# Title: Comparison of NETSPOT Imaging Vs F FDG PET/CT in Head & Neck Cancer Patients

**NCT# NCT03602911**

**Date: December 28, 2017**

Phone: 304-293-7073
Fax: 304-293-3098
http://oric.research.wvu.edu

Chestnut Ridge Research Building
886 Chestnut Ridge Road
PO Box 6845
Morgantown, WV 26506-6845



Subject's
Initials_____
Date_____

# Only Minimal Risk
# Consent Information and HIPAA Form

| | |
|---|---|
| Principal Investigator | **Rusha Patel, MD** |
| Department | **Otolaryngology** |
| Protocol Number | **1804059675** |
| Study Title | **Comparison of NETSPOT Imaging Vs F FDG PET/CT in Head & Neck Cancer Patients** |
| Co-Investigator(s) | **Gary Marano, MD** |
| Sponsor (if any) | **Advanced Accelerator Applications USA Inc.** |

## Contact Persons

In the event you experience any side effects or injury related to this research, you should contact Rusha Patel, MD at (304)293-3457 (After hours contact: Rusha Patel, MD by contacting the ENT resident on call at (304) 598-4000 ). If you have any questions, concerns, or complaints about this research, you can contact Dr. Patel at (304) 293-3457.

For information regarding your rights as a research subject, to discuss problems, concerns, or suggestions related to the research, to obtain information or offer input about the research, contact the Office of Research Integrity and Compliance at (304) 293-7073.

In addition if you would like to discuss problems, concerns, have suggestions related to research, or would like to offer input about the research, contact the Office of Research Integrity and Compliance at 304-293-7073.

## Introduction

You, _____, have been asked to participate in this research study, which has been explained to you by _____. This study is being conducted by Rusha Patel, MD, in the Department of Otolaryngology at West Virginia University with support provided by Advanced Accelerator Applications USA Inc.

## Purpose(s) of the Study

NETSPOT is a radioactive diagnostic agent for PET scan imaging to identify neuroendocrine tumors (NET) in adult and pediatric patients. NETSPOT obtained FDA approval in 2016. Prior to this, three large studies examined the safety of NETSPOT imaging in NET patients; these studies found no adverse side effects and that NETSPOT was a useful imaging modality in this group of patients. Similar studies have suggested that NETSPOT imaging may have a role in head and neck cancer; however it is not currently FDA approved for this indication. For this study we would like to determine the usefulness of NETSPOT imaging for detection of Head & Neck cancer as well its potential for therapeutic use.

## Description of Procedures

1. If it is determined that you meet inclusion criteria and would like to be part of this study you will be asked to review and sign this informed consent form at time of scheduling

2. You will undergo standard of care PET/CT per established protocol

3. Following PET/CT, You will undergo an additional CT from 24 hours later to 7 days utilizing NETSPOT imaging with Advanced Accelerator Applications (AAA) provided dose. Neither you nor your insurance will be charged for this additional scan.

4. Both images will be reviewed by the senior radiologist and the primary surgeon for concordance between images. Standard Update Value (SUV) will be measured for both images and recorded

5. You will undergo clinical follow-up based on standard of care PET/CT results as per protocol

6. True positive results will be recorded for both standard of care PET/ CT and NETSPOT images and analyzed for sensitivity and specificity.

7. For patients undergoing surgical treatment, pathology results including routinely reported human papillomavirus (HPV) markers will be recorded and compared to NETSPOT imaging characteristics.

## Discomforts

You will be asked to have an additional computed tomography (CT) scan. This will increase your radiation exposure by an additional 25%. Potential for intravenous injection complications due to a second injection include fluid infiltration, bleeding or bruising, venous thrombosis, and pain. As with any injected material, the risk of allergy is present; however, no case of anaphylaxis to 68GA-DOTATATE has been reported in the literature. A large meta-analyses on the safety of 68Ga-DOTATATE showed that there were no serious adverse events with use. Minor side effects occurred in 3% of patients and included tachycardia, itching, and a drop in oxygen saturation.

## Alternatives

You do not have to participate in this study.

## Benefits

You may not receive any direct benefit from this study. The knowledge gained from this study may eventually benefit

others.

## Financial Considerations

You will receive a $50.00 visa gift card to help pay for your return trip to WVU Medicine to receive an additional CT scan as requested in the study protocol. You will be paid the day of your return visit.

## Confidentiality

In any publications that result from this research, neither your name nor any information from which you might be identified will be published without your consent.

## HIPAA

We know that information about you and your health is private. We are dedicated to protecting the privacy of that information. Because of this promise, we must get your written authorization (permission) before we may use or disclose your protected health information or share it with others for research purposes.

You can decide to sign or not to sign this authorization section. However, if you choose not to sign this authorization, you will not be able to take part in the research study. Whatever choice you make about this research study will not have an effect on your access to medical care.

## Persons/Organizations Providing the Information

Patient/West Virginia University Hospitals

## Persons/Organizations Receiving the Information

- The research site(s) carrying out this study. This includes UHA or UHA Affiliated, WVU, WVU Hospitals. It also includes each site's research staff and medical staff
- Health care providers who provide services to you as part of this research study.
- Laboratories and other people and groups that look into your health information as part of this study in agreement with the study protocol.
- The United State Department of Health and Human Services (which includes the National Institutes of Health (NIH), Food and Drug Administration (FDA)) and other groups that have the right to use the information as required by law.
- The Sponsor and the people and companies that they use to oversee, manage, or conduct the research.
- The members and staff of any Institutional Review Board (IRB) that oversees this research study.
- West Virginia University Office of Research Integrity and Compliance and Office of Sponsored Programs.

## The Following Information Will Be Used

Information from your existing medical records and new information about you that is created or collected during the study such as: history and physicals, clinic visit notes, nursing and staff notes, laboratory results, x-rays, demographic data, imaging scans and study forms.

## The Information is Being Disclosed for the Following Reasons

- Review of your data for quality assurance purposes
- Publication of study results (without identifying you)
- Other research purposes such as reviewing the safety or effectiveness of products or therapies; conducting performance reviews of products or therapies for patients; developing a better understanding of disease; improving the design of future clinical trials

## You May Cancel this Authorization at Any Time by Writing to the Principal Investigator

Rusha Patel, MD
WVU Medicine
1 Medical Center Drive
Morgantown, WV 26501

If you cancel this authorization, any information that was collected already for this study cannot be withdrawn. Once information is disclosed, according to this authorization, the recipient may re-disclose it and then the information may no longer be protected by federal regulations.

You have a right to see and make copies of your medical records. You will not be able to see or copy your records related to the study until the sponsor has completed all work related to the study. At that time you may ask to see the study doctor's files related to your participation in the study and have the study doctor correct any information about you that is wrong.

This authorization will expire at the end of the study unless you cancel it before that time.

## Voluntary Participation

Participation in this study is voluntary. You are free to withdraw your consent to participate in this study at any time. Refusal to participate or withdrawal will not affect your future care at West Virginia University.

In the event new information becomes available that may affect your willingness to participate in this study, this information will be given to you so that you can make an informed decision about whether or not to continue your participation.

You have been given the opportunity to ask questions about the research, and you have received answers concerning areas you did not understand.

Upon signing this form, you will receive a copy.

I willingly consent to participate in this research.

## Signatures

Signature of Subject

| Printed Name | Date | Time |
|---|---|---|

The participant has had the opportunity to have questions addressed. The participant willingly agrees to be in the study.

Signature of Individual Performing Consent

| Printed Name | Date | Time |
|---|---|---|