

## **INFORMATION ON ANIMAL SAMPLE DONATION FOR DIAGNOSTIC AND MEDICAL RESEARCH**

Dear Owner,

The tests and treatments for companion animals, such as cats and dogs, are much less effective and less studied than those for humans.

To understand diseases, we must learn about their biology. This is why, as the owner of your pet, we ask if you would donate the leftover biological samples and data from your beloved companion. This is after their use for diagnostic or therapeutic purposes. We want to use these for research to develop new diagnostics, medicines, and treatments.

Your vet will only collect samples for routine tests or treatments. No additional harm or stress will be caused for research.

Your vet will not collect any tissue, biopsy, or sample not needed for the animal's treatment or diagnosis.

Upon your approval, only the leftover samples will be sent for further processing to Lab4Paws (a brand of Sellomics GmbH, hereafter "Lab4Paws"). After processing, Lab4Paws will make these samples available to researchers. They will use them to develop new therapies and diagnostic tools for pets.

Your consent to the use of your pet sample donation and associated data is voluntary.

If you do not wish to participate or wish to withdraw your consent later, there will be no disadvantages for you.

### **1. What are the goals of the sample collection?**

Lab4Paws's biobank stores the samples and data for the long term. They are available for research to improve disease prevention, detection, and treatment. This research does not aim to diagnose your pet or others. It also won't prove any disease predispositions. The aim is to find biomedical links in a study of larger animal groups.

### **2. What type of samples and data are involved?**

As part of this biomaterial collection, we ask you to donate one or more of the following samples:

- Serum, plasma and/or whole blood

- Biopsies or punch biopsies from resectates
- Urine
- Samples taken in a non-invasive way (i.e. inducing no additional stress to the animals, including restrictions) such as tears, buccal swabs, faeces
- Other data such as radiographies, exam results, general information regarding the patient (such as age, gender, breed, disease diagnosis or treatment)

You have the right to a free copy of the data collected from your pet.

### **3. How is the sample donation and data used?**

The donated sample and its data are for studying diseases. These include cancer, immunological and inflammatory diseases, and infectious diseases. They aim to improve transplant medicine and treat difficult diseases. Samples can be used for genetic tests to identify disease risks.

The samples are taken only for research and development purposes. Your pet sample and data will not be used for research deemed unethical by the ethics committee (see section 7e). If you have any reservations about the described use, please state in your consent form the research purposes for which you do not want your sample donation to be used.

### **4. What risks are associated with your donation?**

#### **4.1 How does the donation process work and what risks are associated with it?**

Sample collection is derived from routine analysis or treatments. For any procedure more invasive than the insertion of a needle, donation is possible only for samples that were already collected in the course of routine diagnostic or surgical procedures.

For any procedure considered non-invasive and non-stressful to your companion animal (such as collection of swabs, faeces, tears etc), your veterinarian will carry out a medical examination on your pet to determine whether there is anything that speaks against sample collection due to your pet's state of health. Depending on the nature of the analysis, your veterinarian will explain to you the obtaining process.

#### **4.2 Are there any adverse events during/after sample acquisition?**

Many of the samples above are donated only after the vet has requested them for medical reasons. Thus, no extra procedures or interventions are required.

All samples are collected via routine medical procedures. They are safe and gentle. Still, adverse events can occur in individual cases. A donation usually does not disturb physical well-being. Disorders like irregular heart activity and fainting are very rare. So are hyperventilation, vomiting, severe bleeding, and nerve damage. Your veterinarian will inform you of the specific risks associated with the interventions.

### **4.3 Can you become infected when donating?**

No! There is no risk of infection when donating. Only sterile, new, unused disposable materials are used.

### **4.4 Other risks**

Your donation data is collected, stored, and transmitted for research. This poses confidentiality risks due to the traceability of your pet's participation in the study. No data from you as owner is collected. Lab4Paws takes several measures to anonymise data after acquisition. However, these risks cannot be completely ruled out and they increase the more data can be linked together. Under point 7 "Who has access to your donation and data?" we explain in more detail how your privacy is protected.

## **5. What benefit does it give you or your pet personally?**

You cannot expect any direct advantage or benefit for your health from donating your pet samples and data. However, a researcher may find an evaluation result could be important for your animal health. This is true if it strongly suggests a serious, undetected disease. It could be treatable or preventable.

In such a case, you may receive feedback (see point 9). Please tick the box in the consent form to indicate whether you would like to receive feedback in such a case (see also point 9). You can change your decision for or against the possibility of feedback at any time by notifying us. Tests on genetic material are done in some cases. So, the above text may refer to your pet's genetic predisposition to certain diseases.

## **6. What benefit is there for the general public?**

Medical-scientific research projects seek to improve our understanding of diseases. They aim to improve diagnosis. Also, they want to find better treatments and prevention methods. The benefits for the general public cannot yet be foreseen.

## **7. Who has access to your pet sample donation and data and how are you and your pet protected?**

### **a. Coding of your donation and data**

No collected data directly identifies the owner. All data that identifies your pet (name, date of birth, etc.) are replaced by a code (pseudonymized) after obtaining the samples. Only in this form are the samples and data made available for research purposes.

The data that identifies your pet remains in the veterinary clinic. It is stored separately from the sample donation and medical data. The donation and data cannot therefore be assigned to you without the involvement of the veterinary clinic. Your identifiable animal data won't be shared with researchers or others.

