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Privacy and Biobanking in China: A Case of Policy in Transition

Haidan Chen, Benny Chan, and Yann Joly

I. Context

With a population of over 1.3 billion, China is the most populous country in the world. It is facing an acute aging population problem, with a projected 440 million residents over age 60 and 101 million over age 80 by 2050.¹ Furthermore, rapid industrialization and urbanization in China have resulted in serious air pollution and associated public health problems, including an increase in respiratory diseases and cancers. These and other demographic trends have generated concerns about the cost of health care and its impact on population health.² In recent years, the Chinese government has invested heavily in the fields of translational research and biobanking with the hope that research in both fields can yield effective solutions to improve the public's health and quality of life.³ The establishment of national biobanks was identified as a major initiative needed for the biomedical industry in the 12th Five-Year National Development Plan of Strategic Emerging Industries promulgated by the State Council in 2012.⁴ In the meantime, the task of regulating data access and privacy has fallen on a number of government departments as well as on the biobanks themselves. This ensemble of regulators has, in recent years, released various normative instruments on the collection, handling, protection, and transfer of human genetic resources. Taken together, these policies form the data protection framework applied to biobanking initiatives in the People's Republic of China (PRC). This article presents a critical legal analysis of this framework with the aim of identifying areas that merit attention in future regulatory developments.

II. Biobanking Framework

Hospitals and research institutes in China have been involved in running disease-based biobanks for decades. For example, in the early 1970s, the affiliated Hospitals of Fudan University began to collect clinical specimens for in-house biomedical research.⁵ In the 1990s, the Chinese Different Ethnic Groups' Immortalized Cell Line Bank was set up by the Insti-

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tute of Medical Biology at the Chinese Academy of Medical Sciences in Kunming, Yunnan Province, in Southwest China.⁶ After the year 2000, there was a burst of genome-wide association studies, accompanied by the establishment of many population-based biobanks, which resulted in a new wave of biobank studies around the world.⁷ International collaborative biobanks, such as Guangzhou Biobank⁸ and China Kadoorie Biobank,⁹ were set up to study genetic and environmental factors as causes of complex diseases. At the local level, a number of academic leaders, university departments, and hospitals have established their own biobanks. It is likely that virtually every tertiary level hospital in China has its own biobank, and that some cancer hospitals may have several.¹⁰

Following a trend observed in other countries around the world, China recently embarked on a plan to establish biobank networks with the aim of promoting data sharing among the existing biobanks.¹¹ The Clinical Specimen Repository, coordinated by the Beijing Union Medical Hospital, is the largest national clinical biobank in China, with its main funding (approximately USD 33 million) coming from the Beijing Economic and Technological Development Zone. It was set up against the backdrop of China's major science and technology project, "Significant New Drugs' Development," which was established to study four major diseases (malignancies, cardiovascular and cerebrovascular diseases, metabolic diseases, and neurodegenerative diseases).¹² In addition to the Beijing Union Medical Hospital, nine other leading research-based hospitals around the country have taken part in the repository.¹³

The Beijing and Shanghai governments later established their own regional biobank networks in order to remain competitive in the field of biomedicine and advance the development of translational research. In 2009, the Beijing Municipal Science and Technology Commission launched the construction of the Beijing Biobank of Clinical Resources. Coordinated by Capital Medical University, the Beijing Biobank of Clinical Resources involved the recruitment of 11 leading hospitals in Beijing for the study of major diseases, such as diabetes, cardiovascular diseases, and cancer.¹⁴ Three years later, supported by the Shanghai Municipal Commission of Science and Technology, the Shanghai Clinical Biobank for Significant Diseases (also called the Shanghai Disease-Based Biobank Network) was launched. It was led by Shanghai Shen Kang Hospital Center, with the Shanghai Biobank Engineering Research Center functioning as a third-party service provider to build a platform for data-sharing within the network. As of 2015, about 20 tertiary level hospitals and research institutes affiliated with Shanghai

Fudan University, Shanghai Jiao Tong University, and Shanghai Traditional Medical University have become partners in the network.¹⁵

III. Legal and Regulatory Privacy Framework Applicable to Genomic Databases/Biobanks

Privacy in China

As biobanks contain a wealth of genetic and clinical information from participants, the protection of privacy is becoming a key issue in the governance of Chinese biobanks. A notion of privacy has long existed in traditional Chinese society and culture. Privacy was traditionally situated in the realm of the family as distinct from the realm of the state, which was principally concerned with public affairs.¹⁶ This notion of the family as a purely private realm came under sustained attack during the early decades of the People's Republic of China. In the decades following the Cultural Revolution, there was a re-evaluation of the concepts of selfhood and the role of private life among Chinese writers, academics, and politicians. Among the Chinese population, individuals became increasingly conscious of the importance of the right not to be intruded upon along with a corresponding duty not to interfere with the personal matters of others.¹⁷ It was around this time that the Chinese term *yinsi* came to be employed as the Chinese equivalent to the English word "privacy."¹⁸ It is informative to know that while *yinsi* traditionally carried a negative connotation (associated with shameful secrets), the term has recently come to encompass "all personal information that people do not want others to know."¹⁹

This shift in the public's conception of privacy has been especially prominent in the context of genetic information. The increasing use of genetic testing, for instance, has sparked concerns regarding the negative repercussions of third party access to genetic information. In particular, there is a growing fear that genetic information can be used for discriminatory purposes by employers and insurance companies, as evidenced by the widely publicized *Foshan* civil service case. Three civil service candidates were deemed medically unfit when it was discovered, during the mandated physical examinations, that they were carriers of the Mediterranean anemia gene. The candidates brought the local personnel department to court, but were ultimately unsuccessful.²⁰ Such incidents have led ethicists to call for Chinese law to more rigorously affirm the right to genetic privacy.²¹

