

CrescNet ACH Advisory Board

Articles of association

Authorship rules for publications of data collected by the CrescNet growth network

1. Preliminary remarks

Scientific work is subject to legal and professional regulations, rules of conduct such as the Declaration of Helsinki and professional standards. The recommendations on good scientific practice adopted by the Deutsche Forschungsgemeinschaft (DFG) are intended to prevent scientific misconduct.

CrescNet is a network in paediatrics for the early detection of disorders of growth and weight development and for the documentation of the course of treatment when a growth disorder has been detected. The network is based at the Department of Paediatrics and Adolescent Medicine at Leipzig University Hospital. The core of the network is a central register maintained at the medical computer centre of the Leipzig University. Partners in the network are paediatric and adolescent medical facilities in primary and specialised care, with growth and weight development being the focus of data collection. Participation in the network is based on the commitment to quality assurance through the conclusion of a co-operation agreement with the Medical Faculty of the Leipzig University.

The authorship of scientific publications that use data from the CrescNet Register in the context of quality assurance in paediatrics is regulated below.

2. Tasks of CrescNet

CrescNet has the task of promoting quality assurance in patient care in the field of growth and weight development disorders. A major contribution to this is the establishment of a feedback system for percentile deviations to partners in primary care.

CrescNet supports scientific work in the field of growth disorders by maintaining various modules that enable the documentation of growth-related clinical parameters, such as phenotypic manifestations of concomitant symptoms, laboratory values, etc., and can be analysed in relation to diagnosis. CrescNet thus supports the development of guidelines.

3. Ownership of the data

As described in the informed consent form for CrescNet, patients or their legal representatives donate data from the treatment process to the CrescNet Register. Once entered into the CrescNet Register, the data belongs to the University of Leipzig and is subject to the legal provisions of the GDPR. The aim of the register is to map real-world treatment and developmental trajectories. Planned analyses will each draw on the entire dataset available for a given research question. It is not possible to subsequently exclude individual treatment facilities from project proposals that have been approved by the Advisory Board.

The exclusion of data from planned analyses is justified only by the withdrawal of a patient's consent

Staff at CrescNet Leipzig University and its cooperation partners (Cooperation Agreement on CrescNet and Medical Faculty of Leipzig University) are granted access to this data within the framework of project agreements.

Published data remains the property of Leipzig University, irrespective of its evaluation and analysis. Data may only be used for the research and testing purposes described and authorised in the project agreement.

4. Access to the data and evaluation projects

In addition to quality assurance, publications and other scientific projects are supported by the database. The participating centres have committed themselves to joint responsibility for the protection of the collected data in the cooperation agreement with the medical faculty of the Leipzig University.

Valid data protection regulations (GDPR) must be complied with. **The informed consent of the legal guardians** (Informed Consent Form CrescNet) must be kept in the patient file. For data protection reasons, the original data will remain at the participating centre; only anonymised data will be used and published for statistical analyses. The analysing institutions secure the respective data status used for the analysis.

A dataset intended for use in scientific research is created at the CrescNet site in Leipzig in an anonymized form and **made available to the requesting researcher under an approved project agreement**

(can be found in the CrescNet application under Documents > Proposal for project agreement).

Evaluations in the context of scientific analyses are carried out in accordance with the explanations in the application for a scientific project (see point 6).

In principle, the participating centres always have access to their collected data within the framework of quality assurance in paediatrics, which themselves regularly contribute to the development of the data pool.

Scientific questions can be dealt with by CrescNet partners after a project plan has been drawn up and presented to the CrescNet advisory board (see point 6). External researchers only have access to the data in co-operation with one or more CrescNet partners, and only with the express approval of the CrescNet Advisory Board. Evaluations intended for publication, which are produced by the registry's support team, must be communicated in the same manner to the advisory board and the participating centres.

