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Han Kun Newsletter

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Legal Updates

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1. CAC Releases Guidelines for China SCC Filings

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On May 30, 2023, the Cyberspace Administration of China (the "**CAC**") released the *Guidelines for Filing Standard Contract for the Outbound Transfer of Personal Information (First Edition)* (the "**Filing Guidelines**"). The Filing Guidelines provide operational guidance for enterprises planning to transfer personal information from China to overseas recipients by relying on the Standard Contract for the Outbound Transfer of Personal Information (the "**China SCC**" or "**Standard Contract**") safeguard and marks the formal adoption of the Standard Contract for personal information exports.

The Standard Contract has attracted widespread interest due to its broader applicability and flexibility compared to the two other data export compliance safeguards, the CAC data export security assessment ("**CAC Security Assessment**") and personal information protection certification. The previously introduced *Measures for the Standard Contract for Outbound Transfer of Personal Information* (the "**Measures**") only provide principled provisions on the filing and personal information protection impact assessment ("**PIA**") report that needs to be submitted together with the filing. The Filing Guidelines offer clarity on these two steps for the first time.

The Filing Guidelines contain two unexpected developments—submitted filings are subject to review and may be rejected under some circumstances; and the content required in the PIA has not been substantially simplified relative to that for the CAC Security Assessment. Both of these developments have raised concerns among practitioners and relevant enterprises about failing to complete the filing in a timely manner, which increases the uncertainty of adopting the Standard Contract safeguard. The Measures, which came into effect on June 1, stipulate a rectification period of six months which ends on November 30, 2023. Therefore, for enterprises intending to adopt the Standard Contract safeguard, it is advisable to begin preparing the Standard Contract filing materials soon to ensure both timely filing and the continuity of personal information exports.

In *our previous articles*, we analyzed the Measures and the key points of the China SCC. In this article, we analyze the specific requirements outlined in the Filing Guidelines with our experience with CAC Security Assessment to offer our observations and views on issues that have not yet been addressed in the Standard Contract filing process.

Filing requirements

Regarding the filing requirements for Standard Contracts, the Filing Guidelines further specify the following points based on Article 7 of the Measures:

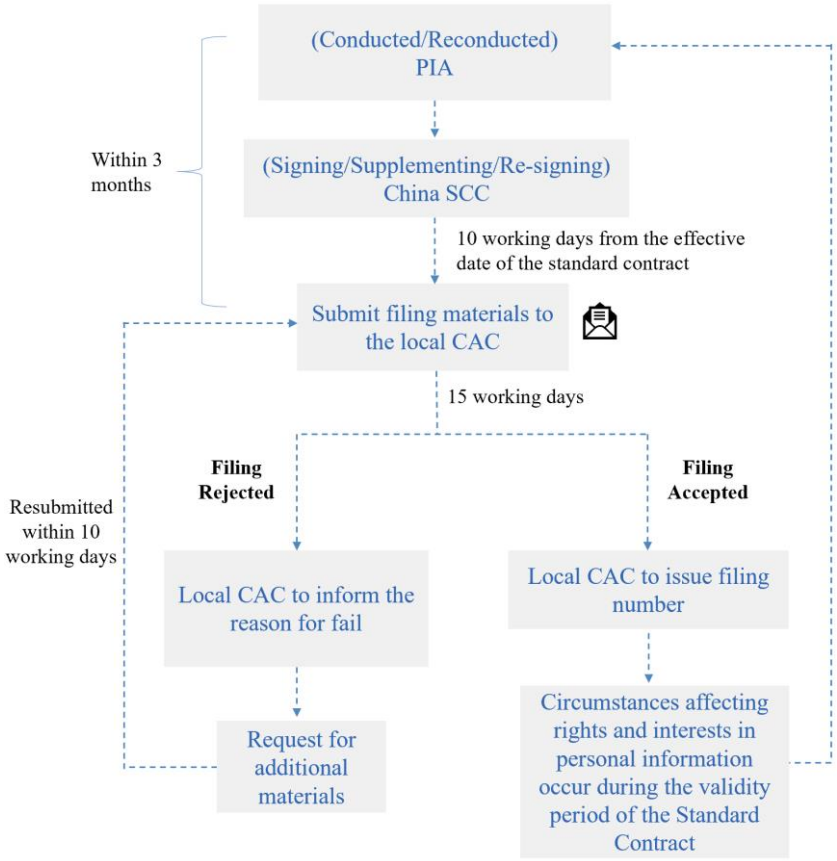
- Filing Time: Within 10 business days from the effective date of the Standard Contract.
- Filing Format: Submit written materials and electronic versions of the materials.
- Filing Authority: Provincial-level Cyberspace Administration ("**local CAC**") where the personal

information handler is located.

Based on current CAC Security Assessment practices, the authority to receive the Standard Contract filing materials is generally the local CAC where the filing applicant is registered. The electronic version of the materials usually refers to editable document files on a compact disc.

Filing process

Regarding the filing process for Standard Contracts, the Filing Guidelines divide the filing process into steps including applicant material submission, CAC material verification, CAC feedback of filing results, and applicant supplementation or re-filing. The key points of this process are presented in the flowchart below.



