



MASTER DISTANCE LEARNING COURSE CURRICULUM

Master of Science in Biobanking

In accordance with § 56 University Law (Universitätsgesetz, UG)
BGBl. I Nr. 120/2002 i.d.g.F.

Version: V1 - 2016

Resolution and change history

Version	Date of resolution (Study Commission)	Date of authorisation (Senate)	Short description of change	Effective date
1	18.01.2016	20.01.2016		

Table of Contents

- § 1 Objectives and target group
- § 2 Duration and structure
- § 3 Course prerequisites
- § 4 Content and applications
- § 5 Curriculum
- § 6 Examination regulations
- § 7 Degree
- § 8 Management
- § 9 Course organizer
- § 10 Validity of the present curriculum

ANNEX

- Arrangement of subjects
- List of abbreviations

§ 1 Objectives and target group

The goal of this post-graduate Master's distance learning course is to acquire knowledge, experience and practical skills that will qualify graduates of the course for working in the multidisciplinary field of biobanking.

The course will provide the following skills and knowledge to students:

- Organisation and implementation of biobanks at the national and international levels
- Quality management and risk management of biobanks as well as representing a biobank
- Infrastructure of a biobank (incl. IT), budgeting and biobank sustainability
- Sample management and ELSI aspects (ethical, legal and societal issues of biobanking)
- Epidemiology, biostatistics and selected areas of research

This university course is open to graduates with a bachelor's degree, whether they are medical-technical specialists or graduates in natural sciences (biology, molecular biology, biotech etc.) or have a degree in medicine or pharmacy, who have interest in the field of biobanking or wish to specialise or broaden their professional knowledge in biobanking. People with expertise working in biobanks (who have appropriate educational qualifications) may also apply, subject to approval by the course management (e.g. IT and commercial area, ethics, etc.)

§ 2 Duration and Structure

- (1) The degree "Master of Science in Biobanking" should be completed within the four semesters of the study (90 ECTS). This university course is a part-time postgraduate programme offered as a distance learning course. It is an international University course, designed to be completed alongside full-time work, in the field of biobanking, in English. The academic year and its division into semesters are based on UG 2002.
- (2) The curriculum comprises 13 modules, of which modules 1 to 12 are mandatory modules and module 13 is an optional mandatory module. Each semester, one compulsory face-to-face course (approximately one week) for all participants will take place. The first of these face-to-face courses will be at the beginning of the study for introduction and to respond to any organisational questions. The event location for these courses will be Graz, Austria.
- (3) Within the four semesters, all mandatory modules, one of the optional mandatory modules and the Master's thesis need to be completed.
- (4) For the period in accordance with section 1 to § 91 section 7 UG (as amended) a course fee has to be paid. More detailed provisions to this are regulated in the terms of university courses of the Medical University of Graz (published in MtBL 2. Stk, RN 10 from 21st of October 2015 – as amended). Only students who have been suspended or given leave from the course under section §67 UG (as amended) are exempted from fee payment.

§ 3 Course prerequisites

Admission to the University course "Master of Science in Biobanking" requires:

- a bachelor's degree for medical / technical specialists or comparable studies or
- a bachelor's degree in natural sciences (biology, molecular biology, biotech etc.) or
- a university degree in medicine or pharmacy

of a nationally or internationally accepted tertiary education institution.

In exceptional cases, an access to the course is possible if participants can demonstrate appropriate experience in biobanking (minimum of three years). Here, a separate application should be submitted in line with international standards.

The head of the Medical University of Graz will decide on admission to the University course based on recommendations of the course management.

The course is held in English. Therefore a good command of English is required.

Modules can be booked separately and finalized with a document stating attendance of the course but, of course, without receiving a Master's degree.

§ 4 Content and applications

The extensive growth of biobanks requires training of highly qualified personnel in the field of biobanking and different disciplines linked to it. To meet this development this University course provides knowledge and practical know-how regarding biobank organisation, management and infrastructure, as well as of emerging challenges in biobanking.

The number of requests to use biological samples for medical research will only increase in future. The requirements for the quality of biobanking samples (and data) will also increase because of the growing spectrum of potential methods for different analyses and applications. For further development of biobanking processes, understanding of such analyses and applications is of crucial importance in order to keep quality of biobank resources abreast with new methods for bio-analytics.

For these demanding requirements in training of experts in the field of biobanking it is essential to offer a well-structured post graduate training programme.

The following professional fields may be considered for graduates of the MSc in biobanking:

- National and international biobanks
 - Establishing biobanks
 - Managing biobanks
- Medical Research
 - Organisation and implementation of multicentre and clinical studies
 - Epidemiological evaluation of studies
- Research into medical fundamentals
- Analytical centres
- The pharmaceutical industry
- Diagnostic companies
- Etc.

