

# Workshop Proceedings: Informed Consent in Biobanking—from the Key Barriers, Challenges, and Perceptions to Digital Innovations

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## INTRODUCTION

Biological material of human and nonhuman origin has been collected for decades, creating repositories through the years that serve as source for research and education, with the ultimate goal to establish a high-quality healthcare system on international levels and to introduce novel therapeutic approaches based on personalization.<sup>[1]</sup> *Biobanking* is a general term used for the collection, storage, and procurement of biological materials, and its standard discipline. Biobanking has evolved from small university-based repositories for specific research to infrastructures that accommodate biosamples for large-scale national and international purposes, annotated with related clinical data and information, essential for fundamental science.<sup>[2,3]</sup> Collection and utilization of human biospecimen in all kinds of research activities have become a priority to health-related organizations; biospecimens have increased rapidly both in size and in number, leading to new trends and needs in biobanking that must incorporate big data and modern technologies requirements.<sup>[4]</sup>

As the biobank market grows globally, international collaborations for sample collection and dissemination have expanded. The demand for evolution in biobanking best practices seems to be unavoidable, so as to prevent not only technical issues in biospecimen collection, processing, and storage but also ethical, legal, and social issues arising from the extended use of biospecimens and their primary and secondary data in new research areas.<sup>[5,6]</sup> For these purposes, standardization of procedures for both biosample and associated metadata management and tracking are essential for current biobank operational systems and biospecimen quality assurance.<sup>[7]</sup>

Biobanks' organization and operation are based on models of working processes as well as national and international regulatory standards for compliance. These processes ensure, on one hand, the proper biosample handling and link of data, and on the other, donors' autonomous rights and data protection.<sup>[8]</sup> International best practices and guidelines for biospecimen handling and facilities requirements that can assure certification or accreditation are already implemented in biobanking networks.<sup>[9]</sup> In addition, inventory database systems for tracking are specifically designed to meet federal requirements related to data privacy and security.<sup>[10]</sup> Nevertheless, sets of compliance requirements for data protection, seem to be more complicated on international levels, considering the main regulations applied in the European Union and United States.<sup>[11,12]</sup> Despite their differences, both sets of standards set the same following goals: to protect individuals' privacy by securing and regulating current and downstream data collection, transmission, analysis, and disclosure; and provide them with rights over their biospecimens and sensitive data.<sup>[13,14]</sup> But, these diverse regulatory schemes and approaches of biobanking governance among countries might lead to significant barriers in biosample export and authorization for worldwide utilization in research activities.<sup>[15]</sup>

As part of the regulatory schemes that have been set, one of the most important principles in current biobanking and research is the consent procedure by which donors' give their permission for future biosample and data processing.<sup>[16]</sup> Informed consent is a mandatory part of the donors' welfare system; it is required for any type of research-related activities that use human beings as subjects, combining ethical, legal, and practical implications.<sup>[17,18]</sup> The main scope of this procedure is to provide information to participants for data disclosure.

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