INTERDISCIPLINARY BANK OF BIOMATERIALS AND DATA WÜRZBURG

ibdw

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For the future of research

The Biobank of the Medical Faculty Würzburg

Contents

It is our great pleasure to provide you with this brochure introducing a key instrument for the progress of medical research at our faculty:
The Interdisciplinary Bank of Biomaterials and Data Würzburg – the »**ibdw**«.
Initialliy the **ibdw** was one amongst the first five centralized German biobanks funded by the Federal Ministry of Education and Research (BMBF) in the framework of the National Biobank Initiative. Today, together with 11 other German biobanks, the ibdw represents one key element of the German Biobank Alliance (GBA), a framework funded by the BMBF until end 2020.

The **ibdw** is an independent interdisciplinary institution of the medical faculty under joint responsibility of the University Hospital and the University of Würzburg.

With the implementation of the **ibdw** it is now possible to systematically collect, portion, and long-term store liquid biosamples (like blood, serum, urine) as well as tissue samples that have been donated by our patients and study participants fulfilling highest quality standards.

Medical research with biological material linked to related clinical data will enrich current medical knowledge. It will foster improvements in the early recognition, diagnosis, treatment, and prevention of known and hitherto unknown diseases.

We invite you to get some deeper insight into the **ibdw** – its objectives and principles, technical capacities, achieved targets and, of course, the team representing the core of the **ibdw**.

Enjoy!

Welcome to the **ibdw**

Prof. Dr. Matthias Frosch
Dean of the Medical Faculty

PD Dr. Tim von Oertzen
Executive Medical Director

Prof. Dr. Roland Jahns
Director of the **ibdw**

Support of Future Research

The **ibdw** is a valuable resource for the progress in medical research

Research based on human biological material and related analytical and clinical data that have been or will be obtained are crucial to foster progress in medical research.

The **ibdw** stores human tissue and liquid biosamples over many decades maintaining highest quality standards and safety conditions.

By provisioning high-quality biosamples the **ibdw** contributes to evidence-based modern medicine. Thus, in the future, everyone will possibly benefit.

On the following pages we would like to introduce you to the **ibdw** of the Medical Faculty Würzburg and give you some insight into the various working fields of a Biobank.

The **ibdw** is the central bank of biological materials and data of the Medical Faculty of Würzburg. It is a joint institution under the responsibility of both the University Hospital and the University of Würzburg. The **ibdw** is governed by its own steering committee and is not associated with a specific department.

The **ibdw** stores liquid biosamples (e.g., blood, serum, blood cells, urine, and cerebrospinal fluid) and solid biosamples (e.g., tissue specimen, biopsies). These samples are long-term stored maintaining highest quality standards for future medical research.

All biological materials hosted by the ibdw are donated on a strictly voluntary basis by patients and study participants for (bio-)medical research.

To protect a donor's privacy all identifying information is replaced by unique number-/letter codes (»double pseudonymized«).

Biosamples are stored for future research maintaining highest quality standards

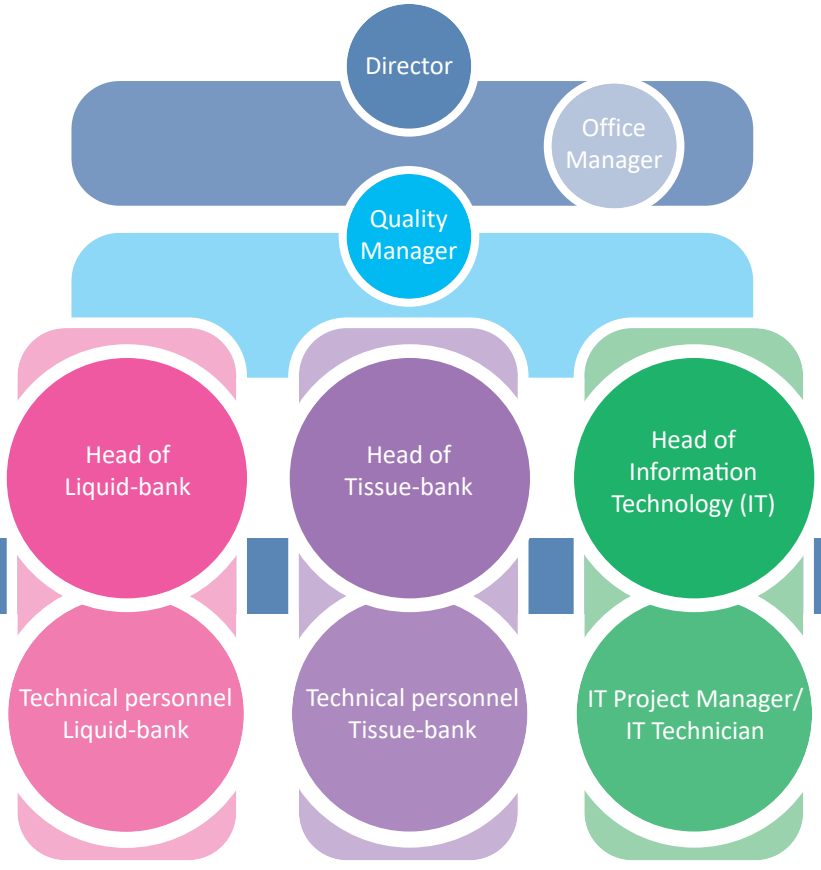
The Central Biobank Würzburg

Donated human biological material is labeled, registered, portioned in small 750 µl tubes (»aliquots«), and stored in fully automated cryo-repositories.

Which data is stored together with the samples?

