manner.

（三）公平公正。应当公平、合理地选择研究参与者，入选与排除标准具有明确的科学依据，公平合理分配研究受益、风险和负担；

(4) Free of charge and compensation. No research-related fees shall be collected from any research participants, and appropriate compensation for reasonable expenses incurred by the research shall be paid to research participants. Research participants shall receive timely and free medical treatment and receive compensation in accordance with laws and regulations and mutual agreements if they suffer research-related damage.

（四）免费和补偿、赔偿。对研究参与者参加研究不得收取任何研究相关的费用，对于研究参与者在研究过程中因参与研究支出的合理费用应当给予适当补偿。研究参与者受到研究相关损害时，应当得到及时、免费的治疗，并依据法律法规及双方约定得到补偿或者赔偿；

(5) Protecting privacy and personal information. The privacy of research participants shall be effectively protected, research participants shall be truthfully notified of the collection, storage, use and confidentiality measures for their personal information and permission shall be obtained, and their personal information shall not be disclosed to any third party without their authorization.

（五）保护隐私权及个人信息。切实保护研究参与者的隐私权，如实将研究参与者个人信息的收集、储存、使用及保密措施情况告知研究参与者并得到许可，未经研究参与者授权不得将研究参与者个人信息向第三方透露；

(6) Special protection. Special protection shall be given to participants in research on specific groups such as children, pregnant and lying-in woman, senior citizens, persons with intellectual disabilities and persons with mental disabilities; and special attention shall be paid to those involving fertilized eggs, embryos, foetuses or those who may be affected by assisted reproductive technology.

（六）特殊保护。对涉及儿童、孕产妇、老年人、智力障碍者、精神障碍者等特定群体的研究参与者，应当予以特别保护；对涉及受精卵、胚胎、胎儿或者可能受辅助生殖技术影响的，应当予以特别关注。

Article 18 Researchers of life science and medical research involving human being shall submit the following materials to the ethical review committee when applying for initial ethical review:

第十八条 涉及人的生命科学和医学研究的研究者在申请初始伦理审查时应当向伦理审查委员会提交下列材料：

(1) The letter of commitment on integrity of research materials.

（一）研究材料诚信承诺书；

(2) The application form for ethical review.

（二）伦理审查申请表；

(3) The information on researchers, the legal qualification certificates of relevant institutions involved in the research institute and the explanations for sources of research funds.

（三）研究人员信息、研究所涉及的相关机构的合法资质证明以及研究经费来源说明；

(4) Research plans and relevant data, including literature review, preclinical studies, animal experiment data and other materials.

（四）研究方案、相关资料，包括文献综述、临床前研究和动物实验数据等资料；

(5) Letter of informed consent.

（五）知情同意书；

(6) Proof of the source of biological samples and information data.

（六）生物样本、信息数据的来源证明；

(7) Scientific argumentation opinions.

（七）科学性论证意见；

(8) Declaration of conflict of interest.

（八）利益冲突申明；

(9) Recruitment advertisements and their forms of issuance.

（九）招募广告及其发布形式；

(10) Explanation for the form of issuance of the research results.

（十）研究成果的发布形式说明；

(11) Other relevant materials required by the ethical review committee.

（十一）伦理审查委员会认为需要提交的其他相关材料。

Article 19 After receiving the application materials, an ethical review committee shall accept and organize the initial review in a timely manner, focusing on the following contents:

第十九条 伦理审查委员会收到申请材料后，应当及时受理、组织初始审查。重点审查以下内容：

(1) Whether the research violates the requirements of laws, regulations, rules and relevant provisions.

（一）研究是否违反法律法规、规章及有关规定的要求；

(2) Whether the qualifications, experience and technical capacity of a researcher satisfy the research requirements.

（二）研究者的资格、经验、技术能力等是否符合研究要求；

(3) Whether the research plan is scientific, has social value and satisfies with the requirements of ethical principles; and traditional practicing experience shall also be considered for the review of traditional Chinese medicine research plans.

（三）研究方案是否科学、具有社会价值，并符合伦理原则的要求；中医药研究方案的审查，还应当考虑其传统实践经验；

(4) Whether the risks that research participants may suffer are within a reasonable range compared with the expected benefits of the research.

（四）研究参与者可能遭受的风险与研究预期的受益相比是否在合理范围之内；

(5) Whether the relevant information provided by the letter of informed consent is sufficient, complete and straightaway, and whether the process of obtaining informed consent is compliant and appropriate.

（五）知情同意书提供的有关信息是否充分、完整、易懂，获得知情同意的过程是否合规、恰当；

(6) Whether the confidentiality measures for research participants' personal information and relevant data are sufficient.

