Service Guide for Administrative Licensing Matters of International Scientific Research Cooperation on Human Genetic Resources in China

1. Scope of Application:

This license applies to the regulation and management of international scientific research collaboration using my country's human genetic resources between overseas organizations and institutions established or controlled by overseas organizations or individuals (hereinafter referred to as "Foreign Entities") and Chinese research institutions, universities, medical

institutions, and enterprises (hereinafter referred to as "Chinese Entities"). Human genetic resources include all types of cells, whole blood, tissues/tissue sections, semen, cerebrospinal fluid, pleural/peritoneal effusions, blood/bone marrow smears, and hair (with hair follicles). Other non-cellular human secretions, body

fluids, and swabs do not require declaration. Human genetic resource information includes data on genes, genomes, transcriptomes, epigenomes, and nucleic acid biomarkers such as ctDNA, as well as information related to diseases and ethnicity associated with such data. Other data types that do not include genetic information on human genetic

resources do not require declaration. International collaborative activities using my country's human genetic resources for clinical diagnosis and treatment, blood collection and supply services, criminal investigation and prosecution, doping control, and funeral services are subject to relevant laws and administrative regulations and are not within the scope of this license.

2. Information

(1) Item Name: Approval of International Scientific Research Cooperation on Human Genetic Resources

in China. (2) Approval Category: Administrative License.

3. Basis for handling

1. Biosafety Law of the People's Republic of China 2. Regulations of

the People's Republic of China on the Administration of Human Genetic Resources 3.

Implementation Rules of the Regulations on the Administration of Human

Genetic Resources 4. Administrative Licensing Law of the People's Republic of China

IV. Acceptance Agency

National Health Commission

V. Decision-making Body

National Health Commission

6. Quantity Restriction No

quantity restriction

7. Service Conditions

(1) Applicant requirements

Chinese and foreign entities with legal person status.

(2) Approval conditions

1. Applications for international scientific research cooperation using Chinese human genetic resources must meet or comply with the following conditions: (1) There is no threat to public health, national security, or social public interests in my country; harm;

(2) The two parties to the cooperation are a Chinese entity and a foreign entity with legal person status. and have the foundation and ability to carry out relevant work; (3) The purpose and

content of the cooperative research are clear and legal, and the time limit is reasonable; (4) The cooperative research

plan is reasonable; (5) The source of the human genetic

resources to be used is legal, and the type and quantity are consistent with the requirements of the relevant laws and regulations;

The research content is consistent;

(6) Pass the ethical review of the respective countries (regions) of the cooperation parties. If the foreign party is unable to provide the evidence of the ethical review of the country (region) where it is located, it may submit evidence of the foreign party's recognition of the ethical review opinion of the Chinese party;

(7) The ownership of the research results is clear, and there is a reasonable and clear benefit distribution plan. The administrative license for international scientific research cooperation shall be jointly applied for by the Chinese and foreign units. The cooperating parties shall make a commitment to the authenticity, accuracy and completeness of the information in the application materials. If the international scientific research cooperation on human genetic resources to be carried out involves multi-center clinical research, it shall not be split up and then applied for administrative license. For multi-center clinical research, the sponsor or the leader unit may apply for administrative license after the leader unit passes the ethical review. After the sponsor or the leader unit obtains the administrative license, the medical and health institutions participating in the clinical research shall submit the ethics review approval of their own unit or the certification materials of the ethics review approval provided by the leader unit and the letter of commitment issued by their own unit to the National Health Commission, and then they can carry out international cooperative clinical research. 2. Prohibition requirements: Applying to use my country's human genetic resources for international scientific research

Academic research cooperation that does not meet the above conditions will not be approved.

(3) Types of matters to be handled

1. If a newly established foreign entity and a Chinese entity use my country’s human genetic resources to conduct international scientific research cooperation activities, they must apply for administrative approval from the National Health Commission before the activities begin. 2. After obtaining the administrative approval for international scientific research cooperation on human genetic resources,

During the process of international scientific research cooperation, if there is a change in the research purpose or content, or a change in the type, quantity, or use of human genetic resources involved in the research plan, or if there is a change in other major matters such as the sponsor, lead unit, contract research organization, or third-party laboratory, the licensee shall submit an application for change to the National Health Commission.