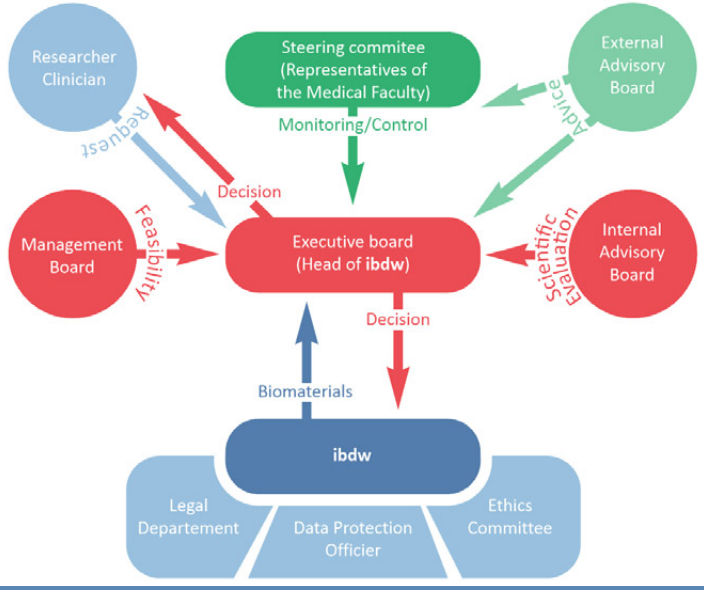
- General personal data (e.g. age, sex)
- Medical data (e.g. main diagnosis)
- Analytical data derived from biological material

The three ibdw-pillars:
- the central liquid-bank
- the central tissue-bank
- the central database



Organisational Structure

The **ibdw** is composed of a core database and two centralized biosample repositories – one for liquid biosamples and the other for solid/tissue biospecimen – and a limited number of specialized decentralized subunits, each of them adhering to **ibdw** standards.




TÜV PROFI CERT

CERTIFICATE

for a management system as per

DIN EN ISO 9001:2015

Evidence of conformity has been furnished:

ibdw

Interdisciplinary bank of biomaterials and data Würzburg (ibdw)
Straubmühlweg 2a Haus A9
97078 Würzburg / Germany
a joint core facility of the University Hospital Würzburg
and the Julius-Maximilians-University Würzburg

scope:

Quality-controlled collection, processing, analysis,
storage and distribution of liquid and
solid human biospecimens, derivatives and associated data

Certificate registration No. 73 100 7355 Certificate valid from 2022-08-17 to 2025-08-17

Audit report No. 4377 4130

IAF DAkkS

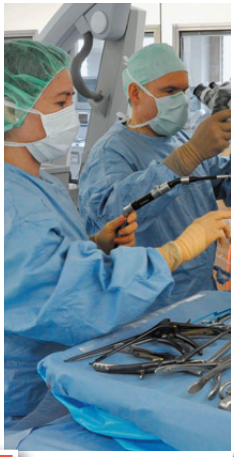
Quality Assurance

National and international scientists and research groups as well as collaborating industry partners may request data and human biological materials hosted by the **ibdw** for biomedical research projects. However, any application requires prior approval by an independent ethics committee.

External advice and internal monitoring ensure highest quality standards of the **ibdw**

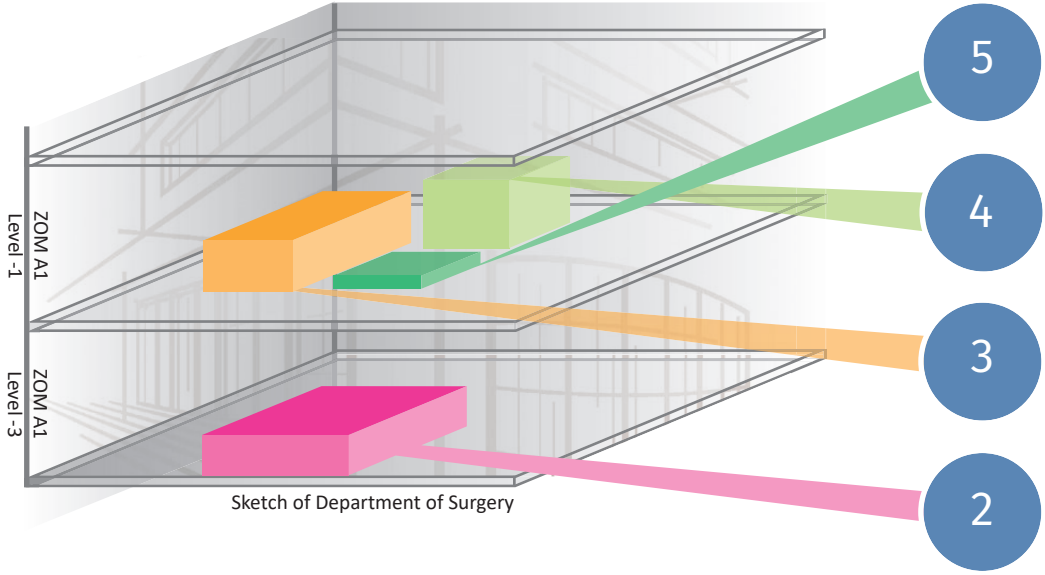
The **ibdw** with its quality management system accomplishes all requirements of the standard DIN EN ISO 9001:2015.

The certification procedure regularly analyses the implementation of a quality policy, the comprehensive documentation of all **ibdw's** procedures as well as its processes and testing measures.



1

Uniklinikum Würzburg



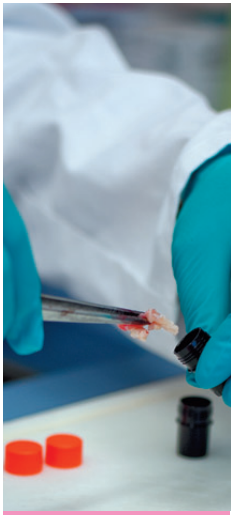
Sketch of Department of Surgery

Workflow – Tissue Samples

Human tissue taken during routine surgery is transferred to the rapid section laboratory where tissue samples are cut and temporarily stored in liquid nitrogen.

Human tissue taken during routine surgery that is not required for further diagnostic evaluation may be donated to the **ibdw's** tissue bank for biomedical research purposes.

Time is an important factor when collecting tissue samples. It takes only a few minutes from the extraction of the material by the surgeon, the pathologist's evaluation in the rapid section laboratory, and the final storage of the specimen in our central tissue repository.
Timestamps at each step of this process serve to monitor and document sample transport and -quality.



2

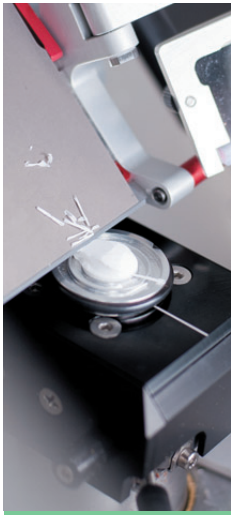
Human tissue samples are analyzed in the rapid section laboratory. Residual tissue is prepared and transferred to the **ibdw** tissue repository in individually labeled tubes.

