

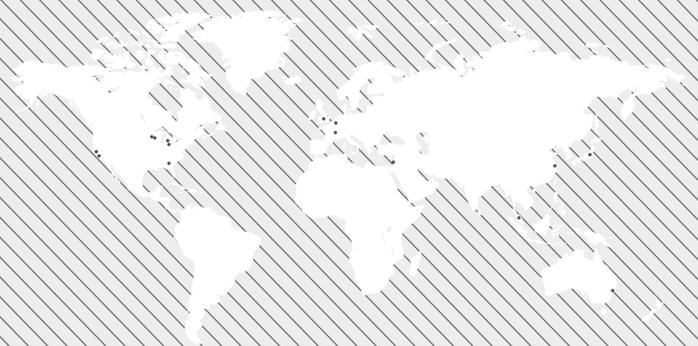
China's New Draft Ordinance on Human Genetic Materials and Its Impact on Clinical Trials

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By Seth J. Goldenberg Ph.D., and An Liu, M.S.

Regulatory

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Seth J. Goldenberg Ph.D., (sgoldenberg@namsa.com) is a Senior Principal Scientist with NAMSA, and was formerly with the U.S. FDA. He holds a Ph.D. in Pharmacology from the University of Washington, and a M.S. from the School of Biomedical Engineering at Drexel University. Dr. Goldenberg focuses on regulatory and quality consulting with firms in the USA and China to overcome hurdles and resolve issues with international regulatory bodies.



An Liu, M.S., (aliu@namsa.com) is General Manager, NAMSA China in Shanghai. He is responsible for the establishment and development for NAMSA China business, often consulting with Chinese government officials. He earned a M.S. in biostatistics from University of Minnesota, USA. He holds a M.S. in environmental biology from Peking University, China, and a B.S. in ecology from Nankai University, China.

Introduction

Carrying out clinical trials in China has always been and continues to be a challenge. The application process to get approval in China can in many cases take 9-12 months, with subsequent challenges of gathering and organizing resources, training staff, and setting up new clinical trial sites for the first time. Now there is a new challenge for clinical trials, as well as for basic research, regarding collection and analysis of genetic data or tissues.

During the clinical trial process, tissue samples and data derived from tissue collection and/or processing frequently are sent back to company headquarters in the West for analysis. On Oct. 30, 2012, China's State Council Legislative Affairs Office issued a draft "Human Genetic Resources Management Ordinance" that implements a system for qualifying, examining, and approving activities where human genetic materials are collected. These new draft regulations define human genetic materials as "resources and materials, such as human organs, tissue, cells, nucleic acid, or nucleic acid products that contain human genome, genes, or gene products, as well as any information derived from such resources and materials." In other words, "human genetic resources" encompass physical human materials and any genetic information derived from them, including data. This could have broad implications for clinical trials and research in China.

The impetus for these new regulations is to "strengthen the protection, management, and research use of human genetic resources in accordance with the law." Human genetic resources are an integral part of the basic resources of genomic research. With the rapid development of life sciences and biotechnology, and the increasingly fierce international competition surrounding the function of genes and the intellectual property rights to mapped genes, the ownership and regulation of human genetic research material becomes particularly important. China's 56 ethnic groups, encompassing more than 1.3 billion people, present an extremely rich reservoir of national genetic resources. Therefore, these new regulations are viewed in China as an important step towards enhancing the biological and pharmaceutical research and development capabilities within China.

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Review of Draft Human Genetic Resource Regulations

The cover letter associated with the draft regulations gives further insight into the reasons for these new requirements. In the cover letter, the authorities state that “some foreign institutions and enterprises have engaged in the illegal collection of human genetic resources” within China. They also note that in some cases this occurred in partnership with domestic Chinese institutions, which transmitted genetic data out of the country or transferred genetic data via the internet.

According to the letter, the new regulations look to accomplish four main goals:

- 1) Establish management procedures governing collection, research, development, trade, and export of genetic material or data.
- 2) Define liability and punishment for those who violate the new provisions.
- 3) Further standardize the administrative procedures and licensing laws.
- 4) Improve the coordination with existing laws governing clinical trials and other medical procedures.

