UNRAVELING CURRENT U.S. AND FOREIGN LEGISLATION AFFECTING INTERNATIONAL RESEARCH

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I. CHINESE LAWS AND REGULATIONS AFFECTING INTERNATIONAL RESEARCH ACTIVITIES

A. Personal Information Protection Law

1. Overview

In August 2021, the People's Republic of China implemented the Personal Information Protection Law ("PIPL") of the People's Republic of China, effective November 1, 2021. The PIPL imposes a very broad set of data privacy regulations and requirements on the handling of personal information ("PI") about individuals located in the PRC. The PIPL outlined the legal bases for collecting and handling personal information, clarified an individual's rights over personal information along with the obligations of personal information handlers. Importantly, the PIPL introduced requirements on the cross-border transfer of personal information.

The PIPL is very similar to the European Union's General Data Protection Regulations ("GDPR") and includes many of the same requirements and restrictions found in those regulations designed to improve data privacy and security for PRC residents. At the same time, the PIPL contains some distinctive elements regarding data privacy that are unique to the Chinese regulatory regime. Common elements of the PIPL with the GDPR include notification and consent requirements, expansive rights of individuals to control how their data is collected, handled, retained, and shared, and the right to have their data deleted.

a. Domestic and Extraterritorial Scope

The PIPL has both a domestic and extraterritorial scope of application. The PIPL applies to the handling of PI related to activities carried out *inside* the PRC and also applies to handling of PI outside the PRC under any of the following conditions: 1) The purpose is to provide products or services to domestic natural persons; 2) The purpose is to analyze and evaluate the activities of domestic natural persons; and/or 3) Other circumstances provided by laws and regulations.

b. Handling Requirements (Including Cross-Border Transfer)

The PIPL defines seven specific conditions, also commonly referred to "legal bases," under which PI can be handled. For research activities, the most relevant bases would typically be the handling of PI based on (i) individual consent and/or (ii) when necessary for the conclusion or performance of a contract.

Under the PIPL, there are specific handling, management and security requirements regarding the sharing or transfer of personal data (referred to as "personal information" under the PIPL) that must be met before any personal information or sensitive personal information can be shared or transferred out of the PRC (including back to the institution). First, the institution must obtain separate, explicit consent specific for the transfer out of the PRC, and the institution must conduct an impact assessment of the policies and procedures used to ensure proper handling of personal information and to document compliance with PIPL requirements. Such impact assessment must be in place prior to transfer of personal information out of the PRC.

Data handling and/or transfer agreements that conform with PIPL requirements will also need to be signed between the institution and certain third parties in China in order to effectuate the cross-border transfer of personal information or sensitive personal information. These requirements include that one of the following conditions be met prior to the transfer:

(i) passing a security assessment conducted by the Cyberspace Administration of China ("CAC");

(ii) undergoing personal information protection certification conducted by an authorized third party;

(iii) forming a contract with the overseas data recipient in accordance with the standard contractual clauses ("SCCs") established by the CAC; or

(iv) other conditions provided in laws or regulations.

Which of the three primary measures—a security assessment, third-party certification, or standard contractual clauses—applies will depend on the nature of the data handler and the data recipient, the type of information being handled, and the amount of information.

Finally, the PIPL also carries significant administrative fines and penalties on institutions, as well as monetary fines and criminal liabilities on responsible personnel who fail to comply.

2. Applicability to Research Activities

As it relates to common research activities, the PIPL will typically apply to human subjects-based research protocols or survey-based research or other similar activities that normally require IRB review. Research activities that do not involve the collection or use of Personal Information (e.g., basic non-human subjects-based research, animal research, physical sciences, etc.) or the use of fully anonymized human subjects-based research are not subject to PIPL.[1] Key provisions of the PIPL that impact research activities include: 1) Explicit consent and reconsent requirements, 2) Rights of individuals regarding their personal information, and 3) Conditions on cross-border transfer of personal information.

If the research activities being conducted on behalf of the institution involve the collecting, storing, handling, transferring, or otherwise interacting with PI or Sensitive Personal Information ("SPI") directly or indirectly from individuals in the PRC, then the PIPL will apply to the research, in which case appropriate policies and processes will need to be put in place and rigorously followed to ensure compliance with all applicable PIPL requirements. Note that the cross-border transfer of PI or SPI out of the PRC to the institution or to other non-PRC locations requires that specific security, contractual, and control elements be in place prior to the transfer of data.

