



**Guideline and implementing provisions for the
Implementation of the Animal Welfare Act
at the Charité - University Medicine Berlin**

- ANIMAL WELFARE Guideline of the Charité -

- Status: June 2023 -

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1. General

- 1.1. The legal basis for the "ANIMAL WELFARE GUIDELINE of the Charité" is in particular the **Animal Welfare Act (TierSchG)**¹ as well as the "Ordinance for the Protection of Animals Used for Experimental Purposes or for Other Scientific Purposes". - **Tierschutz-Versuchstierverordnung (TierSchVersV)**² - in the respective valid versions, whose provisions, specifications and statements apply in principle.
- 1.2. The "ANIMAL WELFARE GUIDELINE OF THE CHARITIE" serves to concretize the applicable legal regulations in the field of animal welfare for internal implementation at the Charité - Universitätsmedizin Berlin (hereinafter referred to as "Charité") incl. the translational research domain managed under the name "Berliner Institut für Gesundheitsforschung in der Charité (BIH)".
Furthermore, it regulates the position and powers of the **Animal Welfare Officers (TierSchB)** of Charité and the framework conditions for the activities of the **Animal Welfare Body (TierSchA)** of Charité.
- 1.3. The "ANIMAL WELFARE GUIDELINE of the Charité" applies to all institutions of the Charité as well as to all persons who carry out animal experiments at the Charité and who use, breed or/and keep vertebrates for scientific purposes or who are appointed as animal welfare officers or/and to the Animal Welfare Body.
- 1.4. The supreme principle is the observance of and compliance with the Animal Welfare Act (TierSchG) and all associated legal provisions. Every person working at the Charité who handles animals at the Charité must familiarize himself or herself extensively with the applicable law and acquire the necessary technical and expert knowledge before beginning work.
- 1.5. For any animal testing projects, interventions and treatments on laboratory animals as well as the sacrifice, breeding and keeping of laboratory animals at the Charité, the official approvals required in accordance with the legal provisions as well as these guidelines and implementation regulations must be obtained prior to the commencement of these activities or the notifications must have been made in accordance with the legal provisions.

2. Organization of animal welfare

- 2.1. Applicants for animal experiments must ensure in advance that the designated animal experiment heads and their deputies have the personal characteristics and position to carry out animal experiment projects, which guarantee that the legal obligations incumbent upon them are fulfilled. The appointment as head or deputy head of animal experimentation projects must be linked to a free and personal decision to take on this function provided for by law, due to the personal liability involved.
- 2.2. The licensee for keeping laboratory animals at the Charité is the Charité, represented by the Chairperson of the Charité Board of Directors. In the context of the application for the respective breeding and husbandry permit, the Charité designates qualified responsible persons whose consent must be obtained.
- 2.3. The Charité appoints a sufficient number of Animal Welfare Officers (TierSchB), whose legal status and powers are also specified within the framework of these guidelines and implementation regulations.

¹ Revised by announcement of May 18, 2006 (BGBl. I p. 1206, 1313), last amended by Article 2 (20) of the Act of December 20, 2022 (BGBl. I p. 2752)

² Animal Protection Experimental Animal Ordinance of August 1, 2013 (BGBl. I p. 3125, 3126), as last amended by Article 1 of the Ordinance of August 11, 2021 (BGBl. I p. 3570).

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- 2.4. All necessary official forms for applications/notifications of changes as well as their templates are made available on the INTER/INTRANet sites of the TierSchB in addition to other current information and recommendations of the TierSchB.
- 2.5. Animal experiment heads or their deputies must ensure, in addition to their personal legal obligations (see § 30 TierSchVersV - personal liability), that all persons involved in the animal experiment
 - have been taught the necessary basics of animal experimental work and the handling of laboratory animals before participating in the experimental project or have attended the corresponding courses;
 - are informed of the content of the applicable permit/notification of amendment, including all conditions, terms and attachments, and have the opportunity to inspect these documents at any time;
 - be presented personally to the responsible animal welfare officer before they start working for the first time;
 - take part once a year in the site-specific training or the self-study training provided on VITA with regard to the required operational and legal provisions and confirm this personally by signature with the animal welfare officer.
- 2.6. The funds required for animal experiments or laboratory animal husbandry at the Charité are provided by the experimental head, insofar as these are not covered by central funds in accordance with Charité regulations.

