

STUDY GUIDE

Introduction to Biobanking: Principles, Practice and Ethics

Medical University of Białystok (MUB), Poland
within the EUNICE European University Alliance

1. IDENTIFYING DATA.		
· Course Name.	Introduction to Biobanking: Principles, Practice and Ethics	
· Coordinating University.	Medical University of Bialystok (MUB)	
· Partner Universities Involved.	Open to all EUNICE partner universities	
· Course Field(s).	Biomedical Sciences; Life Sciences; Health Sciences	
· Related Study Programme.	Transdisciplinary course open to students and researchers from medicine, pharmacy, biology, biotechnology, and related fields.	
· ISCED Code.	0912 – Medicine; 0511 – Biology; 0223: Philosophy and ethics	
· SDG.	The course pays particular attention to: <ul style="list-style-type: none"> • SDG 3 Good Health and Well-being • SDG 4 Quality Education • SDG 9 Industry, Innovation and Infrastructure • SDG 10 Reduced Inequalities • SDG 17 Partnerships for the Goals 	
· Study Level.	Open to all study levels (Bachelor, Master, Doctorate) and university staff.	
· EUNICE Key Competencies	Problem solving	Green – strongly
	Teamworking	Orange – moderately
	Communication	Orange – moderately
	Self-management	Green – strongly
	Cognitive flexibility	Orange – moderately
	Digital competence	Orange – moderately
	Technical competence	Green – strongly
	Global intercultural competence	Green – strongly

· Number of ECTS credits allocated.	2 ECTS points
· Mode of Delivery.	Online self-study
· Language of Instruction.	English

· Course Dates.	1 October 2026 - 31 January 2027
· Precise Schedule of the Lectures.	N/A – asynchronous self-paced course
· Key Words.	Biobanking, Biological Samples, Biorepository, Informed Consent, Sample Quality, Precision Medicine, Ethics in Research, ISO Standards, GDPR
· Catchy Phrase.	Your samples, humanity's future – biobanking bridges today's research with tomorrow's cures.

· Prerequisites and co-requisites.	B2 level English. Basic knowledge of biology or life sciences is recommended but not required.
· Number of EUNICE students that can attend the Course.	Unlimited.
· Number of EUNICE students that can attend the course per institution	Unlimited.
· Course inscription procedure(s).	Course inscription through the EUNICE Moodle Platform. The course is free of charge.

2. CONTACT DETAILS.

· Department.	Biobank, Medical University of Bialystok (MUB)
· Name of Lecturer.	<p>Module I. Introduction to Biobanking</p> <ul style="list-style-type: none"> Anna Michalska-Falkowska, PhD PharmD, MSc in Biobanking, QBRs(ASCP) (MUB) <p>Module II. Sample Collection, Processing and Quality</p> <ul style="list-style-type: none"> Anna Michalska-Falkowska, PhD PharmD, MSc in Biobanking, QBRs(ASCP) (MUB) <p>Module III. Ethics, Law and GDPR in Biobanking</p> <ul style="list-style-type: none"> Anna Michalska-Falkowska, PhD PharmD, MSc in Biobanking, QBRs(ASCP) (MUB)
· E-mail.	anna.michalska@umb.edu.pl
· Other Lecturers.	N/A

3. COURSE CONTENT.

This course offers an accessible, interdisciplinary introduction to biobanking — the systematic collection, processing, storage, and management of biological samples and associated data for research purposes. Biobanks are a cornerstone of modern biomedical research, enabling

breakthroughs in personalized medicine, genomics, epidemiology, and drug development. Drawing on the expertise of the Medical University of Bialystok, which operates one of the most advanced biobanks in Central and Eastern Europe, students will explore the full lifecycle of biological sample management, from donor consent and ethical considerations, through sample collection and quality assurance, to data governance and international interoperability standards. The course addresses key themes including ISO 9001, ISO 17025, ISO 20387, and ISBER Best Practices, GDPR compliance, the role of biobanks in population-based studies, and the future of precision medicine enabled by high-quality biorepositories.

4. LEARNING OUTCOMES.

Knowledge-Based Outcomes:

- Understand the definition, purpose, and importance of biobanking in contemporary biomedical research.
- Identify the main categories of biological samples (blood, tissue, cells, body fluids) and their research applications.
- Recognise relevant European and international legislation governing biobanks, including GDPR, the Declaration of Helsinki, and ISO 9001:2015.
- Understand the roles of donors, researchers, ethics committees, and biobank staff in the lifecycle of a biological sample.
- Describe how biobanks contribute to precision medicine, genomics, and population health studies.

Skills-Based Outcomes:

- Interpret and apply best practice guidelines for sample collection, pre-analytical processing, and long-term storage.
- Navigate basic biobank quality management systems and understand key quality indicators.
- Assess ethical considerations around informed consent, data privacy, and sample governance.
- Critically evaluate the role of biobanking data in supporting large-scale research projects.
- Effectively use standard biobank documentation, including sample tracking and chain-of-custody records.

Attitudinal/Behavioural Outcomes:

- Develop a responsible and patient-centred attitude towards biological sample donation and use.
- Promote a culture of ethical research practice, transparency, and data protection.
- Appreciate the value of international collaboration and standardisation in building high-quality biorepositories.

5. OBJECTIVES.

The EUNICE course "Introduction to Biobanking: Principles, Practice and Ethics" aims to equip students, researchers, and healthcare professionals with foundational knowledge of biobanking as an enabling infrastructure for modern medical research.

The course will:

- Introduce fundamental concepts and terminology of biobanking in an accessible, interdisciplinary format.
- Raise awareness of the critical importance of sample quality, pre-analytical variables, and standardised operating procedures.
- Explain the ethical, legal, and regulatory framework governing the collection, storage, and use of human biological material in Europe.
- Showcase practical applications of biobanking in large-scale population studies, personalised medicine, and translational research.
- Encourage students to appreciate biobanks as essential infrastructure for addressing societal health challenges.

