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## China Unveils Implementing Rules on the Administration of Human Genetic Resources

On June 1, 2023, China's Ministry of Science and Technology (the "MOST") issued the long-awaited Implementing Rules on the Administrative Regulations on Human Genetic Resources (the "Implementing Rules"). The Implementing Rules will become effective on July 1, 2023. The Implementing Rules clarify many operational questions that have emerged since the Administrative Regulations on Human Genetic Resources (the "HGRs Regulation") became effective. The Implementing Rules introduce important changes to the previous draft rules made public for comment on March 22, 2022 (the "Draft Implementing Rules"). Most noteworthy are the following six updates.

**Attorneys**  
[Katherine Wang](#)  
[Bo \(Alice\) Du](#)

### ***1. Simplifying the Requirements and Procedure for Disclosure and Sharing of "HGR data"***

The HGRs Regulation requires a Chinese entity to notify the HGR Administration of China (HGRAC) of its disclosure or sharing of any HGR data with a foreign entity.

The Implementing Rules limit the definition of HGR data to human genes or genomic data derived from HGR materials, which include organs, tissues, cells or other genetic materials that contain a human genome or human genes. Clinical data, medical images, protein data and metabolic data, which were previously regulated as HGR data, are excluded from the scope of HGR data. Data derived from clinical studies will benefit from this narrower definition of HGR data.

No separate notification is required for the disclosure or sharing of HGR data between a Chinese entity and a foreign entity when the following conditions are met: (i) prior approval or a recordation filing has been obtained for the Sino-foreign cooperative research project or clinical trial at issue, and (ii) the parties have agreed by contract to use the HGR data jointly.

### ***2. Tightening Control over Data Protection and National Security***

The Implementing Rules echoed the Chinese government's legislative and enforcement focus on data privacy and national security.

The Implementing Rules expressly provide that written informed consent of human genetic resource donors must be obtained in accordance with relevant regulations. The Implementing Rules also enumerate situations in which a security review organized by the MOST is required for disclosure or sharing of HGR data with a foreign entity such as disclosure or sharing of (i) HGR data about important genetic pedigrees, (ii) HGR data from specific regions, and (iii) exome sequencing and genome sequencing information of more than 500 individuals. A security review by the MOST is mandatory because such disclosure or sharing may affect public health, national security, or public interests. In addition to the MOST's security review, we believe a separate security assessment led by the Cyberspace Affairs Commission of China (the "CAC") would also be required when said HGR data disclosure or sharing involves the cross-border transfer of important data or personal information.

### ***3. Clarifying the Scope of "Foreign Entities"***

The HGRs Regulation imposes various restrictions on the collection, preservation, and exploitation of Chinese human genetic resources by foreign entities. The Implementing Rules draw a clearer line between foreign entities and Chinese entities.

The Implementing Rules define foreign entities as offshore organizations as well as institutions established or actually controlled by offshore organizations or individuals. Control should be deemed to exist where an offshore organization or individual holds more than 50% of the shares, equity, voting rights, or other similar rights and interests, directly or indirectly, in a People's Republic of China (PRC)-domiciled entity.

A foreign organization or individual that can exert control or decisive influence over strategic matters of a PRC-domiciled entity, such as decision-making, operation, or management, will also be deemed to have control, even if such control is achieved by agreement. This means that a PRC-domiciled company adopting the VIE structure can qualify as a foreign entity. Separately, the Implementing Rules clarify that companies registered in Hong Kong or Macau but actually controlled by Chinese entities will be regulated as Chinese entities.

Moving forward, a PRC-domiciled entity with a foreign shareholder will not be regulated as a foreign entity if such foreign shareholder is only a minority shareholder that cannot exert control over the operations or management of the PRC-domiciled entity. It is possible that the MOST may consider waiving its continuous oversight over research collaborations or clinical studies sponsored by such foreign-invested PRC-domiciled entities after July 1, 2023.

#### ***4. Relaxing Intellectual Property Ownership and Data Sharing Obligations***

The Draft Implementing Rules provide detailed guidance on how to allocate the intellectual property derived from Sino–foreign cooperative research utilizing Chinese HGRs. The Implementing Rules delete relevant provisions and only require the parties to ensure that the Chinese partner and its investigators participating in the cooperative research enjoy relevant rights and interests in accordance with the law. This means that foreign entities are not prohibited from sole ownership of non-patentable intellectual property rights derived from Sino–foreign cooperative research utilizing Chinese HGRs.

The HGRs Regulation emphasizes that Chinese parties have the right to be substantially involved in the collaborations and shall have access to all of the data generated from them. The Implementing Rules make it clear that only records and data generated by using Chinese HGRs should be made available to the Chinese partner.

These regulatory changes will allow more flexibility for the allocation of research results derived from research collaborations utilizing Chinese HGRs.

#### ***5. Optimizing the Supervision of HGR-Related Activities***

Some regulatory updates introduced in the Implementing Rules are beneficial as they will reduce the compliance burden of companies.

Under the HGRs Regulation, when applying for advance approval to conduct a Sino–foreign research collaboration utilizing Chinese HGRs, the parties need to provide an ethics review approval obtained in their respective countries/regions. The Implementing Rules relax this requirement and allow foreign entities to use the ethics review opinions obtained by the Chinese partner as a substitute.

The Implementing Rules introduce a bifurcated approach to change management. Substantive changes—i.e., changes to the research contents or study protocols that pertain to the type, quantity, or usage of HGRs and changes in the sponsor, leading site, CRO, or third-party laboratory require an advance approval/a recordation filing to the MOST. For other changes that are non-substantive in nature, the submission of a written statement about the relevant change will suffice.

## ***6. Strengthening Law Enforcement***

The Implementing Rules clarify the responsibilities of the central and local regulatory authorities in the administration of HGRs. Although the HGRAC now reports to the National Health Commission after China's recent government restructuring in March 2023, the MOST continues to be in charge of the administration of human genetic resources, including, but not limited to, administrative review and investigation, administrative license, supervision, inspection, and enforcement. The MOST may delegate its authority to provincial counterparts as needed, which will strengthen law enforcement capacity in this area.

The MOST and its provincial counterparts will carry out a national survey of HGRs once every five years or more often based on actual needs. This implies that the Chinese government may enhance its oversight to ensure proper use of HGRs.