I. PIA must be completed within three months of filing

The Filing Guidelines contain a template "Letter of Undertaking" which explicitly requires the PIA to have been completed within three months of successfully submitting the filing materials with the local CAC. No significant changes to matters addressed in the PIA should occur before or during the filing process.

Based on current CAC Security Assessment practices, when initially submitting filing materials, filing applicants are usually able to ensure that the PIA has been completed within this three-month period. **However, this three-month period may be exceeded if the filing applicant is required to supplement its filing materials, especially for multiple rounds. In such cases, the filing**

applicant may need to conduct additional PIA work.

II. Time limit for filing review

According to the Filing Guidelines, the local CAC will verify the filing materials within 15 working days of receipt and notify the filing applicant of the result. If the filing applicant is requested to supplement the materials, it should do so within ten working days. Thereafter, the local CAC will have an additional 15 working days to verify the materials.

According to the above provisions, a filing applicant can obtain a filing approval within 15 working days if it is not required to supplement its filing materials. However, if supplementation is required, it may take at least 40 working days to obtain the filing result. Based on current CAC Security Assessment practices, assessment applicants have often been required to supplement their security assessment materials. Given this, filing applicants may need to consider reasonably extending the authorization period of their agents tasked with handling the filing materials.

III. Circumstances for supplementing or re-filing

The Filing Guidelines reaffirm the provisions of the Measures and state that if the following circumstances occur during the validity period of the Standard Contract, the personal information handler should conduct a new PIA, supplement or re-execute the standard contract, and fulfill the corresponding filing procedures:

- There are changes in the purpose, scope, type, sensitivity, method, storage location of personal information transferred to overseas recipients, or in the purposes and methods of personal information processing by the overseas recipients, or an extension of the period for retaining personal information overseas;
- Changes occur in the personal information protection policies and regulations of the country or region where the overseas recipients are located, which may affect the rights and interests of personal information subjects;
- Other circumstances that may affect the rights and interests of personal information subjects.

The Filing Guidelines further specify that if supplementary materials need to be provided, the filing applicant should submit the supplementary materials to the local CAC. If a new standard contract needs to be executed, it should be re-filed. However, there is no clear boundary between circumstances requiring supplementary materials and those requiring the re-filing of a Standard Contract. It is also unclear whether filing applicants have the discretion to make the judgment by themselves. Further clarification may be needed in this regard.

Materials to be submitted for filing

Compared to Article 6 of the Measures, the Filing Guidelines further detail the materials to be submitted for the Standard Contract filing, which include the following.

I. Photocopies of:

- The filing applicant's Unified Social Credit Code certificate;
- The legal representative's government-issued identification;
- The agent's government-issued identification;

II. Documents (templates provided):

- Authorized power of attorney for the agent;
- Letter of undertaking;
- Standard contract;
- PIA report.

We note the following key points with respect to these materials.

1. Simplification of required materials

Compared to the *Guidelines for the Security Assessment of Outbound Data Transfer (First Edition)* issued by the CAC on August 31, 2022, filing the Standard Contract does not require an application form and other related supporting documents. However, since the Filing Guidelines still give the local CAC the discretion to conduct supplementary inspections, it is possible that filing applicants may need to submit such supporting documents in practice.

2. Third-party institutions involved in PIA work required to stamp the PIA report

In the filing material templates provided in the Filing Guidelines, the PIA Report Template explicitly requires third-party institutions involved in preparing the PIA work to provide their basic information and participation in the PIA process. Such institutions should affix their official seals on the relevant pages.

3. PIA report focuses on the impact on personal information rights and interests

The PIA Report Template provided in the Filing Guidelines is similar in content to the Data Export Risk Self-Assessment Report Template provided in the *Guidelines for the Security Assessment of Outbound Data Transfer (First Edition)* issued by the CAC on August 31, 2022. **The core difference lies in the fact that the self-assessment for data exports focuses more on the impact of data exports on national security and public interests, while the PIA focuses on the impact on personal information subject rights and interests**. Specifically, it includes:

- Explanations regarding the processing of sensitive personal information and the use of personal information for automated decision-making;
- Explanations regarding whether personal information is to be transferred to third parties; and
- Explanations regarding how both parties ensure the implementation of Standard Contract clauses.

Considering that the assessment points and granularity of the PIA Report Template are similar to the Data Export Risk Self-Assessment Report Template, and no substantial simplification has been made, we recommend that enterprises that intend to submit filings to conduct comprehensive mapping and review of their data processing activities and to begin arranging for rectification in order to complete the filing by the end of the rectification period, which is November 30, 2023.

Our observations and perspectives

The release of the Filing Guidelines provides guidance and assistance for personal information handlers to carry out Standard Contract filing work in a standardized and orderly manner. However, in light of current CAC Security Assessment practices, the following issues still require clarification from the CAC in the subsequent filing process.

I. Can affiliated entities file jointly?

The Filing Guidelines and the Measures do not specify whether joint filings are permitted, e.g., whether affiliated entities within a group may designate one entity, such as the Chinese holding company, to submit a filing on their behalf. Based on current practices, whether joint filings may be made will likely depend on the specific facts and circumstances, taking into consideration factors such as equity relationships, information system relationships, business relationships, data sharing, and data flows between the entities.

