MedStar Health
Research Institute

Office of Research Integrity
6525 Belcrest Rd, Suite 700
Hyattsville, MD 20782

Approval Notice
Continuation

31-Aug-2018

MedStar Washington Hospital Center
110 Irving Street NW
Washington, DC 20010

Protocol Number: **2016-166**

PI Name: **Douglas Van Nostrand MD**

Protocol Title: **Evaluation of 99mTc Sestamibi Scans In Patients who have Differentiated Thyroid Cancer, Elevated Serum Thyroglobulin Levels, and Negative Diagnostic Imaging Studies**

Dear Douglas Van Nostrand MD,

The above-referenced **Continuation** submission was reviewed by **IRB # 3 Washington** in accordance with full board review procedures on **28-Aug-2018**.

The IRB has approved the submission. You can begin research activities. **The approval is valid from *28-Aug-2018* through *27-Aug-2019***. Any modifications to the IRB-approved protocol and other supporting documents must be reviewed and approved by the IRB prior to implementation.

If the study will continue beyond *27-Aug-2019*, please submit a continuation request form forty-five (45) days prior to *27-Aug-2019* to allow the IRB sufficient time to review and approve the request.

If you have any questions, please contact me at 301-560-7338.

Thank you,

Timothy Rodriguez
Office of Research Integrity

Enclosure: IRB Stamped Informed Consent
IRB Stamped HIPAA Waiver

IRB number:	2016-166	**Clinical Site IC Version:**	
Project Title:	Evaluation of 99mTc Sestamibi Scans in Patient Who Have Differentiated Thyroid Cancer, Elevated Serum Thyroglobulin Levels, and Negative Diagnostic Imaging Studies		
Principal Investigator:	Douglas Van Nostrand	**Institution:**	MedStar Washington Hosp Ctr

MedStar Health Research Institute Informed Consent for Clinical Research

INTRODUCTION

We invite you to take part in a research study called "**Evaluation of ^{99m}Tc Sestamibi Scans In Patients who Have Differentiated Thyroid Cancer, Elevated Serum Thyroglobulin Levels, and Negative Diagnostic Imaging Studies.**" You were selected as a possible participant in this study because you have thyroid cancer and an elevated serum thyroglobulin level and all of your standard diagnostic imaging studies have been unable to identify the source of this elevation. Please take your time to read this form, ask any questions you may have and make your decision. We encourage you to discuss your decision with your family, friends and your doctor(s).

WHAT IS THE PURPOSE OF THIS STUDY?

This study is being done to see if the radioisotope ^{99m}Tc sestamibi scans can locate what is causing the elevated serum thyroglobulin in persons with differentiated thyroid cancer who have elevated serum thyroglobulin levels and negative diagnostic imaging tests.

WHAT ELSE SHOULD I KNOW ABOUT THIS RESEARCH STUDY?

It is important that you read and understand several points that apply to all who take part in our studies:

- Taking part in the study is entirely voluntary and refusal to participate will not affect any rights or benefits you normally have;
- You may or may not benefit from taking part in the study, but knowledge may be gained from your participation that may help others; and
- You may stop being in the study at any time without any penalty or losing any of the benefits you would have normally received.

The nature of the study, the benefits, risks, discomforts and other information about the study are discussed further below. If any new information is learned, at any time during the research, which might affect your participation in the study, we will tell you. We urge you to ask any questions you have about this study with the staff members who explain it to you and with your own advisors prior to agreeing to participate.

WHO IS IN CHARGE OF THIS STUDY?

The investigator is Douglas Van Nostrand, MD. The research is being sponsored by the investigator.

WHO CANNOT PARTICIPATE IN THIS STUDY?

You cannot be in this study if any of the following apply to you:

- < 18 years of age,
- Pregnant or breast feeding,
- You have not had ALL of the following diagnostic imaging scans:
  - US (ultrasound),
  - CXR (chest-X-ray),
  - CT (computer tomography scan), and
  - PET scan (^{18}F Fluoro-deoxyglucose positron emission tomography scan).
- Any of the above diagnostic imaging scans identifying a source of the elevated serum thyroglobulin level.
- If any of the additional diagnostic imaging scans noted below were performed and identified a source of the elevated serum thyroglobulin level
  - ^{18}F NaF PET bone scan (^{18}F sodium fluoride positron emission tomography bone scan)
  - Bone scan (^{99m}Tc methylene diphosphonate or other equivalent bone agent)
  - Brain scan (Computer tomography or magnetic resonance imaging)
- Not diagnosed with differentiated thyroid cancer

WHAT IF I AM PRESENTLY PARTICIPATING IN ANOTHER RESEARCH STUDY?

