



## Informed Consent

### INFORMED CONSENT/AUTHORIZATION FOR PARTICIPATION IN RESEARCH

There is no place like home- A Pragmatic Effectiveness Trial of Technology-enhanced Outpatient Symptom Management to Reduce Acute Care Visits due to Chemotherapy-related Adverse Events

2020-0702

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**Subtitle:** There is no place like home

Study Chair: Anaeze C. Offodile II, MD

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Participant's Name

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Medical Record Number

This is an informed consent and authorization form for a research study. It includes a summary about the study. A more detailed description of procedures and risks is provided after the summary.

#### STUDY SUMMARY

The goal of this research study is to learn if telemedicine and remote patient monitoring (RPM) can help cancer patients have better outcomes (such as fewer avoidable Emergency Room [ER] visits and hospitalizations, better quality of life, fewer symptoms, and fewer treatment delays) than those who receive usual care.

This study will be performed while you are receiving chemotherapy, and is being done to track how you respond to chemotherapy using these 2 different methods. The chemotherapy you receive will not be affected by your participation in this study.

**This is an investigational study.**

Taking part in this study may help improve your outcomes during and after chemotherapy. There may be no benefits to you on this study. Future patients may benefit from what is learned.

Your participation is completely voluntary. Before choosing to take part in this study, you should discuss with the study team any concerns you may have, including side effects, potential expenses, and time commitment. It is possible that wearing or being monitored

by the sensing devices (described later) may cause you to become upset, annoyed or distressed.

You can read a full list of potential side effects below in the Possible Risks section of this consent.

Your participation in the study will be over the course of 2 cycles of chemotherapy (up to 6 months).

There will be no cost to you for taking part in this study.

You may choose not to take part in this study.

## 1. STUDY DETAILS

Up to 600 patients receiving chemotherapy at MD Anderson will be enrolled in this study.

If you agree to take part in this study, you will be randomly assigned (like flipping a coin) to 1 of 2 groups:

- If you are in Group 1, you will receive the standard of care.
- If you are in Group 2, you will receive remote monitoring in addition to the standard of care.

You will have an equal chance of being in either group.

All patients in this study will complete questionnaires at the beginning of the study and at the end of each chemotherapy cycle. The questionnaires will be about your quality of life and your engagement in your own health care. The questionnaires should take between 15-20 minutes to complete. The questionnaires may be done over phone or email.

**If you are in Group 2**, you will receive the following RPM devices from Vivify to use at home:

- A blood pressure device to check your blood pressure and heart rate
- A weight scale to measure your weight
- A pulse oximeter to measure blood oxygen saturation
- A thermometer to measure body temperature
- A tablet computer to type in answers to questions about your chemotherapy symptoms. You will answer these questions every day while you are on study.

You will receive training about how to use these devices. You will be asked to use the devices each day during your chemotherapy treatment. It should take about 10-15 minutes to complete the tasks above each day. The study staff will call you after you initially receive the devices to make sure that they are working and will respond to any calls that you may have if you encounter device problems. After each chemotherapy

cycle, you will also be asked questions about how easy the devices were to use, and whether you encountered any problems using them.

The devices will electronically send encrypted (scrambled) information collected from you to a cloud-based platform that is managed by VivifyHealth, a private company that has contracted with MD Anderson to provide remote monitoring devices and services for patients.

MD Anderson staff in the patient call center will view this information using a secure, password-protected website. If the information indicates that you may be experiencing a medical problem, the staff will attempt to contact you by phone or text message.

After completion of your planned treatment cycles, all devices will be returned to the study staff or to VivifyHealth using pre-paid mail.

No matter which group you are assigned to, you will still receive the standard of care, which involves education for you and/or your primary caregiver about chemotherapy. In-person and video follow-up visits with the treating oncology team will be scheduled with you.

During the study, researchers may call to collect additional information about any ER visits or hospitalizations that you may have had. These calls should take about 5-10 minutes each time.