This study will provide the following skills and knowledge to the participants:

- How to establish a biobank
- Implementation of a biobank in the health care system and in existing research infrastructure
- Representing a biobank and networking in the national and international area
- Sample management including pre-analytic handling, logistics, storage and shipment
- Quality management
- ELSI (ethical, legal and societal issues of biobanking)
- Biobanking IT-landscapes and the requirements thereof
- Biobank budgeting, business planning and sustainability for biobanks
- Risk management in biobanking
- Management and communication
- Epidemiology and biostatistics
- Preparation and implementation of presentations and scientific essays
- Expertise in biobanking related research methodologies:
 - Microscopy and Histology
 - Proteomics (Methods of protein extraction, such as LC-MS/MS-analysis, 2D gel electrophoresis)
 - Genomics (RNA, DNA isolation; PCR, RT-PCR, Sequencing, Arrays, etc.),
 - Microbiomics and Metabolomics

§ 5 Curriculum:

Title and numbers of hours for mandatory courses and electives

The course is structured in modules. You can find a detailed description about contents of the modules and a semester schedule in the annex.

Overview of the Curriculum:

Module	TU Face to face (45 min)	TU Distance learning (45min)	ECTS - Credits	Performance Review	Marking scale
Module 1: Introduction to the Study	40	0	1	Assignment to send in	S - w/oS
Module 2: Basic Knowledge Biobanking	0	170	7	Written exam	1-5
Module 3: Ethics and Law	0	100	6	Assignment to send in	1-5
Module 4: Collection and Management of Samples (Hands-on)	40	60	6	Written exam, Continual Assesment	1-5 S - w/oS
Module 5: Risk Management and Biobanking	0	100	6	Assignment to send in	1-5
Module 6: Biobanking IT	0	100	6	Written exam	1-5
Module 7: Sustainability, Budgeting and Business Planning in Biobanks	0	70	5	Assignment in form of a case study	1-5
Module 8: Epidemiology	0	100	6	Written exam	1-5
Module 9: Quality Management and Quality Control	0	100	6	Written exam	1-5
Module 10: Management and Communication	40	60	6	Assignment to send in, Continual Assignment	1-5 S - w/oS
Module 11: Strategy and Development, Networks	0	60	4	Assignment to send in	1-5
Module 12: Research I (Hands on)	40	60	6	Written exam, Continual Assesment	1-5 S - w/oS
Module 13: Designing and Implementation of Clinical Studies OR OPTIONAL Research II	40	60	5	Continual Assesment	S - w/oS
Master's thesis	10	0	20	Presentation of the master thesis	1-5
Total			90		

TU = Teaching Unit

ECTS = European Credit Transfers System

S - w/oS = Success - without Success

Rate 1 = "very good"

Rate 2 = "good"

Rate 3 = "satisfactory"

Rate 4 = "mostly satisfactory"

Rate 5 = "not satisfactory"

The course will be taught in English and most elements of the course contents are taught by e-learning. The modules do not build on one another; hence, the sequence of modules can be changed by the course management without prior notice. The lectures and seminars are taught with written training material in English and they have been developed especially for distance learning. They will be made available for download at the e-learning platform of the Medical University of Graz at the beginning of the semester. For some selected aspects of the course, virtual lectures for download will be provided.

The distance learning training material is used for independent study. For this they are designed to be self-explanatory, meaning they contain all information on the topic and they are designed to enable the distance learning students to learn from the material without any support. Module 13 can be chosen from the modules “Designing and Implementation of Clinical Studies” and “Research II”.

§ 6 Examination regulations

There is a minimum attendance requirement of 80% for each face-to face course independent of the type of lecture. If a participant cannot meet this requirement, a catch-up assignment in accordance of the missed content can be imposed by the study management or the study management could request to make up the content in the next study course.

In order to successfully complete the course students must take the relevant written exams and submit the required assignments (send-in exercises or case studies) as well as their final master thesis (for the type of performance review and grading in each case see table in chapter § 5 Curriculum).

Assignments – send-in exercises (Post Module Assignment):

Within the study course six such assignments are required. The assignments can be completed based on the training material of the respective module and require a deep understanding of the topic. A preparatory assignment with a presentation of the results is planned during the face-to-face courses in the first and third semesters.

Case study:

For the case study we will provide a range of topics with regard to the respective module. The case study should be practice orientated and should run to around 15 –20 pages. A case study is planned in module 7: “Sustainability, Budgeting and Business Planning in Biobanks”.

