

**Regulations for use of the databases, data and biomaterials  
of the DZNE Brain Bank**

Agreed by the DZNE Brain Bank Committee on 20 December 2019  
and approved by the Executive Board on 4 May 2020

Version 1.0 of 20 December 2019

Regulations for use of the databases,  
data and biomaterials of the DZNE  
Brain Bank

**Preamble**

The German Center for Neurodegenerative Diseases (hereinafter referred to as "DZNE") conducts research into neurodegenerative diseases and their early forms. The spectrum of neurodegenerative diseases includes dementias, such as Alzheimer's disease, Lewy body dementia and frontotemporal dementia as well as movement disorders such as Parkinson's disease and ataxias.

The DZNE Brain Bank is a collection of post-mortem human biomaterial samples (CNS tissue, where applicable tissue of other organs, blood, cells, CSF) as well as of clinical and neuropathological data.

The biomaterial collected by the DZNE Brain Bank is to ensure that the DZNE, the contributing university hospitals/universities as well as all research institutes worldwide have access to brain tissue and other biomaterials that have been collected from clinically well defined participants and have undergone high-quality processing. It is to help them to drive research in the field of neurodegenerative disorders and enable them to assist with the improvement of clinical diagnosis criteria, the establishment/validation of new diagnostic procedures and biomarkers among patients with neurodegenerative disorders as well as with the basic research into the molecular mechanisms of neurodegeneration. The storage of biomaterials for an indefinite period of time also facilitates the use for future and currently as yet undefined scientific questions.

These regulations for use (hereinafter referred to as "Regulations for Use") are designed to transparently define the goals pursued by the DZNE Brain Bank and stipulate who may under what conditions use the collected biomaterials and data.

Note: These Regulations for Use define both the use of the databases of the DZNE Brain Bank as well as the request for and the utilisation of data and biomaterials for research projects:

- The request for user accounts and any accompanying rights and obligations are looked at in section II hereunder.
- The requests and its evaluation procedures for the use of data and biomaterials as well as the conditions for their provision are set out in section III hereunder.

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## I. General

### Section 1 – Goals and principles

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Brain Bank

- (1) The DZNE Brain Bank refers to all the structures, be they internal or external, concerning the tissue donor programme, the collection and of human biomaterials acquired during an autopsy as well as the database administration of clinical and neuropathologically acquired data on tissue donors and tissue samples within the DZNE. As to the structure and organisation of the DZNE Brain Bank, we refer to the *Rules of Procedure of the DZNE Brain Bank*.
- (2) The DZNE Brain Bank is an organisational unit of the DZNE e.V., i.e.:
  - a) The DZNE ensures, through contractual agreements with cooperation partners, the safe and proper storage/asservation of data and biomaterials within the DZNE Brain Bank.
  - b) The DZNE is responsible for complying with all accompanying data protection rules and ethics regulations. It therefore acts, with regard to the stored biomaterials and the concomitant data accompanying the samples as well as the organisational data, as the responsible legal entity vis-à-vis the surviving dependants of the donor and, vis-à-vis the user, as responsible custodian that is fully authorised to dispose of the gathered data and biomaterials.
- (3) On principle, all researchers at the DZNE as well as other national and international research institutes and industrial companies that cooperate or undertake contract research work with academic partners may apply for the data and biomaterials. In the case of competing requests for data/biomaterial of the same scientific quality and relevance, the DZNE Brain Bank does, however, primarily support the requests submitted by researchers of the DZNE and/or the cooperation partners. The provision of data/tissue samples to another national and international group of researchers takes second place.
- (4) The collection, processing and use of data as well as every removal, further processing, analysis and evaluation of biomaterials require the informed written consent of the donor. As far as the statutory regulations allow, consent may also be provided by statutory carers or those authorised to decide how the body should be disposed of (*Totensorgeberechtigte*) in line with the alleged will of the donor. The DZNE as the operator of the databases and the data-processing body pursuant to the privacy regulations is responsible for ensuring that the participants are duly informed and give their informed consent prior to the first-time entry of the data. This is achieved by obligating users accordingly.
- (5) In addition to these Regulations for Use and the SOPs, the following provisions, laws including implementation provisions or regulations, in their currently valid versions, must always be observed:
  - EU General Data Protection Regulation
  - Federal Data Protection Act (*Bundesdatenschutzgesetz*)
  - Guidelines for good scientific practice, guidelines for good epidemiological practice, guideline for good clinical practice and guideline for good practice in secondary analysis to the extent applicable to the specific research project

