

Guide to legal aspects of research data management

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The following information does not constitute legal advice or legally binding information. It merely provides an overview of legal aspects referring to German and European law and issues to be considered when dealing with research data.

If you need further advice, please reach out to the responsible contact points.

The following contact points are available at the Technical University of Munich:

- TUM Research Service Centre:
<https://www.ub.tum.de/en/research-data>, researchdata@ub.tum.de
- TUM ForTe - Office for Research and Innovation: Patents and Licenses
<https://www.forte.tum.de/en/forte/patents-and-licenses/>
- Data Protection Officer and authorized representatives for data protection
<https://www.datenschutz.tum.de/datenschutz/der-datenschutzbeauftragte/>
- The Ethics committee at the Technical University of Munich:
<https://www.ek-med-muenchen.de/>
- TUM Legal Office (ZA 5)
https://portal.mytum.de/tum/verwaltung/index_html
- TUM Compliance Office
<https://www.tum.de/ueber-die-tum/ziele-und-werte/compliance>
- Gender Equality Office, Staff Unit Diversity & Equal Opportunities
<https://www.chancengleichheit.tum.de/en/diversity/home/>

Further TUM-internal information:

- TUM Citation Guide
<https://mediatum.ub.tum.de/1236069>
- Guidance for the publication of scientific data and software programs
<https://mediatum.ub.tum.de/1711141>
- Information sheet on the Employee Inventions Act
https://www.forte.tum.de/fileadmin/w00bgt/www/Patent-_und_Lizenzbuero/Merkblatt_Arbeitnehmer_Erfindung_8.12.2020.pdf

1. Copyright

1.1. Copyright protection

Are research data protected by copyright?

Research data are only protected by copyright if they qualify as creative work(s), i.e., individual intellectual creations (§ 2 Abs. 2 UrhG). The following criteria define creative work(s):¹

- identifiable original form
- individual creation by a human being
- intellectual content
- level of creation

Whether research data meet the criteria to be treated as works must be examined on a case-by-case basis. Measurement data alone, for example, do not meet the criterion of the level of creation due to the lack of the necessary degree of individuality and originality. If, however, the data are intellectually processed such that the criterion of creation is met, they may be protected by copyright.

- How long does copyright last?

Copyright applies until 70 years after the author's death (§ 64 UrhG) or 70 years after the death of the longest surviving co-author (§ 65 UrhG). After the death of the author, copyright may be transferred to their heirs (§ 28 UrhG). After the expiry of the period of protection, the work is in the public domain and may be used by anyone without restriction.

Internationally, different periods of protection may apply. In order to guarantee a minimum standard for copyright protection, almost 180 countries have ratified the "Revised Berne Convention", which provides a period of protection of at least 50 years after the author's death (Art. 7 Abs. 1 RBÜ). Within the EU, copyright laws have been harmonized to a much greater extent (cf. 2001/29/EG).

- Who is the copyright owner?

The copyright owner is the creator of a work. Only human beings, i.e., natural persons, can be authors. Several co-authors may also be the copyright owner, provided that they have a creative share in the work and the respective shares of work by the individual co-authors cannot be exploited separately (§ 8 Abs. 1 UrhG). A merely supporting role in the creation of the work, e.g., supervision of a dissertation, is not sufficient for a co-authorship.

In general, the copyright is not transferable. However, the author may grant third parties the right to use his research data.

¹ Schack, H.: Urheberrecht und Urhebervertragsrecht. Mohr Siebeck, Tübingen 2009, p. 103 ff.

1.2. Neighboring rights

- What are neighboring rights?

Neighboring rights are property rights that are closely related to copyright. They are also therefore referred to as related rights (Part 3 and Part 5, subclause 2 UrhG).