（六）研究参与者个人信息及相关资料的保密措施是否充分；

(7) Whether the recruitment methods, approaches, inclusion and exclusion criteria for research participants are appropriate and fair.

（七）研究参与者招募方式、途径、纳入和排除标准是否恰当、公平；

(8) Whether research participants are clearly notified of their rights and interests, including the right to exit from the research at any time without reason and without being unfairly treated as a result of it, the effects of exit from the research, and other treatment methods.

（八）是否向研究参与者明确告知其应当享有的权益，包括在研究过程中可以随时无理由退出且不会因此受到不公正对待的权利，告知退出研究后的影响、其他治疗方法等；

(9) Whether the reasonable expenses incurred by research participants for participation in the research have been appropriately compensated; and whether the treatment and compensation given to the research participants are reasonable and legal.

（九）研究参与者参加研究的合理支出是否得到了适当补偿；研究参与者参加研究受到损害时，给予的治疗、补偿或者赔偿是否合理、合法；

(10) Whether qualified or trained researchers are responsible for obtaining informed consent and are readily available for consultation on research issues.

（十）是否有具备资格或者经培训后的研究者负责获取知情同意，并随时接受研究有关问题的咨询；

(11) Whether there are prevention and response measures for the risks that research participants may assume in the research.

（十一）对研究参与者在研究中可能承受的风险是否有预防和应对措施；

(12) Whether the research involves conflict of interest.

（十二）研究是否涉及利益冲突；

(13) Whether the research involves socially sensitive ethical issues.

（十三）研究是否涉及社会敏感的伦理问题；

(14) Whether the research results are issued in an appropriate manner and at appropriate time.

（十四）研究结果是否发布，方式、时间是否恰当；

(15) Other key contents to be reviewed.

（十五）需要审查的其他重点内容。

Article 20 Members of an ethical review committee that have conflict of interest with the research shall be disqualified from a review. The ethical review committee shall require members that have conflict of interest with the research to be disqualified from a review.

第二十条 与研究存在利益冲突的伦理审查委员会委员应当回避审查。伦理审查委员会应当要求与研究存在利益冲突的委员回避审查。

Article 21 The basic criteria for an ethical review committee to approve the research are:

第二十一条 伦理审查委员会批准研究的基本标准是：

(1) The research is of scientific and social value, does not violate the provisions of laws and regulations or harm public interests.

（一）研究具有科学价值和社会价值，不违反法律法规的规定，不损害公共利益；

(2) The rights of research participants are respected, and their privacy and personal information are protected.

（二）研究参与者权利得到尊重，隐私权和个人信息得到保护；

(3) The research programs are scientific.

（三）研究方案科学；

(4) The criteria for inclusion and exclusion of research participants are scientific and fair.

（四）研究参与者的纳入和排除的标准科学而公平；

(5) The risk-benefit ratio is reasonable and the risks are minimized.

（五）风险受益比合理，风险最小化；

(6) The informed consent is standard and effective.

（六）知情同意规范、有效；

(7) Research institutions and researchers are competent.

（七）研究机构和研究者能够胜任；

(8) The method, content and time of issuance of research results are reasonable.

（八）研究结果发布方式、内容、时间合理；

(9) Researchers shall comply with scientific research norms and integrity.

（九）研究者遵守科研规范与诚信。

Article 22 An ethical review committee may make decisions on approval, disapproval, approval after modification, re-examination after modification, continuation of research, suspension or termination of research under review, and shall explain the reasons.

第二十二条 伦理审查委员会可以对审查的研究作出批准、不批准、修改后批准、修改后再审、继续研究、暂停或者终止研究的决定，并应当说明理由。

A decision made by an ethical review committee shall be approved by more than half of all members of the ethical review committee. Members shall vote after sufficient discussion on ethical issues involved in the research, and any disagreement with a decision on review shall be recorded in detail.

伦理审查委员会作出决定应当得到超过伦理审查委员会全体委员二分之一同意。委员应当对研究所涉及的伦理问题进行充分讨论后投票，与审查决定不一致的意见应当详细记录在案。

Article 23 When the research plans, the letter of informed consent, the recruitment materials, and other materials provided for research participants need to be modified for a research approved by the ethical review committee, researchers shall submit the modified documents to the ethical review committee for review.

