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人类遗传资源管理暂行办法(中英文)

HEALTH.SOHU.COM 2004年7月1日 17:06

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人类遗传资源管理暂行办法 (中英文)

国务院办公厅文件 国办发[1998]36号

国务院办公厅转发科学技术部卫生部



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搜



《人类遗传资源管理暂行办法》的通知

各省、自治区、直辖市人民政府，国务院各部位、各直属机构：

科学技术部、卫生部《人类遗传资源管理暂行办法》已经国务院同意，现转发给你们，请认真贯彻执行。

一九九八年六月十日

人类遗传资源管理暂行办法

(科学技术部 卫生部)

第一章 总 则

第一条 为了有效保护和合理利用我国的人类遗传资源，加强人类基因的研究与开发，促进平等互利的国际合作和交流，制定本办法。

第二条 本办法所称人类遗传资源是指含有人体基因组、基因及其产物的器官、组织、细胞、血液、制备物、重组脱氧核糖核酸（DNA）构建体等遗传材料及相关的信息资料。

第三条 凡从事涉及我国人类遗传资源的采集、收集、研究、开发、买卖、出口、出境等活动，必须遵守本办法。

第四条 国家对重要遗传家系和特定地区遗传资源实行申报制度，发现和持有重要遗传家系和特定地区遗传资源的单位或个人，应及时向有关部门报告。未经许可，任何单位和个人不得擅自采集、收集、买卖、出口、出境或以其他方式对外提供。

第五条 人类遗传资源及有关信息、资料，属于国家科学技术秘密的，必须遵守《科学技术保密规定》。

第二章 管理机构

第六条 国家对人类遗传资源实行分级管理，统一审批制度。

第七条 国务院科学技术行政主管部门和卫生行政主管部门共同负责管理全国人类遗传资源，联合成立中国人类遗传资源管理办公室，负责日常工作。

第八条 中国人类遗传资源管理办公室暂设在国务院科学技术行政主管部门。在国务院科学技术和卫生行政主管部门领导下，中国人类遗传资源管理办公室行使以下职责：

- (一) 起草有关的实施细则和文件，经批准后发布施行，协调和监督本办法的实施；
- (二) 负责重要遗传家系和特定地区遗传资源的登记和管理；
- (三) 组织审核涉及人类遗传资源的国际合作项目；
- (四) 受理人类遗传资源出口、出境的申请，办理出口、出境证明；
- (五) 与人类遗传资源管理有关的其他工作。

第九条 中国人类遗传资源管理办公室聘请有关专家组成专家组，参与拟订研究规划，协助审核国际合作项目，进行有关的技术评估和提供技术咨询。

第十条 各省、自治区、直辖市科学技术行政主管部门和卫生行政主管部门（以下简称地方主管部门）负责本地区的人类遗传资源管理工作。

国务院有关部门负责本部门的人类遗传资源管理工作。

第三章 申报与审批

第十一条 凡涉及我国人类遗传资源的国际合作项目，须由中方合作单位办理报批手续。中央所属单位按隶属关系报国务院有关部门，地方所属单位及无上级主管部门或隶属关系的单位报该单位所在地的地方主管部门，审查同意后，向中国人类遗传资源管理办公室提出申请，经审核批准后方可正式签约。

国务院有关部门和地方主管部门在审查国际合作项目申请时，应当征询人类遗传资源采集地的地方主管部门的意见。

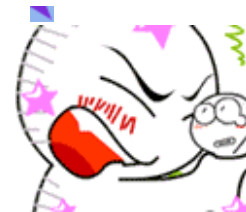
本办法施行前已进行但尚未完成的国际合作项目须按规定补办报批手续。

第十二条 办理涉及我国人类遗传资源的国际合作项目的报批手续，须填写申请书，并附以下材料：

- (一) 人类遗传资源材料提供者及其亲属的知情同意证明材料；
- (二) 合同文本草案；
- (三) 审批机关要求的其他材料。

第十三条 依本办法第十二条提出的申请，有下列情况之一的，不予批准：

GoodFeel铃声：



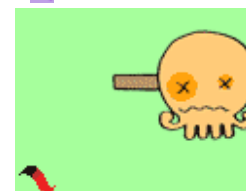
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- (一) 缺乏明确的工作目的和方向;
- (二) 外方合作单位无较强的研究开发实力和优势;
- (三) 中方合作单位不具备合作研究的基础和条件;
- (四) 知识产权归属和分享的安排不合理、不明确;
- (五) 工作范围过宽, 合作期限过长;
- (六) 无人类遗传资源材料提供者及其亲属的知情同意证明材料;
- (七) 违反我国有关法律、法规的规定。