Information about your cancer diagnosis and treatment from your medical record will also be collected and stored in an electronic password-protected research database, which will be accessible only by the study staff. This information will help the study staff understand how the remote monitoring group participants are different, if at all, from those in the standard of care group. Any information that could be used to identify you will not be used. Only information about the group will be used in any publications. You will be asked to provide permission to access medical records if you have an ER visit or are hospitalized outside of MD Anderson.

If you have a caregiver, you will be asked if the study staff can contact him/her to take part in this study. Caregivers will be asked to complete the questionnaires about quality of life and caregiver burden at the beginning of the study and at the end of each chemotherapy cycle. If you have a caregiver who takes part in the study and who completes the questionnaire, the caregiver's questionnaire responses will be linked with your data for analysis.

## 2. POSSIBLE RISKS

While on this study, you are at risk for side effects. You should discuss these with the study staff. The known side effects are listed in this form, but they will vary from person to person.

The **questionnaires** may contain questions that are sensitive in nature. You may refuse to answer any question that makes you uncomfortable. If you have concerns after completing any questionnaire, you are encouraged to contact the study staff.

Using the **study devices** (for example, the blood pressure device) should not take the place of your normal medical care, because the measurements may not always be accurate. If you become concerned about a device reading or a symptom you may be having, it is important that you contact your regular doctor as you typically would.

If any device is stolen or damaged, you will not have to pay for it. However, you must report the loss to the study staff right away. Please note that once you return the devices, any of your information that is stored on them will be deleted.

Using the **internet** for certain purposes outside of this study may put you at risk for identify theft. You should be careful in providing personal information on other websites.

Although every effort will be made to keep study data safe, there is a chance that your **personal health information** could be lost or stolen. All study data will be stored in password-protected computers and/or locked file cabinets. There will be no personal identifying information connected to your questionnaire answers. There are no plans to destroy the study data.

This study may involve unpredictable risks to the participants.

### 3. COSTS AND COMPENSATION

If you suffer injury as a direct result of taking part in this study, MD Anderson health providers will provide medical care. However, this medical care will be billed to your insurance provider or you in the ordinary manner. You will not be reimbursed for expenses or compensated financially by MD Anderson for this injury. You may also contact the Chair of MD Anderson's IRB at 713-792-6477 with questions about study-related injuries. By signing this consent form, you are not giving up any of your legal rights.

There are no plans to compensate you for any patents or discoveries that may result from your participation in this research.

You will receive no compensation for taking part in this study.

### **Additional Information**

4. You may ask the study chair (Dr. Anaeze Offodile, at 713-563-6785) any questions you have about this study. You may also contact the Chair of MD Anderson's Institutional Review Board (IRB - a committee that reviews research studies) at 713-792-6477 with any questions that have to do with this study or your rights as a study participant.

5. You may choose not to take part in this study without any penalty or loss of benefits to which you are otherwise entitled. You may also withdraw from participation in this study at any time without any penalty or loss of benefits. If you decide you want to stop taking part in the study, it is recommended for your safety that you first talk to your doctor. If you withdraw from this study, you can still choose to be treated at MD Anderson.
6. This study or your participation in it may be changed or stopped without your consent at any time by the study chair, the U.S. Food and Drug Administration (FDA), the Office for Human Research Protections (OHRP), or the IRB of MD Anderson.
7. You will be informed of any new findings or information that might affect your willingness to continue taking part in the study, including the results of all of your standard tests performed as part of this research, and you may be asked to sign another informed consent and authorization form stating your continued willingness to participate in this study.

## **Future Research**

### **Data**

Your personal information is being collected as part of this study. These data may be used by researchers at MD Anderson and/or shared with other researchers and/or institutions for use in future research.

Before being used or shared for future research, every effort will be made to remove your identifying information from any data. If all identifying information is removed, you will not be asked for additional permission before future research is performed.

In some cases, all of your identifying information may not be removed before your data are used for future research. If future research is performed at MD Anderson, the researchers must get approval from the Institutional Review Board (IRB) of MD Anderson before your data can be used. At that time, the IRB will decide whether or not further permission from you is required. The IRB is a committee of doctors, researchers, and community members that is responsible for protecting study participants and making sure all research is safe and ethical.

