Since January 2020 Elsevier has created a COVID-19 resource centre with free information in English and Mandarin on the novel coronavirus COVID-19. The COVID-19 resource centre is hosted on Elsevier Connect, the company's public news and information website.

Elsevier hereby grants permission to make all its COVID-19-related research that is available on the COVID-19 resource centre - including this research content - immediately available in PubMed Central and other publicly funded repositories, such as the WHO COVID database with rights for unrestricted research re-use and analyses in any form or by any means with acknowledgement of the original source. These permissions are granted for free by Elsevier for as long as the COVID-19 resource centre remains active.
A short report of Biosafety and Biobanking: current understanding and knowledge gaps

Julie Roux¹,², Maissa Zeghidi¹,², Stephanie Villar¹, Zisis Kozlakidis¹

Institutions

¹ World Health Organization, International Agency for Research on Cancer, Lyon, France.
² Ecole Supérieure de Biologie-Biochimie-Biotechnologies, Université Catholique de Lyon, Lyon, France.

Corresponding author:
Zisis Kozlakidis
International Agency for Research on Cancer/World Health Organization
150 cours Albert Thomas
69372 Lyon CEDEX 08, France
E-mail: kozlakidisz@iarc.fr
Abstract

Infectious disease outbreaks, such as 'Coronavirus Disease 2019' (COVID-19), can constitute major global health threats with far-reaching consequences. As outbreaks develop, the international scientific community must provide high-quality scientific research-ready biological samples to solve the existing clinical and epidemiological questions to better combat the pandemic. Such examples are provided by dedicated biobank facilities, the latter collecting increasingly high volumes of biological samples.

However, the more significant concentrations of infectious or potentially infectious biological materials can create a safety risk. The current short report describes the first attempt to identify the published scientific works on biobanking and safety. Three broad thematic areas have been identified: the physical security relevant to staff and sample integrity, the data safety aspects, and the governance parameters relating to the previous two. While the current publications reflect a broad alignment with existing standards and best practices in the biobanking field, they also demonstrate an opportunity for further in-depth work on this field in the post-COVID-19 era.

Keywords: Biosafety; Biobank; Data safety; Biological safety; Safety regulations
Introduction

Infectious disease outbreaks, such as 'Coronavirus Disease 2019' (COVID-19), can constitute major global health threats with far-reaching consequences. The COVID-19 pandemic swept the world within a short period, causing heavy damage to global public health security and human health [1-3]. As outbreaks develop, the international scientific community must provide high-quality scientific research results to solve the existing clinical and epidemiological questions to better combat the pandemic. The following sample types comprise the essential and fundamental biological materials for such research: blood, serum, throat swabs, sputum, tracheal suction fluid or bronchial lavage fluid, urine, feces. They can be collected after appropriate consent from confirmed patients, asymptomatic infected persons, suspected patients, and their close contacts, as well as from dead patients' cadaver tissues and organs.

The above can prove critical in our understanding and research if accompanied by clinical data – and because the associations are often weak, samples can be needed in large quantities. Simultaneously, several laboratory and analytical processes can accommodate the required high-throughput processing of samples. The implication is clear: if more well-characterized, high-quality pieces are available through biobanks, the faster research will advance and impact healthcare delivery. Thus, biobanking becomes a pivotal element to future treatments' success, relied upon to standardize tissue collection for improved scientific quality. Biobanking is widely defined as a collective term that describes how biological samples (bodily fluid or tissue) and associated data are collected, annotated, stored, and redistributed for future research used to improve our understanding of diseases [4].

The handling of biospecimens in healthcare is not limited only to the technical aspect. Indeed, biobanks have to be subjected to strict ethical and legal regulations, especially those handling potentially infectious materials. Thus, biobanks have to act in concordance with specific regulatory frameworks and to develop strict, auditable procedures and controls ensuring the safety of their staff and quality of their samples for the long term [5,6]. However, the safety implications of concentrating increasingly larger volumes of samples and data within specific facilities, especially of samples that are potentially infectious, as in the case of COVID-19, have been viewed so far in an empirical way as an integral aspect of different studies.

This manuscript is a short report, systematically searching the literature for the published safety aspects of biobanks focusing on the staff's safety and the integrity of the biological materials. It was considered
timely based on the ongoing pandemic and the increasing volumes of biological material collected and utilized in research over the last two decades.

**Method**

Data sources and literature search strategy

The review of published manuscripts followed the PRISMA guidelines (Fig. 1) [7]. Two investigators (MZ and JR) independently conducted a literature search using as combined keywords biobank* or biorepository and safety, security on Pubmed ([https://www.ncbi.nlm.nih.gov/pubmed/](https://www.ncbi.nlm.nih.gov/pubmed/)) and Web of Science (v. 5.35). The database search was run of all the published articles, all languages, from database inception until August 30, 2020. In both databases, the following search strategy was used: pairs of terms were searched as follows: Biobank* AND Safety; Biobank* AND Biosafety; Biorepository AND Safety; Biorepository AND Biosafety; Biobank* AND Security; Biorepository AND Security. Biobank* was used in the search to identify longer forms, such as biobanking. It is thought that these terms would be able to locate the majority of manuscripts within a narrow definition of biosafety and biobanking. However, likely, relevant sections might not be under a separate 'safety' heading and thus more challenging to identify.

Study selection and data synthesis

All studies reporting information on safety, security, and biobanks/biorepositories were included. 766 articles were identified and reviewed independently by two authors (MZ and JR), and after all duplicates were removed, 422 articles were considered. After eliminating articles that were not in English, and those that had simply a mention of the words with no further expansion, 104 articles were considered. Of these 104 articles, 56 have a simple definition of the terms and commonly a statement that these aspects constitute necessary parameters, with no analysis or further expansion/exploration of the subject. Hence these articles are included in Supplementary data Table 1 for transparency and other references. However, they were not considered in the current short report. Among the 104 pieces, 32 devoted a considerable amount of the manuscript to expand on those topics, while 16 articles had much reduced or incomplete analyses. These latter categories (48 manuscripts in total, listed in Supplementary data Table 2) were used in the current short report. Any inconsistencies were resolved.
by consensus with a third author (ZK), while thematic groupings (Figure 2) and analyses were reviewed by an additional author (SV). All outcomes were included due to the relative scarcity of data.

**Results**

The manuscripts identified in this short report (n=48) followed three loosely defined thematic groups: a) the safe handling of samples and the effects this might have on the well-being of staff (n = 27), b) the safe handling of data related to collected samples (n = 10) and c) the legal and ethical aspects regarding the above aspects (n = 11).