II. What is the relationship between the Standard Contract and IGDTAs?

Multinationals often already have intra-group data transfer agreements ("**IGDTAs**") to facilitate cross-border data transfers within the group. These multinationals usually want to utilize existing IGDTAs as much as possible or include the scenarios of providing personal information from China to overseas recipients into their existing IGTDAs. However, according to the Measures, the Standard Contract must be executed strictly in accordance with its terms. Therefore, an IGDTA cannot replace the China SCC for personal information cross-border transfers from China. As long as the content of the IGTDA and the provisions of the China SCC do not conflict, personal information handlers and overseas recipients can include the IGDTA as an appendix to the China SCC or explicitly specify the scope and effectiveness of the China SCC for personal information cross-border transfers from China by referencing it in the IGDTA.

III. Can entrusted parties sign Standard Contracts?

Unlike the EU Standard Contractual Clauses, the current China SCC template does not provide different terms based on the legal status of the contracting parties, e.g., whether they are personal information handlers or entrusted processors. In this respect, it appears that the eligible contracting parties are limited to a domestic transferor that is a personal information handler (i.e., a "data controller" under GDPR) and an overseas recipient that is either a personal information handler or an entrusted processor (i.e., a "data processor" under GDPR). However, based on our CAC Security Assessment experience, the CAC has not sought to distinguish whether the domestic transferor is a personal information handler or an entrusted party. Moreover, in practice, there are often circumstances where

a domestic entrusted party transfers personal information to an overseas personal information handler (entrusting party) or the domestic entrusted party transfers personal information to an overseas entrusted party. Non-compliant cross-border transfers may result if these parties are not eligible to act as parties to the Standard Contract. Therefore, we believe that a domestic transferor that acts as an entrusted party may still be able to rely on the Standard Contract safeguard when transferring personal information to an overseas recipient.

IV. Is the review of the filing materials a formality or can it be more substantive? Will a rejected filing affect the transfer of personal information to overseas recipients?

The Filing Guidelines state that a submitted filing can result in either a "pass" or a "fail", which suggests that the regulatory authorities may substantively review the filing materials. However, neither the Filing Guidelines nor the Measures specify any form of penalty for filing applicants whose filings are rejected. Furthermore, according to Articles 6 and 7 of the Measures, completion of the filing process is not a prerequisite for the effectiveness of the Standard Contract, and a personal information handler is entitled to transfer personal information overseas upon the effectiveness of the Standard Contract.

While it remains unclear, we take the view that a rejected filing could result in an order to halt personal information export activities or other administrative penalties. This is because a rejected filing may indicate the filing applicant has non-compliance issues with respect to the PIA or its executed Standard Contract does not conform to the requirements of the Measures, either of which may constitute a violation of the *Personal Information Protection Law*.

With the Measures coming into effect on June 1, 2023, the countdown to the close of the six-month rectification period has officially begun. From a CAC Security Assessment perspective, it takes substantial time to carry out PIA work, conduct research and sort out data export information, prepare PIA reports, and negotiate with overseas recipients to sign China SCC. Therefore, enterprises that intend to rely on the Standard Contract safeguard for their personal information exports are recommended to begin undertaking this work soon to ensure the legal compliance of their personal information export activities.

2. Highlights on HGR Regulation Implementation Rules

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On June 1, 2023, China's Ministry of Science and Technology ("**MOST**") officially released the *Implementation Rules for the Regulation of Human Genetic Resources Administration* ("***Implementation Rules***"), which will come into effect on July 1, 2023. Since the release of *the Rules for Implementation of the Regulations on Administration of Human Genetic Resources (Draft for Comments)* in March 2022 by MOST ("*Draft Rules*"; for reference, please refer to *Han Kun • Perspective | Highlights on the Draft HGR Regulations Implementation Rules*), the industry has been eagerly awaiting the finalization of the policies outlined in the *Implementation Rules*. We closely followed the updates and noticed that some changes in the *Implementation Rules* have already been reflected in the regulatory practice. The long-awaited release of the *Implementation Rules* marks a new stage in China's regulation of human genetic resources.

The *Biosecurity Law* enacted in 2020, the *Regulations on the Administration of Human Genetic Resources* released in 2019 ("***HGR Regulations***"), and a series of administrative approval/filing service guidelines and regulations issued by MOST in recent years, including Frequently Asked Questions, together form the current overall regulatory framework for human genetic resources in China. However, until now, higher-level regulations such as the *HGR Regulations* lacked detailed implementation measures to further clarify the regulatory scope. The release of the *Implementation Rules* further refines China's overall framework for human genetic resources administration and provides more detailed compliance guidelines for the industry to carry out activities utilizing these resources.

This article will analyze and summarize the key provisions of the *Implementation Rules* such as administration, definition of human genetic resources information, definition of Foreign Parties, ethical review requirements, collection and biobanking requirements, international cooperation requirements, information provision and security review, supervision and administration, and punishment responsibilities.