While Chinese society is increasingly concerned with genetic discrimination, the extent to which this concern is reflected in the biobank context defies any easy generalization. In a study on Chinese and Euro-

pean perceptions of biobanking issues, Chen et al. found that concerns about privacy violations differed between Chinese based on education level. Participants in the less educated focus groups did not raise any initial concerns about privacy, nor were their concerns heightened when the moderator pointed out privacy issues at later points in the discussions. The authors observed that the respondents in the less educated focus groups simply did not perceive themselves as potential targets of abuse owing to their low social status. In contrast, participants in more highly educated groups exhibited preferences with regards to privacy protection that were very similar to those exhibited by their counterparts in Europe.²² These findings are consistent with those of Zhu et al. gath-

ties the personal dignity of the citizens of the People's Republic of China, is the "ultimate source from which legislation on the protection of personal rights emanates."²⁴ Art. 40 guarantees the freedom and privacy of correspondence as a specific instance of the general protection of personal dignity. For much of the 1980s and 1990s, however, the right to privacy was interpreted by the courts as part of the right to reputation. For instance, the Supreme People's Court released a legal interpretation document, the Reply to Several Questions on Adjudicating the Cases of the Right of Reputation, which ordered cases of privacy invasion to be determined in accordance with provisions regarding the right of reputation for the purposes of civil responsibility.²⁵

With the development of information technology and network services, Chinese legislators are paying increasing attention to concerns of data privacy and network security. The Standing Committee of the National People's Congress recently issued the National Security Law of the People's Republic of China, which took effect on July 1, 2015.

ered through surveys conducted on staff in hospitals, medical school students, and teachers in five cities in China. In their paper, Zhu et al. observed that Chinese people in general had a limited awareness of the importance of personal health data protection, as they had yet to draw a close connection between genetic privacy and genetic discrimination. While the majority of participants believed that genetic discrimination was unfair, they lacked a full appreciation of the serious consequences that genetic discrimination could bring about.²³

National Regulatory Instruments

There is presently no comprehensive privacy or data protection legislation in the People's Republic of China. Data sharing and privacy protection for Chinese biobanks are regulated by a combination of laws and other normative instruments issued by various administrative departments under the authority of the Central Chinese Government.

Chinese law has only recently begun to recognize individual privacy as a distinct and independent constitutional right, as evidenced by the intensive developments in China's data protection and network security laws over the past few years. Before that, legal provisions in the Chinese constitution provided little more than indirect protection of privacy. For example, Art. 38 of the Chinese Constitution, which guaran-

Despite the lack of a recognized constitutional right to privacy or a comprehensive privacy law over past decades, efforts have been made in recent years to safeguard personal data, particularly in the healthcare context. Art. 22(3) of the Medical Practitioner's Law of the PRC²⁶ states that doctors have an obligation to protect the privacy of patients. Furthermore, Art. 62 of the Tort Liability Law states "a medical institution and its medical staff shall assume the tort liability if any privacy data of a patient is divulged, or any of the medical history of a patient is open to the public without the consent of the patient, causing any harm to the patient."²⁷ Art. 1 of the Interpretation of the Supreme People's Court on Issues regarding the Ascertainment of Compensation Liability for Emotional Damages in Civil Torts authorizes the people's court to accept cases involving the violation of the public interest where the plaintiff claims emotional damages for the illegal infringement of privacy or other personality interests.²⁸

With the development of information technology and network services, Chinese legislators are paying increasing attention to concerns of data privacy and network security. The Standing Committee of the National People's Congress recently issued the National Security Law of the People's Republic of China, which took effect on July 1, 2015.²⁹ To address a variety of network-based risks, the National People's Congress released a draft of the Network Security

Law (Draft Law) for public comment. The Draft Law focuses on such issues as data privacy (chapter 4) and network monitoring and emergency response (chapter 5), and provides penalties for violation of network security rules (chapter 6).³⁰ On August 29, 2015, the National People's Congress amended the Criminal Law of the People's Republic of China (effective November 1, 2015), modifying and adding provisions associated with data privacy and network security issues, and expanding criminal sanctions and liability for the illegal sale or provision of personal information.³¹

Interim Measures for the Administration of Human Genetic Resources

The Interim Measures for the Administration of Human Genetic Resources (Interim Measures)³² were in effect from 1998 to 2015. They were drafted by the Ministry of Science and Technology, and the Ministry of Health under the authority of the State Council. Under the chapter on general provisions, the term "human genetic resources" referred to the genetic materials, e.g., human organs, tissues, cells, blood specimens, preparations of any types or recombinant DNA constructs, which contain human genome, genes or gene products, as well as to the *information related to such genetic materials*" (emphasis added). The Interim Measures applied to anyone involved in sampling, collecting, researching, developing, trading, or exporting human genetic resources, or taking such resources outside of the territory of the People's Republic of China.³³ Article 4 granted the Human Genetic Resources Administration of China (HGRA) supervisory authority over the collection and international transfer of human genetic resources:

No institution or individual is allowed to sample, collect, trade, export human genetic resources or take them outside the territory of the People's Republic of China, or provide them to other countries in any form without permission from the Human Genetic Resources Administration of China (HGRAC), an institution established to review and approve international collaborative projects involving human genetic resources in China.³⁴

Article 6 reiterated the restrictions on the international transfer of genetic resources: "Any export of important human genetic resources outside the territory of the People's Republic of China or provision of such human genetic resources to foreign institutions or individuals shall be under strict control."³⁵

The Interim Measures provided limited and indirect protection for personal data through intellectual property rights. Under Chapter 4, "no foreign collaborating

institutions or individual that has access to the information of Chinese human genetic resources, particularly the important pedigrees and genetic resources in the specified regions and the relevant data, information, and specimen may publicize, publish, apply for a patent, or disclose it by any other means without permission" of their Chinese collaborators.³⁶ In terms of enforcement mechanisms, Art. 21 in Chapter 5 of the Interim Measures authorized Chinese Customs authorities to confiscate genetic resources from anyone who attempts to export them out of China without authorization. Those in violation of the provisions stipulated in the Interim Measures were subject to administrative penalty or legal liability.

