Regulations for use of Clinical Research databases, data and biomaterials of the DZNE

Agreed by the Clinical Board on 16 July 2019
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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. To be able to study such diseases and potential therapies, the DZNE has decided to create a database structure for the area of Clinical Research, which can be used across different DZNE sites. It will reliably and centrally store research data and information about biomaterials obtained in research contexts as well as imaging data from Clinical Research at the DZNE. It will furthermore provide significant scientific added value via quality controls and opportunities to expand the recruitment of trial subjects.

These regulations for use (hereinafter referred to as “Regulations for Use”) are designed to transparently specify the goals pursued by the DZNE in connection with this database structure for Clinical Research, and stipulate who may under what conditions use the relevant databases, the data they contain and the collected biomaterials. With regard to the use of such biomaterials, we refer to the biobank regulations of Clinical Research in their respective valid versions.
Note: These Regulations for Use define both the use of the Clinical Research databases of the DZNE as well as the application for and the utilisation of data and biomaterials for research projects:

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

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I. General

Section 1 Goals and principles

(1) The DZNE's Clinical Research pursues the long-term goal of developing effective new therapies for neurodegenerative diseases. It seeks to use clinical studies to swiftly test findings gained in fundamental research. Furthermore, its therapeutic research is accompanied by efforts to improve the early diagnosis of neurodegenerative diseases with a view to being able to apply new therapies to the relevant diseases in the early stages. In order to achieve these goals, the DZNE needs to carry out longitudinal studies on persons at risk and those affected by the disease as well as undertake standardised data collection to conduct both monocentric and multicentric studies at the highest scientific level.

(2) The Clinical Research databases are 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 of data and biomaterials within the Clinical Research databases.

   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 collected data, as the responsible legal entity vis-à-vis the trial subjects and, vis-à-vis the user, as responsible trustee that is authorised to dispose of the gathered data and biomaterials as it sees fit.

(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. It is, however, primarily the internal research activities of the DZNE and the cooperation partners of the DZNE providing the data/biomaterials for the purpose of researching neurodegenerative illnesses that is being supported. This includes all data providing researchers who actively contribute to the establishment of the Clinical Research databases of the DZNE, i.e. take part in processes such as the recruitment and execution of study-related assessments. Making the data/biomaterials available to other national and international researchers comes second.

(4) All collection, processing and use of data, and all collection, further processing, analysis and evaluation of biomaterials require the informed consent of the trial subjects as set forth in their written declarations of consent. The DZNE as the operator of the databases and the data-processing body pursuant to the privacy regulations is responsible for ensuring that the trial subjects are duly informed and give their informed consent prior to the first-time entry of their data into the system. This is achieved by obligating users accordingly.
All users are obligated to accept and observe the applicable SOPs for the databases and the relevant studies to assure data quality and scientific comparability. In each case, the SOPs can be found as controlled documents within the relevant study-specific Investigator Site File (ISF) or as a current, daily updated electronic version within the intranet as well as within the documents area of the databases of the DZNE.

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 data analysis to the extent applicable to the specific research project
- Statutes of the DZNE and other relevant regulations (e.g. Rules of Procedure for the Clinical Research of the DZNE, biobank regulations)
- Clinical Research data protection concept of the DZNE
- Medicinal Products Act (*Arzneimittelgesetz*) and 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 committee
- Regulations of the Federal Office for Radiation Protection (*Bundesamt für Strahlenschutz*) where applicable
- Provisions concerning funding laws

Section 2 Clinical Research database structure of the DZNE

The databases have a modular structure to facilitate their use. Information on the planning and execution of studies is included either in the clinical or the studies module depending on the type of study undertaken. While the studies are conducted, records of biomaterials and their analysis results are kept in the biomaterials module while image data and its analysis results is stored in the image data module. In order to enable data mining in closed sets of data of active and inactive studies, data is placed in the research module. Via an encrypted modular web-based application users access the databases in keeping with their rights and roles.

The various modules (clinical module/studies module) are connected with each other via central services (data fiduciary office, consent management,
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central contact management, rights and role management, central quality assurance and management, data management) of the Clinical Research databases of the DZNE.

(3) The Clinical Research databases of the DZNE contain solely data for research purposes. Data is not stored for the purpose of treatment.

(4) An essential function of the databases is the multi-study system, which can be used in the clinical module and in the studies module. If, via the use of forms, the same medical data is to be obtained from trial subjects for several studies at the same time, the multi-study system combines these forms in such a way that data only needs to be entered once. During data processing, this data is automatically allocated to the respective studies. The use of this multi-study system ensures that the work to be undertaken by the volunteers taking part in a trial/study is kept to a minimum.

(5) All studies subject to the provisions of the Medicinal Products Act (Arzneimittelgesetz) or the Medical Devices Act (Medizinproduktegesetz) are set up in their own separate framework.