**Safe handling of samples and staff safety:** The secure handling of biospecimens is one of the first aspects biobanks face. Different steps have to be followed to implement appropriate protocols [10,11]. For example, one of the first steps often mentioned is to define the type of biobank, then based on this definition, the requirements for establishing a collection including those relating to safety. The guidelines and best practices created through established agencies and biobank networks (e.g., NCI, IARC, ISBER) enable smaller structures to have available information and safely build their system(s). Similarly, biobank networks offer an opportunity to harmonize the existing protocols implemented in the biobanking field [12-14], in clinical practice [8], as well as in the risk assessment and preparation in the case of natural disasters [15].

Several manuscripts contained more specific examples, where the safety of the collected specimens or the operator has improved through novel protocols [9, 16, 34]. Such technological innovation positively impacts biospecimens' handling and, consequently, on preserving biological indicators [17] or particular cell types [21,22, 26, 27]. The concept of safety of biological samples extends beyond the immediate collection and handling of biological material and onto the long-term storage conditions. Such aspects were covered in depth using different methodologies, including providing evidence from expert surveys [18] or personal experiences [19,23,24]. In other manuscripts, the mention of safety was directly related to the samples' quality [25]. The quality control needs to generate evidence proving the safety of samples during storage. Some quality control protocols were proposed for this purpose [28,29].
Lastly, the concept of safety within biobanks was linked for some publications to the staff's well-being. The need for informational material that is customized to the operations of the staff members, such as a "newcomer starter pack," was presented, as well as the need for consistent training on the optimal handling of biospecimens [30-32], especially in the case of high pathogenicity organisms requiring a P4 laboratory [33].

Safety of data: The second thematic group of manuscripts focused on the safe handling of data related to collected samples. Biobanks need to increasingly consider the concept of data protection according to national and international ethical and legal regulations to guarantee safer management of data [35]. Establishing an appropriate legal framework of operations is often presented as the first step in ensuring data safety. Specifically, in Europe, the General Data Protection Regulation (GDPR) provides a framework with which biobanks need to facilitate information transfer [36]. The in-depth analysis of the GDPR impact and recommendations on its practical implementation is achieved only in a minimal number of manuscripts [37,38] The general international consensus seems to be that for any transfer of data; three elements are needed: establishing informed consent; the material/data transfer agreements; and a code of conduct [39]. However, imposing such requirements on the safe handling of data necessitates the creation of efficient data infrastructures and databases [40-42] and integrated methods for the tracking of samples [43,44].

However, the concept of safe data handling goes beyond GDPR. It includes additional aspects, such as the data's integrity [59], the appropriate handling of data, installing security measures, and staff training to implement the latter effectively. Data security is likely to dominate future discussions on the subject, especially as the number and types of risks increase. For example, data safety risks can vary widely in complexity and impact: malware attacks that compromise clinical and research data; to the Distributed Denial-of-Service (DDoS) attacks, capable of depriving entire institutional systems ability to operate. In particular, cyber-attacks, such as those caused in recent years by repeated Ransomware attacks, have more significant ramifications that go beyond financial loss or privacy breaches [60, 61]. These latter aspects, though necessary, do not appear strongly in the manuscripts identified in the current short report.

Safety is an ethical aspect: The third thematic group of identified manuscripts focuses on the legal and ethical aspects. Ethical and legal regulations permanently evolve in healthcare, reflecting the progress in infrastructure, processing methodologies, or the depth of collected data [45,46]. The infrastructure-related legal requirements can often be resolved at the technical/engineering level [47]. The legal
definitions of consent vary widely between countries, as does the implementation – including examples such as the specific consent process required in Zambia and Tanzania or the more permissive broad consent implemented in Thailand and Nigeria [62]. In much a similar manner, broader ethical challenges can suffer by the lack or misalignment of definitions [48], hence the need for a consistent purpose and application of informed consent [49,50], even though the latter can also be modified [51]. For example, the new version of the ethics guidelines adopted by the Council for International Organizations of Medical Sciences and WMA World Medical Association caused the inevitable update of consent documents [52] and a different nuanced approach for genetic information [53]. These bioethical constraints have to be taken into account to guarantee the patient's safety and personal information. Using the few available examples identified, in the UK, the UK Biobank succeeded in building trust in the population by relying on altruism, following clear and transparent ethical approaches, and utilizing citizenship language [54]. At the opposite end in the U.S.A., Mexican American individuals view that the lack of available medical research and biobanks negatively acts, disincentivizing individuals to donate their research samples [55].

The above thematic areas reflect existing international independent standards and best practices (e.g., ISO 20387(2018): Biotechnology—biobanking—general requirements for biobanking; ISBER Best Practices) [56-57], as well as the recently launched (ASCP/ISBER) international training qualification in biorepository science examination for biobank technicians [58]. There is an overall thematic alignment though the depth of research is relatively limited per thematic section.

This publication has some inherent limitations, as it did not consider manuscripts from languages other than English. While much research is published globally in English, safety regulations can often be viewed as a national or sectional competency and become available in the local language. Regarding the selection of manuscripts, only the Pubmed and Web of Science platforms have been used, and none of the pre-print deposition archives. The authors considered this acceptable as there is a relative scarcity of data available on the subject. Hence, the inclusion of pre-print depositions would have been somewhat limited to additional sources and incomplete due to the lack of peer review. Lastly, there may be different manuscripts within national and/or international organizations on the topic that are not accessible through the current search but require individual organizations' queries. Accordingly, these have not been included as they are familiar with many scientific literature reviews.
Conclusion

The current manuscript demonstrates some dedicated publications already existing, investigating the relationship between biobanking and safety. According to those, the notion of safety can be viewed through three parameters: biological safety (for the individuals handling samples, as well as for the quality and integrity of the biological samples themselves); data safety, for the sample-associated data; and aspects relating to the governance, rules, and regulations. These findings are in line with expectations in terms of developments in the field. However, the overall volume of research (and consequently the number of publications) remains somewhat limited. It is envisaged that in the post-COVID-19 era, these aspects will be reviewed and perhaps even prioritized, highlighting an essential element in the management of samples.

An exciting observation remains that most publications do not feature scientific journals dedicated to biobanking and/or biosafety. On the contrary, they seem to emerge as ad hoc, ancillary parts of existing projects or activities. This ad hoc nature of most publications raises some questions on the overall depth of awareness of individuals working with and biobanks on those aspects. It does not seem to be an aspect of intense research activity. Perhaps the existence of national and international guidelines is considered as sufficiently addressing this point. Furthermore, such elements are likely embedded within the existing protocol and research activities and not necessarily under a separate 'safety' heading. Therefore, identifying such relevant yet less visible sections remains challenging and might require search strategies utilizing additional keywords.

The current short report provides the first evidence on the scientific publications relating to biobanking and safety. The views identified here reflect existing international standards, best practices, and opinions. However, they are not systematically investigated to a greater depth, which creates an opportunity for further work in this field in the post-COVID-19 era.