Under the PIPL, the handling of PI should be for a definite and reasonable purpose, limited to the minimum necessary to achieve the specific purpose, and should not be excessively collected. PI can only be acquired after identifying one of the following seven legal bases. It is also important for the institution to know from whom the information is being obtained. PI/SPI may be acquired directly from individuals themselves (e.g., in person participation in a research protocol or interaction with the institution's website or social media), or from a third-party collector (e.g., collaborators and/or partner institutions in PRC), or from a Chinese State Organ. It is important to understand that there may be different handling and security requirements depending on the source of the PI and different notice and consent requirements, or handling requirements based on who the individual is (e.g., all personal information of a minor under 14 is considered sensitive personal information, or SPI).

In the research setting, it is anticipated that consent will be the most relevant circumstance under which the institution will be acquiring PI/SPI. Individuals must be fully informed regarding who will be handling their personal information, the purpose, scope, and method of handling, their rights as it relates to their personal information and the manner and length of retention of their personal information. Consent must be explicitly given and if there are any changes to how their personal information is being

[1] *See* PIPL, art. 4 ("'Personal Information' refers to various information related to an identified or identifiable natural person recorded electronically or by other means, but does not include anonymized information") & art. 73 (defining "anonymization" as "the process of handling personal information to make it impossible to identify specific natural persons and impossible to restore").

handled, the individual must be notified and consent re-obtained. Prior to transferring any PI/SPI out of the PRC (including back to the institution), a separate consent specific for the transfer of the PI/SPI out of the PRC must be obtained. Individuals must be able to conveniently withdraw their consent and not have it impact their ability to receive other goods or services unless their consent is required for those goods/services.

Template PIPL consent language can be drafted for inclusion in standard informed consent documents required for human subjects-based research including on-line consent forms, written in-person consent forms, verbal consent forms, and consent forms for the re-use of previously obtained personal information. As noted above, under the PIPL, all personal information relating to minors under 14 is considered SPI. As such, it is recommended that institutions create separate, minor-specific informed consent template language for added clarity when obtaining consent from a minor's parent or guardian.

B. Regulations on the Management of Human Genetic Resources

The Regulation of the People's Republic of China on the Administration of Human Genetic Resources ("HGR Regulations"), which took effect July 1, 2019, covers "materials of human genetic resources," defined as genetic materials such as organs, tissues and cells which contain human genomes, genes and other genetic substances, and "information on human genetic resources," defined as information materials such as data generated from the utilization of materials of human genetic resources.[2] Several provisions pertain to activities involving foreign entities, including the following:

- Article 7 prohibits foreign organizations and individuals and the institutions formed or actually controlled by them from "collect[ing] or preserv[ing] China's human genetic resources within the territory of China" and they may not "provide China's human genetic resources abroad."

- Article 21 states that "Where a foreign organization or an institution formed or actually controlled by a foreign organization or individual . . . needs to use China's human genetic resources to conduct scientific research activities, it shall comply with China's laws, administrative regulations and relevant provisions of the state, and cooperate with China's scientific research institutions, institutions of higher learning, medical institutions and enterprises[.]"

- Article 22 provides that "The scientific research conducted through international cooperation by using China's human genetic resources must meet [seven specified conditions], and both parties to cooperation shall jointly file an application, which shall be subject to approval by the science and technology administrative department of the [Ministry of Science and Technology]."

[2] Regulation of the People's Republic of China on the Administration of Human Genetic Resources, Art. 2.

- Article 27 provides that "Where it is indeed necessary to transport, mail or carry the materials of China's human genetic resources out of China for the purpose of conducting scientific research through international cooperation by using China's human genetic resources or for any other particular circumstances, the following conditions shall be met, and the certificate on the exit of materials of human genetic resources issued by the science and technology administrative department of the State Council shall be obtained. (1) It causes no harm to China's public health, national security and public interest. (2) The entity has the legal person status. (3) There is a specific overseas partner and reasonable exit use. (4) The materials of human genetic resources are legally collected or from a legal preservation entity. (5) It has passed the ethical review."

On March 21, 2022, the Ministry of Science and Technology issued for public comment draft Rules for Implementation of the Regulations on Administration of Human Genetic Resources ("Draft Rules"). The draft rules would, among other things:

- Clarify the meaning of "actual control" as it pertains to the definition of foreign entities;

- Provides further detail on the requirements that a foreign entity must meet if it wishes to obtain marketing authorization in China for drugs or devices or to cooperate with a Chinese entity on clinical trials using China's human genetic resources at clinical institutions; and

- Provides standards pertaining to when change-licenses are needed for international cooperation scientific research.