3. Full and simplified approval procedures

- 3.1. The application for animal experimentation projects in the full or simplified approval procedure at the competent authority is made by the persons responsible for the project using the official forms together with all annexes and with a statement/signature of the TierSchB. A copy of the entire application documents or notification of changes is to be provided to the respective animal welfare officer when submitting the application or notification of changes.
- 3.2. An animal experimentation project may only be started after the official approval has been obtained and in compliance with regulations, conditions and requirements.
- 3.3. If circumstances in approved animal experimentation projects are to change - in particular in the conduct of the experiment, the number or type of animals and the personnel involved - these must be notified to the authority in good time in advance and in writing, with reasons, by the head of the animal experimentation project after the Animal Welfare Officer has given his/her opinion/consent. A copy of the entire notification documents must be provided to the TierSchB when forwarding the notification of change to the authority. The implementation of changes may only take place after official approval/authorization or after expiration of the legal deadlines.
- 3.4. The animal experiment head is responsible for ensuring that all persons performing the experiments have the required expertise according to Annex 1, Section 3 of the Animal Experiments Ordinance (TierSchVersV) and that they undergo regular and verifiable training. The animal experiment head is responsible for providing proof. On request of the board or in its representation by the animal house management or the persons responsible for breeding and husbandry or the responsible animal welfare officer, the proofs are to be presented.
- 3.5. The persons responsible for an animal experiment have to inform the responsible animal welfare officer in due time before the start of the experiment about the time schedule and the premises in which the experiment is to take place.
- 3.6. The animal experiment head is obligated to provide the TierSchB immediately upon request with information on the current status of an experiment requiring a permit and to submit the

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respective required certificates of competence of all persons involved in the animal experiment and/or animal sacrifice.

- 3.7. The animal experiment head is obliged to attend meetings of the Animal Welfare Body of the Charité (see section 10) upon invitation and to provide information and documents to the Animal Welfare Body upon request for the performance of its legal duties (see also section 10.1.3.).

4. Sacrifice of vertebrate animals for scientific purposes

- 4.1. Sacrifice of non-pretreated vertebrates and cephalopods for scientific purposes shall be limited to a scientifically indispensable scope.
- 4.2. At Charité, planned sacrifice of non-pretreated vertebrates or cephalopods for scientific purposes must be notified by the head of the sacrifice project to the responsible Animal Welfare Officer using the notification form provided.
- 4.3. A sacrifice project notified in accordance with point 4.2. may not be started before confirmation by the responsible Animal Welfare Officer(s).
- 4.4. The person(s) responsible for notification in accordance with section 4.2 shall be responsible for ensuring that the persons entrusted with the sacrifice of vertebrates or cephalopods demonstrably possess the necessary expertise in accordance with Annex 1, section 2 of the TierSchVersV and that they undergo verifiable and regular further training. The person responsible according to point 4.2. is responsible for providing proof. Upon request of the board or in its representation by the animal house management or the persons responsible for breeding and husbandry or the responsible Animal Welfare Officers, the evidence shall be presented.
- 4.5. The TierSchB must be provided with information on the current status immediately upon request.
- 4.6. The management of sacrifice projects is obligated to attend meetings of the Animal Welfare Body of the Charité (see item 10) upon invitation and to provide the Animal Welfare Body with information and documents upon request for the performance of its legal duties (see also item 10.1.1. subitem c)).
- 4.7. The animals used according to point 4.1. must be reported according to the laboratory animal reporting regulation. It is recommended to keep accompanying records of the animal species (identity if applicable), number of animals, date and method of sacrifice.

5. Records

- 5.1. The animal experiment head, which is obliged to keep comprehensive records on animal experiments in accordance with the legal provisions, must ensure that the persons performing the animal experiments are instructed with regard to proper documentation of the records. The obligation to regularly check the records for completeness is incumbent on the head of the animal experiment project.
- 5.2. The records must be kept up to date and may be kept electronically. If kept electronically, they must be printed immediately after the completion of each subtest and signed by the head of the animal testing project or his/her deputy and the persons who performed the tests.
- 5.3. Records on animal experiments are to be submitted to the authority as well as to the competent animal welfare officer upon request.
- 5.4. Records of animal experiments must be kept in their entirety by the animal experiment head, irrespective of his or her employment relationship with Charité, for a period of five years,

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beginning with the completion of the animal experiment project.

