Regulations on the Administration of Human Genetic Resources of the PRC

Dan Young Business Consultancy — www.danyoungcpa.com

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Chapter I — General Provisions

Article 1 — These Regulations are formulated for the purpose of effectively protecting and rationally utilizing China's human genetic resources, safeguarding public health, national security and the public interest.

Article 2 — The term "human genetic resources" as used in these Regulations includes human genetic resource materials and human genetic resource information. Human genetic resource materials refer to genetic materials such as organs, tissues and cells that contain human genetic information such as the human genome and genes. Human genetic resource information refers to data and other information materials generated from the utilization of human genetic resource materials.

Article 3 — The collection, preservation, utilization and cross-border provision of human genetic resources within the territory of China shall be governed by these Regulations. The provision of human genetic resources by Chinese organizations and individuals to foreign organizations, individuals or institutions

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established or actually controlled by them shall be governed by these Regulations. The collection, preservation and utilization of human genetic resources for the purposes of clinical diagnosis and treatment, blood collection and supply services, investigation and punishment of violations of law and crimes, doping testing, funeral and interment, and other such activities shall be governed by the relevant laws and administrative regulations.

Article 4 — The administrative department of science and technology under the State Council shall be responsible for the nationwide administration of human genetic resources. The relevant departments under the State Council, such as health, education, and market regulation, shall, within their respective scopes of functions and duties, be responsible for the relevant administration of human genetic resources. The administrative departments of science and technology of the people's governments of provinces, autonomous regions and municipalities directly under the Central Government shall be responsible for the administration of human genetic resources within their respective administrative regions.

Article 5 — The State shall strengthen the protection of China's human genetic resources, carry out surveys of human genetic resources, and implement a declaration and registration system for important genetic families and human genetic resources in specific regions. The administrative department of science and technology under the State Council shall, in conjunction with the relevant departments under the State Council, organize the survey of human genetic resources and formulate management measures for the declaration and registration of important genetic families and human genetic resources in specific regions.

Chapter II — Collection and Preservation

Article 6 — The collection of human genetic resources of important genetic families or human genetic resources in specific regions in China, or the collection of human genetic resources of the types, quantities, or for the purposes specified by the administrative department of science and technology under the State Council, shall meet the following conditions and be subject to the approval of the administrative department of science and technology under the State Council:

(1) Having a clear purpose and a standardized work plan;

(2) The collecting entity having the capacity to undertake the relevant collection activities;

(3) The collection of human genetic resources being conducted in an ethical manner, using methods that comply with relevant national technical specifications and standards;

(4) Having appropriate facilities, premises and equipment for the preservation of human genetic resources.

Article 7 — The preservation of human genetic resources of important genetic families or human genetic resources in specific regions in China, or the preservation of the types and quantities of human genetic resources specified by the administrative department of science and technology under the State Council, shall meet the following conditions and be subject to the approval of the administrative department of science and technology under the State Council:

(1) Having a clear purpose and a standardized preservation plan;

(2) The preserving entity having the capacity to undertake the relevant preservation activities;

(3) The source of the human genetic resources being lawful, and the informed consent of the provider having been obtained;

(4) Having appropriate facilities, premises and equipment that meet the requirements for the preservation of human genetic resources.

Article 8 — The collection and preservation of human genetic resources shall respect the right to privacy of the providers, obtain their informed consent in advance and protect their lawful rights and interests. An ethics review shall be conducted in accordance with the relevant State provisions. The administrative department of

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science and technology under the State Council shall formulate and publish the examination guidelines for the collection and preservation of human genetic resources.

Article 9 — The collection and preservation of human genetic resources shall be conducted in accordance with the approved purposes and plans. No activities beyond the approved scope shall be carried out.

Article 10 — Entities approved to collect or preserve human genetic resources shall submit an annual report to the administrative department of science and technology under the State Council on their collection or preservation activities.

Chapter III — Utilization and Cross-Border Provision

Article 11 — Where a foreign organization, an individual, or an institution established or actually controlled by them (hereinafter referred to as a "foreign party") needs to utilize China's human genetic resources for scientific research, it shall do so in conjunction with a Chinese scientific research institution, institution of higher learning, medical institution or enterprise (hereinafter referred to as a "Chinese party"), and shall meet the following conditions and be subject to the approval of the administrative department of science and technology under the State Council:

(1) Having a clear purpose of utilization and a standardized plan for scientific research;

(2) The Chinese and foreign parties having the capacity to undertake the relevant scientific research activities;

(3) The source of the human genetic resources being lawful and the types and quantities being reasonable;

(4) Having passed ethical review;

(5) Having a reasonable scheme for the sharing of results of scientific research; and

(6) Other conditions as prescribed by laws and administrative regulations.

Article 12 — Where a foreign party utilizes China's human genetic resources for scientific research, it shall ensure that the Chinese party and the foreign party substantially participate in the scientific research throughout the entire process. All records, data and other information generated in the course of the research shall be fully accessible to the Chinese party and shall be made available to the Chinese party in a complete form.