- Statutes of the DZNE and other relevant regulations (e.g. Rules of Procedure of the DZNE Brain Bank, Regulations for Use of Clinical Research databases of the DZNE in their currently valid version)
- Clinical Research data protection concept of the DZNE
- German Medicinal Products Act (*Arzneimittelgesetz*) and German Medical Devices Act (*Medizinproduktegesetz*) as well as subordinate regulations where applicable
- Provisions of local, state and/or federal authorities where applicable
- Votes of the responsible ethics committees
- Regulations of the Federal Office for Radiation Protection (*Bundesamt für Strahlenschutz*) where applicable
- Provisions concerning funding laws

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## Section 2 – Database structure of the DZNE Brain Bank

- (1) The databases of the DZNE Brain Bank are integrated into the structure of the Clinical Research databases of the DZNE and are used to organise and process neuropathological and clinical data (DZNE Brain Bank module of the trial database) as well as to administer samples (biomaterial module of the DZNE Brain Bank). See also section 2 of the *Regulations for Use of the Clinical Research databases, data and biomaterials of the DZNE*.
- (2) The databases of the DZNE Brain Bank only include data for research purposes. There is no storage of data for the purpose of treatment.
- (3) Overall, the databases of the DZNE Brain Bank have a modular structure. The various modules (DZNE Brain Bank module of the trial database, biomaterial module of the DZNE Brain Bank) use the centralised services (data fiduciary office, consent management, central contact management, rights and role management, central quality assurance and management) of the Clinical Research databases of the DZNE.
- (4) The DZNE Brain Bank module of the trial database is used by the recruiting institutions or BBUs to register the (potential) donors and store demographic, clinical and neuropathological data. If consent has been given, the trial data of other DZNE trials may also be used together with the analysis results of the post-mortem tissue for research purposes. The biomaterial module of the DZNE Brain Bank is used to store all data concerning the removed tissue.

## Section 3 – Central services

- (1) **Data fiduciary office (*Datentreuhänderische Stelle*):** All data that may be used to identify persons as well as all pseudonyms and re-pseudonyms are processed by a data fiduciary office as a centralised participant list, across trials and sites.
- (2) **Consent management:** Before data and biomaterials are compiled and handed over following a user request, the consent management, which is part of the CRP, reviews whether the consent given by the donor permits the requested use of data and biomaterials for the respective purpose. In cases

of doubt, the data protection officer of the DZNE is consulted based on the applicable data protection concept. The written information provided to donors and the declaration-of-consent form take account of the applicable privacy provisions. Important principles of information are, among others, voluntary participation, the right of withdrawal and the procedures involved.

- (3) **Central contact management of the CRP:** Central contact management, as part of the CRP, is the port of call for donors or, where applicable, for their statutory representatives/agents or those authorised to decide how the body should be disposed of (*Totensorgeberechtigte*) (request for information and request for erasure).
- (4) **Rights and role management:** Rights and role management, as part of the CRP, controls and monitors the issuance of access rights for the databases of the DZNE Brain Bank. Roles and access rights are, under certain conditions, granted upon request.
- (5) **Central quality assurance and management:** The primary tasks of quality management, as part of the CRP, are to review the standardised validity of the data sets and/or ensure their collection complies with all applicable laws and regulations. The declarations of consent and, where applicable, any documents confirming care issued are checked for completeness and consistency. The standards applied are the *rules of good clinical and good scientific practice*, conformance with legal provisions and protection of the rights of participants.
- (6) **Data management:** Central data management, as part of the CRP, is responsible for the technical set-up of the DZNE Brain Bank module of the trial database, the carrying out of plausibility checks and for engaging in data cleaning, archiving and export.

#### Section 4 – Rights of ownership and use

- (1) Based on the submitted declaration of consent given by the donor or statutory representatives/agents or those authorised to decide how the body should be disposed of (*Totensorgeberechtigte*), the DZNE is the owner of the collected data and asserved biomaterials and/or authorised to dispose of it as it sees fit.
- (2) Users of the DZNE Brain Bank shall, pursuant to these Regulations for Use, pursuant to the request which may have been approved with restrictions and pursuant to the contracts of use to be concluded (if applicable), be granted non-exclusive and non-transferrable rights of utilising the data and/or the biomaterials for a specific purpose if the intended purpose of use reflects the goals of the DZNE Brain Bank.