The new draft regulations are broken down into six chapters and 50 articles. The first chapter describes general provisions of the new regulations. Here the governing agencies are defined as science and technology administrative departments within each of the provinces, autonomous regions, and municipalities directly under the Central Government, which are responsible for the area of human genetic resources management. The first chapter also prohibits the use of human genetic resources to engage in activities that may be a threat to national security or public safety.

The second chapter defines the procedures for collection and preservation of genetic material. Anyone collecting human genetic material must be a legal entity in China with clear reasons to collect the information, and must meet the requirements of an ethics committee (China's equivalent of an institutional review board). Prior to sample collection, the science and technology administrative departments at the provincial level must approve documentation related to informed consent and ethics committee approval, and other mandated regulatory



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documents must be inspected by a review panel of experts. The whole process could take 40 days or longer, depending on how quickly the review panel can complete its task. The draft regulations also give the administrative departments the authority to:

- 1) enter facilities for on-site inspection,
- 2) inspect and copy any relevant information,
- 3) question any persons concerned, and
- 4) seize and detain any illegally collected or preserved human genetic resources or materials.

Genetic research and development is discussed in the third chapter, which encourages government agencies to support genetic research. However, it also places limits and defines new requirements for Chinese entities who are cooperating with international partners. Any application for sharing of genetic data for research and development must include a clear purpose and direction within a scope of work that defines the duration of cooperation, its purpose, and the source of the genetic material. The application also must be carried out by groups that are deemed able to conduct the relevant research, with intellectual property ownership and sharing arrangements clearly defined and deemed reasonable.

The fourth chapter covers transmission of genetic data and material. Articles 31 and 32 go into detail regarding these requirements, maintaining that all entities must guarantee that any cooperative research and development activities with groups outside of China have

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The government also can levy fines ranging from RMB 50,000 (\$8,044) to RMB 200,000 (\$32,176) on those found in violation of any of these restrictions.

been approved. Only groups that have been preapproved to receive data or materials outside of China are eligible to do so, and any material transferred cannot have the potential to harm China's national security, public safety, or national interests. The researchers also must cooperate with ethics committee review and comply with all other laws and regulations. Each application for review must include:

- 1) an administrative license certificate from the institution,
- 2) a description of the cooperative research and development activities,
- 3) a copy of the contract between institutions,
- 4) a defined period of use and the method of disposal of the remaining samples, and
- 5) an agreement from the overseas organization to provide verification of receipt.

Legal liability is laid out in the fifth chapter, where provincial-level science and technology departments assigned to oversee human genetic resource management are given the authority to stop illegal activities, confiscate illegally collected data or preserved human genetic material, and seize any illegal income. The government also can levy fines ranging from RMB 50,000 (\$8,044) to RMB 200,000 (\$32,176) on those found in violation of any of these restrictions. Possible violations might include, but are not limited to, sale of genetic material, any work that leads to discrimination based on genetic data, activities that may harm national or public security, or carrying out research or sharing genetic information without the proper approvals from all relevant authorities.

The sixth and final chapter of the provisions provides an exemption to these regulations for groups that are involved in routine clinical practice clinics, blood collection or plasma for donation, investigation of crimes, carrying out doping tests, or other routine collection situations.

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Discussion

Historically, there always have been challenges with getting biopsies or other samples sent to labs outside of China, requiring numerous customs clearances and delays that could potentially destroy the samples. A common way around this requirement is for basic laboratory processing or histology to be done in China, with the data sent for analysis to the R&D headquarters in the West. With these additional approvals and clearances required for not only all material collection, but also for data transfer, companies currently carrying out or considering clinical trials in China have to factor these new procedures into any strategy. The new regulations introduce another layer of complexity into the clinical trial process. Once genetic information is collected, additional clearances have to be obtained prior to the distribution or publication of genetic data, in that sharing with groups outside of China carries additional requirements. This will be crucial for those who are conducting clinical trials or research in China, given that noncompliance could invoke monetary fines or even cancellation of collection protocols.

NAMSA[®]

World Headquarters
6750 Wales Road
Northwood, OH 43619, USA
clientcare@namsa.com

Telephone
866.666.9455 (toll free)
1.419.666.9455 (Outside of USA)
1.419.662.4386 (fax)

For more information and
a listing of locations worldwide,
visit www.namsa.com