3

Tissue tubes are registered in the central tissue repository. A unique 2D-barcode engraved in the tube-bottom allows identification, allocation, and retrieval of each tissue sample.

4

Subsequently the tissue tubes are stored in online monitored freezers at -80 °C. The location of each single tissue tube is stored in the **ibdw** database.



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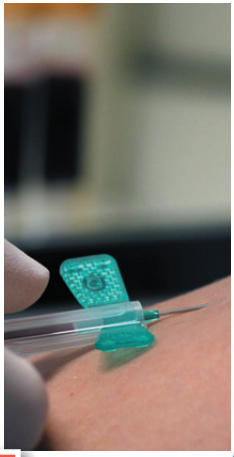
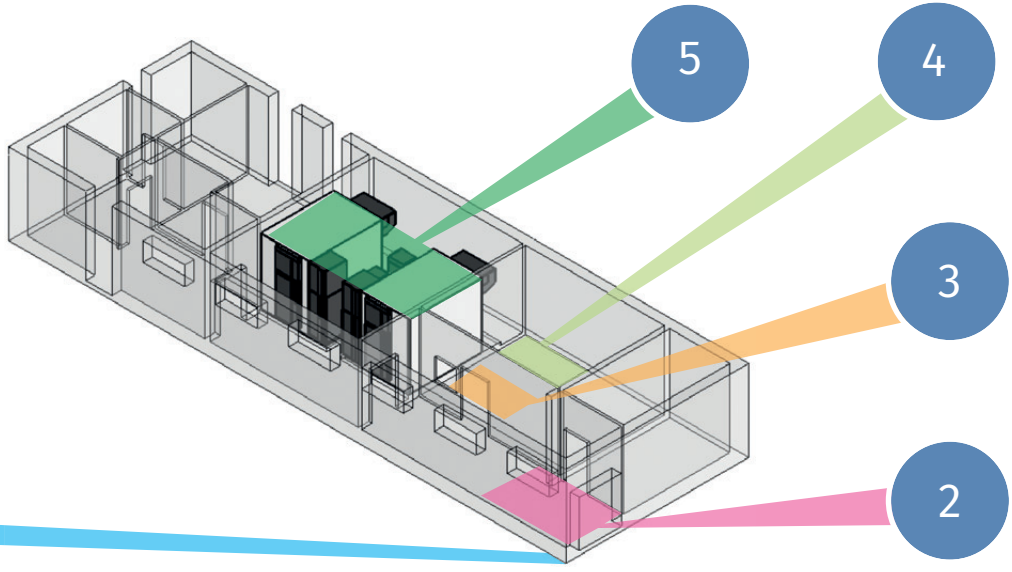
HE-stained reference sections of each tissue sample hosted by the **ibdw** provide information about the type and quality of each individual tissue sample.





1

Uniklinikum Würzburg

Workflow – Liquid Biosamples

Liquid biosamples are collected during routine blood drawing in wards or outpatient departments of the University Hospital.

Sketch of the **ibdw**-building illustrating the interior layout of the liquid repository.

The individual steps of biosample processing are indicated by numbers and different colors.

The workflow from storage to release of individual biosamples is quite complex.
Each step of this process is managed and controlled by competent staff together with a high degree of automation that comprises labelling, tracking, storage and retrieval of biosamples.

2

The registration process of biosamples includes verification of the temperature-track, transport time, and sample integrity.

3

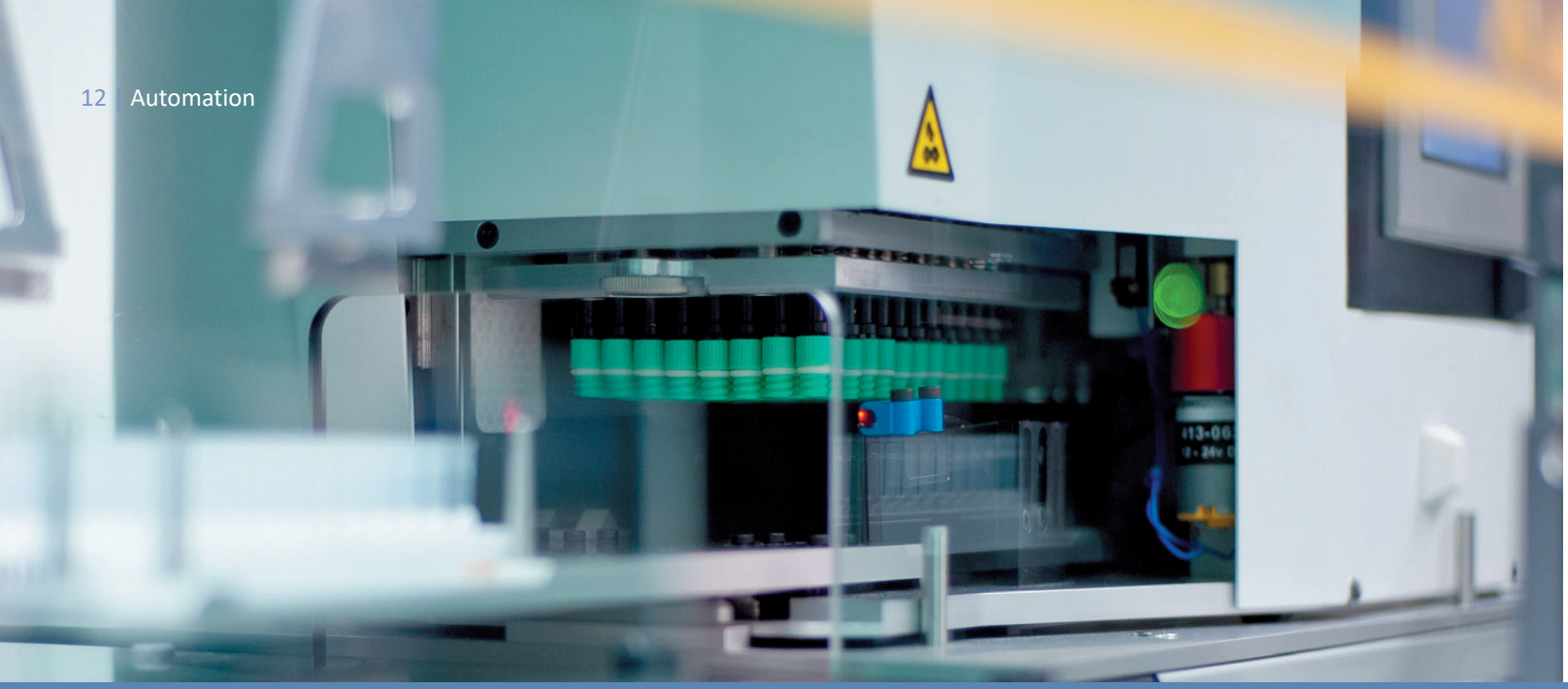
Some liquid biosamples are centrifuged prior to processing. This procedure separates liquid biosamples into individual components.