## II. User accounts of the databases of the DZNE Brain Bank

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### Section 5 – Access regulations and general rules for the databases of the DZNE Brain Bank

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- (1) Persons involved in the activities of the DZNE Brain Bank may request a user account to access the databases of the DZNE Brain Bank. All active processes such as donor recruiting, data entry, autopsy (including sample processing/asservation) and neuropathological analysis (non-exhaustive list) are deemed to be an involvement.
- (2) Any potential user of the databases must submit a request for the creation of a user account pursuant to **SOP-GE-08 User Management** using the respective form sheet. The request must specify and justify the desired roles. The applicant must furthermore submit the *Obligatory Declaration and Consent for Users of the Clinical Databases of the DZNE* form giving his/her approval to the storage and use of his/her own data for administrative purposes, a declaration of conformance with data protection obligations including the obligation to use the identifying and medical data of donors only for the approved purpose, a declaration of conformance with the German Act on the Obligations of Public Servants (*Verpflichtungsgesetz*), a secrecy declaration as well as a declaration of acceptance of the *Regulations for use of the databases, data and biomaterials of the DZNE Brain Bank*. The CRP reviews each request and shall, following approval, arrange for the creation of the respective user account. People have, on principle, no right to have their request approved.
- (3) All user accounts are created for a limited period of time only (two (2) years maximum) to prevent the existence of unused accounts. An extension may be granted on request.
- (4) Users use an encrypted modular web request to access the databases within the context of their rights and roles.
- (5) A request for a user account must be made specifically for a certain role within the data databases. A role or user role defines the tasks (obligations), the characteristics and rights of a user within the databases of the DZNE Brain Bank and therefore the rights of access to these databases. These are granted by the rights and role management of the Clinical Research Platform (CRP) of the DZNE. A user may have several roles with his/her rights resulting from a combination of the rights of all roles allocated to him/her. User may, at any time, make requests for new or other roles as long as the aforementioned access rules are complied with.
- (6) All users are obliged to acknowledge and respect the respective applicable SOPs to guarantee data quality and scientific comparability.
- (7) Access to the database of the DZNE Brain Bank does not establish the right to receive financial or other support and assistance from the DZNE.
- (8) When the employment contract specified in the request for a user account comes to an end, the user in question must notify the CRP immediately. His/her user account shall be blocked forthwith. He/she may apply for a new user account.

### III. Use of data and/or biomaterials

#### Section 6 – Access regulations and general rules for the use of data and biomaterials of the databases of the DZNE Brain Bank for research projects

##### Section 6a – Request and evaluation procedures

- (1) On principle, all researchers of the DZNE as well as other national and international research institutes and industrial companies may request data and biomaterials for the purpose of researching neurodegenerative conditions.
- (2) In order to obtain and use the data and biomaterials of the DZNE Brain Bank for carrying out a research project, the principal investigator (PI) of the respective planned research project must submit a formal written request to the Brain Bank Head Office (BBHO), which must include the following information:
  - a) Project description
  - b) Details on preliminary work
  - c) Details on the biomaterials and data required
  - d) A vote in favour of the research project by the ethics committee responsible for the PI
  - e) Naming the persons involved in the project
  - f) Project start and project duration

All requests must be submitted using the tissue request – DZNE Brain Bank form.

- (3) The heads of the local Brain Bank Units (BBU) and the head of the BBHO have the right, at any time, to request the export of their local data or, as the head of the BBHO, to request, irrespective of the centre, the export of the data of the DZNE Brain Bank at the CRP. They do not require a separate authorisation by the DZNE Brain Bank Tissue Committee to do so.
- (4) The evaluation of and the decision on the user requests shall be made by the DZNE Brain Bank Tissue Committee taking into consideration the following aspects:
  - a) Scientific quality and relevance of the research project applied for including consideration of relevant preliminary work.
  - b) In the case of competing requests of the same scientific quality and relevance, requests by researchers of the DZNE or the cooperation partners shall have priority.
  - c) The direct commercial use of the data and biomaterials of the DZNE Brain Bank is excluded. The use of the data and biomaterials for indirect commercial use within the context of scientific cooperation between industry and scientific institutes is possible upon approval by the donor.
  - d) If several requests for similar research work that are worthy of support are submitted, an endeavour shall be made to ensure the cooperation between the PIs.