5. Publications

The structure of quality assurance in paediatrics means that data is collected on a multi-centre basis. As many people are involved for this reason, the selection and ranking of authors can be difficult. In principle, the authors of a scientific publication should be those, but only those, who have made a significant contribution to the conception and planning or to the analysis and interpretation of the data and to the formulation of the manuscript and who have agreed to publication. Inclusion of documented patients in a study/project does not necessarily lead to co-authorship. In all publications that deal with studies/project questions, all participating clinics should be listed in the addendum, possibly also stating the number of fully documented patients and the responsible physician.

With regard to the order of authors, the first author is usually the person who wrote the manuscript. The study/project leader can claim the position of last author if he/she is not already the first author. If several study/project leaders are involved in a study, they agree on the last authorship according to the extent of their involvement. The other authors are named and ranked by the studies/project leaders involved in the study/project.

The corresponding author is usually the main project leader. Doctoral students are to be considered as co-authors if the results of their dissertation are part of the publication.

Authorship is governed by the rules of good scientific practice, as published in the DFG guidelines (see: <https://zenodo.org/records/14281892>). Priority is given to researchers who have contributed to data collection in the register. Employees of the register's

sponsors may not be listed as co-authors in the register's publications. In exceptional cases, however this is permitted provided they have made a significant scientific contribution to a publication (e.g., by comparing data with the company's own study materials, deep scientific involvement, etc.). Prior to publication, co-authors can withdraw their authorship of a scientific work at any time. However, the data used to support the findings are not affected by this withdrawal (see section 3). All publications based on the data collection of the CrescNet registry must be labelled with a reference to the CrescNet network. The following sentence is proposed:

"We would like to thank all the patients' families who have provided their data to the CrescNet registry, all the participating treatment centres that have carefully recorded this data, and the pharmaceutical companies that have provided financial support for the maintenance of the registry (name of the sponsors)."

If the project results shall be published in a conference paper, the institutions involved must be given the opportunity to review the **abstract four weeks** prior to submission, in order to check the content and confirm co-authorship.

If project results shall be published in an academic publication, all those involved will be given sufficient time to review and discuss the findings so that they can contribute as active co-authors. It is not possible to specify a precise timeframe in this case.

6. Application for a scientific project

Each application is based on a written project outline (CrescNet **project agreement**)

- Title of the project
- Background (why should this evaluation take place, what previous knowledge/data and possibly own preliminary work exists),
- Question formulated as a scientific hypothesis
- Method (statistical design),
- Information about the persons involved
- Information on the time frame,
- Information on the planned publication of the data (congresses, publication, authorship)
- Information on financial support for the project, in particular support from third parties (e.g. industry)

In principle, the outline should be formulated in such a way that it clearly fulfils the requirements for acceptance as a scientific publication. The outline can be submitted to the project coordinator CrescNet (info@crescnet.org) at any time via the project agreement.

Scientific analyses should primarily be formulated and coordinated by active participants in the database. If external persons or institutions or pharmaceutical companies make enquiries, these projects must be led by active users and the CrescNet advisory board must be informed in advance. Adequate funding of the expenditure is necessary.

Process for incoming evaluation requests

Required preparatory work:

1. Submission of the research question, including a project plan to the CrescNet coordination via template for project proposal from CrescNet (CrescNet participant or external researcher together with a CrescNet participant)
2. Feasibility assessment by the CrescNet team (report on the density of available data etc.)
3. Consultation with the project applicant to determine whether the planned analysis is feasible

4. Possible adjustment of the research question

Involvement of the CrescNet ACH Advisory Board

1. Project proposal template and report on data density of available data will be send via mail to all AB members.
2. AB members submit their **approval or rejection** to the project coordination team **within 14 days**.
If the required minimum response rate (quorum) is not reached within this timeframe, the voting period will be extended by an additional 14 days to allow for outstanding feedback.
3. A project may be carried out if the advisory board has a quorum in terms of responses (at least 50%) and a **two-thirds majority has voted in favour** of its implementation.
4. The project results must be reported to the advisory board prior to publication.

7. Composition of the CrescNet Advisory Board

The members of the CrescNet Advisory Board are scientifically recognised experts from the field of paediatrics.