第二十三条 经伦理审查委员会批准的研究需要修改研究方案、知情同意书、招募材料、提供给研究参与者的其他材料时，研究者应当将修改后的文件提交伦理审查委员会审查。

Article 24 Before the implementation of a research approved by the ethical review committee, the researcher, the ethical review committee and the institution shall respectively upload such information as the research, the ethical review opinions and the review opinions of institutions in an authentic, complete and accurate manner according to the requirements of the National Medical Research Registration and Recordation Information System, and upload the information in a timely manner according to the research progress. Researchers, ethical review committees, and institutions shall be encouraged to upload information in real time during the process of research management.

第二十四条 经伦理审查委员会批准的研究在实施前，研究者、伦理审查委员会和机构应当将该研究、伦理审查意见、机构审核意见等信息按国家医学研究登记备案信息系统要求分别如实、完整、准确上传，并根据研究进展及时更新信息。鼓励研究者、伦理审查委员会和机构在研究管理过程中实时上传信息。

The National Health Commission shall continuously optimize the National Medical Research Registration and Recordation Information System.

国家卫生健康委应当不断优化国家医学研究登记备案信息系统。

Article 25 For a research approved to be implemented, a researcher shall, as required, submit various reports on research progress, serious adverse events, deviation of plan, suspension, termination, and completion of research in a timely manner.

第二十五条 对已批准实施的研究，研究者应当按要求及时提交研究进展、严重不良事件，方案偏离、暂停、终止，研究完成等各类报告。

An ethical review committee shall follow up the relevant reports submitted by researchers. The follow-up review shall include the following:

伦理审查委员会应当按照研究者提交的相关报告进行跟踪审查。跟踪审查包括以下内容：

(1) Whether research is carried out in accordance with the approved research plan and reported in a timely manner.

（一）是否按照已批准的研究方案进行研究并及时报告；

(2) Whether the research content is changed without authorization during the research.

（二）研究过程中是否擅自变更研究内容；

(3) Whether the risks of research participants or changes in or new information on the implementation of the research significantly affecting the research are added.

（三）是否增加研究参与者风险或者显著影响研究实施的变化或者新信息；

(4) Whether the research needs to be suspended or terminated in advance.

（四）是否需要暂停或者提前终止研究；

(5) Other contents to be reviewed.

（五）其他需要审查的内容。

The time interval for follow-up review shall not exceed 12 months.

跟踪审查的时间间隔不超过12个月。

Article 26 Unless as otherwise prescribed, researchers shall immediately report the serious adverse events occurred during the research to the ethical review committee; and the ethical review committee shall conduct a timely review to determine whether the measures taken by researchers to protect the personal security and health rights and interests of research participants are sufficient, reassess the risk-benefit ratio of the research and issue review opinions.

第二十六条 除另有规定外，研究者应当将研究过程中发生的严重不良事件立即向伦理审查委员会报告；伦理审查委员会应当及时审查，以确定研究者采取的保护研究参与者的人身安全与健康权益的措施是否充分，并对研究风险受益比进行重新评估，出具审查意见。

Article 27 To conduct research in multiple institutions, a collaborative mechanism for ethical review may be established to ensure that all institutions follow the principles of consistency and timeliness.

第二十七条 在多个机构开展的研究可以建立伦理审查协作机制，确保各机构遵循一致性和及时性原则。

Both the leading and participating institutions shall organize ethical reviews.

牵头机构和参与机构均应当组织伦理审查。

The ethical review committee of a participating institution shall conduct follow-up review of the research in which the institution participates.

参与机构的伦理审查委员会应当对本机构参与的研究进行跟踪审查。

Article 28 If an institution cooperates with an enterprise and other institutions in carrying out life science and medical research involving human being, or provides human biological samples and information data for an enterprise and other institutions to carry out life science and medical research involving human being, the institution shall fully understand the overall situation of the research, pass the ethical review and carry out follow-up review, specify the scope of use and processing of biological samples and information data by agreement, and supervise appropriate disposal of them after completion of the research.

第二十八条 机构与企业等其他机构合作开展涉及人的生命科学和医学研究或者为企业等其他机构开展涉及人的生命科学和医学研究提供人的生物样本、信息数据的，机构应当充分了解研究的整体情况，通过伦理审查、开展跟踪审查，以协议方式明确生物样本、信息数据的使用范围、处理方式，并在研究结束后监督其妥善处置。

Article 29 When publishing research results of life science and medical science involving human being, academic journals shall confirm that the research has been approved by the ethical review committee. Researchers shall provide relevant evidence.

第二十九条 学术期刊在刊发涉及人的生命科学和医学研究成果时，应当确认该研究经过伦理审查委员会的批准。研究者应当提供相关证明。

Article 30 The ethical review work shall be independent. No institution or individual shall interfere with the ethical review process or decision of any ethical review committee.