If this research is not performed at MD Anderson, MD Anderson will not have oversight of any data.

### **Authorization for Use and Disclosure of Protected Health Information (PHI):**

- A. During the course of this study, MD Anderson will be collecting and using your PHI, including identifying information, information from your medical record, and study results. For legal, ethical, research, and safety-related reasons, your doctor and the research team may share your PHI with:
  - Federal agencies that require reporting of clinical study data (such as the FDA, National Cancer Institute [NCI], and OHRP)
  - The IRB and officials of MD Anderson

- VivifyHealth
  - Study monitors and auditors who verify the accuracy of the information
  - Individuals who put all the study information together in report form
- B. Signing this consent and authorization form is optional but you cannot take part in this study or receive study-related treatment if you do not agree and sign.
- C. MD Anderson will keep your PHI confidential when possible (according to state and federal law). However, in some situations, the FDA could be required to reveal the names of participants.

Once disclosed outside of MD Anderson, federal privacy laws may no longer protect your PHI.

- D. The permission to use your PHI will continue indefinitely unless you withdraw your authorization in writing. Instructions on how to do this can be found in the MD Anderson Notice of Privacy Practices (NPP) or you may contact the Chief Privacy Officer at 713-745-6636. If you withdraw your authorization, you will be removed from the study and the data collected about you up to that point can be used and included in data analysis. However, no further information about you will be collected.
- E. 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.

**CONSENT/AUTHORIZATION**

I understand the information in this consent form. I have had a chance to read the consent form for this study, or have had it read to me. I have had a chance to think about it, ask questions, and talk about it with others as needed. I give the study chair permission to enroll me on this study. By signing this consent form, I am not giving up any of my legal rights. I will be given a signed copy of this consent document.

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SIGNATURE OF PARTICIPANT

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DATE

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PRINTED NAME OF PARTICIPANT**LEGALLY AUTHORIZED REPRESENTATIVE (LAR)**

The following signature line should only be filled out when the participant does not have the capacity to legally consent to take part in the study and/or sign this document on his or her own behalf.

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SIGNATURE OF LAR

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DATE

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PRINTED NAME and RELATIONSHIP TO PARTICIPANT**WITNESS TO CONSENT**

I was present during the explanation of the research to be performed under Protocol 2020-0702.

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SIGNATURE OF WITNESS TO THE VERBAL CONSENT  
PRESENTATION (OTHER THAN PHYSICIAN OR STUDY CHAIR)

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DATE

A witness signature is only required for vulnerable adult participants. If witnessing the assent of a pediatric participant, leave this line blank and sign on the witness to assent page instead.

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PRINTED NAME OF WITNESS TO THE VERBAL CONSENT**PERSON OBTAINING CONSENT**

I have discussed this research study with the participant and/or his or her authorized representative, using language that is understandable and appropriate. I believe that I have fully informed this participant of the nature of this study and its possible benefits and risks and that the participant understood this explanation.

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PERSON OBTAINING CONSENT

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DATE

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PRINTED NAME OF PERSON OBTAINING CONSENT

**TRANSLATOR**

I have translated the above informed consent as written (without additions or subtractions) into \_\_\_\_\_ and assisted the people

(Name of Language)

obtaining and providing consent by translating all questions and responses during the consent process for this participant.

\_\_\_\_\_  
NAME OF TRANSLATOR

\_\_\_\_\_  
SIGNATURE OF TRANSLATOR

\_\_\_\_\_  
DATE

Please check here if the translator was a member of the research team. (If checked, a witness, other than the translator, must sign the witness line below.)

\_\_\_\_\_  
SIGNATURE OF WITNESS TO THE VERBAL TRANSLATION  
(OTHER THAN TRANSLATOR, PARENT/GUARDIAN,  
OR STUDY CHAIR)

\_\_\_\_\_  
DATE

\_\_\_\_\_  
PRINTED NAME OF WITNESS TO THE VERBAL TRANSLATION