Acknowledgements

The authors would like to thank Drs Io Hong Cheong for the fruitful discussions that eventually gave rise to the current manuscript.

Conflict of interest statement
The authors declare that there are no conflicts of interest.

Disclaimer:

Where authors are identified as personnel of the International Agency for Research on Cancer/WHO, the authors alone are responsible for the views expressed in this article and they do not necessarily represent the decisions, policy or views of the International Agency for Research on Cancer/WHO.

Author contributions

Zisis Kozlakidis: Conceptualization, Methodology, Supervision and Writing – Reviewing and Editing. Stephanie Villar: Conceptualization, Writing – Reviewing and Editing Writing- Original draft preparation. Maissa Zeghidi: Formal analysis, Writing – Original draft preparation. Julie Roux: Formal analysis, Writing- Original draft preparation.

References:

1. Q. Li, X. Guan, P. Wu, X. Wang, L. Zhou, Y. Tong, R. Ren, K. S. M. Leung, E. H. Y. Lau, J. Y. Wong, X. Xing, N. Xiang, Y. Wu, C. Li, Q. Chen, D. Li, T. Liu, J. Zhao, M. Liu, W. Tu, C. Chen, L. Jin, R. Yang, Q. Wang, S. Zhou, R. Wang, H. Liu, Y. Luo, Y. Liu, G. Shao, H. Li, Z. Tao, Y. Yang, Z. Deng, B. Liu, Z. Ma, Y. Zhang, G. Shi, T. T. Y. Lam, J. T. Wu, G. F. Gao, B. J. Cowling, B. Yang, G. M. Leung, Z. Feng, Early Transmission Dynamics in Wuhan, China, of Novel Coronavirus-Infected Pneumonia. N. Engl. J. Med. 382, 1199–1207 (2020). doi:10.1056/NEJMoa2001316

2. Epidemiology Working Group for NCIP Epidemic Response, Chinese Center for Disease Control and Prevention. The epidemiological characteristics of an outbreak of 2019 novel coronavirus diseases (COVID-19) in China.[Zhonghua Liu Xing Bing Xue Za Zhi]. 2020; 41(2):145-151. doi:10.3760/cma.j.issn.0254-6450.2020.02.003

3. Sohrabi, C., Alsafi, Z., O’Neill, N., Khan, M., Kerwan, A., Al-Jabir, A., et al. (2020). World Health Organization declares global emergency: A review of the 2019 novel coronavirus (COVID-19). International Journal of Surgery.

4. Parodi B (2015) Biobanks: A definition. In Ethics, Law and Governance of Biobanking, Mascalzoni D (ed.), The International Library of Ethics, Law and Technology 14, Springer Science and Business Media. Dordrecht 2015. doi:10.1007/978-94-017-9573-9
5. “Seguridad Biológica En La Preservación y El Transporte de Muestras Biológicas Obtenidas En El Ámbito de Las Enfermedades Respiratorias y Destinadas a La Investigación.” Accessed December 11, 2020. https://www.archbronconeumol.org/es-pdf-S0300289609000969.

6. Schäfer, Stephan C., and Hans-Anton Lehr. "A Case Study on the Proper Use of Human Tissues for Biomedical Research at an Academic Pathology Institution in Switzerland." *Pathobiology* 74, no. 4 (2007): 259–63. https://doi.org/10.1159/000104454.

7. Stewart LA, Clarke M, Rovers M, et al. Preferred reporting items for a systematic review and meta-analysis of individual participant data: the PRISMA-IPD statement. *Jama*, 2015;313(16):1657-1665.

8. Banks, Peter, Richard Brown, Alex Laslowski, Yvonne Daniels, Phil Branton, John Carpenter, Richard Zarbo, et al. "A Proposed Set of Metrics to Reduce Patient Safety Risk From Within the Anatomic Pathology Laboratory." *Laboratory Medicine* 48, no. 2 (May 2017): 195–201. https://doi.org/10.1093/labmed/lmw068.

9. Jackson, Samuel J., Helen Prior, and Anthony Holmes. "The Use of Human Tissue in Safety Assessment." *Journal of Pharmacological and Toxicological Methods*, SPECIAL ISSUE: FIFTEENTH ANNUAL FOCUSED ISSUE ON METHODS IN SAFETY PHARMACOLOGY, 93 (September 1, 2018): 29–34. https://doi.org/10.1016/j.vascn.2018.05.003.

10. McQueen, M. J., J. L. Keys, K. Bamford, and K. Hall. "The Challenge of Establishing, Growing and Sustaining a Large Biobank: A Personal Perspective." *Clinical Biochemistry*, Biorepositories and Biobanks, 47, no. 4 (March 1, 2014): 239–44. https://doi.org/10.1016/j.clinbiochem.2013.11.017.

11. Harati, Mitra D., Ryan R. Williams, Masoud Movassaghi, Amin Hojat, Gregory M. Lucey, and William H. Yong. "An Introduction to Starting a Biobank." *Methods in Molecular Biology (Clifton, N.J.)* 1897 (2019): 7–16. https://doi.org/10.1007/978-1-4939-8935-5_2.

12. Lassalle, Sandra, Vé Hofman, Marius Ilie, Catherine Butori, Christelle Bonnetaud, Marie Clotilde, Gaziello, et al. "Setting up a Prospective Thyroid Biobank for Translational Research: Practical Approach of a Single Institution (2004–2009, Pasteur Hospital, Nice, France)." *Biopreservation and Biobanking* 9 (March 1, 2011). https://doi.org/10.1089/bio.2010.0024.

13. Ravid, Rivka. "Standard Operating Procedures, Ethical and Legal Regulations in BTB (Brain/Tissue/Bio) Banking: What Is Still Missing?" *Cell and Tissue Banking* 9, no. 2 (June 1, 2008): 121–37. https://doi.org/10.1007/s10561-007-9055-y.
14. Ravid, Rivka, and Keiko Ikemoto. "Pitfalls and Practicalities in Collecting and Banking Human Brain Tissues for Research on Psychiatric and Neurological Disorders." *Fukushima Journal of Medical Science* 58, no. 1 (2012): 82–87. https://doi.org/10.5387/fms.58.82.

15. Morrin, Helen R., and Bridget A. Robinson. "Sustaining a Biobank Through a Series of Earthquake Swarms: Lessons Learned from Our New Zealand Experience." *Biopreservation and Biobanking* 11, no. 4 (August 1, 2013): 211–15. https://doi.org/10.1089/bio.2013.0033.

16. Vaught, Jimmie B. "Blood Collection, Shipment, Processing, and Storage." *Cancer Epidemiology and Prevention Biomarkers* 15, no. 9 (September 1, 2006): 1582–84. https://doi.org/10.1158/1055-9965.EPI-06-0630.