第三十条 伦理审查工作应当坚持独立性，任何机构和个人不得干预伦理审查委员会的伦理审查过程及审查决定。

Article 31 The following circumstances may be subject to review by summary procedures:

第三十一条 以下情形可以适用简易程序审查的方式：

(1) Research in which the research risk is not greater than the minimum risk.

（一）研究风险不大于最小风险的研究；

(2) Minor modifications to approved research plans that do not affect the risk-benefit ratio of the research.

（二）已批准的研究方案作较小修改且不影响研究风险受益比的研究；

(3) Follow-up review of an approved research.

（三）已批准研究的跟踪审查；

(4) In a multi-institutional research, the ethical review committees of the participating institutions confirm the ethical review opinions issued by the leading institution.

（四）多机构开展的研究中，参与机构的伦理审查委员会对牵头机构出具伦理审查意见的确认等。

For a review by summary procedure, the chairman of the ethical review committee shall designate two or more members to conduct ethical review and issue review opinions. The review opinions shall be reported at the meeting of the ethical review committee.

简易程序审查由伦理审查委员会主任委员指定两个或者以上的委员进行伦理审查，并出具审查意见。审查意见应当在伦理审查委员会会议上报告。

During the process of review by summary procedure, if there are changes in the risk-benefit ratio of the research, disagreement among members of the review committee, or the review committee suggests the need for review at a meeting, it shall be adjusted to review at a meeting.

简易程序审查过程中，出现研究的风险受益比变化、审查委员之间意见不一致、审查委员提出需要会议审查等情形的，应调整为会议审查。

Article 32 Where human information data or biological samples are used to conduct life science and medical research involving human being under the following circumstances, which does not cause harm to human being, does not involve sensitive personal information or commercial interests, ethical review may be exempted to reduce unnecessary burden on researchers and promote life science and medical research involving human being.

第三十二条 使用人的信息数据或者生物样本开展以下情形的涉及人的生命科学和医学研究，不对人体造成伤害、不涉及敏感个人信息或者商业利益的，可以免除伦理审查，以减少科研人员不必要的负担，促进涉及人的生命科学和医学研究开展。

(1) Utilizing lawfully obtained public data or data generated by observation without interfering with public acts to conduct research.

（一）利用合法获得的公开数据，或者通过观察且不干扰公共行为产生的数据进行研究的；

(2) Using anonymized information and data to conduct research.

（二）使用匿名化的信息数据开展研究的；

(3) Activities of conducting research with existing human biological samples whose sources comply with the relevant laws and regulations and follow the ethical principles, activities of conducting research whose contents and purposes fall under the scope of standardized informed consent, and activities that do not involve the use of human germ cells, embryos, reproductive cloning, chimerism, and heritable gene manipulation.

（三）使用已有的人的生物样本开展研究，所使用的生物样本来源符合相关法规和伦理原则，研究相关内容和目的在规范的知情同意范围内，且不涉及使用人的生殖细胞、胚胎和生殖性克隆、嵌合、可遗传的基因操作等活动的；

(4) Conducting research with human cell strains or cell lines from the biobank source, conducting research whose relevant contents and purposes fall under the scope authorized by the provider, and carrying out activities that do not involve human embryos, reproductive cloning, chimerism, and herbable gene manipulation.

（四）使用生物样本库来源的人源细胞株或者细胞系等开展研究，研究相关内容和目的在提供方授权范围内，且不涉及人胚胎和生殖性克隆、嵌合、可遗传的基因操作等活动的。

Chapter IV Informed Consent

第四章　知情同意

Article 33 Before conducting research, researchers shall obtain a letter of informed consent voluntarily signed by research participants. Research participants do not have the ability to give consent in writing, and researchers shall obtain their oral informed consent and provide process records and supporting materials such as audio and video recordings.

第三十三条　研究者开展研究前，应当获得研究参与者自愿签署的知情同意书。研究参与者不具备书面方式表示同意的能力时，研究者应当获得其口头知情同意，并有录音录像等过程记录和证明材料。

Article 34 Research participants that are incompetent or have limited capacity for civil conduct shall obtain written informed consent from their guardians. While obtaining the guardians' consent, researchers shall also notify research participants of the relevant information within the understandable scope and obtain their consent.

第三十四条　研究参与者为无民事行为能力人或者限制民事行为能力人的，应当获得其监护人的书面知情同意。获得监护人同意的同时，研究者还应该在研究参与者可理解的范围内告知相关信息，并征得其同意。

Article 35 A letter of informed consent shall contain sufficient, complete and accurate information, and expressions in language, video image that research participants may understand.

