Tissue biobanking: minimum interface requirements for efficient and high-quality support for biomedical research –a white paper

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ORIGINAL ARTICLE

Tissue biobanking: minimum interface requirements for efficient and high-quality support for biomedical research – a white paper

Cäcilia Engels[1] · Angela Langer[2,3] · Britta Fritzsche[4] · Carolin Kaufhold-Wedel[5] · Christoph Brochhausen[6] · Heidi Altmann[7,8,9] · Julian Dörenberg[10] · Katharina Hofmann[11] · Michael Linnebacher[12] · Nhu Tuyen Phan[13] · Ronny Baber[14] · Till Braunschweig[3,15] · Tilman Pfeffer[16] · Alexander Brobeil[5,17] · Katja Steiger[3,18,19,20]

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Abstract
Tissue biobanking is essential for biomedical research. Well-defined interfaces and standardised procedures are required to ensure sample quality and the subsequent reproducibility of research results. This paper provides an overview of the key interfaces involved in tissue biobanking workflows, including sample collection, processing, storage, distribution and data management. It outlines the minimum standards required to maintain high-quality samples and associated data, and references relevant national and international guidelines. The paper also addresses the current challenges faced by biobanks, such as harmonisation across institutions, evolving regulatory landscapes, and the integration of digital infrastructure. The primary aim of this work is to present recommendations for the effective implementation and documentation of minimum standards. These recommendations are intended to help biobanks to align with regulatory expectations, optimise operational procedures, and facilitate high-quality, ethically sound biomedical research.

Keywords Tissue processing · Biobanking · Standardisation · Biosamples · Quality management · ISO 20387

Introduction

Biobanks are of crucial importance for biomedical research, particularly for precision medicine [1, 2]. The reproducibility and reliability of research results depend on the quality of the samples and the associated data [3]. This is a basic prerequisite for developing personalised therapeutic approaches and addressing further issues relating to translational research. However, heterogeneous laboratory structures and IT systems that lack interoperability impede the efficient exchange of data. Inconsistent interpretations of quality standards and inconsistent sample preparation procedures also prevent samples from being provided in a timely manner. Therefore, harmonising interfaces in tissue processing in the context of biobanking is crucial for the optimal use of these limited resources. Identifying these interfaces is essential for efficient collaboration. In this context, an 'interface' is defined as the interaction between at least two different areas or organisational units involved in the processing, storing and distributing of tissue samples for research projects. The descriptions and recommendations of interfaces in the following sections always refer to the biobank and a second organisational unit.

Academic biobanks are facilities that collect, process and store human tissue and liquid samples for research purposes [4]. Tissue samples are subject to specific requirements, necessitating close collaboration with the Institute of Pathology [5]. While the Institute of Pathology prepares tissue for diagnostic purposes and documents the relevant qualifying sample data, the aim of biobanking is to ensure that the samples are stored and distributed with a high standard for use in retrospective and prospective scientific analyses and studies. Both the Institute of Pathology and the biobank adhere to international quality standards, such as ISO 17,020 [6] and ISO 20,387 [7].

In terms of sample types, tissue biobanking encompasses three major pillars:

Extended author information available on the last page of the article

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- The selection of fresh tissue samples for research purposes and their immediate transfer to research labs and their instant processing.
- Cryo-preservation of tissue samples (usually in a prospective, undirected manner under broad consent).
- Access to residual tissue samples from routine diagnostics (in collaboration with Institutes of Pathology).

The structure of tissue biobanks varies in terms of storage configuration, governance, and data management. Common organisational models include: (i) centralised cryopreservation and storage of selected formalin-fixed and paraffin-embedded (FFPE) tissue samples within the biobank; (ii) central biobanking of tissue samples with access to diagnostic FFPE samples via the Institute of Pathology; (iii) storage of tissue samples within a pathology-based biobank linked to the FFPE archive; and (iv) decentralised repositories with central IT-based sample representation. Across Germany and Europe, governance may be integrated within the Institute of Pathology, managed jointly, or operate independently under formal agreements. Storage can be co-located, distributed, or a hybrid of the two, and IT systems can range from integrated to separate platforms with varying levels of General Data Protection Regulation (GDPR) compliance. Access procedures may be pathology-led, biobank-led, or require joint approval, reflecting institutional structures, legal frameworks, and research priorities. For any type of tissue biobanking, a close and trusting collaboration with the local Institute of Pathology should be established.

In addition, tissue biobanking in Europe is embedded in a wider European and international regulatory and ethical governance landscape that combines European Union legislation, international guidelines, and research infrastructures. The aforesaid GDPR is a key piece of legislation that governs the harmonisation of personal and genetic data protection in all EU countries and outlines the conditions under which health-related data can be processed for research purposes. Other important European legal frameworks in the area of human tissue and cells are the Human Tissue and Cells Directive, which outlines quality and safety requirements for the donation, procurement, and traceability of human tissues and cells, and the EU Clinical Trials Regulation, which governs clinical research on human participants and related biospecimens. The above European and international legal frameworks address the issue of donor protection, traceability, and responsible use of biospecimens and related data throughout the entire lifecycle of biobank resources.

Apart from legislative measures, a range of initiatives at both national and international levels across Europe has a role to play in promoting the harmonisation of governance practices and operational standards in biobanking. The European research infrastructure BBMRI-ERIC (https://www.bbmri-eric.eu) has a role to play in the coordination of national biobank networks and promoting interoperability of biobank information systems, as well as cross-border access to high-quality biospecimens and associated data across Europe. Professional societies such as the European, Middle Eastern & African Society for Biopreservation and Biobanking (ESBB; https://www.esbb.org) and the International Society for Biological and Environmental Repositories (ISBER; https://www.isber.org) have a role to play in providing internationally recognised best practice recommendations on quality management, governance structures, and ethical approval processes involved in biobanking. Moreover, data models and standards such as the Minimum Information About Biobank Data Sharing framework have been proposed to promote interoperability and responsible reuse of biospecimen-associated data across different countries and institutions.