The committee is made up of the following members.

1. Leipzig University CrescNet:
 - Scientific director
 - CrescNet project coordination
 - CrescNet technical management database
2. Cooperating specialist centres
 - International representatives from sub-project Achondroplasia and other skeletal dysplasias

Interested partners should have the opportunity to participate in the advisory board. Each institution should be represented by one person. Interested parties shall express their interest in participating in project coordination of CrescNet. A decision on participation (addition, replacement) shall be made by the existing advisory board team. A total number of 10 members should not be exceeded.

8. Tasks of the CrescNet advisory board

To promote trusting cooperation between all participants and minimise bureaucracy.

- Pre-selection on the basis of the project outlines
- Coordination of the presentation and discussion
- Awarding the project
- Monitoring the implementation; if there is a lack of activity, the project award can be withdrawn
- Contacts and agreements on coordination before submitting abstracts for congresses (national or international). In the interests of all those involved, critical consideration must be given to the possible negative consequences of the publication for the group as a whole (e.g. abuse in the competition for patients).
- Information on the current status of the register and data density at annual reports to the participating centres

Literature

- (1) Principles for safeguarding good scientific practice (DFG recommendations)

(2) Guidelines for authorship in international journals (<http://icmje.org>)

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by: CrescNet Advisory Board

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by: Ruth Gausche

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by: CrescNet Ach Advisory Board

Annexes

Annex 1 ICF CrescNet

Annex 2 Proposal for project agreement

Annex 3 Guide to the project agreement

Annex 4 Technical and organizational measures data protection of the register



Information on data donation to the CrescNet registry

Dear parents, dear patients

Thank you for taking the time to read this information.

Disturbances in growth and weight development in childhood can be non-specific signs of a disease. In order to be able to better understand these correlations, it is essential to look at the disease process and characteristics in the child's growth and weight development together. We would like to scientifically process data on the growth of children and adolescents in health and disease and develop reference values for a better assessment. For this reason, we would like to ask paediatric patients and, in this case, you as parents and guardians, whether you can provide us with the anthropometric measurements taken in the course of your child's paediatric care. The measurements are stored in a register (CrescNet) and can be linked to associated medical data in the event of a disorder occurring. The CrescNet is operated by the Medical Faculty of the University of Leipzig.

Your consent to the use of the donated anthropometric measurements and associated data of your child / the minor in your care is voluntary. Should you or your child / the minor in your care not wish to participate or later wish to revoke the consent given, neither you nor your child / the minor in your care will suffer any disadvantages.

In the following, we would like to inform you about the objectives as well as the procedures and measures for the protection of personal data of your child / the minor in your care, so that you can form your own opinion and decide on your consent on this basis.

1. What are the aims of CrescNet?

CrescNet stands for quality assurance of anthropometry in general and specialised paediatrics and serves to promote medical research. To this end, anthropometric data are to be stored for the long term and support medical research. The aim is to improve the prevention, diagnosis and treatment of diseases. This primarily involves the comparative analysis of larger patient groups or population cohorts in order to identify general biomedical correlations. If there are any abnormalities in the long-term data for your child, your treating doctor (data collecting agency) will be informed.

2. What data are collected?

The data collected are repeatedly measured anthropometric data that play a role in paediatrics for the assessment of physical development (height, body weight, head circumference, sitting height, arm span, gestational age at birth, parent sizes).

If your child has a chronic disease, the ICD10 code of the diagnosis will be transmitted. If the disease is associated with growth and weight development disorders, disease-relevant diagnostic data (laboratory findings that confirm a diagnosis) and growth-influencing medications are also recorded.

In the case of particularly impairing forms of growth disorders (e.g. achondroplasia), information provided by you or your child in the form of questionnaires on the respective current quality of life is linked to the above-mentioned clinical information in the CrescNet register.

3. How are the data used?

The data donated by your child will be used to create general as well as disease-related reference percentiles for the estimation of body measures mentioned above (growth and weight development curves, etc.). They are also used to assess changes within large groups and fixed observation periods (secular trend).