Section 3 Central services

(1) **Data fiduciary office (datatreuhänderische 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 part of a central trial subject list, irrespective of studies and sites.

(2) **Consent management:** Consent management is part of the CRP. Before data is compiled according to an application for use, and/or before biomaterials are handed over, consent management reviews whether the consent given by the trial subject allows 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 trial subjects and the declaration-of-consent form take account of the applicable data-privacy provisions. Important information to be communicated includes, among others, that participation in the study and any donation of biomaterials (if applicable) are voluntary; trial subjects must also be informed of their right of withdrawal and the procedural options involved.

(3) **Central contact management:** Central contact management, which is also a part of the CRP, is the point of contact for trial subjects (for requests for information and for data erasure), and it is involved in the process of forwarding incidental findings to the relevant sites.

(4) **Rights and role management:** Rights and role management, which is also a part of the CRP, controls and monitors the issuance of access rights for the Clinical Research databases of the DZNE. Role and access rights are granted by application under certain conditions.
(5) **Central quality assurance and management:** The primary tasks of quality management, which is also a part of the CRP, are to review the standardised validity of data records and to ensure that data records have been collected in conformance with all applicable laws and regulations. The declarations of consent issued are checked for completeness and consistency. The standards applied include the rules of good clinical and good scientific practice, conformance with legal provisions, the protocol for the specific study involved and the need to protect the rights of trial subjects.

(6) **Data management:** Central data management, which is also a part of the CRP, is responsible for the technical set-up of studies, implementation of study specifications on the basis of study protocols, for carrying out plausibility checks and for engaging in data cleaning, archiving and export.

**Section 4 Rights of ownership and use**

(1) Based on the declaration of consent given by the trial subject, the DZNE is the owner of the collected data and biomaterials and/or authorised to dispose of it as it sees fit.

(2) Users of the Clinical Research databases of the DZNE shall, pursuant to these Regulations for Use, pursuant to the application which may have been approved with restrictions and pursuant to the contracts of use that may need to be concluded, be granted non-exclusive and non-transferrable rights of using the data and/or the biomaterials for a specific purpose if that intended purpose of use corresponds to the goals of the DZNE.

**II. User accounts of the Clinical Research databases of the DZNE**

**Section 5 Access regulations and general rules for the utilisation of Clinical Research databases of the DZNE**

(1) All employees of the DZNE, employees of cooperating partners of the DZNE, staff involved in projects funded by third parties or other external parties may apply for a user account to access the Clinical Research databases of the DZNE.

(2) Any person wishing to use the databases must submit an application for the creation of a user account pursuant to **SOP-GE-08 User Management** using the respective form in the process. In the application the requested roles must be described and justified. The applicant must furthermore submit the **Obligatory Declaration and Consent for Users of the Clinical Databases of the DZNE** including: a declaration of consent with regard 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 trial subjects only for the approved purpose, a declaration of conformance with the Act on the Obligations of Public Servants (**Verpflichtungsgesetz**), a secrecy declaration as well as
declaration of acceptance of the *Regulations for use of Clinical Research databases, data and biomaterials of the DZNE*. The CRP reviews each application and shall, following approval, arrange for the creation of the respective user account. People have, on principle, no right to have their application 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 application.

4. Users use an encrypted modular web application to access the databases within the context of their rights and roles.

5. An application for a user account must be made based on a specific study and for a certain role within the databases. A role or user role defines the tasks (obligations), the characteristics and rights of a user within the Clinical Research databases of the DZNE 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. People may, at any time, make applications 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 does not establish the right to receive financial or other support and assistance from the DZNE.

8. When a user ends the employment contract that is specified in his/her current application, he 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 Clinical Research databases of the DZNE or research projects

#### Section 6a Application and evaluation procedures

1. On principle, all researchers of the DZNE as well as other national and international research institutes and industrial companies may ask for data and biomaterials. The DZNE does, however, primarily support the in-house research work of the DZNE and the cooperating partners of the DZNE providing the data/biomaterials for the purpose of researching neurodegenerative illnesses.

2. In order to obtain and use the data and biomaterials contained in the databases of the Clinical Research for carrying out a research project,
interested parties must submit a formal written application, which must include the following information:

a) Project description
b) Details on preliminary work
c) Details on the biomaterials and data required
d) Submission of 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 applications are made with the help of the SOP-DM-14-A1 form (application for the release of data/biomaterials).

(3) Local PIs shall, after submitting their application, have the right to receive their local data and biomaterials unless this would put into question the overall objective of the study. The application does not require the consent of the Clinical Board or the Steering Committee. Equally, Clinical Trial Leaders receive the data/biomaterials of the study led by them for the purpose of executing the study.

(4) Researchers involved in the respective study submit a written application for consent to the Steering Committee of the study in question.