Draft Ordinance on the Administration of Human Genetic Resources

Although the Interim Measures played an important role in protecting Chinese human genetic resources, they were not entirely effective in preventing the illegal collection and export of Chinese genetic resources. The Chinese government determined that the Interim Measures were lacking in the following respects: the instrument lacked management measures on the collection, preservation, research and utilization of human genetic resources; legal liability was unclear; punishment for violations was light; and there was a lack of coordination between the Interim Measures and relevant laws.³⁷ As the State Council sought to exercise more effective regulatory control over international collaborative projects involving human genetic resources,³⁸ it initiated a process of standardizing administrative licensing conditions, procedures, and durations.³⁹ The Ministry of Science and Technology, under the authority of the State Council, released a draft version of the Ordinance on the Administration of Human Genetics Resources (Draft Ordinance)⁴⁰ in 2012. Upon final approval, the Draft Ordinance will become the main regulatory instrument governing the collection and transfer of genetic resources in China.⁴¹ Human genetic resources in the Draft Ordinance refer to

resources and materials such as human organs, tissues, cells, nucleic acid, nucleic acid products, which contain human genome, genes or gene products, as well as to the information related to such genetic materials. This regulation applies to the collection, preservation, research and development, and export of human genetic resources for scientific purposes in China.⁴²

The Draft Ordinance retains the Interim Measures' basic principles and main provisions concern-

ing international collaboration on human genetic resources, as well as the management of the entry and export of these resources. According to the accompanying Explanation document, the Regulations are meant to be a summary of previously implemented rules that have proven to be successful. The Explanation also provides a statement of the other objectives and principles underlying the new Draft Ordinance, which include promoting the effective protection and rational use of human genetic resources, promoting international cooperation and exchange, providing for a hierarchical system of management, and setting out detailed requirements for the examination and

of benefits, the protection of individual privacy, the right to voluntarily participate, and the right to unconditionally withdraw at any time, and so on.⁴⁵

Furthermore, Art. 16 states that institutions approved to collect and preserve human genetic resources may provide these resources for others' research and development activities if the resource providers have consented, and effective measures are required to protect resource providers' privacy and safety.⁴⁶ If the purpose of the research is not included in the resource provider's consent, the researcher must reobtain the

Given the numerous procedures and delays involved in finalizing and issuing regulations in the Chinese legal system, the Ministry of Science and Technology, under the authority of the State Council, recently released the Administrative Licensing Service Guide for the Review and Approval of the Collection, Preservation, Trade, and Export of Human Genetic Resources (Service Guide). The objectives of the Service Guide are to rationalize and standardize the approval and examination of the collection, preservation, trade, and export of human genetic resources. The Service Guide has been effective since October 1, 2015, replacing the Interim Measures and serving as transitional regulations pending final approval of the Draft Ordinance.

approval of the export of human genetic resources. Furthermore, the Draft Ordinance provides more details on the legal liability incurred by violating these regulations.⁴³

In stark contrast to the Interim Measures, the Draft Ordinance gives specific attention to the importance of consent and privacy in genetic research. One of the general provisions, Art. 4 states that "any activity involving the collection, preservation, research and development, and international collaboration of human genetic resources shall comply with the recognized ethical principles, and protect the safety and privacy of a resource provider" (资源提供者).⁴⁴ Under Chapter 2, the regulation provides that

the collection and preservation of human genetic resources shall follow voluntary and informed consent principles. Before collecting the materials of human genetic resources, the collection unit shall provide a written informed consent to each resource provider, which includes the purposes of collection, the use of human genetic resources, the potential health risks, the sharing

resource provider.⁴⁷ In Chapter 5 on legal responsibility, the breach of a resource provider's privacy that results in a socially harmful effect will be ordered corrected by the provincial-level science and technology administrative departments. There are also penalty provisions for cases of gross violations.⁴⁸

The Draft Ordinance also provides much more detailed guidelines for cooperative research on human genetic resources between Chinese and foreign entities. The conditions for international cooperation are specified under Art. 22 in Chapter 3, which lists the conditions for the approval of international cooperative research and development activities involving Chinese genetic materials within the territory of the People's Republic of China: the domestic partner shall be a legal entity within the territory of the People's Republic of China; cooperating parties shall have the ability to engage in related research; the duration of cooperation shall also be clear; the source of human genetic resources shall also be clear and legal; the activity shall be approved by cooperating parties' Ethics Review Committees; intellectual property ownership shall be clear; and sharing schemes of research

results shall be reasonable. Finally, no harm shall come to China's national security, national interests, and social and public safety. Art. 31 lists conditions on the export of Chinese human genetic resources that complement the conditions on research collaboration listed under Art. 22. For example, an overseas institution receiving human genetic resources is considered a cooperating party to an approved research and development project.⁴⁹ The Draft Ordinance also stipulates that it shall be "necessary" to export the human genetic resources⁵⁰ as a condition of export approval but does not discuss what constitutes necessity. In keeping with the notion of human genetic resources as a collective good, any export of genetic resources shall not involve any harm to Chinese national security, social and public safety, and national interests.⁵¹

Administrative Licensing Service Guide for the Review and Approval of the Collection, Preservation, Trade, and Export of Human Genetic Resources

Given the numerous procedures and delays involved in finalizing and issuing regulations in the Chinese legal system, the Ministry of Science and Technology, under the authority of the State Council, recently released the Administrative Licensing Service Guide for the Review and Approval of the Collection, Preservation, Trade, and Export of Human Genetic Resources (Service Guide).⁵² The objectives of the Service Guide are to rationalize and standardize the approval and examination of the collection, preservation, trade, and export of human genetic resources. The Service Guide has been effective since October 1, 2015, replacing the Interim Measures and serving as transitional regulations pending final approval of the Draft Ordinance.⁵³ Article 1 of the Service Guides reads as follows:

The license applies to the specification and management of the collection, preservation, trade, and export of Chinese human genetic resources in the territory of the People's Republic of China. Collection applies to the collection activities involving human genetic resources in the territory of the People's Republic of China, including the important pedigrees and genetic resources in the specified regions. Preservation applies to storage, or the preservation of human genetic resources for the purpose of international collaboration. In accordance with relevant laws and regulations, the trade of human genetic resources is prohibited. The transfer of human genetic resources for the purpose of scientific research does not count as trade. Export applies to the circumstances in which human genetic resources are transferred outside China's border.