Neighboring rights relate to the following aspects:

- Creation of scientific editions (§ 70 UrhG; § 124 UrhG)
- Publication of bequeathed works (§ 71 UrhG)
- Production of photo images (§ 72 UrhG; § 124 UrhG)
- Artistic performance (§§ 73 – 83 UrhG; § 125 UrhG)
- Staging events (§ 81 UrhG)
- Creation of sound recordings (§ 85 UrhG; § 126 UrhG)
- Design of radio programs (§ 87 UrhG; § 127 UrhG)
- Creation of databases (§§ 87a – e UrhG; § 127a UrhG)
- Press releases (§§ 87 f – k UrhG; § 127b UrhG)
- Creation of cinematographic works (§ 94 UrhG; § 128 UrhG)
- Creation of image sequences and sound-image sequences (§ 95 UrhG)

These services do not implicitly include only individual intellectual creations but also involve certain types of human, technical or activities involving financial outlay. Neighboring rights principally mean that only the person who provides such service has the right to publish and exploit.

Most neighboring rights are transferable (§ 71 Abs. 1; § 79 Abs. 1; § 85 Abs. 1; § 87 Abs. 1; § 87g Abs. 3; § 94 Abs.2 UrhG). Neighboring rights referring to a database are not explicitly transferable, but they are subject to certain restrictions (§ 87c UrhG) and may be partially extended to additional persons upon consultation with the creator of a database (§ 87e UrhG).

The duration of neighboring rights very much depends on the type of the protected effort or investment (§ 71 Abs. 3; § 76; § 82 Abs. 2; § 85 Abs. 3; § 87 Abs. 3; § 87d; §87j; § 94 Abs. 3 UrhG).

- What protection do databases have?

If the creation of a database requires a costly investment, then the database is subject to neighboring rights protection (§ 87a Abs. 1 UrhG). In case of such investments, a person has the right to publish, distribute and publicly display the database (§§ 87 a, b UrhG). These rights expire 15 years after creation or publication of the database (§ 87 d UrhG).

Where neighboring rights are concerned, the only relevant factor is that the production of the database involves considerable effort and thus requires a substantial investment. In this respect, it is irrelevant whether the database constitutes an individual intellectual creation or not.

Independently of neighboring rights, a database may be protected by copyright, but only if its creation constitutes an individual intellectual creation in the sense of a "database creation" (§ 4

Abs. 1 UrhG). In this case, the creator of the database has the usual copyrights, i.e., author's individual rights (§§ 12-14 UrhG), exploitation rights (§§ 15-23 UrhG), such as the reproduction right (§ 16 UrhG), distribution right (§ 17 UrhG) and presentation right (§ 19 Abs. 4 UrhG), as well as other rights (§§ 25 - 27 UrhG).

1.3. Rights of use

- How can rights to use research data be transferred?

If research data are protected by copyright or neighboring rights, their exploitation by third parties is allowed only upon consent of the copyright owner. In most cases a contract is concluded to confirm the fact of transfer of rights of use. Contracts may be concluded orally or in writing. The written form is preferable in order to document the type and scope of the transferred rights of use in a concrete and verifiable manner. The right of use can be granted as a simple or exclusive right as well as limited in terms of space, time or content (§ 31 UrhG).

License agreements allow copyright owners to determine to what extent they permit third parties to reuse their works. License agreements are normally concluded by means of declarations of intent. If research data are licensed under a free license and the research data are used according to license terms, a contract is automatically concluded between a licensor and a licensee. A direct contact between a licensor and a licensee is not needed. It is recommended that you opt for standardized license texts as they are widely used and are suitable for machine reading. Furthermore, they are associated with greater legal certainty and less work in licensing.

In the context of an employment, the transfer of rights of use is agreed in the employment contract or is implicit in the employee's obligations to the employer (§ 43 UrhG), in particular if the research data is a computer program (§ 69b UrhG).

- Which free licenses can be granted to research data?

When granting a free license, it must be ensured that the rights of third parties, i.e., regarding data protection, personal rights or business secrets, are not infringed. The choice of a license depends on the content and the purpose of research data. In order to enable widespread reuse and dissemination of research data, the chosen licenses should be as open as possible and as closed as necessary.

Creative Commons licenses² are often the preferred choice content for such as datasets, texts, graphics, audio and video material. They offer standardized, internationally recognized licensing agreements that specify whether:

- the creator must be named
- commercial use of the work is permitted
- adaptations or derivations of the work are permitted
- adaptations must be shared under the same terms.