Growth and weight development in chronic and rare diseases represent a special area of research. However, it is not possible to specify the exact research question at present. The data are used in medical research to improve prevention and early detection as well as treatment of diseases.

Various paediatric institutions work with the CrescNet register. In order to ensure that entries from different treatment facilities (e.g. paediatrician and specialist consultation) can be merged for the same child, you grant permission with the declaration of consent that the data material can be checked for matches and a merger can take place. The institution currently recording the data thus has the right to view the developmental history of another paediatric institution that has already been entered and can make additions.

4. What are the risks associated with data donation?

As this is a donation of data collected as part of paediatric status examinations, there is no additional risk to your child's health to identify.

After a formal anonymisation carried out by the registry, a re-identification risk can unfortunately not be completely ruled out, but is exclusively achievable only with a very high technical and time effort.



5. What are the personal benefits for your child / the minor in your care?

You cannot expect any immediate personal benefit or advantage to the health of your child / the minor in your care from the donation of the data. With the intended long-term logging of anthropometric data, disorders of growth and weight development are detected at the earliest possible stage. Your paediatrician in charge of the data transmission can therefore look for causes for the disturbance of growth and weight development as early as possible and take appropriate therapeutic measures.

6. What are the benefits for the general public?

Medical-scientific research projects aim to better understand the development and diagnosis of diseases and to improve treatment and prevention strategies and options on this basis. Particularly in the case of weight development, the scientifically sound statements on changes over time obtained with the CrescNet register represent a special gain for argumentations in public health care.

7. Who has access to the data of your child / the minor in your care and how are they protected?

a. Coding of the data

All data that directly identifies your child / (the minor in your care) is replaced by a code (so-called pseudonymised). For further scientific processing, the data sets are directly recoded and stored. Only in this (double-encoded) form will the data be released for medical research purposes. Data that directly identify your child remain with the sending institution. Therefore, they cannot be identified without the cooperation of this institution. **Identifiable data of your child/the minor in your care will not be shared with researchers or other unauthorised third parties.**

b. Transfer of data

The encrypted anthropometric data and the related medical data are hosted by CrescNet, but may also be transferred for certain medical research purposes, according to predefined rules, to other entities such as universities, research institutes and companies/industries conducting medical research within the EU. In doing so, the data of your child/the minor in your care may also be linked to medical data from other databases if the legal requirements are met. **Data transferred to researchers may only be used for the intended research project and may not be passed on by the recipient for other purposes.**

c. Assessment by an institutional review board

The main prerequisite for the use of anthropometric and medical data from CrescNet in a specific medical research project is usually that the research project has been previously evaluated and approved by an independent ethics committee.

d. Publications

Results of medical research obtained with your data will only be published anonymously, i.e. in a form that does not allow any conclusions to be drawn about the identity of your child / the minor in your care.

8. Do you or your child / the minor in your care or the medical faculty of the University of Leipzig derive any financial benefit from the use of the data of your child / the minor in your care?

When the data is handed over to the Medical Faculty of the University of Leipzig, it becomes the property of the Medical Faculty of the University of Leipzig. You also authorise the Medical Faculty of the University of Leipzig to use the (associated) data of your child / the minor in your care.

You or your child / the minor in your care will not receive any remuneration for donating the data. If any commercial benefit is derived from medical research through the use of the data, you or your child / the minor in your care will not be a beneficiary.

CrescNet will use the data of your child / the minor in your care for medical research purposes only. The data will not be sold.

9. Will you or your child / the minor in your care be contacted again?

a. Especially for participants in childhood and adolescence, it is useful to collect further follow-up data. Therefore, it is possible that you and your child / the minor in your care may be contacted or approached again later. In addition, re-contact may be used, for example, to obtain your consent and the consent of your child / the minor in your care to link his/her data with medical data from other databases.