C. Measures for the Management of Scientific Data

Effective March 17, 2018, the Measures for the Management of Scientific Data was put in place to strengthen and standardize the management of scientific data. Article 2 defines scientific data as "the data generated through basic research, applied research, and experiment and development, among others, in natural science, engineering technology and science and other fields, and the original data obtained through observation and monitoring, investigation and survey, and inspection and testing and other methods and used for scientific research activities and the derived data thereof." For any scientific data to which the law applies, pursuant to Article 14 "When paper authors are required to submit corresponding scientific data outside China when writing and publishing papers on foreign academic journals by utilizing the scientific data formed by government budgetary funding, they shall submit the scientific data to their employers for unified management before the publication of the papers."

D. Export Control

There are two primary laws under China's export control regime: the Foreign Trade Law and the Export Control Law. The Foreign Trade Law controls "prohibited and restricted from export" goods, technologies and services, while the Export Control Law controls dual-use items, military products, nuclear materials, goods, technologies and services. Institutions must consult both laws and affiliated regulations, as an item or technology may be subject to control by one or both lists.

1. Foreign Trade Law

a. Overview

The Foreign Trade Law, first promulgated in 1994 and last amended in 2022, applies to "foreign trade and the protection of foreign-trade-related intellectual property." Foreign trade is defined as "the import and export of goods, technology, and the international trade of services."[3] The law specifies 12 purposes under which the PRC may restrict or prohibit the import or export of relevant goods or technology, and it states that the foreign trade administrative department may use these guidelines to publish a catalogue with restricted or prohibited items.[4]

The associated *Catalogue of Technologies Prohibited and Restricted from Export* was first published in 2001 and continues to be revised. The latest proposed draft, from December 30, 2022, would reduce the current 164 items (most of which are restricted but some of which are prohibited) to 139 items. Several of the existing items, as well as several of the items that the proposed revisions would add to the list, are in the area of biotechnology. For example, the proposed additional items include human cell cloning and gene editing technology, CRISPR gene editing technology, and synthetic biology technology.

b. Licensing

Foreign trade operators no longer have to comply with various filing and registration procedures (which were eliminated by the 2022 amendments). For the goods subject to automatic license of import and export, businesses can apply for an automatic license prior to undergoing customs formalities.[5] For those technologies subject to free import and export, businesses must also register their contracts with the foreign trade administrative department.[6] For businesses

[3] China Foreign Trade Law, Art. 2.

[4] China Foreign Trade Law, Arts. 15-17.

[5] China Foreign Trade Law, Art. 14.

[6] China Foreign Trade Law, Art. 14.

intending to import or export restricted items, a license must be applied for and received in advance.[7]

2. Export Control Law

a. Overview

China's Export Control Law, effective as of December 1, 2020, regulates the transfer out of the PRC of controlled items, defined as "dual-use items, military products, nuclear, and other items such as goods, technologies, and services related to maintaining the national security and interest and performing nonproliferation and other international obligations (hereinafter collectively referred to as the "controlled items").[8] Of particular relevance to those involved in research, China's *List of Biological Articles of Double-Purpose and Related Equipment and Techniques under Export Administration of the People's Republic of China* specifies that genetic material (including chromosomes, genomes, plasmids, transposons and vectors) falls under the controlled items list and requires a license from MOFCOM before exporting.

b. Licensing

Article 12 directs the state to implement a licensing system for the export of controlled items and requires businesses to apply for a license from the Chinese Ministry of Commerce ("MOFCOM") prior to export. If an "export business" is unable to determine whether a good, technology or service to be exported constitutes a controlled item under the law, the business may consult with MOFCOM which will "provide a reply in a timely manner."[9]

Once an application is received, MOFCOM decides whether to grant or deny the application based on the following factors:

- National security and interest;
- International obligations and external commitments;
- The export type;
- The sensitivity of controlled items;
- Export destination country or region;
- End user and end use;
- The relevant credit record of the export business; and
- Other factors set forth by law and regulation.[10]

[7] China Foreign Trade Law, Art. 18.

[8] China Export Control Law, Art. 2.

[9] China Export Control Law, Art. 12.

[10] China Export Control Law, Art. 13.