Are you presently participating in any other research studies? Yes ☐ No ☐

If yes, please state which study(ies)_____

While participating in this study, you should not take part in any other research project without approval from the people in charge of each study. This is to protect you from possible injury arising from such things as extra blood drawing, extra x-rays, interaction of research drugs, or similar hazards.

HOW MANY PEOPLE WILL TAKE PART IN THE STUDY?

About **15** people will take part in this study, worldwide. **15** people will be recruited at this site.

WHAT HAPPENS IF I AGREE TO BE IN THE STUDY?

The following procedures will be done within the Division of Nuclear Medicine at MedStar Washington Hospital Center on an outpatient basis.

Preparation: none

Phase 1: You will receive an injection into your vein of a radioisotope called ^{99m}Tc sestamibi.

Phase 2: You will wait for 60 to 90 minutes in a waiting room

Phase 3: You will then be imaged lying face up on an imaging table while a camera passes around you from the top of your head to approximately the level of your knees. This requires approximately 45 minutes

Phase 4: Your images will be reviewed by the nuclear medicine physician. This will take ~10-15 minutes. If additional images are required to clarify an image, then additional images of that area will be performed. As earlier, you will have the additional images performed with you lying face up. These images require ~20-45 minutes. You will then be released

- The following procedure is part of the research study and would not normally be done as part of your routine care:
  - ^{99m}Tc sestamibi scan.

HOW LONG WILL I BE IN THE STUDY?

If the ^{99m}Tc sestamibi scan does not suggest a possible source for the elevated thyroglobulin, you will be in the study one day.

If the ^{99m}Tc sestamibi scan does suggest a possible source for the elevated serum thyroglobulin, you may be in the study for a longer period of time in order for the study doctor to follow up with you regarding further evaluation and/or treatment of the possible source of elevated serum thyroglobulin. The follow-up is part of the study and will be made over the phone at 1, 3, 6 and 12 months after the research scan and/or until diagnosis of the metastatic site. The actual evaluation and/or treatment itself for the possible source of elevated serum thyroglobulin is not part of the research study.

The investigator may decide to take you off this study if it is believed to be in your best interest, you fail to follow instructions, new information becomes known about the safety of the study, or for other reasons the investigator or sponsor believes are important.

You can stop participating at any time. However, if you decide to stop participating in the study, we encourage you to talk to the investigator and your regular doctor first so they can help you decide what other options may be best for your medical care once you are off study.

If you suddenly withdraw from the study, there are no consequences, but we may not be able to use any of the information gathered from your participation.

WHAT ARE THE RISKS AND SIDE EFFECTS OF THIS STUDY?

If you decide to participate in this study, you should know there may be risks. You should discuss these with the investigator and/or your regular doctor and you are encouraged to speak with your family and friends about any potential risks before making a decision. Potential risks and side effects related to this study include:

Potential risks and side effects ***that may occur*** include:

1. Chemical: You will receive radioactive sestamibi in very small amounts. Tracer doses do not have pharmacologic effects; however, less than 0.5 % of patients have reported the following side effects : headache, abdominal discomfort, irregular heart beat, temporary joint pain, dizziness, vomiting, lightheadedness or fainting, allergic reaction with shortness of breath and decreased blood pressure and heart rate. Flushing, swelling, injection site inflammation, fever, itching rash and hives have also been noted.

2. Radiation exposure: The total radiation exposure resulting from participation in this research study is estimated to be less1/100th (0.1) of the amount of radiation that you will receive if you have been or will be treated with I-131 for your thyroid cancer. In addition, the Food and Drug Administration regulates and limits the amount of radiation exposure to volunteers resulting from participating in a research study such as this to a level that it believes is acceptable. The FDA limit is 5 rem to any organ of the body for a research study such as this. The study meets the FDA requirement.

3. Risks from blood drawing: ^{99m}Tc sestamibi will be injected into a vein in your arm using a needle as if drawing blood. Injection may cause pain and bruising and, rarely, infection at the place where the injection is performed. Sometimes the injection causes people to feel lightheaded or even faint.

4. Claustrophobia (fear of closed spaces): Some patients have reported a feeling of claustrophobia when being imaged by a nuclear medicine camera.