17. Roth, Sharin E., Mark I. Avigan, David Bourdet, David Brott, Rachel Church, Ajit Dash, Douglas Keller, et al. "Next-Generation DILI Biomarkers: Prioritization of Biomarkers for Qualification and Best Practices for Biospecimen Collection in Drug Development." *Clinical Pharmacology and Therapeutics* 107, no. 2 (February 2020): 333–46. https://doi.org/10.1002/cpt.1571.

18. Reesink, H. W., C. P. Engelfriet, C. A. Hyland, P. Coghlan, B. Tait, M. Wsolak, A. J. Keller, et al. "Biobanks of Blood from Donors and Recipients of Blood Products." *Vox Sanguinis* 94, no. 3 (2008): 242–60. https://doi.org/10.1111/j.1423-0410.2007.01020.x.

19. Czerwiński, J. “Biobank Concept in Poland.” *Transplantation Proceedings* 44, no. 7 (September 1, 2012): 2169–70. https://doi.org/10.1016/j.transproceed.2012.07.116.

20. Yong, Kar Wey, Jane Ru Choi, and Wan Kamarul Zaman Wan Safwani. "Biobanking of Human Mesenchymal Stem Cells: Future Strategy to Facilitate Clinical Applications." In *Biobanking and Cryopreservation of Stem Cells*, edited by Feridoun Karimi-Busheri and Michael Weinfeld, 99–110. Advances in Experimental Medicine and Biology. Cham: Springer International Publishing, 2016. https://doi.org/10.1007/978-3-319-45457-3_8.

21. Yong, Kar Wey, Wan Kamarul Zaman Wan Safwani, Feng Xu, Wan Abu Bakar Wan Abas, Jane Ru Choi, and Belinda Pingguan-Murphy. "Cryopreservation of Human Mesenchymal Stem Cells for Clinical Applications: Current Methods and Challenges." *Biopreservation and Biobanking* 13, no. 4 (August 1, 2015): 231–39. https://doi.org/10.1089/bio.2014.0104.

22. Bajerski, F., A. Bürger, B. Glasmacher, E. R. J. Keller, K. Müller, K. Mühldorfer, M. Nagel, et al. "Factors Determining Microbial Colonization of Liquid Nitrogen Storage Tanks Used for Archiving Biological Samples." *Applied Microbiology and Biotechnology* 104, no. 1 (2020): 131–44. https://doi.org/10.1007/s00253-019-10242-1.
23. Washetine, Kevin, Mehdi Kara-Borni, Simon Heeke, Christelle Bonnetaud, Jean-Marc Félix, Lydia Ribeyre, Coraline Bence, et al. "Ensuring the Safety and Security of Frozen Lung Cancer Tissue Collections through the Encapsulation of Dried DNA." *Cancers* 10, no. 6 (June 11, 2018). https://doi.org/10.3390/cancers10060195.

24. Wang, Yaogeng, Hong Zheng, Jie Chen, Xiaorong Zhong, Yu Wang, Zhu Wang, and Yanping Wang. "The Impact of Different Preservation Conditions and Freezing-Thawing Cycles on Quality of RNA, DNA, and Proteins in Cancer Tissue." *Biopreservation and Biobanking* 13, no. 5 (October 1, 2015): 335–47. https://doi.org/10.1089/bio.2015.0029.

25. Denys, Marie, Albertine Léon, Clément Robert, Nathalie Saulnier, Anne Josson-Schramme, Loïc Legrand, Laurence Wimel, Stéphane Maddens, and Stéphane Pronost. "Biosafety Evaluation of Equine Umbilical Cord-Derived Mesenchymal Stromal Cells by Systematic Pathogen Screening in Peripheral Maternal Blood and Paired UC-MSCs." *Biopreservation and Biobanking* 18, no. 2 (January 3, 2020): 73–81. https://doi.org/10.1089/bio.2019.0071.

26. Kawase, Tomoyuki, Kazuhide Hayama, Makoto Tsuchimochi, Masaki Nagata, Kazuhiro Okuda, Hiromasa Yoshie, Douglas M. Burns, and Koh Nakata. "Evaluating the Safety of Somatic Periosteal Cells by Flow-Cytometric Analysis Monitoring the History of DNA Damage." *Biopreservation and Biobanking* 14, no. 2 (February 1, 2016): 129–37. https://doi.org/10.1089/bio.2015.0072.

27. Ribeiro, Victoria Stadler Tasca, Felipe Francisco Tuon, Leticia Kraft, Paula Hansen Suss, Luciana Cristina Wollmann, Joao Gabriel Roderjan, Diego Armando Brito, Fabiana Alexandrino, Juliane Soldi Malgarin, and Luis Gustavo Morello. "Conventional Culture Method and QPCR Using 16S RDNA for Tissue Bank: A Comparison Using a Model of Cardiac Tissue Contamination." *Journal of Medical Microbiology*, n.d., 5.

28. Mercuri, Antonella, Stefano Turchi, Andrea Borghini, Maria Rosa Chiesa, Guido Lazzerini, Laura Musacchio, Ottavio Zirilli, and Maria Grazia Andreassi. “Nitrogen Biobank for Cardiovascular Research.” *Current Cardiology Reviews* 9, no. 3 (August 2013): 253–59. https://doi.org/10.2174/1573403X113099990035.

29. Williams, Ryan R., Diviya Gupta, and William H. Yong. "Orientation and Training of New Biobank Personnel." *Methods in Molecular Biology (Clifton, N.J.)* 1897 (2019): 51–63. https://doi.org/10.1007/978-1-4939-8935-5_6.
30. Asiry, Saeed, and Lee-Cyn Ang. "Laboratory Safety: Chemical and Physical Hazards." In *Biobanking: Methods and Protocols*, edited by William H. Yong, 243–52. Methods in Molecular Biology. New York, NY: Springer, 2019. https://doi.org/10.1007/978-1-4939-8935-5_21.

31. Ta, Lisa, Laura Gosa, and David A. Nathanson. "Biosafety and Biohazards: Understanding Biosafety Levels and Meeting Safety Requirements of a Biobank." *Biobanking* 1897 (December 12, 2018): 213–25. https://doi.org/10.1007/978-1-4939-8935-5_19.

32. Nisii, C., C. Castilletti, A. Di Caro, M. R. Capobianchi, D. Brown, G. Lloyd, S. Gunther, A. Lundkvist, M. Pletschette, and G. Ippolito. "The European Network of Biosafety-Level-4 Laboratories: Enhancing European Preparedness for New Health Threats." *Clinical Microbiology and Infection* 15, no. 8 (August 1, 2009): 720–26. https://doi.org/10.1111/j.1469-0691.2009.02946.x.