² <https://creativecommons.org/licenses/>

If research data is software, a proper software license should be chosen as these licenses specify conditions of use, further development and compatibility of the software. Permissive software licenses, such as BSD³ and MIT⁴, offer the broadest possible distribution and further development of software. Copyleft licenses like GPL⁵ can be used if adaptations and further development of software programs should have the same license as the original software. It guarantees that originally free software will not become proprietary software after being modified. Further assistance in choosing a license can be found e.g., here <https://choosealicense.com>

- What should be considered when combining research data under different licenses?

If research data is to be combined, the original licenses must be taken into account. Research data under different licenses may be combined into a new work only if distribution of adapted work is permitted and the licenses are mutually compatible. For example, if research data licensed under [CC-BY-ND 4.0](#) are mixed with other data, an adapted work may not be distributed. The combination of research data under different copyleft licenses can also cause difficulties. Such licenses state that modifications of the work may be distributed only under the license of the original work. A combination of research datasets with [CC-BY-SA 4.0](#) and [CC-BY-NC-SA 4.0](#) is excluded as in the first case the commercial use is permitted and in the second case the commercial use is prohibited. However, in both cases further distribution of an adapted work must be done under the conditions of the original work.

Works under open licenses can be better combined with other works and facilitate their further use and distribution. If research data with different compatible licenses are combined into a new work, a uniform license can be selected for the new work. This license must be at least as restrictive as the most restrictive license pertaining to the original research data. If it is possible to distinguish parts of the original sources in an adapted work easily, different licenses may be granted to these parts. For example, different parts of a software program can have different licenses.

The version of a license can be decisive for compatibility. For example, Creative Commons licenses cover database creator rights only after version 4.0. As of this version, works under the [CC-BY-SA 4.0](#) license can be modified and redistributed under the [GPLv3](#) license (one-way compatibility).⁶

- How should licenses be indicated?

Licenses should contain the title, the version of the license and a link to the license text. Depending on the license in question, further information may be required. For example, all Creative Commons licenses require attribution to the creator. Author and source citation is in accordance with good scientific practice even if the license text does not require it explicitly. Depending on the type of work and the context, providing additional information such as the logo

³ <https://www.freebsd.org/copyright/freebsd-license/>

⁴ <https://opensource.org/licenses/mit-license.php>

⁵ <https://www.gnu.org/licenses/licenses.html>

⁶ <https://creativecommons.org/2015/10/08/cc-by-sa-4-0-now-one-way-compatible-with-gplv3/>

and the machine-readable identifier (cf. SPDX IDs⁷) of the license or the license text itself can also be helpful for further use.

If works are mixed and do not have a uniform license, a reference to the license must be indicated directly in the work, e.g., in the caption of the copyrighted image. If a software contains different licenses, it is recommended to create a folder in which all used are stored as simple text files. In addition, the corresponding license ID must be specified in the header of the individual code files or in a directory file.⁸

If copyright protected research data are published without a license, all rights belong to the rights holder. The use of research data is permitted within the framework of legal provisions. These include, e.g., the right of citation (§ 51 UrhG) and under certain circumstances the use of research data for scientific research (§ 60c UrhG).

- How can research data be indicated as being in the public domain?

If the owner or the holder of a neighboring right wishes to release research data into the public domain and thereby waive any conditions of use, the Creative Commons license [CC0 1.0](#) can be used for this purpose.

If, on the other hand, there are no copyrights or neighboring rights, e.g., due to falling short of the threshold of creativity or 70 years have elapsed since author's death, works are in the public domain and may be used without any restrictions. In order to indicate it in a clear way and help avoid uncertainties regarding the possible reuse, works can be identified with [Public Domain Mark 1.0](#). This designation is not a license and is merely declarative.

If a license was granted to research data although they are in the public domain, unlawful copyright infringement (copyfraud) has occurred. Re-use has thus been illegally restricted and a defense claim may be made on this basis (§ 97 UrhG).

2. Data protection

2.1. Definitions

- What are personal data?

According to Art. 4 Abs. 1 of the General Data Protection Regulation (GDPR) personal data is "any information relating to an identified or identifiable natural person". This is data that directly identifies a person, such as a first and a last name, or data that makes it possible to identify a person with the help of additional information. Additional information can include, for example,

⁷ <https://spdx.dev/ids/>

⁸ <https://reuse.software/spec/>

the assignment of an identification number to a name or particular physical, social or cultural characteristics.