- 5.5. According to the Laboratory Animal Notification Ordinance, animal experiment head or persons responsible for animal sacrifice are obliged to report the legally required information for each calendar year to the State Office for Health and Social Affairs (LaGeSo, as the competent state authority) by March 31 of the following year in the file specified by the Federal Institute for Risk Assessment (BfR) via the notification platform provided by Charité 3R. The TierSchB are available to advise on questions regarding laboratory animal reporting. After counting, the annual laboratory animal numbers are published centrally for the Charité on the Charité 3R homepage.
- 5.6. All addressees of recommendations of the TierSchA are obliged to adequately document all decisions made on the basis of the recommendations and to file them together with the recommendations. They are to be presented to the authority upon request. The documented decisions are to be sent immediately in writing to the chairperson of the TierSchA.

6. Laboratory animal husbandry

- 6.1. For the keeping or breeding of laboratory animals at the Charité, permission must be obtained from the supervisory authority, which must be applied for in advance and in good time by the management of the Research Facilities for Experimental Medicine (FEM) via the Chairman of the Board of the Charité. Keeping animals in laboratories is generally prohibited.
- 6.2. Veterinary care of animals is provided by the veterinary service of the FEM.
- 6.3. The management of the research facilities for experimental medicine (FEM) must ensure and provide evidence that the persons entrusted with the care of the animals have the appropriate expertise and undergo regular training for this purpose. The management is responsible for providing evidence. Upon request of the board of directors, the evidence shall be presented.
- 6.4. The head of the experimental projects as well as the persons responsible for the breeding and keeping of vertebrate animals are obliged, in addition to the responsibilities arising from the legal provisions, to immediately inform the responsible veterinarian as well as the animal welfare officer in case of irregularities in the behavior of the animals, but especially in case of frequent deaths. In case of suspected epidemics, the official veterinarian is to be informed by the veterinary service in consultation with the management and hygiene officer of the FEM.
- 6.5. The entry of animals into the animal husbandry is recorded in the database exclusively via the animal husbandry section of the FEM. The exit of animals must be recorded in the site-specific stock documentation by the experimenters. This data is entered into the database by the animal care section.
- 6.6. A card must be attached to each cage used to house the laboratory animals, on which the project-, animal- and test-related data, including the official approval number, must be legibly noted. The start of the experiment must be noted with the date. Animals that are exclusively used for breeding must also be marked as such. The reassignment of animals to other experimental projects may only take place in agreement with the responsible animal welfare officer. The responsibility for a complete, current and sufficient identification lies with the respective experimentation head.
- 6.7. In all other respects, the operation of the laboratory animal facility is carried out in accordance with the applicable internal regulations of the FEM for user operation.
- 6.8. In the case of planning and structural changes to animal facilities, the responsible animal welfare officers and the Animal Welfare Body are to be consulted in an advisory manner via their chairperson(s).

7. Procurement and transport of laboratory animals

- 7.1. The procurement of laboratory animals must always be carried out via the Animal Welfare Officer (TierSchB) by authorized employees of the laboratory animal facilities via the data entry masks available in the FEM animal facility database or for transport orders within the Charité or orders from external sources via the forms for imports/exports/TVP. No laboratory animals may be procured, transferred to the Charité premises or transferred from breeding without the approval of the Animal Welfare Officer.
- 7.2. Before procuring animals from external sources, the animal stock of the Charité must be checked (e.g. animal/organ pool).
- 7.3. Before taking over laboratory animals from other animal husbandries, the health status of the stock of origin must be certified by a health certificate and permission to employ these animals must be obtained via the hygiene officer of the FEM and the animal welfare officer of the respective animal husbandry.
- 7.4. The transport of animals within the facility must be carried out in accordance with animal welfare requirements. Incidents during transport that lead to an avoidable impairment of the animals must be reported immediately to the animal welfare officers.
- 7.5. In all other respects, the current regulations and procedural requirements for animal procurement, import, and export published by the FEM apply.