With the integration of multimodal biomedical data, such as molecular data, clinical data, and imaging data, into biobanks, there is an added layer of complexity to governance models. Concepts such as imaging biobanks, which integrate medical image data with clinical and molecular data and enable radiomics and radiogenomics, which correlate phenotypic imaging biomarkers with molecular characteristics of diseases, have emerged [8]. However, all these developments also give rise to other medico-legal and ethical issues like issues concerning validity in consent, data ownership, anonymisation of imaging data, and data governance in big data [8]. Despite harmonisation efforts, it has been noted that due to variations in legislation, consent procedures, and ethics review in different countries in Europe, it has been challenging to facilitate collaboration and data exchange between biobanks [9]. For effective governance in tissue biobanks, it has been highlighted that it is important to develop clear interfaces between institutions in areas like pathology, care structures, and research infrastructures to meet legislative requirements and to facilitate data sharing in research networks at national and international levels [10].

Although funding of biobanks is not the focus of this white paper, especially in tissue biobanking, it is important to ensure for sustainable funding and transparent contributions of the different institutions involved (i.e., pathology, surgical clinics, biobanks, faculties/schools/universities) [11]. This paper aims to identify and describe the interfaces between biobanks, institutions that provide samples, the Institute of Pathology, and researchers. Based on an analysis of the current interface-related challenges, it sets out minimum requirements in terms of patient safety, diagnostics, reproducible research results, data protection and ethical standards. It also provides examples of best practice

in accordance with ISO 20,387 requirements and other standardised processes for optimising interface quality. The paper was developed by the Tissue Working Group of the German Biobank Network (GBN). The GBN is the central platform for academic biobanking in Germany [12]. By 2025, the network has grown to encompass 37 biobank sites representing almost all German medical faculties, as well as several biobanks from the German Centres for Health Research (DZG). From July 1, 2025, the GBN operates within the Network University Medicine (NUM), which is funded by the newly formed Federal Ministry for Research, Technology, and Space (BMFTR).

The life cycle of a tissue sample

Ideally, tissue samples in biobanks are collected prospectively and non-selectively under a broad consent. This approach facilitates the preservation and utilisation of high-quality, versatile samples, even for analytical methods that may not yet have been established at the time of collection. To support advanced analytical techniques, samples must therefore be processed to meet rigorous scientific standards. Quality encompasses sample integrity, controlled processing and storage, and data provenance [13, 14]. Robust sample and data management ensures the reliability and reproducibility of the resulting research data.

The life cycle of a tissue biosample (see Fig. 1) begins with tissue resection at a clinical site. The sample is then transported to the Institute of Pathology in a (cooled) container by courier or a pneumatic dispatch system. Quality control can be conducted upon receipt of the sample (e.g. an intraoperative frozen section), before it is transferred to the biobank. This procedure helps to ensure that the tissue transferred to the biobank contains the anticipated lesion. If the sample is not intended for immediate diagnostic evaluation, it proceeds directly to biobanking. Depending on the intended use, samples are processed as fresh tissue, or cryopreserved, or fixed in formalin and embedded in paraffin wax (FFPE). The latter is the usual approach also for diagnostic specimen within the Institute of Pathology. Cryopreservation and formalin fixation may be conducted in accordance with ISO 20,184 [15] and ISO 20,166 [16], respectively. Diagnostic FFPE samples are archived at the Institute of Pathology. Meanwhile cryopreserved tissue and non-diagnostic FFPE samples are transferred to the biobank for further quality-controlled processing, detailed documentation, secure storage and distribution. Multiple quality control checkpoints in biobank workflows ensure sample integrity and reliable processing [17]. Clear responsibilities at institutional interfaces (especially between the Institute of Pathology and the biobank) are essential, as deficiencies in sample or data quality can compromise the validity and comparability of research results. These initial steps in tissue biobanking clearly demonstrate the close and essential interaction between biobanking and the Institute of Pathology.

The biobank provides biosamples (either stored or freshly collected) to researchers upon request, provided that the ethical, data protection and scientific requirements have been met. Histopathological evaluation is essential for all distributed tissue samples, to ensure their quality and suitability for the intended research. In this context, the analytical contribution of the pathologist, who provides morphological expertise to ensure the suitability or tumour cell content of a set of tissue samples, should be recognised as a scientific contribution that warrants co-authorship in a later publication. FFPE samples that have been stored for diagnostic purposes without research consent can only be used in exceptional cases following a risk-benefit assessment. In accordance with the guidance (currently only a recommendation) of the Arbeitskreis Medizinischer Ethik-Kommissionen (AKEK) [18], archived diagnostic samples obtained without prior consent may be used for research purposes following an ethical review, provided that re-consent is impracticable and that the scientific interest clearly outweighs the potential risks to donors. Alternatively, the material must be fully anonymised. Similar positions have been outlined by the Zentrale Ethikkommission der Bundesärztekammer (ZEK) for legacy samples ("Altproben") from the archives of the Institute of Pathology, provided that there is no ongoing clinical need and that appropriate safeguards are in place. It is important to note that samples from the pathology archive must not be depleted if they may still be required for patient care. The final decision rests with the Institute of Pathology, in consultation with the relevant ethics committee, to safeguard donor rights and promote responsible research. If a patient withdraws their consent, the samples in the biobank are destroyed and associated data are anonymised or deleted in accordance with established biobank protocols and applicable data protection regulations. However, data required for the traceability of samples already used must not be discarded; it must simply not be used again.