- What are sensitive personal data?

Sensitive personal data denotes information “revealing racial or ethnic origin, political opinions, religious or ideological beliefs, or trade union membership” as well as “genetic data, biometric data for the purpose of uniquely identifying a natural person, data concerning health or data concerning a natural person’s sex life or sexual orientation” (Art. 9 Abs. 1 GDPR). These “special categories” of personal data are subject to stricter rules, as they deserve a higher level of protection.

- Which laws regulate data protection?

As an EU ordinance, the General Data Protection Regulation (GDPR) has general validity and direct effect in Germany. However, individual articles of GDPR can be specifically formulated in accordance with individual state data protection law (Landesdatenschutzgesetze (LDSG)) or the federal data protection law (Bundesdatenschutzgesetzes (BDSG)). For example, Articles 27 and 28 of the BDSG determine the conditions under which sensitive personal data may be processed for research or archiving purposes.

2.2. Processing of personal data

- How can the processing of personal data be enabled?

In general, the processing of personal data is prohibited. However, there are possible exceptions according to certain legal regulations or under consent of the individual(s) whose personal data is to be processed. In other words, any processing of personal data is prohibited but subjected to the possibility of authorization.

Permission may be granted for scientific and statistical purposes, provided that the data processing is necessary for this purpose and the interests of those responsible for processing significantly outweigh interests of the non-consenting individual(s) (§ 27 BDSG). Since these requirements are often not clearly fulfilled and allow only the processing of personal data but not its publication, it is recommended that formal consent is obtained from the individual(s) whose personal data is to be processed.

- What is to be considered regarding a consent to personal data processing?

The consent to personal data processing must always relate to a specific case. It is given by the individual(s) whose personal data is to be processed. Consent must be voluntary, informed and unambiguous. It can be expressed either by a statement or an affirmative action. It is important that the individual(s) responsible for data processing must always be able to prove that consent was given. If a written form of consent is chosen, it must be ensured that the consent is not obscured by other topics, is formulated in comprehensible and easily accessible form, using clear and plain language (Art. 7 Abs. 1 and 2 GDPR).

eTIC⁹ (electronic Tool for Informed Consent documents) software offers support to scientists in writing generally comprehensible, ethically and legally compliant documents for informed consent for different studies.

- Can the consent be withdrawn? What are the consequences?

The individual(s) concerned can withdraw the consent at any time. The process of consent withdrawal must be as easy as the process of giving consent.

From the time of withdrawal, no further personal data of that person may be processed. However, the lawfulness of processing data up to that point is not affected by withdrawal. This fact must be clearly explained before consent is given (Art. 7 Abs. 3 GDPR).

- What must be considered while personal data are being processed?

In accordance with Art. 5 GDPR the processing of personal data must meet the following criteria:

- lawful (“lawfulness”)
- fair/moral (“fairness”)
- comprehensible for the individual(s) concerned (“transparency”)
- serving a specific purpose (“purpose limitation”)
- appropriate for this purpose and limited to the necessary extent (“data minimization”)
- accurate and up-to-date (“accuracy”)
- preventing of identification once the purpose has been achieved (“storage limitation”)
- reasonable safe (“integrity and confidentiality”)
- responsible individual(s) must be able to demonstrate compliance with these principles. (“accountability”)

These data protection principles serve to protect the rights of individuals whose data will be processed. The principles can be complied with by means of appropriate technical and organizational measures.

- How is transparency achieved?

The individual(s) responsible for personal data processing is/are obliged to inform concerned individuals about the processing. This must be conducted by the responsible individual(s) on their own initiative and upon request.

In accordance with Art. 13 GDPR, the following information must be provided before the processing of personal data starts:

- Name and contact details of the responsible individual(s)
- Contact details of the data protection officer
- Purposes of processing and legal basis

⁹ <https://etic.med.tum.de/>

- Recipient, if applicable
- Transfer to third country or international organization, if applicable
- Duration of data storage
- Right of individual(s) concerned to request access to personal data
- Right to rectification or deletion
- Right to restrict processing
- Right to withdraw consent
- Right to lodge a complaint with a supervisory authority

If during data processing the concerned individual(s) make(s) a request for information on any of these points, this information must be provided. In addition, a free copy of personal data processed must be provided if the individual(s) concerned has/have made such a request (Art. 15 GDPR).