(5) For any other release of data or biomaterials, a written application must be submitted to the Clinical Board. The Clinical Board shall, for that purpose, be assisted by the PI(s) of the study from which the data/biomaterials are to be taken. The application shall furthermore be presented to the respective Steering Committee for information purposes.

(6) The evaluation of and the decision on the application for use shall be made taking into consideration the following aspects:

a) Scientific quality and relevance of the research project applied for including consideration of relevant preliminary work.

b) The direct commercial use of the data and biomaterials is excluded. The use of the data and biomaterials for indirect commercial use, e.g. for scientific cooperation between industry and scientific institutes is possible upon approval.

c) If several applications for similar research work that are worthy of support are submitted, an endeavour shall be made to ensure the cooperation between the PIs.

d) The interests of researchers who have provided data and/or biomaterials that are considered to be of special value must be considered. If applications are made that concern an above-average amount of data and/or biomaterials of one researcher, he/she must be consulted.
e) Researchers involved in and providing material to the DZNE study 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 also section 8, paragraph 1 below).

f) The data protection officer of the DZNE shall, where appropriate, be consulted in the event of applications by third countries whose data protection regulations are considered unsafe or if there are deviations from the data protection concept.

g) Irrespective of the scientific quality of a research project, the Clinical Board and/or the Steering Committee may, in particular in the event of prior breaches committed by the PI against the Regulations for use of the Clinical Research databases, decide to reject the application for the release of data and/or biomaterials.

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) Submission of an application at the DZNE

b) In the event of section 6a (4) and (5), approval of the application by the Steering Committee or the Clinical Board

c) Consent of the trial subject

d) Valid ethic committee vote approving the intended activities

e) Availability of the data/biomaterials

f) Where appropriate, a Data Use Agreement (DUA) and/or a Material Transfer Agreement (MTA):

DZNE researchers neither need a Material Transfer Agreement nor a Data Use Agreement.

In the case of external researchers (researchers not connected to the DZNE) the transfer and use is set out in a Data Use Agreement between the DZNE and the receiving institute. The transfer and use of biomaterials 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 has a right to be provided with data or biomaterials. Provision within a certain period of time is not guaranteed.
The handing over of biomaterials and data from the Clinical Research databases does not establish the right to receive financial or other support and assistance from the DZNE.

The export of the data takes place after the application has been confirmed by Data Management according to SOP-DM-14 data export and transfer. The data is transferred via a download.

Biomaterials are exclusively dispatched to a person named by and working for the applicant; the passing on to third parties shall only be permitted on application.

Utilisation of the transferred data or the provided biomaterials shall exclusively be granted for the use applied for under the conditions agreed in line with the application that may have been approved with restrictions and shall be bound by the duration of the project and/or the validity of the Data Use Agreement and/or Material Transfer Agreement.

The PI of the research project is responsible and liable for the received biomaterials and the transferred data.

Section 7 Costs and fees

- No general fees are charged for the provision of data and biomaterials for scientific, non-commercial purposes.
- The DZNE may charge the applicant for the actual material costs that have been incurred for the provision and shipment of biomaterials.
- If additional work due to, for example, special sample processing and shipment pursuant to paragraph 2 of section 7 has been undertaken, the DZNE reserves the right to also charge for such work.
- 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.

Section 8 Publications

All written publications concerning data from Clinical Research databases of the DZNE must, at least thirty (30) days prior to submission for publication, be presented to the Clinical Board of the DZNE for evaluation. The Clinical Board of the DZNE will assess whether proper reference is made to the participation of the DZNE in the publication, e.g. through co-authorship or the correct naming of the DZNE as data source. Participation of the DZNE in publications in the form of co-authorship is required by the DZNE in line with the rules of good scientific practice and should correspond to the agreements made in advance. Authorship should be agreed between all scientists involved in a research project when the application for use is...
made. The names of the employees and study centres who have generated and/or processed the data and biomaterials must be duly included.

(2) Unless the DZNE, having received a draft version of the publication from the data user, objects to the publication within thirty (30) days, the feature may be published. Within the set period, the DZNE may object to the publication only for important reasons, which must be specified. An important reason is, in particular, the impending pre-release of patentable results, however, only until a patent application establishing priority has been submitted, at most for another ninety (90) days after the DZNE has objected to the publication. The result of the assessment shall be made known to the applicant in writing.

(3) After the feature has been published, the responsible scientist shall provide the DZNE 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.

IV. Legal consequences of violations

Section 9 Revocation or restriction of user rights/user account

(1) In cases of violations of these Regulations of Use or of provisions set forth in the relevant agreement on data use or the material transfer agreement, the DZNE may, at any time, restrict or revoke the rights to use the databases via the user account and to revoke all rights of use to the data and biomaterials made available.

(2) The same applies in cases where the security of the databases and the data stored therein could be compromised.