Face-to-face course:

During the whole study course „MSc in Biobanking“, all participants are obliged to attend four face-to-face courses. The face-to-face courses take place in Graz. The first face-to-face course is the opening event at the beginning of the course to introduce to the course.

Master’s thesis and Master’s examination

The students have to write an independent Master’s thesis, which corresponds to the provisions of the guidelines for drafting a Master thesis in a study course (published in MTBI of the Medical University of Graz 25c Stk, Rn141, 30th of June 2015 – as amended). The Master’s thesis shall be submitted in the final semester and serves as the proof of the capability to independently handle a scientific issue. The topic of the Master’s thesis can be chosen from a subject pool or can be suggested by the student. As preparation for the Master’s thesis, a research proposal has to be submitted to the study management by the end of the third semester. The Master’s thesis will be written in English and should be presented to the study management.

The grading is in accordance to 73 UG (ad amended).

§ 7 Degree

Students of the MSc distance learning course „Biobanking“ will be awarded the academic degree “Master of Science in Biobanking” (MSc) after completing all required modules and a positive evaluation of the Master’s thesis.

§ 8 Management

The study management and the management representatives are appointed by the rector of the Medical University of Graz.

§ 9 Course organizer

Medical University of Graz

§ 10 *Validity of the present curriculum*

The curriculum will apply as from the date of the publication in the official newsletter of the Medical University of Graz.

ANNEX

Arrangement of subjects

Module No.	Module	Content	Teaching Unit (TU) Face-to-face study	TU Distance learning study	TU assessment of exercises	Self-study in hours	ECTS*	Study and exam achievements
MANDATORY MODULES								
1	Introduction to the Study	<ul style="list-style-type: none"> Professional field Requirements Type of business Aspects Presentation of the preliminary assignment Introduction to scientific working/writing Operational concept of a biobank A Biobank in practice (Guided tour) 	40	0	0	0	1	Assignment to send in
2	Basic Knowledge Biobanking	<ul style="list-style-type: none"> International Guidelines and Regulatory Affairs Financial aspects and financing Integration of a biobank into the Health Care System and in an academic environment Different kinds of biobanks (human, non-human, population, clinical,...) Fundamental biobank facilities Workplace design Infrastructure (security, technical and analytical devices, storage, ...) Workflow and logistics Important services of a biobank Samples: Acquisition/Input/Import/Export Coding of samples Documentation and traceability Technical management Laboratory routines, protocols, cleanliness, contamination, handling of biological substances, manufacture of media and reagents, tissue cultures, sample processing Storage processing: Environment for storage at low and ultra-low temperature, protection against cold, cryo-conservation, cryo-banking, cryobiomics Critical factors of storage: sample processing prior and after storage, preanalytical variables and biomarkers Measurement after storage: degradation and viability testing, testing of stability 	0	170	0	50	7	Written exam
3	Ethics and Law	<ul style="list-style-type: none"> Basics (Declaration of Helsinki, ICH Guidelines: GCP, new EU regulations) Medicine Law, Ö-AMG, CH-Medicine law Medical products law Data protection Patent protection Insurance coverage Informed Consent (problems and solutions) Aspects to confidentiality Regulatory, legal and ethical aspects of biobanking: <ul style="list-style-type: none"> General international and regulatory conditions Specific biobanking laws and administrative controls General laws on the collection, storage and distribution of human samples and derivatives Rules for the acquisition of human samples, Material Transfer Agreements (MTAs) Legal and official obligations Ethical issues and obligations, approved methods and legal penalties Technical requirements for donations, testing human tissue and cells, EU directives for samples, 2001/20/EC Ethical and legal aspects regarding biobanking in other countries (topic for assignment to send in) 	0	100	30	50	6	Assignment to send in
4	Collection and Management of Samples (Hands on)	<ul style="list-style-type: none"> Feedback and questions to contents of modules Scientific working/writing Sample Collection and Management <ul style="list-style-type: none"> Requirements to biobank infrastructure and consumables Storage systems and laboratory automation Different types of sample storage temperature (-80°C, -196°C, RT, ...) Optimization of workflows Collection and storage methods Measurement of quality assurance Process of sample input: <ul style="list-style-type: none"> Acquisition, processing, storage, transfer Service and appreciation of biobanks in different fields (clinic, health care, biotechnology, environment,...) Implementation of samples in genomics, proteomics and in other -omics fields Cryo biology <ul style="list-style-type: none"> Basics of cryo conservation of cells and tissues Cells and their environment (ischemia, hypoxia, molecular and cellular responses on an altered cellular environment) Viability and verification of the efficacy of cryo conservation Cryo conservation versus fixation Liquid nitrogen: <ul style="list-style-type: none"> Effect of liquid nitrogen, security measures Sample transport and shipping: <ul style="list-style-type: none"> International regulations for the transport of dangerous materials (ICAO, IATA) Classification of dangerous materials; nomenclature; packaging and documentation Freezing agents 	40	60	30	50	6	Written exam Continual assessment

