

New Standards and Updated Best Practices will Give Modern Biobanking a Boost in Professionalism

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The biobank community is facing great times but also huge changes in the near future. We are entering a new phase in modern biobanking characterized by professionalism in all areas of biobanking, driven by and based on newly developed standards and best practices (BP). All these activities will have a significant impact on the future of modern biobanking and usher in a new era. Modern biobanking in the narrower sense has not existed for that long. Of course, samples and data have been collected for a long time and research has been conducted. But only the publication of the human genome at the turn of the millennium increased the demands for well-annotated samples and data of defined quality. In the first decade of this century, the major issues for biobankers were questions such as who actually owns the samples and data, what form of informed consent should be used, or what is the definition for a biobank? In addition to the mentioned ethical, legal, and social issues, questions about the quality and how the samples should be collected and stored were discussed intensively. In the following decade, the focus shifted more toward the sustainability of biobanks. As a result, the financial, social, and operational dimensions of sustainability were intensively discussed. A second issue was the non-reproducibility of preclinical research and how to deal and overcome this very costly problem. And now, shortly before the 2020s, the introduction of various standards and BP will lead to further and increased professionalism in modern biobanking.

Therefore, the past two decades have shown an impressive development in modern biobanking. The International Society of Biological and Environmental Repositories (ISBER), established in 1999, played a key role in shaping the area of biobanking during this period. Sharing successful strategies for conserving biological and environmental samples for research and ensuring biodiversity was one of the early driving forces behind the creation of ISBER. In addition, ISBER promotes education and research and promotes quality and safety in all activities related to the collection, storage, and distribution of samples. Out of this endeavor arose the first edition of the ISBER BP more than 10 years ago. From the beginning, the BP reflected the collective experience of ISBER members. The focus of the first edition was on the management of human sample collections. However, since most of the contributions to the first edition came from individuals based in the United States, this edition was considered as mainly reflecting the perspectives of the United States. In the next two editions of the ISBER BP published in 2008 and 2012, respectively, the focus has been expanded to include new and relevant areas in biobanking and a wider viewpoint.

The first and second editions of the ISBER BP were the work products of the ISBER Education and Training (E&T) Committee under the leadership of Karen E. Pitt as editor-in-chief. For the third and fourth editions, Lori D. Campbell served as editor-in-chief. For the fourth edition, the ISBER Standards Advisory Committee that was established early in 2017 provided leadership and oversight in the development. An International Review Board including non-native English-speaking experts in the field reviewed the different documents of the update at a very early stage and provided support to make sure the text will be easily understood even by non-native English-speaking biobankers. Still, the ISBER

BP will be translated into different languages according to the needs of the ISBER members in the different regions. Lori and her team did a tremendous job developing and updating the fourth edition of ISBER BP into an extremely valuable source that will enable the biobanking community to meet the challenges of the next years to come.

In this issue of BIO, there is a “Special Section on Standards, Tools and Best Practices for Modern Biobanking.” This special section includes a summary of the fourth edition of the ISBER BP. The full text of ISBER BP can be downloaded free of charge from the ISBER website (www.isber.org/bestpractices). This summary outlines the most relevant changes from the third to the fourth edition. In addition, you will find four articles about tools and programs that are based on ISBER BP and as such will need to be updated in the near future to include the changes of the fourth edition of the ISBER BP. One such tool is the ISBER Self-Assessment Tool (SAT) that is available at no cost for ISBER members. Fay Betsou in her article gives an overview of SAT and why it should be used as part of any quality management system. The SAT algorithm is based on ISBER BP as is SPREC (Standard PREanalytical Code). The ISBER Biospecimen Science Working Group has updated some of the seven-element codes corresponding to the most critical preanalytical variables of fluid and solid biospecimens. The article by Sheila O’Donoghue et al. outlines the ISBER—CTRNet (Canadian Tissue Repository Network) education program for biobanking, which is also based on the ISBER BP. Programs like this are a crucial part of improving professionalism in biobanking. Also based on ISBER BP and other standards is the College of American Pathologists Biorepository Accreditation Program (CAP BAP). The CAP BAP was launched in 2012 for U.S.-based biobanks. Shannon McCall et al. shared the results of the first 5 years of CAP BAP. A need for additional education and clarification was identified to continue the growth and acceptance of this program. Also, we expect the publication of the international biobanking standards (ISO 20387) later this year. Koh Furuta et al. provide the latest update of the activities in ISO/TC 276/WG 2 Biobanks & Bioresources.

What will be the next steps? As already mentioned, tools such as the ISBER SAT, SPREC, ISBER—CTRNet biobanking education program, CAP BAP, and others that are based on ISBER BP will need to be updated. Workshops and symposia about the changes in the fourth edition are being organized. A communication plan was developed by the ISBER communication committee under the leadership of its chair, Cathy Seiler, and with the input of multiple senior leaders of ISBER. So, you will hear a lot about ISBER BP in the next few months. This includes, but is not limited to, ISBER BP activities planned at the annual ISBER meeting in Dallas, TX, in May of this year. We are convinced that the fourth edition will help you and your biobank to improve and allow biobanks to better serve the research community. Please keep in touch with us. Comments and suggestions are welcome (bestpractices@isber.org).