33. Han, S. N., F. Amant, E. H. Cardonick, S. Loibl, F. A. Peccatori, O. Gheysens, C. A. Sangalli, et al. "Axillary Staging for Breast Cancer during Pregnancy: Feasibility and Safety of Sentinel Lymph Node Biopsy." *Breast Cancer Research and Treatment* 168, no. 2 (April 1, 2018): 551–57. https://doi.org/10.1007/s10549-017-4611-z.

34. Müller, A., Hovanec, J., Josephs, B., Wiethege, T., Brüning, T., Behrens, T. “A Two-Level Biobank Data Protection Concept for Project-Driven Human Sample Collections.” *Biopreservation and Biobanking* 2019, 17 (4), 312–318. https://doi.org/10.1089/bio.2018.0112.

35. Isasi, R., Knoppers, BM, and Lomax G. "Sustained interaction: the new normal for stem cell repositories?" *Regenerative Medicine*.

36. Clarke, N., Vale, G., Reeves, E.P. et al. "GDPR: an impediment to research?" *Ir J Med Sci* 188, 1129–1135 (2019). https://doi.org/10.1007/s11845-019-01980-2

37. Takai-Igarashi, T., Kinoshita, K., Nagasaki, M. et al. « Security controls in an integrated Biobank to protect privacy in data sharing: rationale and study design." *BMC Med Inform Decis Mak* 17, 100 (2017). https://doi.org/10.1186/s12911-017-0494-5

38. Morrison, M., Bell, J., George, C., Harmon, S., Munsie, M., & Kaye, J. (2017). The European General Data Protection Regulation: Challenges and considerations for iPSC researchers and biobanks. *Regenerative Medicine*, 12(6), 693–703. https://doi.org/10.2217/rme-2017-0068

39. Boutin, N., Holzbach, A., Mahanta, L., Aldama, J., Cerretani, X., Embree, K., Leon, I., Rathi, N., & Vickers, M. (2016). The Information Technology Infrastructure for the Translational Genomics Core and the Partners Biobank at Partners Personalized Medicine. *Journal of Personalized Medicine*, 6(1), 6. https://doi.org/10.3390/jpm6010006
40. Mariette, C., Renaud, F., Piessen, G., Gele, P., Copin, M.-C., Leteurtre, E., Delaeter, C., Dib, M., Clisant, S., Harter, V., Bonnetain, F., Duhamel, A., Christophe, V., & Adenis, A. (2018). The FREGAT biobank: A clinico-biological database dedicated to esophageal and gastric cancers. *BMC Cancer, 18*. https://doi.org/10.1186/s12885-018-3991-8

41. Benner, J. (2009). Establish a Transparent Chain-of-Custody to Mitigate Risk and Ensure Quality of Specialized Samples. *Biopreservation and Biobanking, 7*(3), 151–153. https://doi.org/10.1089/bio.2010.0002

42. Zarabzadeh, A., Hayati, F., Watson, R., Bradley, G., & Grimson, J. (2009). A sample identification and tracking system for biobanks. 2012 25th IEEE International Symposium on *Computer-Based Medical Systems* (CBMS), 0, 1–4. https://doi.org/10.1109/CBMS.2009.5255276

43. Lou, J. J., Andrechak, G., Riben, M., & Yong, W. H. (2011). A review of radio frequency identification technology for the anatomic pathology or biorepository laboratory: Much promise, some progress, and more work needed. *Journal of Pathology Informatics, 2*. https://doi.org/10.4103/2153-3539.83738

44. The International Society of Biological and Environmental Repositories Presents Abstracts from Its Annual Meeting Breaking Down Walls: Unifying Biobanking Communities to Secure Our Sustainability April 5–8, 2016 Berlin, Germany | *Biopreservation and Biobanking*. (n.d.). Retrieved February 4, 2021, from https://www.liebertpub.com/doi/10.1089/bio.2016.29001.abstracts

45. Lauss, G., Schröder, C., Dabrock, P., Eder, J., Hamacher, K., Kuhn, K. A., & Gottweis, H. (2013). Towards Biobank Privacy Regimes in Responsible Innovation Societies: ESBB Conference in Granada 2012. *Biopreservation and Biobanking, 11*(5), 319–323. https://doi.org/10.1089/bio.2013.0036

46. Baird, P. M., & Gunter, E. W. (2016). Repository Planning, Design, and Engineering: Part I—Infrastructure. *Biopreservation and Biobanking, 14*(2), 180–189. https://doi.org/10.1089/bio.2015.0084

47. Calzolari, A., Napolitano, M., & Bravo, E. (2013). Review of the Italian Current Legislation on Research Biobanking Activities on the Eve of the Participation of National Biobanks' Network in the Legal Consortium BBMRI-ERIC. *Biopreservation and Biobanking, 11*(2), 124–128. https://doi.org/10.1089/bio.2012.0058

48. Cervo, S., De Paoli, P., Perin, T., Canzonieri, V., & Steffan, A. (2015). Cost-Effective Organization of an Institutional Human Cancer Biobank in a Clinical Setting: CRO-Biobank Experience Toward
Harmonization. *The International Journal of Biological Markers*, 30(2), 243–251.  
https://doi.org/10.5301/jbm.5000138

49. Hansson, M. G. (2007). For the Safety and Benefit of Current and Future Patients. *Pathobiology*, 74(4), 198–205. https://doi.org/10.1159/000104445

50. Kapp, M. B. (2006). Ethical and legal issues in research involving human subjects: Do you want a piece of me? *Journal of Clinical Pathology*, 59(4), 335–339.  
https://doi.org/10.1136/jcp.2005.030957

51. Sánchez, M., & Sarria-Santamera, A. (2019). Unlocking data: Where is the key? *Bioethics*, 33.  
https://doi.org/10.1111/bioe.12565

52. Mehring, Sigrid. "9 The Documents by the World Medical Association (WMA)." *First Do No Harm: Medical Ethics in International Humanitarian Law*. Brill Nijhoff, 2015. 360-419.

53. Khan, A., Capps, B. J., Sum, M. Y., Kuswanto, C. N., & Sim, K. (2014). Informed consent for human genetic and genomic studies: A systematic review. *Clinical Genetics*, 86(3), 199–206.  
https://doi.org/10.1111/cge.12384

54. Petersen, A. (2005). Securing our genetic health: Engendering trust in UK Biobank. *Sociology of Health & Illness*, 27(2), 271–292. https://doi.org/10.1111/j.1467-9566.2005.00442.x

55. Heredia, N. I., Krasny, S., Strong, L. L., Von Hatten, L., Nguyen, L., Reininger, B. M., McNeill, L. H., & Fernández, M. E. (2017). Community perceptions of biobanking participation: A qualitative study among Mexican-Americans in three Texas cities. *Public Health Genomics*, 20(1), 46–57.  
https://doi.org/10.1159/000452093

56. International Organizations for Standardization (ISO). ISO 20387:2018. Biotechnology—biobanking—general requirements for biobanking. Available at: https://www.iso.org/standard/67888.html Accessed on February 08, 2021.