Please tick in the consent form whether you wish to be contacted again in such cases or not.

b. In rare cases, a researcher may conclude that a research finding may be of significant importance to the health of your child / the minor in your care (see point 5 above). In such cases, the results will be communicated to your attending physician (data submitting physician). Contact with you will be made exclusively via your attending physician in writing or by telephone.



c. Upon reaching the age of majority and especially in cases where anthropometric development is still relevant after the age of 18, the treating paediatrician/adolescent doctor will contact your child / the minor in your care to give him/her the opportunity to decide for him/herself on the future use of his/her data. If it is not possible to establish contact within one year after your child / the minor in your care has reached the age of majority, data collected so far will be kept and used exclusively in anonymised form in the database. Anonymization means that information that could identify the person from whom the data was donated is deleted (see point 7.a/7.b above).

10. What does your right of withdrawal include?

You may withdraw your consent to the use of the anthropometric and medical data of your child / the minor in your care at any time without giving any reason and without any disadvantage to you or your child / the minor in your care. Similarly, your child / the minor in your care may withdraw his/her consent at any time. The lawfulness of the use of the data collected until the revocation remains unaffected.

In the event of revocation, the anthropometric and medical data will be deleted. Data from analyses already carried out cannot be removed (especially if they have already been published).

Instead of deleting the data, you and your child / the minor can also agree that your data may be used in anonymised form for medical research purposes. Anonymization means that the identification code is deleted (see points 7.a/7.b and 9.c above). Once anonymization has been carried out, targeted destruction or modification of such data is no longer possible.

Please contact your supervising paediatrician or adolescent doctor if you wish to have your data revoked. You can also contact CrescNet directly: **CrescNet Growth Network, Project Coordination, Liebigstraße 22a, 04103 Leipzig, Phone: 0341 9726148, Mail: <mailto:info@crescnet.org>**

11. Anonymization of data after the age of 18

All data of subjects who have reached their adult age and from whom no decision on further use has been obtained by the attending physicians within one year after reaching their adult age will be anonymised (without the possibility of attribution to a person) kept in the database and used for the scientific purposes described under point 3.

12. What other data protection rights do you and your child / the minor in your care have?

The legal basis for the processing of your child's / the minor's data is your consent in accordance with Article 6(1)(a) and Article 9(2)(a) of the General Data Protection Regulation. The person responsible within the meaning of the General Data Protection Regulation is **your attending paediatrician/adolescent doctor and the Medical Faculty of the University of Leipzig**, Liebigstraße 27, 04103 Leipzig.

You and your child / the minor in your care can request information from CrescNet at the Faculty of Medicine of the University of Leipzig about the data stored about you within the framework of the legal requirements. In addition, you and your child / the minor in your care may request the correction of incorrect data, the transfer of the data provided by you and your child / the minor in your care as well as the deletion of the data or the restriction of its processing. To exercise these rights, you and your child / the minor in your care may contact **your attending paediatrician/adolescent doctor**.

If you have concerns about data processing and data protection compliance, you and your child / the minor in your care can also contact the (institutional) data protection officer:

Data Protection Officer of the Medical Faculty of the University of Leipzig, dsbmf@medizin.uni-leipzig.de

You and your child / the minor in your care also have a right of appeal to a data protection supervisory authority. You can find a list of supervisory authorities in Germany at:

https://www.bfdi.bund.de/DE/Infothek/Anschriften_Links/anschriften_links-node.html

13. Where can you and your child / the minor in your care get more information?

If anything is unclear to you, please ask your treating paediatrician or adolescent doctor before giving your consent. If you have further questions, you can also contact the project coordination of CrescNet (info@crescnet.org) later.



Declaration of consent

Patient/subject (surname, first name)

Date of birth

I have read the information document and have had the opportunity to ask questions. I am aware that the participation of my child / the minor is voluntary and that I and my child / the minor in my care may withdraw consent at any time without giving reasons and without any resulting disadvantages.

