“UMBRELLA Biobank Urologie” Regulation

Version: 3.1 March 1st 2024

With these regulations, the Biobank undertakes to protect the fundamental rights of the participants[1] , namely their dignity, autonomy, privacy and confidentiality with regard to their data as well as their personal rights. It undertakes to respect the legal requirements and ethical and professional standards in its work and to adhere to the governance principles listed below.

[1] For reasons of readability, the masculine form has been chosen in the following text; nevertheless, the information refers to members of both genders.

The document is supported by Swissethics

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1 GENERAL PROVISIONS

1.1 AREA OF APPLICATION

These regulations define the objectives as well as the organisation and functioning of the Umbrella Biobank Urologie. They take into account all the requirements related to associated with the collection, storage and dissemination of biological material and the associated data (i.e. biological resources).

1.2 APPLICABLE LAW

These regulations have been drawn up in accordance with the applicable standards, in particular the Federal Act on Research involving Human Beings (HRA), cantonal legislation and the Federal Act on Data Protection (FADP). The regulations follow the recognised ethical and professional principles, in particular the ethical aspects related to health databases and biobanks listed in the Declaration of Taipei from 2016.

1.3 DEFINITIONS

The definitions of the technical terms used in these Regulations are taken from the Swiss Biobanking Platform (SBP) and are listed in Annex I of this document.

1.4 ABBREVIATIONS

FEDERAL CONSTITUTION Federal Constitution of the Swiss Confederation of 18 April 1999; SR 101

ZGB Swiss Civil Code of 10 December 1907; SR 210

FADP Data Protection Act of 25 September 2020, SR 101

DTA Data Transfer Agreement

HRA Federal Act on Research involving Human Beings of 30 September 2011; SR 810.30

MTA Material Transfer Agreement

HRO Ordinance on Human Research with the Exception of Clinical Trials of 20 September 2013; SR 810.301

SBP Swiss Biobanking Platform

2 DESCRIPTION OF THE BIOBANK

2.1 PURPOSE OF THE BIOBANK

1. This biobank is a biological and genetic collection of samples from tumour patients from the University Clinic for Urology at the Inselspital in Bern.

2. The Umbrella Biobank Urologie is located at the University Hospital Insel Bern, Department of Urology, Wilhelm-Fabry-Haus, Freiburgstrasse 37, 3010 Bern.

3. The Umbrella Biobank Urologie is responsible for recruiting patients, obtaining informed consent and collecting biological material samples. The collected samples are then sent to the Liquid Biobank Bern (LBB).

4. The Umbrella Biobank Urologie uses the services provided by the Liquid Biobank Bern (LBB) of the Inselspital. The Liquid Biobank Bern is in charge of the preparation, storage and delivery (on request) of samples of the Umbrella Biobank Urologie samples.

2.2 AIM OF THE BIOBANK

1. This biobank has been established for research purposes.

2. This Biobank is intended for current and future research projects whose primary user is the University Department of Urology, Inselspita University Hospital Bern. Secondarily, and only after an approved request application to the Biobank Scientific Board, the collected samples could be made available for research purposes at other health institutions operating in the academic and private sector.

2.3 STAKEHOLDERS BENEFITS

The biobank can offer numerous benefits to various stakeholders, including researchers, healthcare providers, patients, and society as a whole:

1. Researchers:
Access to a large and diverse collection of biological samples and associated data for conducting studies.
Accelerated research and discovery by providing a vast resource of specimens, reducing the need for sample collection and processing.
Facilitation of translational research to bridge the gap between basic science and clinical applications.
Collaboration opportunities with other researchers and institutions, enhancing the potential for groundbreaking discoveries.
2. Healthcare Providers:
Improved diagnostics and personalized treatment options based on genetic and molecular data from biobank samples.
Enhanced ability to study rare diseases or conditions, leading to more effective treatments.
Better understanding of disease progression, allowing for early intervention and preventive measures.
Support for evidence-based medicine through access to real-world patient data.
3. Patients:
Potential access to cutting-edge treatments and therapies resulting from research conducted with biobank samples.
Improved healthcare outcomes through personalized medicine tailored to individual genetic profiles.
Contribution to the advancement of medical science and improved care for future generations.
Increased transparency and trust in healthcare institutions through ethical and consent-driven practices.
4. Society:
Advancement of medical knowledge and the development of new treatments and drugs, benefiting public health.
Economic growth and job creation in the biotechnology and healthcare sectors.
Increased awareness and understanding of health-related issues, fostering public health education.
Ethical, regulated, and transparent practices set a positive example for the biobanking and research community.
5. Regulatory Bodies and Policymakers:
Oversight and regulation of biobanks to ensure ethical standards, privacy, and data protection.
Utilization of biobank data for healthcare policy development and evidence-based decision-making.
Development of guidelines and standards for biobanking practices to maintain data quality and integrity.
Promoting research that addresses public health challenges and improves healthcare systems.

It's important to note that the success and benefits of the biobank depend on ethical considerations, informed consent, data security, and adherence to

regulatory frameworks to protect the rights and privacy of donors. Transparent communication and collaboration among stakeholders are key to realizing the full potential of biobanks for all affected parties.

2.4 TYPE OF BIOLOGICAL RESOURCES

1. The type of biological resources stored in the biobank is described in Annex II.

2. These biological resources originate from outpatient and inpatient voluntary tumour patients of the University Department of Urology at the Inselspital.

2.5 STORAGE PERIOD

The biological resources will be stored in the biobank service provider Liquid Biobank Bern (LBB) for at least 20 years.

Note: If the biobank has a limited lifespan, the provisions on "Dissolution of the biobank" listed in these regulations under 3.10 apply.

3 GOVERNANCE

3.1 FOUNDATION OF THE BIOBANK

The Umbrella Biobank Urologie was founded on 01 November 2023.

3.2 LEGAL FORM

The Umbrella Biobank Urologie is affiliated to the Department of Urology at the University Hospital Insel Bern and has no legal personality of its own.

3.3 STRUCTURE

1. The organisational structure of the biobank consists of: medical and strategic Head, Operational-, Administrative- and IT-Management (see organisation chart and list of responsible persons in charge and members of the various structures in Appendix III).
2. A scientific committee will be responsible for reviewing any request for samples from the Umbrella Biobank Urologie to be used in a research project.

3. The person(s) responsible for the biobank shall be listed in Annex III.

3.4 CONSENT

1. The collection, storage and use of biological resources for the Umbrella Biobank Urologie is based on a specific informed consent, including the possibility of re-use for future research projects, given by the patient during their outpatient and inpatient treatment
2. After being informed by a clinic physician about the Umbrella Biobank research project, patients will be given a copy of the project information and terms of consent, and will be given at least 24 hours to give their voluntary consent to participate in the project. Only after patients have given and signed a prior voluntary consent to participate in this research project will the clinic be able to collect samples for the Biobank..
   . The status of the participant's consent is documented and the declaration of consent form is archived. The template consent form is provided in Appendix IV.
3. Consent may be revoked by the participant at any time without giving reasons. This revocation will not result in any disadvantage to the participant in terms of medical care. The modalities for revocation are included in the declaration of consent. For further information, the participant can contact the biobank using the details given in Chapter 7 of these regulations under "Contact".
4. After withdrawal of consent, the samples and associated data of the respective participant stored in the biobank for research purposes may no longer be used. In this case, the samples and data will be destroyed according to the disposal concept of the Inselspital Bern.
   Note: Withdrawal only affects the future use of biological resources for research purposes. Previously obtained results and their analyses are not affected.