5. False positive result: This is possible if the procedure incorrectly indicates that thyroid cancer is present in a particular location or if the sestamibi appears to find a possible source for thyroglobuling but the source actually does not exists. A false positive result may result in unnecessary additional testing, biopsy and/or treatment.

Please tell the investigator about all medications including over-the-counter drugs or herbal supplements you are taking, even if you don't think they are important.

There may also be risks and side effects other than those listed above that we cannot predict. Many side effects go away in a short time after the injection of the ^{99m}Tc sestamibi, but, in some cases, side effects can be serious, long lasting and/or life threatening. If you have any unwanted side effects, you should ask the investigator what may be done to make the side effect less uncomfortable.

For more information about risks and side effects, please ask Douglas Van Nostrand, MD.

ARE THERE ANY BENEFITS TO TAKING PART IN THE STUDY?

You may or may not benefit in participating in this study. The ^{99m}Tc sestamibi scan may identify the source of your elevated serum thyroglobulin level that had not previously been identified by your physician or any of the other diagnostic imaging studies. This may in turn potentially allow earlier treatment of a site of cancer before that site of cancer becomes a problem to you.

However, you may not get any direct benefit from being in this study. We cannot promise that you will experience any benefits from participating in this study. We hope the information learned from this study will benefit others in the future.

WHAT OTHER OPTIONS ARE THERE?

Instead of being in this study, you have these options:

- Continued active surveillance with no treatment intervention.
- A therapy with ^{131}I without knowing ahead of time whether or not there will be any uptake in any site of cancer or any benefit from that therapy.
- A therapy with a tyrosine kinase inhibitor (TKI). A TKI is a drug that interferes with selected chemical processes in the cell that may or may not stabilize progressive metastatic disease.

- You always have the option to not be in this study.

WHAT ABOUT CONFIDENTIALITY?

Your personal health information (PHI) will be kept private to the extent allowed by law. Study records identifying you will be kept confidential and will not be made publicly available. You will not be identified by name in any publications resulting from this study. You will be asked to sign a separate form that will give permission to the investigator, representatives from government agencies, including the Food and Drug Administration (FDA), institutional review boards, the sponsor and/or the sponsor's representative(s), and certain other people, agencies or entities, to look at and review the records related to this study including your personal health information and the information discovered during this study. This separate form explains in greater detail who will have access to your records, what type of information will be reviewed

and for what purposes, how long your permission for others to review and release your records will last, and how you may withdraw your permission if necessary. If you do not wish to sign this permission form you will not be allowed to participate in this study.

A Data Safety and Monitoring Board, which is a group of experts not connected to the study, will be reviewing the data from this research throughout the study. This Data Safety and Monitoring Board is the Radioactive Drug Research Committee. We will tell you about any new information from this or other studies that may affect your health, welfare, or willingness to stay in this study.

WILL I BE PAID FOR PARTICIPATING IN THIS STUDY?

You will not be paid for being in this study.

WHAT ARE THE COSTS?

You do not have to pay anything to be in this study. However, if taking part in this study leads to procedures for care not included in the study, it may lead to added costs for you or your insurance company. You will not be charged the ^{99m}Tc sestamibi scan that is part of this research study.

However, you, or your insurance company, will be charged for any other portion of your care that is considered standard of care. You may be responsible for any co-payments and deductibles that are standard for your insurance coverage. This may include any additional diagnostic tests, biopsies, follow up appointments, and/or therapies.

WHAT IF I'M INJURED OR BECOME ILL DURING THE STUDY?

We will make every effort to prevent injuries or illness from occurring while you are in the study. In the case of an injury, illness, or other harm occurring to you during, or resulting from, the study, you should seek medical treatment. You should also contact the study doctor as soon as possible. You or your insurance company will be charged for any continuing medical care and/or hospitalization that are not a part of the study.
If you suffer an injury related to the study drug or study procedures, the reasonable costs of necessary medical treatment of the injury **will not** be reimbursed by the principal investigator, MedStar Health Research Institute or MedStar Washington Hospital Center, MedStar Health or its affiliated entities to the extent these costs are not covered by your insurance or other third party coverage.

No funds have been set aside, by MedStar Washington Hospital Center, the MedStar Health Research Institute, MedStar Health, or its affiliated entities to repay you in case of injury, illness, or other harm occurring during, or resulting from the study, and their current policies do not provide for payments for lost wages, cost of pain and suffering, or additional expenses. By agreeing to this you do not give up your rights to seek compensation in the courts.