#### **b. Sharing your pet sample donation and data**

Lab4Paws's biobank stores the coded sample donation and medical data. It can be shared, per rules, with universities and companies worldwide for specific medical research. Researchers may link the data to medical data in other databases if they meet the legal requirements. Researchers may only use the samples and data for the stated research purpose. The recipient may not share them for other purposes. Unused material is returned to the biobank or destroyed. Lab4Paws will receive fair compensation for processing your pet sample donation for research.

#### **c. Sharing to countries outside the European Union**

Your pet samples and data can be shared with recipients in non-EU countries if the European Commission has found their data protection to be adequate. If this has not been done, Lab4Paws will agree to data protection clauses with the research partners approved by the European Commission or the relevant authority. You can get a copy of these data protection clauses from Lab4Paws. Also, samples and data may be passed to research partners in third countries that meet neither requirement. These countries may have a lower level of data protection than the EU. Lab4Paws will contractually require the research partners to meet the EU data protection level in these cases, as far as legally possible.

#### **d. Publications**

Scientific publications of results are only made anonymous. They are in a form that does not allow any conclusions to be drawn about you. This also applies, in particular, to genetic information. Yet, genetic information may be in protected scientific databases. They are not accessible to the public.

### **8. Do you or the biobank gain a financial advantage from the use of your pet sample donation and data?**

When you hand over the sample donation to Lab4Paws, it becomes the property of Lab4Paws. You also allow Lab4Paws to use the medical data. Lab4Paws uses your pet sample donation and data only for science. It is paid for by users for managing the samples and for any science work done with them.

## **9. What does your right of withdrawal include?**

You can withdraw your consent to use your pet sample donation and data at any time. You do not need to give a reason. There will be no negative consequences for you. However, the legality of the use of the donation and data up to the time of withdrawal remains unaffected.

If you withdraw, we will destroy the sample and delete the data, as much as possible with reasonable effort. Data from analyses that have already been carried out can no longer be removed. Instead of destruction, you can also agree that the sample donation and data may be used in an anonymized form for scientific purposes. Anonymization means deleting the identification code that links the sample to its animal (see point 7a/b above). As soon as anonymization has taken place, targeted destruction based on your decision is no longer possible. To revoke your consent, please contact Lab4Paws at Veillodterstrasse 29, 90409 Nürnberg. The contact person is Davide Confalonieri. You can reach him at +49 172 460 5978 or [info@lab4paws.com](mailto:info@lab4paws.com).

## **10. What other data protection rights do you have?**

No data protection rule applies to pets. So, Lab4Paws requires owners' consent to use their pets' data. This is not a legal requirement but an ethical one. It lets owners control how their pets' data is used.

The legal basis for processing the owner's data is your consent in accordance with Art. 6 Paragraph 1 Letter a and Art. 9 Paragraph 2 Letter a of the General Data Protection Regulation. The controller within the meaning of the General Data Protection Regulation is Lab4Paws (see point 10 for the address). You can request info about your data from Lab4Paws and its data protection officer, as allowed by law. You can also request to correct incorrect data. You can ask to transfer your data, delete it, or restrict its processing. You also have the right to lodge a complaint with any data protection supervisory authority.

## **11. Where can I get more information?**

If you are unsure about anything, please ask your veterinarian before you give your consent.

## INFORMED CONSENT FORM

Please read the following consent form carefully, tick the appropriate boxes and then sign at the end of this consent form if you agree.

### Consent form

Subject (name, species): \_\_\_\_\_

Gender, breed: \_\_\_\_\_

Date of birth: \_\_\_\_\_

I have read the information leaflet and had the opportunity to ask questions. I know that my participation is voluntary and that I can withdraw my consent at any time without giving reasons and without any disadvantages.

I consent to donate tissue samples and data from my pet, as described in the information leaflet, being given to the Lab4Paws's biobank and used for the medical research purposes stated in the information leaflet. In particular, I agree that, as described in the information document,

- the veterinary clinic collects data from my pet, in particular information about its health, and stores the data in pseudonymised (i.e. coded) form;
- the sample donation is stored pseudonymised in the Lab4Paws's biobank. I transfer ownership of the sample donation to Lab4Paws;
- the sample donation with the aforementioned data may be passed on pseudonymously to universities, research institutes and research companies for the purposes of medical research
- this may also include passing on data for research projects in countries outside the EU. This is generally permitted if there is an adequacy decision from the European Commission or if officially approved data protection clauses are applied
- furthermore, I consent to the passing on of my donation and data to countries outside the EU even in cases where there is no adequacy decision from the European Commission and no officially approved data protection clauses are applied. I have been informed of the possible risks of such a transfer (Section 7c in the information).

☐ Yes

☐ No

**I agree that I may be contacted again at a later date**

- for the purpose of obtaining further information or a new sample donation,

☐ Yes

☐ No

- for the purpose of obtaining my consent to linking with medical data from other databases,

☐ Yes

☐ No

- for the purpose of providing feedback on important health-related results for me and my pet

☐ Yes

☐ No

This feedback should be provided via the facility in which my pet's sample donation / data was obtained or via the following veterinary doctor (please specify if desired):

Name and address of the veterinary doctor: .....

**I rule out the use of my sample donation for the following research projects:**

\_\_\_\_\_

I have received a copy of the subject information and consent form. The original remains in the veterinary clinic.

\_\_\_\_\_

Name of the owner

\_\_\_\_\_

Place, date and signature of the owner

I have conducted the information session and obtained the consent of the pet owner.

\_\_\_\_\_

Name of the informing doctor

\_\_\_\_\_

Place, date and signature of the veterinary doctor