5. Only additional biological samples will be collected and stored for the purposes ot the Umbrella Biobank. No residual material from the outpatient and / or inpatient's treatment will be used for the Umbrella Biobank Urologie.
6. No samples will be collected for the Umbrella Biobank Urologie without the patient's prior Biobank-specific signed informed consent.

3.5 UNDERAGE OR INCAPABLE OF JUDGEMENT PARTICIPANTS

The Umbrella Biobank Urologie only enrols patients over the age of 18 who are able to provide a signed informed consent.

3.6 DATA PROTECTION MEASURES

1. The biological resources are stored in encrypted form at the Liquid Biobank Bern. For further use in future research projects, the biological samples and health data will be used in encrypted form.
2. The rules of the Insel Data Science Centre (IDSC) apply to the encryption.
3. A declared confidential holder of the Umbrella Biobank Urologie who is not directly involved in the research with the samples and data of the biobank can request to the IDSC the encryption key at any time to ensure the data quality management process. The declared confidentiality holder is the medical and strategical head of the Umbrella Biobank Urologie, Prof. Dr. med. Bernhard Kiss, as well as the operational Manager Mr. Anselm Lafita.In case the operational manager Mr. Anselm Lafita will be involved on the application to the EC of future clinic research projects, the key holder will be the administrative manager Mr. Herold Bumann.

   Encryption/coding:

4. The information on the samples stored at the Liquid Biobank Bern (LBB) is managed in a Biobank Management System (BIMS), including an access track documentation. The management system ensures that: a) patient safety is not compromised, b) all processing procedures relevant to ensuring traceability are documented. Health-related data is stored outside the sample management system. This data is managed in the Clinical Information and Control System (KISS) of the Inselspital.
   The Umbrella Biobank Urologie manages the linking of sample to patient. The encryption key of the health-related data will be managed by the IDSC in coordination with the Umbrella Biobank Urologie. This ensures that: a) the handling of health-related personal data is restricted to those persons who need this data to fulfil their tasks, b) unauthorised or inadvertent disclosure, modification, deletion and copying of health-related personal data is prevented.
   The patients and health-related information recorded by the Umbrella Biobank Urologie will be documented in a SharePoint based Database, including access track system) and managed by the CTU Bern.

5. When to biological material and/or associated data is granted to a researcher who fulfils the conditions for access to the Umbrella Biobank

Urologie resources, no personal information (like name, birth date, address or contact items) about the participant will be disclosed.

6. The participant is informed of the consequences of encryption.

7. Any request for biological and health-related data for future research projects using the resources of the Umbrella Biobank Urologie, must be submitted by the Umbrella Biobank Urologie to the DLF Governance and IDSC Departments of the Inselspital Bern for approval before being made available to researchers. Research projects that apply for biobank resources must have the prior approval of the relevant ethics committees.

8. The coding key used to identify the donor reference , is based on the IDSC data protection guidelines as well as on national legal and ethical guidelines. Access to the coding key is restircted to IDSC staff and granted personal of the Umbrella Biobank Urologie. No person directly involved in the research projects will have access to the coding key and any conflict of interest will be eliminated.

9. Employees of the Liquid Biobank Bern do not have the acces to modifying or canceling the key.

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10. In order to check the appropriateness of the biobank processes and compliance with the quality requirements for data protection, regular quality controls are carried out, which are summarised in a Data Quality SOP including a Data Management Plan after the SBP Templates and requirements.

3.7 ACCESS AND TRANSFER

The Umbrella Biobank Urologie has clear rules regarding access to and transfer of biological resources, in accordance with the participant's consent. The access and transfer modalities are listed in Chapter 5, "Transfer of Biological Resources", of these Regulations.

3.8 PARTICIPANT'S RIGHT TO INFORMATION

3.8.1 Right of inspection

The participant may at any time inspect all the information held by the Umbrella Biobank Urologie about him or her in order to update or delete it if necessary and to find out what happens to hi or/her biological samples data. The participant may contact the Umbrella Biobank Urologie in accordance with the provisions set out in Chapter 7 of these Regulations under "Contact".

3.8.2 Complaints

The development of a complaint procedure to allow participants to easily submit complaints and requests to the biobank (Art 21 Taipei), the Umbrella Biobank Urologie has developed a SOP Safety and Compliance for this purpose.

An Compliance application form will be available on the website of the Umbrella Biobank.

3.8.3 Communication of research results

11. A participant has the right to be informed of the results of research concerning his or her health, in accordance with his or her consent and applicable ethical standards. The research results about which the participant is informed, must meet at least the following criteria: analytical[2] , clinical relevance[3] and possibility of action[4].

12. Research projects performed by the University clinic for Urologie at the Inselspital, will be published and made available on the Umbrella Biobank Urologie Website as well as on the clinic's Website.

13. The participant will be informed of the policy on the communication of research results and the nature of the results that will be communicated to him/her (see Annex V).

14. The release of individualised research results will decided on a case-by-case basis by a team of experts. The right not to know must be respected in all cases.

15. Any unexpected discoveries made during a future research project using the Umbrella Biobanking Ressoruces are not part of this Biobank itself. Any incidents and findings taking place during the collection an processing of the Biobank samples itselt, will be documented and registered.

3.8.4 Activities of the biobank

1. The Umbrella Biobank Urologie informs the public about its organisation, its functioning and its activities via the website of the University Department of Urology of the Inselspital Bern.

2. An overview of the research projects using the Biobank's biological resources is givenv in Annex VI.

3.9 FINANCING

The financing of the Umbrella Biobank Urologyie is secured by the University Department of Urology at the Inselspital Bern, which is provided by the Clinic Fund for an expected period of 20 years. The funding will cover the entire lifespan of the biological resources stored in the biobank.

3.10 DISSOLUTION OF THE BIOBANK

1. In accordance with the participant's consent, following the cessation of activities and/or the dissolution of the biobank, the biological resources stored in the biobank shall either be transferred to and integrated into another biobank with an equivalent standard of protection, or destroyed.

2. The provisions on destruction of the Inselspital Bern are set out in Annex VII.

[2] They describe a specific clinical situation precisely and reliably.

[3] They provide information about a known and significant risk of a potentially serious health problem.

[4] Recognised therapeutic or preventive treatment or other possible measures can be used to potentially influence the course of the disease or condition.