WHAT ARE MY RIGHTS AS A PARTICIPANT?

- You have the right to be told about the nature and purpose of the study;
- You have the right to be given an explanation of exactly what will be done in the study and given a description of potential risks, discomforts, or benefits that can reasonably be expected;
- You have the right to be informed of any appropriate alternatives to the study, including, if appropriate, any drugs or devices that might help you, along with their potential risks, discomforts and benefits;
- You have the right to ask any questions you may have about the study;
- You have the right to decide whether or not to be in the study without anyone misleading or deceiving you; and
- You have the right to receive a copy of this consent form.

By signing this form, you will not give up any legal rights you may have as a research participant. You may choose to not take part in or to leave the study at any time. If you choose to not take part in or to leave the study, your regular care will not be affected and you will not lose any of the benefits you would have received normally. We will tell you about new information that may affect your health, welfare, or willingness to be in this study.

WHO DO I CALL IF I HAVE QUESTIONS OR PROBLEMS?

For questions about the study or a research-related injury, contact the investigator, Douglas Van Nostrand at (telephone number 202-877-0300). If you are having a medical emergency, you should call 911 or go directly to the nearest emergency room.

For questions about your rights as a research participant, contact the MedStar Health Research Institute. Direct your questions to the Office of Research Integrity at:

Address: MedStar Health Research Institute
6525 Belcrest Rd.
Suite 700
Hyattsville, MD 20782

Telephone: (301) 560-2912
Toll Free: (800) 793-7175
Fax (301) 560-7336

THIS SPACE INTENTIONALLY LEFT BLANK

SIGNATURES

As a representative of this study, I have explained the purpose, the procedures, the possible benefits and risks that are involved in this research study. Any questions that have been raised have been answered to the individual's satisfaction.

_____ _____
Signature of Person Obtaining Consent Date of Signature

Printed Name of Individual Obtaining Consent: _____

I, the undersigned have been informed about this study's purpose, procedures, possible benefits and risks, and I have received a copy of this consent. I have been given the opportunity to ask questions before I sign, and I have been told that I can ask other questions at any time. I voluntarily agree to be in this study. I am free to stop being in the study at any time without need to justify my decision and if I stop being in the study I understand it will not in any way affect my future treatment or medical management. I agree to cooperate with Douglas Van Nostrand and the research staff and to tell them immediately if I experience any unexpected or unusual symptoms.

_____ _____
Participants signature Date of Signature

Printed Name of Participant _____

_____ _____
Signature of Witness **(If applicable but not required)** Date of Signature

Printed Name of Witness: _____

As the Principal Investigator (or designee) for this research study, I attest that the participant has voluntarily agreed to be part of this study, the risks and benefits of the study have been fully explained, and any questions have been addressed to the participant's satisfaction.

_____ _____
Principal Investigator's Signature Date of Signature

APPLICATION FOR WAIVER (OR ALTERATION) OF HIPAA AUTHORIZATION FOR RESEARCH PURPOSES

(FULL AND PARTIAL WAIVER REQUEST FORM)

INSTRUCTIONS TO INVESTIGATOR

When is this form required? Unless certain limited exceptions apply, this request for *Full or Partial* Waiver of Authorization must be completed and approved prior to creating, obtaining, using and/or disclosing Protected Health Information ("PHI") for research purposes in the absence of a patient's written HIPAA Authorization. This form should also be used to request *an Alteration* to the core elements of the MHRI Authorization form. In addition, if the researcher or other member of the research staff, such as a Clinical Coordinator, needs to obtain or use PHI to screen medical records or to contact prospective participants in order to obtain their Authorization and the individual is not themselves the treating provider, a request for Partial Waiver of Authorization must be approved by the Institutional Review Board (IRB). If the researcher or their staff has the patient's written Authorization, this form is not necessary, provided that the Authorization permits the requested use or disclosure of PHI to or by the researcher and their staff. Please refer to the MHRI HIPAA Decision Matrix for additional information on which forms to use for which specific research-related activities. Please contact the MedStar Health Research Institute, Office of Research Integrity for more information.