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- e) The interests of researchers who have provided data and/or biomaterials that are considered to be of special value must be considered. If requests are made that concern an above-average amount of data and/or biomaterials of one researcher, he/she must be consulted.
  - f) Researchers involved in and providing material to the DZNE Brain Bank must, via co-authorship, be considered in publications in line with the rules of good scientific practice and, where necessary, as part of a prior arrangement with the PI (see section 8, paragraph 2 below).
  - g) The data protection officer of the DZNE shall, where appropriate, be consulted in the event of requests by third countries whose data protection regulations are considered unsafe or if there are deviations from the data protection concept.
  - h) Irrespective of the scientific quality of a research project, the DZNE Brain Bank Tissue Committee may, in particular in the event of prior breaches committed by the PI against the Regulations for Use of the DZNE Brain Bank, decide to reject the request for the release of data and/or biomaterials.
- (5) Decisions (approval/rejection/enquiries concerning specification of the research request) by the DZNE Tissue Committee must be submitted in writing to the PI of the respective research project.

#### Section 6b – Provision of biomaterials and data

- (1) The following requirements must be met to ensure the release of biomaterials and data for research projects:
- a) A request must be submitted
  - b) The request for use must be approved by the DZNE Brain Bank Tissue Committee
  - c) The donor or, where applicable, his statutory representatives/ agents or those authorised to decide how the body should be disposed of (*Totensorgeberechtigte*) must have given their consent
  - d) Valid ethic committee vote approving the intended activities must have taken place
  - e) Availability of the data/biomaterials
  - f) Where appropriate, a Data Use Agreement (DUA) and/or a Material Transfer Agreement (MTA) must exist:

DZNE researchers neither need a Material Transfer Agreement nor a Data Use Agreement. In the request for the collection of data/biomaterials they do, however, with their signature confirm that they are aware of these Regulations for Use and their adherence.

In the case of external researchers (researchers without DZNE affiliation) the transfer and use of data of the DZNE Brain Bank is set out in a Data Use Agreement between the DZNE and the receiving institute. The transfer and use of biomaterials of the DZNE Brain Bank



with the accompanying data (age, diagnosis, sex) is set out in a Material Transfer Agreement.

Depending on the type of employment relationship for which the data/biomaterials are to be used, researchers who are affiliated to two entities may, where applicable, also require a Data Use Agreement and/or a Material Transfer Agreement.

- (2) Nobody is entitled to be provided with data or biomaterials. Provision within a certain period of time is not guaranteed.
- (3) The transfer of biomaterials and data from the DZNE Brain Bank does not establish the right to receive financial or other support and assistance from the DZNE.
- (4) The export of the data takes place after the request has been confirmed by Data Management according to **SOP-DM-14 data export and transfer**. The data is transferred via a download.
- (5) Tissue samples are exclusively dispatched to a person named by and working for the applicant.
- (6) The passing on of data/biomaterials to third parties is not permitted and only possible following a renewed request.
- (7) Utilisation of the transferred data and/or the provided biomaterials shall exclusively be granted for the project described in the request form and for the purpose of use included therein and shall be bound by the duration of the project and/or the validity of the Data Use Agreement and/or Material Transfer Agreement.
- (8) The PI of the research project is responsible and liable for the received biomaterials and the transferred data.

#### Section 7 – Costs and fees

- (1) No general fees are charged for the provision of data and biomaterials for scientific, non-commercial purposes.
- (2) The DZNE Brain Bank may charge the applicant for the actual material costs that have been incurred for the provision of biomaterials.
- (3) If additional work due to, for example, the provision of special sample processing and shipment pursuant to section 7 paragraph 2 has been undertaken, the DZNE Brain Bank reserves the right to also charge for such work.
- (4) In the case of indirect commercial use, provided that it was approved by the donor of the data/biomaterials, the user must pay a licence fee to the DZNE, which is set out in the relevant accompanying contract.
- (5) The cost for the transport of tissue samples shall be borne by the recipient.

#### Section 8 – Publications

- (1) Whenever publications use data and/or biomaterials originating from the DZNE Brain Bank, the DZNE Brain Bank must be mentioned as the source

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in the section on the material used and the acknowledgement. The wording used for this purpose must be the one provided by the DZNE Brain Bank.

