Vanderbilt University Institutional Review Board
Informed Consent Document for Research

Principal Investigator: Derek Smith **Revision Date: 9/27/2017**
Study Title: A Randomized Phase III Trial of Gabapentin versus Standard of Care for Prevention and Treatment of Mucositis in Locally Advanced Head and Neck Cancer Patients Undergoing Primary or Adjuvant Chemoradiation
Study ID: HN 1541
Institution/Hospital: Vanderbilt Medical Center

This informed consent applies to adults

Name of participant: _____ 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 copy of this consent form.

You do not have to be in this research study. You may choose not to be in this study and get other treatments without changing your healthcare, services or other rights. 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. Your medical record will contain a note saying you are in a research study. Anyone you authorize to receive your medical record will also get this note.

1. What is the purpose of this study?

You are being asked to take part in this research study because you have been diagnosed with head and neck cancer and will be treated with radiation therapy. Radiation therapy to the head and neck may cause a burn involving the inside of the mouth, throat and nasal passages. This results in pain. Pain from radiation may cause difficulty with swallowing and speaking. It may require pain medication including opioid analgesics. In addition, the painful burn may result in long-term sensitivity of the lining of the mouth and throat.

Gabapentin is a medication that is commonly used to treat nerve related pain. Specifically, it has been used to treat pain involving the mouth, throat and nasal passages in head and neck cancer patients treated with radiation.

There is recent interest in using medications like gabapentin to try and **prevent** pain from developing. In this study we will be recruiting 150 Patients to determine whether gabapentin is effective in preventing (or minimizing) mouth pain from radiation in patients with head and neck cancer.

2. What will happen and how long will you be in the study?

If you agree to participate in this study, you will be randomly assigned to **usual pain management** or **usual pain management plus gabapentin.** Randomization is a process like flipping a coin. If you are to receive usual pain management, your healthcare providers may use any necessary medications to attempt to control pain with the exception of gabapentin. If you receive usual pain management plus gabapentin, you will be given a prescription for gabapentin which will be filled at your pharmacy. The gabapentin will be started at the same time you start radiation therapy. To minimize side effects the gabapentin dose will be increased over a two-week period. Patients on gabapentin will remain on gabapentin throughout the duration of radiation.

Gabapentin is an approved drug for pain management and should be covered by your insurance company.

All patients who participate in the study will complete a series of questionnaires before the start of the radiation therapy.

All patients will be asked to complete a daily pain diary which describes the severity of her pain and the use of pain medications.

Patients who are receiving gabapentin will also be asked to complete a diary documenting compliance with taking the gabapentin.

All patients will be seen by the study nurse once a week during the radiation for a study visit. At each study visit, the study nurse who will do the following: 1) review the pain/compliance diaries, 2) administer a questionnaire to determine whether you are having any side effects of therapy, and 3) for patients on gabapentin, the study nurse with determine there are any gabapentin related side effects. If patients on gabapentin report any substantial side effects, the medication dose will be decreased or the medication will be discontinued.

After completion of radiation therapy, you will meet with the study nurse once a month for 3 months. At each of these visits the study nurse review the pain/compliance diaries, will have you complete questionnaires, and evaluate any side effects from treatment or study drug (if applicable). Your participation in the study will and 3 months after completing radiation therapy with the final study visit.

Throughout the course of the study, adjustment in pain medications will be made by your physician or nurse practitioner per usual care. Once you have completed radiation treatment, your pain will slowly go away. As your pain goes away, your physician may slowly take you off of the gabapentin. It may be three to six months before you are off all pain medications. Some patients treated for head and neck cancer are on pain medication long term.

3. Costs to you if you take part in this study:

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

4. Side effects and risks associated with patients only taking Gabapentin that you can expect if you take part in this study:

Common side effects (greater or equal ten percent)
Dizziness, drowsiness, unsteady on your feet, fatigue

Uncommon side effects (less than 10%)
Tremor, twitching, moods swings, hostility, nervousness, difficulty with focus or memory loss, headache, diarrhea or vomiting, impotence, vision changes, swelling

Rare Side Effects (less than 1 percent)
Allergic reaction, liver or kidney problems

These side effects are only related to Gabapentin and do not include the side effects associated with chemoradiation that you may be receiving with your cancer therapy.

5. Risks that are not known:

Because this treatment is being used for a new purpose, there may be risks that we do not know about at this time. Currently, Gabapentin is listed as a FDA Pregnancy Category C (i.e. risk cannot be ruled out). Women of childbearing age who undergo chemotherapy and radiation are already stringently counseled regarding the need to avoid pregnancy. The added risk of Gabapentin to a developing embryo or fetus is nothing in comparison to active chemotherapy radiation. However, if Gabapentin is continued following active chemotherapy for management of pain, the risk to a fetus cannot be ruled out.

6. Payment in case you are injured because of this research study:

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:

a) The benefits to science and humankind that might result from this study.

This study may help determine whether the routine use of gabapentin can diminish pain in head and neck cancer patients undergoing radiation

b) The benefits you might get from being in this study.

Because this is a randomized trial, there are no direct benefits to you for participating in the study.

8. Other treatments you could get if you decide not to be in this study:

If you decide not to participate in this study you may receive standard pain medicine for control of radiation mouth pain. This includes the use of gabapentin.

9. Payments for your time spent taking part in this study or expenses:

There will be no payment as a part of this study.

10. Reasons why the study doctor may take you out of this study:

You may be taken off of the study if it is deemed in your best interest by the principal investigator, you are having toxicities from the gabapentin, or for failure to comply with study procedures.

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

If you decide to stop being part of the study, you should tell your study doctor. Deciding to not be part of the study will not change your regular medical care in any way.

12. 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 Barbara Murphy, MD at 615-322-4967. If you become injured or hurt as part of your participation in this study, Dr. Barbara Murphy can help discuss any medical treatments available to you.

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

13. Clinical Trials Registry.

A description of this clinical trial will be available on 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.

14. Confidentiality:

You will be given a unique identifier that will link your name to the study related information. Only the principle investigator and study staff will have access to this information. Electronic study related information will be kept on a password protected database on a secure server. Paper copies of study related information will be kept in a locked office. After the study has been completed and the results reported, all electronic and paper information will be destroyed.

Vanderbilt may share your information, without identifiers, to others or use it for other research projects not listed in this form including the National Cancer Institute. Vanderbilt, Dr Murphy 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.

15. 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, Dr. Murphy and her study team may share the results of your study and/or non-study linked, 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, [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 Dr. Murphy in writing and let her know that you withdraw your consent. Her mailing address *is 777 Preston Research Building, 2220 Pierce Ave, Nashville TN 37232*. 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

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.

Date _____ Signature of patient/volunteer _____

Consent obtained by:

Date _____ Signature _____

Printed Name and Title _____ Time _____

Date of IRB Approval: 01/23/2019
Date of Expiration: 01/22/2020