What are the limited exceptions? HIPAA permits researchers to obtain and use PHI without a patient's Authorization for certain research-related activities if the researcher has completed: 1) A Certification of Review Preparatory to Research; 2) A Certification of Review of Decedent Information; or 3) A Data Use Agreement (DUA) with the records custodian for use of a Limited Data Set (LDS) in research. Please refer to the MHRI HIPAA Decision Matrix for additional information on which forms to use for which specific research-related activities. Please contact the MedStar Health Research Institute, Office of Research Integrity for more information.

When is a Waiver of Authorization Appropriate? A waiver of Authorization may be appropriate in those instances when it is impractical or impossible to obtain a patient's written Authorization. This may occur for instance in studies that involve only chart reviews or database reviews and the research also involves a Waiver of Informed Consent or the research is exempt from Informed Consent requirements. If the participants in the study will be required to give their Informed Consent to participate, it is unlikely that a request for a waiver of HIPAA Authorization will be approved by a Institutional Review Board. However, a request for an alteration of the HIPAA Authorization may be possible.

What is the difference between a Partial and Full Waivers of Authorization? A Partial Waiver of Authorization is used when the researcher needs to obtain PHI for the sole purposes of contacting prospective participants and obtaining their written Authorization. A Full Waiver would be used when the PHI is obtained for the purposes of conducting the research and it is otherwise impractical or impossible to obtain the person's written Authorization.

When is an Alteration of the General HIPAA Authorization Appropriate? Alterations of the Authorization may be appropriate in those instances where the General Authorization form is a barrier to obtaining requested PHI. For example, in some research settings, use of the General Authorization form may be impracticable and the IRB may determine that altering the form poses no more than minimal risk to participants' privacy.

What are the Requirements for Obtaining a Waiver/Alteration of Authorization? The criteria required by the HIPAA privacy regulations for approving a waiver or alteration of HIPAA Authorization are built into this form. These criteria are similar to the criteria the IRB must use in considering whether to grant a waiver of Informed Consent to participate in a research study.

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APPROVAL EXPIRES N/A
IRB APPROVED

What Additional Requirements Might I Have? Even if the Institutional Review Board (IRB) approves a Full or Partial Waiver of HIPAA Authorization, the Covered Entity providing the PHI for your study is not required to release PHI for research purposes and may impose additional requirements upon researchers.

- ***Accounting for Disclosures***. The Covered Entity may need to account for all disclosures made to persons other than the entity's own workforce if the subject of the disclosure requests an "accounting" under the HIPAA privacy regulations. Therefore, researchers may be required to assist the Covered Entity in creating documentation and information to enable an accounting of disclosures. The accounting must include the individual's name, purpose of the disclosure, date, recipients of the PHI, and a description of the PHI provided. Some Covered Entities, including most MedStar facilities may have systems in place that will require you to provide this information at the time of disclosure. Other Covered Entities may expect the personnel conducting the study to maintain a log of all such disclosures and provide a copy to the respective data managers.
- ***Contacting Treating Providers***. HIPAA permits researchers to obtain, use and disclose PHI of individuals they do not treat. In some cases, treating providers may feel it is inappropriate for the patient to enroll in a research trial and the Covered Entity may require the researcher to obtain approval of the treating provider prior to releasing the PHI.
- ***Check with local Privacy Officer (Privacy Liaison)***. In some cases, the Covered Entity may have other conditions which restrict the use or disclosure of certain types of PHI to researchers and the researcher may be required to consult the institutions Privacy Officer.

What is Protected Health Information (PHI)?
Protected Health Information (PHI) means any information, whether oral or recorded in any form or medium, that: (1) Is created or received by a health care provider, or other Covered Entity; and (2) Relates to the past, present, or future physical or mental health or condition of an individual; the provision of health care to an individual; or the past, present, or future payment for the provision of health care to an individual; and identifies the individual or reasonably could be used to identify the individual

Protected Health Information is any health information that contains any of the following pieces of information:

1. Names
2. Geographic subdivisions smaller than a State
   - street address
   - city
   - county
   - precinct
   - zip codes and their equivalent geocodes, except for the initial three digits of a zip code if, according to the current publicly-available data from the Bureau of the Census:
     (i) the geographic unit formed by combining all zip codes with the same three initial digits contains more than 20,000 people, and
     (ii) the initial three digits of a zip code for all such geographic units containing 20,000 or fewer people is changed to 000.
3. Dates (except year) directly related to patient (*i.e.,* DOB, Date of Service, etc.)
4. Telephone numbers
5. Fax numbers
6. E-mail addresses
7. Social security numbers
8. Medical record numbers
9. Health plan beneficiary numbers
10. Account Numbers
11. Certificate/license numbers
12. Vehicle identifiers and serial #'s
13. Device identifiers and serial #'s
14. Web URLs
15. Internet Protocol (IP) address #'s
16. Biometric identifiers, including finger and voice prints
17. Full face photographic images and any comparable images
18. Any other unique identifying number, characteristic, or code, except as permitted under HIPAA to re-identify data (may include tattoos, disease condition, predisposition to condition, etc.)

