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## **Pet FMT Project Agreement**

This document is the translation into English of the original document in Italian, carried out using automatic tools. Date and signatures must be affixed to the Italian document.

### **Between**

**EuBiome** Srl, VAT number 05195360283, Piazza Luigi da Porto, 20, cap. 35131 Padua, PD, registration no. in the "Registro Imprese" PD-450438, in the person of the legal representative *pro tempore* Barbara Caterina Eva Simionati (from now on also, for the sake of brevity, *Eu-Biome*)

### **AND**

Name and surname \_\_\_\_\_  
 Entity (optional) \_\_\_\_\_  
 Address\* \_\_\_\_\_  
 City, province and ZIP code\* \_\_\_\_\_  
 VAT number and cf \_\_\_\_\_  
 Register Registration No \_\_\_\_\_  
 (from now on also, *Veterinarian*)

*EuBiome* and the *Veterinarian* also called "*Parties*"

\* relating to the workplace

*Given that*

**EuBiome** is an innovative start-up engaged in research, development, production, and marketing of high-technology products and services supporting, among other fields, microbiomics in the broadest sense, molecular biology, bioinformatics, laboratory automation, and quality control.

- **EuBiome**, in particular, has launched the project called “*Pet FMT Project*”, aimed at the targeted and evidence-based use of fecal microbiota transplantation (FMT) in dogs and cats suffering from chronic enteropathies and atopic dermatitis.
- The *Pet FMT Project* is a research initiative approved by the Animal Welfare Organization of the University of Padua (OPBA), under protocol no. **369551** dated **31/07/2020** for chronic enteropathic animals, and protocol no. **58560** dated **05/04/2023** for animals with atopic dermatitis.
- In order to carry out the *Pet FMT Project*, **EuBiome** intends to rely on the expertise of veterinary facilities operating in Europe.
- The **Veterinarian** is a veterinary practice/outpatient clinic/hospital/freelance professional qualified to provide veterinary services in compliance with the applicable regulations and wishes to participate and collaborate in the *Pet FMT Project*.
- It is the mutual understanding of the Parties, through this Agreement, to act jointly for the purpose of implementing the *Pet FMT Project* described above, under the terms, conditions, and methods set out below.

All this being said, the *Parties* agree as follows.

## **Art. 1 – Effectiveness of premises and annexes**

The preamble and annexes to this Agreement form an integral part of it.

## **Art. 2 – Definitions**

For the purposes of this Agreement, the following terms shall have the meanings set out below:

- **“Research activity”**: the set of research activities conducted by EuBiome, either through its internal and/or external collaborators or through other entities or institutions appointed by EuBiome.
- **“Animal”**: the dog or cat under the direct or indirect care of the Veterinarian, who has provided veterinary services at a clinic, outpatient center, or hospital with which the Veterinarian collaborates, and who will take part in the *Pet FMT Project* upon the decision of the respective Owner.
- **“FMT Pet Kit”**: the set of products and materials described in *Annex A*, which EuBiome provides to the Veterinarian upon request.
- **“Consent form”**: the document referred to in *Annex B* of this Agreement, containing the information that the Veterinarian must provide to the Owner for signature.
- **“Owner”**: the legal owner of the Animal (for dogs, and for cats when applicable, the holder of the corresponding electronic microchip).
- **“Research results”**: any tangible or intangible asset, as well as any knowledge or information obtained during or as a result of the research activities carried out by EuBiome within the framework of the Project, as specified in Article 7.
- **“E-mail”**: unless otherwise specified, refers to the address **info@eubiome.it**.

### Art. 3 – Object

The object of this Agreement is the performance, by EuBiome and the Veterinarian in collaboration with each other, of activities aimed at carrying out research and development within the framework of the *Pet FMT Project*.

### Art. 4 – Activities of the Veterinarian

The Veterinarian shall select the recipient Animal in accordance with the inclusion and exclusion criteria defined in the Pet FMT Project for the relevant recipient category indicated in Annex C, or according to alternative criteria declared by the Veterinarian at the request stage, following his or her professional medical assessment.

The Veterinarian shall inform the Owner by providing the documentation relating to the Pet FMT Project made available by EuBiome, and by offering any additional information deemed useful or appropriate based on his or her professional knowledge and training.

The Veterinarian shall submit to the Owner the Consent Form (Annex B), and, once it has been signed – including consent to data processing – shall forward it to EuBiome together with the related data processing information.

The Veterinarian undertakes to assess the Animal's state of health according to the specific criteria and parameters defined by EuBiome (as described in Annex C), and to transmit to EuBiome the data and information collected (as described in Annex D), after obtaining the Owner's informed consent (Annex B). The Veterinarian also undertakes to update such data on the basis of subsequent monitoring of the Animal's health status, in accordance with the aforementioned criteria.