- (2) Furthermore, and in line with *Good Scientific Practice*, the DZNE Brain Bank Tissue Committee may, while evaluating a request for use, ask that researchers taking part in or contributing to the DZNE Brain Bank, have to be named as co-authors in publications. This shall be documented in writing prior to the provision of data and biomaterials and be implemented accordingly by the PI whenever publications take place.
- (3) After an article has been published, the responsible project leader of the respective study shall provide the BBHO with an electronic copy.
- (4) The modus operandi to be applied to the publications of projects that have been submitted to study-specific steering committees for evaluation is set out in the relevant statutes.

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#### IV. Legal consequences of violations

##### Section 9 – Revocation or restriction of user rights/user account

- (1) In cases of violations of these Regulations for Use or provisions set forth in the relevant agreement on data use or the material transfer agreement, the DZNE Brain Bank may, at any time, restrict or revoke the rights to use the databases via the user account and revoke all rights of use of the data and biomaterials made available. Data and biomaterials that have already been handed over must be destroyed or returned as the case may be.
- (2) The same applies in cases where the security of the database and the data stored therein could be compromised by the user.
- (3) The procedure for a restriction or revocation of the right of use is set forth in **SOP-GE-08 User Management**.
- (4) Other claims of the DZNE Brain Bank, especially in cases involving culpable violations, shall not be affected.

#### V. Liability

##### Section 10 – Operation and use of databases

- (1) The DZNE shall manage the database of the DZNE Brain Bank, which is made available free of charge, and their use appropriately and to the best of its knowledge, taking into account the state of the art in science and technology. The DZNE shall not guarantee that the database is available at all times, without interruption, when needed, secure and error-free. Neither shall the DZNE guarantee that the database functions error-free at all times. The DZNE has the right to carry out maintenance work on the database at any time. The DZNE will strive to keep disruptions to a minimum. In the event of impairments, users shall not be entitled to a reduction or the reimbursement of potential costs nor shall they be able to claim compensation.

- (2) The DZNE shall, in particular, not be liable for any loss/damage incurred by users as a result of the non-availability of the database.

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#### Section 11 – Other liability

- (1) Data and biomaterials may contain inherent errors or be damaged.
- (2) Biomaterials may be infectious. It is incumbent upon the users of these potentially infectious biomaterials to undertake, on their own account, the respective protective measures. The DZNE shall not be liable if such precautions are not observed.
- (3) The DZNE assumes no liability for the accuracy, usability and suitability of the data or biomaterials of the DZNE Brain Bank for certain purposes.
- (4) The DZNE assumes no liability for any loss/damage that may result from working with the data or biomaterials of the DZNE Brain Bank.
- (5) The above liability limitations set forth in sections 10 and 11 do not apply to cases of wilful misconduct or gross negligence on the part of the DZNE; nor do they apply to claims under the German Product Liability Act (*Produkthaftungsgesetz*). Neither do the restrictions and exclusions of liability apply to any loss/damage resulting from death, bodily injuries or impairments to health. In cases of slight negligence, liability is limited to the foreseeable loss/damage that is typical for the type of agreement in question. The above restrictions and exclusions of liability also apply to the personal liability of its legal representatives, employees and vicarious agents.

#### VI. Entry into force

These Regulations for Use shall become effective after consultation of the DZNE Brain Bank Committee, of the Clinical Board and following approval by the Executive Board of the DZNE.

#### VII. References/supplementary documents

- (1) Rules of procedure of the DZNE Brain Bank
- (2) SOP-DM-14 Data export and transfer
- (3) SOP-GE-08 User Management
- (4) Data Use Agreement (DUA)
- (5) Material Transfer Agreement (MTA)
- (6) Obligatory declaration and consent for users of the clinical databases