- How to achieve data minimization?

Data minimization can be achieved by pseudonymization. In this process, personal data is reduced to the extent that it can only be attributed to a natural person if additional information (e.g., a list of names and identifiers) is used. This additional information must be kept separately and only authorized person(s) can access it. If any attribution to a natural person is completely removed, anonymization/anonymisation has been implemented. This removes the personal reference to the data and (after anonymization has been completed) is then beyond the scope of data protection.

In other cases, it must also be ensured that personal data is processed only to the extent necessary for a specific purpose. For example, an exact date of birth could be replaced by year of birth or a specific age group, or a postal code area could be specified instead of a complete postal code.

- What exactly is meant by the storage limitation for research data?

Archiving of research data in the sense of good scientific practice stands opposed to the data protection principle of storage limitation, i.e., limitation of storage period. Thus, legislative authority has made an exception regarding the period of storing personal data if it serves legitimate scientific purposes. In this case, the storage of data is permitted even after the actual purpose has been achieved provided that technical and organizational measures are taken to protect the individual(s) concerned (Art. 5 Abs. 1 lit. e GDPR). These measures can include pseudonymization, anonymization or encryption and may even go beyond measures that were implemented during the personal data processing. In this context, it is important to weigh the extent to which such data minimization impairs the subsequent usability of the research data.¹⁰

¹⁰ Putnings, Markus, Neuroth, Heike and Neumann, Janna. Praxishandbuch Forschungsdatenmanagement, Berlin, Boston: De Gruyter Saur, 2021. <https://doi.org/10.1515/9783110657807>

3. Labor Legislation

- Who owns works that are created in the course of an employment?

Copyright is not transferable. The owner of the copyright is always the creator of the work, even if the creation of the work arose from the duties of an employment. However, the employer has the right to use the copyrighted work as stated in the employment contract.

If the type and scope of the rights of use to be transferred have not been explicitly specified, the employer acquires rights of use in accordance with the purpose of the contract on which both parties have agreed (§ 43 UrhG, § 31 Abs. 31 UrhG). If the work is a computer program, the employer is exclusively entitled to all proprietary rights to the computer program, unless otherwise agreed (§ 69b UrhG).

- What are particular features of legal ownership of research data in the higher education context?

Unless otherwise regulated, the following cases are to be distinguished in the higher education context:

- Research data generated by university teaching staff members (professors, university lecturers, teaching assistants):
In the sense of freedom of research (Art. 5 Abs. 3 GG) university staff members can dispose of their research results and are owners of the right of use.
- Research data generated by scientific staff:
If research data are generated under instructions, the employer has the rights of use. If research data are generated without instructions, e.g., within a doctorate or a habilitation, the employer possesses no rights to the research data.¹¹
- Research data generated by students, e.g., doctoral candidates, who are not employed by the university:
Unless otherwise contractually agreed, students retain all rights to self-generated research data.¹²
- Research data generated within the framework of research projects that are financed by third-party funds:
The rights to the data are usually clarified in advance in a grant notice or other contractual agreements.¹³
- Research data obtained from patient body materials:
Materials, that have been separated from a patient's body, are in the first instance

¹¹ Lauber-Rönsberg, A. (2021). Rechtliche Aspekte des Forschungsdatenmanagements. In: Praxishandbuch Forschungsdatenmanagement. De Gruyter Saur, Berlin, Heidelberg. <https://doi.org/10.1515/9783110657807>. p. 92

¹² Lippert, HD. (2009). Wem gehören Daten, die im Rahmen von Forschungsprojekten gewonnen werden?. In: Medizin und Haftung. Springer, Berlin, Heidelberg. https://doi.org/10.1007/978-3-642-00612-8_22. p. 369

¹³ *ibid.*

the patient's property. By transfer of ownership, the body material becomes the property of the university. By processing the material, property can be acquired according to § 950 BGB. However, it is not applicable in cases where individuals are required to provide scientific services as part of their employment.¹⁴

- What is the legal claim to research data once an employment is terminated?