Administration refinement

I. Delegation of regulatory authority

According to the *HGR Regulations*, the supervision and administration of human genetic resources in China is jointly carried out by the national competent departments and provincial competent departments in accordance with administrative authority. Meanwhile, the national competent departments are directly responsible for the administrative approval and filing of the collection, biobanking, international cooperation, and provision of human genetic resources to foreign parties. The *Implementation Rules* further explore the delegation and decentralization of China's HGR regulatory authority, which helps to enrich regulatory resources. Article 3 of the *Implementation Rules* stipulates that MOST may delegate relevant organizations to carry out formal review and technical review of HGR applications, as well as the administration of filing, prior reporting, supervision,

[1] Shuwen Sun and Leyi Wang have contributions to this article.

inspection, and administrative penalty of HGR activities. Article 4 clarifies that provincial departments of science and technology, in addition to being responsible for the daily supervision and administration in their respective regions, can also review HGR approvals under the delegation of MOST. It is thus evident that under the *Implementation Rules*, **MOST can delegate its responsibility to review administrative approval to the provincial level and entrust its duties to review filing, supervision, and administration to relevant organizations**. For example, by the end of 2022, the Shanghai Science and Technology Commission, with the support of the National HGR Office, established the Shanghai Human Genetic Resources Administration Service Station, based on the Shanghai Biomedical Technology Development Center. The station primarily conducts HGR business consultations, HGR specialist training, and assists in the pre-, in-, and post-event HGR compliance.

II. Competent regulatory authorities

Notably, the *Implementation Rules* are promulgated by MOST, which is consistent with the long-standing practice of MOST supervising the utilization of human genetic resources in China. However, in March, 2023, the Central Committee of the Communist Party of China and the State Council issued the "Plan for the Reform of the Party and State Council," and decided to re-organize MOST and transfer China Biotechnology Development Center, which is responsible for the daily work of Human Genetic Resources Administration concerning biosecurity and biological resource administration, to be under the jurisdiction of the National Health Commission. This change may lead to the alteration of the competent department for the supervision and administration of human genetic resources in China. However, consistent with the current *Biosecurity Law* and *HGR Regulations*, Articles 3 and 4 of the *Implementation Rules* clearly stipulate that **the supervision of HGR is still the responsibility of MOST**. We understand that the institutional reform plan is still in the implementation phase, and the upper-level regulatory laws and competent departments for human genetic resources may still change in the future. However, given that the administrative approval and filing requirements for the collection, biobanking, international cooperation, and provision of human genetic resources to foreign parties are stipulated in the *Biosecurity Law*, the regulation framework of China's human genetic resources will not undergo fundamental changes unless the National People's Congress amends the law.

Definition of human genetic resources information

According to Article 2 of the *HGR Regulations*, human genetic resources information refers to data and other information materials generated from the use of human genetic resources materials. However, such criterion is relatively broad and brings uncertainties in practice.

In Article 2 of the *Implementation Rules*, human genetic resources information refers to data and other information such as human genes and genome data generated from the use of human genetic resources materials, **excluding clinical data, imaging data, protein data, and metabolic data.** This further clarifies the regulatory scope of human genetic resources information in China. The *Implementation Rules* specify that imaging data such as B-ultrasound and CT are not included in the human genetic resources information, which is consistent with the interpretations in the Q&A released by MOST in March and April 2022. However, it is worth noting that, according to our previous understanding, the regulatory authorities once considered adding "**biomarker**" data to the definition of human genetic resources

information, but this was not included in the finalized *Implementation Rules*. We understand that biomarkers are not explicitly excluded from the scope of human genetic resources information by authorities, and the regulatory requirements still apply when the biomarker data contains human gene and genome data information. In addition, it remains uncertain whether the data analysis conclusions and other information generated from the research using human genetic resources fall under the scope of human genetic resources information. We understand that, based on the definition of the *Implementation Rules*, the analysis conclusions and other information materials, in the absence of gene and genome data information, will not be subject to human genetic resources regulatory requirements.

Clear definitions of human genetic resources are the prerequisites for the regulation applications. Only when the regulatory rules properly define human genetic resources can industry practitioners more accurately fulfill their compliance obligations. It can be seen that the current *Implementation Rules* have returned to the essence of regulating human genetic resources and have reasonably defined the regulatory scope of human genetic information, which is in line with MOST's HGR regulatory principle of "stringent regulation where necessary and reasonable flexibility where appropriate".

Scope of foreign parties

Pursuant to the *HGR Regulations*, foreign parties are facing more restrictions on utilizing human genetic resources than Chinese parties. For example, foreign parties are prohibited from collection and biobanking of human genetic resources, and it would be necessary to cooperate with Chinese parties and go through approval and filing procedures in order to conduct scientific research utilizing human genetic resources. MOST has always been treating entities with any foreign capital as foreign parties since the *Interim Measures for Administration of Human Genetic Resources* in 1998. The term "foreign party" was more clearly defined as "foreign organizations and institutions that are established or actually controlled by foreign organizations or individuals" by the current *HGR Regulations* promulgated in 2019, based on which the *Implementation Rules* have further improved the standards for recognizing foreign parties.