## VIII. Glossary/Definitions

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<b>Biomaterials</b>	Materials that have been collected from the human body for diagnostic or scientific purposes. Examples of biomaterials are blood and blood components, other bodily fluids (such as urine, liquor, saliva), feces, cells, tissue, RNA, DNA and organs. As far as the Brain Bank is concerned, most of the biomaterial stored originates from the tissue of the central nervous system (brain and spinal cord).
<b>Brain Bank Head Office (BBHO)</b>	The head of the Brain Bank Head Office (BBHO) is in charge of the scientific management of the DZNE Brain Bank and assumes full project responsibility. The BBHO coordinates the processing of requests for use that are decided upon by the DZNE Brain Bank Tissue Committee.
<b>Brain Bank Unit (BBU)</b>	The DZNE Brain Bank consists of decentralised Brain Bank Units (BBUs) with full service (full/fBBUs) and Brain Bank Units with partial service (partial/pBBUs) at institutes of the cooperating universities at DZNE sites. It is at these sites that – depending on the service – the autopsy, the processing and the asservation of the tissue takes place.
<b>Clinical Research</b>	Clinical Research includes clinical cross-sectional and longitudinal observation and intervention studies on healthy and ill persons as well as their relatives. They may be conducted for the purpose of researching basic mechanisms in the human organism, disease and therapy progression as well as for the purpose of evaluating new diagnostic and therapeutic procedures.
<b>Clinical Research Platform (CRP)</b>	The Clinical Research Platform is the central organisational structure for Clinical Research. It is where the central services of the DZNE Brain Bank such as consent management, central contact management, rights and role management, central quality assurance and management, data management and project management are localised. The CRP also defines the biobank structures for Clinical Research. Further areas include the project management and quality management of clinical studies.
<b>Commercial Use</b>	Forms of the commercial use of data and biomaterials include the sale, the licensing or another type of transfer of data and biomaterials for profit-orientated purposes and any related research activities. Commercial use also

covers the undertaking of contract research work for commercially active companies, the screening of compound libraries and the manufacture of products for general sale.

A distinction is made between direct and indirect commercial use.

Direct commercial use is deemed to be the direct sale or the licensing of data and biomaterials for undefined purposes.

Indirect commercial use is deemed to be the licensing of research results or another transfer of data and biomaterials for research projects with subsequent profit-orientated intentions.

The use of data and biomaterials as part of scientific cooperations with commercially active companies or academic institutes is not deemed to be commercial use.

The DZNE is under no obligation to approve any commercial use. In every case, the purpose is assessed during the evaluation of the request for use. Direct commercial use is excluded.

Data	All data that is collected and stored as part of trials and/or registers of the Clinical Research of the DZNE and the DNZE Brain Bank such as medical data, image data, voice recordings or analysis results. Biomaterials themselves and any data accompanying biomaterials are not deemed to be data.
Data use	Data use is any use, storage or transfer of data.
Pseudonymisation	Pseudonymisation is the “processing of personal data in such a way that the personal data can no longer be allocated to a specific person without the use of additional information as long as this additional information is stored separately and subject to technical and organisational measures guaranteeing that the personal data is not allocated to an identified or identifiable natural person”.
Researchers	Reseachers are deemed to be all persons who are seeking to carry out a research project involving the use of data and/or biomaterials. A distinction is made between DZNE researchers who are employed by the DZNE and external researchers who are not employed by the DZNE.
Role/user role	A role or user role defines a user's tasks, characteristics

and rights within the DZNE Brain Bank and/or the databases of the Clinical Research of the DZNE. A user can have more than one role. In such cases, his/her rights result from a combination of the rights of all roles assigned to him/her.

<b>Standard Operating Procedure (SOP)</b>	SOPs are written process descriptions and work procedure instructions that stipulate how processes and activities are to be carried out taking into account the relevant responsibilities and resources used. This is meant to standardise processes in order to enhance their reproducibility, reliability and traceability and thus improve the quality of the results.
Tissue Committee of the DZNE Brain Bank	The DZNE Brain Bank Tissue Committee decides upon user requests and the provision of biomaterials and/or data from the DZNE Brain Bank. Its decisions must be based on the quality of the request and the biomaterials available. The modus operandi is stipulated in the Regulations for Use of the DZNE Brain Bank.
User	A user is any person who is given access to the databases of the DZNE Brain Bank or the databases of the Clinical Research of the DZNE. To be able to use the databases of the DZNE Brain Bank a user must have his/her request approved by his/her superior or study director. To be able to access the biomaterials, a user must have his/her request approved by the Tissue Committee.
User account	A user account is an authorisation for access to a restricted-access IT system. To log onto such a system via his/her user account, a user authenticates himself/herself by entering his/her user name and password. In the context of Clinical Research, a user's user account will always be the user's DZNE account within the DZNE Lightweight Directory Access Protocol (LDAP).