Alongside the physical transport of biosamples, structured data management and transfer are essential to ensure sample traceability and the data quality. Biobank Information Management Systems (BIMS) facilitate transparent processes and inventory control. Adherence to data protection regulations, particularly the General Data Protection Regulation (GDPR), is paramount. Safeguarding patient data and reliably documenting informed consent are essential for ensuring ethical and legal compliance in biobanking. Although interfaces with hospital information

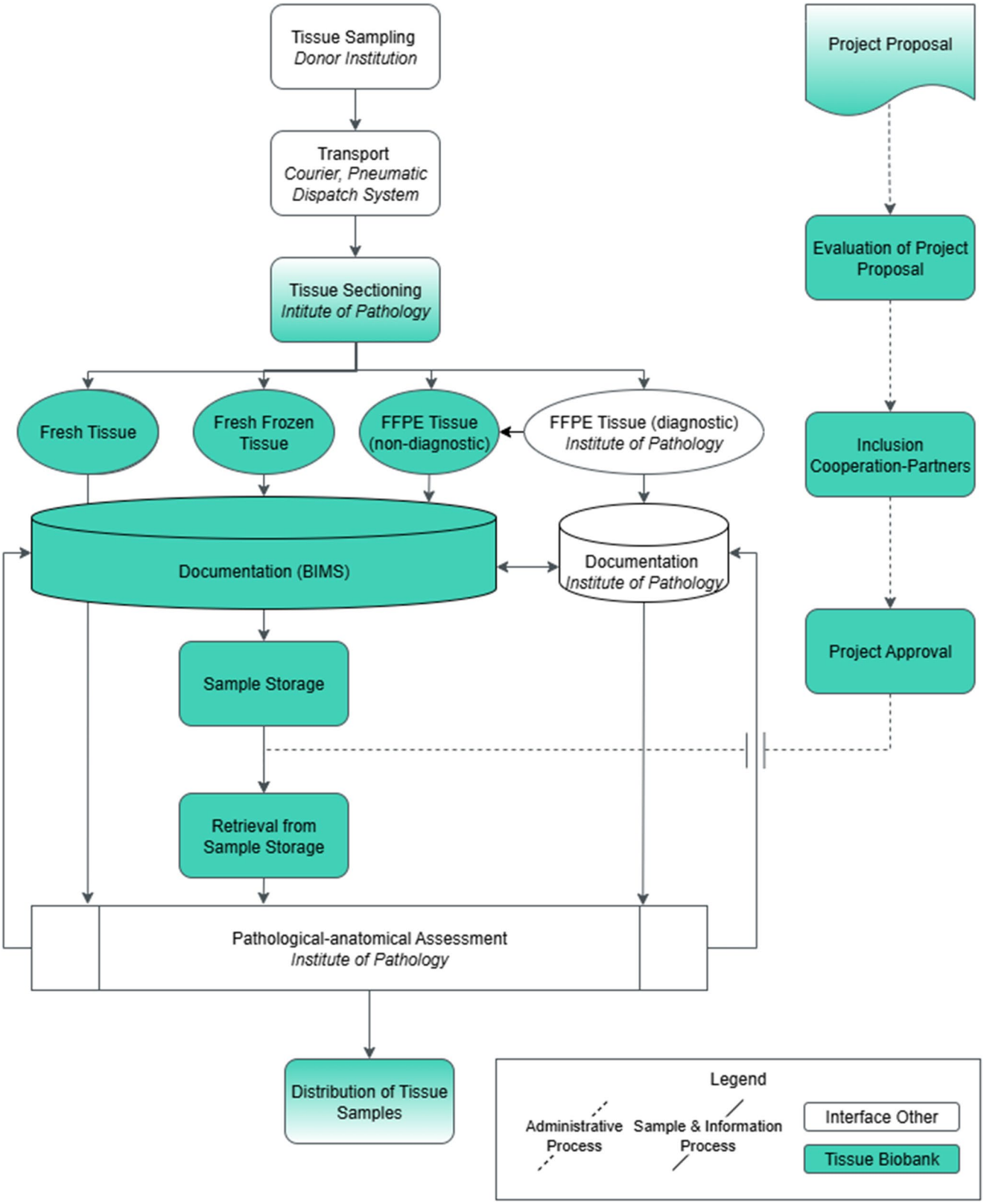

Fig. 1 Interfaces and responsibilities in tissue biobanking. The process of a tissue sample from collection to distribution. All of the steps shown are important and are chronologically interdependent. Right: Review and approval of a project application (shown by the dashed lines), which is a prerequisite for utilising of samples and data. The documentation of sample-associated data ensures traceability and quality

systems (HIS) and pathology information management systems (PathoLIMS) facilitate the secure exchange of data, existing software solutions often require substantial modifications to meet the requirements of biobanking. For example, an electronic interface with pathology information management systems and/or hospital information systems is required. Such adaptations are mandatory in order to prevent potential transcription errors and ensure that relevant data modifications are reliably provided to the Biobank Information Management System (BIMS). Copying or transmitting large amounts of raw data, such as whole slide images, is generally not recommended; instead, a reliable interface for live (meta-)data recall should be provided. Additionally, efficient data management must support the selection of sample cohorts via advanced search functions.

Interface: "Sample providing institution"

Sample providing institutions (mainly surgical clinics, or f.e. endoscopy units) play a pivotal role in the standardised collection and transfer of tissue samples to biobanks. Written Standard Operating Procedures (SOPs) are recommended for this process. Tissue can be sent to the Institute of Pathology for diagnostic purposes, such as intraoperative frozen section analysis. In this case biobank sampling can then be incorporated. Alternatively, tissue can be collected directly during surgery under the supervision of a pathologist. Key parameters, such as sampling time and ischaemia time should be documented immediately. Non-diagnostic samples (e.g. atherosclerotic plaques, or non-suspicious reductive skin resections) can be transferred directly to a research laboratory for processes requiring fresh tissue samples, such as organoid development. Alternatively, they can be processed and preserved by the biobank or the Institute of Pathology for subsequent biobanking. For large resections, selective sampling under pathological supervision is strongly recommended. To ensure sample quality and data integrity, well-defined responsibilities, efficient logistics and secure data transfer protocols are required between all parties involved.

