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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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.)

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: 31 May 2013

Applicant: Vanita Aroda MD **Telephone Number:** 301-560-2940 **e-mail**: vanita.aroda@medstar.net

Institutional Affiliation: MedStar Community Clinical Research Center 6525 Belcrest Road Suite 700

Project Title: **Vitamin D and type 2 diabetes (D2d Study)**

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:
To assess whether, in participants with pre-diabetes, oral daily vitamin D3 supplementation reduces the rate of progression from pre-diabetes to clinical diabetes.

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: We require access to electronic medical records within the MedStar Health system in order to accrue the required number of patients for this trial and in order to identify patients who have a high probability of qualifying and thus minimize screen failures.
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: Patients need to be contacted for recruitment purposes so they can consider study participation.
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. We require access to a patient's electronic medical chart including contact information and medical history including medications, appointments and progress notes. ☐ **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 were created for operational (i.e. non-research) purposes
	☐ 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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<table>
<tr><td>Access to and Collection of PHI</td><td>7) Describe how PHI is to be accessed or obtained for the purposes of this Waiver request?</td></tr>
<tr><td rowspan="3">❒ 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

❒ IRB must consider whether there is an adequate plan to limit access based on the needs of the research-related activity.</td><td>☐ 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)</td></tr>
<tr><td>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”.)</td></tr>
<tr><td>Investigators and trained study staff will have access to the PHI and it will be temporarily stored on a spreadsheet accessible only on secure MHRI computers. At the end of the study period this spreadsheet will be destroyed by the investigator and no PHI of nonconsenting patients will be permanently retained.</td></tr>
<tr><td>Recruitment Plan and Plans for Using PHI</td><td>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?</td></tr>
<tr><td rowspan="3">❒ 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.</td><td>(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):</td></tr>
<tr><td>10) Describe who will make initial contact with potential research participants and how?</td></tr>
<tr><td>(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)</td></tr>
</table>

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) NIH (describe purpose) Data integrity and patient safety ☐ CRO (please identify) (describe purpose) ☒ Study monitor(s) (i.e. DSMBs) (please identify) Data integrity ☒ Government oversight agencies (FDA, OHRP, etc.) (describe purpose) Patient safety & data integrity ☐ Other (please explain)
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)

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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). Vanita Aroda, MD - Principal Investigator c) How will the identifiers be destroyed? (Placing identifiers in trash is not an acceptable method for disposing of identifiers). Other (describe) Digital file will be deleted securely. ☐ **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]:**
	Most PHI will simply be reviewed within the existing EMR databases accessed. For patients who potentially qualify for the study, only the minimum possible amount of information required to contact the patient will be transferred to a secure electronic screening spreadsheet (log) and this spreadsheet will be destroyed at the end of the study. The amount of risk introduced to patient privacy by this process is considered minimal.

[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 **Date**

[Protocol number and title]
[Principal Investigator's name]

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:** _____
- ☐ **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:**_____

_____

_____ _____
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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