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APPLICATION FOR WAIVER (OR ALTERATION) OF HIPAA AUTHORIZATION FOR RESEARCH PURPOSES

***NOTE:** Please complete each section in its entirety. If you feel that a question, section or the potential selections below are not applicable to your situation, you MUST explain why IN DETAIL on the form and in the cover memo that accompanies your submission. Failure to do so may result in this application being delayed or rejected.*

Contact Information for Investigator:

Date: 17 August 2018

Applicant: Douglas Van Nostrand **Telephone Number:** 202-877-0300 **e-mail:** douglas.van.nostrand@medstar.net

Institutional Affiliation: MedStar Washington Hospital Center

Project Title: **Evaluation of 99mTc Sestamibi Scans In Patients who have Differentiated Thyroid Cancer, Elevated Serum Thyroglobulin Levels, and Negative Diagnostic Imaging Studies**

IRB Application Number (if known) ***2016-166***

Purpose of Application (select all that apply):

☒ **Partial Waiver of Authorization**
- ☒ *To screen medical records, operational databases and systems (i.e. lab systems), or appointment logs (i.e. surgical schedules), admissions logs, etc. to identify potentially eligible research participants.*
- ☒ *For recruitment to contact potential participants in order to obtain their Authorization.*

☐ **Full Waiver of Authorization**
(For use when it is impractical or impossible to obtain a person's written Authorization)

☐ **Alteration of Authorization Requirements**
(For use when the form or core components of the form are a barrier to obtaining Authorization)

Purpose of the Study: Please provide a brief summary of what is being investigated by this study:
To perform a pilot study of the utility of the 99mTc sestamibi scans in patients who have differentiated thyroid cancer, positive serum thyroglobulin levels, and negative standard and/or extensive diagnostic clinical imaging studies.

Waiver/Alteration Application Criteria

IRB Checklist	***Investigators Questionnaire***
	For each subpart below, the IRB must agree that the use or disclosure of PHI involves no more than a minimal risk to the privacy of individuals based on the responses below.
HIPAA Applicability	**1) Will you be accessing, using, receiving, or disclosing any health information relating to any individual that includes any PHI identifiers (described in instructions above)?**
	☒ Yes. HIPAA applies and this form may be required. ☐ No. STOP - HIPAA is not applicable you need not fill out this form.

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Necessity of Waiver	**2) Could the proposed research practicably be conducted without the waiver or alteration of Authorization?**
☐ IRB must agree that that it is truly impractical (not just inconvenient) for the researcher to obtain written Authorization from the research participants. Waiver of Authorization is not appropriate if Informed Consent is to be obtained.	☐ **Yes.** STOP – the study is not eligible for a waiver or alteration of Authorization. ☒ **No.** Please describe why it would be impossible or impractical to obtain each subject's Authorization for use and/or disclosure their health information using the standard written form of HIPAA Authorization: This partial HIPAA waiver is to screen patients who are referred for this study. Patients who are eligible will then be contacted to obtain their informed consent and HIPAA authorization.
Necessity of PHI	**3) Could the proposed research-related activity practicably be conducted without the access, use or disclosure of Protected Health Information (PHI)?**
☐ IRB must agree that that PHI is necessary (not just preferred) for the proposed research activity.	☐ **Yes.** STOP – the study is not eligible for a waiver or alteration of Authorization. ☒ **No.** Please explain why PHI is necessary for the proposed research-related activity: The patient's name, age, and medical records needs to be reviewed to evaluate eligibility for the study. The patient's telephone number, mailing address or e-mail address will be needed to obtain informed consent and HIPAA authorization prior to enrollment.
Scope of PHI Requested	**4) Is the PHI to be accessed, used or disclosed the minimum necessary to accomplish the research objectives described in this Waiver request?**
☐ IRB must consider whether the scope of PHI requested is appropriate for the proposed research-related activity. (i.e. only contact information may be needed for recruitment)	☒ **Yes.** Please describe the specific PHI elements needed for the research-related purposes giving rise to this Waiver request. Patient name, age, MRN, date of medical procedures, mailing address, email address, telephone number. ☐ **No.** STOP. The IRB may not approve your Waiver request.
Sources of Protected Health Information?	**5) Please identify the facility location(s) where PHI will be accessed or obtained?**
	Washington Hospital Center (WHC) (or list multiple sites here):
	6) What are the anticipated sources of PHI?
	(Choose all that apply) ☒ Physician records ☒ Hospital records ☐ Billing system records ☒ Laboratory results ☒ Pathology results ☒ Radiology results ☐ Mental Health Records (may requires specific approvals) ☐ Interviews/surveys/questionnaires ☐ Databases or tissue repositories that
	☐ Tissue samples, research repositories previously collected for research purposes. If yes, was research data and/or samples collected pursuant to: 1) An IRB approved protocol? ☐ Yes ☐ No 2) Informed Consent? ☐ Yes ☐ No 3) Waiver of Informed Consent? ☐ Yes ☐ No 4) HIPAA Authorization? ☐ Yes ☐ No 5) Waiver of Authorization? ☐ Yes ☐ No