The growing interest in the characterization of the intratumoral microbiome highlights [19] additional pre-analytical considerations for tissue biobanking. Because tumor tissues generally represent low-biomass microbial environments, they are particularly susceptible to contamination during surgical sampling, specimen handling, and laboratory processing [20]. Where microbiome analyses are anticipated, measures such as sterile tissue collection, the use of dedicated instruments and containers, and the implementation of appropriate negative controls should be considered to minimize contamination by commensal or environmental microorganisms. Biobanks should therefore be aware that pre-analytical handling, additionally to reagent or laboratory contamination [21], can substantially influence microbiome-related downstream analyses. Sterile handling might also be very relevant if organoid or tissue slice culturing is anticipated.

Recommendation: Sample transport from "Sample providing institution"

Improper handling during transport can significantly compromise tissue quality. Unlike liquid biobanking, tissue biobanking lacks standardised containers, increasing the risk of artefacts, such as compression due to undersized vessels or improper fixation. The choice and volume of the fixative are critical: for formalin-fixed samples, a 1:10 tissue-to-fixative ratio is recommended. Commonly used solutions for formalin-fixed paraffin-embedded (FFPE) preparation include 4% paraformaldehyde or 10% neutral buffered formalin [22]. Alternatively, fresh tissue must be transported promptly at stable temperatures. Snap-frozen samples should be shipped in liquid nitrogen or on dry ice to maintain ultra-low temperatures, ideally with the temperature being monitored using appropriate technical solutions. Accurate coordination of pick-up and delivery times between the sample providing institution, the Institute of Pathology, and the biobank is essential. Ideally, the biobank interface should be co-located within the Institute of Pathology to streamline handover and ensure quality.

Recommendation: Data transfer from "Sample providing institution"

To ensure sample quality and traceability, it is essential that reliable, and standardised documentation and data are transferred from the sample providing institution to the biobank. Clear labelling on pathology request forms (e.g. 'fresh tissue') triggers the appropriate biobank workflow, which are supported by predefined protocols and Biobank Information Management Software-compatible flagging. Seamless communication and coordination, as well as clearly designated tissue biobank contacts within the Institute of Pathology, are required for efficient coordination and consistent data flow.

In accordance with ISO 20,387, the documentation accompanying each sample must include a unique identifier (ID) for each sample, information on consent status, and details of the time and location of collection. It must also include information on the biosafety level and any relevant pre-analytical variables (see Table 1), such as warm and cold ischaemia times. Ideally, all this information should be transmitted electronically in a structured manner through integration with the BIMS. Additionally to these parameters

Table 1 shows the minimum dataset (biosample accompanying documentation) required for the transfer of tissue samples from the donor institution to the biobank

Attribute	Data Type/Values	Information needed from the sample providing institution: Required (*R*) vs. Supplementary (S)	Additional information provided by the biobank or HIS: Required (*R*) vs. Supplementary (S)
Location/department of collection	text	Required	-
Date of collection	date	Required	-
Time of collection	time	Supplementary	No possibility of retrieving this information later on.
Unique Patient Identifier	Internal code allowing assignment of patient in HIS	Required	-
Consent Information	Yes/No/NA	Supplementary	Required
Estimated diagnosis	ICD-10/11 (standardised system used to code diseases and medical conditions (morbidity) data)	Supplementary (often delivered in unstandardised manner)	Required (standardisation might be provided by biobank)
Anatomical localisation	ICD-O-3 (classification system to code the site (topography) and the histology (morphology))	Supplementary (often delivered in unstandardised manner)	Required (standardisation might be provided by biobank)
Unique Sample Identifier	Numeric and/or Letter code	Required	-
Sample type	Bone, Cells, etc. (SPREC 4.0 or MIABIS [25])	Supplementary (often in unstandardised manner)	Required (standardisation can be provided by the biobank)
Type of collection	Autopsy, Biopsy etc. (SPREC 4.0)	Supplementary	Supplementary
Cold ischaemia time	Minutes (SPREC 4.0)	Supplementary	Supplementary
Warm ischaemia time	Minutes (SPREC 4.0)	Supplementary	No possibility of retrieving this information later on.
Biosafety level	2 or 3	Supplementary	Required

usability of samples for specific downstream methods strongly relies on additional time points such as time of start of transport, time of receipt of sample in the laboratory, time of sectioning the tumor/tissue of interest, and time of freezing. While DNA and proteins are quite robust, RNA and phospho-proteins are sensitive to different sample related interventions as fixation or longer duration of necessary handling [23, 24].With respect to current cutting-edge methods as phospho-proteomics with a small time-window for tissue handling, specific protocols might be necessary.

The parameters listed above form the basis for the generation of the Standard Preanalytical Code (SPREC) [25], consisting of seven elements: type of sample, type of collection, warm/cold ischaemia time, fixation/stabilisation type, fixation time, and long-term storage. These elements capture the key preanalytical factors that influence sample integrity and subsequent research. Accurate SPREC annotation allows samples to be compared across studies, thereby enhancing reproducibility.

At the time point of collection, only an expected diagnosis can be stored alongside the tissue sample in the Biobank Information Management System. The final histopathological diagnosis for each case should be entered in a structured, coded format. The International Classification of Diseases (ICD), either versions 10 or 11, or the International Classification of Diseases for Oncology (ICD-O), currently version 3, should be used for this purpose. This allows cohorts to be compiled quickly based on specific entities. However, the initial diagnosis may change, since the characteristics of each tissue sample can only be fully assessed by a pathologist through histopathological inspection, typically just before distribution to a researcher.