第十四条 重要人类遗传资源严格控制出口、出境和对外提供。

已审核批准的国际合作项目中, 列出人类遗传资源材料出口、出境计划的, 需填写申报表, 直接由中国人类遗传资源管理办公室办理出口、出境证明。

因其他特殊情况, 确需临时对外提供人类遗传资源材料的, 须填写申报表, 经地方主管部门或国务院有关部门审查同意后, 报中国人类遗传资源管理办公室, 经批准后核发出口、出境证明。

第十五条 中国人类遗传资源管理办公室对国际合作项目和人类遗传材料的出口、出境申请每季度审理一次。对于符合本办法要求的, 核发批准文件, 办理出口、出境证明, 并注明《商品名称及编码协调制度》中相对应的编码; 不符和本办法要求的, 不予批准; 对于申请文件不完备的, 退回补正, 补正后可重新申请。

第十六条 携带、邮寄、运输人类遗传资源出口、出境时, 应如实向海关申报, 海关凭中国人类遗传资源管理办公室核发的出口、出境证明予以放行。

第四章 知识产权

第十七条 我国境内的人类遗传资源信息, 包括重要遗传家系和特定地区遗传资源及其数据、资料、样本等, 我国研究开发机构享有专属持有权, 未经许可, 不得向其他单位转让。获得上述信息的外方合作单位和个人未经许可不得公开、发表、申请专利或以其他方式向他人披露。

第十八条 有关人类遗传资源的国际合作项目应当遵循平等互利、诚实信用、共同参与、共享成果的原则, 明确各方应享有的权利和承担的义务, 充分、有效地保护知识产权。

第十九条 中外机构就我国人类遗传资源进行合作研究开发, 其知识产权按下列原则处理:

(一) 合作研究开发成果属于专利保护范围的, 应由双方共同申请专利, 专利权归双方共有。双方可根据协议共同实施或分别在本国境内实施该项专利, 但向第三方转让或者许可第三方实施, 必须经过双方同意, 所获利益按双方贡献大小分享。

(二) 合作研究开发产生的其他科技成果, 其使用权、转让权和利益分享办法由双方通过合作协议约定。协议没有约定的, 双方都有使用的权利, 但向第三方转让须经双方同意, 所获利益按双方贡献大小分享。

第五章 奖励与处罚

第二十条 对于发现和报告重要遗传家系和资源信息的单位或个人，给予表彰和奖励；对于揭发违法行为的，给予奖励和保护。

第二十一条 我国单位和个人违反本办法的规定，未经批准，私自携带、邮寄、运输人类遗传资源材料出口、出境的，由海关没收其携带、邮寄、运输的人类遗传资源材料，视情节轻重，给予行政处罚直至移送司法机关处理；未经批准擅自向外方机构或个人提供人类遗传资源材料的，没收所提供的人类遗传资源材料并处以罚款；情节严重的，给予行政处罚直至追究法律责任。

第二十二条 国（境）外单位和个人违反本办法的规定，未经批准，私自采集、收集、买卖我国人类遗传资源材料的，没收其所持有的人类遗传资源材料，并处以罚款；情节严重的，依照我国有关法律追究其法律责任。私自携带、邮寄、运输我国给人类遗传资源材料出口、出境的，由海关没收其携带、邮寄、运输的人类遗传资源材料，视情节轻重，给予处罚或移送司法机关处理。

第二十三条 管理部门的工作人员和参与审核的专家负有为申报者保守技术秘密的责任。玩忽职守、徇私舞弊，造成技术秘密泄露或人类遗传资源流失的，视情节给予行政处罚直至追究法律责任。

第六章 附 则

第二十四条 军队系统可根据本办法的规定，制定本系统的实施细则，报中国人类遗传资源管理办公室备案。武警部队按照本办法的规定执行。

第二十五条 本办法由国务院科学技术行政主管部门、卫生行政主管部门负责解释。

第二十六条 本办法自发布之日起施行。

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Interim Measures for the Administration of Human Genetic Resources

Promulgated by the General Office of the State Council upon the approval of the State Council on June 10, 1998

The Ministry of Science and Technology

And

The Ministry of Public Health

The People' s Republic of China

Chapter One: General Provisions

Article 1 The interim Measures for the Administration of Human Genetic resources (hereinafter referred to as the Measures) are enacted for the purpose of efficiently protecting and rationally utilizing human genetic resources in the People' s Republic of China, strengthening the research and development of human genes and promoting international cooperation and exchange on the basis of equality and mutual benefits.