First, **the *Implementation Rules* clearly emphasize the "50%" ratio** for defining foreign parties, and stipulate that circumstances where an overseas organization(s) or an individual(s) **establishes** or **actually controls** an institution include: "(1) an overseas organization or an individual holds or indirectly holds 50% or more of the shares, equity, voting rights, property shares or other similar rights and interests of the entity" or "(2) although the shares, equity, voting rights, property shares or other similar rights and interests of the entity directly held by an overseas organization or an individual do not reach 50%, the voting rights or other rights and interests it owns are sufficient to control or have significant influence on the resolutions, decision-making and internal management of the entity." After the *Implementation Rules* come into effect, an entity will no longer be regarded as a foreign party if overseas organizations or individuals have less than 50% of the equity and have no significant influence on the decision-making or internal management of the entity. This would potentially bring convenience to entities with only limited foreign ownership in utilizing human genetic resources. However, it remains to be seen how the regulatory authorities will determine the term "significant influence" in practice. In addition, the *Implementation Rules* have unified the criteria for recognizing foreign parties when they are **established** or **actually controlled** of overseas organizations and individuals compared with the Draft for Comments to make the provisions more reasonable.

Second, consistent with the Draft for Comments, **the *Implementation Rules* have made it clear that Chinese entities with VIE structures will be recognized as foreign parties**. The third paragraph of Article 12 of the *Implementation Rules* stipulates that "investment, agreements, or other arrangements by an overseas organization(s) and an individual(s) are sufficient to control or have significant influence on the decision-making, internal management and other major matters of an entity". Although pursuant to the *HGR Regulations*, VIE structures have already been covered as "actual control" in the definition of foreign parties, the *Implementation Rules* has put an end to the controversy about the nature of entities with VIE structures in practice, and such entities will be required to conduct their business activities related to human genetic resources in compliance with the regulatory requirements for foreign parties.

Third, Article 11 of the *Implementation Rules* stipulates that **entities in Hong Kong and Macau actually controlled by Chinese capital will be regarded as Chinese parties**. The definition of "actually controlled by Chinese capital" needs further interpretation from regulatory bodies, and from our point of view, the companies established in Hong Kong and Macau or the subsidiaries in Hong Kong and Macau actually controlled by Chinese companies may fall under the scope of Chinese parties, while as for subsidiaries established in Chinese mainland by Hong Kong and Macau companies, they will not fall under the scope of Article 11 and their status still need to be further examined based on the criteria stipulated in Article 12.

Ethics review requirements

The *Implementation Rules* have refined the ethics review requirements for the utilization of human genetic resources in China. Article 8 of the *Implementation Rules* stipulates that the collection, biobanking, utilization, and external provision of human genetic resources in China shall conform to the ethics principles, and the ethics review shall be conducted by the Ethics (Review) Committee, which has been filed by the relevant regulatory authorities. The ethics review shall be carried out in accordance with the law, administrative regulations, and other relevant provisions. Compared with the Draft for Comments, where the specific requirements for ethics review shall refer to the relevant provisions in the *Measures for the Ethical Review of Life Science and Medical Research Involving Humans* by the National Health Commission, the *Implementation Rules* generally stipulate that the review should be conducted by the Ethics Committee filed with the relevant regulatory authorities and comply with relevant laws and regulations. From our understanding, **the *Implementation Rules* have left space for the technology ethics review regulations**, such as the *Technology Ethics Review Method (Pilot Implementation) (Draft for Comments)* issued by MOST in in April 2023. Given that the regulations of technology ethics review have not been officially promulgated, it is still uncertain about the application and relationship between the ethics review regulations issued by the Health Commission and the technology ethics regulations. The ethics review requirements in the utilization of human genetic resources in China in the future still need further observation to future legislations (for reference, please refer to *Han Kun • Perspective | Technology Ethics Review Method (Trial) (Draft for Comments): a Brief Overview* and *Han Kun • Perspective | New Ethics Review Regulations: Key Takeaways*).

Changes in collection and biobanking requirements

I. Changes in the scope of collection approval

In accordance with the *Biosecurity Law of the PRC* and the *HGR Regulations*, the collection of human genetic resources of important genetic families, in specific regions, or the specified categories and quantity shall be approved by relevant regulatory authorities. The *Guidelines for the Collection Approval of the Collection of Human Genetic Resources in China* (the "***Guidelines***") further stipulates the specific requirements in scope for the collection approval of human genetic resources. The *Implementation Rules* have updated the scope requirements for collection approval. Please see below the comparison:

	Guidelines	Implementation rules
Important Genetic Families	The group of people with blood relationship and with hereditary diseases or hereditary physical or physiological characteristics, and three generations and more than five members within the group have such hereditary diseases or hereditary physical or physiological characteristics.	The collection of human genetic resources of important genetic families. The term "important genetic families" refers to the group of people with blood relationship and with hereditary diseases or hereditary physical or physiological characteristics, and the three or more generations within the group have such hereditary diseases or hereditary physical or physiological characteristics. **Common diseases such as hypertension, diabetes, red-green color blindness, and hemophilia are not within the scope of important genetic families.**
Specific Regions	The human genetic resources originated from isolated or special environment for a long term and have special physical characteristics or physiological adaptive characteristics. The specific regions are not divided based on whether they are ethnic minority inhabited areas.	The collection of human genetic resources in specific regions. The term "human genetic resources in specific regions" refers to human genetic resources that originated from isolated or special environment for a long term and have special physical characteristics or physiological adaptive characteristics. The specific regions are not divided based on whether they are ethnic minority inhabited areas.
Specified Categories	Rare diseases, special physical or physiological characteristics with significant differences	/