The collection, preservation, trade, and export of Chinese human genetic resources for the purposes of clinical diagnosis and treatment, blood (plasma) collection service, forensic identification, criminal investigation, drug testing, and funeral do not fall within the scope of the Service Guide.⁵⁴

The conditions for the export of human genetic resources in the Service Guide are virtually identical to those listed in Art. 31 of the Draft Ordinance. For example, cooperating parties shall have the basis and ability to carry out relevant research; the collaborative objectives and procedures shall be clear; the human genetic resources shall be lawfully obtained; intellectual property ownership shall be expressed and reasonable; and there shall not be any harm to China's national security, national interests, and public safety.⁵⁵

Management Measures for Population Health Information (Trial Implementation)

China's National Health and Family Planning Commission (NHFPC)⁵⁶ released the Management Measures for Population Health Information (Trial Implementation or PHI Measures) on May 5, 2014 as the first legislative attempt to regulate health data specifically. An accompanying document, the Interpretation on Population Health Information Management Measures (Trial Implementation)⁵⁷ (Interpretation) was published eight days after the PHI Measures to provide background information and explanations of the PHI Measures' specific provisions.⁵⁸ The aim of the PHI Measures is to standardize and strengthen the collection, management, utilization, security, and individual privacy protection of population health information linked to medical, health and family planning institutions at various levels, which are responsible entities.⁵⁹

The PHI Measures may have a wide-ranging impact on how genetic information is handled in health settings. In contrast with the Interim Measures and Draft Ordinance, both of which focus on genetic materials, the PHI Measures focuses on data.⁶⁰ With regard to the kind of data covered by the regulation, the term "population health information" is defined very broadly and encompasses a wide range of personal health data. Based on their discussions with officials from the National Health and Family Planning Commission, Carlson and Livingston note that the term "population health information" is meant to cover personal health information, such as that contained in an individual's medical records, and aggregated or derivative data.⁶¹ This also seems to capture genetic

information that is routinely collected by Chinese health institutions in the context of the various genetic services they offer. For instance, since 2000, nearly all maternal and pediatric hospitals are able to perform karyotyping and offer basic genetic counseling services. Genetic testing is presently available for many common genetic disorders in these institutions.⁶² As the clinical data generated by these services would fall into one's personal medical record, there is no reason to believe that genetic data would not be covered by the PHI Measures.

In terms of the substance of the new regulation, the PHI Measures contain fairly extensive provisions concerning the quality and protection of personal health data. Data collection units are obligated to adhere to the principle of "one data, one source."⁶³ The Interpretation clarifies this requirement by stating that responsible entities should limit their data collection to the minimum data necessary for service and management needs.⁶⁴ This provision may be seen as an attempt to officially recognize existing data collection practices that aim at limiting unnecessary access to and storage of personal data. Furthermore, the PHI Measures obligate data collection units to safeguard the integrity of the data by setting in place data recovery and data back-up processes.⁶⁵ The Interpretation expands on this point by obligating the responsible entities to utilize data storage, backup, and management devices that meet national standards, including the use of backup mechanisms that will be reliable in the eventuality of a disaster.⁶⁶

Art. 10 of the PHI Measures requires that collection units ensure that data are up-to-date, continuous, and valid, while also prohibiting the storage of population health data on servers overseas. This latter requirement is a significant departure from the approach of the Interim Measures and the Draft Ordinance, neither of which contains such a blanket prohibition in their provisions regarding overseas data sharing. The PHI Measures place emphasis on data sharing among health institutions in China: Art. 1 lists the promotion of "interconnection, intercommunication and shared use of population health information" as among the *raison d'être* of the PHI Measures. This is reiterated twelve articles later in Art. 13, which enjoins responsible entities to ensure that population health information is "gradually interconnected and shared." Both the text of Art. 13 and the Interpretation clarify that this greater interconnectivity shall promote the improvement of medical research, and services for the convenience of the people.

The PHI Measures impose several requirements on data access and use. In the area of data access, Art. 13 provides for a timely and proactive disclosure of infor-

mation, subject to the condition that such information can be legally disclosed in the first place. The responsible entities shall provide secure channels through which data subjects can inquire about their population health information and obtain reproductions of such data.⁶⁷ On this point, the Interpretation adds that the informational statistical yearbook should be open to the public and released on time. Furthermore, the Interpretation explicitly states that it is forbidden to leak confidential and private information, but refrains from defining the terms "confidential" and "private information."

Data use is subject to similar regulatory requirements as those of data access. The PHI Measures direct responsible entities to establish a system for the comprehensive use of population health information, but does not go into any specific details except to empower responsible units to "authorize the use of relevant population health information." Both individuals and responsible entities are prohibited from publishing any information beyond the scope of what is authorized by these responsible entities.⁶⁸ The Interpretation adds that requests for data access shall be done in writing; data users and responsible data entities shall sign an agreement clarifying the methods and purposes for which the data will be utilized. This agreement shall also outline who can be held responsible for possible adverse consequences that flow from the data being improperly accessed.

