Vanderbilt University Institutional Review Board
Informed Consent Document for Research

Principal Investigator: Mary Jo Gilmer, PhD, MBA, RN-BC, FAAN **Revision Date: Sept 18, 2019**

Study Title: Effects of Animal-Assisted Interactions (AAI) on Quality of Life in Children with Life-Threatening Conditions and their Parents

Institution/Hospital: Vanderbilt University Medical Center

This informed consent document applies to Parent/ Legal Guardian

Name of participant:_____ Age: _____

The following information is provided to inform you about the research project and your child's participation in it. Please read this form carefully and feel free to ask any questions you may have about this study and the information given below. You will be given an opportunity to ask questions, and your questions will be answered. Also, you will be given a copy of this consent form.

This study is voluntary. You are also free to withdraw your child from this study at any time. If new information becomes known, that affects the risks or benefits linked with this study or your child's choice to take part in it, you will be told so that you can make a decision whether or not to continue your child's participation in this study.

If you are a parent or legal guardian of a child who may take part in this study, permission from you is required. The assent (agreement) of your child may also be needed if she/he is between seven and seventeen years of age. When we say "your child" in this consent form, we mean your child who has been diagnosed with cancer; "we" means the researchers and/or hospital staff.

1. **Purpose of the study:**

   The purpose of this study is to see if having animal-assisted interactions (AAI) visits on a routine basis with a trained animal-handler and his/her dog makes the cancer treatment process less stressful for you and your child.

   The number of people enrolled in this study is expected to be fewer than 135, locally.
   You are being asked, as the parent and/or legal guardian of this child, to allow your child to take part in this study because your child is between the ages of 3 and 17 and has been diagnosed with cancer.

2. **Procedures to be followed and approximate duration of the study:**
   Kids participating in the study will continue to receive their treatment for cancer. Once you have provided consent for your child to take part in this study, your child will be randomly chosen to be in either our "usual care" group or our "animal-assisted interactions" group.

   Participants enrolled in the "usual care" group of our study will be asked to do the following:
   - Complete several short surveys about your family.
   - During no more than 12 sessions over the next three months:
     - Complete the STAI, the Pediatric Inventory for Parents (PIP) the Pediatric Quality of Life (Peds QoL) surveys. The STAI survey takes about 5 minutes; the PIP takes 5-10 minutes and the Peds QoL takes about 5-10 minutes to finish. The survey questions can be given to you if you would like to see them.

Participants enrolled in the "animal-assisted interaction" group of our study will be asked to do the following:

- Complete several short surveys about your family.
- Take part in AAI sessions each week for up to 15 minutes when you come to the hospital or clinic.
- During no more than 12 treatment sessions over the next four months:
  - Have your child's blood pressure taken at the beginning and end of a session where the therapy dog is present.

•Complete the STAI, the Pediatric Inventory for Parents (PIP)the Pediatric Quality of Life (Peds QoL) surveys. The STAI survey takes about 5 minutes; the PIP takes 5-10 minutes and the Peds QoL takes about 5-10 minutes to finish. The survey questions can be given to you if you would like to see them.

- Allow your child's sessions with the therapy dog videotaped so that we can observe the therapy dog's behavior during the session.
- Assist your child in providing saliva samples for analysis

3. **Expected costs:**
The only cost to you for taking part in this study is your time.

4. **Description of the discomforts, inconveniences, and/or risks that can be reasonably expected as a result of participation in this study:**
There are few risks linked with being in this study. The risks to being in this study are the release of information while being videotaped; however, there are measures in place to protect this information and are described later in this document. Your child may feel some discomfort from having the blood pressure cuff put on them or from collecting the saliva samples.

If you are chosen to take part in the "animal-assisted interactions" group, you will never be left alone with the therapy dog and its handler. Even with the training and experience that therapy dogs and animal-handlers have, small risks may still be linked with the therapy animal visits. These risks may include potential injury (such as from a bite or scratch), as is the case in any interaction between humans and animals. Allergic reactions are another potential risk, especially if your child or other members of the family who may be with her/him have a history of animal allergies.

If you are chosen to take part in the "usual care" group, you may not have regular access to a therapy dog.

One other risk to you and/or your child is the possible demand of you and your child's time in attending sessions and answering the surveys listed above.

In addition to these risks above, there may be risks that are not known, or risks that we did not know of, linked with being in the study.

5. **Unforeseeable risks:**
There may be risks that are not known with being in this study. You will be told of any big findings we learn about this study if we think it may change your mind about taking part in the study.

6. **Compensation in case of study-related injury:**
If it is determined by Vanderbilt and the Investigator that an injury occurred as a direct result of the tests or treatments that are done for research, then you and/or your child's insurance will not have to pay for the cost of immediate medical care provided at Vanderbilt to treat the injury.

There are no plans for Vanderbilt to pay for the costs of any additional care. There are no plans for Vanderbilt to give you money for the injury.

7. **Good effects that might result from this study:**
If you are in the "animal-assisted interaction group, we anticipate that you and your child will benefit from having visits with the therapy dog. Studies have shown that animals can be entertaining and promote relaxation and comfort during stressful events.

If you are in either the "animal-assisted interaction" group or the "usual care" group, the benefit of this study is that we will be able to collect data about the stress that families feel while taking part in childhood cancer treatment, as well as see if animal-assisted therapy can help lower the amount of stress that is felt.

We expect that the information learned from this study will benefit other patients in the future.

8. **Alternative treatments available:**
This is not a treatment study. You can choose not to take part.

9. **Compensation for participation:**
Compensation is being offered only to participants randomized to the "usual care" group. We will send gift cards via email in the amounts of $10 for each session and $50 at the conclusion of the study.