4

Material from routine blood vials is automatically transferred into 750 µl tubes by a robot. 96 of such tubes fit on a single carrier rack.

5

Carrier racks with 96 tubes are transferred into our fully automated cryo-repositories at constant -80 °C temperature.



Automation

A high degree of automation ensures a reliable high quality of the biosamples

Routine vials are divided into multiple 350 µl-portions (»aliquots«). Thus, each aliquot contains sufficient material for most analytical tests.
The advantage: Utilizing only one aliquot for analytical testing leaves the other aliquots of the same sample untouched. This strategy guarantees constant high quality of the biosamples.

The fully automated pipetting-device processes (»aliquots«) up to eight routine vials simultaneously.

Each »aliquot« has a unique identifier represented by a scanner readable two-dimensional barcode engraved in the bottom of each 750 µl tube.

The design of our cryo-repositories follows the principle of a chest freezer. The temperature is maintained at constant -80 °C.
Sensitive moving parts are localized in a special chamber at -20 °C. Here, the 750 µl tubes can be reorganized/picked and/or compiled and released for analytical testing. During these processes the system keeps humidity below 25 % thus preventing icing of the tubes .

The name »Kiwi Tube Store« for the cryo-repositories is derived from the operation method of the robot handling individual tubes.
Similar to the running bird from New Zealand that »pecks« its prey with his long beak, the robot's gripper arm selects individual 750 µl tubes for reorganization or release.

Freezing Concepts

A single cryo-repository contains 196 movable shelves that are divided into 28 slots each.
Each section provides storage space for a carrier rack holding up to 96 sample tubes (»aliquots«).

Thus, one cryo-repository may contain up to 526.848 sample tubes.

As a backup in case of technical failure each cryo-repository has two independent cooling units.
If the main unit breaks down, the backup unit automatically takes over. If both cooling units fail simultaneously, an automated emergency system based on liquid nitrogen will be activated immediately to ensure low storage-temperatures

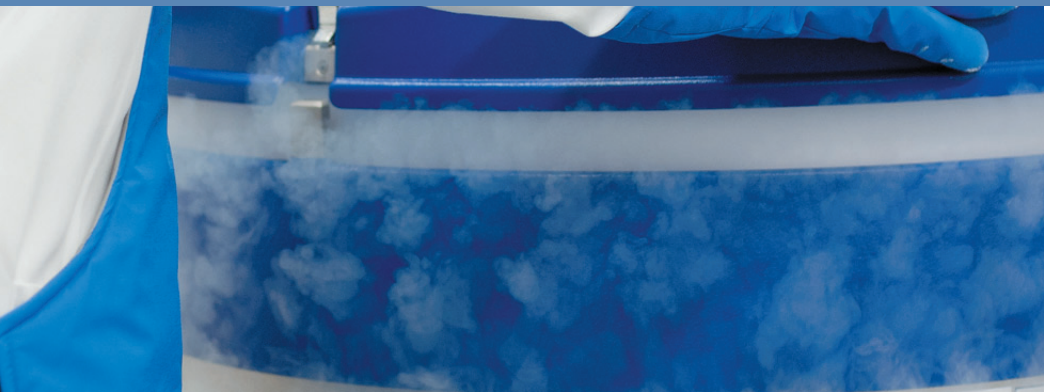
»Kiwi«: Like the running bird from New Zealand the robot »pecks« single tubes

Biosamples for sensitive analytical methods are stored at ultra-low temperatures at -180 °C

Based on fee-for-service a limited number of biosamples for sensitive analytical methods (e.g. proteomics, metabolomics) can be stored at ultra-low temperatures (-180 °C).

This low temperature is achieved by filling the storage containers with liquid nitrogen. The samples are not in direct contact with the liquid nitrogen itself but stored in the vapor that hovers above.

Ultra-low Temperature Storage (-180 °C)



As described before single carrier racks, each of them holding 96 tubes are registered in the **ibdw** database and placed manually in each slot of a storage tower. Each tank contains 32 storage towers resulting in a total of 34.000 tubes per tank.
Due to the ultra-low temperatures transfer and release of single tubes have to be carried out very carefully. For security reasons our staff is equipped with special protective garment, visor masks and gloves.

The Engine-Room of the **ibdw**

Sophisticated technology is the basis for maintaining a constant and high quality of the stored biosamples. The engine-room of the **ibdw** building contains almost all high-tech equipment required for heating, ventilation, air conditioning, water supply, and air compression.
All technical systems are redundant by design ensuring constant functioning in case of power breakdown or failure of air conditioning.

The backbone of all cross-linked technical systems is formed by a total of about 12.5 km of power- and network-cabling.
The capacity of the **ibdw's** ventilation system would be able to inflate 420,000 footballs within one hour.

An emergency cooling system with 3,500 liters of liquid nitrogen safeguards our stored biosamples in case of any severe cooling failure.

ibdw's air ventilation would be able to inflate 420,000 footballs within one hour

»Broad Consent« – The consent management of the **ibdw**

The hospital's **broad consent** procedure facilitates the collection of human biosamples long-term stored for (bio-)medical research not bound to specific research purposes.
Human biosamples collected under the Broad Consent are also called **faculty biosamples**.