Article 2 The term "human genetic resources" in the Measures refers to the genetic materials such as human organs, tissues, cells, blood specimens, preparations of any

types or recombinant DNA constructs, which contain human genome, genes or gene products as well as to the information related to such genetic materials.

Article 3 Whoever involved in such activities in China as sampling, collecting, researching, developing, trading or exporting human genetic resources or taking such resources outside the territory of the People' s Republic of China shall abide by the Measures.

Article 4 The State adopts a reporting and registration system on important pedigrees and genetic resources in specified regions. Any institution or individual who discovers or holds important pedigrees and genetic resources in the specified regions shall immediately report to the relevant departments. No institution or individual may sample, collect, trade, export human genetic resources or take them outside the territory of the People' s Republic of China, or provide them to other countries in any form without permission.

Article 5 Where the human genetic resources and the relevant information or data are classified as State scientific or technological secrets, the Rules for the Protection of State Secrets in Science and Technology shall be observed.

Chapter Two: Administration

Article 6 The State adopts a unified review-and-approval system regulated at different levels over human genetic resources.

Article 7 The administrative department of science and technology and the administrative department of public health under the State Council shall be jointly in charge of the administration of human genetic resources of China in a national scale and shall jointly establish the Human Genetic Resources Administration of China (hereinafter referred to as the HGRAC) to carry out routine duties.

Article 8 The HGRAC is initially placed under the administrative department of science and technology under the State Council. Under the direction of the administrative department of science and technology and the administrative department of public health under the State Council, the HGRAC shall perform the following responsibilities.

1) To draft the relevant rules and implementary documents, promulgate such rules for entering into force upon approval and ensure the enforcement of the Measures through co-ordination and supervision;

2) To be in charge of the registration and administration of the important pedigrees and genetic resources in the specified regions;

3) To review and examine international collaborative projects involving human genetic resources in China;

4) To review and approve applications for exportation of human genetic resources, and thereafter to issue Export Permit for Human Genetic Materials (hereinafter referred to as the Export Permit and

5) Other duties related to the administration of human genetic resources in China.

Article 9 An expert panel shall be formed by the HGRAC to participate in formulating research plans, assist in reviewing and examining international collaborative projects, undertake relevant technical appraisal and provide professional consultation.

Article 10 The administrative department of science and technology and the administrative department of public health at the level of provinces, autonomous regions or municipalities directly under the Central Government (hereinafter referred to as the local administrative departments), shall be in charge of the administration of human genetic resources in their own respective regions.

The relevant departments under the State Council shall be in charge of the administration of human genetic resources within their own administrative domains.

Chapter Three: Application, Examination and Approval

Article 11 Where human genetic resources in China are involved in any international collaborative project, the Chinese collaborating party shall be responsible for going through the due formalities of application for approval. Institutions directly under the Central Government shall apply to the relevant administrative department under the State Council and local institutions or institutions without a specific supervisory department shall apply to the local administrative departments, and upon receiving the approval of the relevant departments, the Chinese collaborating party shall apply to the HGRAC for examination and approval prior to entering into an official contract.

Relevant departments under the State Council and local administrative departments, in reviewing any application for international collaborative projects, shall consult the relevant local administrative departments of the region where human genetic materials are to be collected.

Any international collaborative project which has been carried out but has not been completed prior to the implementation of the Measures shall follow up application for examination and approval as a makeup in accordance with the Measures.

Article 12 An application form shall be filled in and the following documents be included in going through the applying and approving formalities of an international collaborative project involving human genetic resources of China:

- (1) Informed consent form of the donor of the human genetic materials and/or his (her) legal representatives;
- (2) Draft contract; and
- (3) Other documents required by the examining and approving departments.

Article 13 No application submitted in accordance with Article 12 of the Measures shall be approved if any of the following circumstances is involved:

- (1) Where the project lacks a precise objective or purpose;
- (2) Where the foreign partner fails to possess adequate research capability or advantage in the research and development;

(3) Where the Chinese partner fails to possess the required basis and conditions for the collaborative research;

(4) Where the proportioning of ownership and share of intellectual property right is unfair or unclear;

(5) Where the collaboration exceeds the proper scope or time limit;

(6) Where informed consent forms of the donor of the human genetic materials and/or his (her) legal representatives are lacking; or

(7) Where the relevant State laws or rules and regulations are violated.

Article 14 Any export of important human genetic resources outside the territory of the People' s Republic of China or provision of such human genetic resources to foreign institutions or individuals shall be under strict control.

Where, in an international collaborative project which has already been examined and approved, the plan is made for the report of human genetic materials outside the territory of the People' s Republic of China, the application form shall be filled in and the Export Permit issued by the HGRAC.