Interface: "Institute of pathology"

The interface between the Institute of Pathology and the tissue biobank is crucial for ensuring the quality, diagnostic value and usability of samples for research purposes. The Institute of Pathology provides expert gross and histopathological processing and assessment and can be accredited as an inspection body in accordance with ISO 17,020 or ISO 15,189 [26]. The biobank operates in accordance with ISO 20,387 to ensure sample traceability and suitability for research.

The Institute's diagnostic expertise is essential for quality control during the acquisition and/or the distribution of samples. This ensures that the tissue is fit for purpose and that the results of experiments conducted using it might be reproduced. One persistent challenge is the delineation of which assessment activities should be included in the tissue biobank's conformity assessment, and which should be classified as diagnostic inspection services. Additionally, the pathomorphological service provided by the pathologist must be recognised. Any service outside the remit of a diagnostic centre should be defined as either an individual scientific contribution or might be a biobank service, as defined in the local biobank services.

Recommendation: Contractual agreement with the "Institute of pathology"

If the tissue biobank is independent of the Institute of Pathology, a formal service-level agreement or collaboration contract should be in place between the two organisations. This agreement should define the legal, ethical and logistical framework for the provision and use of tissue samples for research purposes. Particular attention should be paid to data protection, especially with regard to sensitive patient data and access to archived FFPE samples. Additionally, the agreement should explicitly define the role of the pathologist, detailing their responsibilities, duties, and obligations. Furthermore, it should delineate the pathologist's rights and entitlements with regard to contributions, authorship, and claims arising from scientific or academic work conducted within the scope of the agreement. Also ownership terms, the period of use, and the respective logistical and financial responsibilities should be outlined in the agreement. It should also set out the conditions for sample retrieval, processing, and returning data to the Institute of Pathology. Procedures for re-identification of samples within the biobank must also be in place to facilitate the potential return of samples.

Integrating the pathology archive provides access to long-term preserved specimens, including both diagnostic and autopsy-derived samples, which are highly valuable for retrospective and biomarker studies. Access rights must be defined and are usually limited to authorised biobank personnel for specific samples and purposes.

Recommendation: Data transfer from/back to the "Institute of pathology"

The transfer of data from pathology information management systems (PathoLIMS) must comply with data protection regulations, including the General Data Protection Regulation (GDPR), and be subject to ethical approval and local laws. Patient data must always be kept confidential and intact, and data stored in the biobank must be pseudonymised. In accordance with relevant privacy protocols, the pseudonymisation secret should be stored securely and separately.

To ensure an efficient data transfer from the "Institute of Pathology" as well as from the "Sample Providing Institution" without compromising the performance of the pathology information management system, the biobanks should be provided with a minimum dataset via a dedicated interface. This dataset should include the following: diagnosis (ICD-10 or later versions); donor sex; and anatomical site (according to MIABIS [27]). For tumour resections, additional data according to local tumour documentation (or derived from the LIMS of the Institute of Pathology) should be included for tumour resections, such as tumour entity and classification/grading (ICD-O-3, TNM or UICC, etc.). Any additional cancer-relevant documentation as required by the German minimal dataset 'Basisdatensatz' (https://www.basisdatensatz.de/) should also be included, such as genetic variants (name and expression), tumour therapy, and the patient's vital status and response to treatment/disease progress. As indicated above, duplicate data storage should be avoided wherever possible, which can be achieved by installing reliable interfaces for live (meta-)data recall. Regarding the different possible organisational structures of tissue biobanks described above, ranging from those identical to the Institute of Pathology to integrated separate units and independent core facilities, please refer to Fig. 2 for a generalised overview of the data workflow for tissue samples via different interfaces between organisational units.

In accordance with ISO 17,020 and ISO 20,387 (see "Sample distribution" below), the samples and the descriptive data should be handed over to the Institute of Pathology for diagnostic verification before biosamples are distributed from the biobank for research purposes. Restrictions on the use of samples and data for research purposes must be defined to ensure that routine diagnostics can be completed first. The transfer details and storage parameters must be clearly documented to ensure the traceability and re-identification of samples, as well as the potential return of samples to routine diagnostic workflows.

Interface: "Researcher/core facility"

Tissue biobanks provide researchers with access to tissue samples and act as central interfaces. The enquiry process involves providing a detailed specification of the required tissue type and format. As samples are limited in availability, access must be strictly regulated.