Research with »Broad Consent«-Biosamples

These faculty biosamples are not bound to specific research purposes. They can be used for (bio-)medical research worldwide under clearly specified conditions.

The University Hospital of Würzburg is the owner of these biosamples.

A **standard sample** collected under Broad Consent conditions includes:
2 **Serum**-tubes à 4,7ml
1 **EDTA** tube à 2,8 ml
1 Tube for **Spontaneous urine**

Labels for faculty biosamples are generated by the hospital's laboratory order entry system (Lauris) available throughout all departments of the University Hospital.

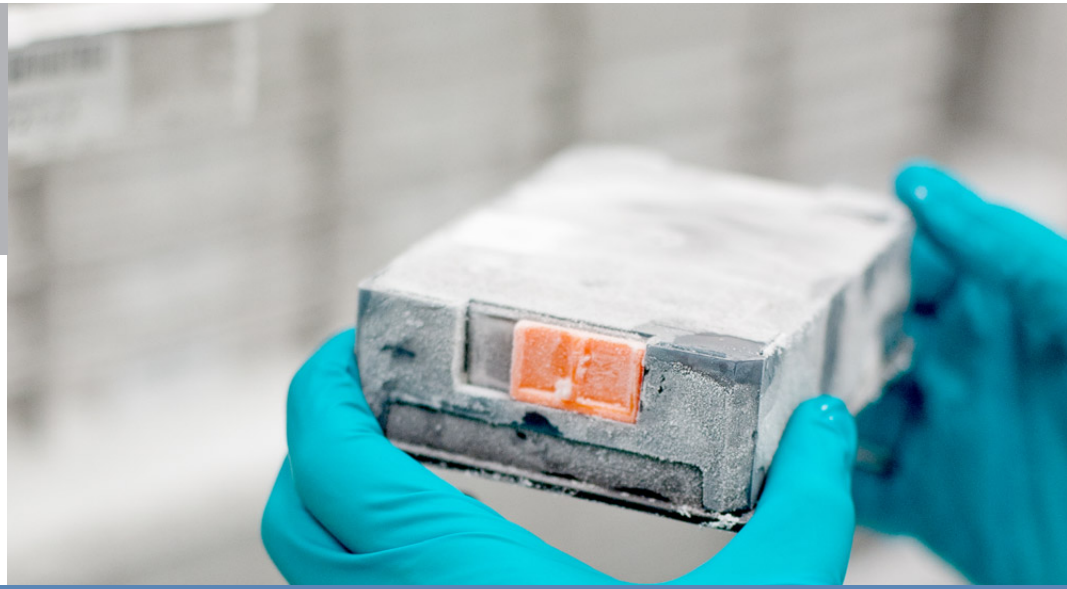
Together with its research partners, the **ibdw** has developed a simplified procedure for researchers to obtain easy access to broad consent biosamples. Further information on the easy access procedure can be found on page 18 of this brochure.

Your precious clinical study samples are safe in **ibdw's** cryorepositories

Unlike broad consent samples, samples from **clinical studies** are based on a project-specific informed consent.

The number of biosamples and storage-duration are given by the study protocol. The study-PIs are owner of the respective biosamples.

For biosamples collected in the frame of a clinical study specificially tailored labels are generated in accordance with the study-PIs.

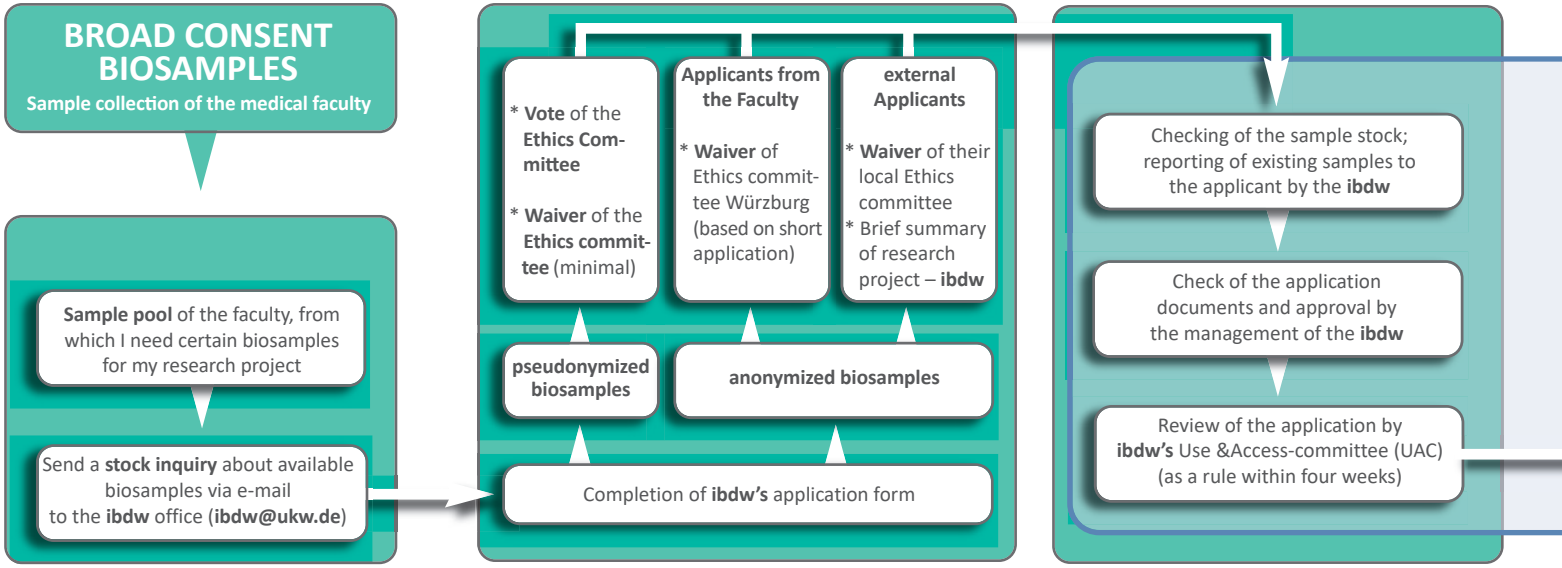


Research with Clinical Study Samples

Reciept, storage and release of study samples are associated with costs.