4 OPERATIONAL PROCESSES

4.1 GENERAL PRINCIPLE

Samples and data will be collected, stored, and used in sccordance eith applicable laws, ethical and professional standards and informed consent.

Samples will be collected from outpatients and in-patients with tumours at the University Department of Urology, Inselspital Bern, after written consent has been obtained.

Collected samples (fluid and tissue) are stored at the service provider Liquid Biobank Bern (LBB)

BIOBANK BERN
LIQUID

Biobank Bern of the Inselspital is a member of the Swiss Biobanking Platform and is in possess of all quality labels of the Swiss Biobanking Platform for its propose, “Vita”, “Norma” and “Optima”.

4.2 COLLECTION AND MANAGEMENT OF SAMPLES AND DATA

1. The Umbrella Biobank Urologie is responsible for ensuring that all samples and/or data it collects can be attributed to valid informed consent of the Umbrella Biobank Urologie and will implement a data quality management process and associated standard operation procedures (SOPs) to ensure compliance.

2. The collection of biological samples and the generation of data do not give rise to any right to financial compensation or other material benefits.

4.3 CONSERVATION OF BIOLOGICAL RESOURCES

4.3.1 Material

Access to the rooms where the samples are stored is secured and controlled according the regulations of Liquid Biobank Bern Inselspital. The temperature of the storage facilities is monitored around the clock (24/7). Information on the following measures such as central alarm system, temperature monitoring, backup freezer, backup CO2, air conditioning, room temperature monitoring, secured freezers have been taken to protect the samples. We refer to the Liquid Biobank regulations, which can be found in Appendix II of this document.

4.3.2 Related data

1. The pre-analytical data are managed in the Clinical Information and Control System of the Inselspital.

2. Personal data, including health-related data, will be automatically collected in the Clinic Information and Control System of the Inselspital. The data collected for research purposes will always be analysed and processed by the Insel Data Science Centre (IDSC) before being made available for any research projects.

5 ACCESS TO BIOLOGICAL RESOURCES

5.1 ACCESS CONDITIONS

1. Access to biological resources shall be granted by the management of the Biological Resources Management Committee according to the following criteria: "first come, first served".
The process flow request to receipt of the biological resources is described in detail in Annex VIII.

2. A researcher who receives authorisation to use the biological resources of the Umbrella Biobank Urologie undertakes not to re-identifying the participant, except in the circumstances set out in Art. 27 paragraph 2 of the HRO.

3. The Umbrella Biobank Urology shall grant access to its biological resources only to those projects for which the competent ethics committee or an equivalent body has given its prior approval.

5.2 TRANSFER

1. All transfers must be verifiably regulated and documented. The transfer of biological samples collected at the Umbrella Biobank Urologie is bubject to the approval of the application procedure by its scientific board.

2. The DTA/MTA defines the obligations and responsibilities of the parties involved in the transfer of biobank material prior to its delivery. A DTA is mandatory when personal data are transferred to third parties. Obligations not explicitly transferred to the recipient by the DTA/MTA remain the responsibility of the biobank. In any case, the biobank is responsible to the participant at all times and within the scope of its responsibility.

3. Future research projects aiming to use biological material from the biobank or its related data must be submitted to the responsible (lead) ethics committee as a new project in accordance with Art. 45 of the HRA. In order to link these research projects to this Biobank statement in BASEC, the applicant must enter the Statement ID “AO_2023-00086” in the application form of the ethics committee for its research project application form.

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4. In case or research projects carried out abroad, the recipient must also guarantee at least the same conditions as in Switzerland with regard to the rights of the participants and data protection.

5. If a financial contribution is levied for the transfer of biological resources for external research projects, the following costs will be covered: the authorisation process by the Management Committee, sample preparation and storage, sample transport and collection will be borne by the recipient, as well as data processing costs.

6 QUALITY

1. The Liquid Biobank (LBB) has a quality management system. Since 19 October 2015, it has been certified by the Swiss Biobanking Platform (SBP) in accordance with the following quality standards Biobanking Quality Labels: "Norma”, “Optima" sowie “Vita”.

BIOBANK QUALITY LABEL BY SWISS BIOBANKING PLATFORM
NORMA
GOVERNANCE PROCESS

BIOBANK QUALITY LABEL BY SWISS BIOBANKING PLATFORM
OPTIMA
GOVERNANCE PROCESS QMS

2. The Umbrella Biobank Urologie is registered with the SQAN of the Swiss Biobanking Platform (SBP) and certified according to the qualitystandards of the Biobanking Quality Label "Vita" of the Swiss Biobanking Platform (SBP).

3. The Umbrella Biobank Urology entrusts the Liquid Biobank Bern(LBB) with the following processes: Processing, storage and documentation of the samples collected.
4. The Biobank Regulations will be reviewed annually by its Manament Committee with regard to their purpose within the framework of the quality management system. A CAPA (Corrective And Preventive Action) plan is drawn up for this purpose. The decisions of this annual quality management review and the resulting actions will be recorded and documented in the Research Project Annual Report.

7

CONTACT

For questions or additional information, please contact:

Umbrella Biobank Urologie

University Hospital Insel Bern

University Department of Urology

Mr Anselm Lafita – Biobank Operational Manager

Wilhelm-Fabry-Haus

Freiburgstrass 37

3010 Berne

Phone: 031 632 23 32

Email: biobank.urologie@insel.ch

8 APPENDICES

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Prof. Dr. med. Bernhard Kiss

Umbrella Biobank Urologie - Medical and strategical Manager

CHANGE HISTORY

Version	Date of entry into force	Details Changes
1.0	01.11.2023	Biobank foundation and first publication of the regulations
1.1	05.12.2023	EC and SBP Review
2.0	04.01.2024	Final Version ready for application to the EC and publication
3.0	01.02.2024	Review after EC 1st application statement
3.1	01.03.2024	Review after EC 2nd application statement

ANNEX I
Definitions

8.1 ANONYMISATION
Irreversible removal of the reference of the biological material and/or the associated data to the participant, so that identification of the participant is impossible.

8.2 BIOBANK
A legal entity responsible for the management of biological resources with existing governance.

8.3 BIOBANK GOVERNANCE
The structures and rules for the operation of a biobank that have been developed taking into account the respective objectives and the applicable legal and ethical provisions.

8.4 BIOBANK INFRASTRUCTURE
Infrastructure service provider to which the biobank transfers outsourced processes.

8.5 BIOLOGICAL RESOURCES
Biological material and the associated data.

8.6 BIOLOGICAL MATERIAL
All material derived from or extracted from a biological organism.

8.7 DATABASE
An organised collection of data.

8.8 DATA TRANSFER AGREEMENT (DTA)
Bilateral contract that regulates the transfer of data for research purposes. It describes the rights and obligations of the data provider and the recipient with regard to the use of the data and clarifies other issues such as confidentiality and intellectual property.