3. No Fundamental Research Exclusion

Under U.S. export control law, many researchers and others at institutions benefit from an exception called the Fundamental Research Exclusion. A carve out for research purposes, the Fundamental Research Exclusion allows for "technology and software that arises during or results from fundamental research" to not be subject to export control regulations and allows foreign persons to participate in the research at the institution without the need for a license. China's Foreign Trade and Export Control laws, in contrast, contain no such exception.[11]

E. Anti-Espionage Law

On April 26, 2023, the Chinese government amended the Anti-Espionage Law of the People's Republic of China. Among other things, the revised law—which takes effect July 1, 2023— expands the scope of espionage activities to include "[j]oining an espionage organization or accepting a task by an espionage organization or its agent, or seeking refuge with an espionage organization or its agent."[12] The law applies if an espionage organization or its agent "engages in espionage activities against a third country within the territory of the [PRC] or by taking advantage of any citizen, organization, or other conditions of the [PRC], which compromises the national security of the [PRC]."[13] Objects of espionage are also expanded to include "[s]tealing, spying, purchasing, or illegally providing any state secret or intelligence, and other documents, data, materials, and items relating to the national security and interest.]"[14]

Although the law does not define "national security," Article 2 of the National Security Law provides the following broad definition: "National security means a status in which the regime, sovereignty, unity, territorial integrity, welfare of the people, sustainable economic and social development, and other major interests of the state are relatively not faced with any danger and not threatened internally or externally and the capability to maintain a sustained security status."

The new law also grants national security agency staff the authority to "inspect" the personal articles carried by "any unidentified person who is suspected of espionage."[15]

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[11] The List of Biological Articles of Double-Purpose and Related Equipment and Techniques under Export Administration of the People's Republic of China (available in Chinese only) does permit knowledge necessary for basic scientific research to be exempted from export control. Basic scientific research is defined as experimental or theoretical work aimed at gaining new knowledge about the fundamental principles of phenomena or observable facts, and which has essentially no specific practical purpose or objective.

[12] China Anti-Espionage Law, Art. 4(2).

[13] China Anti-Espionage Law, Art. 4.

[14] China Anti-Espionage Law, Art. 4(3).

[15] China Anti-Espionage Law, Art. 24.

This may include examination of "electronic equipment, facilities, and relevant programs and tools of a relevant individual or organization[.]"[16]

Given the expanded scope of the law, U.S. institutions should heighten their compliance awareness in this area and ensure that their due diligence of any partner institutions in China includes Anti-Espionage Law compliance. Any entities participating in international research collaborations should ensure that internal data privacy and security mechanisms are in place from the beginning of the collaboration. Additionally, any U.S. institution with a Chinese office or other presence in China will likely want to review the broadened inspection authority under the new law in order to understand potential implications for its activities and its employees in China.

II. CHECKLIST FOR IDENTIFYING LAWS AND REGULATIONS AFFECTING INTERNATIONAL RESEARCH COLLABORATION

According to the UNESCO Science Report 2021, during the 2017-2019 period the United States' top five foreign collaborators, as measured by number of scientific publications, were China, the United Kingdom, Germany, Canada and France, respectively. While those countries may top the current lists, it's clear that international research collaboration is growing, with faster rates of growth in high-income countries like the United States. The rates of collaboration among different countries are also changing, making it likely that U.S. researchers and compliance professionals will need to familiarize themselves with foreign laws from myriad countries in order to ensure successful research partnerships. This section therefore provides a checklist with questions for research compliance professionals to consider when entering into research collaborations with institutions or other organizations in other countries.

⇒ What are the regulatory compliance requirements governing the specific research sector (e.g., biological resources, human genetics)?

⇒ What are the regulatory compliance requirements governing the type of research or type of collaboration (e.g., clinical trials, scientific data, joint research lab, etc.)?

⇒ What goods/technologies do I need to import/export?

- What laws/regulations might prohibit or restrict those imports/exports?
- Is there an exclusion or exception for research?
- Are there filing and registration requirements?
- If a license is required, what foreign entity grants the relevant license?

[16] China Anti-Espionage Law, Art. 25.

- How long does approval take?

⇒ Does the research collaboration involve data that would constitute personal information and/or sensitive personal information?

- What data privacy and security laws/regulations in the foreign country would apply to that data?
- What cross-border transfer restrictions may be in place?
- What consents will need to be obtained prior to conducting the research and/or transferring the data?
- Does the country require that data be stored locally?

⇒ What training do the U.S. researchers/other participants need in order to ensure compliance with foreign laws and regulations?

⇒ For all laws/regulations:

- What advance approvals are needed, and from which entities?
- What is the typical timeline for receiving such approvals?

⇒ What due diligence do I need to conduct on entities with which I might partner?