Assent 13-17

Please complete the survey below.

Thank you!

NCT04310345

Institutional Review Board
Assent Document for Research Study
Study Title: Exploring the Impact of Human-Animal Interactions on Children with Life-Threatening Conditions and their Parents
Principal Investigator: Mary Jo Gilmer, PhD, MBA, RN-BC, FAAN
Institution/Hospital: Vanderbilt University Medical Center

Version Date: January 27, 2021
IRB Approval Date: Pending
IRB Expiration Date: Pending

This assent document applies to: children 13-17 years of age

1) Name of participant _____

2) Age _____

The following information is provided to inform you about the research project and your 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.

Key information about this study:
You are being asked to take part in this study because you are between the ages of 8 and 17 and are sick.

You do not have to be in this research study. You may choose not to be in this study. You can stop being in this study at any time. If we learn something new that may affect the risks or benefits of this study, you will be told, so that you can decide whether or not you still want to be in this study.

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

Procedures to be followed and approximate duration of the study:
Children participating in the study will continue to receive their treatment for cancer. Participants enrolled in 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 3 treatment sessions over the next two months:
o Have your blood pressure taken at the beginning and end of a session where the therapy dog is present.
o Complete the State/Trait Anxiety Inventory (STAI), the PROMIS depression survey, the Pediatric Quality of Life (Peds QoL) survey, and a brief survey on the impact of the COVID-19 pandemic. The surveys take about 30-45 minutes. The survey questions can be given to you if you would like to see them.
o Have your sessions with the therapy dog videotaped so that we can observe the therapy dog's behavior during the session.
o Provide saliva samples for analysis.
o A small amount of blood (about ½ tsp) taken during routine port access will also be analyzed for norepinephrine and epinephrine. Respond to interview questions about your family's experience with the COVID-19 pandemic, which will take 15-20 minutes and will be audio-recorded. Respond to interview questions at the end of the study, which will take about 10-20 minutes and will be audio-recorded.

3) I give permission to have a small amount of blood (about ½ tsp) drawn during routine port access to be analyzed for norepinephrine and epinephrine.

○ Yes
○ No

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

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. You may feel some discomfort from having the blood pressure cuff put on or from collecting the saliva samples. There may be some inconvenience in collecting the urine specimens.

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 you or other members of the family who may be with you have a history of animal allergies.

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

Unforeseeable risks: 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.

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 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 or National Institutes of Health (NIH) to pay for any injury caused by the usual care you would normally receive for treating your illness or the costs of any additional care. There are no plans for Vanderbilt or NIH to give you money for the injury.

Good effects that might result from this study:
a) The benefits to science and humankind that might result from this study. We expect that the information learned from this study will benefit other patients in the future. Another benefit of this study is that we will be able to collect data about the stress that families feel while taking part in treatments, as well as see if animal-assisted therapy can help lower the amount of stress that is felt.
b) The benefits you might get from being in this study. We anticipate that you 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.

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

Compensation for participation: No compensation other than the animal-assisted interactions is being offered.

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.

What happens if you choose to withdraw from study participation? if you decide not to take part in this research study, it will not affect your treatment, payment or enrollment in any health plans, or affect your ability to get benefits. Furthermore, if you 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.

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 [redacted]

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 Institutional Review Board Office at (615) 322-2918 or toll free at (866) 224-8273.

Confidentiality: All efforts, within reason, will be made to keep your personal information in your 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 medical record, and the information collected for the purposes of this study, will be kept confidential. However, we cannot guarantee total privacy. Your personal information may be given out if required by law. if information from this study is published or presented at scientific meetings, your name and other personal information, or any other way that you and your family can be publicly identified, will not be used.

If you agree to take part in this study, you may be videotaped and you and the dog will be the main focus of the taping. We will ensure that only [illegible] access to the videotapes. The videos will be recorded for a maximum of 15 minutes each session, for no more than 3 sessions. Once the treatment session has ended and/or the therapy dog has left

the room, the camera will be turned off by amember 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 your 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.

Certificate of Confidentiality: This research is covered by a Certificate of Confidentiality from the National Institutes of Health. This means that the researchers cannot release or use information, documents, or samples that may identify you in any action or suit unless you say it is okay. They also cannot provide them as evidence unless you have agreed. This protection includes federal, state, or local civil, criminal, administrative, legislative, or other proceedings. An example would be a court subpoena.

There are some important things that you need to know. The Certificate DOES NOT stop reporting that federal, state or local laws require. Some examples are laws that require reporting of child or elder abuse, some communicable diseases, and threats to harm yourself or others. The Certificate CANNOT BE USED to stop a sponsoring United States federal or state government agency from checking records or evaluating programs. The Certificate DOES NOT stop disclosures required by the federal Food and Drug Administration (FDA). The Certificate also DOES NOT prevent your information from being used for other research if allowed by federal regulations.

Researchers may release information about you when you say it is okay. For example, you may give them permission to release information to insurers, medical providers or any other persons not connected with the research. The Certificate of Confidentiality does not stop you from willingly releasing information about your involvement in this research. It also does not prevent you from having access to your own information.

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

As part of the study, Dr. Mary Jo Gilmer and her study team may share the results of the study and/or non-study linked information as well as parts of your medical record, to the groups

named below.

These groups may include people from the Federal Government Office for Human Research Protections, the Vanderbilt University Institutional Review Board, and the National Institutes of Health. 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 PHI private.

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

The sponsor and/or Vanderbilt may give or sell your 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 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 medical record will be kept for an unknown length of time. Any research data that has been put into your medical record will also be kept for an unknown length of time.

Unless told otherwise, your consent to use or share your 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 consent.

Her mailingaddress is [redacted] At that time, we will stop getting any more data about you. The health data we stored before you withdrew your consent may still be used for reporting and research quality.

STATEMENT BY PERSON AGREEING TO PARTICIPATE 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 participate.

4) Date:

(Click "Today" button.)

5) Signature of patient/volunteer

(Click "Add signature" and use your mouse (or finger on a touchscreen device) to sign.)

6) Consent obtained by (please enter full name and title):