8.9 ASSOCIATED DATA
Personal data and/or pre-analytical data.

8.10 VOLUNTARY AND INFORMED CONSENT (INFORMED CONSENT)
Voluntary and informed written consent of the participant that his/her biological material and/or related data may be collected, stored, used and disclosed for research purposes.

8.11 GENERAL CONSENT
Voluntary and informed consent of the participant that his/her biological material and/or the associated data may generally be collected, stored, used and passed on for future research projects, including those not yet defined.

8.12 HEALTH-RELATED PERSONAL DATA
Data relating to a participant's health or illness, including genetic data (e.g. clinical, epidemiological, socio-economic data, etc.).

8.13 CODING KEY
Information that can be used to establish a direct link from the biological material and/or the associated data to the participant.

8.14 MATERIAL TRANSFER AGREEMENT (MTA)
Bilateral agreement that regulates the transfer of biological material and data for research purposes. It describes the rights and obligations of the supplier and the recipient with regard to the use of the material and data and clarifies other issues such as confidentiality and intellectual property.

8.15 PERSONAL DATA
Any information relating to an identified or identifiable person, including health-related data.

8.16 PRE-ANALYTICAL DATA
Data on the collection, processing, storage and use of the biological material (e.g. time of sample collection, transport temperature, centrifuge speed, storage temperature, etc.).

8.17 PROBE
A certain amount of biological material, such as plasma, serum, DNA, RNA, cells, etc., from a specimen.

8.18 PARTICIPANTS
A living or deceased person who makes their biological material and/or the associated data available to the biobank.

8.19 SPECIFIC CONSENT
Voluntary and informed consent of the participant that his/her biological material and/or related data may be collected and stored and used and shared for a specific research project.

8.20 SPECIMEN
A specific amount of biological material, such as tissue, blood or urine, taken from a subject or participant at a specific point in time.

8.21 ENCRYPTION
Reversible removal of the reference of the biological material and/or the associated data to the participant, so that the participant can only be identified with a coding key.

8.22 REPEAL
Withdrawal of the previously given consent. (The consequences of withdrawal are defined in the declaration of consent and must be communicated to the participant concerned during the consent process).

8.23 RIGHT OF OBJECTION
In this case, tacit consent applies if an action has not been expressly objected to after prior information.

ANNEX II
Biological resources of the biobank

These biological resources originate from outpatients and inpatients at the Department of Urology at Inselspital.

Biological material
- Specimen 1: Body fluids, Origin: Biological. Storage at Liquid Biobank Bern
- Specimen 2: Tissue, Origin: Biological. Storage at Liquid Biobank Bern

- Sample 1: [Blood serum], storage temperature: -80°C
- Sample 2: [blood plasma], storage temperature: -80°C
- Sample 3: [Blood EDTA with RNAlater], storage temperature: -80°C
- Sample 4: [Urine], storage temperature: -80°C
- Sample 5: [faeces], storage temperature: -80°C
- Sample 6: [tissue], storage temperature: -130°C

Inclusion criteria:
- Every person, regardless of their gender
- Older than 18 years old,
- who receive medical treatment or care at the Department of Urology at the University Hospital Insel Bern.
- who are able to provide a written declaration of consent
- diagnose prostate, bladder, kidney or testicular cancer or
- Patients undergoing transurethral resection of the bladder (TUR-B)

Exclusion criteria:
- Insufficient knowledge of the project language
- Inability to give consent
- Minors or persons under legal guardianship

Target diagnoses and timetable for the collection of biobank samples:
Prostate cancer:
- Primary diagnosis
- Preoperative
- 3 mo. postoperative
- Suspicion of progression

Muscle-invasive bladder cancer:
- Primary diagnosis / Preoperative (radical cystectomy)
- 3 + 6 + 12 months postoperative
- Suspicion of progression
- Pre-neoadjuvant chemotherapy
- Post-neoadjuvant chemotherapy

Non-muscle-invasive bladder cancer:
- Preoperative (transurethral resection of the bladder (TUR-B)
- 3 mo. postoperative
- 3 mo. post-instillation therapy

Kidney cancer:
- Primary diagnosis / Preoperative
- Suspicion of progression

Testicular cancer:
- Primary diagnosis / Preoperative
- After completion of chemotherapy
- Progression

Health-related personal data

Health-related personal data which will be made available for future research projects:

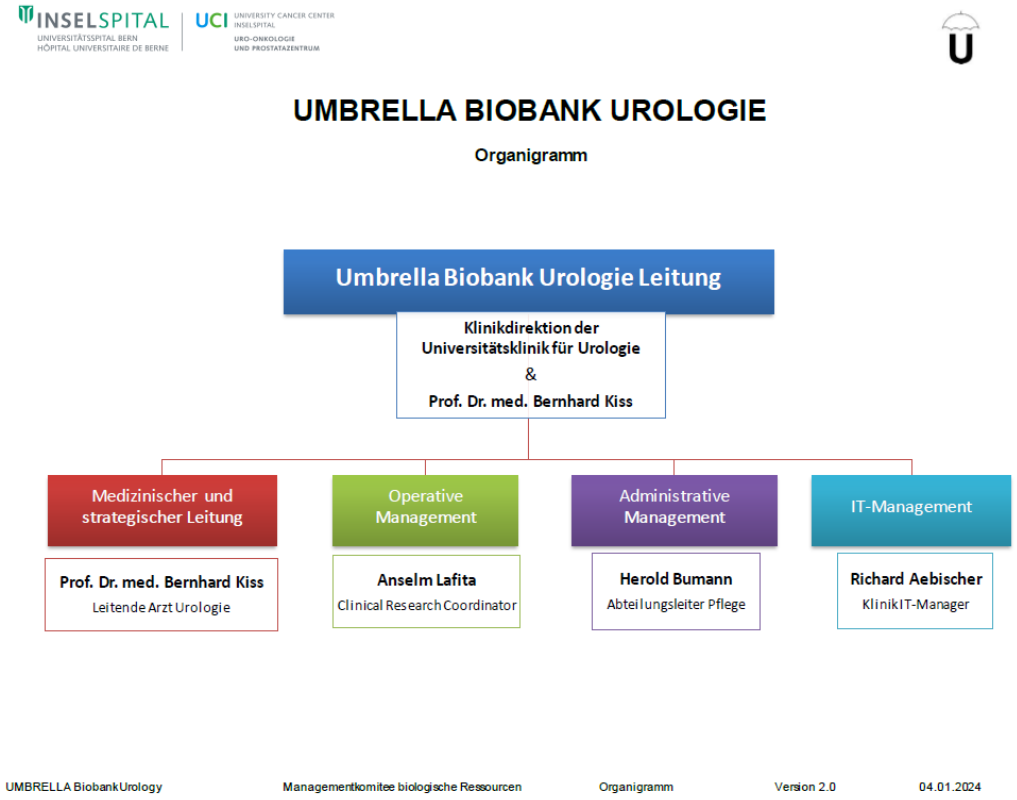
- Year of birth
- Gender
- Diagnosis and diagnosis date
- Operation and date of operation
- Health information collected during outpatient and/or inpatient hospitalisation.
- Tumour pathology status

The coding key for the coded biological resources in the biobank is in the hands of the Umbrella Biobank Urology medical and strategical head, Prof Bernhard Kiss, MD, and Mr Anselm Lafita, operational Manager of the Umbrella Biobank Urology..In case the operational manager Mr. Anselm Lafita will be involved on the application to the EC of future clinic research projects, the key holder will be the administrative manager Mr. Herold Bumann.

