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Data Protection and Network Security

State Council Publishes Regulations for the Management of Human Genetic Resources

On May 28, 2019 the State Council published the *Regulations for the Management of Human Genetic Resources* (the "**Regulations**"), which will come into effect on July 1, 2019. Key elements of the Regulations are summarized as follows.

I. Definition of HGR

Article 2 of the Regulations defines human genetic resources ("**HGR**") as including HGR materials and HGR information. "HGR materials" include genetic materials that contain human genomes and genes, such as organs, tissues and cells. "HGR information" refers to data derived from genetic resource materials.

II. Requirements for collection and storage of HGR

Articles 11 and 12 of the Regulations provide for the conditions for the collection of HGR of important genetic genealogy or in specific regions, and include relevant requirements for the protection of privacy, reiterating that such collection is subject to approval by the Ministry of Science and Technology (MST).

Articles 13 to 16 address the conditions and security requirements for the storage of HGR and provisions of basic platforms for scientific research, including that they should be approved by the MST, and comply with various requirements including passing ethical review.

III. Provisions for International Research Cooperation and Export of HGR

Article 7 of the Regulations stipulates that foreign organizations, individuals and institutions established or controlled by foreign organizations, individuals and institutions ("**foreign parties**") are prohibited from collecting and storing China's HGR within China or from exporting them overseas. Article 21 further provides that foreign parties that utilize Chinese HGR to conduct scientific research are required to do so in collaboration with a Chinese partner.

Article 22 further provides various conditions for international cooperation and that international cooperation involving Chinese HGR should be approved by the MST. International cooperation to obtain marketing approval for drugs and medical devices does not require approval, but should be filed with the MST.

Article 27 of the Regulations stipulates that the export of Chinese HGR for the purposes of international research cooperation or other special purposes requires an export certificate from the MST.

IV. Security Review and Record-filing for Provision or Open-up of HGR Information to Foreign Parties

The Regulations provide new requirements for HGR information. Specifically, the provision of HGR information to Foreign Parties or making it available to the general public requires:

(a) A security review organized by the MST, if it may affect public health, national security or the public interest; and

(b) Record-filing with the MST (Article 28).

Since HGR information is included within the definition of HGR, it is unclear how the above requirements will coordinate with the approval requirements for HGR as referred to in Sections 3 above.

V. Other Key Points

Other noteworthy provisions of the Regulations include:

(a) Article 3 provides for exceptions to the application of the Regulations, such as the collection and storage of HGR for purposes such as clinical treatment, blood collection and supply, and the investigation of crimes, which should be conducted in accordance with the relevant laws and regulations. However, it remains to be clarified whether the relevant international cooperation and export of HGR for the above listed purposes are also exempted from the Regulations.

(b) HGR are prohibited from being sold, although payment for or collection of reasonable costs for the provision and use of HGR for scientific research is not considered buying and selling (Article 10).

(c) Prior to the implementation of the Regulations, the legal liabilities provided for violations of the earlier HGR regulations remain general, and any punishment was imposed on the basis of other regulations. With the introduction of the Regulations, companies found to be in violation may now face fines of up to ten million RMB.

VI. Our Observations

Compared with the previous *Interim Measures for Management of Human Genetic Resources* (1998) and the related implementation guidelines, the Regulations take a more systematic and comprehensive approach to regulating the collection, storage, usage and export of HGR. They specify the relevant legal liabilities and also provide clear provisions for the storage and export of HGR information. However, certain provisions remain to be clarified in practice, such as the exceptions to the provisions for approval for international cooperation, and the application of fines.

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信息保护和网络安全法律热点问题

国务院发布《人类遗传资源管理条例》

2019 年 5 月 28 日，国务院发布了《人类遗传资源管理条例》（以下简称“**《条例》**”），自 2019 年 7 月 1 日起施行。《条例》的重要内容简要总结如下。

一、人类遗传资源的定义

《条例》第 2 条规定，人类遗传资源包括人类遗传资源材料和人类遗传资源信息。其中，人类遗传资源材料是指含有人体基因组、基因等遗传物质的器官、组织、细胞等遗传材料。人类遗传资源信息是指利用人类遗传资源材料产生的数据等信息资料。

二、对人类遗传资源的采集和保藏的规定

《条例》第 11 条、第 12 条规定了采集重要遗传家系、特定地区的人类遗传资源应符合的条件、关于隐私保护的要求，并重申了该等采集须经国务院科学技术行政部门批准。

《条例》第 13 条至第 16 条对于保藏人类遗传资源，为科学研究提供基础平台的单位需满足的条件、安全要求，以及须经国务院科学技术行政部门批准，并符合包括通过伦理审查在内的一系列要求进行了规定。

三、国际合作科学研究、对外提供人类遗传资源的规定

《条例》第 7 条规定，外国组织、个人及其设立或者实际控制的机构（以下称“**外方单位**”）不得在我国境内采集、保藏我国人类遗传资源，不得向境外提供我国人类遗传资源。《条例》第 21 条进一步规定，需要利用我国人类遗传资源开展科学研究活动的外方单位应当采取与我国科研机构、高等学校、医疗机构、企业合作的方式进行。

《条例》第 22 条进一步规定了国际合作的条件，并明确了应经国务院科学技术行政部门批准。以获得相关药品和医疗器械在我国上市许可为目的但不涉及人类遗传资源出境的国际合作不需要审批，但是应当向国务院科学技术行政部门备案。

另，《条例》第 27 条进一步规定，利用我国人类遗传资源开展国际合作科学研究，或者因其他特殊情况确需将我国人类遗传资源对外提供的，应当取得国务院科学技术行政部门出具的人类遗传资源材料出境证明。

四、将人类遗传资源信息向外方单位提供或者开放使用的安全审查和备案

《条例》对人类遗传资源信息提出了新的特殊

要求。将人类遗传资源信息向外方单位提供或者开放使用的，应符合以下条件：

1、 如果可能影响我国公众健康、国家安全和社会公共利益，须通过国务院科学技术行政部门组织的安全审查；以及

2、 向国务院科学技术行政部门备案（第二十八条）。

由于人类遗传资源信息属于人类遗传资源，上述要求将会如何与《条例》第四和第五章规定的批准要求及法律责任相协调还有待观察。

五、其他

其他《条例》中的值得注意的条款包括：

1、 《条例》中的第三条提出了不适用于本《条例》的特殊情况，例如为临床诊疗、采供血服务和查处犯罪等需要而采集和保藏人类遗传资源的，应当依照相关法律法规规定执行。然而，以上述为目的的相关国际合作和我国人类遗传资源的对外提供是否不受《条例》约束还有待澄清。

2、 人类遗传资源禁止买卖，但是为科学研究依法提供或者使用人类遗传资源并支付或者收取合理成本费用的，不视为买卖（第十条）。

3、 在《条例》施行以前，对违反人类遗传资源管理规范的行为规定的法律责任较为笼统，需参照相关的规定进行处罚。《条例》规定，违规的公司可能会面临最高 1000 万元人民币的罚款。

六、我们的观察

对比现行的《人类遗传资源管理暂行办法》（1998）和相关施行指南，《条例》对采集、保藏、利用和对外提供人类遗传资源作了更加全面系统的规定，明确了相应的法律责任，也对保藏和对外提供人类遗传资源作出了更明确的规定。但是，《条例》的一些相关条款，例如国际合作的审批例外情形、罚款的适用等，还将待具体执法过程之中进一步确认。

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