I agree that the anthropometric and related medical data of my child / the minor in my care may be disclosed to CrescNet as described in the information notice and used for the medical research purposes stated in the information notice. In particular, I agree that, as described in the information document,

- **my attending paediatrician/adolescent doctor** collects personal anthropometric data of my child/the minor in my care and forwards it to CrescNet, supplements it with information about his/her health if necessary and stores the data in pseudonymised form (i.e. encrypted).
- The data will be stored in pseudonymised form by **CrescNet (Medical Faculty of the University of Leipzig)**. I transfer ownership of the data to the Medical Faculty of the University of Leipzig on behalf of my child / the minor in my care.
- The anthropometric and medical data may be shared in anonymised form to universities, research institutes and companies/industry conducting medical research for medical research purposes.

I agree that my child / the minor in my care and I may be contacted again at a later date

- for the purpose of obtaining further information ☐ yes ☐ no
- for the purpose of obtaining my consent to link the data of my child / the minor in my care with medical data from other databases ☐ yes ☐ no

In addition, my child / the minor in my care will be contacted by the attending physician to give him/her the opportunity to make his/her own decision about the future use of his/her anthropometric and related medical data. If contact cannot be made within one year of reaching adult age, previously collected data may be used anonymously for research purposes. **I have received a copy of the parent/guardian information and consent form. The original remains with the child and adolescent medical care facility.**

Name of the legal guardian/s in block capitals

Place, Date

Signature(s)

If only one parent or guardian can sign, please check and tick the following confirmation:

- ☐ I confirm that I am not aware of any objections on the part of the other guardian and that this consent is given in agreement with the other guardian.

I have conducted the informed consent interview and obtained the consent of the parents/guardians.

Place, Date

Name of the person providing the information in block capitals

Signature



CrescNet Project Proposal

New proposal: ☐yes ☐no

Request for project prolongation: ☐yes ☐no

Request for project extension: ☐yes ☐no

Agreement concerns only centre-owned datasets: ☐yes ☐no

(if yes, only fill out section 1, 2, 4 and 7, no acknowledgement by Advisory Board required)

Project number, to be assigned by CrescNet: _____

Date of receipt: _____

1.	Responsible applicant	Further contact person
Name, first name:		
Institute, Organization:		
Address:		
Tel.-no.:		
E-mail:		

2. Project title

Abbreviation: _____

Full title: _____

3. Relation to other projects

☐no ☐unknown

☐yes, no./short titles of other projects: _____

4. Scientific question

(Research hypothesis, specific objectives, max.1/2 page)

→

5. Period of data use

(for larger projects, work plan for data use)

→

6. Planned applications for third-party funding

Is a third-party funding application planned/foreseen on the basis of this project?

☐yes ☐no ☐not foreseeable

7. Concretisation of the data request

(Inclusion and exclusion criteria, required visit/master data, etc.)

→

8. Other comments

→

9. Signatures

Declaration of Commitment to Maintaining Confidentiality when Processing Personal Data

You are obliged to maintain the confidentiality of personal data pursuant to Art. 5 (1) f, Art. 32 (4) of the General Data Protection Regulation (DS-GVO) to which you gain access or knowledge in the course of your work. You are prohibited from processing personal data without authorisation. This obligation continues even after the termination of your activities under this project agreement.

Violations of confidentiality may be punished with imprisonment or a fine in accordance with Art. 83 (4) DS-GVO, Sections 42, 43 BDSG and other criminal provisions. A breach of confidentiality may also constitute a breach of confidentiality obligations under employment or service law.

By signing this form, you confirm that you have been informed about the obligation of confidentiality and the resulting conduct.

☐ Applicant commits to maintain data secrecy

☐ Applicant agrees to the Project Agreement Guide

Date: _____

Responsible applicant

Further contact person for the data set

CrescNet
Prof. Dr. Roland Pfäffle

10. Acknowledgement by the Advisory Board of the disease-related registry

☐ Data set is part of a disease-related cohort

Agreed: ☐ yes
☐ no

Reason for rejection:

Signature



Guide to the preparation of CrescNet project agreements

Version 2, 2025-07-08

1. Ownership

- 1.1. All data are property of the Leipzig University and are subject to the legal provisions of GDPR. Staff of the University Medicine Leipzig and their cooperation partners (cooperation agreement with CrescNet) is granted access to this data within the framework of project agreements.
- 1.2. Published data remain the property of the University of Leipzig regardless of their evaluation and analysis. Data may only be used for the research and test purposes described and activated in the project agreement.