ANNEX III
Governance

The Umbrella Biobank Urology is organised as follows:

UMBRELLA Biobank Urology organisation chart



Management Committee

A management committee (Biobank Governance) authorises access to the biobank's biological resources.
Management Committee members:

Medical and strategical Head	Prof. Dr Bernhard Kiss
Operational management	Mr Anselm Lafita
Administrative management	Mr Herold Bumann
IT management	Mr Richard Aebischer

Scientific Committee

Prof. Dr. med. Bernhard Kiss
Prof. Dr. med. Beat Roth
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Responsible for the operational management of the biobank is:
Mr Anselm Lafita
Clinical Research Coordinator
Phone: +41 31 632 23 32
E-Mail: anselm.lafita@insel.ch

ANNEX IV
Consent template

8.24
8.25 UMBRELLA Biobank Urologie

8.26 Information und Einwilligung zur (zusätzlichen) Entnahme von biologischem Material zur Weiterverwendung in einer Biobank für die Forschung nach Art.8 HFV

Sehr geehrte Patientin, sehr geehrter Patient

Obwohl die biomedizinische Forschung in den letzten Jahrzehnten grosse Fortschritte gemacht hat, gibt es noch viele Bereiche, in denen das Wissen über Ursachen, Erkennung und Behandlung von Krankheiten zum Wohle der betroffenen Patientinnen und Patienten verbessert werden kann. Viele Biobanken in diesen Gebieten sind heute nur realisierbar, wenn biologisches Material zur Verfügung steht.

Um solche Biobanken aufbauen zu können, möchten wir im Rahmen Ihres geplanten (ambulant oder stationär) Klinikaufenthaltes (zusätzliches) biologisches Material von Ihnen erhalten.

Diese zusätzliche Entnahme von biologischem Material im Rahmen einer regulär geplanten Entnahme während einer Routine- und/oder geplanten Untersuchung umfasst Folgendes:

- zusätzliche 24 ml Blut anstelle der routinemässig erforderlichen 10 ml
- andere Körperflüssigkeiten wie z. B. 10 ml Urin und
- eine Stuhlprobe sowie
- gegebenenfalls eine kleine Menge Biopsie- oder Resektionsgewebe aus der geplanten Operation.

Ablauf

Da es sich um zusätzliches biologisches Material in Rahmen einer Routineentnahme handelt, ist die Entnahme für Sie mit keinem zusätzlichen gesundheitlichen Risiko verbunden. Dennoch können wie bei jeder Blutentnahme minimale Risiken oder Unannehmlichkeiten/Nebenwirkungen auftreten, wie z. B. lokale Hautrötungen oder Blutergüsse.

Die Sammlung, Lagerung und Verwendung biologischer Ressourcen für die Umbrella Biobank Urologie basiert auf der freiwilligen, informierten Einwilligung der Patientinnen und Patienten während ihrer ambulanten und stationären Behandlung, die auch die Möglichkeit der Weiterverwendung für zukünftige Forschungsprojekte einschliesst.

Die Einwilligung muss freiwillig erfolgen und die Patientin bzw. der Patient muss zuvor angemessen informiert worden sein. Die Einwilligung kann vom Teilnehmer jederzeit und ohne Angabe von Gründen widerrufen werden. Durch den Widerruf dürfen dem Teilnehmer keine Nachteile in der medizinischen Versorgung entstehen. Detaillierte Informationen zum Widerruf der Einwilligung finden Sie unten in diesem Dokument.

Hinweis: Der Widerruf bezieht sich nur auf die zukünftige Nutzung der biologischen Ressourcen zu Forschungszwecken. Bereits gewonnene Ergebnisse und Auswertung bleiben davon unberührt.

In die Umbrella Biobank Urologie werden nur Patienten ab 18 Jahren aufgenommen, die in der Lage sind, eine unterschriebene Einwilligungserklärung abzugeben.

Aufbewahrung in der Biobank und Datenschutz

Das so gewonnene biologische Material wird zusammen mit den zugehörigen Personendaten in einer sogenannten Biobank aufbewahrt und der Forschung zur Verfügung gestellt. Aus den Proben können auch so genannte genetische Daten gewonnen und gespeichert werden. Genetische Daten können Rückschlüsse auf Ihr Erbgut zulassen.

Das biologische Material und die Daten werden verschlüsselt gespeichert. Verschlüsselt bedeutet, dass alle Angaben, die Sie identifizieren könnten (z.B. Name, Geburtsdatum etc.), durch einen Code (Schlüssel) ersetzt werden, sodass

Personen, die den Code nicht kennen, keine Rückschlüsse auf Ihre Person ziehen können. Innerhalb der Universitätsklinik für Urologie des Inselspitals Bern können die Daten auch unverschlüsselt von berechtigten und klar bezeichneten Personen eingesehen werden. Der Schlüssel bleibt immer bei der Institution.

Die Institution, welche die Umbrella Biobank Urologie betreibt, ist für die sichere Aufbewahrung und den Schutz des biologischen Materials verantwortlich. Das Reglement der Umbrella Biobank Urologie ist unter folgendem Link zu finden:

http://www.urologie.insel.ch/de/lehre-und-forschung/biobank

Ihr biologisches Material und die dazugehörigen Personendaten dürfen nur in verschlüsselter Form an Forschende innerhalb und ausserhalb der Institution Universitätsklinik für Urologie des Inselspitals Bern weitergegeben werden. Die Forschenden können in schweizerischen oder ausländischen Institutionen wie Spitälern, Hochschulen oder in der Industrie arbeiten. Im Ausland müssen jedoch mindestens die gleichen gesetzlichen Anforderungen an den Datenschutz bestehen wie in der Schweiz. Für die Umsetzung der Datenschutz ist die Projektleitung im Ausland verantwortlich, welche die Proben und Daten für ihr Forschungsprojekt verwendet, und jedoch die notwendigen Massnahmen zum Schützt der Rechte der Teilnehmenden getroffen hat. Zukünftige Forschungsprojekte mit dem von Ihnen zur Verfügung gestellten biologischen Material und den dazugehörigen Daten dürfen nur mit einer Bewilligung der zuständigen Ethikkommission durchgeführt werden (gilt für Forschungsprojekte in der Schweiz).

Ergebnisse und Zufallsbefunde

Viele Forschungsergebnisse sind für den einzelnen Patienten nicht relevant. Die Ergebnisse von Forschungsprojekten werden in der Regel veröffentlicht und können zur Verbesserung der Behandlung beitragen. Einzelne Personen werden bei einer Veröffentlichung nicht identifizierbar sein.