57. International Society for Biological and Environmental Repositories (ISBER). ISBER best practices. Available at: https://isber.org/general/custom.asp?page=BPR Accessed February 08, 2021.

58. Schacter, Brent, et al. "A new qualification for the new year: ISBER and American Society of Clinical Pathology Board of Certification announce new qualification in biorepository science examination for biobank technicians." *Biopreservation and biobanking* 18.1 (2020): 43-44.

59. A. K. Pandey *et al.*, "Key Issues in Healthcare Data Integrity: Analysis and Recommendations," in *IEEE Access*, vol. 8, pp. 40612-40628, 2020, doi: 10.1109/ACCESS.2020.2976687
60. M. Ahmed and A. S. S. B. Ullah, "False data injection attacks in healthcare", Proc. Australas. Conf. Data Mining, pp. 192-202, 2017.

61. E. AbuKhousa, N. Mohamed and J. Al-Jaroodi, "e-Health cloud: Opportunities and challenges", Future Internet, vol. 4, no. 3, pp. 621-645, 2012.

62. P. Vodosin et al., "A review of Regulatory Frameworks Governing Biobanking in the Lower- and Middle- Income Member Countries of BCNet", Biopreserv Biobank, (epub) 2021.
| Manuscript                                                                 | DOI                                |
|---------------------------------------------------------------------------|------------------------------------|
| [Biobanking requirements from the perspective of the clinician : Experiences in hematology and oncology] | 10.1007/s00292-018-0434-x          |
| [Biobanks and use of samples of human origin for surgical research. Current regulatory framework] | 10.1016/j.ciresp.2010.07.014       |
| [Current legal framework conditions for running and utilization of biobanks : part 1: legal principles] | 10.1007/s00104-013-2606-9          |
| [The German Environmental Specimen Bank]                                   | 10.1007/s00103-015-2298-z          |
| A Review of Research-Grade Human Induced Pluripotent Stem Cells Qualification and Biobanking Processes | 10.1089/bio.2016.0097              |
| A sample storage management system for biobanks                            | 10.1093/bioinformatics/btq502       |
| A Strategic Plan for the Second Phase (2013–2015) of the Korea Biobank Project | 10.1016/j.phrp.2013.03.006        |
| A study of bioethical knowledge and perceptions in Korea                    | 10.1111/j.1467-8519.2008.00706.x    |
| Assessment of DNA Encapsulation, a New Room-Temperature DNA Storage Method | 10.1089/bio.2013.0082              |
| Biobank linked to SWEDHEART quality registry—routine blood sample collection opens new opportunities for cardiovascular research | 10.1080/03009734.2018.1498957  |
| Biobanking: towards increased access of biomaterials in cystic fibrosis. Report on the pre-conference meeting to the 13th ECFS Basic Science Conference | 10.1016/j.jcf.2017.04.009         |
| Biobanks for life sciences and personalized medicine: importance of standardization, biosafety, biosecurity, and data management | 10.1016/j.copbio.2019.12.004       |
| Biological sample collection and processing for molecular epidemiological studies | 10.1016/S1383-5742(02)00090-X    |
| Cervical cytology biobanking in Europe                                     | PMID: 20872354                     |
| Comprehensive Outsourcing Biobanking Facility to Serve the International Research Community | 10.1089/bio.2011.0002            |
| Cryopreservation of the human gut microbiota: Current state and perspectives | 10.1016/j.ijmm.2019.06.001         |
| Current status, challenges, policies, and bioethics of biobanks             | 10.5808/G1.2013.11.4.211          |
| Discovering time-trends of the German populations exposure to contaminants by analysis of human samples of the German Environmental Specimen Bank (ESB) | 10.1016/j.toxlet.2018.06.007     |
| EFS Centre-Atlantique donor's biobank: Ten years of samples usage          | 10.1016/j.tracl.2015.11.002        |
| Enhancing Autonomy in Biobank Decisions: Too Much                           | 10.1177/1556264617753483           |
| Title                                                                 | DOI               |
|----------------------------------------------------------------------|-------------------|
| of a Good Thing?                                                      |                   |
| Ethical issues in stem cell research and therapy                      | 10.1186/scrt474    |
| Ethical review of biobank research: Should RECs review each release   | 10.1016/j.ejmg.2015.09.008 |
| of material from biobanks operating under an already-approved broad  |                   |
| consent and data protection model?                                    |                   |
| Ethical, legal and economic issues raised by the use of human tissue | 10.1159/000067677  |
| in postgenomic research                                              |                   |
| Ethics in studies on children and environmental health                | 10.1136/jme.2006.016212 |
| Ethics review of studies during public health emergencies - the      | 10.1186/s12910-017-0201-1 |
| experience of the WHO ethics review committee during the Ebola virus  |                   |
| disease epidemic                                                     |                   |
| Highlights of Indian Council of Medical Research National Ethical    | 10.4103/0253-7613.262456 |
| Guidelines for Biomedical and Health Research Involving Human        |                   |
| Participants                                                         |                   |
| Impact of National and International Stem Cell Banking Initiatives    | 10.1016/j.biologicals.2015.07.007 |
| on progress in the field of cell therapy: IABS-JST Joint Workshop:    |                   |
| Summary for Session 5                                                |                   |
| Implementation of a Multicenter Biobanking Collaboration for         | 10.1634/theoncologist.2016-0085 |
| Next-Generation Sequencing-Based Biomarker Discovery Based on Fresh  |                   |
| Frozen Pretreatment Tumor Tissue Biopsies                            |                   |
| International Guidelines for Privacy in Genomic Biobanking (or the   | 10.1111/jlme.12312  |
| Unexpected Virtue of Pluralism)                                       |                   |
| Legal aspects of biobanks                                            | PMID: 18792524    |
| Long-Term Room Temperature Storage of Dry Ribonucleic Acid for Use   | 10.1089/bio.2017.0024 |
| in RNA-Seq Analysis                                                  |                   |
| Molecular epidemiology biomarkers—Sample collection and processing   | 10.1016/j.taap.2004.10.024 |
| considerations                                                       |                   |
| Patients to learn from: on the need for systematic integration of   | 10.18053/jctres.03.2017S3.001 |
| research and care in academic health care.                           |                   |
| Piloting the European Unified Patient Identity Management (EUPID)     | PMID: 27139382    |
| Concept to Facilitate Secondary Use of Neuroblastoma Data from       |                   |
| Clinical Trials and Biobanking                                       |                   |
| Preanalytic specimen triage: Smears, cell blocks, cytospin           | 10.1002/cncy.21850 |
| preparations, transport media, and cytobanking                      |                   |
| Preparedness for a Natural Disaster: How Coriell Planned for         | 10.1089/bio.2013.0035 |
| Hurricane Sandy                                                      |                   |
| Preservation, Characterization and Exploitation of Microbial         | 10.3390/microorganisms7120685 |
| Biodiversity: The Perspective of the Italian Network of Culture      |                   |
| Collections                                                         |                   |
| Manuscript                                                                 | Thematic group                                                                 | DOI                                |
|--------------------------------------------------------------------------|-------------------------------------------------------------------------------|-----------------------------------|
| Privacy and Security within Biobanking: The Role of Information Technology |                                                                                | 10.1177/1073110516644206          |
| Providing Contemporary Access to Historical Biospecimen Collections: Development of the NHLBI Biologic Specimen and Data Repository Information Coordinating Center (BioLINCC). |                                                                                | 10.1089/bio.2014.0050            |
| Public Attitudes toward Biobanking of Human Biological Material for Research Purposes: A Literature Review |                                                                                | 10.3390/ijerph16122209           |
| Publicly-funded biobanks and networks in East Asia                       |                                                                                | 10.1186/s40064-016-2723-2.       |
| Rationale and design of three observational, prospective cohort studies including biobanking to evaluate and improve diagnostics, management strategies and risk stratification in venous thromboembolism: the VTEval Project |                                                                                | 10.1136/bmjopen-2015-008157      |
| Sample Collection, Biobanking, and Analysis                              |                                                                                | 10.1007/978-3-642-20195-0_10      |
| SARS and the Academic Health Sector                                       |                                                                                | 15770880                         |
| Separation of personal data in a biobank information system              | Stud Health Technol Inform. 2014;205:388-92.                                   |                                   |
| Similar or the Same? Why Biosimilars are not the Solution                |                                                                                | 10.1177/1073110518804241         |
| Sustainability in Biobanking: Model of Biobank Graz                      |                                                                                | 10.1089/bio.2015.0087            |
| The Biomaterial bank of the German Competence Network of Heart Failure (CNHF) is a valuable resource for biomedical and genetic research. |                                                                                | 10.1016/j.ijcard.2008.03.089      |
| The College of American Pathologists Biorepository Accreditation Program: Results from the First 5 Years |                                                                                | 10.1089/bio.2017.0108            |
| The foundation of personalized medicine is the establishment of biobanks and their standardization |                                                                                |                                   |
| The Implementation of an Integrated Management System at Qatar Biobank    |                                                                                | 10.1089/bio.2019.0076            |
| The Ministry of Health and Sanitation, Sierra Leone – Public Health England (MOHS-PHE) Ebola Biobank |                                                                                | 10.12688/wellcomeopenres.15279.2 |
| The Role of Government in Precision Medicine, Precision Public Health and the Intersection With Healthy Living |                                                                                | 10.1016/j.pcad.2018.12.002       |
| Use of electronic patient records for research: views of patients and staff in general practice |                                                                                | 10.1093/fampra/cms069             |
| Vascular Biomaterial Banking in Academia                                 |                                                                                | 10.1159/000495525                |

