Perspectives

The Biobank Act as a Route to Responsible Research: A First Step for Taiwan?

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In recent years, biobanks have been established around the world to monitor the health status of participants over time, to assess the natural occurrence and progression of common diseases. Therefore, it is not surprising to learn that traditional ethical and legal issues such as informed consent, privacy protection, data security, non-discrimination, autonomy and self-determination have occupied a central place in the regulatory debates on biobanks. In the midst of controversies raised by human rights organizations and aboriginal rights groups, Taiwan’s Human Biobank Management Act (“the Act”) was passed by the Legislative Yuan on January 7, 2010 and came into effect on February 3 in the same year. While the Act addresses the absence of biobank regulations, it could also have a marked impact upon local biomedical research communities. It is therefore necessary to address the coverage of the Act, which is one of the key issues surrounding this legislation.

The Act was originally designed to regulate the establishment and management of biobanks; mainly, the collection and storage of human biological samples and associated data. According to Article 3(4), a regulated biobank that contains biological specimens from human subjects, along with related information and data, should also have the following two characteristics: (1) it should provide for biometrics-related research, which is population- or specific-group-based; and (2) it should be maintained with linkable data. In other words, in addition to the regulation of biobanking, the Act also regulates biomedical research activities that originate from the use of biological specimens and data from biobanks.

Biomedical research that does not use biological specimens or data from biobanks is not covered by the Act. Any specific research in which biological specimens and associated data are collected and then destroyed or delinked upon completion of the research is not deemed to be a biobanking project. On the contrary, archive collections without a defined research purpose are targets of the Act. This includes collections that have biological specimens and data collected for a general, undefined purpose other than immediate research use, as well as those maintained by many university laboratories from earlier studies.

Among other things, it is worthwhile to note that Article 29 does give rise to a question regarding...
the precise coverage of the Act. This Article provides that “Articles 6, 15, 16 and 20 shall apply, where appropriate, to the collections and use of biological specimens used in biomedical research which is not based on population groups or specific groups, unless otherwise provided.” Under this Article, some specimen collections or uses that do not fit into the definition of a biobanking project or biobank-related research are still subject to Articles 6, 15, 16 and 20 of the Act. Article-29-type research only refers to biomedical research that is not based upon populations or specific groups, therefore, it is certainly an exaggeration to say that the Act governs all kinds of medical research. However, it does raise a difficult question as to how and to what extent Articles 6, 15, 16 and 20 are applicable to Article-29-type biomedical research.

Clearly, the application of Article 6, which regulates consent to biobank research, to Article-29-type biomedical research does not give rise to any difficulties. Article 6 of the Act requires that the collection of biological specimens be conducted in compliance with medical ethics and research ethics, as well as undertaken with legally valid, written informed consent from participants. However, the application of Article 15 to Article-29-type research seems troublesome, because the former states that “biological specimens of the Biobank, other than the derivatives, shall not be exported” and “any international transmission of Biobank data or the export of any derivatives mentioned in the preceding Paragraph shall be submitted to the Competent Authority for approval” [Articles 15(1) and 15(2)]. In the case of specimen collection and uses limited to specific population-based research, such as disease-specific clinical trials, Article 15 is inapplicable because it is not a biobanking project nor biobank-related or Article-29-type research. However, for non-population-based biomedical research, the prohibition on exporting biological specimens might become a new obstacle for those who need some freedom to transfer biological specimens internationally for a specific research purpose. In other words, this new legal approach regarding exportation of biological specimens is to some extent at odds with biomedical research practices. Some minor revisions of Articles 15 and 29 might be unavoidable in the near future.

A more careful reading of Article 20, which requires biobank-related and Article-29-type research to follow the “biomedical research purposes only” principle, also raises uncertainties as to how and under which criteria ethics committees, at the biobank operator and Department of Health levels, will determine whether medical research is qualified for exemption from Article 20. Article 20 provides that “any use of biological specimens, derivatives and relevant data and information in the Biobank shall not be used for purposes other than biomedical research. Medical research approved in accordance with Article 5, Paragraph 3 hereof shall not be subject to this rule.” Is it the true intent of the legislature to authorize the ethics committees to exercise a general consent power on behalf of the participants? If so, what are the conditions and limitations that should be taken into account when the ethics committees grant such permission? Such questions, along with the obligations imposed by Article 30 that require corrective actions in accordance with the Act for pre-existing biobanks, present a serious challenge for ethical governance of medical institutions and researchers. Article 30 provides that for any biobank established prior to the enforcement of the Act, its operator shall destroy and may not reuse any and all biological specimens and related data and information, if the operator fails to finalize the necessary corrective actions in accordance with the Act within 1 year after the Act takes effect.

In conclusion, this new Act does add something meaningful to the incomplete legal landscape for the regulation of biomedical research in Taiwan. However, it is fair to say that the extended coverage of the Act, enabled by Article 29 and the ambiguous definition of biomedical research in Article 3(3), has created difficulties that are not easily resolvable through any reasonable interpretation of the above Articles. The interpretative difficulties will soon emerge as one of the
major regulatory uncertainties for local biomedical research communities. On balance, as the Act was originally designed to regulate biobanking and biobank-related research, it is a more sensible proposal to have this Act play a constrained role. Although it is now time for medical research institutions to stop complaining about the burden imposed by the Act, and to figure out a practical model for maintaining and overseeing their pre-existing biobanks, it is also urgent for the legislature to pass a general law to regulate biomedical research and excuse the Biobank Act from its current awkward role as soon as possible.

References