第三十五条　知情同意书应当包含充分、完整、准确的信息，并以研究参与者能够理解的语言文字、视频图像等进行表述。

Article 36 A letter of informed consent shall include the following contents:

第三十六条　知情同意书应当包括以下内容：

(1) Research purpose, basic research content, process, method and time limit for research.	（一）研究目的、基本研究内容、流程、方法及研究时限；
(2) Basic information on researchers and qualifications of the research institution.	（二）研究者基本信息及研究机构资质；
(3) The benefits that the research may bring to the research participants, relevant personnel and society, as well as the discomfort and risks that may be caused to the research participants.	（三）研究可能给研究参与者、相关人员和社会带来的益处，以及可能给研究参与者带来的不适和风险；
(4) Protective measures for research participants.	（四）对研究参与者的保护措施；
(5) The scope and method of using the research data and the personal data of research participants, whether it is shared and reused, and the scope and measures of confidentiality.	（五）研究数据和研究参与者个人资料的使用范围和方式，是否进行共享和二次利用，以及保密范围和措施；
(6) Rights of research participants, including voluntary participation and exit at any time, informed, consent or disagreement, confidentiality, compensation, free treatment and compensation in case of damage, access to new information, re-entering into a new version of letter of informed consent, obtaining a letter of informed consent, etc.	（六）研究参与者的权利，包括自愿参加和随时退出、知情、同意或者不同意、保密、补偿、受损害时获得免费治疗和补偿或者赔偿、新信息的获取、新版本知情同意书的再次签署、获得知情同意书等；
(7) Matters needing attention of research participants before, after and during the research.	（七）研究参与者在参与研究前、研究后和研究过程中的注意事项；
(8) The contact person and contact method of researcher, the contact person of the ethical review committee, and the contact person and contact method when problems occurs.	（八）研究者联系人和联系方式、伦理审查委员会联系人和联系方式、发生问题时的联系人和联系方式；

(9) Duration of the research and the number of research participants.

（九）研究的时间和研究参与者的人数；

(10) Whether the feedback of research results will be sent to the research participants.

（十）研究结果是否会反馈研究参与者；

(11) Notifying research participants of possible alternative treatments and their main benefits and risks.

（十一）告知研究参与者可能的替代治疗及其主要的受益和风险；

(12) Where collection of human biological samples is involved, it shall also include the type, quantity, use, storage and utilization of the biological samples (including whether they are directly used for product development, sharing and secondary utilization), privacy protection, external provision, destruction and other relevant contents.

（十二）涉及人的生物样本采集的，还应当包括生物样本的种类、数量、用途、保藏、利用（包括是否直接用于产品开发、共享和二次利用）、隐私保护、对外提供、销毁处理等相关内容。

Article 37 In the process of obtaining informed consent, researchers shall explain to research participants one by one according to the contents of a letter of informed consent.

第三十七条 在知情同意获取过程中，研究者应当按照知情同意书内容向研究参与者逐项说明。

A researcher shall give research participants sufficient time to understand the contents of the letter of informed consent, and research participants shall decide whether to agree to participate in the research and enter into a letter of informed consent.

研究者应当给予研究参与者充分的时间理解知情同意书的内容，由研究参与者作出是否同意参加研究的决定并签署知情同意书。

In psychological research, if informed consent may affect the research participants' answers to questions and affect the accuracy of the research results, it shall be reviewed and approved by the ethical review committee under the premise of ensuring that research participants are not harmed. The researcher may sufficiently notify research participants and obtain their consent after the completion of the research, otherwise the data shall not be included in the research.

在心理学研究中，因知情同意可能影响研究参与者对问题的回答，而影响研究结果准确性的，在确保研究参与者不受伤害的前提下经伦理审查委员会审查批准，研究者可以在研究完成后充分告知研究参与者并征得其同意，否则不得纳入研究数据。

Article 38 A researcher shall obtain informed consent of research participants again under the following circumstances during the research:

第三十八条 研究过程中发生下列情形时，研究者应当再次获取研究参与者的知情同意：

(1) Substantial changes have been made in the research content related to research participants.

（一）与研究参与者相关的研究内容发生实质性变化的；

(2) Research-risks are substantially increased or added.

（二）与研究相关的风险实质性提高或者增加的；

(3) The level of civil capacity of research participants has been raised.

（三）研究参与者民事行为能力等级提高的。

Chapter V Supervision and Administration

第五章 监督管理

Article 39 The National Health Commission shall, in conjunction with other relevant departments, be responsible for the supervision and administration of the ethical review of life science and medical research involving human being across the country.