We will gladly support you in the planning of your biosample collection and best storage conditions for the success of your research project.

Please contact our office: **ibdw@ukw.de**



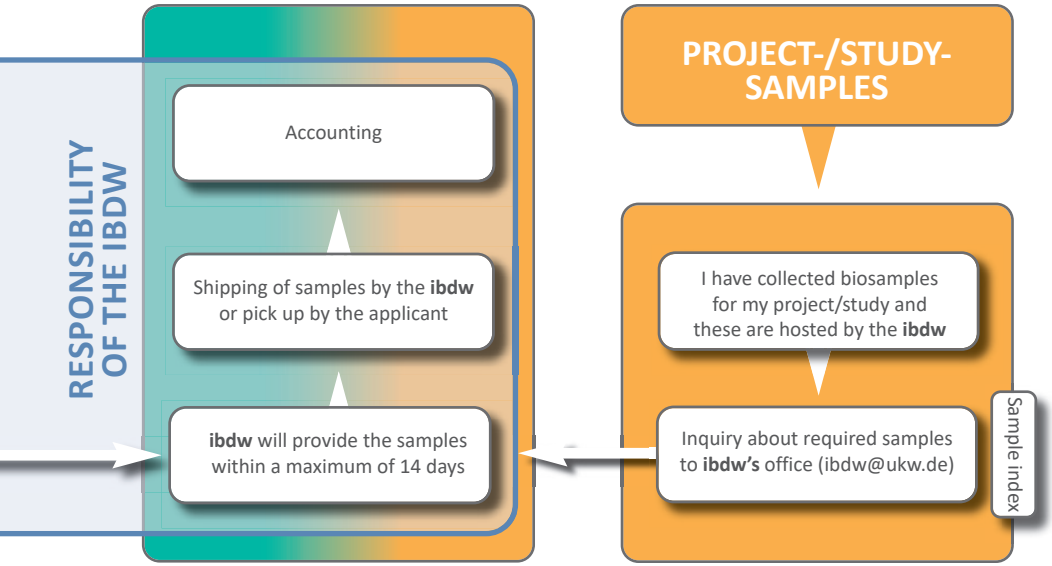
Request and Delivery of Biosamples

Human Biosamples can be easily requested from the **ibdw**.

The **ibdw** has designed a straight forward process that enables researchers to obtain easy access to biosamples.

In the case of research taking advantage of **broad consent biosamples**, the **ibdw** office can check whether the required samples are available.

Thereafter researchers enter the required details in the sample application form provided by **ibdw**. When applying for pseudonymized biosamples, an ethics vote and a study protocol must be submitted. When applying for anonymized biosamples, a waiver of the responsible by the ethics committee and a brief description of the project are required.



Human samples of a **clinical study** are hosted by the **ibdw** and are ordered on demand.

Study samples are delivered by the **ibdw** within 14 days after the order.

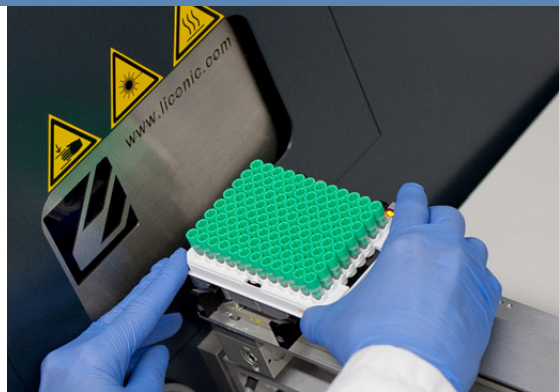
Samples are shipped by the **ibdw** but can also be picked up by the study/project staff.

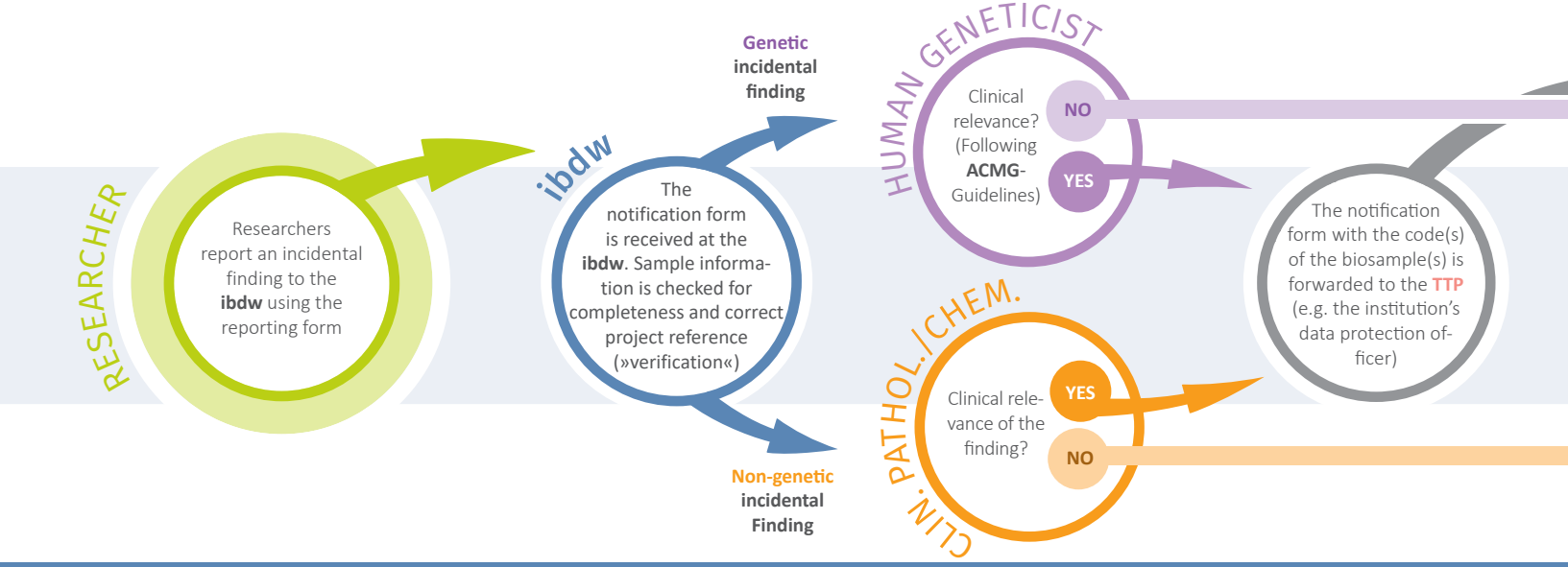
Subsequently, the **ibdw** sends an invoice for the delivered samples and, if necessary, for shipping.