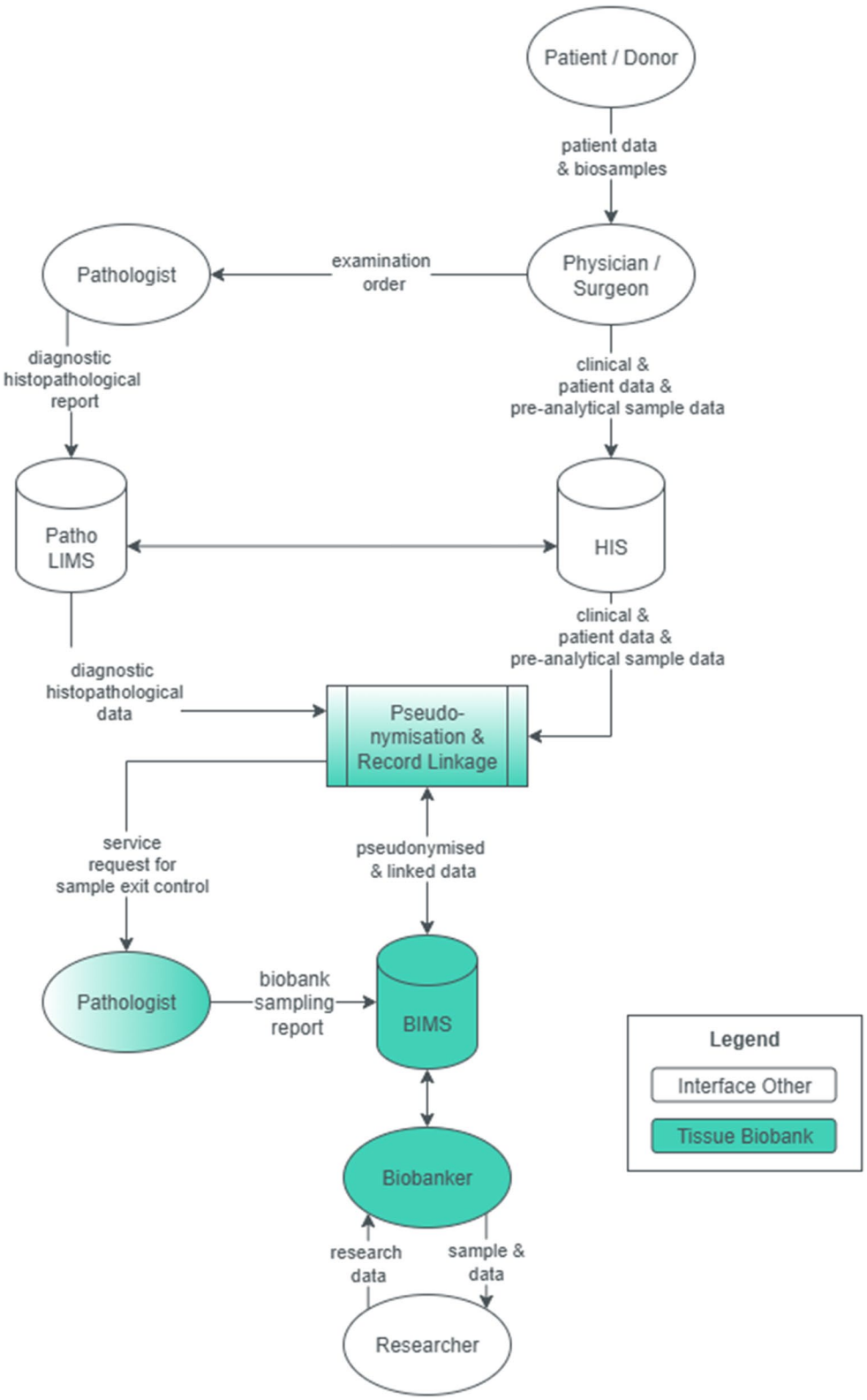

Fig. 2 Data flow for tissue sample-associated data (generic estimation). The process of collecting, processing and managing human tissue samples and associated data begins when the sample is collected by medical staff. Patient and clinical data, as well as pre-analytical sample data, are documented in the Hospital Information System (HIS). The sample's diagnostic and histopathological report is entered into the Pathology Laboratory Information Management System (PathoLIMS). The clinical patient data (HIS) and the diagnostic histopathological data from the PathoLIMS are then pseudonymised and linked with sample-specific data that is then documented within the Biobank Information Management System (BIMS). It is important to note the difference between a 'diagnostic histopathological report' and a 'biobank sampling report'. Information flows in both directions, since the pathologist needs the sample-specific data from the biobank for evaluation. Trained biobank personnel process the samples, uniquely identifying them using specific codes or barcodes and assigning a storage location within the BIMS. All sample-associated data is linked there and is thus available for downstream research projects

Table 2 shows the minimum information required for a project proposal sample request

Attribute	Description
Project Information:	
Researcher contact	Name and contact of the researcher
Researcher affiliation	Institute affiliation of the researcher
Project title	Project title (internal project ID if given)
Study objective	Objective/aim of the project, hypothesis description
Planned analysis method	Description of the planned analysis method (e.g. immunohistochemistry, whole genome sequencing, etc.) the samples are required for. Information on who is planned to perform the analysis.
Ethical approval given?	Disclosure whether ethical approval would be needed for the project or has already been.
Donor & Biosample Requirements:	
Number of subjects	Number of different subjects (donors) needed for the planned analysis.
Clinical data	Specification of additional data needed, inclusion or exclusion criteria on the patient, tumor documentation etc.
Type of tissue fixation	Fresh tissue, fresh frozen tissue, FFPE
Tissue histopathological diagnosis	ICD-10 (minimum for non-oncological projects)
Tissue histopathological morphology and topography	ICD-O-3 (in oncology projects)
TNM classification	TNM and Grading terminologies if required
Type of tissue collection	Autopsy, biopsy, resection etc.- if relevant
Tissue preparation specification	Size/weight of whole tissue samples, tissue sections (type of glass slides), TMA
Slide specifications	Section thickness, staining method

Recommendation: Study planning with "Researcher/core facility"

To ensure optimal planning, resource allocation and sample quality, it is essential to involve the tissue biobank early in tissue-based studies. Transparent cost structures and standardised processes promote Good Scientific Practice, adherence to the budget, and equitable access to samples.

Project proposals submitted by researchers to the biobank for tissue-based studies should include the following information: the name and affiliation of the applicant, the study objective, and the planned analysis method, and a statement whether ethical approval for the project has already been obtained. The required number of subjects (donors), the diagnosis that the sample should represent, and the location of the tissue sample (e.g. liver, colon, lung parenchyma etc.) should be specified. The preservation type of the sample (fresh, frozen or FFPE), the collection method (e.g. autopsy, biopsy, resection, etc.), the required materials (e.g. tissue sections, tissue microarrays (TMAs) etc.), the section thickness, the slide specifications, and any additional required clinical data should also be specified. For TMA projects, a designated contact at the Institute of Pathology must be appointed and project approval must be obtained prior to commencement Table 2.