6. COURSE ORGANISATION.

UNITS

1.	<p>Module I. Introduction to Biobanking</p> <p>Topic A: What is a biobank? Definitions, types, and historical development</p> <p>Topic B: The role of biobanks in modern biomedical research and precision medicine</p> <p>Topic C: Key international biobank networks and initiatives (BBMRI-ERIC, ISBER, IARC)</p> <p>Topic D: Biological sample types – blood, tissue, cells, body fluids, DNA/RNA</p> <p>Topic E: Overview of the sample lifecycle from donation to research use</p> <p>Topic F: Introduction to the MUB Biobank</p>
2.	<p>Module II. Sample Collection, Processing, and Quality Management</p> <p>Topic A: Pre-analytical variables and their impact on sample quality</p> <p>Topic B: Standard operating procedures (SOPs) for sample and data collection</p> <p>Topic C: Sample processing, aliquoting, and storage conditions (cryopreservation, -80°C, liquid nitrogen)</p> <p>Topic D: Quality management systems – ISO 9001, ISO 17025, ISO 20387, and ISBER Best Practices</p> <p>Topic E: Sample tracking, inventory management, and Laboratory Information Management Systems (LIMS)</p> <p>Topic F: Freeze-thaw cycles, sample degradation, and quality indicators (haemolysis, RNA integrity)</p>

	Topic G: Biosafety measures in biobank operations
3.	<p>Module III. Ethics, Law, and Data Governance in Biobanking</p> <p>Topic A: Ethical principles governing human biological material – Declaration of Helsinki, Oviedo Convention</p> <p>Topic B: Informed consent – types, broad consent, dynamic consent, and re-consent</p> <p>Topic C: GDPR and data protection in biobanking – pseudonymisation, anonymisation</p> <p>Topic D: European legal frameworks: EU Regulation on clinical trials, national legislation</p> <p>Topic E: Ethics committee review and institutional oversight</p> <p>Topic F: Access policies – sample and data sharing, Material Transfer Agreements (MTA) and Data Transfer Agreements (DTA)</p> <p>Topic G: Biobank sustainability, governance models, and participant engagement</p>
LEARNING RESOURCES AND TOOLS.	
The learning resources and assessment tools of the course are available at the EUNICE Moodle Platform.	
PLANNED LEARNING ACTIVITIES AND TEACHING METHODS.	
<p>Students will have access to written course contents, video explanations, and an automatic online exam in the EUNICE Moodle online environment. The course is fully asynchronous and self-paced; students can review materials and complete assessments at their own convenience during the course delivery period.</p> <p>Student activities in EUNICE Moodle will include:</p> <ul style="list-style-type: none"> • Reading and familiarization with text materials and case studies available on the course site. • Watching short video presentations from MUB Biobank available on the course site. • Taking the exam, which measures students' knowledge and understanding of biobanking concepts. <p>The course is completed by independently working and by taking the exam which consists of multiple-choice questions covering the course topics. The course is graded “passed” or “failed”.</p> <p>As an optional additional activity, each module will include a discussion forum for students to share questions, reflections, or experiences. These forums will be moderated by the course lecturer, who may contribute responses when appropriate.</p>	

7. ASSESSMENT METHODS, CRITERIA AND PERIOD.

To complete the course and receive a certificate, students must:

1. Review at least 70% of the course materials across all three Modules, going through all Sub-Topics.

2. Successfully pass the Automatic Online Assessment by correctly answering at least 6 out of 10 questions. Please note: students have only two attempts to complete the assessment.
3. Complete both the pre-course and post-course surveys. These surveys take approximately 3–5 minutes each and are essential for issuing the free certificate and for reporting and evaluation purposes.

The course is not graded; student performance is evaluated according to pass/fail criteria.

Upon fulfilling all course completion criteria, students will be able to download their Course Certificate directly from the EUNICE Moodle Platform.

OBSERVATIONS.

8. BIBLIOGRAPHY AND TEACHING MATERIALS.

- ISBER Best Practices: Recommendations for Repositories (5th edition). International Society for Biological and Environmental Repositories.
- European Parliament and Council. Regulation (EU) 2016/679 (General Data Protection Regulation – GDPR). Official Journal of the European Union, 2016.
- World Medical Association. Declaration of Helsinki – Ethical Principles for Medical Research Involving Human Subjects (latest revision).
- Council of Europe. Convention on Human Rights and Biomedicine (Oviedo Convention), 1997.
- International Organization for Standardization. ISO 9001:2015 – Quality Management Systems. Requirements.
- European Commission. Regulation (EU) 536/2014 on clinical trials on medicinal products for human use.
- Aarden, E. (2025). Mapping materials, drawing Europe: Sample and data quality and accessibility in the biobanking infrastructure BBMRI-ERIC. *Big Data & Society*, 12(1).
- Kinkorová J, Topolčan O. Biobanks in the era of big data: objectives, challenges, perspectives, and innovations for predictive, preventive, and personalised medicine. *EPMA J.* 2020 Jun 18;11(3):333-341. doi: 10.1007/s13167-020-00213-2. PMID: 32849924; PMCID: PMC7429593.
- ISO 9001:2015 Quality management systems – Requirements.
- ISO/IEC 17025:2017 General requirements for the competence of testing and calibration laboratories
- ISO 20387:2018 Biotechnology – Biobanking – General requirements for biobanking.
- ISO 21899:2020 Biotechnology — Biobanking — General requirements for the validation and verification of processing methods for biological material in biobanks.