8. Disposal

The disposal of animal carcasses or parts and used bedding and other waste from animal husbandry and laboratories must be carried out in accordance with official requirements, applicable legal provisions and in consideration of environmental compatibility.

9. Animal Welfare Officer (TierSchB)

9.1. Appointment

- 9.1.1. TierSchB are appointed in writing by the Chairmen of the Board of Directors of Charité and the Chairperson of the Board of Directors of BIH. An appointment is only possible with the consent of the person concerned.
- 9.1.2. In the case of the appointment of several TierSchB, the delimitation of the areas of responsibility as well as the corresponding representation regulations shall be conclusively regulated in the respective written orders.

9.2. Position

- 9.2.1. TierSchB are free from instructions in the performance of their duties and may not be disadvantaged because of the performance of their duties.
- 9.2.2. TierSchB in secondary office shall be granted the time necessary for the fulfillment of their duties; they shall be relieved accordingly in their actual area of responsibility during their activity as animal welfare officers.
- 9.2.3. TierSchB can submit proposals and concerns of fundamental importance for animal welfare as well as submissions to the Animal Welfare Body or directly contact the Chairperson of the Board of Directors of the Charité incl. the Chairperson of the Board of Directors of BIH orally or in writing. Individual questions of animal husbandry and experimental conditions, but also serious disagreements between TierSchB and a person

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responsible for the experiment are first dealt with by the Animal Welfare Body.

9.3. Tasks and duties

In addition to the legally prescribed tasks of the TierSchB according to § 5 TierSchVersV applies:

- 9.3.1. TierSchB advise in their area of responsibility the respective responsible head and in particular all persons involved in animal experiments and the keeping of laboratory animals.
- 9.3.2. Animal Welfare Officers consult with the responsible animal experiment head on aspects of the experiment that are relevant to animal welfare and laboratory animal science before submitting an application for approval of an animal experiment project. Animal welfare officers shall work towards the development and introduction of procedures and means to restrict animal experiments.
- 9.3.3. TierSchB should work towards ensuring that suitable biometric procedures are already used in the planning of experimental projects.
- 9.3.4. TierSchB must submit a statement to the competent authority for each complete application for approval of an experimental project. The statement should refer in particular to the indispensability and ethical justifiability of the animal experimentation project and the material, spatial and personnel requirements of the persons involved as well as to the accommodation, care, supervision and medical care of the laboratory animals.
- 9.3.5. Each animal welfare officer keeps an overview of all animal experimentation projects supervised by him/her in a suitable form, as well as the necessary documents for the individual projects.
- 9.3.6. TierSchB ensure compliance with the regulations, conditions and requirements in the interest of animal welfare. This applies in particular to the conduct of the experiment and the participants involved in the experiment as well as the animal welfare-friendly husbandry and care of the animals in the experiment. Animal welfare officers must pay particular attention to compliance with the limitation of suffering in animal experiments that involve pain, suffering or harm. TierSchB can be supported by competent and reliable persons (e.g. animal keepers).
- 9.3.7. In the event of violations of regulations, conditions and requirements in the interest of animal welfare, TierSchB are obliged to prohibit the performance of the test immediately until the deficiencies have been eliminated. The corresponding instructions of TierSchB are to be followed. TierSchB have to inform the chairperson of the board of directors of Charité and the chairperson of the board of directors of BIH about this measure immediately in writing by e-mail with reasons.
- 9.3.8. Animal Welfare Officers have the right of access at all times to all premises in their area of responsibility where animal experiments or sacrifice are carried out or animals are kept or bred. The necessary preconditions for this are to be ensured by the persons responsible for the activities in each case. The occupational safety regulations applicable to the rooms as well as applicable hygiene requirements for access are to be complied with.
- 9.3.9. TierSchB are obliged to provide information to the licensing authority. There is no obligation to provide information to third parties.
- 9.3.10. TierSchB involve, as far as necessary, the specialists for occupational safety as well as the company physicians of the Charité in matters relevant to occupational safety and work closely together with these bodies to solve possible problems. Responsibility with regard to compliance with occupational safety-related measures and prerequisites rests with the

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respective laboratory/animal experiment head. If the prerequisites are not fully clarified when the application is submitted and/or the spatial and/or personnel requirements are not met, the application may not be submitted to the authority.