In contrast to both the Interim Measures and Draft Ordinance, the PHI Measures offer extensive provisions on information security and privacy protection. Responsible entities are charged with setting up and strengthening measures that guarantee the security of population health information systems.⁶⁹ The PHI Measures also require that responsible entities establish tracing systems that identify and monitor users who create, amend, or make inquiries into population health information.⁷⁰ Similarly, responsible entities are tasked with implementing a notification system whereby the relevant data entity will be contacted upon discovery of a data violation.⁷¹

The PHI Measures and the Interim Measures/Draft Ordinance/Service Guide: Key Differences

The privacy interests of research participants play a more prominent role in the PHI Measures than they do in the Interim Measures, Draft Ordinance, or Service Guide. For one, information security and protection of privacy are both affirmed as overarching concerns in the collection, use, and administration of population health information in the PHI Measures.⁷² Likewise, the Interpretation document affirms the importance of protecting citizens' privacy given the increasing security threats confronting population

health information. Such an emphasis on the importance of privacy and information protection may stem from recent high profile legal cases involving genetic discrimination, such as the *Foshan* case discussed above. In conjunction with a relatively greater focus on privacy, the PHI Measures also offer provisions on data quality and data access that are absent in the Interim Measures, the Draft Ordinance, and the Service Guide. Arts. 13–18 of the PHI Measures require responsible entities to establish various systems to ensure the protection of data, including the establishment of security structures⁷³ and tracing systems,⁷⁴ thereby imposing more extensive data protection requirements than either the Interim Measures, the Draft Ordinance, or the Service Guide. A particularly important difference in the requirements relates to overseas storage of information. While the Interim Measures permitted foreign collaborators to have access to Chinese genetic information as long as they receive the permission from the Chinese partner institutions, the PHI Measures include a blanket prohibition on the storage of population health information overseas.⁷⁵ While the rationale behind this prohibition is unclear, it may reflect a continuing concern — as seen in the Interim Measures — with the exploitation of human genetic materials by foreign enterprises.

Interim Measures on the Ethical Review of Biomedical Research Involving Human Subjects

The Interim Measures on the Ethical Review of Biomedical Research Involving Human Subjects (Ethical Review) was released by the Ministry of Health (renamed National Health and Family Planning Commission in 2013) in 2007 as an overarching guideline for research ethics.⁷⁶ Section 14(4) lists respect for the privacy of research participants as one of the ethical principles of biomedical research involving human subjects. Researchers are charged with truthfully communicating to research participants any information relating to the storage and use of their private data as well as the privacy protection measures employed by the researchers. Furthermore, researchers are explicitly prohibited from disclosing a research subject's data to unrelated third parties or the media. Beyond these prohibitive clauses, there is no mention of procedures for data transfer, data collection, or data quality. In April 2014, the National Health and Family Planning Commission decided to revise the Interim Measure on the Ethical Review of Biomedical Research Involving Human Subjects, and openly solicited public opinion on the matter.⁷⁷

Table 1

Laws and Regulations on Genetic Privacy in China

Regulation	Scope of Application	Main Provisions on Privacy Protection	Status	Overseas Data Sharing
Chinese Constitution [last revision 2004]	Supreme law within the PRC	Art. 38: <i>guarantees personal dignity</i> Art. 40: <i>guarantees the freedom and privacy of correspondence</i>	In force.	N/A
Interim Measures for the Administration of Human Genetic Resources [1998]	Genetic materials and derivative data (including biobank samples and data)	Art. 4: <i>No institution or individual is allowed to sample, collect, trade, export human genetic resources or take them outside the territory of the People's Republic of China, or provide them to other countries in any form without permission.</i>	Replaced by the Service Guide in 2015.	Art. 17: <i>The Chinese research and development institution shall have the priority to access information about the human genetic resources within the territory of the People's Republic of China, particularly the important pedigrees and genetic resources in the specified regions and the relevant data, information and specimens and any transfer of such human genetic resources to other institutions shall be prohibited without permission. No foreign collaborating institution or individual that has access to the above mentioned information may publicize, publish, apply for a patent right or disclose it by any other means without permission.</i>

Table I (continued)

Laws and Regulations on Genetic Privacy in China

Regulation	Scope of Application	Main Provisions on Privacy Protection	Status	Overseas Data Sharing
Draft Ordinance on the Administration of Human Genetic Resources [2012]	Genetic materials and derivative data (including biobank samples and data)	<p><i>Art. 14: The collection and preservation of human genetic resources shall follow voluntary and informed consent principles. Before collecting the materials of human genetic resources, the collection unit shall provide a written informed consent to each resource provider, which includes the purposes of collection, the use of human genetic resources, the potential health risks, the sharing of benefits, the protection of individual privacy, the right to voluntarily participate, and the right to unconditionally withdraw at any time, and so on</i></p> <p><i>Art. 16: The institutions approved to collect and preserve human genetic resources may provide these resources for others' research and development activities that resource providers have consented to, but take effective measures to protect resource providers' privacy and safety.</i></p>	Draft stage. May replace the Service Guide when it comes into force.	<p><i>Art. 22: Any international collaborative research and development activity involving Chinese genetic materials within the territory of the People's Republic of China is subject to the following requirements: (1) The domestic partner is a legal entity within the territory of the People's Republic of China; (2) Cooperating parties have the basis and ability to engage in related research; (3) The duration of cooperation is clear; (4) The source of human genetic resources is clear and legal; (5) It is approved by cooperating parties' Ethics Review Committees; (6) Intellectual property ownership is clear, and sharing schemes of research results are reasonable; (7) There is no harm to China's national security, national interests, and social and public safety.</i></p> <p><i>Art. 30: The export of human genetic resources collected within the territory of the People's Republic of China requires approval from science and technology administration authorities under the State Council.</i></p> <p><i>Art. 31: The export of Chinese human genetic resources outside China's borders is subject to the following conditions: (1) The purpose of export is to carry out approved collaborative research and development activities; (2) It is indeed necessary to export human genetic resources outside China's borders; (3) After export, research and development activities to be carried out are in accordance with approved collaborative research and development programs; (4) Foreign entities receiving human genetic resources are cooperating partners of approved research and development activities; (5) There is no harm to national security, social and public safety, and national interests; (6) It is reviewed and approved by Ethics Review Committees from cooperating parties; (7) It complies with other conditions provided by relevant laws and regulations.</i></p>