After termination of an employment, collected research data may be subject to a conflict of interest. In particular, if the employees who are leaving the institution conduct further research on their collected research data or wish to take the data to another institution. The DFG Code of Conduct – Guidelines for Safeguarding Good Scientific Practice¹⁵ – strongly recommends documenting in the employment contract or in other written agreements where research data will be held and what the legal ownership of the data will be after termination of the employment (Guideline. 10 DFG Code of Conduct). At the same time, those who collect research data are in principle entitled to use them (Guideline 10 DFG Code of Conduct).

4. Inventions

4.1. Patent rights

- What is a patent?

A patent is a protective right for a technical invention granted by the patent office. The patent prohibits all persons other than the patent holder(s) and persons authorized by them from using the invention for commercial purposes (§ 9 PatG).

The patent specification contains an abstract, state of the art, a description of the invention, drawings and patent claims (§ 32 Abs. 3 PatG).

- Under what conditions will a patent be granted?

A patent will be granted if the invention is novel, is the result of innovative activity and has a commercial application (§ 1 Abs. 1 PatG).

- Novelty means that the invention is not already part of the state of art (§ 3 PatG).
- Innovative activity means that a person skilled in the art would not have come up with the same idea solely based on the state of art (§ 4 PatG).
- Commercial application means that the invention can be exploited for a commercial purpose (§ 5 PatG).

¹⁴ *ibid.*

¹⁵ <https://wissenschaftliche-integritaet.de/en/code-of-conduct/>

In order that all three conditions can be checked, a patent application must be submitted to the patent office (§ 34 Para. 1 PatG). The application will contain the name of the applicant(s), a proposed name or designation for the invention, a description of the invention, drawings and patent claims (§ 34 Abs. 3 PatG). The applicant(s) must submit a summary of the invention within 15 months after submission of the application (§ 36 Abs. 1 PatG).

- Who can apply for a patent?

The applicant(s) can be, but need not be, the inventor(s) (§ 37 PatG). For example, in the case of service inventions, the inventor's employer is normally obliged to register the invention (§ 13 ArbNErfG). The applicant(s) must name all inventors involved within 15 months at the latest (§ 37 PatG).

- What rights does/do the inventor(s) have?

The inventor(s) (or their legal successor(s)) has/have a right to the patent. If multiple inventors have jointly created the invention, they have joint right to the patent. If multiple inventors create the same invention independently, only the inventor(s) with the earliest application is/are entitled to the patent (§ 6 PatG).

- What rights does/do the patent holder(s) have?

The patent holder(s) has/have the right to forbid other persons from using the invention (§ 9 PatG, cf. § 23 Abs. 3 PatG). The patent holder(s) is/are entitled to legal aid for the procedure for granting the patent and for annual fees (§ 130 PatG). The patent holder(s) has/have the right to withdraw or retroactively restrict the patent (§ 64 PatG). The patent holder(s) has/have the right to compensation if the state prohibits the publication and exploitation of the patent on the grounds of state secrets (§ 55 PatG).

- How long does patent protection last?

The patent is valid only as long as the patent holder(s) annual fees are paid in due time and the patent is not withdrawn in writing (§ 20 Abs. 1 PatG). A German patent is valid for a maximum of 20 years from the date of application (§ 16 PatG, cf. Kostenmerkblatt des DPMA). Moreover, the patent can be withdrawn by the patent office at any time if, in retrospect, it does not meet the requirements for a patent (§ 21 PatG).

4.2. Employee Inventions Act

- Who is considered an inventor in accordance with the Employee Inventions Act (ArbNErfG)?

As per the ArbNErfG, an inventor is an employee in the private or public sector, a civil servant or a soldier who creates an invention or makes a proposal for a technical improvement (cf. § 1 ArbNErfG).

- What is an invention in accordance with ArbNErfG?

As per ArbNErfG, “inventions can be considered as inventions if they are patentable or eligible for protection as an innovative design (§ 2 ArbNErfG). An invention is patentable or eligible for protection as an innovative design if it is new, based on an innovative contribution and exploitable (cf. § 1 Abs. 1 PatG and § 1 Abs. 1 GebrMG). With regard to innovative contribution, different standards apply: patents must be “based on innovative activity” (§ 1 Abs. 1 PatG); innovative designs need only be “based on an innovative step” (§ 1 Abs. 1 GebrMG).