10. **Circumstances under which the Principal Investigator may withdraw you from study participation:** We do not see any reasons that would cause you to be taken out of this study; but if you are, you will be told why.

11. **What happens if you choose to withdraw from study participation:**
If you or your child decides not to take part in this research study, it will not affect your child's treatment, payment or enrollment in any health plans or affect your child's ability to get benefits. Furthermore, if you or your child's child should choose to withdraw from the study, no more data will be collected. However, we will use any previously collected data prior to study withdrawal for our data analysis. Data will be destroyed following the completion of all data analyses.

12. **Contact Information.**
If you should have any questions about this research study or possibly injury, please feel free to contact **Dr. Mary Jo Gilmer** at **615-343-0938.**

For additional information about giving consent or your rights as a participant in this study, to discuss problems, concerns and questions, or to offer input, please feel free to contact the Vanderbilt University Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

13. Confidentiality:

All efforts, within reason, will be made to keep your child's personal information in your child's research record confidential but total confidentiality cannot be guaranteed. The data collected will be stored by the research team and only the research team will have access to it. After the audio-recorded discussion has been transcribed, the audio-tapes and transcriptions will be stored in a locked filing cabinet. Participants in the research study will be asked to keep the identity of the other participants and the nature of the discussion confidential. However, there is no way to ensure that this will be done. Participants will not be asked to disclose protected health information (PHI) and will be instructed that they do not have to answer any question that makes them uncomfortable.

Any personal information in your child's medical record and the information collected for the purposes of this study will be kept confidential. However, we cannot guarantee total privacy. Your child's or your child's personal information may be given out if required by law. If information from this study is published or presented at scientific meetings, your child's name, your child's name, other personal information, or any other way that you and your child's family can be publically identified will not be used.

If you agree to take part in this study, you may be videotaped even though your child and the dog will be the main focus of the taping. We will ensure that only research staff members will have access to the videotapes. The videos will be recorded for a maximum of 15 minutes each session for no more than 12 sessions. Once the treatment session has ended and/or the therapy dog has left the room, the camera will be turned off by a member of the research team and no further video footage will be recorded. The video tapes will only be used for the purposes of the research to observe and record the behavior of your child's behavior and/or the therapy dog.

All of the data collected for this study, including the videotapes, will be kept on password protected computers located in a locked room at each hospital site; only research staff and animal-handlers (accompanied by a research team member) will have access to these rooms and computers. Any paper copies of the data will be kept in a locked file cabinet maintained within a locked room at each hospital site; only the research team will have access to these rooms and file cabinets.

14. Privacy of Protected Health Information:

All efforts, within reason, will be made to keep your child's protected health information (PHI) private. PHI is your child's health information that is, or has been gathered or kept by Vanderbilt as a result of your child's healthcare. This includes data gathered for research studies that can be traced back to you or your child. An example of your child's PHI is your child's diagnosis (e.g., acute lymphoblastic leukemia). Using or sharing ("disclosure") such data must follow federal privacy rules. By signing the consent for this study, you are agreeing ("authorization") to the uses and likely sharing of your child's PHI. If you decide to be in this research study, you are also agreeing to let the study team use and share your child's PHI as described below.

As part of the study, Dr. Mary Jo Gilmer and her study team may share the results of your child's study and/or non-study linked information as well as parts of your child's medical record, to the groups named below. Your information may be shared with Vanderbilt or the government, such as the Vanderbilt University Institutional Review Board, Federal Government Office for Human Research Protections, and the National Institutes of Health. If you or someone else is in danger or if we are required to do so by law. [INSERT IF SHARING DATA] Vanderbilt may give or sell your data without identifiers for other research projects not listed in this form. There are no plans to pay you for the use or transfer of this de-identified information. Federal privacy rules may not apply to these groups; they have their own rules and codes to assure that all efforts, within reason, will be made to keep your child's PHI private.

A description of this clinical trial will be available on http://www.ClinicalTrials.gov, as required by U.S. Law. This Web site will not include information that can identify you. At most, the Web site will include a summary of the results. You can search this Web site at any time.

The sponsor and/or Vanderbilt may give or sell your child's health data, without identifiers, to others or use it for other research projects not listed in this form. The sponsor, Vanderbilt, Dr. Gilmer and her staff will comply with any and all laws regarding the privacy of such information. There are no plans to pay you for the use or transfer of this de-identified information.

The study results will be kept in your child's research record for at least six years after the study is finished. At that time, the research data that has not been put in your child's medical record will be kept for an unknown length of time. Any research data that has been put into your child's medical record will also be kept for an unknown length of time.

Unless told otherwise, your child's consent to use or share your child's PHI does not expire. If you change your mind, we ask that you contact Dr. Gilmer in writing and let her know that you withdraw your child's consent. Her mailing address is 417 Godchaux Hall, Vanderbilt University School of Nursing, 461 21st Ave South, Nashville, TN 37240. At that time, we will stop getting any more data about you. But, the health data we stored before you withdrew your child's consent may still be used for reporting and research quality.

If you decide not to take part in this research study, it will not affect your child's treatment, payment or enrollment in any health plans or affect your child's ability to get benefits. You will get a copy of this form after it is signed.

STATEMENT BY PERSON AGREEING TO TAKE PART IN THIS STUDY

I have read this informed consent document and the material contained in it has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in

_____ _____
Date Signature of patient/volunteer

Consent obtained by:

_____ _____
Date Signature

_____
Printed Name and Title

This study would like to asked permission to possibly use brief sections of the video when presenting findings from this study at a research conference.

_____Yes, you have my permission to show portions of the video recording to researchers at a conference.

_____No, I would prefer you do not show any portion of the video recording from my assisted therapy session to anyone outside the research team in this study.