5	Risk Management and Biobanking	<ul style="list-style-type: none"> • Risk management and risk reduction • Risk management of infrastructure • Security training • Risk assessment, risks for staff, visitors, samples, facilities • Safety development • Storage • Packaging (Maintaining of the cooling chain) • Duplicates and backups • Escape plans and emergency plans • Security of IT, databases and computer systems • Biological risks • Chemical risks • Physical risks • Ethical risks • Financial risks • Impact of pre-analytical variations in research: <ul style="list-style-type: none"> – Analysis of variability – Intra-individual, inter-individual, analytical and pre-analytical differences – Risks of pre-analytical changes during collection, transport and processing or storage of samples 	0	100	30	50	6	Assignment to send in
6	Biobanking IT	<ul style="list-style-type: none"> • IT and knowledge management • Organisation of an IT-infrastructure • Definition of devices and differences of biobanks (f. e. clinical biobanks, population based biobank, ...) • Type of data • Data quality • International standardisation versus harmonization • Data protection strategy • Concepts of data management • Bioinformatics • Biobank statistics and strategy: <ul style="list-style-type: none"> - Specific requirements for the collection (population,...) - Minimal number of samples for storing in a biobank - Statistical power • Retrospective and prospective collection 	0	100	30	50	6	Written exam
7	Sustainability, Budgeting and Business Planning in Biobanks	<ul style="list-style-type: none"> • Preparation of a business plan for a biobank • Instruments for planning and organisation • Budget and performance planning • Research promotion • Decision making methods in biobank institutions • Decision problems with house keeping • Cost calculation and user fees (full costs/direct costs) • Cost analysis: Biobank Operating Procedures • Cost analysis of direct and indirect costs • Planning in the areas of tension between research, quality and business economy 	0	70	30	50	5	Assignment in form of a case study
8	Epidemiology	<ul style="list-style-type: none"> • Activities in epidemiology • Study types • Build up of an epidemiologically relevant study cohort • Epidemiological key figures • Epidemiological methods • Recognition of errors in studies, assessing methodological quality of studies • Data quality audit • Health care systems research and health economics • Concepts of public health reporting • Data generation and data sources • Analysis of public health reports (generic, thematic and specific to target groups) 	0	100	30	50	6	Written exam
9	Quality Management and Quality Control	<ul style="list-style-type: none"> • Monitoring and reporting • Quality assurance: audit / service • Standard operating procedures (SOP) • Best Practices (BPs) • Framework conditions for quality agreement (organisational, management, administration, training, staff consequences, customer orientation) • Certification, quality agreement, audits, external quality assurance f. e. ISO9001: 2008, ISO17025: 2005; ISO 34 Reference Material (new ISO guideline) • Quality management and different QM-systems • Process support and competence training • Technology transfer • Method validation (process methods, quality control, instability of data, critical points, strategies for validation of qualitative, quantitative and semi-quantitative methods) • Quality regulations and records • Documentation control and verification • Quality control of samples (standardized/optimized and validated process and storage protocols) • Biomarkers and pre-analytical variables • Legalisation of samples • Stability, pureness, stable traceability (processing upon receipt, handling, storage, distribution and transport, records) <ul style="list-style-type: none"> – Performance indicator, feedback of customers and clients – Validation of samples: fixed tissues, biological fluids, cell lines, other samples 	0	100	30	50	6	Written exam
10	Management and Communication	<ul style="list-style-type: none"> • Feedback and questions to contents of modules • Scientific working/writing • Basics of management and business economics • Project and process management (process map) • Knowledge management • Operational and strategic controlling • Sponsor (evaluation, acquisition and support) • Collaboration with academic and industrial partners • Basics of communication • Conversational skills • Presentation techniques (poster and lecture) • Conflict management, negotiation strategies 	40	60	30	50	6	Assignment to send in / Continual assessment

List of abbreviations

ECTS – Credits: *European Credit Transfer and Accumulation System (ECTS) is a standard for comparing the study attainment and performance of students of higher education across the European Union and other collaborating European countries. For successfully completed studies, ECTS credits are awarded. One academic year corresponds to 60 ECTS credits that are equivalent to 1500 hours of study in all countries respective of standard or qualification type and is used to facilitate transfer and progression throughout the Union.*

TU = Teaching Unit - 1 TU means 45 minutes