Sollten jedoch im Rahmen des Forschungsprojektes jedoch Ergebnisse gefunden werden, die Ihre Gesundheit direkt betreffen und präventive oder therapeutische Maßnahmen möglich machen, werden Sie darüber informiert. Wenn Sie nicht informiert werden möchten, teilen Sie dies bitte der am Ende des Dokuments genannten Kontaktperson mit.

Freiwilligkeit und Widerruf der Einwilligung

Ihre Einwilligung für die (zusätzliche) Entnahme von biologischem Material ist freiwillig. Sie können die (zusätzliche) Entnahme ohne Angabe von Gründen ablehnen, ohne dass Ihnen daraus Nachteile für eine medizinische Behandlung entstehen. Sie können Ihre Einwilligung auch jederzeit ohne Angabe von Gründen zurückziehen (widerrufen). In diesem Fall werden Ihre Daten und die Probe vernichtet, laufende Projekte werden jedoch zu Ende geführt. Der Widerruf der Einwilligung ist schriftlich an die Leitung der Biobank zu richten. Bitte verwenden Sie dazu die in diesem Dokument angegebenen Kontaktdaten. Ab dem Zeitpunkt des Widerrufs der Einwilligung der Patient:innen werden das bis dahin gesammelte biologische Material sowie die nicht gesundheitsbezogenen und gesundheitsbezogenen Personendaten nicht mehr für die Forschung zur Verfügung gestellt und nach dem Entsorgungskonzept des Inselspitals Bern vernichtet.

Hinweis: Der Widerruf bezieht sich nur auf die zukünftige Nutzung der biologischen Ressourcen zu Forschungszwecken. Bereits gewonnene Resultate und deren Analysen von den bisherigen gesammelten Proben sind davon nicht betroffen.

Schutz

Sollte Ihnen durch die (zusätzliche) Entnahme von biologischem Material ein Schaden entstehen, der nicht vorhersehbar war, so haftet die Institution oder Firma, welche die (zusätzliche) Entnahme veranlasst hat und dafür verantwortlich ist, in diesem Fall das Universitätsspital Insel Bern. Die Voraussetzungen und das Verfahren sind gesetzlich geregelt. Sollten Sie zu Schaden gekommen sein, wenden Sie sich bitte an die am Schluss dieses Dokuments aufgeführte verantwortliche Person.

Datenschutzmassnahmen

Die biologischen Ressourcen werden in verschlüsselter Form aufbewahrt. Für Weiterverwendung in zukünftigen Forschungsprojekten werden die biologischen Proben und Gesundheitsdaten in verschlüsselter Form verwendet. Für diese Weiterverwendung gelten die Regeln des Insel Data Science Center (IDSC) des Inselspitals.

Ein erklärter Geheimnisträger der Umbrella Biobank Urologie, der nicht direkt an der Forschung mit den Proben und Daten der Biobank beteiligt ist, kann der Verschlüsselungsschlüssel jederzeit beim Inselspital anfordern, um den Prozess des Datenqualitätsmanagements sicherzustellen. Die Mitarbeiter der Universitätsklinik für Urologie des Inselspitals welche in Besitz der Verschlüsselungsinformation sind, sind der medizinische und strategische Leiter der Umbrella Biobank Urologie, Prof. Dr. med. Bernhard Kiss, sowie die weiteren Mitglieder des Biobank-Managementkomitees, soweit sie nicht in zukünftigen Forschungsprojekten involviert sind.

Finanzierung

Das Projekt wird aus klinikinternen Mitteln finanziert.

Sollten Ergebnisse aus den Daten und Proben kommerziell verwendet, habe ich keinen Anspruch auf einen Anteil an der kommerziellen Verwertung.

Nehmen Sie sich Zeit für Ihre Entscheidung. Für Fragen stehen wir Ihnen jederzeit gerne zur Verfügung.

Umbrella Biobank Urologie

Herr Anselm Lafita – *organisatorischer Manager der Biobank*

Wilhelm-Fabry-Haus

Freiburgstrasse 37

3010 Bern

Schweiz

Telefon: 031 632 23 32

E-Mail: biobank.urologie@insel.ch

Einwilligungserklärung

Schriftliche Einverständniserklärung zur Teilnahme an der Biobank «Umbrella Biobank Urologie».

Bitte lesen Sie dieses Formular sorgfältig durch. Fragen Sie nach, wenn Sie etwas nicht verstehen oder wissen möchten. Ihre schriftliche Einwilligung ist Voraussetzung für die Teilnahme.

Mit Ihrer Einwilligung zur (weiteren) Entnahme und Verwendung von biologischem Material und den damit verbundenen personenbezogenen Daten leisten Sie einen wertvollen Beitrag zur biomedizinischen Forschung. Dafür danken wir Ihnen herzlich.

BASEC Advisory Board Nummer:	AO_2023-00086
Name der Biobank:	**Umbrella Biobank Urologie**
Verantwortliche Institution:	Insel Gruppe AG Vertreten durch: Prof Dr. med. Bernhard Kiss Inselspital Bern Universitätsklinik für Urologie Freiburgstrasse 37 3010 Bern
Ort der Durchführung:	Inselspital Bern Universitätsklinik für Urologie Wilhelm-Fabry-Haus Freiburgstrasse 37 3010 Bern
Biobankleiter vor Ort:	Prof. Dr. med. BERNHARD KISS
Teilnehmerin/Teilnehmer: Name und Vorname in Druckbuchstaben: Geburtsdatum:	

- Ich bin von der unterzeichnenden Prüfärztin/dem unterzeichnenden medizinischen Leiter der Biobank mündlich und schriftlich über den Zweck, den Ablauf des Biobank mit der Prüfsubstanz, die Behandlungsmethode, die möglichen Vor- und Nachteile sowie über allfällige Risiken aufgeklärt worden. Ich nehme freiwillig an dieser Biobank teil und akzeptiere den Inhalt der mir ausgehändigten schriftlichen Informationen. Ich hatte ausreichend Zeit, meine Entscheidung zu treffen. Meine Fragen im Zusammenhang mit der Teilnahme an dieser Biobank wurden beantwortet. Ich behalte die schriftliche Information und erhalte eine Kopie meiner schriftlichen Einwilligungserklärung.
- Im Falle einer Weiterbehandlung ausserhalb des Biobank-Zentrums ermächtige ich meine weiterbehandelnden Ärzte, meine für das Biobank-Forschungsprojekt relevanten Daten an den Biobank-Leiter weiterzugeben. Über Ergebnisse und/oder Zufallsbefunde, die meine Gesundheit direkt betreffen, werde ich informiert. Falls ich dies nicht wünsche, informiere ich den Biobankleiter. Mir ist bekannt, dass meine gesundheitsbezogenen und persönlichen Daten (und Proben) dieser Biobank nur in verschlüsselter Form zu Forschungszwecken für die Biobank auch ins Ausland weitergegeben werden dürfen. Die Forschungsprojekte, welche die Biobank-Proben verwendet, wird den Datenschutz nach Schweizer Standard gewährleisten und einhalten.
- Ich kann jederzeit und ohne Angabe von Gründen von der Teilnahme an der Biobank zurücktreten. Meine weitere medizinische Behandlung ist unabhängig von der Studienteilnahme gewährleistet. Die bis zum Rücktritt erhobenen Daten und Proben werden noch im Rahmen der Studie ausgewertet.