After obtaining an administrative license for international scientific research cooperation on human genetic resources, if the following circumstances occur, the licensee does not need to submit an application for change, but must submit a written explanation of the change and relevant materials to the National Health Commission:

(1) The research content or research plan remains unchanged, and the total amount does not exceed 10% of the approved amount; (2) There are changes in

participating units other than the sponsor, the group leader, the contract research organization, and the third-party laboratory; (3) There is a change in the name of the

cooperating legal entity; (4) There is a change in the research content or

research plan, but it does not involve changes in the type, quantity, or use of human genetic resources, or the content after the change does not exceed the approved scope. Special Notes:

(1) After the applicant submits the materials for non-major matters, the National Health Commission will conduct a formal review of the application materials to confirm whether they fall within the scope of non-major changes. If they meet the requirements, they will be accepted; if they do not meet the requirements, they will be returned.

(2) The cumulative total amount of non-major changes not exceeding 10% means that the cumulative increase on the basis of the approved total amount does not exceed 10%. For the addition of new types of human genetic resources, it shall be reported as a major change; if the total amount of different types of human genetic resources changes by more than 10%, it shall be reported as a major change.

(3) If the amount of approved human genetic resources is reduced or the unit size of human genetic resources is reduced, no declaration is required. (3) If the amount of change exceeds

10% of the initial approved amount after multiple non-major changes, when declaring the change that exceeds 10% of the initial approved amount, all previous non-major changes should be accumulated and declared as a major change.

3. If the

licensee needs to extend the validity period of the administrative license, he/she shall apply to the National Health Commission thirty working days before the expiration of the validity period of the administrative license. The National Health Commission shall make a decision on whether to grant the extension based on the application of the licensee before the expiration of the validity period of the administrative license; if no decision is made within the time limit, it shall be deemed to be granted the extension. 4. Revocation If any of the following circumstances occurs, the National

Health

Commission shall, based on the request of the interested party,

The administrative license for human genetic resources may be revoked upon request or based on authority:

(1) Abuse of power or dereliction of duty in making a decision to grant an administrative license; (2) Exceeding statutory authority in making a decision to grant an administrative license; (3) Violating statutory procedures in making a decision to grant an administrative license; (4) Approving an applicant who does not have the application qualifications or does not meet statutory requirements;

Granting of administrative license;

(5) Other circumstances under which administrative licenses may be revoked according to law.

If the licensee obtains the administrative license by fraud, bribery or other improper means,

The National Health Commission should be abolished.

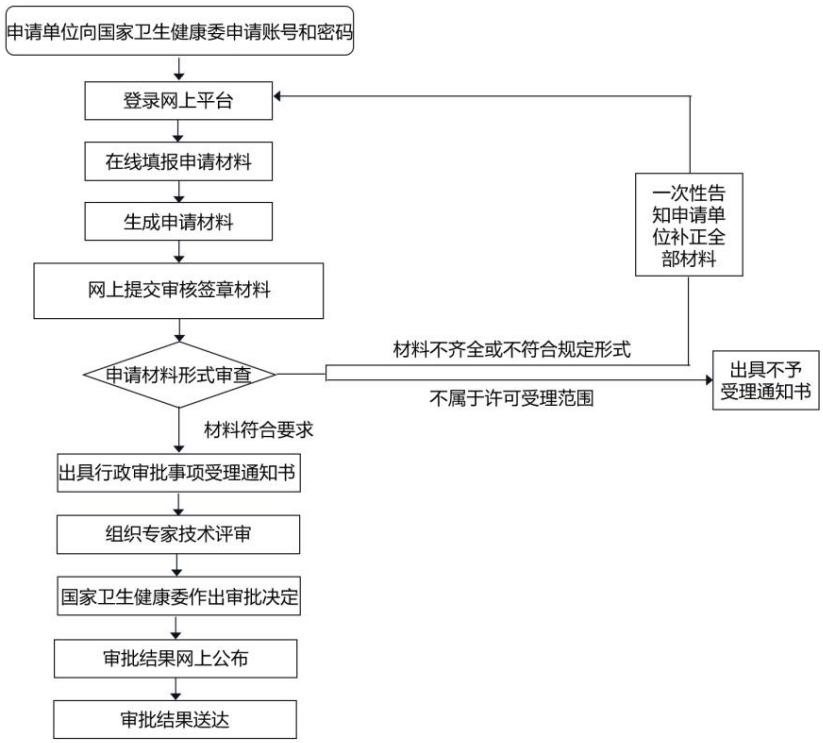
If the revocation of an administrative license in accordance with the provisions of the preceding two paragraphs may cause significant damage to the public interest, it shall not be revoked.

