MedStar Health
Research Institute

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Approval Notice
Initial Review

16-Dec-2015

110 Irving street, NW Suite 1A50
Washington, DC 20010

Protocol Number: **2015-245**
PI Name: **Anand Nath**
Protocol Title: **Dysphagia after sleeve gastrectomy: evaluation of risk factors and assessment of the various interventions.**

Dear Anand Nath,

The above-referenced **Initial Review** submission was reviewed by **IRB # 3 Washington** in accordance with expedited review procedures on **04-Dec-2015**.

Protocol October 29, 2015

The IRB has approved the submission. You can begin research activities. **The approval is valid from *04-Dec-2015* through *03-Dec-2016***. 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 *03-Dec-2016*, please submit a continuation request form forty-five (45) days prior to *03-Dec-2016* to allow the IRB sufficient time to review and approve the request.

Please refer to the Office of Research Integrity website to review the **Principal Investigator's Responsibilities** as a MedStar researcher on http://www. medstarresearch.org/Body.cfm?id=243.

If you have any questions, please contact me at 301-560-7339.

Thank you,

Crystal Bland
Office of Research Integrity

Enclosure: IRB Stamped HIPAA Waiver

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: November 8, 2015

Applicant: Anand Nath, M.D. **Telephone Number:** 202-689-4836 **e-mail:** anand.x.nath@medstar.net

Institutional Affiliation: MedStar Washington Hospital Center

Project Title: **Dysphagia after sleeve gastrectomy: evaluation of risk factors and assessment of the various interventions.**

IRB Application Number (if known) ____

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:
The primary objective of this chart review study is to determine the prevalence of post-operative dysphagia and emesis in patients who have undergone sleeve gastrectomy, study causal factors and assess the efficacy of various treatment modalities for this complication.

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 ☐ 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.	**2) Could the proposed research practicably be conducted without the waiver or alteration of Authorization?** ☐ **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 study involves patients who underwent sleeve gastrectomy in the Center for bariatric surgery at the Medstar Washington Hospital Center. We no longer have clinical contact with a significant percentage of patients who would be eligible for this study. It is not feasible to obtain authorization from all of the eligible patients.
Necessity of PHI ☐ IRB must agree that that PHI is necessary (not just preferred) for the proposed research activity.	**3) Could the proposed research-related activity practicably be conducted without the access, use or disclosure of Protected Health Information (PHI)?** ☐ **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: This study requires access to Protected Health Information that is present in the medical records and this Protected Health Information is the foundation of this study. Without access to medical records, this study can not be completed.
Scope of PHI Requested ☐ 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)	**4) Is the PHI to be accessed, used or disclosed the minimum necessary to accomplish the research objectives described in this Waiver request?** ☒ **Yes.** Please describe the specific PHI elements needed for the research-related purposes giving rise to this Waiver request. I need to review the patient's records in order to obtain the specific clinical information that will be used to complete this study. No other patient information will be collected or maintained. ☐ **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?** (Choose One) (or list multiple sites here): Medicine ambulatory care clinic (Centricity), Medical Records Department MedStar Washington Hospital Center, Center for advanced bariatric procedure
	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 ☐ 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

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	specific approvals) ☐ Interviews/surveys/questionnaires ☐ Databases or tissue repositories that were created for operational (i.e. non-research) purposes	5) Waiver of Authorization? ☐ Yes ☐ No

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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.	**Access will be controlled by Anand Nath, M.D. No individual patient identifier will be recorded.**
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
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) Materials will be destroyed 6 years after date of publication in a journal. b) Who will destroy the identifiers (Name the specific person(s) and titles). Anand Nath, M.D. , Principal Investigator c) How will the identifiers be destroyed? (Placing identifiers in trash is not an acceptable method for disposing of identifiers). Shreading (in Office) ☐ **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]:**
	I am only using the patients' medical records to collect information. No direct patient contact is made. No patient identifier is collected. Attempts will be continuously used to safeguard patient confidentiality to the greatest extent possible.

[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.

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.

Signature of Investigator

11/9/15
Date

Anand Nath, MD

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MEDSTAR HEALTH RESEARCH INSTITUTE AND
GEORGETOWN UNIVERSITY MEDICAL CENTER
INSTITUTIONAL REVIEW BOARDS

Dysphagia after sleeve gastrectomy: evaluation of risk factors and assessment of the various interventions.
2015-245

Statement of Approval/Denial of Waiver/Alteration of Authorization

To Custodian of Patient Information: Federal privacy standards issued by the Department of Health and Human Services pursuant to the Health Insurance Portability and Accountability Act of 1996 ("HIPAA") permit you to use or disclose to an investigator, patient information pursuant to documentation of waiver/alteration of patient Authorization by the investigator's Institutional Review Board (IRB) (45 C.F.R. § 164.512(i)). This Statement satisfies the HIPAA requirement for documentation that the IRB has reviewed the waiver/alteration request in accord with the requirements of Federal human subject protection regulations and, having determined that the criteria set forth at 45 C.F.R. § 164.512(i)(2)(ii) have been met and have been approved as follows:

Purpose of the Waiver. This statement certifies that the IRB named below approved a request to [*waive/alter*] the HIPAA Authorization requirement to permit the use or disclosure of patient protected health information (PHI) to the investigator named above for purposes of:

- ☐ *Partial Waiver.* For screening or identifying prospective research participants.
- ☐ *Partial Waiver.* For contacting or recruiting prospective research participants.
- ☒ *Full Waiver.* Conducting the entire study named above without Authorization.
- ☐ Alteration of the Authorization requirement as follows (Describe nature of alteration):_____

PHI Permitted to Be Released. In approving the waiver/alteration the Board has determined that access/use by the investigator named above to/of the following information is necessary for the research activity and that the investigator is permitted to use/disclose the following:

- ☒ All information described in the Investigator's Request for Waiver or Alteration of HIPAA Authorization for Research; ***OR***
- ☐ The following information: _____

The scope of the Board's W*aiver/Alteration to* Authorization is limited solely to this information. Please contact the MedStar Health Research Institute Office of Research Integrity (ORI) at 301-560-7339 should you have any questions regarding this statement.

Institutional Review Board Action (For IRB Use Only)

- ☒ **Approved**
  - ☒ **Via Expedited Review by IRB Chair (or Designee) On:** 04 December 2015
  - ☐ **Via Full IRB Committee On:**_____
- ☐ **Not Approved**
  - ☐ **Via Expedited Review by IRB Chair (or Designee) On:** _____
  - ☐ **Via Full IRB Committee On:**_____
- ☐ **Approval Deferred Pending the Following Actions:**_____

_____ 16 December 2015
Signature of IRB Chair (or Designee) **Dated**

Covered Entity Tracking Data *Date of Initial Disclosure:*_____

Recipient and Contact Information:_____

Description of Patient Information Disclosed:_____

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Georgetown University

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APPROVAL EXPIRES NA
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