For projects requesting the compilation of larger (>10 samples) tissue cohorts (FFPE, or cryopreserved tissue), the time needed for sample selection from Biobank and/or Pathology Information Management System, as well as the corresponding resources, have to be taken into account and should be communicated transparently to the researcher.

In general, as in liquid biobanks, the governance structure of a tissue biobank has to integrate a Use and Access Commitee (UAC), that can include for example stakeholder from the ethical commitee, the surgical institutions, Faculty/School or University as well as a biobank coordinator and – in the case of tissue biobanks – necessarily also the chair of pathology.

Depending on the governance structure, UAC either decide on each request or only on a specific subset of precious samples depending on decision of the biobank coordinator.

Recommendation: Sample distribution to "Researcher/core facility"

The distribution of tissue samples to researchers must be governed by clearly defined standard operating procedures (SOPs), as well as a robust interface with the Institute of Pathology, described above in the agreement setting out the division of responsibilities between the Institute of Pathology and the tissue biobank, including protocols for safeguarding patient-identifying information and ensuring that sufficient diagnostic material is retained. This ensures diagnostic quality, regulatory compliance and patient safety. For fresh tissue for which immediate histological assessment is not feasible, a pathologist must visually evaluate a representative sample to confirm tissue integrity.

This is especially relevant for tissue samples that are used for generation of a "next-generation" of biobanks – namely organoids or mouse xenografts (generated for example as patient-derived xenografts (PDX) or from organoids (PDOX). These are important tools for drug testing/cancer pharmacology [28] and precision medicine [29]. Tissue sampling for these "living biobanks" needs to consider additional aspects that are beyond the scope of this white paper.

FFPE samples can be obtained from the pathology archive or prepared by the tissue biobank, provided that traceability and sample quality are maintained in accordance with ISO 20,387. It is strongly recommended that a pathologist

carries out exit quality control, including documentation of a structured evaluation report. In tissue biobanks accredited under ISO 20,387, the evaluation of the tissue by a qualified pathologist is mandatory. The same requirement applies to biobanks operating in accordance with the standard. For other biobanks, while not compulsory, pathological assessment is strongly recommended to ensure sample quality and reliability. The role of the pathologist must be clearly defined, either through a contractual agreement or individual rules. The results of the evaluation should be included in the sample report (see below). If histological evaluation is not possible, this must be transparently communicated to the researchers who requested the sample.

To ensure the reproducibility and ethical integrity of the research, all processes should be designed to meet the requirements of ISO 17,020 for diagnostic reliability and ISO 20,387 for biobank conformity.

For external requests, sample distribution must be accompanied by a detailed internal sample report and a Material and Data Transfer Agreement (MDTA). The MDTA governs data protection, intended use, publication rights and liability. The sample report should include key metadata such as the sample ID, SPREC (if available), storage conditions and analytical results to ensure traceability, quality assurance and regulatory compliance.

Both the MDTA for external requests and the project agreement for internal collaborations should stipulate that all data generated by research projects must be returned to the biobank. This includes all data that could potentially be relevant for future biobank projects such as specified by ISO 20387:2018 clause, 3.3 [7]. These data can then be made available to interested parties, such as the Institute of Pathology or other researchers. This will support future studies, ensure the reusability of data and diagnostic samples, and encourage continued scientific collaboration.

Conclusion & outlook

High-quality tissue biobanking requires reliable and well-coordinated interfaces between sample-providing institutions, Institutes of Pathology, biobanks and researchers. Standardised processes for the acquisition, transport, processing, storage, distribution and documentation of tissue samples that are aligned with ISO 20,387 and ISO 17,020 ensure the integrity and traceability of samples and guarantee regulatory compliance.

To facilitate reproducible, scientific research using high-quality, well-annotated tissue samples, it is essential to establish interconnections between the various clinical and scientific organisations within university hospitals to ensure seamless collaboration. The following key recommendations for purpose-oriented collaboration are summarised below, as outlined in comprehensive detail above:

- Early integration of tissue biobanks into research planning ensures optimal sample quality, efficient resource allocation, a smooth project workflow and ethical alignment.
- Standardised procedures for tissue transport, including appropriate fixation, labelling and temperature control, are essential, particularly for fresh or cryopreserved specimens.
- Comprehensive data transfer protocols that meet GDPR and ethical requirements are also essential as well as use of interoperable terminology standards e.g. MIABIS, SPREC coding and integration in the Biobank Information Management System.
- Expected diagnoses relating to the tissue samples should be entered into the Biobank Information Management System, using structured documentation (e.g. ICD). The actual histopathological alteration must be validated by a pathologist to ensure research and data quality. If this is not possible, this must be explicitly noted. The time needed for pathological evaluation must be taken into account.
- There must be defined responsibilities and contractual agreements between biobanks and Institutes of Pathology, particularly with regard to access to and handling of archival FFPE samples, and vice versa for access to biobanked tissue samples for diagnostic purposes, where necessary. The time needed to compile FFPE cohorts, and the corresponding resources must be taken into account.
- The role of collaborating pathologists from the Institute of Pathology has to be clearly defined.
- There must be transparent and well-documented workflows for distributing and returning samples, including material and data transfer agreements, and quality review protocols.
- Encouraging the return of data from researchers to biobanks enriches the scientific value of the stored biosamples and promotes collaborative reuse.

A key future objective is to integrate matched samples from individual patients, linking tissue samples with liquid samples (e.g. liquid biopsies) collected in both routine and research settings. This combined biobanking approach will enable more comprehensive molecular profiling across sample types and time points, facilitating longitudinal analyses and advanced personalised medicine. Seamless integration of clinical and research samples via shared infrastructure and interoperable information systems will be key to realising this potential.