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	were created for operational (i.e. non-research) purposes	

Access to and Collection of PHI	**7) Describe how PHI is to be accessed or obtained for the purposes of this Waiver request?**
☐ IRB must consider whether direct access to records or databases would adversely affect the rights and interests of individuals and/or exceeds the minimum necessary requirements of HIPAA	☒ Direct access to Covered Entity's paper-based medical records ☒ Direct access to Covered Entity's electronic medical records (or Azyxxi) ☐ Direct access to Covered Entity's operational databases (laboratory, billing, etc.) ☐ Direct access to research database ☒ Receipt of reports/data from Physicians or the Covered Entity ☐ Other (please explain)
	8) Identify who on the research team will control access to the PHI obtained as a result of the Waiver of Authorization? (If PHI will be accessed for the purpose of this waiver request but will not be in any way recorded or stored (e.g a database is viewed but no identifiers are recorded), please indicate "N/A – No PHI will be recorded or stored".)
☐ IRB must consider whether there is an adequate plan to limit access based on the needs of the research-related activity.	**The principle investigator, Dr. Douglas Van Nostrand, will control access to the PHI obtained.**
Recruitment Plan and Plans for Using PHI	**9) Describe how the PHI obtained will be used in identifying and recruiting research participants or in conducting the study or for any other purpose?**
☐ IRB must agree that recruitment plan/use of PHI is consistent with the plan described in the research protocol and protects the interests of potential research participants as well as the interests of those who may not wish to participate.	*(Choose all that apply)* ☒ To screen medical records or operational databases to identify potentially eligible research participants. ☒ To contact treating providers and obtain their permission to contact potential participants in order to obtain their Authorization (please attach proposed Authorization). ☒ To contact potential participants directly in order to obtain their Authorization (please attach proposed Authorization). ☒ Treating Physicians will provide a list or otherwise identify potentially eligible research participants. ☐ PHI obtained will be used to conduct the entire research project (i.e. chart reviews) and no individuals will be contacted. ☐ Other (please describe):
	10) Describe who will make initial contact with potential research participants and how?
	(Choose all that apply) ☒ Telephone contact ☒ By Investigator or Research Coordinator ☐ By Treating Physician or their staff ☒ Letter, e-mail or other written correspondence ☐ Not applicable – No research participants will be contacted ☐ Other (please describe)