Table 2.
| An introduction to starting a biobank | The safe handling of samples, and the effects this might have to the well-being of staff | 10.1007/978-1-4939-8935-5_2 |
| Setting up a Prospective Thyroid Biobank for Translationa l Research: Practical Approach of a Single Institution (2004–2009, Pasteur Hospital, Nice, France) | The safe handling of samples, and the effects this might have to the well-being of staff | 10.1089/bio.2010.0024 |
| Standard Operating Procedures, ethical and legal regulations in BTB (Brain/Tissue/Bio) banking: what is still missing? | The safe handling of samples, and the effects this might have to the well-being of staff | 10.1007/s10561-008-9101-4 |
| The challenge of establishing, growing and sustaining a large biobank: a personal perspective | The safe handling of samples, and the effects this might have to the well-being of staff | 10.1016/j.clinbiochem.2013.11.017 |
| Pitfalls and practicalities in collecting and banking human brain tissues for research | The safe handling of samples, and the effects this might have to the well-being of staff | 10.5387/fms.58.82 |
| Title                                                                 | Abstract                                                                                                                                 | DOI                        |
|----------------------------------------------------------------------|------------------------------------------------------------------------------------------------------------------------------------------|----------------------------|
| Blood Collection, Shipment, Processing, and Storage                  | The safe handling of samples, and the effects this might have to the well-being of staff                                                 | 10.1158/1055-9965           |
| Sustaining a Biobank Through a Series of Earthquake Swarms: Lessons Learned from our New Zealand Experience | The safe handling of samples, and the effects this might have to the well-being of staff                                                 | 10.1089/bio.2013.0034       |
| Biosafety and Biohazards: Understanding Biosafety Levels and Meeting Safety Requirements of a Biobank. | The safe handling of samples, and the effects this might have to the well-being of staff                                                 | 10.1016/j.copbio.2019.12.004 |
| Laboratory Safety: Chemical and Physical Hazards                    | The safe handling of samples, and the effects this might have to the well-being of staff                                                 | 10.1007/978-1-4939-8935-5_21|
| Orientation and Training of New Biobank Personnel to esophageal and gastric cancers | The safe handling of samples, and the effects this might have to the well-being of staff                                                 | 10.1007/978-1-4939-8935-5_6  |
| The European network of Biosafety-Level-4 laboratories: enhancing European preparedness for new health threats | The safe handling of samples, and the effects this might have to the well-being of staff | 10.1111/j.1469-0691.2009.02946.x |
|---|---|---|
| A Proposed Set of Metrics to Reduce Patient Safety Risk From Within the Anatomic Pathology Laboratory | The safe handling of samples, and the effects this might have to the well-being of staff | 10.1093/labmed/lmw068 |
| Axillary staging for breast cancer during pregnancy: feasibility and safety of sentinel lymph node biopsy | The safe handling of samples, and the effects this might have to the well-being of staff | 10.1007/s10549-017-4611-z |
| The use of human tissue in safety assessment. | The safe handling of samples, and the effects this might have to the well-being of staff | 10.1016/j.vascn.2018.05.003 |
| Biosafety Evaluation of Equine Umbilical Cord-Derived Mesenchymal Stromal Cells (UC- | The safe handling of samples, and the effects this might have to the well-being of staff | 10.1089/bio.2019.0071 |
| Study Title                                                                 | DOI                                      |
|---------------------------------------------------------------------------|------------------------------------------|
| MSCs) by Systematic Pathogen Screening in Peripheral Maternal Blood and Paired UC-MSC |                                          |
| Conventional culture method and qPCR using 16S rDNA for tissue bank: a comparison using a model of cardiac tissue contamination | 10.1099/jmm.0.000837                     |
| Evaluating the Safety of Somatic Periosteal Cells by Flow-Cytometric Analysis Monitoring the History of DNA Damage | 10.1089/bio.2015.0072                    |
| Next-Generation DILI Biomarkers: Prioritization of Biomarkers for Qualification and Best Practices for Biospecimen Collection | 10.1002/cpt.1571                         |
| Title                                                                 | Abstract                                                                 | DOI                                      |
|----------------------------------------------------------------------|--------------------------------------------------------------------------|------------------------------------------|
| Biobank Concept in Poland                                            | The safe handling of samples, and the effects this might have to the well-being of staff | 10.1016/j.transproceed.2012.07.116       |
| Biobanking of Human Mesenchymal Stem Cells: Future Strategy to Facilitate Clinical Applications | The safe handling of samples, and the effects this might have to the well-being of staff | 10.1007/978-3-319-45457-3_8              |
| Biobanks of blood from donors and recipients of blood products.      | The safe handling of samples, and the effects this might have to the well-being of staff | 10.1111/j.1423-0410.2007.01020.x          |
| Cryopreservation of Human Mesenchymal Stem Cells for Clinical Applications: Current Methods and Challenges | The safe handling of samples, and the effects this might have to the well-being of staff | 10.1089/bio.2014.0104                    |
| Ensuring the Safety and Security of Frozen Lung Cancer Tissue Collections through the Encapsulation of Dried DNA | The safe handling of samples, and the effects this might have to the well-being of staff | 10.3390/cancers10060195                   |
| Factors determining microbial                                        | The safe handling of samples, and the effects this might have to the well-being of staff | 10.1007/s00253-019-10242-1               |
| Title                                                                 | Abstract                                                                 | DOI                                      |
