# A Practical Discussion on Scope of HGR Administration

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With the development of bio-pharmaceutical technology, human genetic resource has increasingly been an area which attracts great attentions and heavy investment. In response, the government has been strengthening the administration on researches by using human genetic resources ("***HGR***"). The Ministry of Science and Technology issued the *Administrative Regulation of Human Genetic Recourses* (the "***HGR Regulation***") which became effective on 1 July 2019 to replace the *Provisional Measure for HGR Administration* (the "***HGR Measure***") effective on 10 June 1998; and the Standing Committee of the National People's Congress promulgated the *PRC Biological Safety Law* (the "***Biological Safety Law***") which will become effective on 15 April 2021.

The HGR Regulation and the Biological Safety Law have established an administrative system and imposed requirements on foreign participations in HGR researches. In practice, however, there are often controversies as to whether certain material or information is considered HGR or whether certain specific activities fall within the HGR administrative regime.

## 1. Is urine or blood serum considered HGR?

Although there is no clear answer, we are of the view that blood serum is more likely considered HGR than urine.

Under the HGR Regulation, HGR includes human genetic resource materials (the "***HGR Material***") and human genetic resource information (the "***HGR Information***"). The HGR Material is defined as organs, tissues, cells and other genetic materials that contain gene, genome, and other genetic substance. Both blood serum and urine are obtained from human being but they themselves do not contain cells but only very little traceable DNA or other genetic substance. The question is whether such traceable DNA or other genetic substance is sufficient to qualify blood serum or urine as HGR.

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This appears to be a scientific issue but the answer may not be limited to the scientific area. From a scientific point of view, neither blood serum nor urine by their natures contains DNA. Urine is seldom considered materials containing genetic information. Even if traceable DNA can be found in urine, it deteriorates more quickly in urine than in blood, making it difficult to extract and produce reliable test results. However, with technological development, it is increasingly realistic to test DNA from urine. Some publications even suggest that "urine is an ideal liquid biopsy for detecting tumor-derived DNA and more precisely reflects tumor mutational profiles than plasma." Serum is the same: although serum is the product by removing fibrinogen from plasma (which is in turn generated by removing cells from whole blood) and, in theory, contains very little DNA substance, technology development makes it possible to abstract cell-free DNA from serum to define tumor-specific genetic and epigenetic markers. As a result, it appears to be uncertain as to whether blood serum and urine contains DNA and thus considered HGR Materials.

Despite of the similarity between blood serum and urine, there are key differences. Blood serum is a part of blood, which is a part of human being and a typical sample of HGR Material. However, urine is only discharge from metabolization and not a part of human being. As such, blood serum is more likely able to reflect biological features of people of a race. Consequently, given that the HGR Regulation is enacted to safeguard public health, blood serum may be more relevant to public health and fall within the scope of HGR Materials.

## 2. Are data generated from analysis of blood, organs, tissues, cells etc that do NOT contain genetic information still considered HGR Information?

Under the HGR Regulation, the answer is probably yes.

From a legislative aspect, the definition of HGR captures HGR Materials and HGR Information, which is in turn defined as data or other information generated by analyzing HGR Materials. Please note that, according to the definition of the HGR Information, the inclusion of genetic information is not a condition. In other words, as far as the data reflect or are generated from analysis of HGR Materials, they will likely be considered HGR Information even if they themselves do not contain genetic information.

From a legislative intent aspect, Article 1 of the HGR Regulation states the legislative intent to protect genetic resources, to safeguard public health and public security, which replaces Article 1 of the HGR Measure which defines the legislative intent as, among others, to promote researches in genetic areas. As such, it appears that the HGR Regulation has a broader coverage and is not limited to researches about genetic information. In other words, all data generated from HGR Materials may be considered HGR Information because they concern public health.

From a practical aspect, according to a government form used for approval for HGR researches, the information of which the sharing with foreign parties requires approvals or filing includes, among others, general laboratory data, ultrasonic data, MRI data, PET-CT data. These data, by their natures, do not contain information about gene or genome but generated from examination of blood, organs and tissues which contain gene and genome. The inclusion of these data into the scope of information of which the

sharing is subject to approval or filing requirements suggests that as far as data are generated from blood, organs, tissues, and other materials which contain genetic substance, they are considered HGR Information even if they themselves do not contain genetic information.

## 3. Regulated Activities: What administrative procedure is required for use of HGR Information by foreign parties?

Foreign parties participate in research projects in various forms, including joint researches, commissioned researches, and researches by using HGR Information in stock. Are these forms of researches subject to approval or filing requirements under the HGR Regulation?

The answer is that different forms of participations may be subject to different administrative requirements.

Under the HGR Regulation, foreign parties may have access to HGR Information through either an International Research Project, which is subject to an approval requirement, or a Foreign Disclosure, which is subject to a filing requirement. According to the HGR Regulation, an International Research Project refers to a scientific research project which a foreign organization or an organization controlled by a foreign entity or foreign individual performs by utilizing Chinese HGR, and as required by the HGR Regulation, in cooperation with a Chinese partner. In other words, an International Research Project is an HGR research project in which both Chinese and foreign parties participate. The HGR Regulation prohibits foreign parties from undertaking HGR researches alone to avoid foreign parties' monopolization of HGR Information.

The Foreign Disclosure where a filing is required refers to the provision of HGR Information to a foreign organization or an organization controlled by a foreign entity or a foreign individual, or provision of public access. The base for a Foreign Disclosure is that the relevant HGR Information is in the sole possession of a Chinese party. The filing procedure is designed to allow the government to monitor the disclosure of HGR Information to foreign parties and identify security risks if any.

A project where foreign and Chinese parties participate in researches is a typical International Research Project because both parties are involved in the substantive researches and have access to the raw data. Therefore, such type of projects will be subject to an approval procedure.

Controversy may exist as to whether a commissioned research is an International Research Project, thus requires an approval. In a typical commissioned research project, the foreign party engages a Chinese party to perform the collection and preliminary analysis and then to hand over the data to the foreign party for further researches. On one hand, the foreign party does not participate in the frontier line researches and have no access to the raw data, a commissioned research is primarily a provision of the HGR Information to the foreign party. On the other hand, the foreign party may participate in design of researches and not be a passive data receiver. As such, the extent to which a commissioned research will be considered a Foreign Disclosure depends on the level of depth at which the foreign party participates in the research itself.

If a foreign party analyses the HGR Information which has already been in its possession, such analysis may not require any approval or filing. The analysis of the HGR Information for research purpose is a "utilization" of Chinese HGR Information. However, regardless of how the foreign party receives the HGR Information, the research project from which the HGR Information is generated has been completed and the transfer of the HGR Information to it has already happened. Therefore, no further approval or filing requirement would apply.

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