Table I (continued)

Laws and Regulations on Genetic Privacy in China

Regulation	Scope of Application	Main Provisions on Privacy Protection	Status	Overseas Data Sharing
Administrative Licensing Service Guide for the Review and Approval of the Collection, Preservation, Trade, and Export of Human Genetic Resources [2015]	Genetic materials and derivative data (including biobank samples and data)	N/A	In force. Transitional regulations pending final approval of the Draft Ordinance on Human Genetic Resources.	Regulated <i>7(2) Export of Human Genetic Resources</i> <i>2.1: Applications for carrying out the export of human genetic resources are subject to the following conditions: (1) Cooperating parties have the basis and ability to engage in related research; (2) The collaborative objectives and schemes are clear; (3) The duration of cooperation is clear; (4) The source of human genetic resources is clear and legal; (5) There is a draft text of the contract; (6) It is approved by the cooperating parties' Ethics Review Committees, and the informed consent form is provided to the human genetic resource provider; (7) Intellectual property ownership is clear, and sharing schemes are reasonable; (8) There is no harm to national security, national interests, and social and public safety; (9) (7) It complies with other conditions provided by relevant laws and regulations.</i>
Interim Measures on the Ethical Review of Biomedical Research Involving Human Subjects [2007]	Research data	<i>Sec. 14(4): The respect for the privacy of research subjects is one of the ethical principles of biomedical research involving human subjects. Researchers are charged with truthfully communicating to research subjects' any information relating to the storage and use of their private data as well as the privacy protection measures employed by the researchers. Furthermore, researchers are explicitly prohibited from disclosing a research subject's data and situation to unrelated third parties or the media.</i>	Under revision as of October 2015.	N/A

Table I (continued)

 Laws and Regulations on Genetic Privacy in China

Regulation	Scope of Application	Main Provisions on Privacy Protection	Status	Overseas Data Sharing
Management Measures for Population Health Information (Trial Implementation) [2014]	Population and personal health information. Genetic information in health institutions?	<p><i>Art. 8: Data collection units are obliged to adhere to the principle of “one data, one source”.</i></p> <p><i>Art. 9: Responsible entities shall safeguard the integrity of the data by setting in place data recovery and data back-up processes.</i></p> <p><i>Art. 10: Responsible entities shall ensure that data is up-to-date, continuous and valid, while also prohibiting population health data from being stored on servers overseas.</i></p> <p><i>Art. 13: Confidential information and individual private information shall not be provided to the external parties.</i></p> <p><i>Art. 14: Individuals and responsible entities are prohibited from publishing any information beyond the scope of what is authorized by these responsible entities.</i></p> <p><i>Art. 15: The responsible entities shall provide secure channels through which data subjects can inquire about their population health information and obtain reproductions of such data.</i></p> <p><i>Art. 16: Responsible entities are charged with setting up and strengthening measures that guarantee the security of population health information systems.</i></p> <p><i>Art. 18: Responsible entities shall establish tracing systems that identify and monitor users who create, amend or make inquiries into population health information.</i></p>	In force.	<p>Overseas data storage prohibited.</p> <p><i>Art. 10: ...The responsible entities cannot store population health information on servers located overseas, and cannot host or rent servers located overseas.</i></p>
Law of the People’s Republic of China on Medical Practitioners [1999]	Personal health information	<i>Art 22(3): Doctors are subject to criminal sanctions if they sell or illegally provide personal information of citizens to others which results in serious consequences.</i>	In force.	N/A

IV. Critical Evaluation of Privacy Framework *Genetic Data as “National Resources”*

It is important to note that the Chinese laws applicable to biobanks were not drafted with the protection of personal privacy as their highest priority. In the incipient stages of biobank development in China, the overriding concern was bio-piracy by foreign researchers who, it was feared, would help themselves to Chinese genetic materials in the same way the European powers used Chinese raw materials during the Western imperialism period. Indeed, the Interim Measures were enacted in 1998 following a few high profile incidents of bio-piracy including the “Anhui incident,” first reported by *Science* magazine in 1996.⁷⁸ The controversy centered on a scientific project affiliated with Harvard University and Millennium Pharmaceutical Company involving the collection of 200 million DNA blood samples in a rural part of Anhui province. While the lead scientist was himself an Anhui native and the sampling was done as part of a study of various major diseases, the Chinese somewhat paradoxically framed the incident as one of foreign exploitation. Prominent Chinese scientists warned that China’s population genetic data could become a priceless resource for foreign pharmaceutical companies.⁷⁹ The negative attention given to the *Science* report eventually led President Jiang Zemin to comment publicly on the need to “cherish our genetic resources.”⁸⁰ Shortly thereafter, the Ministry of Science and Technology and the Ministry of Health released the Interim Measures in order to restrict foreign researchers’ ability to collect and transfer genetic samples outside of the country.

Critique of the Interim Measures

As the Interim Measures were crafted to respond to fears of foreign exploitation, it should not be surprising that the protection of the privacy of the genetic data does not feature prominently in the document. Most of the provisions were concerned with what researchers and institutions may or may not do with the samples. There was no mention in the general principles of the rights or interests of the research participant. The bulk of Chapters 2 and 3 of the Interim Measures was concerned with the administrative oversight of genetic research and with articulating the requirements that an international collaborator would have to meet in order to obtain approval for research projects carried out in China. Chapter 4, on intellectual property, provided a passing mention of personal data (discussed below). As such, the most important sections of the Interim Measures had little bearing on data transfer and privacy protection.