|----------------------------------------------------------------------|--------------------------------------------------------------------------|------------------------------------------|
| The Impact of Different Preservation Conditions and Freezing-Thawing Cycles on Quality of RNA, DNA, and Proteins in Cancer Tissue | The safe handling of samples, and the effects this might have to the well-being of staff | 10.1089/bio.2015.0029                   |
| Nitrogen Biobank for Cardiovascular Research                         | The safe handling of samples, and the effects this might have to the well-being of staff | 10.2174/1573403X113099990035             |
| A Case Study on the Proper Use of Human Tissues for Biomedical Research at an Academic Pathology Institution in Switzerland | The safe handling of samples, and the effects this might have to the well-being of staff | 10.1159/000104454                        |
| A review of radio frequency identification technology for the anatomic pathology | The safe handling of data related to collected samples                     | 10.4103/2153-3539.83738                 |
| or biorepository laboratory: Much promise, some progress, and more work needed |  |
|---|---|
| **A Two-Level Biobank Data Protection Concept for Project-Driven Human Sample Collections** | The safe handling of data related to collected samples 10.1089/bio.2018.0112 |
| **GDPR: an impediment to research?** | The safe handling of data related to collected samples 10.1007/s11845-019-01980-2 |
| **Security controls in an integrated Biobank to protect privacy in data sharing: rationale and study design** | The safe handling of data related to collected samples 10.1186/s12911-017-0494-5 |
| **Sustained interaction: the new normal for stem cell repositories?** | The safe handling of data related to collected samples 10.2217/rme.11.93 |
| **The European General Data Protection** | The safe handling of data related to collected samples 10.2217/rme-2017-0068 |
| Regulation: challenges and considerations for iPSC researchers and biobanks | The FREGAT biobank: a clinico-biological database dedicated to esophageal and gastric cancers. |
| --- | --- |
| The safe handling of data related to collected samples | 10.1186/s12885-018-3991-8 |
| A sample identification and tracking system for biobanks | The safe handling of data related to collected samples |
| 10.1109/CBMS.2009.5255276 | |
| Establish a Transparent Chain-of-Custody to Mitigate Risk and Ensure Quality of Specialized Samples | The safe handling of data related to collected samples |
| 10.1089/bio.2010.0002 | |
| The Information Technology Infrastructure for the Translationa l Genomics Core and the Partners Biobank at Partners Personalized Medicine | The safe handling of data related to collected samples |
| 10.3390/jpm6010006 | |
| Title                                                                 | Abstract                                                                 | DOI                        |
|----------------------------------------------------------------------|--------------------------------------------------------------------------|----------------------------|
| Community Perceptions of Biobanking Participation: A Qualitative Study among Mexican-Americans in Three Texas Cities | The legal and ethical aspects regarding the above aspects                 | 10.1159/000452093          |
| For the safety and benefit of current and future patients.           | The legal and ethical aspects regarding the above aspects                 | 10.1159/000104445          |
| Review of the Italian Current Legislation on Research Biobanking Activities on the Eve of the Participation of National Biobanks’ Network in the Legal Consortium BBMRI-ERIC | The legal and ethical aspects regarding the above aspects                 | 10.1089/bio.2012.0058      |
| Towards Biobank Privacy Regimes in Responsible Innovation Societies: ESBB Conference in Granada 2012 | The legal and ethical aspects regarding the above aspects                 | 10.1089/bio.2013.0036      |
| Title                                                                 | The legal and ethical aspects regarding the above aspects | DOI                           |
|----------------------------------------------------------------------|----------------------------------------------------------|-------------------------------|
| Ethical and legal issues in research involving human subjects: do you want a piece of me? |                                                          | 10.1136/jcp.2005.030957      |
| Informed consent for human genetic and genomic studies: a systematic review |                                                          | 10.1111/cge.12384             |
| Repository Planning, Design, and Engineering: Part I—Infrastructu re  |                                                          | 10.1089/bio.2015.0084        |
| Securing our genetic health: engendering trust in UK Biobank         |                                                          | 10.1111/j.1467-9566.2005.00442.x |
| The International Society of Biological and Environmental Repositories Presents Abstracts from Its Annual Meeting Breaking Down Walls: Unifying Biobanking Communities |                                                          | 10.1089/bio.2016.29001 |


**Title:** A short report of Biosafety and Biobanking: current understanding and knowledge gaps.

**Highlights:**

- Increasing numbers of research-ready biological samples and data are collected in biobanks
- During the pandemic, such samples can be infectious or potentially infectious collected in large volumes
- The biosafety considerations for biobanks were reviewed in light of the above

| Topic                                                                 | Summary                                                                 | DOI                      |
|----------------------------------------------------------------------|-------------------------------------------------------------------------|--------------------------|
| Unlocking data: Where is the key?                                    | The legal and ethical aspects regarding the above aspects               | 10.1111/bioe.12565       |
| Cost-effective organization of an institutional human cancer biobank | The legal and ethical aspects regarding the above aspects               | 10.5301/jbm.5000138      |
| in a clinical setting: CRO-Biobank experience toward harmonization   |                                                                         |                          |
• Three thematic areas were identified: physical safety, data safety, and governance/compliance
• There is currently a limited depth of active research on the field, likely to increase in the post-COVID-19 era.