Scope and Procedures for Filing International Collaborative Clinical Trials Using Human Genetic Resources in China

I. Scope of Filing

In order to obtain marketing authorization for relevant drugs and medical devices in my country, clinical medical... Medical and health institutions that use my country's human genetic resources to conduct international collaborative clinical trials, without involving the export of human genetic resource materials, do not require approval, but must meet one of the following conditions and file with the National Health Commission before conducting the clinical trials: (I) The collection, testing, analysis, and remaining human genetic resources involved.

Processing of genetic resource materials, etc., is carried out within clinical medical and health institutions;

(ii) The human genetic resources involved were collected within clinical medical and health institutions. The testing, analysis, and processing of remaining samples are carried out by domestic units designated in the relevant drug and medical device marketing authorization clinical trial protocols.

The aforementioned clinical medical and health institutions refer to those registered with the relevant departments in my country. Medical institutions and disease prevention and control institutions that conduct clinical trials in accordance with the law.

For the exploratory research portion of clinical trials used to obtain marketing authorization for relevant drugs and medical devices in my country, an administrative license for international scientific research cooperation on human genetic resources must be applied for. Human genetic resource

materials include all types of cells, whole blood, tissue/tissue sections, semen, cerebrospinal fluid, pleural/peritoneal effusion, blood/bone marrow smears, hair (with follicles), etc. Other non-cellular human secretions, body fluids, swabs, etc., do not need to be declared. Human genetic resource information includes genes, genomes, transcriptomes, and epigenomes.

Data and information such as nucleic acid biomarkers like ctDNA, as well as related information such as diseases and ethnicities, are required to be declared. Other data types that do not contain human genetic resources do not need to be declared.

II. Filing Requirements

(a) Applicant Qualifications

Chinese and foreign entities with legal person status.

(II) Filing Content

1. Basic information of all collaborating

parties; 2. Types, quantities, and uses of human genetic resources involved in the research; 3.

Research protocol; 4.

Ethics review approval document from the lead

institution; 5. Other supporting materials.

(III) Precautions

1. The registration of international collaborative clinical trials should be jointly completed by the Chinese and foreign entities. The application is subject to the same conditions. All parties involved in the collaboration should commit to the authenticity, accuracy, and completeness of the information in the

application materials. 2. The proposed international collaboration on human genetic resources involves multi-center clinical research. It is not allowed to split up and then apply for registration.

3. For multi-center clinical studies, the lead institution must pass the ethical review before proceeding. The applicant or the team leader unit may apply for registration.

4. After the sponsor or lead unit completes the registration, the medical and health institutions participating in the clinical research shall submit their own ethics review approval documents or proof of acceptance of the ethics review approval documents provided by the lead unit, as well as a commitment letter issued by their own unit, to the National Health Commission, and then they can carry out international collaborative clinical research.

III. Types of Filing Items

(a) New construction

In order to obtain marketing authorization for relevant drugs and medical devices in my country, clinical medical... Medical and health institutions that use my country's human genetic resources to conduct international collaborative clinical trials, without involving the export of human genetic resource materials, shall file a record with the National Health Commission before conducting the clinical trials.

For applications to register international collaborative clinical trials, prior approval from the drug regulatory authority is required. Clinical trial approval documents, notifications, or registration materials issued by the regulatory authorities.

Once the applicant obtains the registration number, it can begin international collaborative clinical trials.

(ii) Change

After an international collaborative clinical trial has been registered, if there are any changes to the type, quantity, or use of the human genetic resources involved, or any significant changes to the collaborators, research protocol, research content, or research objectives, the registrant shall promptly apply for a registration change. If the changes to the research protocol or research

content do not involve changes to the type, quantity, or use of human genetic resources, a registration change is not required, but a written explanation of the changes and relevant materials shall be submitted to the National Health Commission before the change activity begins.

(III) Continuation

If a registrant needs to extend the validity period of their registration, they should submit an application to the National Health Commission 30 days before the expiration date. The National Health Commission should complete the extension registration before the expiration date; failure to do so within the stipulated time shall be deemed as completion of the extension registration.

(iv) Revocation

Under any of the following circumstances, the National Health Commission may, upon request of an interested party or ex officio, revoke the registration of an international collaborative clinical trial involving human genetic resources:

1. Approving registration by abusing power or neglecting duty; 2. Approving registration beyond the scope of statutory authority; 3. Approving registration in violation of statutory procedures; 4. Approving registration for applicants who do not meet the eligibility requirements or statutory conditions.

5. Other circumstances under which registration may be revoked according to law.

If the registrant obtains registration through deception, bribery, or other improper means, the National Health Commission shall revoke it. If revoking registration in accordance with the preceding two paragraphs may cause significant damage to the public interest, it shall not be revoked.

(v) Report on International Cooperation

Both parties to an international collaborative clinical trial registration should jointly submit a report on the collaborative research to the National Health Commission within six months of the expiration of the registration period. The report should include the following: 1. Changes in research objectives and content; 2. Implementation status of the research protocol; 3. Completion status of the research content; 4. The use and disposal of human genetic resources in my country; 5. All records and data collected and stored during the research process.