第三十九条 国家卫生健康委会同有关部门共同负责全国涉及人的生命科学和医学研究伦理审查的监督管理。

The National Health Commission shall be responsible for the supervision over the ethical review of life science and medical research involving human being carried out by medical and health institutions across the country, and the National Administration of Traditional Chinese Medicine shall be responsible for the supervision over ethical review of traditional Chinese medicine research involving human being. The Ministry of Education shall be responsible for the supervision over ethical review of life science and medical research involving human being carried out by institutions of higher learning across the country and administer related work of institutions of higher learning directly under the Ministry of Education. The supervision and administration of the ethical review of life science and medical research involving human being carried out by other institutions of higher learning and scientific research institutes shall be in the charge of the relevant departments according to the relationship of administrative subordination.

国家卫生健康委负责全国医疗卫生机构开展的涉及人的生命科学和医学研究伦理审查监督，国家中医药局负责涉及人的中医药学研究伦理审查监督。教育部负责全国高等学校开展的涉及人的生命科学和医学研究伦理审查监督，并管理教育部直属高等学校相关工作。其他高等学校和科研院所开展的涉及人的生命科学和医学研究伦理审查的监督管理按行政隶属关系由相关部门负责。

The health, education and other departments of the local people's governments at or above the county level shall, in accordance with the division of functions and responsibilities, be responsible for the supervision and administration of the ethical review of life science and medical research involving human being within their jurisdiction.

县级以上地方人民政府卫生健康、教育等部门依据职责分工负责本辖区涉及人的生命科学和医学研究伦理审查的监督管理。

Supervision and inspection of the following contents shall be mainly conducted:

主要监督检查以下内容：

(1) Whether the institution has established an ethical review committee and undergone recordation formalities as required.

（一）机构是否按照要求设立伦理审查委员会，并进行备案；

(2) Whether the institution provides sufficient funds for the ethical review committee, whether it has full-time and part-time staff members, equipment, and premises, and whether the relevant measures adopted may ensure that the ethical review committee can carry out work independently.

（二）机构是否为伦理审查委员会提供充足经费，配备的专兼职工作人员、设备、场所及采取的有关措施是否可以保证伦理审查委员会独立开展工作；

(3) Whether the ethical review committee has established and improved the management mechanism for conflict of interest.

（三）伦理审查委员会是否建立健全利益冲突管理机制；

(4) Whether the ethical review committee has established an ethical review system.

（四）伦理审查委员会是否建立伦理审查制度；

(5) Whether the contents and procedures of ethical review satisfy the requirements.

（五）伦理审查内容和程序是否符合要求；

(6) Whether the information on the research reviewed is uploaded and updated in the National Medical Research Registration and Recordation Information System in a timely manner.

（六）审查的研究是否如实、及时在国家医学研究登记备案信息系统上传、更新信息；

(7) The implementation of the results of ethical review.

（七）伦理审查结果执行情况；

(8) The information on the management of ethical review documents.

（八）伦理审查文档管理情况；

(9) The ethical training and learning of the members of the ethical review committee.

（九）伦理审查委员会委员的伦理培训、学习情况；

(10) Other relevant contents requiring supervision and inspection.

（十）其他需要监督检查的相关内容。

The competent health departments at all levels shall establish an effective mechanism with the relevant government departments at the same level to strengthen work consultation and information communication.

各级卫生健康主管部门应当与同级政府各相关部门建立有效机制，加强工作会商与信息沟通。

Article 40 The national and provincial competent health departments shall take the lead in setting up medical ethics expert committees at the same level or entrust the work of medical ethics expert committees at the same level to relevant institutions, provide technical support for health, education and other departments to carry out ethical review, supervision and administration, train members of ethical review committees within their jurisdictions on a regular basis, and assist health, education and other departments at the same level in carrying out supervision and inspection.

第四十条 国家和省级卫生健康主管部门应当牵头设立同级医学伦理专家委员会或者委托相关机构承担同级医学伦理专家委员会工作，为卫生健康、教育等部门开展伦理审查及其监督管理提供技术支持，定期对辖区内的伦理审查委员会委员进行培训，协助同级卫生健康、教育等主管部门开展监督检查。

Article 41 An institution shall strengthen the routine management of the ethical review work of life science and medical research involving human being carried out by the ethical review committee set up by the institution, evaluate the work quality and review efficiency of the ethical review committee on a regular basis, put forward opinions or suggestions for improvement of the problems found, and adjust the ethical review committee or its members according to the needs.