	Guidelines	Implementation rules
Specified Quantity	500 people or more	**The collection of human genetic resources for large-scale population studies with more than 3000 cases.** Such large-scale population studies include but not limited to cohort studies, clinical research, physiology studies, and etc. **The collection in clinical trial for the purpose of obtaining approval for marketing drugs and medical devices are exempted from collection approval for marketing drugs and medical devices are exempted from collection approval.**

The *Implementation Rules* have broadened the scope of collection in need of approval, and have clarified that common diseases such as hypertension, diabetes, red-green color blindness, and hemophilia are not within the scope of important genetic families. The *Implementation Rules* have also eliminated the collection approval requirements for specific categories such as rare diseases, and meanwhile, have raised the minimum requirement for the specified quantity for collection approval. It is stipulated that only collection activities for large-scale population studies with more than 3000 cases need to be declared for collection approval, and the collection in clinical trial for the purpose of obtaining approval for marketing drugs and medical devices are exempted from collection approval, for example, **the collection of human genetic resources in international cooperative clinical trials for obtaining marketing approval will no longer need collection approval even though the quantity of collection exceeds 3,000**. The *Implementation Rules* will significantly ease the approval and regulatory burden of Chinese parties in collecting human genetic resources and conducting human genetic resource utilization activities and conserve the regulatory resources.

II. Changes in biobanking regulatory requirements

Regarding the regulatory requirements for the biobanking of human genetic resources, the *Implementation Rules* refined the provisions of the *HGR Regulations* in terms of the definition of biobanking activities and collection exemption permits. In terms of the definition of biobanking activities, Article 28 of the *Implementation Rules* stipulates that biobanking activities refer to the behavior of preserving legally obtained human genetic resources under suitable environmental conditions to ensure their quality and safety for future scientific research. It does not include temporary storage activities for teaching purposes or biobanking in accordance with legal requirements or clinical research protocol agreements after lab testing, which is consistent with the provisions of the *Chinese Human Genetic Resources Biobanking Approval Administrative Service Guide* ("*Biobanking Approval Guide*"). The *Implementation Rules* reiterate the distinction between biobanking and temporary storage activities at the regulatory level. Therefore, temporary storage of human genetic

resource materials involved in clinical trials or investigator initiated trials (IIT) initiated by sponsors in cooperation with trial sites in practice does not require biobanking approval procedures to be performed. In terms of exemption for HGR collection approval, Article 29 of the *Implementation Rules* explicitly stipulates that if the requirements for biobanking approval application are met, applicants do not need to additionally apply for collection approval, which simplifies administrative approval regulatory requirements.

In addition, compared with the *HGR Regulations* and other regulations such as the *Collection Approval Guide* and the *Biobanking Approval Guide*, the *Implementation Rules* clearly stipulate the change procedures for the collection/biobanking of human genetic resource approvals, providing clear compliance guidance.

Section 6: Changes in International Cooperation Regulatory Requirements

Regarding the regulation of international cooperation, the *Implementation Rules* have detailed provisions on the approval/filing requirements, approval/filing process, and cooperation reporting requirements. Among them, the relaxation of international cooperation filing requirements and the changes in the definition of non-major changes in international cooperation approval are noteworthy. The key points of analysis and introduction are as follows:

1. Relaxation of international cooperation filing requirements for international cooperation

Firstly, the *Implementation Rules* further expands the scope of international cooperation filing. According to the *HGR Regulations*, compared with the international cooperation administrative approval process, only the filling process needs to be followed if the following conditions are met:

- In order to obtain the marketing license for relevant drugs and medical devices in China;
- Conducting international cooperative clinical trials using Chinese human genetic resources in clinical trial sites;
- Not involving the export of human genetic resource materials.

However, the *HGR Regulations* haven't clearly defined the scope of "conducting clinical trials in clinical trial sites". According to the "Guidelines for the Filling of International Cooperative Clinical Trials on Chinese Human Genetic Resources" ("International Cooperation Filing Guidance"), "conducting clinical trials in clinical trial sites" are not limited to the internal processing of human genetic resources in clinical trial sites, but also include the collection of human genetic resources by clinical trial sites and the testing, analysis and disposal of residual samples by parties entrusted by clinical trial sites through written agreements. The *Implementation Rules* further expands the scope of "conducting clinical trials in clinical trial sites" to include not only internal processing within clinical medical and health institutions but also the collection of human genetic resources by clinical medical and health institutions and the testing, analysis and disposal of residual samples by domestic institutions **designated by the clinical trial protocol**. In view of this, in the future, the industry can make more flexible cooperation arrangements in international clinical trials, such as the sample testing service entrustment agreement, which does not have to be signed by clinical medical and health institutions and the entrusted parties,

but can be signed by the sponsor or even the contract research organization ("**CRO**") on behalf of the sponsor and the entrusted parties, which is more in line with industry practice.