Subsequently, the **ibdw** management board checks the application documents and the availabilty of the requested biosamples.
If the request complies with the specifications and there are no objections from the ethics committee, the **ibdw** management acknowledges correctness and feasibility of the application.

Within the following 7-22 working days the application is reviewed, a decision is made by the **ibdw's** Use & Access committee.

After UAC approval, the **ibdw** delivers the requested biosamples within a maximum of 14 days.



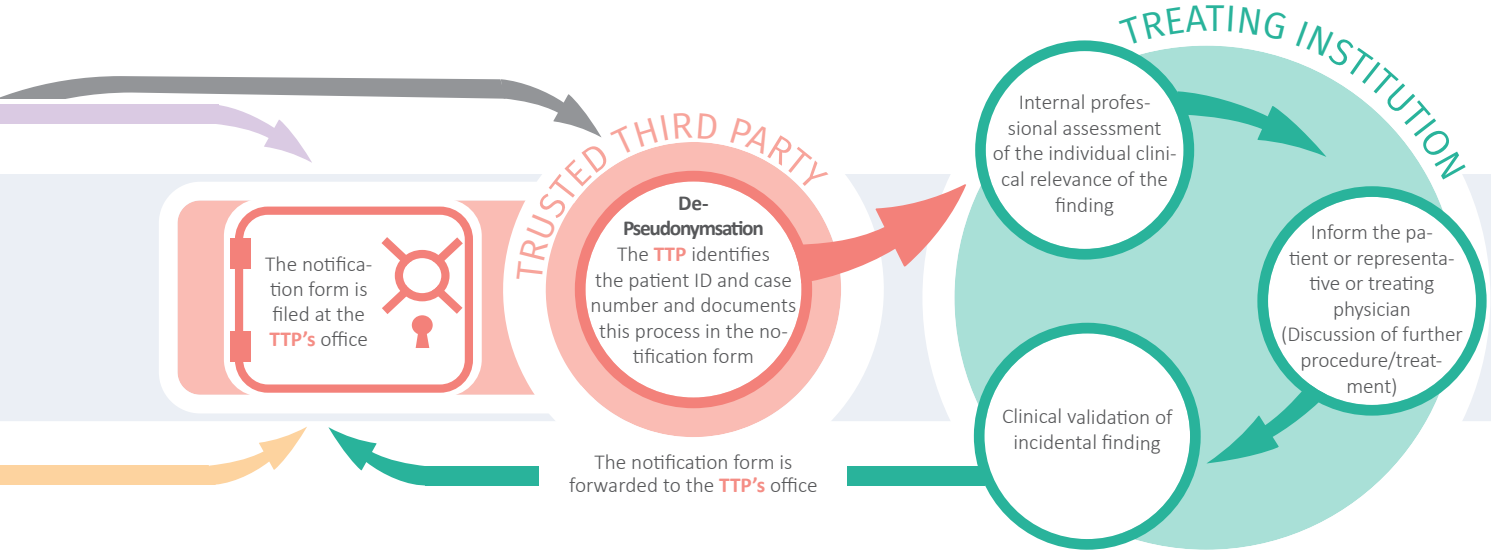


Management of Incidental Findings

Incidental findings can be a challenge for researchers

Incidental findings are often regarded as a challenge for the researcher(s).
If additional or random incidental findings are made during a research project with »Broad Consent« samples from the **ibdw**, it is possible to contact the respective donor mediated by the **ibdw**, the custodian (i. e. the institutional Data Protection Officer), and the clinic involved.

The management board of the **ibdw** together with the ethics committee, the legal department and the institutional data protection officer of the university hospital developed a workflow (including documentation-templates) with a sequential notification process shown in the scheme above.



The workflow starts with a researcher reporting an incidental research finding to the **ibdw**.
The sample pseudonym is checked against the sample database of the **ibdw** to the verify identity.
The incidental finding is then referred to an appropriate authority, either a human geneticist, pathologist or laboratory physician, for review.
If the incidental finding is valid and clinically relevant, the trusted third party holding the patient information is instructed to resolve the pseudonym and forward the patient's identity and incidental finding to the treating clinic.
The providing department (1) will check the medical records for the broad consent form (consent to re-contact or right not to know), (2) discuss the potential clinical relevance of the finding with specialists, and (3) finally organize an appointment with the patient/donor. During this appointment in hospital the patient/donor will be informed and will recieve medical advice.

If you have any further questions regarding the topic of incidental findings in human samples please contact our office: **ibdw@ukw.de**

ibdw offers additional comprehensive services

The key task of the **ibdw** is to collect, store and retrieve human biosamples based on a broad consent scheme. The hosted biosamples comprise all kinds of body fluids as well as tissue specimen.

In addition the **ibdw** offers project-specific processing, storage and retrieval of human biosamples as a service for the Medical Faculty.

Storage

- Sample registration
- Sample processing and preperation (if necessary)
- Semi-automatied storage of »fresh frozen« tissue specimen and biopsies
- Automated storage of liquid biosamples at -80 °C
- Semi-automatic storage of liquid biosamples at -180 °C

Training and Logistics

- Training of sample providers (medical and nursing staff, study staff)
- Setup of specific primary sample labels in the Lauris system of the UKW
- Planning of biosample logistics including sample tracking and quality controlled storage, documentation and reporting for studies/projects
- Quality controlled isolation of DNA/RNA from human liquid samples and tissues

Services of the **ibdw**

All **ibdw**-processes are controlled and monitored according to DIN EN ISO 9001:2015.

Backup and emergency concepts also secure an optimal environment for biosamples and data.