(IV) Report on International Cooperation

The two parties who have obtained the administrative license for international scientific research cooperation shall jointly submit a report on the cooperative research to the National Health Commission within six months after the expiration of the administrative license. The report on the cooperative research shall include the following contents: 1. Changes in the purpose and content of the research; 2. Implementation of the research plan; 3. Completion of the research content; 4. Use and disposal of human genetic resources in my country; 5. All records of the research process and the recording, storage, and use of data information; Usage, etc.

6. Full and substantive participation of Chinese institutions and their researchers in the research and the participation of foreign institutions in the research; 7. The output, ownership and equity distribution of research results; 8. The ethical review of the research.

(V) Application process



Note: If the applicant withdraws the application in writing before the administrative licensing decision is made,

The National Health Commission terminates the review of administrative license applications.

8. Online Application Materials

Serial number	Name of electronic materials submitted	Require
1	application	Fill in the online platform
2	Legal person qualification materials	Legal person qualification materials such as business license or business license of corporate entity Business entity legal person certificate or private non-enterprise entity registration Certificates and other materials Upload as an attachment to your application
3	Study plan	Upload as an attachment to your application
4	Text of informed consent form	Upload as an attachment to your application
5	The countries (regions) where the two parties are located Ethical review approval	The foreign party is unable to provide the local country (region) If the foreign party has the necessary documents for the review and approval of the documents, the foreign party may submit Evidence of approval of the ethical review opinion of the Chinese institution Upload as an attachment to your application
6	International Cooperation Agreement	Please provide the Chinese version of the international cooperation agreement, including

		The sponsor, lead organization, contract research organization, and third-party laboratory must submit a signed and sealed agreement as an attachment to the application.
7	Clinical trial approval, notification or preparation Case registration materials	If relevant, please provide it and upload it as an attachment to the application form.
8	Other supporting documents	If applicable, please provide Upload as an attachment to your application
9	Letter of Commitment (for participating clinical medical and health institutions)	Please participate in the clinical medical and health institutions in the declaration system Upload
10	Ethical review approval (for participating clinical medical and health institutions)	The ethics review document should include review opinions, a list of review materials, a signature and seal page, an ethics committee member sign-in sheet, etc. If the review materials involve version numbers and version dates, please indicate them and upload them in the application system to the participating clinical medical and health institutions.

IX. Application for Acceptance

Electronic application materials are received through an online platform. The platform website is: https://www.hgrg.net/loginÿ

10. Application Methods

This administrative license is handled in accordance with the general procedures, including application, acceptance, technical Review, decision and delivery of documents, etc.

(1) Online application

The applicant's administrator (legal person account) creates a new project and authorizes the applicant (natural person account). The applicant then logs into the system and fills in the project information. After the applicant completes the information and submits it to the administrator for review, the application materials are generated. The applicant then directly downloads and uploads the signed and stamped review opinion, and the administrator then submits the formal application.

(2) Acceptance

If the applicant's application materials are complete and in the required form, the National Health Commission shall accept the application and issue a paper or electronic certificate with a special seal and date. If the application materials are

incomplete or do not comply with the legal form, the National Health Commission shall inform the applicant of all the necessary supplements within five working days of receiving the formal application materials.