The Veterinarian, or alternatively the Owner, shall pay EuBiome the agreed amount corresponding to the Pet FMT Kit supplied in support of the Pet FMT Project, upon which EuBiome will issue an invoice and dispatch the materials.

The Veterinarian shall promptly inform EuBiome of any significant changes in the Animal's health condition and/or any unexpected events or symptoms which, in light of the criteria established by EuBiome and/or at the Veterinarian's own discretion, may render the Animal's participation in the Project, or its continuation, unsafe and/or inappropriate. Any adverse effects shall be recorded in a dedicated register.

It is understood that, in performing his or her professional activities, the Veterinarian does not assume any obligations on behalf of EuBiome, nor does he or she represent EuBiome in any capacity, acting at all times solely in his or her own name, on his or her own account, and under his or her own professional responsibility.

#### **Art. 5 - Optional activities of the veterinarian**

The Veterinarian may, if he or she so wishes, share his or her experience with FMT conducted within the Pet FMT Project through public events, blogs, or other means of dissemination, undertaking to give appropriate acknowledgment to the Project itself (e.g., by using the Pet FMT Project logo in informational or presentation materials at conferences, workshops, or study meetings).

Any material co-produced on such occasions may be used by EuBiome for dissemination purposes, without the need for explicit prior authorization, unless the Veterinarian expressly objects. In such cases, or upon the Veterinarian's subsequent written request, EuBiome shall remove the material within 1–2 business days.

The Veterinarian may also, if he or she so wishes, participate in the analysis of the data collected for the purposes of scientific publication.

Furthermore, the Veterinarian may, if he or she so wishes, authorize (by signing at the end of this document) the use of his or her logo on EuBiome's website ([www.eubiome.it](http://www.eubiome.it)) in the Partners section. This authorization may be withdrawn at any time by simple written request via email, and EuBiome shall remove the logo within 1–2 business days.

The Veterinarian may likewise authorize (by signing at the end of this document) the inclusion of his or her name and contact details in the list of veterinary professionals affiliated

with EuBiome for the use of fecal microbiota transplantation within the Pet FMT Project. This list will be publicly available on EuBiome's website ([www.eubiome.it](http://www.eubiome.it)). The authorization may be withdrawn at any time by written email request, and EuBiome shall execute such removal within 1–2 business days.

## Art. 6 - EuBiome's activities

EuBiome shall provide the Pet FMT Kit, specific for dogs or cats, upon request from the Veterinarian and after receipt of payment.

EuBiome shall support the Veterinarian by preparing the documentation and forms to be submitted to the Owner.

EuBiome shall make itself available to respond to any reports and/or requests for information from the Veterinarian and/or the Owner.

EuBiome undertakes to collect and store all data accurately and in compliance with applicable legislation, and to share the results of the analyses and research activities carried out within the framework of the Pet FMT Project, without prejudice to the provisions of Article 7.

## Art. 7 - Duration and withdrawal

This Agreement shall remain in force for an indefinite period and, in any case, for the time necessary to complete the research activities provided for under the Pet FMT Project.

Either Party shall retain the right to withdraw from this Agreement at any time by giving notice to the other Party via certified e-mail and/or e-mail.

## Art. 8 - Search results

The Parties agree that all data and results arising from the research activities conducted by EuBiome within the framework of the Pet FMT Project, as well as any related findings or inventive outcomes, shall be and remain the exclusive property of EuBiome.

EuBiome nevertheless reserves the right to share the data and information generated within the Pet FMT Project with the Veterinarian and the Owner, and, more broadly, with the scientific community through publications and/or by any other means it deems appropriate.

## Art. 9 - Privacy - Data processing

Pursuant to Legislative Decree No. 196 of 30 June 2003, as amended by Regulation (EU) 2016/679 of the European Parliament and of the Council (GDPR), the Parties declare that they are mutually informed that any personal data provided or otherwise collected, even verbally,



in connection with this Agreement shall be processed lawfully and fairly, solely for the purposes set out in this Agreement and in compliance with applicable laws and regulations.

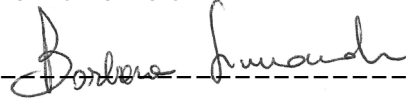
The Parties undertake to treat all data and information obtained from each other in the course of this collaboration as strictly confidential.

**Art. 10 - Disputes**

The Parties agree to make every reasonable effort to settle amicably any dispute that may arise from the performance or interpretation of this Agreement.

