

# **Consent to Participate in a Research Study**

## **Advances in Heart and Lung Sound Capture and Analysis Developing a Database of High Quality Digital Recordings of Canine Heart and Lung Sounds**

### **WHY ARE YOU BEING INVITED TO TAKE PART IN THIS RESEARCH?**

You and your dog are being invited to take part in the first phase of a research study that hopes to develop new and inexpensive diagnostic methods for numerous conditions via acoustic analysis. You are being invited to take part in this research study because you have a generally healthy dog with a routine appointment scheduled during this phase of the study. If you volunteer to take part in this study, your dog will be one of about 50 other dogs to do so.

### **WHO IS DOING THE STUDY?**

Bongiovi Medical and Health Technologies in conjunction with Brighton Animal Clinic is conducting the study. The persons in charge of this study are Daniel Weiss, MD and Kris Montgomery, DVM.

### **WHAT IS THE PURPOSE OF THIS STUDY?**

By conducting this study, we hope to develop a database of high quality, digital recordings of canine heart and lung sounds. Analysis of this data may lead to additional studies concerning the efficacy of various stethoscopes currently in use, and potentially develop techniques using modern digital sound processing to detect various medical conditions in a more rapid and cost-effective manner. This is only phase I of a potential multi-phase study.

### **WHERE IS THE STUDY GOING TO TAKE PLACE AND HOW LONG WILL IT LAST?**

The research will be conducted at the Brighton Animal Clinic and data analyzed in the Medical Acoustics Laboratory of Bongiovi Medical and Health Technologies in Port St. Lucie, Florida. You are being asked to participate in this phase because your dog has an appointment scheduled during the data collection phase and your dog is in generally good health.

Information regarding this study is posted at <http://bongiovimedical.com/small-animal-study>. The owners of dogs of Brighton Animal Clinic that meet the research criteria are being invited to allow their dogs to participate. The research team does not receive any information about you or your dog from Brighton Animal Clinic unless you agree to participate. None of your personal information (Name, Address, etc.) will ever be released to the research team.

### **WHAT WILL YOU BE ASKED TO DO?**

You will be asked to let two Veterinarian Technicians take your dog into an examination room and, using a digital electronic stethoscope, record the heart and lungs sounds of your dog. You are also asked to sign this consent form.

### **WHAT ARE THE POSSIBLE RISKS AND DISCOMFORTS?**

This is a non-invasive test. To the best of our knowledge there is no specific medical risk to participate in this study. There are no anticipated discomforts.

### **WILL YOU BENEFIT FROM TAKING PART IN THIS STUDY?**

You may not get any personal benefit from taking part in this study. However you may help us to develop techniques that will lead to earlier diagnoses of various conditions at less cost. This research is applicable not only to Veterinary medicine but to Human medicine also.

### **DO YOU HAVE TO TAKE PART IN THE STUDY?**

If you decide to take part in the study, it should be because you really want to volunteer your dog. You will not lose any benefits or rights you would normally have if you choose not to volunteer. You can stop at any time during the study and still keep the benefits and rights you had before volunteering. If you decide not to take part in this study, your decision will have no effect on the quality of veterinarian care you receive.

### **IF YOU DON'T WANT TO TAKE PART IN THE STUDY, ARE THERE OTHER CHOICES?**

If you do not want to be in the study, there are no choices except not to take part in the study.

### **WHAT WILL IT COST YOU TO PARTICIPATE?**

You will not be responsible for the costs of this study. There is no cost to you, other than a few minutes of your time.

### **WHO WILL SEE THE INFORMATION GATHERED?**

We will keep all research records private. No personal information about you is gathered during this study. The information about your dog and its heart and lungs sounds will be combined with information from other dogs taking part in the study. When we write about the study to share it with the research team, we will write about the combined information we have gathered. You and your dog will not be personally identified in these written materials. We may publish the results of this study.

We will make every effort to prevent anyone who is not on the research team from knowing that you gave us information, or what that information is. The data will be stored on a secure computer. Your dog will only be identified by a number. None of your personal information will be stored with the research data. Only a Veterinarian at Brighton Animal Clinic will be able to identify your dog and you.

### **CAN YOUR TAKING PART IN THE STUDY END EARLY?**

If you decide to take part in the study you still have the right to decide at any time that you no longer want to continue. You will not be treated differently if you decide to stop taking part in the study.

### **WHAT HAPPENS IF YOUR DOG GETS HURT OR SICK DURING THE STUDY?**

Since all we are doing is recording the heart and lung sounds of your dog, we do not foresee any problems during this study, but if you believe your dog got hurt or sick because of something that is related to the study, you should call Dr. Kris Montgomery at (859) 543-1583 immediately. Dr. Montgomery, will determine what type of treatment, if any, is best for your dog at that time.

It is important for you to understand that the Brighton Animal Clinic and Bongiovi Medical and Health Technologies does not have funds set aside to pay for the cost of any care or treatment that might be necessary because your dog got hurt or sick while taking part in this study. You do not give up your legal rights by signing this form.

**WILL YOU RECEIVE ANY REWARDS FOR TAKING PART IN THIS STUDY?**

You will receive no rewards, but Bongiovi Medical and Health Technologies will contribute \$1 for every dog that participates to the Lexington Humane Society.

**WHAT IF YOU HAVE QUESTIONS, SUGGESTIONS, CONCERNS, OR COMPLAINTS?**

Before you decide whether to take part in the study, please ask any questions that might come to mind. Later, if you have questions, suggestions, concerns, or complaints about the study, you can contact the investigators, Daniel Weiss, MD and Kris Montgomery, DVM by email: [SmAnimalStudy@bmhtllc.com](mailto:SmAnimalStudy@bmhtllc.com). We will return a signed copy of this consent form for your own records. You may also report your concerns to Glenn Yeaw, COO, Bongiovi Medical and Health Technologies, 649 S.W. Whitmore Dr., Port Saint Lucie, FL 34984, Phone: (772) 284-3136, Fax (772) 879-0028, or email: [Glenn@bmhtllc.com](mailto:Glenn@bmhtllc.com)

**WHAT IF NEW INFORMATION IS LEARNED DURING THE STUDY THAT MIGHT AFFECT MY DECISION TO PARTICIPATE?**

If the researcher learns of new information in regards to this study, and it might change your willingness to stay in this study, the information will be provided to you. You may be asked to sign a new consent form if the information is provided to you after you have joined the study.

Data acquired during this study may have some commercial value. By signing this consent form, you give up all rights to any commercial application related to data obtained during your participation in this research project.

\_\_\_\_\_  
Signature of dog owner person agreeing to take part in the study

\_\_\_\_\_  
Date

\_\_\_\_\_  
Printed name of dog owner agreeing to take part in the study

\_\_\_\_\_  
Name of [authorized] person obtaining informed consent

\_\_\_\_\_  
Date

\_\_\_\_\_  
Signature of Investigator