(3) Technical review

The National Health Commission entrusts the China Biotechnology Development Center to organize experts to conduct technical reviews of accepted applications and form expert review opinions as a reference for making administrative licensing decisions.

(4) Approval decision

The National Health Commission will make a decision to approve or disapprove based on the review results.

Certainly.

(V) Announcement of Results

The decision to grant administrative license made by the National Health Commission will be

The information will be made public on the website of the National Health Commission.

(6) Service

The National Health Commission will deliver the approval decision letter to the address or email address/ website designated by the applicant by mail or electronic delivery within 10 working days, and will also copy it to the human genetic resources authorities of the provincial, autonomous regional, and municipal people's governments. The applicant can check the delivery status in the application system.

11. Administrative License

China's decision on approval of international scientific research cooperation on human genetic resources.

12. Approval Time Limit

The National Health Commission will make a decision to approve or disapprove within 20 working days of formally accepting an application. If, due to special reasons, the approval decision cannot be made within the prescribed time limit, an extension of 10 working days may be granted with the approval of the head of the National Health Commission. If the National Health Commission makes an

administrative licensing decision that requires a hearing, inspection, testing, quarantine, appraisal, or technical review, the time required will not be counted within this time limit, but the applicant will be notified of the required time in writing.

13. Approval Fees: There is no fee

for this approval matter.

14. Rights and Obligations of Applicants

(1) In accordance with the Administrative Licensing Law of the People's Republic of China, the Regulations of the People's Republic of China on the Administration of Human Genetic Resources and the Implementation Rules of the Regulations on the Administration of Human Genetic Resources, applicants shall enjoy the following rights in accordance with the law: 1. They shall have the

right to make statements and defenses regarding the administrative licenses implemented by administrative agencies; if their legitimate rights and interests are damaged due to the illegal implementation of administrative licenses by administrative agencies, they shall have the right to demand compensation in accordance with the law.

2. If the applicant has any objection to the approval decision, he or she may apply for administrative reconsideration to the National Health Commission within 60 days from the date of receipt of the notice, or may file a lawsuit with the People's Court within 6 months from the date of receipt of the notice.

(2) In accordance with the Administrative Licensing Law of the People's Republic of China, the Regulations of the People's Republic of China on the Administration of Human Genetic Resources and the Implementation Rules of the Regulations on the Administration of Human Genetic Resources, applicants applying for administrative licenses shall truthfully submit relevant materials to the administrative authorities and reflect the actual situation, and shall be responsible for the authenticity of the substantive content of their application materials.

If an applicant engages in fraud or other acts during the administrative application process, the National Health Commission will terminate the review of its application or revoke the approval decision, notify its competent department in writing, and, depending on the circumstances, hold its applicant accountable in accordance with the Administrative Licensing Law of the People's Republic of China, the Administrative Penalty Law of the People's Republic of China, the Regulations of the People's Republic of China on the Administration of Human Genetic Resources, and the Implementation Rules of the Regulations on the Administration of Human Genetic Resources.

15. Consultation Channels

(1) Window consultation: China Biotechnology Development Center (Address: 1st Floor, Building 4, No. 16, West Fourth Ring Road, Haidian District, Beijing, China Biotechnology Development Center);

(2) Email consultation: ycb@cncbd.org.cn; (3) Telephone consultation: 010-88225151/88225168. (4) Consultation hours: Weekdays 8:30-11:30 and 13:30-16:30.

16. Supervision, Complaint and Reporting Channels

(1) Telephone complaints: National Food Safety Risk Assessment Center Discipline Inspection and Supervision Room 010-52165515;

(2) Email complaints: jishenchu@cfsa.net.cn; (3) Letter complaints: Discipline Inspection and Supervision Department of National Food Safety Risk Assessment Center Room 2, Building 2, No. 37 Guangqu Road, Chaoyang District, Beijing, China (Postal Code: 100022).

17. Public Inquiry

After 20 working days from the date of acceptance, you can The query results can be obtained from the National Health Commission's website or the service system.