Given the Interim Measures’ primary concern that China’s genetic resources remain in the hands of Chi-

nese researchers and institutions, it was criticized as a weak instrument for the protection of personal data. Wang criticized the Interim Measures for being “reactive legislation” to genetic resource loss cases such as the Anhui incident and for focusing almost exclusively on the interests of the state in genetic research while lacking protection for human subjects and target groups.⁸¹ Such a critique is not unwarranted. While Art. 17 constituted the Interim Measures’ most explicit attempt to protect the private nature of personal data, by prohibiting foreign collaborators from publicizing and publishing data that is relevant to Chinese genetic resources, the interests of the resource provider were not the real focus of the protection. Particularly telling is the provision’s placement in the document: Art. 17 was under the chapter on “Intellectual Property Rights,” appearing in the same provision as the prohibition on foreign collaborators applying for patent rights. Furthermore, the Interim Measures were silent on the research participant’s access to his or her genetic data and on requirements of informed consent, data storage, and preservation. Read in this context, the prohibitions against disclosure existed essentially to ensure that Chinese scientists remained, as Wen-Ching Sung puts it, the “gatekeepers” of Chinese genetic materials.⁸²

Critique of the Draft Ordinance

The Draft Ordinance devotes marginally more attention to data protection and privacy while retaining its predecessor’s focus on the state’s interest in genetic resources. The Draft Ordinance contains a provision stating that institutions and individuals handling genetic resources may provide genetic data derived from their collection to third parties for research purposes only upon receiving the consent of the resource provider.⁸³ The additional requirements that institutions keep detailed records of data usage and take measures to protect a resource provider’s privacy and security signal an increasing recognition of the importance of protecting the personal interests of the resource provider rather than an exclusive focus on the collective interest in protecting ownership of human genetic resources.

That being said, one should be careful not to overemphasize the Draft Ordinance’s concern with the interests of the donor. Like the Interim Measures it is meant to replace, the Draft Ordinance continues to view genetic material first and foremost as a resource that exists for the benefit of the collective Chinese population. That the Chinese legislature primarily sees genetic materials through a collective interest lens is confirmed in the section on legal liability, which imposes liability for privacy violations that *bring*

about a socially harmful effect (造成不良社会影响的) (emphasis added).⁸⁴ In addition, the provisions on privacy protection are buried in a chapter that is largely concerned with the various administrative processes involved in obtaining permission to collect and preserve genetic materials (e.g., deadlines for obtaining various certificates). Other than issuing requirements for consent, detailed records, and effective privacy and security measures, the provisions on data protection and privacy are short on details; there is no informa-

ter in the world,⁸⁵ also collaborates with hospitals by analyzing clinical samples. BGI provides testing services in the areas of reproductive health, infectious diseases, blood diseases, and cancer.⁸⁶ Many disease-specific biobanks are also set up in Chinese hospitals.⁸⁷ Given the high degree of interaction, resource sharing, and proximity between these biobanks and their host/partner hospitals, it may be somewhat artificial (or even inaccurate) to categorize such biobanks' data as exclusively "research data" for the purposes of regulat-

The increased blurring of the lines between research and health care raises the problem of institution-specific or sector-specific regulation of personal data. Insofar as such an approach relies on strict compartmentalization of the institutions (i.e., as research or health) handling the information, it risks overlooking the symbiotic relationship between genomic research and health care. This relationship is implicitly recognized in the PHI Measures; Art. 1 states that the PHI Measures are formulated in such a way that the administration of population health information can "*propel scientific development of the health and family planning industries*" (emphasis added). Insofar as there is a subset of health information susceptible to being appropriated for research purposes, the PHI Measures' blanket prohibition on the storage of population health information outside the PRC may have a particularly negative effect on Chinese research institutions' ability to collaborate with foreign institutions on major genetic research projects.

tion concerning the concrete steps that a research entity should take to protect a donor's privacy and to ensure that the data are kept at a certain quality. The idea of genetic materials as an important repository of personal data warranting protection, while recognized more explicitly in the Draft Ordinance than in previous laws, continues to be an ancillary concern.

The Scope of the PHI Measures

Despite its obvious implications for the use and protection of genetic and health information, it remains to be seen whether the PHI Measures apply to biobanks. As the wording of Art. 3 seems to limit the scope of the PHI Measures to health institutions, biobanks that perform a purely research function will almost certainly be governed by the Draft Ordinance rather than the PHI Measures. However, it is more difficult to predict whether biobanks that collaborate closely with health institutions will fall within the scope of the PHI Measures. For instance, the Beijing Genomic Institute (BGI), the largest genome sequencing cen-

ing data protection and data transfer. As a corollary, it may be equally artificial and inaccurate to characterize host/partner hospitals purely as health care institutions when they are so heavily involved in the work of research biobanks.

The increased blurring of the lines between research and health care raises the problem of institution-specific or sector-specific regulation of personal data. Insofar as such an approach relies on strict compartmentalization of the institutions (i.e., as research or health) handling the information, it risks overlooking the symbiotic relationship between genomic research and health care. This relationship is implicitly recognized in the PHI Measures. Art. 1 states that the PHI Measures are formulated in such a way that the administration of population health information can "*propel scientific development of the health and family planning industries*" (emphasis added). Insofar as there is a subset of health information susceptible to being appropriated for research purposes, the PHI Measures' blanket prohibition on the storage of popu-

lation health information outside the PRC may have a particularly negative effect on Chinese research institutions' ability to collaborate with foreign institutions on major genetic research projects.

Furthermore, it may be worth asking whether it is in the interest of patients/donors to have divergent data protection regimes governing the same kind of data. Considering that the hospitals performing genetic counselling services for patients are also the sites where biobanks collect tissue samples, there may be a legitimate expectation on the part of the patient/donor that the same data will be subject to identical or similar privacy, security, and transfer measures. Any sort of uncertainty as to the degree of protection genetic data will receive once entered into biobanks risks undermining public confidence in biobanks and discouraging potential research participants.