2. Responsibilities/contact persons

The contact and correspondence address for all questions relating to project agreements is the office of the growth network CrescNet.

Growth Network CrescNet
Medical Faculty Leipzig University
Liebigstr. 20a
04103 Leipzig
Tel.: 0341 – 97 26 148
Fax: 0341 – 97 28 123

3. Application for project agreement

- 3.1. A project agreement must be applied for each research project. One person is entitled to submit several project applications or to process several project agreements.
- 3.2. If the application is submitted by external persons or institutions, the applicant and the member of the growth network CrescNet / University Medicine must be named jointly in the application.
- 3.3. Doctoral and Master's students of the University of Leipzig apply for the project agreement through their responsible supervisor of the University Medical Centre Leipzig. The name of the supervisor has to be stated together with the doctoral student/Master's student in the application. External doctoral and master's students apply for the project agreement through their supervisor in compliance with section 3.2.
- 3.4. The completed project application must be submitted to the growth network CrescNet. The form will be handed out by the growth network CrescNet on request or can be downloaded by the CrescNet cooperation partner from <https://crescnet.medizin.uni-leipzig.de>. Project agreements which have not been signed by the applicant will not be processed. By signing the form, the applicant confirms that he/she accepts responsibility for the rights and obligations set out in the CrescNet Regulation on Project Agreements.

4. Modification of project agreements

It is possible to merge project agreements for scientific reasons. For this purpose, a technical justification and information on the content must be sent to the growth network CrescNet. The joint handling of the data must be agreed in principle with the CrescNet data management.

5. Data management and data delivery

- 5.1. The data management of the growth network CrescNet coordinates the delivery of the data.
- 5.2. The delivery of the data is carried out according to the project agreement. The delivered data set is archived by the data management.
- 5.3. Before receiving the data, the applicant must sign a declaration of commitment to maintain confidentiality when processing personal data. The obligation is included in the project agreement.

6. Duration and reporting obligation

- 6.1. The Project Agreement shall have a duration of one year after its activation. During this period, the scientific question will not be released for any further project agreements. Irrespective of this, the same data may be released for several Project Agreements. After the expiry of this period, the applicant must apply in writing to the growth network CrescNet for an extension of the Project Agreement. This can also be done in the form of an e-mail.
- 6.2. The office of the CrescNet Growth Network is entitled to check the status of the Project Agreements at regular intervals. For this purpose, an informal written information on the processing status shall be submitted by the applicant. If the form is not submitted after the office has requested it, the Project Agreement may be terminated.
- 6.3. Cooperation agreements with commercial applicants may require additional provisions in accordance with scientific and academic requirements, including, for example, an obligation to disclose and share (including a transfer of the relevant rights of use) information and results obtained or derived directly or indirectly from the data.

7. Costs/fees

- 7.1. Applicants are obliged to pay for any costs arising from the project agreement. A detailed budget must be attached to the Project Agreement if necessary.
- 7.2. In general, the requested data and samples are free of charge according to the Project Agreement. However, the CrescNet Growth Network reserves the right to charge a fee depending on the scope, context and dimensions of the requested data and samples. Shipping costs are to be paid by the applicant.
- 7.3. Data for commercial/industrial partners will be provided on the basis of individual agreements which will regulate the fees on a case by case basis.

8. Data protection

The legal provisions of the GDPR apply within the framework of the project agreement. The applicant is obliged to maintain data secrecy. With the release of the data, the applicant signs the "Declaration of Commitment to Maintain Confidentiality when Processing Personal Data" according to item 5.3.