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Re-use or Disclosure of PHI to Third Parties	**11) For the period during the study and afterwards, please identify who else will or is likely to receive or view PHI obtained pursuant to the Waiver of Authorization and for what purpose? (Please note: This includes the disclosure of screening logs to the study sponsor if such logs include any identifiers including dates.)**
☐ IRB must determine that the re-use or disclosure of PHI to third parties is permitted because it is ▪ Required by law, ▪ For authorized oversight of the research study, or ▪ For other research purposes permitted under HIPAA	*(Choose all that apply)* ☐ Other investigators (please identify) (describe purpose) ☐ Study sponsor (please identify) (describe purpose) ☐ CRO (please identify) (describe purpose) ☐ Study monitor(s) (i.e. DSMBs) (please identify) ☐ Government oversight agencies (FDA, OHRP, etc.) (describe purpose) ☒ Other (please explain) None. PHI will not be disclosed to investigators or persons who are not involved in this research study.
Data Security and Plans to Protect Identifiers	**12) Describe the plan to protect identifiers received (i.e. those identified above) from improper *uses.***
	(Choose all that apply) ☐ Only de-identified data will be released by the Covered Entity and retained by the research staff. ☒ Only a limited data set will be released by the Covered Entity and retained by the research staff. ☐ Only coded information will be used in connection with the research study (Please Note: Under HIPAA regulations the code may not be based upon any element of any of the 18 HIPAA identifiers (e.g. patient initials, a permutation of the patient's social security number, etc.) ☒ All research team members will sign Confidentiality statements agreeing not to use or disclose PHI except as permitted as part of their duties. ☒ PHI will be released by the Covered Entity only to a MedStar Workforce member who is permitted to use the PHI for operational purposes ☐ PHI will be released by the Covered Entity only to recipients who have a MedStar Health-approved Business Associate Agreement and who have agreed to protect the PHI. (Please attach a copy of the Business Associate Agreement.) ☐ Other (please explain):
	13) Describe the plan to protect identifiers received (i.e. those identified above) from improper *disclosures.* *(Choose all that apply)* ☒ Electronic PHI will be stored on a secure network ☒ Electronic PHI will be encrypted ☐ Electronic PHI will be password protected ☒ Paper-based PHI will be secured in a locked office ☐ Paper-based PHI will be secured in a locked cabinet ☐ All PHI will be de-identified (with all identifiers properly destroyed) ☐ All PHI will be coded by Investigator with re-identification link securely stored in a separate location. ☐ Other (please explain)

Plan to Destroy Identifiers	**14) Will all PHI elements received (i.e. those identified above) be destroyed at the earliest possible opportunity? *Identifiers obtained via Waiver of Authorization must be destroyed at the earliest possible opportunity unless there is a health or research justification for retaining the identifier (or such retention is otherwise required by law).***
☐ IRB must determine that the PHI is to be destroyed at the earliest possible time.	☒ **Yes.** a) Materials containing PHI such as screening logs will be destroyed upon completion of: ☐ Recruitment attempt without enrollment ☐ Enrollment in the study ☐ Chart Review/Data Analysis ☐ Subject participation and record-keeping requirements ☒ FDA-approval or end of record-keeping requirements ☐ Specimen Processing ☐ Other (please explain) b) Who will destroy the identifiers (Name the specific person(s) and titles). Dr. Douglas Van Nostrand, principle investigator, Director of nuclear medicine research at MHRI c) How will the identifiers be destroyed? (Placing identifiers in trash is not an acceptable method for disposing of identifiers). Shreading (Contracted Vendor) Recall services ☐ **No.** Justify the need for retaining the identifiers. (Choose One)
Alteration of Authorization Requests	**15) If alteration of the standard HIPAA Authorization form (instead of a Waiver) is requested, explain why and how the form of Authorization would be altered and attach the proposed altered Authorization that you proposed to use.**
	N/A
Minimal Risk to Privacy	**16) Explain why the proposed research-related activity (or the alteration) presents no more than a "minimal risk" to privacy[1]:**
	Patient PHI is collected and used only for this research study. No PHI will be shared with other investigators or entitites who are not directly involved in the patient's medical care. PHI is securely stored in encrypted hardrives and in locked rooms. PHI will be destroyed according to regulations at the end of the study.

[1] "Minimal risk" means that the probability and magnitude of harm or discomfort anticipated in the proposed research are not greater, in and of themselves, than those ordinarily encountered in daily life or during the performance of routine physical or psychological examinations or tests.

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INVESTIGATOR'S ASSURANCES:

I certify and agree that the above statements and representations are truthful and accurate. I further agree that I will not reuse the protected health information ("PHI") for which I have requested this Waiver or Alteration of HIPAA Authorization (i.e., use other than as described in this application form) or disclose the PHI to any person or entity other than those listed above, except as required by law, for authorized oversight of this research study, or as specifically approved for use in another study by an IRB. I also assure the IRB that the PHI for which I have requested this waiver or alteration is the minimum amount of PHI necessary for the research purpose described in this application. I understand that any misrepresentations may result in disciplinary actions, loss of privileges, reporting to licensure boards, and/or other sanctions.

~~Douglas Van Nostrand, M.D.~~
Signature of Investigator

Nuclear Medicine
Phone: 70348 Pgr # 1503

27 August 2018
Date

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