- 9.3.11. The TierSchB create and maintain a microsite on the INTERNet and INTRANet portals of the Charité as an independent component of the INTERNet and INTRANet offerings of the FEM, taking into account the applicable editorial guidelines and the corporate design of the Charité.
- 9.3.12. Regular participation in the meetings of the TierSchB in the working group "Berlin Animal Welfare Officers" and membership in the Animal Welfare Body is obligatory for the TierSchB.
- 9.3.13. The Animal Welfare Body appoints a veterinarian from among its members, who is a member of the Charité 3Rs Board of Spokespersons and ensures the exchange of information between the Animal Welfare Body and the Board of Spokespersons.
- 9.3.14. The Animal Welfare Officer shall submit a report to the Chairperson of the Animal Welfare Body by its first meeting of the year, which contains processes, incidents and measures in their area of responsibility of the previous year. A summary is presented by the Chairperson of the TierSchA at the first meeting of the TierSchA. With the minutes of the meeting, this summary is given to the board of directors for their information.

9.4. Material equipment

- 9.4.1. The Charité provides factual support to the TierSchB in the performance of their activities and enables them to use the existing systems of literature search and to collect the literature necessary for their activities.
- 9.4.2. The Charité ensures that the TierSchB regularly keep up to date with the state of the art in science and technology through further training in the interest of the service, in accordance with the statutory provisions for the unrestricted performance of their duties. The funds required for participation in these advanced training courses are provided in consideration of the regulations applicable to advanced training courses.
- 9.4.3. The TierSchB must be provided with their own working space.
- 9.4.4. For reasons of data protection, a lockable cabinet for the available documents must be made available to the TierSchB. In addition, a telephone, the right to use a fax machine as well as a PC with Internet access/e-mail and printer are part of the minimum technical equipment for the proper performance of the tasks of the TierSchB.

10. Animal Welfare Body (TierSchA)

At Charité, an Animal Welfare Body (TierSchA) has been established in accordance with the Animal Welfare Experimental Animal Ordinance (TierSchVersV), whose main statutory tasks include issuing recommendations on animal welfare issues. To this end, it monitors the development and results of animal experimentation projects at Charité, promotes a climate of care, and recommends tools for the practical application and timely implementation of recent technical and scientific developments related to the principles of avoidance, improvement, and reduction in the field of animal welfare (3R principle: "Replace", "Reduce", "Refine").

10.1. Tasks

According to § 6 paragraph 2 TierSchVersV the TierSchA has the task,

1. to support the animal welfare officers in the fulfillment of their tasks according to § 5 paragraph 4 sentence 1 number 2 and sentence 2 number 2 TierSchVersV,

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2. to participate in the establishment of internal operating procedures related to the conduct and evaluation of animal welfare monitoring and related follow-up, and verify compliance with operating procedures,
3. to follow the development of animal experiments and their results, taking into account the impact on the animals used,
4. to act in an advisory capacity with regard to the development and implementation of programs in accordance with § 10 Paragraph 2 TierSchVersV,
5. to advise personnel of the institution or establishment involved in animal testing and in the breeding, keeping, care and sacrifice of animals
 - a. with regard to the fulfillment of the requirements of § 7 paragraph 1 sentence 2 and 3 as well as § 7a paragraph 2 number 2, 4 and 5 of the Animal Welfare Act and with regard to measures that contribute to the improvement of breeding, housing and care and the procedures used in the sacrifice of animals
 - b. and keep informed of technical and scientific developments to meet the requirements of Section 7(1), sentences 2 and 3, and Section 7a(2), numbers 2, 4 and 5, of the Animal Welfare Act and to improve breeding, housing and care and the procedures used to sacrifice animals, in particular developments on ways to improve animal welfare,
6. to monitor the developments and results of animal experiments, taking into account the effects on the animals used, and
7. to identify factors, including those based on the findings of in-house testing, that contribute to further compliance with the requirements of Section 7(1), sentences 2 and 3, and Section 7a(2), numbers 2, 4, and 5, of the Animal Welfare Act and to improving breeding, housing, and care and the procedures used in the sacrifice of animals, and make appropriate recommendations, particularly to improve animal welfare.