Article 13 — Where it is necessary to provide human genetic resource materials abroad in the course of international cooperative scientific research conducted by a Chinese party and a foreign party, the approval of the administrative department of science and technology under the State Council shall be obtained and the following conditions shall be met:

(1) There is no harm to China's public health, national security or the public interest;

(2) There is a lawful cooperation agreement between the Chinese and foreign parties, which clearly stipulates the purpose and use of the human genetic resource materials provided abroad, and the rights and obligations of the Chinese and foreign parties;

(3) The consent of the provider of the human genetic resources has been obtained and ethical review has been passed.

Article 14 — Where it is necessary to provide human genetic resource information abroad, or to make such information accessible from abroad, a record filing shall be made with the administrative department of science and technology under the State Council and a copy of the information shall be submitted. The following conditions shall be met:

(1) The purpose and use of the human genetic resource information to be provided abroad are lawful;

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(2) The quantity of the human genetic resource information does not exceed the scope necessary for the scientific research or other legitimate purpose;

(3) Ethical review has been passed.

Where the provision of human genetic resource information abroad may affect China's public health, national security or the public interest, a security assessment shall also be conducted.

Article 15 — Entities that have obtained approval for the provision of human genetic resources abroad shall submit a report on the use of the human genetic resources to the administrative department of science and technology under the State Council.

Chapter IV — Regulation of Service Providers

Article 16 — The administrative department of science and technology under the State Council shall strengthen the supervision and administration of entities conducting the collection, preservation, utilization and cross-border provision of human genetic resources, and shall establish and improve a credit management system for human genetic resources.

Article 17 — The administrative department of science and technology under the State Council shall formulate and publish guidelines for the examination and approval, and record filing, regarding human genetic resources.

Article 18 — The administrative department of science and technology under the State Council and the administrative departments of science and technology of the people's governments of provinces, autonomous regions and municipalities directly under the Central Government shall conduct supervision and inspection of the collection, preservation, utilization and cross-border provision of human genetic resources, and entities and individuals under inspection shall extend cooperation.

Article 19 — The administrative department of science and technology under the State Council shall establish a human genetic resources expert advisory body to provide advisory opinions on the examination and approval and record filing regarding human genetic resources.

Chapter V — Legal Liability

Article 20 — Where an entity, in violation of the provisions of these Regulations, collects or preserves human genetic resources without approval, the administrative department of science and technology under the State Council shall order it to cease the illegal activity, confiscate the illegally collected or preserved human genetic resources and the illegal gains, and impose a fine of not less than RMB 500,000 but not more than RMB 5,000,000. Where the illegal gains exceed RMB 1,000,000, a fine of not less than five times but not more than ten times the illegal gains shall be imposed.

Article 21 — Where a foreign party, in violation of the provisions of these Regulations, utilizes China's human genetic resources without approval or without conducting the required record filing, the administrative department of science and technology under the State Council shall order it to cease the illegal activity, confiscate the illegally utilized human genetic resources and the illegal gains, and impose a fine of not less than RMB 500,000 but not more than RMB 5,000,000. Where the illegal gains exceed RMB 1,000,000, a fine of not less than five times but not more than ten times the illegal gains shall be imposed.

Article 22 — Where an entity, in violation of the provisions of these Regulations, provides human genetic resources abroad without approval, the administrative department of science and technology under the State Council shall order it to cease the illegal activity, confiscate the illegally provided human genetic resources and the illegal gains, and impose a fine of not less than RMB 500,000 but not more than RMB 5,000,000. Where the illegal gains exceed RMB 1,000,000, a fine of not less than five times but not more than ten times the illegal gains shall be imposed.

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Article 23 — Where an entity commits any of the following acts, the administrative department of science and technology under the State Council shall order it to take corrective action, issue a warning, and may impose a fine of not more than RMB 500,000:

(1) Providing human genetic resource information abroad without conducting the required record filing or without submitting a copy of the information;

(2) Failing to submit the annual report or the use report as required;

(3) Failing to cooperate with the supervision and inspection conducted by the administrative department of science and technology.

Article 24 — Where the violation of the provisions of these Regulations constitutes a crime, criminal liability shall be pursued in accordance with the law.

Chapter VI — Supplementary Provisions

Article 25 — The term "institution established or actually controlled by a foreign organization or individual" as used in these Regulations means an institution that meets any of the following conditions:

(1) An institution lawfully established within the territory of China by a foreign organization or individual, either independently or jointly with other foreign organizations or individuals;

(2) An institution lawfully established within the territory of China by a foreign organization or individual, jointly with a Chinese organization or individual, where the foreign party actually controls the institution through an agreement or arrangement;

(3) An institution lawfully established within the territory of China that is actually controlled by a foreign party through an agreement or arrangement, such as investment or shareholding;

(4) Other institutions specified by laws, administrative regulations or the State.

Article 26 — These Regulations shall take effect as of July 1, 2019. The Interim Measures for the Administration of Human Genetic Resources promulgated by the General Office of the State Council on June 10, 1998 shall be repealed simultaneously.

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