第四十一条 机构应当加强对本机构设立的伦理审查委员会开展的涉及人的生命科学和医学研究伦理审查工作的日常管理，定期评估伦理审查委员会工作质量和审查效率，对发现的问题及时提出改进意见或者建议，根据需要调整伦理审查委员会或者委员等。

Article 42 An institution shall urge its ethical review committee to implement the rectification opinions put forward by the relevant government departments at or above the county level; and if the ethical review committee fails to complete rectification within the prescribed time limit or refuses to conduct rectification, and the violation is serious or causes serious consequences, the institution to which the ethical review committee belongs shall adjust the ethical review committee, revoke the chairmanship of the ethical review committee, and hold the relevant personnel liable.

第四十二条 机构应当督促本机构的伦理审查委员会落实县级以上政府相关部门提出的整改意见；伦理审查委员会未在规定期限内完成整改或者拒绝整改，违规情节严重或者造成严重后果的，其所在机构应当调整伦理审查委员会、撤销伦理审查委员会主任委员资格，追究相关人员责任。

Article 43 Any entity or individual shall have the right to tip off violations of medical research ethics, violations of laws and regulations or misconduct in life science and medical research involving human being.

第四十三条 任何单位或者个人均有权举报涉及人的生命科学和医学研究中存在的违反医学研究伦理、违法违规或者不端行为。

Article 44 Where a medical and health institution fails to set up an ethical review committee or entrust review to an ethical review committee according to the provisions, and conducts life science and medical research involving human being without authorization, the local competent health department at or above the county level shall impose administrative penalties and sanctions upon the relevant institution and personnel according to the law.

第四十四条 医疗卫生机构未按照规定设立伦理审查委员会或者未委托伦理审查委员会审查，擅自开展涉及人的生命科学和医学研究的，由县级以上地方卫生健康主管部门对有关机构和人员依法给予行政处罚和处分。

Other institutions shall be handled by the competent departments at higher levels according to their administrative affiliations.

其他机构按照行政隶属关系，由其上级主管部门处理。

Article 45 If a medical and health institution and its ethical review committee violate the provisions of these Measures and fall under any of the following circumstances, the local competent health department at or above the county level shall impose administrative punishment and sanction upon the relevant institution and personnel according to the law:

第四十五条 医疗卫生机构及其伦理审查委员会违反本办法规定，有下列情形之一的，由县级以上地方卫生健康主管部门对有关机构和人员依法给予行政处罚和处分：

(1) The composition of the ethical review committee and the qualifications of its members do not satisfy the requirements.

（一）伦理审查委员会组成、委员资质不符合要求的；

(2) The ethical review committee has not established a management mechanism for conflict of interest.

（二）伦理审查委员会未建立利益冲突管理机制的；

(3) Failing to establish a working system or develop operating rules for ethical review.

（三）未建立伦理审查工作制度或者操作规程的；

(4) Failing to conduct review under the principles of ethical review and according to the relevant rules and regulations.

（四）未按照伦理审查原则和相关规章制度进行审查的；

(5) Disclosing research information or personal information of research participants.

（五）泄露研究信息、研究参与者个人信息的；

(6) Failing to undergo recordation formalities and upload information to the National Medical Research Registration and Recordation Information System in accordance with the relevant provisions.

（六）未按照规定进行备案、在国家医学研究登记备案信息系统上传信息的；

(7) Failing to accept formal entrustment to issue ethical review opinions for other institutions.

（七）未接受正式委托为其他机构出具伦理审查意见的；

(8) Failing to urge researchers to submit relevant reports and carry out follow-up review.

（八）未督促研究者提交相关报告并开展跟踪审查的；

(9) Other circumstances that violate the provisions of these Measures.

（九）其他违反本办法规定的情形。

Other institutions shall be handled by the competent departments at higher levels according to their administrative affiliations.

其他机构按照行政隶属关系，由其上级主管部门处理。

Article 46 If researchers of a medical and health institution violate the provisions of these Measures and fall under any of the following circumstances, the local competent health department at or above the county level shall impose administrative punishment and sanction upon the relevant institution and personnel according to the law:

第四十六条 医疗卫生机构的研究者违反本办法规定，有下列情形之一的，由县级以上地方卫生健康主管部门对有关机构和人员依法给予行政处罚和处分：

(1) Carrying out research work without authorization before the research or research plan is reviewed and approved by the ethical review committee.

（一）研究或者研究方案未获得伦理审查委员会审查批准擅自开展研究工作的；

(2) Failing to report serious adverse reactions or serious adverse events occurred during the research to the ethical review committee in a timely manner.

（二）研究过程中发生严重不良反应或者严重不良事件未及时报告伦理审查委员会的；

(3) Conducting research in violation of relevant provisions on informed consent.