Referenced ISO standards and community standards

ISO Standard	Title	Organisation	Application
ISO/IEC 17020:2012	Conformity assessment - Requirements for the operation of various types of bodies performing inspection	International Organization for Standardization	Institute of Pathology
ISO 20387:2018	Biotechnology - Biobanking - General requirements for biobanking	International Organization for Standardization	Core international standard for establishing and operating biobanks; covers governance, quality management, personnel competence, and traceability
ISO/TS 23494-1:2023	Biotechnology - Provenance information model for biological material and data, Part 1: Design concepts and general requirements	International Organization for Standardization	Biobank
ISO 20184-2:2018	Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for frozen tissue, Part 2: Isolated proteins	International Organization for Standardization	Institute of Pathology, Biobank
ISO 20166-1:2018	Molecular in vitro diagnostic examinations - Specifications for pre-examination processes for formalin-fixed and paraffin-embedded (FFPE) tissue, Part 1: Isolated RNA	International Organization for Standardization	Institute of Pathology, Biobank
ISO 15189:2022	Medical laboratories - Requirements for quality and competence	International Organization for Standardization	Relevant for pathology laboratories linked to biobanks and for pre-analytical handling of biospecimens
MIABIS		BBMRI-ERIC	Facilitates interoperability and harmonised description of biobanks, sample collections and associated datasets

Glossary

AKEK	Arbeitskreis Medizinischer Ethik-Kommissionen
BIMS	Biobank Information Management System
HIS	Hospital Information System
DZG	German Centers for Health Research
DIN EN ISO	International Organisation for Standardisation (ISO) adopted as European (EN) and subsequently as German standards (DIN)
BMFTR	German Federal Ministry for Research, Technology, and Space
FFPE	Formalin-fixed, paraffin-embedded
GBN	German Biobank Network
GDPR	General Data Protection Regulation
ICD-10	International Statistical Classification of Diseases, 10th revision
ICD-O-3	International Classification of Diseases for Oncology, third edition
ID	Unique Identifier
MDTA	Material and Data Transfer Agreement
MIABIS	Minimum Information About Biobank Data Sharing
NUM	German Network University Medicine
PathoLIMS	Pathology Information Management System
SOP	Standard Operating Procedure
SPREC	Standard PREanalytical Code
TMA	Tissue microarray
TNM	Tumor, Node, Metastasis
UICC	Union Internationale Contre le Cancer
ZEK	Zentrale Ethikkommission der Bundesärztekammer

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Authors and Affiliations

Cäcilia Engels[1] · Angela Langer[2,3] · Britta Fritzsche[4] · Carolin Kaufhold-Wedel[5] · Christoph Brochhausen[6] · Heidi Altmann[7,8,9] · Julian Dörenberg[10] · Katharina Hofmann[11] · Michael Linnebacher[12] · Nhu Tuyen Phan[13] · Ronny Baber[14] · Till Braunschweig[3,15] · Tilman Pfeffer[16] · Alexander Brobeil[5,17] · Katja Steiger[3,18,19,20]

✉ Katja Steiger
katja.steiger@tum.de

1 German Cancer Consortium (DKTK), partner site Berlin, a partnership between DKFZ and Charité - Universitätsmedizin Berlin, Berlin, Germany

2 Augsburg Central BioBank, Medical Faculty, University of Augsburg, Augsburg, Germany

3 Bavarian Cancer Research Center (BZKF), Augsburg, Germany

4 University Cancer Center Hamburg, Universitätsklinikum Hamburg-Eppendorf (UKE), Hamburg, Germany

5 Tissue Bank of the National Center for Tumor Diseases (NCT) Heidelberg, Heidelberg, Germany

6 Institute of Pathology, Medical Faculty Mannheim, University Medical Center Mannheim, Heidelberg University, Mannheim, Germany

7 Dresden Integrated Liquid Biobank/BioBank Dresden, Institute for Clinical Chemistry and Laboratory Medicine, Dresden, Germany

8 German Cancer Consortium (DKTK), partner site Dresden, a partnership between DKFZ and the Dresden, University Hospital and Faculty of Medicine, TU Dresden, Dresden, Germany

9 National Center for Tumor Diseases, Dresden (NCT/UCC), Dresden, Germany

10 Core Facility Biobank, Medical Faculty, University of Tübingen, Tübingen, Germany

11 BioMaterialBank Heidelberg (BMBH), Institute of Pathology, Heidelberg University Hospital, Heidelberg, Germany

12 BioBank Rostock, Clinic of General Surgery, Rostock University Medical Center, Rostock, Germany

13 German Biobank Network (GBN) Coordination Office, Network of University Medicine (NUM), Charité - Universitätsmedizin Berlin, Berlin, Germany

14 Leipzig Medical Biobank (LMB) and Institute of Laboratory Medicine, Clinical Chemistry and Molecular Diagnostics, University Leipzig, Leipzig, Germany

15 Institute of Pathology, Ludwig Maximilian University of Munich, Munich, Germany

16 Tissue Bank of the German Center for Infection Research (DZIF), Partner Site Heidelberg, Institute of Pathology, Heidelberg University Hospital, Heidelberg, Germany

17 Institute of Pathology, Heidelberg University Hospital, Heidelberg, Germany

18 Technical University of Munich, TUM School of Medicine and Health, Department of Preclinical Medicine, Institute of Pathology, Munich, Germany

19 German Cancer Consortium (DKTK), partner site Munich, a partnership between DKFZ and TUM University Hospital, Munich, Germany

20 IBioTUM, TUM School of Medicine and Health, TU Munich, Munich, Germany