Health Sciences Informed Consent

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VUMC Institutional Review Board

Informed Consent Document for Research Study Title: Testing for Pain, Stress, and Affect in the Infusion Clinic

PI: Cody Stansel

Version Date: 07/29/2021

Date of IRB Approval: [INSERT APPROVAL DATE EXACTLY MATCHING IRB STAMP after obtaining approval]

Date of IRB Expiration: [INSERT EXPIRATION DATE EXACTLY MATCHING IRB STAMP after obtaining approval, if applicable]

1) Name of Participant:

_____
(First Last)

2) Age:

_____

The following is given to you to tell you about this research study. Please read this form with care and ask any questions you may have about this study. Your questions will be answered. Also, you will be given a hard copy of this consent form.

Key Information: The first section of this document contains some key points that the research team thought you would find important. The study is described in more detail after this section. If you do not understand something, please ask someone.

Key information about this study:

The purpose of this study is to investigate your experience in the outpatient infusion clinic. This study involves randomization. Randomization is assignment by chance, similar to flipping a coin. Participants will be randomized 1:1, with an equal chance of being in each cohort. Participating in this study may/may not benefit your stress, pain, and/or affect. Risks of participating in this study may include an increase in some of the negative symptoms (e.g. nausea) that patients are already experiencing due to their cancer therapy and/or a loss of confidentiality. This study will only require approximately 30 minutes of your time in the infusion clinic. This will consist of three surveys and heart rate measurements using a pulse oximeter. Your medical records will also be accessed to record the specific therapy and medication you are receiving and your date of birth.

Detailed Information:The rest of this document includes detailed information about this study (in addition to the information listed above).

You are being asked to take part in this research study to help build a better understanding of the patient experience in the out-patient infusion clinic with regards to pain, stress, and affect.

You do not have to be in this research study and can stop being in this study at any time.

Side effects and risks that you can expect if you take part in this study:

Side effects with regards to participation in this study are minimal and have not been observed in pre-clinical testing. However, in rare instances, participation in the study could exacerbate some of the negative side effects (e.g. nausea) that patients are already experiencing due to chemotherapy treatment. To mitigate this, you can withdraw from the study at any time. Additionally, a risk of participating in this study is a potential loss of confidentiality.

Risks that are not known:

Because this study is novel, there may be risks that we do not know about at this time.

Good effects that might result from this study:

Participation in this study could positively impact your pain, stress, and/or affect. Additionally, your participation in this study could further the understanding of the patient experience within outpatient infusion clinics. However, you may receive no benefit from participating in this study.

Procedures to be followed:

This study will be conducted in the infusion clinic while you are receiving your standard therapy. This study will not interfere with your treatment schedule in any way. All surveys will be completed digitally on a tablet. First, a study personnel will approach you to determine if you are eligible to participate in this study based on a short pre-screening survey. If you are eligible, you will be asked to consent to this study. Upon consenting to this study, you will be randomized into one of two cohorts. In both cohorts, you will participate in an 11 minute experience during your infusion treatment. You will also complete three surveys. The first survey will collect your demographics. The following two surveys will be a pre-experience and a post-experience survey. Additionally, your heart rate will be measured two times using a pulse oximeter, a commonly used and non-invasive device. General information, including your demographics, the therapy you are currently receiving, and prescribed medications, will also be recorded from your medical records.

Costs to you if you take part in this study:

There is no cost to you or your insurance for taking part in this study.

Who to call for any questions or in case you are injured:

If you should have any questions about this research study or if you feel you have been hurt by being a part of this study, please feel free to contact Cody Stansel at (615) 322-7462.

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

What will happen if you decide to stop being in this study?

Your participation in this study will not affect your clinical care. If you decide to stop being part of this study, you should inform the study personnel conducting the study with you or your nurse in the infusion clinic. You may withdraw at any time during the study if you feel uncomfortable with any aspect of the experience. In the case that you decide to withdraw consent, the records that you have already provided will be de-identified and stored. You will not be required to complete the remainder of the study.

Privacy/Confidentiality:

All reasonable efforts will be made to keep a patient's protected health information (PHI) private and confidential. There will be limited access to electronic medical records and de-identification of all records. Federal privacy guidelines will be followed when using or sharing any protected health information.

To protect the privacy of patients, all participants will be assigned a unique identifier (e.g., number) for data storage. In addition, data will be stored on REDCap's secured encrypted SQL server with limited access (the PI of this study and sub-investigators may access the data). Data from the study will be reported only in the aggregate.

All study staff have completed employee education regarding patient confidentiality and have completed Human Subjects protection education (CITI course) as specified by the Vanderbilt IRB.

Through these interventions, we expect risks to privacy and confidentiality to be minimized.

Study Results:

In the event that the data from this study gets published in the future, the publication will be shared with participants of the study.

Authorization to Use/Disclose Protected Health Information

All efforts, within reason, will be made to keep your protected health information (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. 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 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, Vanderbilt University Medical Center may share the results of your study and/or non-study linked treatment regimen, 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 VUMC Institutional Review Board, and Vanderbilt University. 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.

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 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 Cody Stansel in writing and let him know that you withdraw your consent. His mailing address is 2955 The Vanderbilt Clinic, 1301 Medical Center Drive, Nashville, TN 37232-5536. At that time, we will stop getting any more data about you. But, the health data we stored before you withdrew your 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 treatment, payment or enrollment in any health plans or affect your ability to get benefits. You will get a copy of this form after it is signed.

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STATEMENT BY PERSON AGREEING TO BE IN THIS STUDY

3) I have read this consent form and the research study has been explained to me verbally. All my questions have been answered, and I freely and voluntarily choose to take part in this study.

◯ Yes ◯ No

4) Date:

_____
(Date of Volunteer Signature)

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):

_____

7) Date and Time:

_____
(Date and time of staff signature.)

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◯ Yes ◯ No

4) Date:

_____
(Date of Volunteer Signature)

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):

_____

7) Date and Time:

_____
(Date and time of staff signature.)