（三）违反知情同意相关规定开展研究的；

(4) Failing to submit relevant research reports in a timely manner.

（四）未及时提交相关研究报告的；

(5) Failing to upload information in a timely manner to the National Medical Research Registration and Recordation Information System.

（五）未及时在国家医学研究登记备案信息系统上传信息的；

(6) Other circumstances that violate the provisions of these Measures.

（六）其他违反本办法规定的情形。

Other institutions shall be handled by the competent departments at higher levels according to their administrative affiliations.

其他机构按照行政隶属关系，由其上级主管部门处理。

Article 47 An institution, ethical review committee or researcher that violates the requirements of the laws and regulations in carrying out life science and medical research involving human being shall be handled according to the relevant laws and regulations.

第四十七条 机构、伦理审查委员会、研究者在开展涉及人的生命科学和医学研究工作中，违反法律法规要求的，按照相关法律法规进行处理。

Article 48 Administrative actions taken by the relevant administrative departments of the people's governments at or above the county level against institutions and individuals that violate these Measures shall be disclosed to the public. Institutions and individuals that seriously violate the provisions of these Measures shall be recorded in the database of serious dishonesty in scientific research, be incorporated into the credit information system in accordance with the relevant rules of the state, and be jointly punished according to the law and regulations.

第四十八条 县级以上人民政府有关行政部门对违反本办法的机构和个人作出的行政处理，应当向社会公开。机构和个人严重违反本办法规定的，记入科研诚信严重失信行为数据库，按照国家有关规定纳入信用信息系统，依法依规实施联合惩戒。

Article 49 Any organization or individual that violates the provisions of these Measures and causes damage to the person or property of others shall assume civil liability according to the law; and where a crime is constituted, the violator shall be held criminally liable according to the law.

第四十九条 机构和个人违反本办法规定，给他人人身、财产造成损害的，应当依法承担民事责任；构成犯罪的，依法追究刑事责任。

Chapter VI Supplementary Provisions

第六章 附 则

Article 50 For the purposes of these Measures, “research participants” include subjects for human research and individuals who provide personal biological samples, information data, health records and behaviors for life science and medical research involving human being.

第五十条 本办法所称研究参与者包括人体研究的受试者，以及提供个人生物样本、信息数据、健康记录、行为等用于涉及人的生命科学和医学研究的个体。

Article 51 For the purposes of these Measures, “human being or human biological sample” includes human body itself, human cells, tissues, organs, body fluids, flora, fertilized eggs, embryos and fetuses.

第五十一条 本办法所称人或者人的生物样本包括人体本身以及人的细胞、组织、器官、体液、菌群等和受精卵、胚胎、胎儿。

Article 52 If state secrets are involved, they shall be declassified when submitting ethical review and obtaining the informed consent of research participants. If it is impossible to conduct declassification, a confidentiality agreement shall be entered into and administration shall be strengthened. A research that has not been declassified shall not be uploaded to the National Medical Research Registration and Recordation Information System.

第五十二条 涉及国家秘密的，在提交伦理审查和获取研究参与者知情同意时应当进行脱密处理。无法进行脱密处理的，应当签署保密协议并加强管理。未经脱密处理的研究不得在国家医学研究登记备案信息系统上传。

Article 53 The ethical review of life science and medical research involving human being included in the list of high-risk scientific and technological activities of science and technology ethics shall also satisfy the relevant requirements of the state for ethical review of high-risk scientific and technological activities of science and technology ethics.

第五十三条 纳入科技伦理高风险科技活动清单的涉及人的生命科学和医学研究的伦理审查，还应当遵守国家关于科技伦理高风险科技活动伦理审查的相关要求。

Article 54 These Measures shall come into force on the date of issuance. If, before these Measures come into forc e, an institution carrying out life science and medical rese arch involving human being have set up an ethical review committee, the recordation formalities shall be undergone within six months from the date when these Measures com e into force, and the information shall be uploaded to the National Medical Research Registration and Recordation In formation System. For life science and medical research in volving human being that has been subject to approval up on ethical review, the information shall be uploaded to the National Medical Research Registration and Recordation In formation System within nine months from the date when these Measures come into force. No information shall be a ccepted upon expiration.

第五十四条 本办法自发布之日起施行。本办法施行前，从事涉及人的生命科学和医学研究的机构已设立伦理审查委员会的，应当自本办法施行之日起6个月内按规定备案，并在国家医学研究登记备案信息系统上传信息。已经伦理审查批准开展的涉及人的生命科学和医学研究，应当自本办法实施之日起9个月内在国家医学研究登记备案信息系统完成上传信息。逾期不再受理。