Delivery

- Delivery of human biological materials, including the preparation and special stainings of sections of tissue samples, if this is is applied for (Standard: HE staining for reference sections)
- Delivery of quality-controlled purified DNA/RNA in single tubes or on 96-Well carriers (rack)

As a key member of the German Biobank Alliance (GBA), the **ibdw** regularly participates in ring-trials.

By these trials techniques and measurement procedures in the field of tissue and liquid sample biobanking are assessed with regard to quality and reproducibility. These trials serve as a benchmark in order to optimize and harmonize biobank-processes

Research Projects of the **ibdw**

One kind of ring trial comprises the processing the processing of a same source material by different biobanks. The results are sent to a reference laboratory where the data are analysed and compared.

Stakeholder engagement is a critical factor for the success of a biobank. Biobanks must take into account the views of various interest groups and integrate these different view-points into their daily work.

Stakeholders of the **ibdw** include representatives from medicine, research and science, the press, funding organisations, the biobank community, industry and, in particular, donors, namely patients and test persons.
As a corner stone of the GBA, **ibdw** significantly contributes to the development of strategies and concepts to integrate the different stakeholder view-points in modern biobanking.

In addition to its range of services, **ibdw** carries out research in its own projects

May 2011: Founding of the **ibdw** in the frame of the BMBF-funded National Biobank Initiative
September 2011: National pilot-approach: implementation of a broad consent for donation, long-term storage and thematically unrestricted use of human biological material for (bio-)medical research purposes
December 2012: Enacting of the statutes of the **ibdw**
June 2013: Grand opening & first public »Open Day« of the **ibdw**
January 2014: Quality-controlled storage of the first tissue samples
February 2014: Cooperation contract with the Blood Donor Service of the Bavarian Red Cross (»BioKEP«)
December 2014: Quality-controlled storage of the first liquid biosamples in the automated cryorepositories
August 2016: ISO certification of the **ibdw** according to DIN EN ISO 9001:2015 (Certificate No: Z13305)
May 2017: ibdw becomes member of the BMBF-funded German Biobank Node »GBN«
May 2019: ibdw becomes member of the BMBF-funded German Biobank Alliance »GBA«
July 2019: Re-certificationof of the **ibdw** according to DIN EN ISO 9001:2015 (Certificate No: Z13305R1)

History and Development of the **ibdw**

July 2022: Re-certificationof of the **ibdw** according to DIN EN ISO 9001:2015 (Certificate No: 73 100 7355)
May 2023: »10 years of the **ibdw**«: Scientific symposium and open day at the **ibdw**
April 2024: Ground-breaking ceremony for the expansion of the **ibdw**

Map of the University Hospital of Würzburg

ibdw-administration and central cryo-repositories are located in the north of the hospital grounds


TECAN

Imprint

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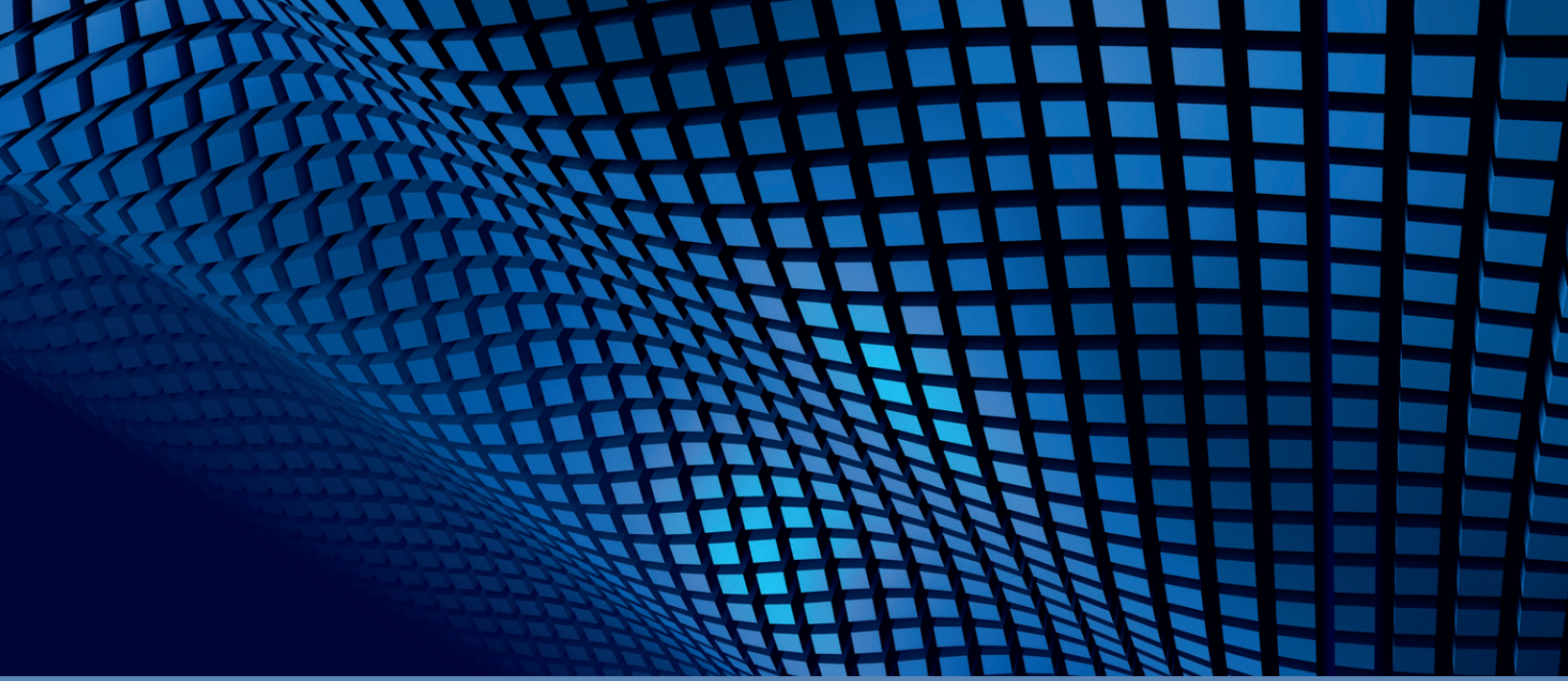

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INTERDISCIPLINARY BANK OF BIOMATERIALS AND DATA WÜRZBURG
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