9. Good scientific practice / data return / results

- 9.1. The applicant is obliged to carry out his work with data from the growth network CrescNet in accordance with the "Statutes for the Safeguarding of Good Scientific Practice at the University of Leipzig".
- 9.2. The applicant is obliged to refer to the growth network CrescNet as the author of the data and samples in all communication and information measures. This can be done by a written reference in the form of an affiliation communicated by the CrescNet growth network or by affixing the CrescNet logo in a sufficiently visible manner.
- 9.3. The applicant is obliged to make publications resulting from the data available to the CrescNet growth network in the form of a PDF file without being asked to do so.
- 9.4. The applicant is obliged to report industrial property rights, in particular patents, to the office of the CrescNet growth network.
- 9.5. For disease-related cohorts in the CrescNet dataset, separate policies regarding publications and data origination may apply. If relevant to the project agreement, these guidelines must be taken into account. Applicants will be informed of the existence of such policies by the CrescNet Growth Network Data Management.



Redundant data centre network (data protection by design)

Physical structure

The UKL operates a redundant computer centre network at two locations. The sites are all built according to the same guidelines.

- a) **Access control:** The sites are screened using a multi-zone concept. The authorised persons are documented for each zone. The zone transitions are legitimised by knowledge and possession, and all zones are video-monitored.
- b) **Alarm:** The inner zones are alarm-monitored. In addition to video surveillance, an alarm is triggered in the event of unauthorised access attempts and to secure unattended operation.
- c) **Protection against elementary events:** The sites are protected against penetration, water and fire; a fire protection system is installed.
- d) **Energetics:** Both sites are energetically redundant secured until the sites are fully developed.
- e) **Networking:** The connection to the campus network is redundant, WLAN via dark fibre to DFN

Logical structure

The operating concept for the computer centre network is consistently geared towards virtualisation and centralisation and is fail-safe across the locations.

- a) Virtualisation of computer, storage and network close to 100%
- b) Storage and archive keep the correspondingly classified data synchronised with dedicated strategies at both locations
- c) Operating and failure concepts are documented
- d) Access to the data network of the UKL (including MF) is managed centrally; further access to subject-specific information systems is partly linked to the central user management and partly dedicated.
- e) Virus signatures and (critical) operating system patches are distributed centrally and automatically.
- f) Internal and external networks are separated by means of firewalls and DMZ.
- g) A connection between the networks is only possible via secure connections.

Measures for data security (data protection by default)

Pseudonymisation/anonymisation

As a rule, personal data is pseudonymised in the course of the supply processes. In the case of a direct connection to the CrescNet Web Application, it is up to the User to decide whether patient data is pseudonymised or required as clear data. If there is a need or necessity to use data outside of the supply, the regulated extraction is carried out by the CrescNet growth network in pseudonymised form.

Encryption

Encryption is used in these cases:

- a) Data connection beyond the Intranet borders
- b) For mobile devices which, due to the deployment scenario, must carry sensitive data.

Confidentiality

Access to the data network of the UKL is managed centrally. Authorisations are derived from the employment relationships of UKL and MF employees.

Access to the specialist departmental systems is defined by authorisation concepts.

Integrity

The integrity of the data is ensured by various measures.

- a) After completion of the treatment documentation and during the generation of unchangeable data (in particular, for example, in the case of radiation-based diagnostics), audit-proof archiving takes place.
- b) For application systems classified as critical by the UKL, a backup is performed during operation. Depending on the technical suitability of the application system, strategies are used to protect against logical errors (e.g. trailing shadow systems)
- c) Various application systems have plausibility checks.

Availability

The set-up and operation concepts presented in the chapter on redundant data centre networks enable maximum availability with economic justifiability.

Capacity

The concept of virtualisation enables the resilience of computer resources to be ensured, e.g. by load distribution methods.

The load capacity of the data network is determined by the respective physical limits, taking into account the economic viability.

Recovery

Data and systems are restored from the archive or backup according to the agreed service level.

Monitoring

The application systems classified as critical by the UKL are subject to continuous review (monitoring). This means that in the event of warnings or errors, measures for prevention and/or rectification are also associated with this.

Further regular reviews:

- Within the framework of the documented procedural descriptions
- Within the framework of the ISMS