- Ich bin darüber informiert, dass das Inselspital eine Versicherung abgeschlossen hat, welche Schäden deckt, die auf das Biobank zurückzuführen sind, deckt.
- Ich bin damit einverstanden, dass das im Institut für Pathologie vorhandene Restgewebe meines Tumors für Forschungsuntersuchungen verwendet wird. Ich bin mir bewusst, dass das abgegebene Restgewebe für weitere diagnostische Untersuchungen am Institut für Pathologie unter Umstände nicht mehr zur Verfügung steht.

Ort, Datum	Rechtsgültige Unterschrift der Patientin / des Patienten:
Ort, Datum	Unterschrift des medizinischen und strategischen Biobankleiters

Für Fragen und Anregungen steht Ihnen zur Verfügung:

UMBRELLA Biobank Urologie

Medizinischer und strategischer Leiter: Prof. Dr. med. Bernhard Kiss

Organisatorischer Manager: Herr Anselm Lafita

Wilhelm-Fabry-Haus
Freiburgstrasse 37
3010 Bern
Schweiz
Telefon: 031 632 23 32
E-Mail: biobank.urologie@insel.ch

ANNEX V
Communication of research results to participants

The participants will be informed by the biobank about the general results of the research project as follows:

The publications that refer to data from the Umbrella Biobank Urology are linked on the clinic homepage.

The information below is taken from the MASTER LEGAL INSTRUMENT - MTA - Version 3.0 document template of the Swiss Biobanking Platform, which we adopt and use for our Umbrella Biobank Urology:

> *"Upon completion of the Research Project or at the request of the Umbrella Biobank Urology Project Leader, the Research Project Leader using the Biobank Samples shall disclose to Umbrella Biobank Urology all results obtained in the conduct of the Research Project that relate to the processing of the Biological Resources, including, without limitation, copies of relevant summaries and reports. The Umbrella Biobank Urology project leader undertakes to keep these results confidential until publication.*
>
> *Publication of the results:*
> *Since the main purpose of using original biological resources is scientific research, the research project must ensure that its project leader makes every effort to publish its results in a timely manner.*
>
> *Review by the provider's project manager:*
> *The Recipient's Project Manager shall be free to disclose and publish the Results, provided that the proposed disclosure is submitted to the Provider's Project Manager for review at least thirty (30) days prior to the scheduled submission for publication or disclosure.*
> *The provider has the right to submit comments on the manuscript no later than 15 days before the proposed publication.*
> *Submission.*
> *The parties shall discuss in good faith to include all reasonable comments in the publication or disclosure. disclosure.*
> *If the provider does not respond within the above-mentioned deadlines, this shall be deemed as consent to publication.*
>
> *Recognition:*
> *The Recipient shall acknowledge the Provider's project leader as a co-author of the publication and/or credit the Provider as the source of the original biological resources in any written publications, posters or oral presentations. This applies to any publication on biological resources that discloses or in any way refers to the processing of the biological resources by the Recipient, unless otherwise agreed in writing by the Parties."*

ANNEX VI
Overview of research projects with biological resources from the biobank

Authorisation date	BASEC ID	Project name	Multi-/ monocentric	Participating locations	Principal investigator	Type of resources used	Risk category	Project status
30.01.2018	2017-02295	Avatar		Inselspital Bern - University Clinic for Urology	Prof George Thalmann, MD	Blood	A	open

ANNEX VII
Provisions on the destruction of biological resources of the biobank

The disposal concept of the University Hospital Insel Bern is used for the destruction of biological resources of the Umbrella Biobank Urology.

Under the following link you will find detailed information about this concept:
https://collaboration.insel.ch/sites/managementservices/si/Entsorgungskonzept/Forms/Entsorgungskonzept.aspx

B1.2-Blut-, Urin- und Stuhlproben

Blut-, Urin- und Stuhlproben

von Laboruntersuchungen

Gruppe BAFU

B1.2

Behälter	**Hinweise zum Behälter**
 	- Behälter (30/50 Liter) wird von der Abteilung Distribution im Austauschverfahren bereitgestellt - Bei vereinzeltem Bedarf bei der Abteilung Distribution bestellen, Tel. 22877

Hinweise zum Umgang	- Kontamination vermeiden - Nicht volle Behälter mit dem Tagesdeckel verschliessen - Voller Behälter muss vor der Abgabe korrekt verschlossen werden
Sammelstelle Station/Abteilung	Entsorgungsraum oder gemeinsam definierter Ort / Raum
Transport	Abteilung Distribution nach Tourenplan oder Auftrag erteilen, Tel. 22877
Sammelstelle Areal	Abteilung Distribution
Abnehmer	Einwurf direkt in den Trichter der Kehrichtverwertungsanlage KVA

Besonders zu beachten

Gefahrenkennzeichnung Entsprechende Schutzmassnahmen treffen

Abfallklassierung nach VeVA

LVA-Code	Klassierung	Herkunft	Beschreibung
18 01 02	[S]		Abfälle mit Kontaminationsgefahr (z.B. Gewebeabfälle, Abfälle mit Blut, Sekreten und Exkreten, Blutbeutel und Blutkonserven)

Gefahrgutklassifizierung nach ADR/SDR

Klasse	UN-Nr.	Bezeichnung	VG	Zettel	Freigrenze
6.2	3291	Klinischer Abfall, unspezifiziert n.a.g.	II		333 kg oder Liter

© Insel Gruppe	AG Entsorgung	Verabschiedet am: 01.01.2017	Überarbeitet:

B1.1-Körperteile, Organe, Gewebe

Körperteile, Organe, Gewebe, Plazenten

Pathologieabfälle, human

Gruppe BAFU

B1.1

Behälter	**Hinweise zum Behälter**
 	- Spezialbehälter mit violettem Deckel - Pathologie-Behälter vom Institut für Pathologie oder je nach Grösse in Kunststoffsäcke doppelt und dicht verpackt (2 Säcke)

Hinweise zum Umgang	- Behälter / Sack beschriften mit: Verbrennen und mit dem Absender - Achtung: keine Patientendaten - Wenn eine Zwischenlagerung stattfindet, muss diese gekühlt, evtl. tiefgekühlt, sein
Sammelstelle Station/Abteilung	Entsorgungsraum oder gemeinsam definierter Ort / Raum
Transport	Durch Operationspersonal und Hebammen
Sammelstelle Areal	M31 Institut für Pathologie
Abnehmer	Konzessionierte Entsorgungsfirma; Verbrennung in Spezialofen

