The Biobank of the Medical Faculty Würzburg
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«.

Initially 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.

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.

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.

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!

Prof. Dr. Matthias Frosch
Dean of the Medical Faculty

Prof. Dr. Jens Maschmann
Executive Medical Director

Prof. Dr. Roland Jahns
Director of the ibdw
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 specimens, 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 biomedical research.

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

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

Biosamples Würzburg are stored for future research maintaining highest quality standards.
The three ibdw-pillars:
- the central liquid-bank
- the central tissue-bank
- the central database

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.

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.

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

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

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.

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.

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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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 labeling, tracking, storage and retrieval of biosamples.

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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.

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

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

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

1. Sketch of the ibdw building illustrating the interior layout of the liquid repository.
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8. Carrier racks with 96 tubes are transferred into our fully automated cryorepositories at constant -80 °C temperature.
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.

A high degree of automation ensures a reliable 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. 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.

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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.

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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 garments, visor masks, and gloves.

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.

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.
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 4.7 ml
- 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.

Receipt, 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

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 specifically tailored labels are generated in accordance with the study PIs.

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.
**Request and Delivery of Biosamples**

Human Biosamples can be easily requested from the ibdw.

The ibdw has designed a straightforward 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, if the required samples are available, researchers enter the required details in the sample application form provided by the 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 ethics committee and a brief description of the project are required.

Subsequently, the ibdw management board checks the application documents and approves the application. 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.

**Responsibility of the ibdw**

- **Applicants from the Faculty**
  - Application form
- **External Applicants**
  - Waiver of their local ethics committee
- **Review of the application by the ibdw’s Use & Access committee (UAC)**
  - Brief summary of research project – ibdw
- **Completion of ibdw’s application form**
- **Check of the application documents and approval by the management of the ibdw**
- **Check of the sample stock; reporting of existing samples to the applicant by the ibdw**
- **Review of the application by the ibdw’s Use & Access committee (UAC)**
  - as a rule within four weeks

**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.
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 DPO), and the clinic involved.

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

After verification if the respective biosample(s) do in fact originate from the ibdw, in case of non-genetic incidental findings for de-identification of the donor, the master-workflow involves a trusted third party – in our case the institutional DPO.

The DPO informs the head of the respective department where the patient donated her/his biosamples.

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 receive medical advice.

If you have any further questions regarding the topic of incidental findings in human samples please contact our office: ibdw@ukw.de
One kind of ring trial comprises 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 viewpoints into their daily work.

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.

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 into their daily work.

In addition to its range of services, ibdw carries out research in its own projects.
History and Development of the ibdw

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 2018
ibdw becomes member of the BMBF-funded German Biobank Node »GBN«

May 2019
ibdw becomes member of the BMBF-funded German Biobank Alliance »GBA«

August 2019
Re-certification of the ibdw according to DIN EN ISO 9001:2015 (Certificate No: Z13305R1)