If an amicable settlement cannot be reached, the Parties agree that the Court of Padua (Italy) shall have exclusive jurisdiction over any such dispute.

Place and date \_\_\_\_\_

<p>For EuBiome Srl</p>  <p>-----</p>	<p>The veterinarian</p> <p>-----</p>
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## ATTACHMENTS

### **Annex A: Content FMT Pet Kit**

The basic *FMT Pet Kit* (dog or cat) contains:

- 1 container with faecal capsules (no. variable based on the duration of the chosen treatment)
- 2 kits for microbiome analysis (PRE-FMT and POST-FMT)
- the instructions for use
- 2 sample return envelopes

The continuation *Pet FMT Kit* (dog or cat) contains:

- 1 container with faecal capsules (variable no. based on the duration of the chosen treatment)
- 1 kit for microbiome analysis (POST-FMT only)
- the instructions for use
- 1 sample return envelope

### **Attachment B (ext.): Informed consent**

Website

### **Annex C: Enrollment**

#### **Chronic enteropathy**

Dogs or cats with chronic gastrointestinal symptoms (unresponsive/resistant to therapy) for at least 3 weeks or chronically recurring symptoms, possibly with endoscopic and histological diagnosis of chronic enteropathy, resistant or unresponsive to pharmacological therapy, are considered eligible for FMT.

#### **Inclusion** criteria:

- presence of enteric enteropathy demonstrated by classification index **CCECAI** for dogs and that **FCEAI** for cats

Allenspach K. et al., 2007 And Jergens AE et al., 2010

- possible availability to carry out a control period of 2 weeks of daily administration of placebo capsules (empty, i.e. without faecal material), in order to ensure the persistence of the pathology in the absence of any therapy.

#### **Exclusion** criteria:

- parasitic enteropathy
- endocrinopathy
- neoplastic pathologies

## **Atopic Dermatitis**

**inclusion criteria:** dogs or cats that satisfy Favrot's criteria.

### **Dogs**

Satisfaction of **at least 5** of the following Favrot criteria (sensitivity 85.4%, specificity 79.1%):

1. Age of onset less than 3 years
2. Life predominantly in a closed domestic environment
3. Corticosteroid responsive pruritus with a dosage of less than 1mg per kg body weight per day
4. Chronic or recurring yeast infection
5. Forelimbs involved
6. Base of ear affected
7. Outer edge of ear NOT affected by lesions
8. Back-lumbar area unaffected

(Favrot C. et al. A prospective study on the clinical features of chronic canine atopic dermatitis and its diagnosis. *Vet Dermatol.* 2010).

### **Cats**

Fulfilment of 6 of the following Favrot criteria (sensitivity 90%, specificity 83%)

1. At least two body sites involved
2. Presence of itching at onset
3. Presence of at least two of the following clinical pictures:
  - Symmetrical alopecia
  - Miliary dermatitis
  - Eosinophilic dermatitis
  - Erosions/ulcerations of the head and neck
4. Presence of miliary dermatitis as the dominant pattern
5. Presence of eosinophilic dermatitis or symmetrical alopecia or erosions/ulcerations on the head, face, lips, ears or neck
6. Presence of asymmetrical alopecia on the rump, tail or hind limbs
7. Presence of symmetrical alopecia on the abdomen
8. Absence of erosions/ulcerations on the forelimbs
9. Absence of lesions on the sternum or axilla
10. Absence of nodules or tumors

Favrotc. et al. "Establishment of diagnostic criteria for feline nonflea induced hypersensitivity dermatitis." *Veterinary Dermatology* 2012

Before the actual recruitment, all secondary forms of bacterial infection or yeast over-growth must be excluded and possibly treated, according to the protocols reported in the literature.

**Exclusion criteria:** dermatological pathologies not attributable to CAD or FASS

Hensel, P. et al. Canine atopic dermatitis: detailed guidelines for diagnosis and allergen identification. *BMC Vet. Res.* 2015

## **Annex D: Clinical data to be provided (online file)**

### **generals**

- BCS extension
- Fecal SCORE
- current weight and ideal weight
- diagnosis
- nature and frequency of seizures
- drug therapy in progress (antibiotics, anti-inflammatories, immunosuppressants, etc.)
- previous drug therapies
- recent surgeries
- previous surgeries
- type of diet (industrial, homemade, BARF, other)
- supplements and probiotics
- other active pathologies
- other underlying pathologies
- family pathologies
- analyses available related the diagnosis and treatment performed

### **Specific**

Chronic enteropathy

- CCECAI/FCEAI index

Atopic dermatitis

- index CADESI-04 (dog)
- SCORFAD index (cat)