Usage and other situations;

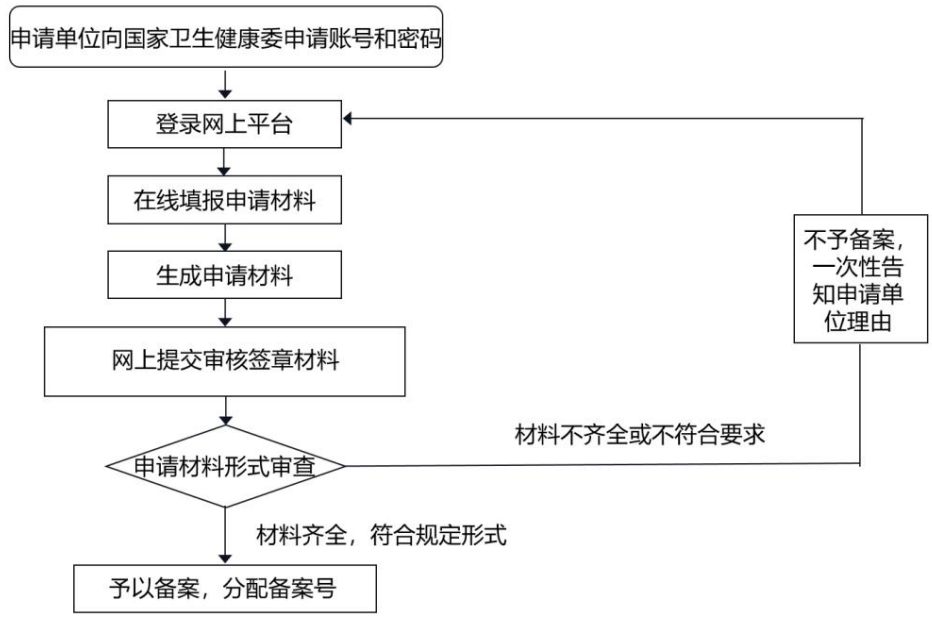
6. The full and substantive participation of Chinese institutions and their researchers in the research process.

And the participation of foreign institutions in the research;

7. The status of research outputs, ownership, and rights distribution;

8. The ethical review process involved in the research.

(vi) Filing process



Note: If the applicant submits a written request to withdraw the filing application, the National Health Commission...

The review of it has been terminated.

IV. Online Filing Materials

Serial Number | Submitted Electronic Material Name		Require
1	Filing Information Form	Fill out on online platform
2	Legal person qualification materials	Documents proving legal person status, such as a business license for an enterprise or institution. Certificate of Legal Person or Registration Certificate of Private Non-Enterprise Unit Materials Upload as an attachment to the filing information form
3	Research Plan	Upload as an attachment to the filing information form
4. Informed Consent Form Text		Upload as an attachment to the filing information form
5. Ethics review approval document from the team leader's unit		If multiple centers are involved, only the ethics review approval from the group leader's unit should be uploaded. Item. The ethics review approval document should include the review opinion and review materials. Material list, signed and stamped page, and attendance record of ethics committee members. Tables and other related information. Review materials should include version numbers and version dates.

		The period should be noted The international cooperation agreement, signed and
6	International Cooperation Agreement	stamped in Chinese, should be uploaded as an attachment to the filing information form.
7	Clinical trial approval documents, notifications, or registration materials	Upload as an attachment to the filing information form
8	Other supporting documents	If applicable, please provide Upload as an attachment to the filing information form
9	Commitment Letter (Participation in Clinical Medical and Health Care) (Life institution)	Please participate in the clinical medical and health institution registration process in the application system. Upload
10	Ethics review approval (for participating clinical medical and health institutions)	The ethics review approval document should include the review comments, a list of reviewed materials, a signed and stamped page, and a sign-in sheet for ethics committee members. If the review materials involve version numbers and version dates, they should be... Please specify that you should upload the information when registering clinical medical and health institutions in the application system.

V. Application Acceptance

Electronic application materials are received through an online platform. The platform's website is:

https://www.hgrg.net/loginÿ

VI. Filing Procedures

This filing process includes application and formal review.

(a) Online application

The administrator of the applying unit (legal entity account) creates a new project and authorizes the applicant.

(Natural person account), the applicant logs into the system and fills in the project information. Applicant

After completing the form and submitting it for review by the unit administrator, the application materials will be generated and you can directly submit it.

Download and upload the signed and stamped review comments, and then the unit administrator will submit the formal application.

please.

(ii) Formal review

Applications with complete and compliant materials will be filed.

Applications that are incomplete or do not meet the relevant requirements will not be registered, and the reasons for the non-registration will be explained.

The National Health Commission will review the applications for registration based on the following circumstances:

Action taken:

1. If there are correctable errors in the application materials, the applicant may return them.

correct;

2. Applications with incomplete materials or that do not conform to legal requirements will not be registered.

The applicant will be informed of the reasons for not being allowed to register in one go.

3. If the application materials are complete and meet the legal requirements, they will be filed and allocated accordingly.

With the case number, the applicant can begin international collaborative clinical trials.

VII. Contact Information

(a) In-person consultation: China National Center for Biotechnology Development (Address: Beijing)

1st Floor, Building 4, No. 16 Courtyard, West Fourth Ring Road, Haidian District, Beijing, China Biotechnology Development Center

Exhibition Center);

(ii) Email inquiries: ycb@cncbd.org.cn;

(iii) Telephone inquiries: 010-88225151/88225168;

(iv) Consultation hours: 8:30-11:30 and 13:30-16:30 on weekdays.

VIII. Channels for Supervision, Complaints and Reports

(a) Telephone complaints: Discipline Inspection and Supervision Department of the National Center for Food Safety Risk Assessment

(i) Telephone: 010-52165515; (ii)

Email complaints: jishenchu@cfsa.net.cn;

(III) Complaints by Letter: Discipline Inspection and Supervision Department of the National Center for Food Safety Risk Assessment

Room (Building 2, No. 37 Guangqu Road, Chaoyang District, Beijing), Postcode 100022.