Where, under special circumstances, temporary provision of human genetic materials to other countries is needed, the application form shall be filled in and submitted to the HGRAC for approval upon the examination and approval of the local administrative departments or the relevant administrative departments under the State Council, and then the Export Permit shall be issued upon the approval of the HGRAC.

Article 15 The HGRAC shall handle the applications for international collaborative projects and export of human genetic materials outside the territory of the People' s Republic of China every quarter. Approval shall be granted if the applications meet the requirements stipulated in the Measures, Export Permit issued and the corresponding code stipulated in the Harmonized Commodity Description and Coding System noted; no approval shall be granted if the applications fail to meet the requirements stipulated in the Measures: and such applications as fail to provide adequate documents shall be returned for revision and re-applying shall be permitted upon revision.

Article 16 All human genetic materials to be exported by means of hand carrying, mailing and transporting should be truthfully declared to the Chinese Customs. The Chinese Customs will give clearance to those accompanied by the Export Permit issued by the HGRAC.

Chapter Four: Intellectual Property Right

Article 17 The Chinese research and development institution shall have the priority to access information about the human genetic resources within the territory of the People' s Republic of China, particularly the important pedigrees and genetic resources in the specified regions and the relevant data, information and specimens and any transfer of such human genetic resources to other institutions shall be prohibited without permission. No foreign collaborating institution or individual that has access to the above mentioned information may publicize, publish, apply for patent right or disclose it by any other means without permission.

Article 18 International collaborative projects involving human genetic resources shall follow the principles of mutual benefits credit and trust joint participation and share of achievements; all rights and obligations of each party should be explicated in order to fully and effectively protect their own respective intellectual property rights.

Article 19 In a collaborative research and development of human genetic resources of China between any Chinese and foreign institutions, intellectual property right therefore shall be disposed according to the following principles:

(1) Patent shall be jointly applied by both parties and the consequent patent right shall be owned by both parties if an achievement resulted from the collaboration is patentable. Either party has the right to implement such patent separately or jointly in its own country in accordance with the contract; however, the transfer of such patent to any third party or the permission of authorizing any third party to implement such patent shall be carried out upon agreement of both parties, and the benefits obtained thereof shall be shared in accordance with their respective contributions; and

(2) The right of utilizing, transferring and sharing any other scientific achievement resulted from the collaboration shall be specified in the collaborative contract or agreement signed by both parties. Both parties are equally entitled to make use of the achievement which is not specified in the contract or agreement; however, the transfer of such achievement to any third party shall be carried out upon agreement of both parties, and the benefits obtained thereof shall be shared in accordance with their respective contributions.

Chapter Five: Rewards and Penalties

Article 20 Any institution or individual that discovers and reports important human genetic resources shall be praised and rewarded: whoever exposes illegal activities shall be rewarded and protected.

Article 21 If any Chinese institution or individual, in violation of the provisions stipulated in the Measures, exports the human genetic materials without authorization by hand carrying, mailing, or transporting, the human genetic materials shall be confiscated by the Chinese Customs and the institution or individual shall be punished ranging from administrative sanctions to prosecution by the judicial department according to the seriousness of the circumstances: if anyone, in violation of the provisions stipulated in the Measures, provides human genetic materials to foreign institutions or individuals without permission, the human genetic materials shall be confiscated and the institution or individual shall be fined, if the circumstances are serious, he shall be investigated for legal responsibility according to the Chinese law. If anyone exports the human genetic resources outside China by hand carrying, mailing, or transporting without authorization, the human genetic materials shall be confiscated by the Chinese Customs and he shall be punished or put under the prosecution of the judicial department according to the seriousness of the circumstances.

Article 23 Any staff member of the administrative department or expert engaging in the examination shall have the duty to keep technological secret for the applicants. Whoever causes the exposure of technological secrets or loss of the human genetic resources of China due to negligence in his duty or malpractice for personal gains shall be imposed with a punishment ranging from administrative sanctions to being investigated for legal responsibility.

Chapter Six: Supplementary Provisions

Article 24 The military forces may formulate their own specific supplementary rules in accordance with the provisions stipulated in the Measures and submit to HGRAC for record. The armed police force shall observe the Measures.

Article 25 The administrative departments of science and technology and the administrative department of public health under the State council shall be responsible for the interpretation of the Measures.

Article 26 The Measures shall enter into effect on the date of promulgation.

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言语传情

短信内容:

细数往日的点滴，有过欢笑泪水和珍贵的记忆。朋友不在于多少，真心才好。在我的生命里没几个真正的知己，惟独有你！

手机

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