V. An Example of Implementation of the Legal Framework at the Local Level: The Shanghai Biobank Network

While the national instruments collectively seem to cover the main topics of biobank regulation, the task of implementing these requirements (e.g., security policies, informed consent) in the context of international genomic research is left largely to the individual biobanks. To help them fill the regulatory gaps, Chinese biobanks look increasingly to international norms. The guidelines released by the Shanghai Biobank Network in 2014 serve as a good example of this trend and are worthy of close examination.

Following international guidelines, such as UNESCO's International Declaration on Human Genetic Data and the U.S. National Bioethics Advisory Commission's policy guidance document, *Research Involving Human Biological Materials*, the Shanghai Clinical Research Center Independent Ethics Committee formulated the Ethical Management Guidelines for the Shanghai Biobank Network (Shanghai Guidelines). The Guidelines are composed of seven chapters: general principles; informed consent; use of bio-samples from persons without the capacity to consent; privacy and confidentiality; applications of use of biological samples and data; intellectual property and resource sharing; and conflict of interest.⁸⁸

The Shanghai Guidelines stress the importance of privacy protection in biobanking. The section on privacy and confidentiality explicitly recognizes that discrimination and stigmatization can result from infringements of privacy.⁸⁹ In contrast with the national regulatory and legal instruments, the Shanghai Guidelines contain detailed de-identification policies, requiring "institutes involved in the storage, use, and disclosure of information concerning their

biological materials and relevant data should follow well-documented procedures to protect the privacy and confidentiality of the donors. Such procedures may include: encoding, encrypting, anonymizing, or removing all identifying information."⁹⁰ The Guidelines further specify the kinds of the information that should be encrypted, listing names, ID card numbers, and date of birth as examples. Where permission is granted to match data with the biological specimen for the purposes of a study, researchers shall restore the encryption immediately upon expiration of the permission.⁹¹ Along the same lines, any comparative study that involves matching data with personal information shall have such data de-identified immediately upon the conclusion of the study.⁹²

The Shanghai Guidelines also request that all participating institutes establish information security regulations. Concerning tiered access to specimens and data, the Shanghai Guidelines provide that only authorized staff shall be given access to particularly sensitive information, such as the donor's identifiers, diagnoses, family history, and medical history. Staff shall be required to sign a confidentiality agreement.⁹³ The different tiers of access shall be stipulated in the operations manual and, when appropriate, access shall be subject to the approval of an ethics review committee.⁹⁴ Finally, the number of staff given such authorization shall be kept to a minimum and those authorized shall be subject to timely supervision to ensure that standard procedure is being duly followed.⁹⁵

In terms of data sharing, the Shanghai Guidelines provide that prior to the transfer of biobanking material, all participating institutes shall receive the permission of the Ethics Review Committee and sign Material Transfer Agreements. Furthermore, there is a requirement that the process for releasing the specimens, data, and information be based on the principle of fairness and impartiality.⁹⁶ Biological materials and associated data stored in the Shanghai Biobank Network shall not be exported overseas except under special circumstances, such as when biological samples of rare diseases are needed for research in a foreign country. Exportation of biological materials and associated data is subject to the requirements found in the Draft Ordinance on the Administration of Human Genetic Resources and shall be approved by competent authorities.⁹⁷

On the topic of informed consent for use of samples in future research, the Shanghai Guidelines explicitly recommend the model of "broad consent" with an opt-out option.⁹⁸ This explicit endorsement of broad consent marks a new development in the regulation of Chinese biobanks, bringing with it both promise and peril. While broad consent lightens the load

for researchers, it may be problematic in the case of uneducated participants who, in addition to being underexposed to concepts such as privacy and consent, will likely struggle to grasp the abstract concept of consenting to future, unspecified research on their biological materials. There is indeed evidence to suggest that Chinese biobank participants do not always understand what it means to give informed consent or what it is that they are consenting to.⁹⁹ The Chinese legislature may wish to consider ways of protecting this vulnerable population in future policy developments.

VI. Conclusion

The increasing importance of biobanks in China's national research agenda, along with the emerging consensus around the value of individual privacy, has spurred the establishment of new privacy policies at the national level. The distinctive regulatory approaches adopted by different departments have, however, resulted in a certain degree of uncertainty, confusion, and tension that continues to go unresolved. This has had the effect of hindering policy implementation. In particular, our analysis has revealed a tension between conceiving genetic information as a repository of personal information and as a collective national resource. Furthermore, the increasing collaboration between biobanks and hospitals has brought into question the distinction between information used for research and information used for clinical care on which recent regulations seem to be premised. Greater dialogue and cooperation between government departments in regulatory drafting and implementation could provide greater certainty and coherence to the privacy landscape with regards to biobanks. Furthermore, while the recently released Shanghai Guidelines should be applauded as an effective attempt at regulatory "gap-filing," establishing uniform standards at the national level and applying them consistently will help facilitate large-scale collaboration between Chinese biobanks in the future. Finally, these guidelines also raise issues relative to "broad consent" given the lack of appreciation for the concept and importance of informed consent among some segments of the Chinese population. Greater attention to such a risk may help increase overall confidence and trust among potential biobank participants.

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92. *Id.*, at Art. 23.
93. *Id.*, at Arts. 26 and 28.
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95. *Id.*, at Art. 29.
96. *Id.*, at Art. 35.
97. *Id.*, at Art. 37.
98. *Id.*, at Arts. 11 and 33.
99. During a study conducted with participants in a population-based biobank project in rural China, for instance, Chen observed that many participants did not understand the concept of informed consent and had barely even read the consent form. See H. Chen, "Governing International Biobank Collaboration: A Case Study of China Kadoorie Biobank," *Science, Technology and Society* 18, no. 3 (2013): 321-338, at 329.