Secondly, the *Implementation Rules* further clarifies that the human genetic resource information generated from international cooperation can be shared among cooperative partners. Paragraph 3 of Article 28 of the *HGR Regulations* stipulates that the human genetic resource information generated from the use of China's human genetic resources in international cooperations can be used by both partners. Based on this, Article 36 of the *Implementation Rules* clearly stipulates that during the implementation of international cooperations that has obtained administrative approval or has completed filings, the Chinese party provides the foreign party with the human genetic resource information generated from the cooperation, if it has been agreed in the international cooperation agreement that the information can be used by both partners, there is no need to submit a separate prior reporting and information backup. This position is consistent with previous regulatory practice and is now reflected in the *Implementation Rules.*

In addition, the *Implementation Rules* have added provisions for the change of filing procedure for international cooperation filings. Previously, according to the *International Cooperation Filing Guidelines*, significant changes in international cooperation required re-filing, while non-significant changes **only required uploading an explanation of the change on the platform**. The newly introduced Article 53 of the *Implementation Rules* supplements the provisions for non-significant changes, requiring the uploading of a change report in advance on the platform, and stipulating that the record-keeper should promptly submit change filings in case of significant changes, which is conducive to reducing the compliance burden of applicants.

2. Definition of non-significant changes for international cooperation approval/filing

The *HGR Regulations* stipulate that changes in major matters such as the cooperating partners, research objectives, research content, and cooperation period of international cooperation activities should be subject to change approval procedures. However, the major changes listed in the *HGR Regulations* are relatively general and have a broad scope. Therefore, the *Implementation Rules* provide criteria for non-significant changes, which are useful for practical reference. Non-significant changes mainly include the following situations:

- Changes that only involve a total amount not exceeding 10% of the approved amount of HGR without changing the research content or research plan;
- Changes in participating parties other than the sponsors, leading sites, CROs, and third-party laboratories;
- Changes in the name of the legal entity of the cooperating partner;
- Changes in the research content or research plan without changes in the type, quantity, and purpose of human genetic resources or without exceeding the approved scope after the change.

In the case of non-significant changes, the parties only need to submit relevant materials to MOST for explanation and filing, without the need for change approval procedures. Therefore, in situations

where the research activities only involve changes within 10% of the approved amount or changes in participating units such as the Electronic Data Collection System (EDC) supplier, the simplified explanation procedure for non-significant changes can be applied.

3. Intellectual property sharing provisions

The Article 17 of the *Draft Rules* had explicitly stipulated that the cooperation parties could agree on the use rights, transfer rights, and profit-sharing methods of other scientific and technological achievements such as works, data, standards, and process flows generated by international cooperations through agreements. The relevant provisions were deleted in the *Implementation Rules*. From the perspective of legislative methodology, the *Implementation Rules* have deleted many overlapping and repetitive provisions in the *Draft Rules* and the *HGR Regulations*. Considering the current regulatory positions on patent rights and other intellectual property rights in the *HGR Regulations*, we understand that unlike patents, research results such as clinical trial data may not necessarily be jointly owned by Chinese and foreign cooperation parties. The Chinese and foreign parties have more autonomy in determining data ownership. Well aware of the value and importance of research data and other information materials for pharmaceutical companies, we understand, on the one hand, such research data is likely to be used to support future drug market authorization submissions to drug regulatory authorities of different jurisdictions; on the other hand, such data may have significant value in pharmaceutical companies' subsequent licensing and cooperative research and development projects, as an integral part of technology transfer. Furthermore, it may even become the basis for payment of royalties when licensing patents expire, as licensed know-how.

Information provision and security review

A significant change in the regulation of information provision is that the *Implementation Rules* **modified the filing procedure stipulated in the *HGR Regulations* to a prior reporting procedure**. Under the previous filing procedure, in practice, completing the filing procedure for the external provision or open utilization of human genetic resources information usual took several weeks. Since the *Implementation Rules* adjusts the filing procedure to a prior reporting procedure, it remains to be seen whether the time limits will be shortened.

Furthermore, Section 4 of the *Implementation Rules* also supplements the regulations for the changing report procedure. Going forward, after a company has completed the backup and reporting procedures for external provision of information, any changes regarding the usage purpose of information provision or the recipients, among others, will require prior reporting.

The improvement of the security review is another significant provision in the *Implementation Rules*. While the *HGR Regulations* only stipulate that security review should be conducted when the provision of information might affect public health, national security, and public interest of China and provides corresponding penalties, the *Implementation Rules* **elaborate the applicable scope and procedures of security review**, as follows：

1. **Applicable scope of security review:**

- Human genetic resource information of important genetic families;
- Human genetic resource information in a specific area;
- Human exome sequencing and genome sequencing information resources of more than 500 individuals;
- Other situations that may affect public health, national security, and public interest of China.