10.2. Composition

10.2.1. The members of the TierSchA of the Charité are:

- a) the animal house manager, his deputy and the foreman/forwoman as the persons responsible for supervising the care of the animals,
- b) the veterinarians of the veterinary service as the persons responsible for the welfare of the animals, and
- c) one scientific member active in animal experiments and his/her deputy, who are members of the research commission of the Charité.

10.2.2. The persons according to clause 10.2.1. are appointed by the Chairperson of the Board of Directors of Charité, by the Chairperson of the Board of Directors of BIH and by the Dean for a period of 3 years on the proposal of the Management of the Research Institutions for Experimental Medicine and after coordination in the TierSchA. The persons according to item 10.2.1. c) are appointed by the Chairperson of the Board of Directors of Charité, by the Chairperson of the Board of Directors of BIH and by the Dean for a period of 3 years upon proposal of the Research Commission after voting in the TierSchA.

Each of the members according to clause 10.2.1. may be dismissed prematurely if they so request or if there are important reasons. In this case, a new member shall be appointed for the remaining term of office in accordance with the aforementioned provisions.

10.3. Chairperson of the Animal Welfare Body

The member in charge of the Animal Welfare Body of the Charité and his/her deputy in

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absence are elected by majority vote of all members of the Animal Welfare Body for the duration of the current term of office of 3 years. They remain in office until their successors are elected. Re-election is possible.

10.4. Organization

- 10.4.1. For the procedure within the TierSchA, the TierSchA adopts rules of procedure in accordance with the following regulations, which must be made known to the Board of Directors of the Charité and the Board of Directors of the BIH. An amendment of the rules of procedure requires a 2/3 majority of the members present.
- 10.4.2. The TierSchA shall meet at least twice per calendar half-year. Further details are regulated in the rules of procedure. The chairperson of the TierSchA shall invite the TierSchA to the meetings in writing. The Animal Welfare Body shall not meet in public.
- 10.4.3. The Animal Welfare Body has a quorum if at least half of its members, including the chairperson or his/her representative, are present. The Animal Welfare Body passes its resolutions with a simple majority of votes. In the event of a tie, the chairperson of the Animal Welfare Body shall have the casting vote. The Animal Welfare Body may adopt resolutions by written procedure under the above-mentioned conditions, provided that no member objects.
- 10.4.4. The TierSchA shall keep records of recommendations it makes in the course of fulfilling its tasks specified in items 10.1.1. to 10.1.7. The addressees of such recommendations may be the Board of Directors of the Charité and the Board of Directors of the BIH, the persons responsible for the respective operation, planners and heads of experimental projects and the responsible persons according to § 4 TierSchVersV. The persons or bodies who make decisions based on the recommendations of the TierSchA document them and forward a copy of this documentation to the management of the TierSchA without delay. The respective addressee of the recommendations shall be responsible for the timeliness of the documented decision based on recommendations of the TierSchA. The chairperson of the TierSchA shall keep the records of the recommendations as well as the documentation received on decisions for at least three years and shall submit them to the competent authority upon request.
- 10.4.5. The members shall be bound to secrecy with regard to all matters and facts of which they become aware in connection with the activities of the Animal Welfare Body.
- 10.4.6. At the request of the Chairperson of the Board of Directors of the Charité and the Chairperson of the Board of Directors of the BIH, the TierSchA reports to them on its work. Minutes of meetings are regularly brought to their attention by the chairperson.
- 10.4.7. In order to fulfill its tasks, the TierSchA may invite expert persons and guests who are not members of the TierSchA to the respective meetings.
- 10.4.8. TierSchB may submit submissions to the TierSchA.

11. Final regulations / entry into force

This guideline shall be effective immediately.

At the same time, the "Guideline and Implementation Regulations for the Implementation of the Animal Welfare Act at the Charité - Universitätsmedizin Berlin (Animal Welfare Guideline of the Charité)", as of June 2020, shall expire.

The "Guideline and Implementation Regulations for the Implementation of the Animal Welfare Act at the Charité - Universitätsmedizin Berlin (Animal Welfare Guideline of the Charité)" are to be given to all Animal Welfare Officers, all members of the Animal Welfare Body as well as all persons responsible according to the Animal Welfare Act for their knowledge and attention and are to be published permanently on the website of the Animal Welfare Officers of the Charité.

Berlin, the

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