A distinction must be drawn between a service restricted and unrestricted invention. Restricted inventions (service inventions) are created during a service relationship, either by means of service activity or with the help of service expertise (cf. § 4 Abs. 2 ArbNErfG). Unrestricted inventions are all non-restricted inventions (cf. § 4 Abs. 3, 4 ArbNErfG).

- What are an inventor’s obligations according to ArbNErfG?
 - Obligation to report restricted inventions (§ 5 ArbNErfG).
 - Obligation to maintain confidentiality for restricted and unrestricted inventions (§ 24 Para.2 ArbNErfG).
 - Obligation to inform of free inventions (§ 18 ArbNErfG).
 - Obligation to offer unrestricted inventions (§ 19 ArbNErfG).

- What are inventor’s rights according to ArbNErfG?
 - Right to remuneration, if the restricted invention is exploited by the employer (§ 9 ArbNErfG; cf. § 42 Abs. 4 ArbNErfG).

 - For inventions at higher education institutions, the inventor has additional rights based on the freedom of research and teaching: right of disclosure in research and teaching (§ 42 Abs. 1 ArbNErfG); conditional right to waive notification (§ 42 Abs. 2 ArbNErfG); non-exclusive right of use for teaching and research (§ 42 Abs. 3 ArbNErfG).

5. Ethics

- What are ethics committees responsible for?

Ethics committees are independent bodies that ethically evaluate research projects involving human subjects and identifiable human material. Thereby, they must consider the protection of study participants, their physical and psychological integrity, the preservation of human dignity, and carefully weigh potential risks against expected benefits.

Ethics applications must be submitted to responsible ethics committee prior to the start of a research project, which may only be initiated after an ethical approval has been issued. Jurisdiction of an ethics committee is based on the location of principal investigator or the study itself and institutional affiliation of the principal investigator. For university members, this is the ethics committee of their university, and for physicians conducting research outside of universities

and university hospitals, the ethics committee of the medical association or state authorities. As a rule, multicenter studies must be reviewed by several ethics committees, whereby the ethics committee responsible for the study management is the lead committee.

An overview of medical ethics committees in Germany is provided by the Association of Medical Ethics Committees in the Federal Republic of Germany e.V.: <https://www.akek.de/en/ethik-kommissionen/>

- When must ethical approval be obtained?

Ethical approval must be obtained when research is conducted on or with human subjects in scientific studies. Ethical approval is often required by universities, higher education institutes, third-party funders and publishers. In the following cases, ethical approval is mandatory for the conduct of studies and is enshrined in law:¹⁶

- Drug Trials:
In accordance with the German Medicinal Products Act (AMG) and Regulation (EU) No. 536/2014 of the European Parliament and of the Council of April 16, 2014, a conclusion of the responsible ethics committee must be taken into consideration for the approval of clinical trials of medicinal products.
- Medical Device Testing:
In accordance with the Medical Devices Implementation Act (MPDG), the Medical Device Regulation (Regulation (EU) 2017/745) and the European In Vitro Diagnostics Regulation (IVDR), clinical studies on and with medical devices must be reviewed by the responsible ethics committee.
- Other Studies:
Other studies are medical research projects on and with humans which are not regulated by special legislation and in which physicians are involved. Whether an ethics committee decision or advice is required depends on the version of the professional code of conduct for physicians adopted by the individual state medical associations in each case. The same applies to the use of identifiable body material or data as well as research involving vital human gametes (i.e. reproductive cells) and living embryonic tissue (§ 15 Musterberufsordnung für Ärztinnen und Ärzte). For members of a university, a duty to provide advice may arise in accordance with the university statutory law.
- Radiation protection:
In accordance with § 36 Abs. 3 Strahlenschutzgesetz (StrlSchG) the ethical justifiability of research projects in which radioactive substances or ionizing radiation are used must be reviewed by an ethics committee. If the use of radioactive substances or ionizing radiation is not itself the subject of the research but is used as an

¹⁶ <https://www.akek.de/einreichung-von-forschungsvorhaben/>

accompanying diagnostic, the evaluation must also be carried out in accordance with the AMG, MPG or the applicable professional law.

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researchdata@tum.de

www.ub.tum.de

www.tum.de

Last modified: December 2023