Besonders zu beachten

Gefahrenkennzeichnung Entsprechende Schutzmass-nahmen treffen

Abfallklassierung nach VeVA

LVA-Code	Klassierung	Herkunft	Beschreibung
18 01 02	[S]		Abfälle mit Kontaminationsgefahr (z.B. Gewebeabfälle, Abfälle mit Blut, Sekreten und Exkreten, Blutbeutel und Blutkonserven)

Gefahrgutklassifizierung nach ADR/SDR

Klasse	UN-Nr.	Bezeichnung	VG	Zettel	Freigrenze
6.2	3291	Klinischer Abfall, unspezifiziert, n.a.g.	II		333 kg oder Liter

© Insel Gruppe	AG Entsorgung	Verabschiedet am: 01.01.2017	Überarbeitet:

Umbrella Biobank Urology Regulations are published on the website of the Department of Urology and can be found at the following link:

http://www.urologie.insel.ch/de/lehre-und-forschung/biobank

For more information about the Biobank Bern, please see the regulations below:

https://www.biobankbern.ch/app/download/10778552471/Reglement_LiquidBiobankBern_Aug2020.pdf?t=1680681659

ANNEX VIII
Detailed process flow from enquiry to receipt of biological resources

- Internal and external research projects wishing to benefit from the sample collection of the UMBRELLA Urology Biobank must submit an application to the Umbrella Biobank.
  To this end, the research project leaders are asked to complete the "Feasibility and Request Form" to describe their project objectives and outcomes and send it to biobank.urologie@insel.ch. (Appendix IX)

- The Umbrella Biobank Urology Management Committee will carefully review the request and respond as soon as possible. Requests will be answered no later than 30 days after receipt of the request form.

- After approval of the application by the Umbrella Biobank Management Committee, the MTA/DTPA Agreement is completed and signed by both parties.

- The order request is forwarded to Biobank Bern to prepare the processing and storage of the samples for transfer.

- The research project that submitted the request will be informed directly by Biobank Bern when the ordered samples will be ready for collection.

- The applicant will bear the costs of sample processing and collection, which will be invoiced by Biobank Bern.

- For further information and requirements regarding the transfer of biological samples from the Umbrella Biobank Urology, please refer to the Master Legal Instrument MTA Version 3.0 for the Transfer and Use of Human Biological Material and Associated Data and the MTA v3.0 Project Specific Agreement document.

ANNEX IX
UMBRELLA Urology Biobank Feasibility and Order Form

INSELSPITAL
UNIVERSITÄTSSPITAL BERN
HÔPITAL UNIVERSITAIRE DE BERNE

BIOBANK BERN
LIQUID

☐ I) Feasibility request for samples of the Umbrella Biobank Urology
☐ II) Order request for usage of samples of the Liquid Biobank Bern [1]

1. Project Data

*You need to send your request pplication form to **biobank.urolgie@insel.ch** for project feasibility evaluation*

Last Name, First Name	
Project Leader	
Date	
Department/Clinic/Institute address	
E-Mail	
Phone	
Collaboration Partner	○ Not applicable ○ Collaboration Partner:

2. Project Description

(enables the review panel to determine the scientific validity of the study)

Title and abstract/summary/objectives of the project (~300 words)

Expected duration of the study:

What Sample Types and Numbers are needed? *(please specify minimal number, concentration)*

☐ EDTA-Plasma		☐ matching Tissue	
☐ Serum		☐ Other:	
☐ RNAlater		☐ Urine	

What assays or analyses are planned to be performed? *(please specify)*

☐ Genomics		☐ Metabolomics	
☐ Transcriptomics		☐ Other	
☐ Proteomics			

3. Requested Patient/Sample Data

- ◯ Critera requested at IDSC→ *Please provide IDSC ID[3]*
- ◯ Samples with specific PID-number → *Please provide a list of PID numbers via **HIN-secured email*** [2]
- ◯ Samples are required based on specified criteria → *Please fill tables below*

Inclusion Criteria *e.g. specific diagnosis (please use ICD10 codes), sample collection date, sex, age*	
Exclusion Criteria	
Request for additional Patient/Sample Data	

4. Specific Requirements / Additional Comments

5. Additional Information

Please provide KEK-Nr. by ethical committee or state «in preparation»

Please specify study-no. by DLF or state «in preparation» [3]

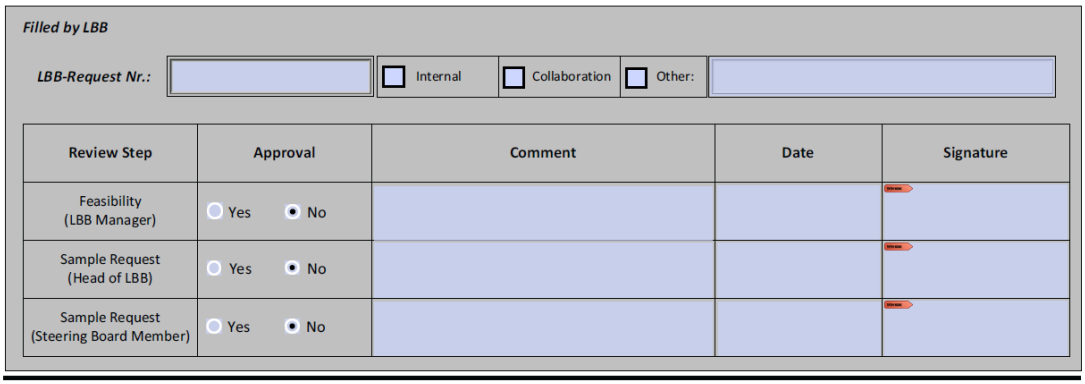
The investigator confirms appropriate acknowledgment of the source material with the following statement: "Samples were provided by the Liquid Biobank Bern" in all publications and agrees to send LBB a copy of any such publications at the time of submission for publication. By signing a material transfer agreement document (MTA), the investigator confirms that the appropriate ethical permissions have been obtained if samples are handed to a third party for analysis. After the project is finished, the investigator should inform LBB and return the feedback form, which will be provided by LBB.

Place:

Date:

Signature of project leader:

[1] Attach studyprotocoll and BASEC when ordering samples
[2] When ordering samples via PID the PI commits himself to encrypt the samples for analysis
[3] ONLY for Inselspital internal research projects)



Filled by LBB

LBB-Request Nr.: ☐ Internal ☐ Collaboration ☐ Other:

Review Step	Approval	Comment	Date	Signature
Feasibility (LBB Manager)	○ Yes ● No			
Sample Request (Head of LBB)	○ Yes ● No			
Sample Request (Steering Board Member)	○ Yes ● No			

Liquid Biobank Bern, Zentrum für Labormedizin, Inselspital, Universitätsspital Bern, 3010 Bern - www.biobankbern.ch - biobank@insel.ch