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China on the Move: China's Proposed Implementing Regulation Over Human Genetic Resources

In 2019, China published the Administrative Measures on Human Genetic Resources (HGR Measures), setting forth a comprehensive regulatory system over the collection, preservation, use, and export of human genetic resources (HGR) in China. Under the HGR Measures, participation by foreign entities in scientific and medical projects involving HGR in China, including clinical trials sponsored by foreign pharmaceutical companies, must be pre-approved or pre-recorded by the China Human Genetic Resources Administration Office (CHGRAO).[1]

However, implementation of HGR Measures has left certain important questions unanswered, causing concern among foreign participants in such scientific and medical activities in China. On March 22, 2022, to address those ambiguities, the Ministry of Science and Technology (MOST) issued draft Implementing Rules on the Administrative Regulations on Human Genetic Resources for public comment (Draft Implementing Rules).

This GT Advisory summarizes the operational details the Draft Implementing Rules provide.

[1] Please see our prior alert "China on the Move: An Improving Regulatory Landscape with New Challenges Ahead – Genomics and National Security."

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1. Narrow the scope of human genetic data

Under the HGR Measures, HGR consists of both human genetic materials and human genetic data. Human genetic materials are defined to include human organs, tissues, cells, and other materials containing hereditary substances such as genome and gene. The definition of "human genetic data" under the HGR Measures is worded broadly, permitting interpretation that any data derived from scientific and medical study of HGR materials should be treated as "human genetic data."

The Draft Implementing Rules, however, limit "human genetic data" to hereditary data such as gene and genome derived from utilization of human genetic materials. This clarification will exclude routine clinical data that does not indicate human genetic attributes, such as ultrasound, CT, PET-CT, MRI, X-ray, interventional, ophthalmoscopy, endoscopy, dermoscopy, pathological diagnosis image data, and general lab test results other than data relating to demographic genetic research.

2. Clarify the definition of foreign entity

Pursuant to the HGR Measures, any foreign entity including foreign controlled entities are prohibited from collecting, preserving, and exporting HGR. The definition of foreign controlled entities remains unclear under the HGR Measures. The Draft Implementation Rules clarify that "foreign controlled entities" refer to China-domiciled entities where foreign entities or individuals (1) hold 50% or more of its equity, voting rights, membership rights, or other similar interests; (2) otherwise have the ability to direct or decisively influence its decision-making, operation, or management of an organization including through equity ownership or contractual arrangements. The definition encompasses China-based operating entities controlled by foreign investors through the popular Variable Interest Entity, so-called VIE structure, and suggests that China-domiciled entities with foreign minority investor(s) that do not have the ability to decisively influence the entity's operation and management will not be deemed foreign entities under the HGR Measures.

3. Add more details in HGR security review

Pursuant to the HGR Measures, a prior HGR security review is required if sharing HGR data with foreign entities would jeopardize China's public health, national security, and public welfare. However, the HGR Measures fail to specify the exact circumstances where a HGR security review is required. Pursuant to the Draft Implementation Rules, if any of the following data is provided or made available to foreign entities, a HGR security review will be triggered: (i) data relating to significant genetic pedigree, including data relating to genetic diseases or hereditary physical characteristics; (ii) HGR collected from certain populations in particular regions, including long-time residents under isolated or unique environments having developed adaptive physical or physiological traits; (iii) exon or genome sequencing data of more than 500 people; and (iv) other sensitive human genetic data as determined by MOST. A panel of experts will be called upon to conduct the security review and provide its opinion for MOST's decision. MOST will publish detailed rules for the HGR security review.

Certain sensitive genetic data specified may constitute sensitive personal data under China's Personal Information Protection Law (PIPL) and important data under China's Data Security Law (DSL). It is currently unknown whether the HGR security review regime will be coordinated with the risk assessment regimes required for export of the same data under PIPL and DSL.

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4. Improve IP and data ownership conditions to foreign entity

The HGR Measures require that any patents generated as a result of international collaboration utilizing China HGR must be jointly owned between Chinese entities and foreign entities, and ownership of non-patent results may be allocated between the parties through negotiation. The Draft Implementation Rules clarify that non-patent results include scientific and technical results including works, data, standards, and methods, and the parties are permitted to negotiate to agree over the use, transfer, and profit-sharing of such results, and absent an agreement between the parties, such results shall be deemed jointly owned and the profit generating from such results will be equally shared between the parties. As such, the foreign entity is able to seek sole ownership of such non-patent results.

5. Clear recordation and approval procedures for clinical trials

Under the HGR Regulation, human clinical trials conducted for obtaining market authorization of drugs and medical devices with participation of foreign entities must be pre-recorded with CHGRAO, and if human genetic materials will be exported outside of China, such clinical trials will be subject to CHGRAO's approval, which process is in general more time-consuming than the recordation procedure.

The Draft Implementation Rules clarify that to qualify for the recordation procedure, the collection of HGR must be conducted within the medical institutions selected as the site for such clinical trials, and testing, analyzing of such HGR and the treatment of remaining HGR samples must be conducted either at the medical institutions or a third-party lab designated by the medical institutions. This clarification corroborates the practice that when the third-party laboratory is designated by the sponsor instead of the medical institutions, the clinical trials will be disqualified for the recordation procedure and CHGRAO's pre-approval will be required. The Draft Implementation Rules further clarify that exploratory studies with participation of foreign entities are subject to CHGRAO's pre-approval.

With those clarifications, the Draft Implementation Rules show the regulator's attempt to balance the regulatory agenda aimed at safeguarding China's biosecurity against the need to minimize disruption to international scientific and medical collaborations, especially when foreign entities' access to human genetic resources in China is unavoidable. On the other hand, several outstanding issues remain in relation to the exact scope of the applications.

Life sciences companies will still need and pursue answers to lingering questions under this new landscape under the Draft Implementation Rules. In the partnership setting particularly, foreign life sciences companies must assess their partnership models so as not to leave their local partners or themselves over-exposed in the complex arena of genetic materials. Life sciences companies looking to capitalize on the China market may wish to revisit their operations, especially in research and development, and monitor China's ongoing legislative and regulation progress.

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