2. **Procedures of security review：**

- Formulate security review principles and establish an expert pool: MOST, in collaboration with relevant departments, will formulate security review principles, establish an expert pool, and enhance the expert administration systems;
- Conduct security review: Randomly select review experts from the expert pool and conduct security reviews through online reviews (under normal circumstances) or through meetings, on-site inspections, and other methods;
- Security review decision: MOST, in collaboration with relevant departments, will organize experts from relevant fields to conduct security reviews and make review decisions based on the security review opinions.

Administrative supervision and penalty

I. Enforcement requirements

The *Implementation Rules* reflect the ongoing trend in China of continuously emphasizing and strengthening the regulation of human genetic resources. Since the promulgation of the *HGR Regulations*, MOST has only published one administrative penalty case, which involved sanctions for submitting false application materials to obtain approval. However, from the provisions of the *Implementation Rules*, it is evident that the future regulation of human genetic resources in China will display a stronger regulatory intensity. It can be observed that from Article 57 to Article 61 of the *Implementation Rules*, detailed arrangements have been made for the supervisory and inspection work of the competent authorities, including the **annual supervision and inspection plan, key supervision and inspection requirements, random supervision and inspection arrangements, specific supervision and inspection actions, and the supervision and inspection information archiving**. This signifies a clear strengthening of the trend towards enhanced enforcement.

The *Implementation Rules* further refine the enforcement focus of the regulatory authorities regarding human genetic resources. Notably, the second paragraph of Article 56 in the *Implementation Rules* supplements the focus of supervision and inspection for human genetic resources regulation regarding "**the exportation, external provision, open utilization and usage after exportation of materials or information**". This addition, compared to the *Draft Rules*, highlights the regulatory authorities' focus on the external provision of human genetic resources. In the future, the industry should pay

more attention on fulfilling compliance obligation when engaging in human genetic resource-related activities, with particular attention to the requirements of prior reporting before providing human genetic resource information to foreign parties.

While strengthening enforcement, the *Implementation Rules* also adhere to the regulatory authorities' targeted approach as demonstrated through past communications and practices. MOST clearly emphasizes in the document *Policy Interpretation of the Rules for Implementation of Regulations on the Administration of Human Genetic Resources* that, while firmly safeguarding national biosecurity, the administration of human genetic resources shall adhere to the principle of "**stringent regulation where necessary and reasonable flexibility where appropriate**". Additionally, Article 66 of the *Implementation Rules* emphasizes that the regulatory authorities should standardize the exercise of administrative penalty discretion, ensure penalty proportionality, and prevent over-punishment or under-punishment. Furthermore, MOST will formulate and publish separate discretion criteria for the administrative penalty of human genetic resources, which deserves further attention.

II. Penalty calculation basis

"Illegal income" serves as the basis for calculating fines under the *HGR Regulations*. However, the current *HGR Regulations* do not provide a specific definition of "illegal income". The Implementation Rules further specify the concept of "illegal income" by stipulating that it should be calculated by **deducting reasonable expenses from the total income obtained through the implementation of illegal activities**; and if such calculation is impractical, the value of the human genetic resources involved in the illegal activities or the amount of funds invested in those resources can be used as a basis for determining the amount of the fine. Compared to the *Draft Rules*, the *Implementation Rules* prioritize the calculation method for determining "illegal income" by deducting "reasonable expenses" from the "total income". Given that the income obtained from the utilization of human genetic resources is usually relatively limited, the fines are more likely to be reasonable in amount. This provision is consistent with the enforcement principle of preventing over-punishment or under-punishment, as stipulated in Article 66 of the *Implementation Rules* mentioned earlier.

Conclusion

The *Implementation Rules* have further refined and implemented the relevant regulatory provisions of the *HGR Regulations*, taking into account the industry's concerns and practical needs. From the provisions of the *Implementation Rules*, it is evident that regulatory authorities are dedicated to implementing a regulatory approach that firmly safeguards national biosecurity while effectively adhering to the principle of "stringent regulation where necessary and appropriate flexibility where applicable": On the one hand, the *Implementation Rules* optimize many administrative approval and filling requirements and procedures for human genetic resources-related activities, facilitating the fulfillment of compliance obligations for the industry and alleviates their compliance burden. On the other hand, the *Implementation Rules* strengthen the necessary regulatory force by specifying administrative requirements and implementing supervision and inspection measures, leading to a significant enhancement of the trend towards regulatory enforcement.

The finalization of the *Implementation Rules* signifies a new phase in the regulation of human genetic resources in China, and the regulatory requirements outlined in the *Implementation Rules* deserve due attention from the industry. We will also actively participate in discussions with regulatory authorities and industry entities, accompanying the industry in comprehending and acknowledging this regulation, as well as China's constantly evolving regulatory requirements for human genetic resources. With the continuous enhancement of regulatory measures concerning human genetic resources, we are committed to assisting the industry in effectively utilizing China's human genetic resources and facilitating the smooth operation of their business activities.

Important Announcement

This Newsletter has been prepared for clients and professional associates of Han Kun Law Offices. Whilst every effort has been made to ensure accuracy, no responsibility can be accepted for errors and omissions, however caused. The information contained in this publication should not be relied on as legal advice and should not be regarded as a substitute for detailed advice in individual cases.

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