(3) The procedure for a restriction or revocation of the authorisation of use is set forth in SOP-GE-08 User Management.

(4) Other claims of the DZNE, 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 databases, which are made available free of charge, and their use appropriately, 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 databases will be available at all times, without interruption, when needed, secure and error-free. Neither shall the DZNE guarantee that the databases function error-free at all times. The DZNE has the right to carry out maintenance work on the databases 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 databases.

Section 11 Other liability

- Data and biomaterials may contain inherent errors or be damaged. Biomaterials may be infectious.
- The DZNE assumes no liability for the correctness of the data and for the suitability of the biomaterials for the requested and approved purposes.
- The DZNE assumes no liability for any loss/damage that may result from working with the data or biomaterials.
- The above liability limitations set forth in sections 10 and 11 do not apply to cases of willful 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 statutory liability of the DZNE and the personal liability of its legal representatives, employees and vicarious agents.

VI. Entry into force

These Regulations for Use shall enter into force by resolution of the Clinical Board and following approval by the Executive Board of the DZNE.

VII. References/supplementary documents

- Rules of Procedure for the Clinical Research of the DZNE
- SOP-DM-14 Data export and transfer
- SOP-GE-08 User Management
- Data Use Agreement (DUA)
- Material Transfer Agreement (MTA)
- Biobank regulations of the DZNE
- Obligatory declaration and consent for users of the clinical databases of the DZNE
VIII. Glossary and Definitions

Biomaterials
Materials that have been collected from human bodies, for diagnostic or scientific purposes. Examples of biomaterials include blood and blood components, other body fluids (such as urine, liquor, saliva), feces, cells, tissue, RNA, DNA and organs.

Clinical Board
A DZNE body; its members are the Director of Clinical Research and the clinical coordinators of the DZNE's sites. Details pertaining to the composition of the Clinical Board are provided in the Rules of Procedure for the Clinical Research of the DZNE.

Clinical research
Clinical research comprises clinical studies, including cross-sectional and longitudinal studies as well as observational and interventional studies of healthy and sick persons and their family members. Such tests are carried out for the purposes of studying fundamental mechanisms in the human organism as well as the progression of diseases and therapies, and reviewing new diagnostic and therapeutic procedures.

Clinical Research Platform (CRP)
The Clinical Research Platform is the central organisational structure for Clinical Research. It administers central services pertaining to databases of Clinical Research of the DZNE, such as consent management, central contact management, rights and role management, central quality assurance and management, data management and project management. The CRP also defines the biobank structures for Clinical Research. In addition, it provides project management and quality management for clinical studies.

Commercial use
Forms of commercial use of data and biomaterials include the sale, the licensing or any other provision of data and biomaterials for profit-oriented purposes and any research activities based on that. Commercial use also includes contract research for companies carrying out economic activities, the screening of substance libraries and the production of products for general sale.

A distinction is made between direct and indirect commercial use:

The direct sale or licensing of data and biomaterials for undefined purposes is considered to be direct
commercial use.

The licensing of research results or another way of providing data and biomaterials for research projects with subsequent profit-oriented intentions is referred to as indirect commercial use.

Use of data and biomaterials as part of scientific cooperation between industry and academic institutions is not considered a commercial use.

The DZNE is not obligated to consent to any commercial use. In each case, the review of a request for data/biomaterials submitted includes assessment of the purpose of the pertinent uses. Direct commercial use is excluded.

Data

All data that is collected and stored in the framework of Clinical Research studies or registers such as medical data, image data, voice recordings or analysis results. They do not include the biomaterials themselves and accompanying data for biomaterials.

Databases for the area of Clinical Research

The databases of Clinical Research have the purpose of supporting the organisation, processing and analysis of the DZNE's Clinical Research data. They are structured in accordance with a modular architecture. Their various modules (clinical module/studies module, biomaterials module, image data module, research module) are linked via central services (data fiduciary office, consent management, central contact management, rights and role management, central quality assurance and management, data management).

Data use

Data use is any use, storage or forwarding of data.

Local Principal Investigator (PI)

The person who has the scientific responsibility for a specific study carried out at a study center/site. In the case of monocentric studies, the local PI is always also the study director/director (clinical trial leader (CTL)).

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
Researchers

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's databases of Clinical Research. 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.

Standard Operating Procedure (SOP)

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.

Steering Committee

The Steering Committee is a study-specific body whose members include the study directors and, wherever necessary, study-specific staff from the standardisation groups. The actual composition is stipulated in writing and depends on the specific study.

Study director/clinical trial leader (CTL)

The person who has the main scientific responsibility for a study. In the case of multi-centric studies, the CTL has the overall responsibility for the multi-centric study.

User

Any person who receives access to the databases of Clinical Research of the DZNE. To be able to use the databases, a user must submit an application, which must be approved by his/her superior or study director.

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).